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**Examining the feasibility of a full-scale trial of the
TAKE 5 weight management intervention for adults
with intellectual disabilities.**

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BSc (Hons), MSc (Med Sci)

Submitted in the fulfilment of the requirements for the
Degree of Doctor of Philosophy

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Veterinary and Life Sciences November, 2016

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Abstract

Background

Adults with intellectual disabilities experience equivalent or higher rates of obesity in comparison to the general population. This increases the risk for health conditions associated with adverse weight gain including cardiovascular disease and type II diabetes. Clinical guidelines on the management of obesity recommend multi-component interventions which include an energy deficit diet (EDD) of 600 kcal per day, support to increase physical activity and key behaviour change techniques including goal setting and self-monitoring to facilitate these healthy lifestyle changes. However, the current evidence base and provision of health services on the management of obesity in adults with intellectual disabilities is limited. A systematic review of multi-component weight management interventions was conducted and identified only seven randomised controlled trials of weight management interventions in adults with intellectual disabilities and obesity. The intervention components primarily focussed on a health education approach including diet, physical activity, and behaviour change techniques. However, no intervention adhered to clinical recommendations in terms of including an EDD, a weight maintenance intervention or investigating the long term efficacy of the intervention at 12 months. Meta-analyses revealed that post intervention (Weighted mean difference; WMD: -0.92kg; 95% CI -2.11kg, 0.28kg; $p = 0.13$) and at 12 months (WMD: -1.15 kg (95% CI -4.15 kg to 1.86 kg; $p = 0.45$), current multi-component weight management interventions are not more effective than no treatment. The results of this review illustrate that the current evidence base is insufficient to support multi-component weight management interventions focussed on a health education approach and therefore, future studies should investigate the efficacy of an alternative approach and the inclusion of an EDD to examine the efficacy of this approach to the management of obesity in adults with intellectual disabilities.

Methods

The primary aim of this thesis was to add to the limited evidence base on multi-component weight management interventions in adults with intellectual disabilities by examining the feasibility of conducting a full-scale trial of a multi-component intervention, TAKE 5. TAKE 5 adheres to clinical recommendations on weight management and was specifically designed for adults with intellectual disabilities, and where applicable implemented with support from carers. The study design was a single blind cluster randomised controlled trial

comparing two active interventions. The comparator intervention, WWToo, was based on a health education approach and consisted of multiple components focussed on diet, physical activity and behaviour change techniques. A multi-point recruitment strategy was piloted. Participants were recruited from multiple organisations, from specialist intellectual disabilities services, provider organisations and local day centres. Additional feasibility outcomes included retention rates and the fidelity and implementation of the intervention. The primary efficacy outcome was change in body weight at 12 months. Additional secondary outcomes included anthropometric outcomes (BMI, waist circumference, percentage body fat), objective measure of physical activity (time spent in light, moderate to vigorous intensity and total physical activity) and sedentary behaviour and health related quality of life.

Results

The multi-point recruitment strategy was shown to be feasible and 50 participants were successfully recruited to the study. This study design was shown to be acceptable to adults with intellectual disabilities as retention to both interventions was high with 90% of participants completing the intervention. The TAKE 5 multi-component weight management intervention with support from carers led to significant reductions in weight, BMI, waist circumference and percentage body fat at six and 12 months. Furthermore, 50% of the participants in the TAKE 5 intervention achieved a clinically significant weight loss of 5% or greater of initial body weight in comparison to 21% of the participants in the WWToo intervention. Significant improvements in the above outcomes were not found in participants completing the WWToo intervention. A limitation of both interventions was the inability to engage participants in physical activity, reduce the sedentary lifestyle behaviours and improve health related quality of life of this population group. Both interventions were implemented as intended, and both interventions were shown to be feasible and accessible to all adults with varying levels in intellectual disabilities due to the social support provided by carers in implementing the interventions.

Conclusion

This study is the first ever randomised controlled trial of a weight management intervention that adheres to clinical recommendations in adults with intellectual disabilities. This study provided evidence on the feasibility of this study design in adults with intellectual disabilities and demonstrated the acceptability of the EDD approach tailored to meet the needs of adults with intellectual disabilities. Furthermore, this study has provided preliminary evidence that

an EDD may be an efficacious approach to weight management, and provided further evidence that current service provision based on health education approach is ineffective in the treatment of obesity in adults with intellectual disabilities. On the basis of these findings a future full-scale randomised controlled trial is necessary to confirm these findings and provide evidence on the optimum approach to weight management in this population group.

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Publications

Articles

1. Harris, L., Melville, C., Jones, N., Pert, C., Boyle, S., Murray, H., Tobin, J. & Hankey, C. (2015). A single-blind, pilot randomised trial of a weight management intervention for adults with intellectual disabilities and obesity: study protocol. *Pilot and Feasibility Studies*, 1(1), 5, 1-12
2. Harris, L., Hankey, C., Murray, H., & Melville, C. (2015). The effects of physical activity interventions on preventing weight gain and the effects on body composition in young adults with intellectual disabilities: systematic review and meta-analysis of randomized controlled trials. *Clinical obesity*, 5(4), 198-210.

Conference proceedings

1. Harris, L., Hankey, C., Jones, N., Bleazard, L., Melville, C.A. (2016). A single-blind, pilot randomised controlled trial of a multi-component weight management intervention for adults with intellectual disabilities and obesity. Poster presentation at International Society of Behavioral Nutrition and Physical Activity, Cape Town, South Africa.
2. A cluster randomised control trial of a multi-component weight management programme for adults with intellectual disabilities and obesity. Oral presentation at the Seattle Club, Glasgow, United Kingdom.

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Author's Declaration

“I hereby declare that I am the sole author of this thesis, except where the assistance of others has been acknowledged.

It has not been submitted in any form for another degree or professional qualification.”

Leanne Harris

November, 2016.

Abbreviations

AAIDD	American Association of Intellectual and Developmental Disabilities
ADHD	Attention Deficit Hyperactivity Disorder
BMI	Body Mass Index
BMR	Basal Metabolic Rate
CALO-RE	Coventry Aberdeen London Refined
CENTRAL	Cochrane Central Register of Controlled Trials
CH	Dr Catherine Hankey (Supervisor)
CI	Confidence Interval
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CM	Dr Craig Melville (Supervisor)
CPM	Counts Per Minute
DEXA	Dual Energy X-ray Absorptiometry
EDD	Energy Deficit Diet
ERIC	Education Resource Information Centre
GCWMS	Glasgow and Clyde Weight Management Service
GGC	Greater Glasgow and Clyde
HA-ID	Healthy Ageing and Intellectual Disabilities
ICC	Interclass Correlation Coefficient
ICD	International Classification of Diseases
IQ	Intelligence Quotient
ISAK	International Society of Anthropometry and Kinesiology
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention To Treat
IVRS	Interactive Voice Response System
Kcal	Kilocalories
LH	Leanne Harris (author of this thesis)
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute of Clinical Excellence
PAL	Physical Activity Level
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis

SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SIGN	Scottish Intercollegiate Guidelines Network
SIMD	Scottish Index of Multiple Deprivation
SLAN	Survey of Lifestyle, Attitudes and Nutrition
SMART	Specific, Measurable, Achievable, Relevant and Time specific
TAU	Treatment As Usual
TEE	Total Energy Expenditure
UK	United Kingdom
USA	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation
WMD	Weighted Mean Difference
WWT00	Waist Winners Too

Chapter 1: Background

1.1 Introduction

This chapter will provide an overview of the global burden of obesity. Followed by a review of the evidence of the burgeoning obesity epidemic and determinants of obesity for adults with intellectual disabilities. Current guidelines on the management of obesity will be presented, followed by research guidance on developing and evaluating complex interventions. This chapter will provide a summary of the research conducted prior to this PhD, based on the TAKE 5 multi-component weight management intervention for adults with intellectual disabilities. Finally, this chapter will conclude with how this thesis aims to enhance our knowledge of the field, and address any gaps identified in the current research base.

1.2 Definition of obesity

Obesity is a major public health concern internationally [World Health Organisation (WHO), 2004]. Obesity is characterised by an excessive quantity of body fat, that negatively impairs health (WHO, 2004). The WHO reported rates of obesity have more than doubled since 1980, and in 2014 it was estimated that 1.9 billion adults (≥ 18 years) were overweight and of these, 600 million were obese (WHO, 2016). Obesity rates are projected to continue to increase in prevalence with conservative estimates of rates of 2.16 billion and 1.12 billion adults expected to be overweight and obese, respectively, by 2030 (WHO 2016). The extent of the obesity epidemic in the United Kingdom (UK), is illustrated by the findings reported in the Health Survey for England (Department of Health, 1998) and Scottish Health Surveys (Scottish Executive, 2006). In 2014, 41% of men and 33% of women in England were overweight, and 26% of men and 24% of women clinically obese (Health Survey England, 2014). Prevalence rates in Scotland, in a more recent update in 2015, revealed even higher rates, with 65% of adults classified as overweight, including 29% classified as obese (Health Survey Scotland, 2015).

The burden of obesity on health is well recognised, increasing the risk of chronic diseases including type II diabetes (Mokdad, Ford, Bowman, Dietz, Vinicor, Bales, & Mark, 2003),

cardiovascular disease (Wilson, D'Agostino, Sullivan, Parise, & Kannel, 2002) and some cancers (Hu, Tuomilehto, Silventoinen, Barengo, Peltonen, & Jousilahti, 2005).

Body mass index (BMI) is the most commonly used measure to classify obesity and is calculated as the ratio of weight in kilograms (kg) divided by height in meters (m) squared (kg/m^2). Obesity is classified as a $\text{BMI} \geq 30 \text{ kg/m}^2$ and is subdivided into level of severity of obesity, with each level associated with increased risk of chronic diseases. The classification of weight status for adults by BMI is presented in Table 1.1.

Table 1.1. The International Classification of adult underweight, overweight and obesity according to BMI. (Adapted from the WHO, 2004).

Classification of weight status	Body Mass Index (kg/m^2)
Underweight	< 18.5
Normal Weight	18.5 – 24.9
Overweight	> 25.0
Pre-obese	25.0 – 29.9
Obese Class 1	30.0 – 34.9
Obese Class 2	35.0 – 39.9
Obese Class 3 (Morbid obesity)	≥ 40.0

The aetiology of obesity is multi-factorial and thought to be influenced by many factors such as genetic disorders, psychological and environmental factors (WHO, 2004). The primary determinants of obesity in the general population are thought to be related to modern day lifestyle factors, such as readily available, energy dense food, promoting dietary indulgence and increased energy intake; the technological advances in transport; and more sedentary jobs leading to limited physical activity participation and reduced energy expenditure. This creates a physiological imbalance within the body. Energy intake exceeds energy expenditure resulting in an increase in body weight (Catenacci, Hill, & Wyatt, 2009). In order to prevent a positive imbalance resulting in weight gain, interventions have focused on the prevention and management of body weight through modifiable determinants of diet and physical activity, aiming to change these behaviours and adoption of healthier lifestyle habits. The determinants of obesity consistent with the general population and specific to adults with intellectual disabilities will be further discussed in section 1.7.

1.3 Economic cost of obesity

The increasing prevalence of obesity and its associated health inequalities is a burgeoning financial burden in the UK (Murray, Richards, Newton, Fenton, Anderson, Atkinson, & Braithwaite, 2013). It is reported that health conditions associated with overweight/obesity cost the National Health Service (NHS) greater than £5 billion per year (Scarborough, Bhatnagar, Wickramasinghe, Allender, Foster, & Rayner, 2011). Quantifying the economic costs of obesity is difficult due to the numerous health inequalities associated with obesity. The Foresight report (Butland, Jebb, Kopelman, McPherson, Thomas, & Mardell, 2007) is the most widely cited report on UK obesity trends, which predicted that greater than half of the UK population could be obese by 2050 and that associated total costs could increase to £50 billion per year. It is now thought that as obesity prevalence has continued to increase that these figures are conservative and the true burden of obesity in the future could be even more extreme.

The current estimates of the cost of obesity to the NHS in Scotland are attributed to prescribed medication (60%); hospital care (30%) and General Practitioner consultations (10%). In total, it is estimated that this corresponds to £223 million (accounting for inflation). However, the cost of obesity on health care is only part of the economic burden, other expenditures include societal costs including community support services, travel expenses to appointments and absences from employment. Research on prevention and management strategies are therefore a priority to reduce the associated cost of obesity on society.

1.4 Individuals with intellectual disabilities

1.4.1 Definition of intellectual disabilities

Intellectual disabilities is defined by the American Association of Intellectual and Developmental Disabilities (AAIDD) as, “significant limitations both in intellectual functioning and in adaptive behaviour as expressed in conceptual, social, and practical adaptive skills. This disability originates before age 18” (Schalock *et al.*, 2010, pg.1).

Intellectual disabilities is currently the most widely accepted term internationally (WHO, 2007). Other terms used simultaneously and interchangeably with intellectual disabilities

include learning disabilities, developmental disabilities and also mental retardation. There has been a lot of confusion over the application of these terms and classification used to define intellectual disabilities has been debated over recent years as sometimes the above terms are used to mean different populations with disabilities. For example, in the UK the term learning disabilities is used concurrently with intellectual disabilities. However, this does not meet the definition used in the United States of America (USA), which denotes learning disabilities as distinct from intellectual disabilities. Furthermore, the term developmental disabilities is used in the USA. This is an overarching term that encompasses cognitive and/or physical disabilities and includes intellectual disabilities. Other examples of developmental disabilities include cerebral palsy which is characterised as a physical disability or fetal alcohol syndrome which has both physical and intellectual impairments.

In addition, acceptability of terms has also changed over recent years. Previous terms have also included moron and mentally handicapped, however these are considered to be offensive and no longer deemed acceptable to describe individuals with intellectual disabilities (Schalock, Luckasson, & Shogren, 2007). This is also currently applicable to the utility of the term mental retardation. Although this is still currently used by the WHO International Classification of Diseases (ICD), recent publications from the WHO no longer used this term (Schalock *et al.*, 2007).

Despite differences in the terminology and definitions, the classification of intellectual disabilities is generally consistent based on the following three main criteria:

- 1) limitation in intellectual functioning;
- 2) limitations in adaptive behaviour, specifically related to conceptual skills (e.g., language and literacy, money, time, and number concepts; and self-direction), Social skills (e.g. interpersonal skills, social responsibility, problem solving and ability to understand/follow rules and laws) and practical skills (e.g., daily living activities such as personal care and healthcare, occupational skills, travel and transportation);
- 3) the onset of the disability prior to 18 years (Schalock *et al.*, 2010, WHO, 2007).

In keeping with current practice this thesis will use the term intellectual disabilities throughout, based on the above definition and classification.

1.4.2 Level of intellectual disabilities

The level of intellectual disabilities can be categorised into four groups, mild, moderate, severe and profound using the intelligence quotient (IQ) testing. An IQ < 70, (or 2 standard deviations (SD) below the mean) is indicative of a limitation in intelligence. The IQ scores used to identify level of intellectual disabilities are presented in Table 1.2.

Individuals with intellectual disabilities are a heterogeneous population and have a large range of abilities with some individuals' dependent on a higher level of support from carers than others. For example, adults with mild intellectual disabilities in general can communicate effectively, can live independently and require minimum support. Adults with moderate intellectual disabilities are not fully independent and require additional support needs, with communication, everyday activities such as accessing services in the community, self-care and decision making. Adults with more severe or profound intellectual disabilities require full time support from carers, can have problems with mobility and communication. Adults with an increased severity of disabilities can also require assistance with personal care, and may be fully reliant on others to make decisions.

Table 1.2. Level of intellectual disabilities

Level of intellectual disabilities	IQ Score
Mild	50-69
Moderate	35-49
Severe	20-34
Profound	<20

1.4.3 Genetic syndromes

There are a number of genetic syndromes associated with intellectual disabilities, including Prader–Willi syndrome, Cohen syndrome and Bardet–Biedl syndrome (Allison, Packer-Munter, Pietrobelli, Alfonso, & Faith, 1998; Farooqi & O'Rahilly, 2005). Specific

characteristics of these genetic disorders include high rates of obesity, developed from early onset. Individuals with genetic syndromes and obesity represent only a small proportion of the intellectual disabilities population and require intensive support for weight management including prescription of a low calorie diet, restricted access to food and in some cases pharmacological intervention (Goldstone, Holland, Hauffa, Hokken-Koelega, & Tauber, 2008). Therefore, this review will only focus on research on individuals without the above genetic syndrome as their origin of intellectual disabilities with the exception of adults with Down syndrome.

1.4.3.1 Down syndrome

Down syndrome is the most common genetic condition in individuals with intellectual disabilities. It is characterised by an extra chromosome on chromosome 21 and often referred to as Trisomy 21. Individuals with Down syndrome have distinct characteristics such as short stature, low muscle tone and poor cardiorespiratory fitness (Rimmer, Heller, Wang, & Valerio, 2004). Unlike the syndromes described above, individuals with Down syndrome do not have a genetic cause of obesity, however, there is evidence to support that individuals with Down syndrome have higher rates of obesity than participants without Down syndrome as their origin of intellectual disabilities (Bhaumik, Watson, Thorp, Tyrer, & McGrother, 2008; Hsieh, Rimmer, & Heller, 2014; Melville, Cooper, Morrison, Allan, Smiley, & Williamson, 2008). The inclusion of adults with Down syndrome in weight management interventions is also a priority for this subpopulation of adults with intellectual disabilities. Adults with Down syndrome have been included in previous weight management interventions and shown to be able to make healthy lifestyle choices and reduce body weight (Melville *et al.*, 2011; Spanos, Melville, & Hankey, 2013a).

1.5 Prevalence of obesity in individuals with intellectual disabilities

Estimates of the prevalence of obesity in adults with intellectual disabilities is important due to the prevalence of a wide -range of serious health complications associated with obesity (Hu *et al.*, 2005; Mokdad *et al.*, 2003; Wilson *et al.*, 2002). To highlight the severity of the problem, studies comparing prevalence estimates of obesity with the general population will be discussed. The available evidence on prevalence rates of obesity in national and international

studies has been reviewed by Rimmer & Yamaki, (2006) and Melville, Hamilton, Hankey, Miller, & Boyle, (2007). The latter review systematically examined the available evidence on rates of obesity in studies conducted between 1985 and 2006. The results revealed that prevalence rates of obesity varied across studies from 2% to 31% in males and 15% to 51% in females and that there was a trend for obesity to increase with time. However, caution in the interpretation of these results was advised, as the authors reported limitations in the results such as whether or not the samples studied were representative of adults with intellectual disabilities and the diverse geographical locations of those studied, which made it difficult to compare prevalence rates. Overall, this review found that despite the small samples size of studies, prevalence rates of obesity were greater than in the general population.

Studies of UK prevalence rates of obesity in adults with intellectual disabilities have been compared to the general population from national surveys. Melville *et al.*, (2008) compared a cross-sectional study of 945 adults with intellectual disabilities identified through primary care settings with the general population based on data obtained from the Scottish Health Survey 2003 (Scottish Executive 2006). The main results of this study were that the prevalence of obesity in women (39.3%) and men (27.8%) with intellectual disabilities was greater than women (25.1%) and men (22.7%) in the Greater Glasgow Health board sample from the Scottish Health Survey. Bhaunik *et al.*, (2008) also found that in a sample of 952 adults with intellectual disabilities (≥ 25 years), women with intellectual disabilities (32%) were more likely to be obese in comparison to women in the general population (23%). This finding was not replicated in men with intellectual disabilities, reporting lower rates of obesity in comparison to the general population, 15% and 19%, respectively. Adults with intellectual disabilities were identified from an epidemiological health register and the comparison sample on the general population from the Health Survey for England (Department of Health 1998).

In agreement with the above studies, data on the prevalence of obesity for adults with intellectual disabilities (≥ 16 years) was obtained in primary care general practices in Bristol, UK (Gale, Naqvi, & Russ, 2009). Comparison of 688 adults with intellectual disabilities with evidence from the general population in the South West of England (National Centre for Health Outcomes Development, 2008) revealed that the difference in prevalence estimates of obesity was nearly 10% greater in adults with intellectual disabilities, 33% and 24%, respectively. A recent study by Robertson, Emerson, Baines, & Hatton, (2014), utilised methods of self-report of intellectual impairment obtained from the secondary analysis of the Understanding Society

survey (McFall & Garrington, 2011) to assess prevalence rates of obesity in adults with intellectual disabilities in the UK. Data on BMI was self-reported in the first wave of the survey and collected by trained nurses in the second. In both methods of data collection, adults with intellectual disabilities were reported to have higher rates of obesity in comparison to individuals without intellectual disabilities participating in the same survey, 27% vs 17% and 41% vs 26%, respectively.

In agreement with the evidence published based on UK studies, international studies have also reported high rates of obesity in adults with intellectual disabilities. For example, studies conducted in the USA, New Zealand and the Netherlands. In a large longitudinal study conducted in the USA by Hsieh *et al.*, (2014) data on the prevalence of intellectual disabilities obtained from the Longitudinal Health and Intellectual Disabilities Study (Hsieh, Rimmer, & Heller, 2012) were compared to data on the general population from the 2010 National Health Interview Survey. The results from 1450 adults with intellectual disabilities (≥ 18 years), reported higher prevalence of obesity in comparison to the general population, 38% and 28%, respectively. Furthermore, a greater proportion of adults with intellectual disabilities were at risk of morbid obesity in comparison to the general population (7% and 4%, respectively).

Prevalence rates of obesity in adults with intellectual disabilities receiving services from an intellectual disabilities provider in New Zealand were compared to the general population in a small ($n = 141$), single geographical setting study (Stedman & Leland, 2010). Results illustrated that adults with intellectual disabilities also showed the higher rates of obesity in comparison the general population ($p < 0.001$). This finding was also replicated in the Netherlands in adults (> 50 years) with intellectual disabilities in the study by de Winter, Bastiaanse, Hilgenkamp, Evenhuis, & Echteld, (2012). Data available from 945 participants mean age 61 (range 50-93 years), participating in the 'Healthy Ageing and Intellectual Disabilities' (HA-ID) study demonstrated that obesity levels (measured by BMI, assessed through objective measurements of weight and height) were significantly higher for adults with intellectual disabilities (25.6%, 95% Confidence Interval (CI) 22.8%–28.5%) in comparison to the general population (9.6%, 95% CI 8.7%–10.6%).

The above research provides an overview of the high prevalence rates of obesity in adults with intellectual disabilities in comparison to the general population. However, comparison of prevalence rates of obesity between studies in adults with intellectual disabilities should be

interpreted with caution due to methodological limitations in conducting epidemiological research, particularly in this population (Leonard & Wen, 2002). Issues affecting the robustness of the evidence-base in reviewed studies include, variability in the definition and classification of intellectual disabilities with some studies using self-report measures (Hsieh *et al.*, 2014; Robertson *et al.*, 2014), which also extends to the estimate of BMI (Hsieh *et al.*, 2014; Robertson *et al.*, 2014) used to classify participants as overweight or obese. Self-report measures are subject to reporting error and recall bias and should be interpreted with caution. In summary, the findings from the available research illustrate that adults with intellectual disabilities have a high prevalence of obesity, at least equivalent to or greater than the general population. This raises concern as obesity has shown to have a negative impact on the health of this population group, increasing the prevalence of obesity related co-morbidities including type II diabetes and cardiovascular disease and therefore highlights the need for further research in the treatment of obesity in adults with intellectual disabilities.

1.6 Prevalence of obesity related co-morbidities in adults with intellectual disabilities

Obesity is shown to have a negative impact on health and health care resources due to the wide range of associated comorbidities. Obesity has shown to increase the risk of numerous health conditions including cardiovascular disease, type II diabetes, some cancers, and musculoskeletal conditions (NICE, 2014; SIGN, 2010). Furthermore, obesity and these associated comorbidities have also shown to have a negative impact on health related quality of life in adults with intellectual disabilities, through contributing to further disability posed by exacerbating existing mobility restrictions, and thus reducing individuals' capacity to participate in social and leisure activities (Rimmer & Yamaki, 2006) This can also extend to increasing mental health problems including depression (Morris, Koehn, Happell, Dwyer, & Moxham, 2010). Evidence on the extent of the adverse effects of obesity on health is illustrated in Table 1.3. This section will focus on the most predominant health conditions associated with obesity, cardiovascular disease, and type II diabetes (Loveman *et al.*, 2011; WHO, 2004).

Table 1.3. Health conditions associated with obesity. Adapted from the WHO (WHO, 2004).

High increase in risk (relative risk >3)*	Moderate increase in risk (relative risk 2-3)*	Slight increase in risk (relative risk 1-2)*
Type II diabetes	Coronary heart disease	Cancer (breast cancer in postmenopausal women, endometrial cancer, colon cancer)
Gallbladder disease	Hypertension	Reproductive hormone abnormalities
Insulin resistance	Osteoarthritis (knee joints)	Polycystic ovary syndrome
Breathlessness	Hyperuricaemia and gout	Impaired fertility
Sleep apnoea		Low back pain due to obesity
		Increased risk of anaesthesia complications
		Fetal defects associated with maternal obesity

*Relative risk values are approximate.

1.6.1 Cardiovascular disease

Cardiovascular disease is an overarching term that encompasses conditions including coronary heart disease, peripheral artery disease and cerebrovascular disease. Cardiovascular disease is one of the leading causes of mortality in individuals with intellectual disabilities (Emerson & Banes, 2011). There is limited available evidence that make a direct comparison between prevalence rates of cardiovascular disease in adults with intellectual disabilities and the general population. However, in a study of 66 adolescents with intellectual disabilities conducted in Sweden, Wallén *et al.*, (Wallén, Müllersdorf, Christensson, Malm, Ekblom, & Marcus, 2009) found than in comparison to a sample of 34 adolescents without intellectual disabilities, adolescents with intellectual disabilities had more severe cardiovascular disease risk factors. The mean age of participants in this study was 18.6 (SD 1.3) and therefore the results may not be generalizable to older adults with intellectual disabilities. However, this is concerning that the risk factors for cardiovascular disease already exist at this young age and have shown to

increase throughout adulthood (Draheim., 2006). Risk factors in adults with intellectual disabilities have shown to include sedentary behaviour, elevated cardiometabolic factors including glucose and lipoprotein profiles and overweight and obese (Wallace & Schluter, 2008).

1.6.2 Type II diabetes

Type II diabetes is a common condition associated with obesity and has also shown to increase the risk of developing cardiovascular disease (Draheim, 2006; Heslop, Blair, Fleming, Hoghton, Marriott, & Russ, 2014). The available evidence on the prevalence of type II diabetes in adults with intellectual disabilities is limited. Two systematic reviews have investigated the prevalence of diabetes in individuals with intellectual disabilities (MacRae *et al.*, 2015; McVilly, McGillivray, Curtis, Lehmann, Morrish, & Speight 2014). Both reviews identified a paucity of evidence of the prevalence of this condition in adults with intellectual disabilities. Moreover, the prevalence rates of type II diabetes are uncertain as all but one study (Butler, Whittington, Holland, Boer, Clarke, & Webb, 2002), identified in both reviews, provided a clear distinction between diabetes classification (type I and type II). However, this study was conducted in individuals with Prader-Willi syndrome in which obesity is associated with genetic abnormalities. Therefore, prevalence rates cannot be generalised to all adults with intellectual disabilities.

The prevalence of combined diagnosis of diabetes (type I and type II) was reported by both reviews to be higher in individuals with intellectual disabilities in comparison to the general population MacRae *et al.*, (2015). The uncertainty in accurate assessment of the prevalence of type II diabetes is concerning due to the high risk factors associated with the development of this condition in adults with intellectual disabilities, including obesity, unhealthy diet, and high levels of physical inactivity and sedentary behaviour (Bartlo & Klein, 2011; McGuire *et al.*, 2007). Research should therefore aim to develop interventions to target these risk factors in particular management of obesity in order to help reduce the risk of obesity associated comorbidity and improve the health of this population group.

1.7 Determinants of obesity in adults with intellectual disabilities

The aetiology of obesity in adults with intellectual disabilities is complex and multi-factorial. The determinants of obesity in this population group can be categorised into modifiable and non-modifiable factors. Identifying and understanding of the determinants of obesity, in particular related to lifestyle, is vital to the development of effective weight management interventions.

1.7.1 Non-modifiable determinants

1.7.1.1 Age

In the general population, there is a strong linear relationship between increase in BMI with age (Flegal, Carroll, Ogden, & Curtin, 2010; Rennie & Jebb, 2005). However, the relationship between increasing age and weight gain in adults with intellectual disabilities is unclear. This is perhaps confounded by the heterogeneous population of adults with intellectual disabilities and the high prevalence of underweight in adults within this population group. This is particularly evident in adults with more severe and profound intellectual disabilities (Emerson, 2005) the reduced life expectancy of this population group (Bittles, Petterson, Sullivan, Hussain, Glasson, & Montgomery, 2002).

The age of onset of obesity in individuals with intellectual disabilities is reported to be lower than that of the general population (Emerson, 2005; Melville *et al.*, 2008; Hsieh *et al.*, 2014). Melville and colleagues (2008) reported that for all age categories up to the age of 74 in women and greater than 75 in men (with the exception of age category 65-74), adults with intellectual disabilities reported greater prevalence rates of obesity in comparison to the general population. Furthermore, the prevalence rates of obesity in adults (18-86 years) with intellectual disabilities in a study conducted in the USA (Hsieh *et al.*, 2014) increased with age between subgroups; 36.9% of adults aged 18-39 years, 42.2% of adults ages 40-59 years and decreased slightly to 33.6% in adults aged ≥ 60 years. The most concerning finding from this study was the prevalence of morbid obesity ($BMI \geq 40 \text{ kg/m}^2$) in the subgroup of adults aged 18-39 years, which was almost double the prevalence rates reported in the general population for the equivalent age range. This is of concern as the development of obesity in early adulthood has

been shown to continue throughout life and exacerbate the already reduced life expectancy of adults with intellectual disabilities (Cooper, Melville, Morrison, 2004).

1.7.1.2 Gender

Studies comparing the prevalence estimates of obesity by gender have continuously reported that women with intellectual disabilities are at greater risk of obesity in comparison to men with intellectual disabilities (Melville *et al.*, 2008; Bhaumik *et al.*, 2008). Bhaumik and colleagues (2008) examined the prevalence of obesity in adults with intellectual disabilities using objective measures of BMI assessed through measurement of height and weight of a cohort of 1119 adults (≥ 20 years) obtained from the Leicestershire Learning Disabilities Register in the UK. Rates of obesity were reported to be almost double in women with intellectual disabilities (29%) in comparison to men (15%) ($p < 0.001$). This finding is consistent with the evidence of studies comparing prevalence rates of obesity in men and women in the general population. For example, Melville *et al.*, (2008) reported that in their comparison sample of adults without intellectual disabilities (obtained from Scottish Health Survey), there is a greater prevalence of obesity for women (39.3–26.0%) than men (27.8–22.4%).

The extent of the gender effect is further highlighted by comparison studies investigating prevalence rates of obesity in adults with intellectual disabilities with the general population. Bhaumik *et al.*, (2008) reported that compared with data from the general population obtained from the Health Survey for England (Department of Health 1998), women with intellectual disabilities had higher prevalence of obesity than women in the general population, 32% and 23%, respectively.

The findings of UK studies of the effect of gender are in agreement with the prevalence in international studies. For example, a study conducted in the Netherlands in older adults reported that female participants have a higher prevalence of obesity in comparison to females in the general population (38.0% vs 14.8%, respectively (de Winter *et al.*, 2012).

In addition, results from a systematic review of the comparison of the prevalence rates in women with intellectual disabilities to women in the general population is consistently reported to be greater (Melville *et al.*, 2007), with the degree of difference ranging from 18% to 30%.

An explanation for the effect of gender in adults with intellectual disabilities is uncertain. It is postulated that this may be due to evidence illustrating the differences in lifestyle determinants such as physical activity levels between men and women with intellectual disabilities, with men shown to engage in higher levels of total physical activity and moderate to vigorous physical activity (Phillips & Holland, 2011).

1.7.1.3 Level of intellectual disabilities

Research has consistently shown that the prevalence of obesity varies with level of intellectual disabilities, with individuals with mild to moderate intellectual disabilities shown to have higher prevalence than individuals with severe to profound intellectual disabilities (Melville *et al.*, 2007). In a sample of 540 adults with intellectual disabilities living in different residencies, village communities, residential campuses and dispersed housing schemes Robertson, Emerson, Gregory, Hatton, Turner, Kessissoglou, & Hallam (2000) reported that obesity was more prevalent in adults classified as being more able (OR = 2.25, $p < 0.001$). This is further supported, by a relatively large scale study of 1542 adults with intellectual disabilities, conducted in the UK by Emerson, (2005). Results illustrated that individuals defined as the most able (OR = 2.5, $p < 0.001$) and moderately able (OR = 1.8, $p = 0.01$) were significant predictors of risk of obesity. In the study by Heish *et al.*, (2014) rates of obesity were significantly higher for individuals with mild and moderate intellectual disabilities (41% and 44%, respectively) compared to individuals with severe or profound intellectual disabilities (26%). These findings are in agreement across different sample populations of adults with intellectual disabilities (Emerson, 2005; Melville *et al.*, 2008; Stancliffe, Lakin, Larson, Engler, Bershinsky, Taub, & Ticha, 2011), reporting that risk of obesity is reduced as level of intellectual disabilities increases in severity.

Possible explanations for the differences in obesity prevalence across level of intellectual disabilities, is thought to be due to a number of factors including environmental factors, autonomy and individual skills in self-care and decision making. Individuals with severe and profound intellectual disabilities typically reside in institutional settings which are supported by care staff in a more structured routine. There is often less freedom of choice than for individuals with mild/moderate intellectual disabilities living in their own home or supported family home (Lakin, Doljanac, Byun, Stancliffe, Taub, & Chiri, 2008). Individuals with more mild intellectual disabilities are shown to have more autonomy over everyday choices than

individuals with more severe intellectual disabilities (Lakin *et al.*, 2008). An increased ability to make choices is associated with unhealthy lifestyle choices such as physically inactive lifestyles and unhealthy food choices (Rimmer & Yamaki, 2006). Furthermore, limited ability in self-care such as additional support needs with eating and drinking is also thought to be a potential explanation for the lower prevalence rates in adults with increased severity of intellectual disabilities.

1.7.2 Modifiable determinants

1.7.2.1 Environmental factors

Reviews of environmental determinants of obesity in adults with intellectual disabilities have explored the effect of living arrangements and obesity in adults with intellectual disabilities (Rimmer & Yamaki, 2006; Melville *et al.*, 2007). It has been reported that individuals who live in less restrictive environments are associated with increased risk of obesity (Rimmer & Yamaki, 2006; Melville *et al.*, 2007). In addition, persons who live in more restrictive environments such as supported group homes are less likely to be obese compared with individuals who live independently or in family homes (Robertson *et al.*, 2000).

Hsieh *et al.*, (2014) investigated type of residence, categorised into three levels based on level of support received. Living in their own home or supported living was categorised as least supported; living with a family member or relative/welfare guardian was categorised as moderately supported and living in a care or group home was categorised as a high level of support. Results illustrated that although there were no significant differences in rates of obesity between the type of residence, the highest prevalence rates were reported in adults considered to live in less supported environments (41.7%). This was followed by adults living in moderate supported living (37.3%) and those in receipt of high support in care homes (35.3%). The effect of the environment as a risk factor for obesity is further supported by a study examining prevalence rates at the time of discharge from an institutional resident setting to follow up assessments at one year when resident the community. Obesity prevalence increased by 5% in women and 6% in men over the one year period (Bryan *et al.*, 2000).

In summary, the influence of the environment on the development of obesity includes living in a less restricted setting, such as living in the community where there is an increased availability of food. Individuals with intellectual disabilities living independently in the community have less support from carers, and therefore choose uninformed lifestyle choices. This inability to manage their own environment is due to a limited cognition and understanding of the consequences of obesity (Smyth & Bell, 2006). Individuals with intellectual disabilities are often excluded from education and health promotion strategies (Emerson & Bains, 2011) and therefore adopt uninformed decisions in particular, unhealthy food choices which are easily available and the adoption of sedentary behaviours (Rimmer & Yamaki, 2006).

1.7.2.2 Physical activity

There is a general consensus in the available research that adults with intellectual disabilities engage in lower levels of physical activity and lead more sedentary lifestyles in comparison to the general population (Bartlo & Klein., 2011; Temple & Walkley., 2003). This is thought to be due to the increased barriers in engaging in an active lifestyle experienced by adults with intellectual disabilities which include a lack of support, finances and transportation (Hawkins & Look, 2006; Bodde & Seo, 2009). Population level data on physical activity in adults with intellectual disabilities has been in general obtained by indirect measures of physical activity such as questionnaires, either reported by the individual with intellectual disabilities or by proxy responses from carers. Comparisons of physical activity levels with the general population have continuously reported lower levels of physical activity in adults with intellectual disabilities, with these findings consistently reported across national and international studies.

Robertson *et al.*, (2000) assessed levels of physical activity during the previous four weeks prior to interviews with adults with intellectual disabilities and their carers. Assessment of physical activity levels was based on physical activity questions from the Health Survey for England 1993 (Department of Health, 1998). Physical activity was categorised based on the definitions of the Health Survey for England 1993; 'frequency-intensity activity level' (defined as the number of occasions of moderate or vigorous activity) and physical inactivity was defined as participating in less than 12 bouts of moderate or vigorous physical activity in the previous four weeks. Based on these definitions it was reported that a high proportion of participants, 53% of men and 64% of women were defined as physically inactive, with this

level of physical inactivity shown to be an independent risk factor for cardiovascular disease (Ekblom-Bak, Hellénus, Ekblom, Engström, & Ekblom, 2010). Comparison of these results with the general population data (from Health Survey for England 1996) revealed that irrespective of residential setting both men and women with intellectual disabilities were overall more likely to lead physically inactive lifestyles.

Physical activity levels of adults with intellectual disabilities were compared with the general population in a large-scale study of 1458 adults with intellectual disabilities in England (Emerson, 2005). Comparison data of adults with intellectual disabilities was obtained from Health Survey for England 2001 (National Centre for Social Research, 2003). Physical activity levels were assessed using the same methodological approach as by Robertson *et al.*, (2002). Both men and women with intellectual disabilities were reported to participate in less physical activity in comparison to the general population ($p < 0.001$). Moreover, only 8% of participants described as being physically able to engage in physical activity were considered to be active.

McGuire, Daly, & Smyth, (2007) examined the physical activity levels of adults with intellectual disabilities in Ireland. Although the Irish Health Department recommendations are consistent with UK physical activity guidelines, the measurement tool utilised was the National Survey of Lifestyle, Attitudes and Nutrition (SLAN; Kelleher *et al.*, 2003) to compare adults with intellectual disabilities with the general population defined physical activity as 20 minutes of mild exercise four or more times per week. Comparison of physical activity levels in adults with intellectual disabilities with the general population reported that the only 29.5% of participants with intellectual disabilities met the physical activity recommendations in comparison to 59% in the general population.

Finlayson *et al.*, (2009) conducted a large prospective cohort study, assessing physical activity levels in 433 adults with intellectual disabilities. Assessment of physical activity was through a semi-structured interview addressing physical activity questions on the type, the duration and the frequency of physical activity undertaken by adults with intellectual disabilities. The results of the interview were defined into intensity of physical activity, vigorous, moderate and light and combined with the data obtained on frequency and duration into summary categories of physical activity based on the Scottish Health Survey 2003 (Scottish Executive 2006). The results reported that most popular type of physical activity in adults with intellectual disabilities was walking. However, only 5.6% of men and 4.5% of women met the physical activity

recommendations set by the Scottish Health Survey 2003 (Scottish Executive 2006). Comparison of physical activity levels of this sample population with the general population was only available for moderate intensity physical activity. Adults with intellectual disabilities spent a significantly less mean amount of time walking at a moderate physical activity level per week (15 minutes) in comparison to adults in the general population (162 minutes), respectively.

Comparison between studies conducted internationally is difficult due to the different definitions of physical activity recommendations. However, the trend in low levels of physical activity in this group is commonplace and has been agreed internationally. For example, a systematic review by Temple & Walkley, (2003) reported that across studies, only 17.5% to 33% of participants met current physical activity recommendations.

Walking is a common form of physical activity in adults, and recent attention has been made in health promotion initiatives to encourage this form of physical activity by setting activity goals such as the 10 000 steps/day monitored with the use of a pedometer. This is thought to be consistent with the recommendations for health benefits of 30 minutes of moderate to vigorous physical activity (Donnelly, Blair, Jakicic, Manore, Rankin, & Smith, 2009). Only a few studies have examined the validity of this target, though it has increasingly gained acceptance as a public health goal/message. Stanish & Drahiem, (2005) investigated the walking activity of 103 adults with intellectual disabilities using pedometers. The mean daily step counts ranged from 6590 (SD 4652) steps to 9548 (SD 9865) across days of the week. Furthermore, only approximately 21% of participants achieved the recommended step count.

It is important to note that the above assessments of physical activity although providing assessment of physical activity in large populations, are subject to limitations. This is particularly relevant for adults with intellectual disabilities due to their cognitive abilities to recall physical activity participation, acquiescence and the level of understanding of this population group (Finlay & Lyons, 2001). The assessment of physical activity across studies in terms of validity varies from direct assessment from observational or accelerometer methodologies to indirect assessment from pedometers and self-report or informant report data (Esliger & Tremblay, 2007). Accelerometers are considered the criterion method of measuring physical activity (Lee, Williams, Brown, & Laurson, 2015) as they can provide additional information on energy expenditure and time spent in levels of physical activity. Only a few

studies have utilised this methodology in adults with intellectual disabilities. For example, Frey, (2004) investigated the physical activity habits of 22 adults with intellectual disabilities in the USA using the Actigraph 7164 model. Direct comparison of physical activity levels was made with two groups of age and gender matched adults without intellectual disabilities defined as sedentary (< 3 days per week of 30 minutes of moderate to vigorous physical activity) or active (> 3 days per week of 30 minutes of moderate to vigorous physical activity) based on self-reported physical activity. Adults with intellectual disabilities engaged in the less moderate to vigorous physical activity (19.7 ± 17.6 minutes/day), in comparison to sedentary (31.6 ± 21.8 minutes/day) and active (55.9 ± 18.2 minutes/day) adults without intellectual disabilities.

Studies that have measured physical activity with accelerometers have in general been limited by small sample sizes. However, a large-scale study of 152 individuals (age range 12 to 70 years) with intellectual disabilities (including 79 participants with Down syndrome) conducted by Phillips & Holland, (2011) in the UK objectively assessed physical activity with accelerometers (Actigraph GT1M). The results are consistent with previous research and demonstrated that overall adults with intellectual disabilities engage in high levels of physical inactivity and time spent in sedentary behaviour (608.1 mins/day). Furthermore, no participant engaged in enough moderate to vigorous physical activity to the level required to be considered to meet physical activity recommendations for adults (Department of Health, 2011). In this overview of the evidence of physical activity levels, irrespective of methodological assessment, adults with intellectual disabilities have consistently been shown to engage in low levels of physical activity that do not meet current physical activity recommendations.

1.7.2.3 Diet

The extent of available evidence on nutritional habits and the quality of dietary intake (adhering to dietary recommendations on a healthy balanced diet) of adults with intellectual disabilities, is limited. This is primarily due to the difficulties in accurately and reliably assessing dietary intake in adults with intellectual disabilities. Studies in adults with intellectual disabilities have utilised a range of methodologies such as. 24 hour recall, food frequency questionnaires, weighed dietary intake, and food diaries (Humphries, Traci, & Seekins, 2009). The most common methodological approach in population based studies involved nutrition questionnaires which require recall of dietary intake.

Robertson *et al.*, (2000) investigated the nutritional intake of adults with intellectual disabilities sampled from different residential settings. Data were obtained from proxy respondents by carers using the recommendations on a healthy balanced diet by Thameside and Glossop Health Needs Survey (Turner, 1997). The results reported that across settings adherence to a healthy balanced diet was low (7-8%) and that only 16-22% of participants consumed a sufficient intake of fruit and vegetables.

McGuire *et al.*, (2007) investigated the nutritional status of adults with intellectual disabilities living in residential settings or in family settings. Assessment was made by proxy respondent by carers completing a questionnaire based on a modified version of the National SLAN (Kelleher *et al.*, 2003). Information on 157 adults with intellectual disabilities was obtained. Nutritional assessment was based in the 'Food Pyramid' which examined intake of food groups, fruit and vegetables, carbohydrates, dairy products, protein, and foods high in sugars and fats. Comparison of nutritional intake with the general population revealed that the percentage of participants with intellectual disabilities (42.4%) meeting guidelines on the recommended portion of daily fruit and vegetables (> 4 portions) intake was less in comparison to the general population (72%) completing the survey.

These findings were reinforced by a study of adults with intellectual disabilities in Australia (Koritsas & Iacono, 2015). This study examined the nutritional status and food choices of 68 adults (age range 19 to 73 years) with intellectual disabilities. A questionnaire was developed which included a screening tool for malnutrition, The Australian Nutrition Screening Initiative checklist (Lipski, 1996). The questionnaire was administered by health professionals ranging from GPs, nurses to disability care workers supporting adults with intellectual disabilities. The results reported that the mean score on the screening tool was associated with moderate risk (38.2% of participants) of malnutrition, with a further 42.6% of participants at minimum risk and 17.6% at high risk. It was postulated by the authors, that due to the high rates of overweight and obesity that the result of malnutrition may be due to the new paradox prevalent in the general population of over-nutrition (Tanumihardjo, Anderson, Kaufer-Horwitz, Bode, Emenaker, Haqq, & Stadler, 2007). Over-nutrition occurs when the quantity of energy intake is sufficient or exceeds energy expenditure. However, it is often limited in the quality of nutritional content to provide a healthy balanced diet and may not meet micronutrient requirements (Tanumihardjo *et al.*, 2007). The results reported that the majority of adults with intellectual disabilities, exercised little choice on their dietary intake (60.3%). The

consumption of takeaway foods was considered to be low with the mean frequency of takeaways reported to be less than once per week (range 0 to 3.5 times per week). The participant population was reported to be predominately adults with severe to profound intellectual disabilities, therefore, the results may not be generalizable to adults with more mild to moderate intellectual disabilities who have shown to have more autonomy (Lakin *et al.*, 2008). Exploring the cause of the results of this study are important. Due to the limited choice over dietary intake and the high prevalence of malnutrition in adults with intellectual disabilities in this study, the authors implied that this was probably due to the lack of knowledge or informed choice for a healthy diet by carers supporting this population group. These findings are in agreement with previous research showing that carers had poor knowledge of nutrition recommendations (Melville, Hamilton, Miller, Boyle, Robinson, Pert, & Hankey, 2009) and by Humphries *et al.*, (2009) reporting that the nutritional quality of the diets of adults with intellectual disabilities living in the community was poor due to undertrained staff responsible for the preparation of meals.

The association between consuming an unhealthy diet and the risk of obesity in adults with intellectual disabilities has not been extensively investigated due to the difficulties in accurately measuring dietary intake. One study by Draheim, Williams, & McCubbin, (2002) investigated the health status of 145 adults with intellectual disabilities. Two food frequency questionnaires were administered to participants, with support from carers. The Block Screening Questionnaire intake (Block, Clifford, Naughton, Henderson, & McAdams, 1989) and the Behavioral Risk Factor Surveillance System, Fruit and Vegetable Module (Serdula, Coates, Byers, Mokdad, Jewell, Chavez, & Block, 1993) both of which aimed to assess intake of food groups, fat, fruit and vegetables. The results demonstrated only 36.6% of participants met the dietary recommendations (> 5 portions per day) for fruit and vegetable intake and 64.1% of participants consumed above average fat intake ($\geq 35\%$ of total dietary intake). Participants who were thought to consume a fat intake above the recommended were more likely to have abdominal obesity. However, this finding is not supported by other studies by Cunningham, Gibney, Kelly, Kevany, & Mulcahy, (1990) & Braunschweig, Gomez, Sheean, Tomey, Rimmer, & Heller, (2004). The latter study investigated the dietary intake of 48 adults with Down syndrome resident in group homes in the USA. Assessment of dietary intake was made by proxy-response by carers using the same Block screening food frequency questionnaire as used by Draheim *et al.*, (2002). Although participants' diet was shown to not meet recommendations on a healthy balance diet it was not associated with increased body weight.

Overall comparison of dietary intake in adults with intellectual disabilities across studies is difficult due to the limited validity and diverse methodology utilised. No studies have validated a measure of dietary intake due to similar barriers previously discussed in completing physical activity questionnaires including challenges with comprehension, memory and communication of adults with intellectual disabilities. Proxy-respondents for dietary assessment are also subject to limitations due to carers not being present at every meal, and food choices made by individuals when out of their care could not be accounted for. Furthermore, difficulties in comparison of dietary assessment also occur due to the heterogeneity in the sample of participants studied. A systematic review of nutrition in adults with intellectual or developmental disabilities by Humphries *et al.*, (2009) revealed that there is an apparent disparity in the quality of nutritional intake in adults with intellectual disabilities resident in the community or more supported institutional settings. It is reported that the nutritional intake of individuals in institutional residences generally correlates with acceptable nutrition recommendations for a healthy balanced diet (Cunning *et al.*, 1990). However, this acceptable diet has not been replicated in a community setting (Bryan, Allan, & Russell, 2000; Robertson *et al.*, 2000). This is supported by evidence when participants transition from institutional settings into the community and is associated with a decline in estimated dietary quality and increase in BMI (Bryan *et al.*, 2000).

In summary, the available literature illustrates that current methods are not sufficiently accurate or reliable to assess dietary intake in adults with intellectual disabilities. This prevents firm conclusions to be drawn on the nutritional assessments of this population group. However, the majority of studies report nutritional intakes that are insufficient and do not meet national recommendations for a healthy balanced diet. It is known that consumption of energy dense foods can increase energy intake and result in an energy imbalance and increased body weight (Catenacci *et al.*, 2009). Interventions aimed at weight loss should therefore target this lifestyle behaviour in order to control fluctuations in body weight that could result in weight gain. Where individuals with intellectual disabilities are dependent on carers it is important that appropriate education and support is provided so that carers are actively involved in facilitating healthy dietary intake.

1.7.2.4 Obesogenic medication

Mental health problems have often been shown to be more prevalent in adults with intellectual disabilities in comparison to the general population (Smiley *et al.*, 2007; Deb, Thomas, & Bright, 2001) and have shown to include mood disorders and anxiety resulting in problem behaviours, attention deficit hyperactivity disorder (ADHD), bipolar affective disorder and schizophrenia (Devine & Taggart, 2008). A cause and effect relationship between obesity and mental health is proposed, as individuals who are overweight and obese may have a poorer quality of life and thus at increased risk of depressive symptoms (Markowitz, Friedman, & Arent, 2008; Morris *et al.*, 2010). Depression can often lead to adverse weight gain by influencing unhealthy lifestyle behaviours in overeating or a reduced motivation for engagement in physical activity (Morris *et al.*, 2010). Furthermore, the treatment of these conditions through prescribed medication, especially that prescribed on a long term basis, is a contributing factor to weight gain. Studies in the general population (Domecq *et al.*, 2015; Leslie, Hankey, & Lean, 2007) and specific to adults with intellectual disabilities (Cohen, Glazewski, Khan, & Khan, 2001; Boksanska, Martin, Vanstraelen, Holt, Bouras, & Taylor, 2003) have reported increased body weight in particular in response to antidepressants, antipsychotics and antiepileptic medications.

Boksanska *et al.*, (2003) examined the side effects of two widely prescribed atypical antipsychotics (Olanzapine and risperidone) in fifty adults with intellectual disabilities. Although both medications were shown to be effective in treating the symptoms designed to target, adverse weight gain occurred at three months and continued to be increased at 12 months of administration of these medications. Hsieh *et al.*, (2014) explored the modifiable factors associated with obesity after adjusting for non-modifiable risk factors in adults with intellectual disabilities. Forty-five percent of adults were taking medication associated with weight gain and this was significantly associated with obesity (OR 1.80; 95% CI 1.38 to 2.37; $p < 0.001$).

Due to the high prevalence of obesity in adults with intellectual disabilities it is important that alternative medications that do not increase body weight are considered wherever possible. Furthermore, weight management interventions that improve health behaviours such as diet and physical activity should be implemented in some circumstances to reduce medication use, for example in the treatment of obesity related comorbidities.

In summary adults with intellectual disabilities are reported to have higher rates of obesity in comparison to the general population. Non-modifiable risk factors for obesity in this population group include being female, Down syndrome as the origin of intellectual disabilities and increasing prevalence with aging. Modifiable determinants include, in some circumstances, taking obesogenic medication, and unhealthy lifestyle habits such as diet and physical activity. These risk factors have a cumulative effect on the risk of obesity in adults with intellectual disabilities and interventions should aim to modify these risk factors associated with adverse weight gain.

1.8 Management of obesity

1.8.1 Clinical guidelines

Treatment of overweight and obesity is initially managed within primary care settings and founded on clinical guidance. The first guidelines on weight management of overweight and obese adults were established by the Scottish Intercollegiate Guidelines Network (SIGN; SIGN 1996). The guidelines were the first ever worldwide, and aimed to improve the effectiveness of the prevention and management of obesity. These recommendations have since been updated and revised guidelines in adults were published in 2010 (SIGN, 2010). In addition to the guidelines from SIGN, are the clinical guidelines on the management of obesity published in the UK (England and Wales) by the National Institute of Clinical Excellence (NICE; NICE 2006; NICE 2014). Both guidelines aim to improve the care provided to individuals with obesity and are formed from evidence synthesis of systematic reviews and the highest quality research. This thesis will focus on the UK clinical guidelines only, as the studies carried out for the purpose of this thesis were conducted in Scotland and therefore both the UK guidelines are considered relevant.

The recommendations from these current clinical guidelines state that overweight and obese adults should aim for a sustainable weight loss of 0.5-1 kg [1-2 pounds (lb)] per week, with an overall aim to achieve a clinically significant/important weight loss of 5-10% (~5-10 kg) of initial body weight. This is supported by both guidelines; however, SIGN provides further guidance based on differentiation between BMI categories and advocates, largely through evidence from clinical opinion, that in individuals with a higher BMI of $> 35 \text{ kg/m}^2$, greater

weight loss of the order of 15-20% (~15-50 kg) may be required to facilitate improvements in health risk factors.

1.8.2 Multi-component weight management interventions

To achieve clinical improvements in health, multi-component weight management interventions are recommended as the optimal treatment approach. Recommendations state that “weight management programmes should include behaviour change strategies to increase people’s physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person’s diet and reduce energy intake” (NICE 2014).

The supporting evidence for the recommendation of multi-component weight management interventions is based on a meta-analysis of five studies, comparing interventions including a combination of diet, physical activity and behaviour change techniques to single component dietary interventions. Meta-analysis of the results reported that median weight change was -4.60 kg (range -3.33 kg to -5.87 kg) for the multi-component interventions in comparison to -0.48 kg (range -2.40 kg to 0.53 kg) for the dietary interventions (NICE 2006). Recommendations on the content of the intervention components; diet, physical activity and behaviour change strategies are also provided and will be discussed along with the supporting evidence.

1.8.2.1 Diet

To facilitate a healthy sustainable weight loss, a negative energy balance created through modification in primarily the quantity of dietary intake has been recommended. To achieve a weight loss of 0.5 kg per week, an energy deficit of 3500 kilocalories (kcal) week, equivalent to 500 kcal per day is required (Lean & James, 1986). In practice 600 kcal energy deficit diet (EDD) is recommended to ensure this deficit is achieved. Consideration of lower EDD (800-1800 kcal/day) and very low EDD (< 800 kcal/day) are also recommended in certain circumstances, to be associated with a clinical important weight loss ($\geq 5-6\%$). However, caution over the nutritional adequacy of this approach is warranted and current advice suggests these lower energy approaches should only be undertaken with medical supervision.

1.8.2.2 Physical activity

The current physical activity recommendations for moderate to vigorous physical activity of 30 minutes on five or more days of the week are based on the amount of physical activity required to achieve benefits in health risk factors including reducing the risk of type II diabetes and cardiovascular disease. The ‘dose’ of physical activity to prevent and increase in body obesity is recommended to be equivalent to 225-300 minutes/week of moderate to vigorous physical activity (Donnelly *et al.*, 2009). This may be achieved through regular physical activity, five sessions per week of moderate intensity for 45 to 60 minutes. This is equivalent to an energy expenditure of approximately 1800 to 2500 kcal/week. Further increases in physical activity levels of 60 to 90 minutes are advocated for those who have lost weight and want to maintain weight and avoid weight regain. Clinical recommendations advocate that this dose can be accumulated in multiple bouts of ten minutes over the course of a day.

1.8.2.3 Behaviour change techniques

To support these changes in diet and physical activity, behaviour change techniques should also be incorporated and include the following to be used flexibly where applicable:

- self-monitoring of behaviour and progress
- stimulus control
- goal setting
- slowing rate of eating
- ensuring social support
- problem solving
- assertiveness
- cognitive restructuring (modifying thoughts)
- reinforcement of changes
- relapse prevention
- strategies for dealing with weight regain.

In addition to these intervention components, it is recognised that multi-component weight management interventions need to be tailored to an individual’s needs and support to enable this should be provided, if necessary. The need for multi-component weight management interventions to be adapted to the specific requirements of individuals, including individuals

with intellectual disabilities is further highlighted in the updated recommendations by NICE, (2014) including guidance on adapting resources and communicating at a level that will facilitate understanding.

In order to examine the effectiveness of a multi-component weight management intervention, a duration of at least 12 months has been recommended, including the intervention and follow up period is required. Furthermore, the distinction between weight loss and weight maintenance should be emphasised at six and nine months of treatment, incorporating the development of skills essential to each stage of weight management.

The above guidance on weight management is focussed on previous research of multi-component weight management interventions in the general population. However, there is a limited evidence base for the treatment of obesity in adults with intellectual disabilities.

1.8.3 Weight management services

In the UK, current weight management services are based on clinical guidance (NICE 2014; SIGN 2010). The Glasgow and Clyde Weight Management Service (GCWMS) is an example of a weight management service available to the general population living in Greater Glasgow and Clyde (GGC). It was developed in 2004, to offer evidence based treatment approaches to support individuals to achieve a clinically significant weight loss, in response to the first SIGN obesity guidance. The GCWMS is part of a hierarchical approach offered by the NHS in this area of Scotland for weight management. The services available are based on severity of obesity, according to BMI and range from primary prevention (BMI \geq 18.5-24.9 kg/m²), local authority (community based interventions, BMI \geq 25 kg/m²), specialist services (GCWMS, BMI \geq 35 kg/m² or \geq 30 kg/m² with co-morbidities) and surgery (following completion of the GCWMS programme). The GCWMS is the third treatment option under specialist services not delivered in the community. The GCWMS delivery uses a multi-disciplinary team of health professionals including dietitians, psychologists and physiotherapists.

The service comprises three structured phases delivered approximately over a two year period:

- Phase 1: Weight loss – Multi-component intervention (diet, physical activity, psychology – behaviour change techniques, motivational enhancement)

- Phase 2: Continued weight loss – Lower calorie diet or pharmacological treatment approach
- Phase 3: Weight maintenance – Learning to keep the weight off, through using support systems in place in the local community such as those available in tier two of the overall approach to weight management.

A prospective cohort study was conducted in order to evaluate the first phase of the GCWMS. The study was conducted between 2004 to 2007 and published by Morrison and colleagues in 2012 (Morrison, Boyle, Morrison, Allardice, Greenlaw & Forde, 2012). Evaluation of the intervention at the end of phase three and approximately 12 months from baseline, was reported based on last observation carried forward (LOCF). Patients significantly lost weight mean change was -3.6 kg (95% CI -3.9 kg to -3.3 kg) and 24% lost a clinically important weight loss of greater than 5% (Logue, Allardice, Gillies, Forde, & Morrison, 2014). Therefore, based on the above evaluation the service was considered an effective approach supporting individuals to achieve a clinically significant weight loss.

1.8.4 TAKE 5 multi-component weight management intervention

Prior to this study it was identified that there was a gap in service provision for weight management for adults with intellectual disabilities in the UK. This was supported by a review of the evidence on lifestyle interventions for obesity management in this population group (Hamilton, Hankey, Miller, Boyle, & Melville, 2007; Spanos *et al.*, 2013a). In particular, it was identified that no interventions had been developed that met clinical recommendation on multi-component weight management in the general population (NICE 2014; SIGN 2010). An attempt to fill the gap in the evidence base for weight management for adults with intellectual disabilities and obesity, the TAKE 5 multi-component weight management intervention was developed (Melville *et al.*, 2011; Spanos, Hankey, & Melville, 2015). TAKE 5 was developed in collaboration with NHS GCWMS (Morrison *et al.*, 2012). The intervention satisfied evidence-based recommendations for weight management interventions within current clinical guidelines, and was designed to be used with support from carers, or significant others, wherever possible.

Melville and colleagues initially conducted pilot investigations into the feasibility and acceptability of the intervention to individuals with intellectual disabilities. This study also provided preliminary results on any clinical benefits of the intervention, worthy of conducting further evaluations, as recommended by the Medical Research Council (MRC) research framework (MRC, 2000; MRC, 2008). A single-stranded feasibility study of the TAKE 5 intervention was conducted (Melville *et al.* 2011). Fifty-four individuals met the criteria for inclusion and consented to participate in the pilot study. Of the individuals, three dropped out, and four did not complete the intervention within the study period. Therefore, retention to the intervention was high with forty-seven (87.0%) participants completing the intervention. The study reported a significant decrease in participants' body weight (mean difference – 4.47kg; $p < 0.001$), with seventeen participants (36.2%) losing 5% or more of initial body weight. TAKE 5 also found significant results in other health risk factors including an increase in daily time spent in physical activity (mean difference 1.87%; $p < 0.05$) and a decrease in daily time spent sedentary (mean difference -2.60%; $p < 0.05$).

The second phase of the TAKE 5 intervention consisted of a 12 month weight maintenance phase (Spanos *et al.*, 2015). Participants who completed the weight loss phase and achieved a minimum 3% weight loss of initial body weight were invited to continue to maintain their weight loss. Thirty-one participants were eligible to participate, however two participants withdrew from the study and one participant died, leaving twenty-eight participants who took part and completed (90.3%) the weight maintenance phase. There were no statistically significant changes in anthropometric outcomes (weight, BMI or waist circumference) or physical activity post intervention, at 12 months. However, 50.4% of participants maintained their body weight (mean weight change -0.5 kg, SD 2.2 kg) and 21.6% of participants continued to lose weight (mean weight change -8.0 kg, SD 3.0 kg).

1.8.5 Role of carers

Social support from family or paid carers has been highlighted by previous studies as playing an important role in supporting adults with intellectual disabilities to lose weight (Fox, Rosenberg, & Rotatori, 1985; Hamilton *et al.*, 2007; Spanos *et al.*, 2013a). The roles of carers involved in weight management and lifestyle interventions has ranged from encouragement and reinforcement of key healthy lifestyle messages to actively participating in physical

activities such as walking with adults with intellectual disabilities and decision making on consumption of a healthy balanced diet. (Fox *et al.*, 1985; Matthews *et al.*, 2016; Spanos *et al.*, 2013b). The level of carer involvement is dependent on the individual needs of adults with intellectual disabilities and research has recommended that weight management interventions should aim to involve carers to facilitate changes in body weight in this population.

A qualitative study was also conducted which aimed to explore the role and experiences of carers and the identification of barriers and facilitators in implementing the TAKE 5 intervention and supporting adults with intellectual disabilities and obesity to make healthy lifestyle choices. Semi-structured interviews were conducted with 24 carers (Spanos *et al.*, 2013b). This was a purposive recruited sample of carers: 16 paid and eight family carers who supported participants who achieved a 5% weight loss ($n = 12$) or did not ($n = 12$). All carers completed the interviews, however, data from two interviews were of insufficient quality to be analysed qualitatively. Therefore, twenty-two participant interviews (91.6%) were included in the analysis. Carers reported the need for ongoing support and opportunities for training from health professionals. They also reported that lack of communication between staff in a team, supporting a participant, was an important barrier in their efforts to support weight loss. Carers of participants who did not lose weight described barriers associated with the complexity of some aspects of the intervention, including the prescribed diet.

1.9 Research guidance on developing and evaluating complex interventions

For a complex weight management intervention to be implemented into clinical practice, it needs to have undertaken a comprehensive research process. The MRC framework provides best practice guidance on the development, evaluation and implementation of complex interventions (MRC, 2000; MRC, 2008). The framework aims to identify the ‘active ingredients’ of an intervention in order to provide an understanding of the causal mechanisms which are essential for replicating an intervention in different contexts and for developing future effective interventions. The MRC framework provides an outline of key stages of this complex process, from exploratory stages of research, addressing issues in design to an evaluation stage and finally long-term implementation. The key stages of this process and activities to be undertaken at each stage are illustrated in Figure 1.1. These include:

Development of an evidence-based intervention; feasibility and piloting; evaluation of the intervention and implementation.

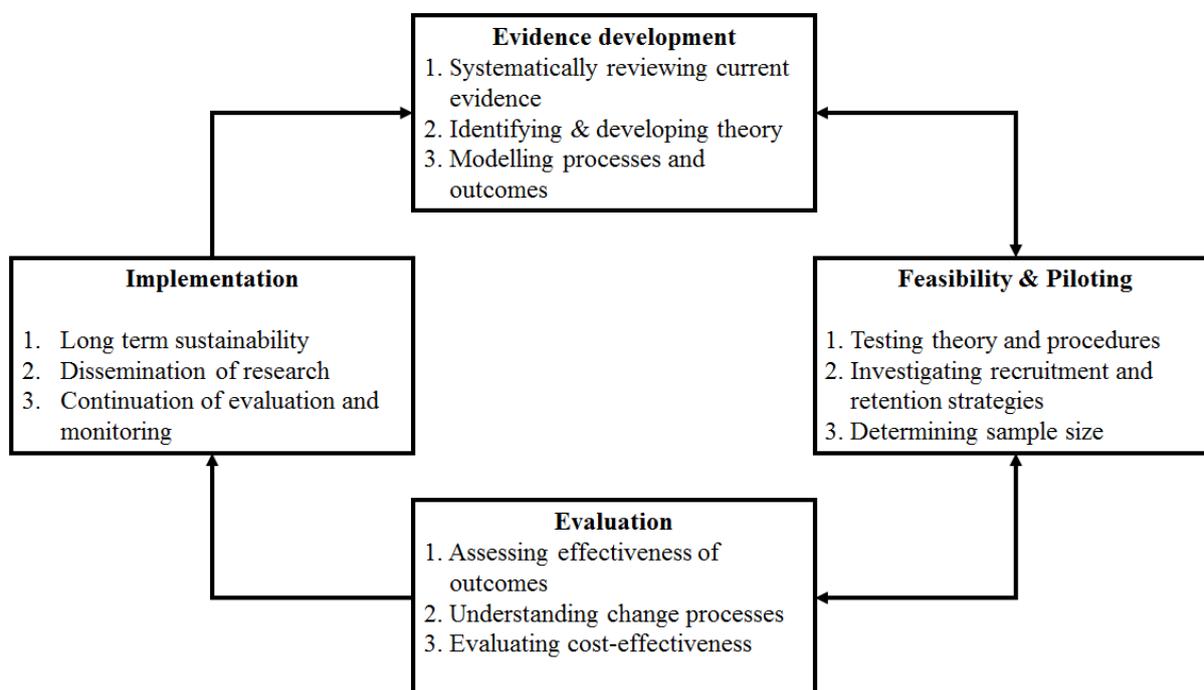


Figure 1.1. Key stages in developing and evaluating complex interventions. Adapted from MRC, (2008).

1.9.1 Development of an evidence-based intervention

The MRC guidelines on developing and evaluating complex interventions advocate that prior to the development of an intervention it is important to identify the existing evidence through conducting a systematic review. In cases where current systematic reviews exist it is important to update these as the evaluation of the evidence evolves, prior to any implementation of recommendations. This is essential to developing the relevant theory on which the intervention will be founded upon. An intervention based on theory will allow the effective components of the intervention to be identified in order to attribute the causes of the changes in outcomes observed.

1.9.2 Feasibility and piloting

Examining the feasibility of an intervention prior to a full-scale trial is important to provide essential information on the design of the intervention and also the evaluation process. This stage involves testing procedures associated with conducting clinical trial research such as the

acceptability of recruitment strategies, retention of participants and the acceptability of patient centred outcome measurements. Pilot studies prior to full-scale trials also provide valuable information on the sample size requirements for such a trial in order to include enough participants to detect a statistically significant effect, and try to avoid inconclusive findings (type II error). At this stage, it is also recommended that a number of studies may be carried out either simultaneously such as the investigation into the process evaluation and feasibility measures of an economic evaluation.

1.9.2.1 Process evaluation

Process evaluations of complex interventions was conducted as early as the 1960s. In Suchman's (1967) textbook on program evaluation, process evaluation was defined:

“In the course of evaluating the success or failure of a program, a great deal can be learned about how and why a program works or does not work. Strictly speaking, this analysis of the process whereby a program produces the results it does is not an inherent part of evaluation research. An evaluation study may limit its data collection and analysis simply to determine whether or not a program is successful... However, an analysis of process can have both administrative and scientific significance, particularly where the evaluation indicates that a program is not working as expected. Locating the cause of the failure may result in modifying the program so that it will work, instead of its being discarded as a complete failure [p. 66].”

This description at the time was not coined process evaluation, however, it is still used as the definition that current concepts and frameworks are modelled on today. The evolution of research over the years has led to more comprehensive definitions and concepts (Baranowski & Stables, 2000; Linnan & Steckler, 2002). Process evaluation can be conducted for a number of reasons including the interpretation of successful and unsuccessful components, monitoring of the fidelity of the intervention (i.e. whether delivery of the intervention is consistent with that planned from the outset) and assessing the influence contextual factors could have on intervention outcomes (Linnan & Steckler, 2002; Saunders, Evans, & Joshi, 2005). There is no comprehensive approach or gold standard for a process evaluation. It may be conducted formatively to provide feedback during a complex intervention to inform the researchers or in a summative manner to provide information on the causality of outcomes. Both these evaluations can be applied to all stages of the research process whether it is at the feasibility

and piloting stage to assist in redefining the intervention and modelling to inform future trials (Linnan & Steckler, 2002) or at the implementation stage to assist with the adoption and translation of the intervention into routine practice (Glasgow, Vogt, & Boles, 1999). The importance of conducting process evaluations has recently been emphasised by the publication of distinct guidelines from outcome evaluations, aimed at consolidating the available literature (Moore *et al.*, 2015).

1.9.2.2 Economic evaluation

In addition to the benefits of conducting a process evaluation to gain insight into the implementation process, the inclusion of an economic evaluation can also provide important insights into the study design, the components of the intervention and the resources necessary to implement the intervention. Economic evaluations can be conducted at any stage of developing and evaluating complex interventions. Economic evaluation at the feasibility and pilot stage will help identify data collection methods (i.e. staff costs, intervention resources) and limitations in the cost-effectiveness which could be refined prior to a full-scale trial. An economic evaluation will also generate pilot data to inform the sample size required for a full-scale trial to provide enough power to detect economically important differences in cost-effectiveness. Furthermore, economic evaluation conducted concurrently to evaluating the effectiveness of an intervention will make the interpretation of the results more informative for decision and policy makers. This could for example help provide estimates on funding requirements and whether or not an intervention is viable for implementation into practice.

1.9.3 Evaluation of the intervention

In order to examine the efficacy of an intervention it is recommended, where possible, that a randomised controlled trial design be implemented. Randomised controlled trials represent the gold standard approach to examining the efficacy of healthcare interventions (MRC, 2008). Randomised controlled trials aim to eliminate risk of bias. The main sources of bias in conducting clinical trial research can be categorised into six classifications; selection bias (sequence generation and allocation concealment), performance bias, detection bias, attrition bias, reporting bias and other potential risks of bias (Higgins *et al.*, 2011). A description of each risk of potential bias is illustrated in Table 1.4.

Table 1.4. Classification of bias in clinical trials. Adapted from the Cochrane Handbook (Higgins *et al.*, 2011).

Bias	Description	Risk of bias domains
Selection bias	Systematic differences between baseline characteristics of the groups that are compared.	Sequence generation Allocation concealment
Performance bias	Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest.	Blinding of participants and researchers
Detection bias	Systematic differences between groups in how outcomes are determined.	Blinding of outcome assessment
Attrition bias	Systematic differences between groups in withdrawals from a study.	Incomplete outcome data
Reporting bias	Systematic differences between reported and unreported findings.	Selective reporting of outcomes
Other bias	Systematic differences not specified by the above i.e. in relation to study design, such as recruitment bias, or incorrect analysis.	Other potential sources of bias (e.g. related to study design, contamination of interventions, related to clinical setting)

Advantages of conducting randomised controlled trials are that they allow the investigation of causal associations between interventions and outcomes, which is not permitted with other types of study designs such as observational studies (cross-sectional or longitudinal studies). The random allocation of participants to each treatment arm of a trial, permits that all factors will be equal and the only factors which differentiate between groups are the interventions they received. Associations can be investigated in observational studies however, due to confounding factors, causality cannot be inferred. Therefore, randomised controlled trials are the most powerful research method for providing robust evidence on the efficacy of an intervention.

1.9.4 Implementation of the intervention

There is not a clear pathway for implementing interventions and the evidence for this process remains limited (Grimshaw *et al.*, 2004). However, adherence to the guidelines discussed above provides a strong evidence base for interventions. Reporting of findings at all stages of the research process, and dissemination and translation of findings to a large audience such as service users, stakeholders, and policy makers is imperative. The authors of the MRC research framework, have highlighted a lack of available evidence on the key processes of implementation research, and advocate that future research is necessary to help facilitate the move from interventions conducted in controlled research settings into routine practice. Furthermore, they suggested that long term follow up of studies may assist in providing valuable insight into whether the short term changes and benefits that occur in the original study are persistent over time, thus providing findings more generalizable to real world situations.

In summary, complex interventions are widely used in health care research. Weight management interventions can be defined as complex interventions due to the multiple-components including, diet, physical activity and behaviour change techniques in the treatment of obesity. In order to examine the efficacy of a multi-component weight management intervention effectively it has to go through a series of research studies which continuously aim to redefine the intervention components and develop effective evaluation methods. The MRC framework for developing and evaluating complex interventions is based on best practice guidelines. The initial stages of this framework, that assessed feasibility and piloting methods, are particularly relevant for this thesis which will examine the feasibility of a full-scale trial of

the TAKE 5 weight management intervention for adults with intellectual disabilities and obesity. This stage involves testing methodological procedures for their acceptability, including testing recruitment strategies, and estimating rates of recruitment and retention, the acceptability of patient centred outcomes and providing estimates of sample sizes for future trials.

Chapter 2: Aims of thesis and research questions

2.1 Aims

The aims of this thesis were formulated based on the existing literature discussed in chapter one and in accordance to current research recommendations on developing and evaluating complex interventions.

The overall aim of this thesis was to examine the effectiveness of multi-component weight management interventions for adults with intellectual disabilities and to inform the development of a future randomised controlled trial.

This aim was addressed by conducting two studies which aimed

1. To systematically review the available literature on randomised controlled trials of multi-component weight management interventions for adults with intellectual disabilities and obesity.
2. To examine the feasibility of a full-scale clinical trial of the TAKE 5 multi-component weight management intervention in comparison with an active comparator intervention.

2.2 Research questions

In order to address the above aims of this thesis, the following research questions were developed. The research questions (1-4) in relation to the first aim were addressed in chapter three, by undertaking a systematic review of the literature. The research questions (5-10) in relation to the second aim were addressed in chapters four to six, through conducting a pilot randomised controlled trial.

1. What are the components included in weight management interventions for adults with intellectual disabilities?

2. Do multi-component interventions adhere to clinical guidelines on weight management?
3. What is the intervention effect of multi-component interventions on body weight in comparison to a control or comparator intervention?
4. Did participants achieve a clinically significant weight loss of 5-10% of initial body weight?

2.2.1 Feasibility

5. Can adults with intellectual disabilities and obesity be recruited to a randomised study of the TAKE 5 intervention, versus a comparator health education intervention?
6. What attrition rates are observed at six and 12 months post-randomisation?

2.2.2 Potential efficacy

7. Did participating in the weight management interventions result in a clinically important weight loss of 5-10% of initial body weight?
8. Were there between group differences in secondary outcomes: arthrometry; physical activity and sedentary behaviour; and health related quality of life?

2.2.3 Process evaluation

9. Were the weight management interventions implemented as intended?
10. Were there any effective and ineffective components of the interventions?

Chapter 3: The effects of multi-component weight management interventions on body weight loss in adults with intellectual disabilities and obesity: A systematic review and meta-analysis of randomised controlled trials

3.1 Introduction

Chapter one highlighted the extent of the obesity epidemic in adults with intellectual disabilities and the clinical and research processes relevant to the management of obesity. This chapter will present a review of the available evidence on multi-component weight management interventions in adults with intellectual disabilities and obesity. This review will aim to expand on previous knowledge of lifestyle interventions for the treatment of obesity in adults with intellectual disabilities and systematically review the ‘active ingredients’ of the current literature to inform the successful components in supporting adults with intellectual disabilities to lose weight.

3.2 Systematic review of weight management interventions

The available literature on the management of obesity in adults with intellectual disabilities has been previously reviewed (Hamilton *et al.*, 2007; Jinks, Cotton, & Rylance, 2011; Spanos *et al.*, 2013a). Hamilton and colleagues (2007) identified eight studies focussed on behavioural, physical activity and health promotion interventions for weight loss. The role of carers in supporting weight management was also explored. The involvement of carers in the intervention was associated, in some studies, with increased weight loss and adherence to the intervention sessions. Subsequent to this review, Jinks *et al.*, (2011) conducted an integrative systematic review, including both quantitative and qualitative studies. Twelve studies were identified and complied with the study definitions of intervention components of Hamilton *et al.*, (2007). Although both of these reviews concluded the interventions were successful in supporting short term weight loss or changes in BMI, they reported a key limitation was the small sample sizes of the studies. The most recent review by Spanos *et al.*, (2013a) identified studies characterised as single component lifestyle interventions that focused on diet, physical

activity or behaviour change, but also identified eight interventions that were characterised as multi-component interventions (comprising all three lifestyle components). This review provided further evidence for the vital role of carers in supporting adults with intellectual disabilities to make healthy lifestyle choices.

Limitations with the current available evidence included the limited use of systematic methodology to effectively examine the available evidence (Hamilton *et al.*, 2007; Jinks *et al.*, 2011). Hamilton *et al.* (2007) did not provide eligibility criteria for the inclusion of studies in their review, therefore selection of studies could have been biased, based on subjective and individual judgement on the study selection process. Although, Jinks *et al.* (2011) used systematic search methods, the identification of searches was limited in range to studies published after 1998, which may have excluded important findings from earlier studies. A limitation identified in all of the above reviews was the inclusion of heterogeneous study designs which are subject to bias and associated with reverse causality. To facilitate decisions on the most effective approach for weight management for adults with intellectual disabilities, it is important that systematic reviews are based on randomised controlled trials in order to provide a more accurate estimate of the effect of the intervention.

The identification of intervention components was based on information from the study titles and methods of the primary studies and not based on standardised terminology. Recent research has been conducted to assist in the accurate reporting and identification of the 'active ingredients' of complex interventions through the development of standardised definitions of intervention components and behaviour change techniques (Abraham & Michie, 2008; Michie, Ashford, Sniehotta, Dombrowski, Bishop, & French, 2011; Michie *et al.*, 2013). The identification of effective behaviour change techniques associated with changes in lifestyle outcomes would help inform the development of future interventions. Michie and colleagues have been at the forefront of research developing behaviour change taxonomies. The 40 item Coventry Aberdeen London REfined (CALO-RE) taxonomy has been used to reliably classify behaviour change techniques to help people change their physical activity levels and eating behaviours and therefore is particularly relevant to examining the intervention components of multi-component weight management interventions (Michie *et al.*, 2011). This review systematically coded the behaviour change techniques reported in the primary studies of multi-component interventions to provide greater insight into the effective components in supporting adults with intellectual disabilities and obesity to lose weight.

3.3 Research questions

The overall aim of this study was therefore to systematically review the available literature on randomised controlled trials of multi-component weight management intervention for adults with intellectual disabilities and obesity. Specific research questions to be addressed in this chapter were:

1. What are the components included in weight management interventions for adults with intellectual disabilities?
2. Do multi-component interventions adhere to clinical guidelines on weight management?
3. What is the intervention effect of multi-component interventions on body weight in comparison to a control or active comparator intervention?
4. Did participants achieve a clinically significant weight loss of 5-10% of initial body weight?

3.4 Methods

This study was conducted in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (Moher, Liberati, Tetzlaff, & Altman, 2009). The guidelines included a flow diagram of the phases to be reported in conducting a systematic search (identification, screening, eligibility and inclusion of primary studies in the review) and a 27 item checklist of items to be reported throughout each stage of the review process.

3.4.1 Search strategy

A systematic search strategy was conducted which aimed to identify published studies, systematic reviews, research theses, and abstracts from conference proceedings in order to increase the identification of relevant studies. An electronic literature search was performed of

six bibliographic databases; Medline, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Cumulative Index of Nursing and Allied Health Literature (CINHAL), PsychINFO and Education Resource Information Centre (ERIC) from 1946 to and including January 2016. The International Standard Randomised Controlled Trial Number (ISRCTN) trials registry was also searched to identify current relevant trials. The search strategy consisted of MeSH subject headings and keywords or phrases such as intellectual disabilities, diet, physical activity and behaviour change interventions and obesity. The full Medline search strategy is in Appendix i and was adapted for the other databases. Hand searching of key journals, previous systematic reviews and the reference lists of identified studies was also conducted.

3.4.2 Eligibility criteria

Studies were assessed for their eligibility. Studies were included in this review if they met the following inclusion criteria:

- Participants diagnosed with intellectual disabilities
- Adults (≥ 18 years)
- Randomised controlled trial (based on the definition and criteria by the Cochrane Collaboration, i.e. the study explicitly states that the interventions compared in the study were established by the procedure of random allocation (Higgins & Green, 2011))
- Multi-component intervention (diet, physical activity, behaviour change)
- Study included obese participants, $\text{BMI} \geq 30 \text{ kg/m}^2$
- Report objective measure of body weight or BMI at baseline and follow up.

Studies excluded from this review were:

- Studies published in non-English language journals
- Surgical or pharmacological interventions
- Participants with the following genetic syndromes Prader-Willi Syndrome, Cohen Syndrome or Bardet-Biedl syndrome as discussed in section 1.4.3 Genetic syndromes
- Special Olympic athletes due to the higher levels of physical activity in the sub-population.

3.4.3 Data collection and analysis

3.4.3.1 Selection of studies

Assessment of identified studies obtained from the search was conducted by screening information provided in the title and abstract (performed by LH). Obviously irrelevant studies were excluded at this stage for example not involving adults with intellectual disabilities or focused on weight management. Titles and abstracts that obtained information relevant to this review such as the investigation of a multi-component weight management intervention, including participants with intellectual disabilities, and studies of randomised controlled trial design were considered for further assessment of the full text. In cases where there was uncertainty about a studies eligibility, the full text of the article was obtained for further investigation. Full texts articles were then assessed for their eligibility, meeting the above criteria. Full text screening was performed independently, by two researchers (LH, CM). Consensus on included studies was agreed and the final list of studies included in this review.

This review categorised studies by research design into studies that examined the efficacy of a multi-component weight management intervention against a control intervention (no treatment/ treatment as usual) and studies that utilised an active comparator intervention. The interventions in the latter study design typically involved two multi-component interventions, one with additional intervention components and for the purpose of this review defined as a more comprehensive multi-component weight management intervention, and a less intense active comparator intervention.

3.4.3.2 Data extraction

Data extraction was conducted to obtain relevant data for this review. This included general study details such as the author, title, and year of publication; participant characteristics; research objectives; intervention components (i.e., duration and frequency of the intervention sessions); quantitative outcome measures of body weight, and/or BMI, and result statistics such as means and standard deviations of pre and post and change in body weight. In cases where there were duplicate publications or a protocol paper had been published all versions of the study were considered to maximise the extraction of all available information. The identification of behaviour change techniques was conducted independently by two reviewers (LH, CH) who then compared ratings and discussed any discrepancies to come to a consensus

and final score. The methodology section of studies detailing intervention components was screened against the CALO-RE taxonomy (Michie *et al.*, 2011). If a behaviour change technique was identified it was coded 'yes,' if the technique was absent or there was insufficient detail to determine if a technique was utilised it was coded 'no'.

3.4.4 Risk of bias

Risk of bias assessment for the reporting of included studies was conducted using the Cochrane Collaboration's tool for assessing risk of bias (Higgins *et al.*, 2011). The tool examined six classifications of bias: selection bias; performance bias; detection bias; attrition bias; reporting bias; and other potential risks of bias (Table 1.4). The bias is then categorised into seven corresponding domains which aim to address the following questions:

Selection bias: Was the allocation sequence adequately generated? Was allocation adequately concealed? Performance bias: Was knowledge of the allocated interventions adequately prevented during the study? Detection bias: Was knowledge of the allocated intervention adequately prevented by outcome assessors? Attrition bias: Were incomplete outcome data adequately addressed? Reporting bias: Are reports of the study free of suggestion of selective outcome reporting? Other bias: Was the study apparently free of other problems that could put it at a risk of bias? Each bias was rated as low, unclear or high risk of bias based on the criteria by the Cochrane Collaboration (Higgins *et al.*, 2011). Two reviewers independently assessed the primary studies for risk of bias (LH, CH) and consensus agreed as described above.

3.4.5 Publication bias

Publication bias was examined visually by funnel plots of the Weighted Mean Difference (WMD) against the standard error of the WMD of the included studies and investigated statistically using linear regression (Egger, Smith, Schneider, & Minder, 1997). This test investigates the association between the WMD and the standard error for each individual study. Evidence of publication bias was present at a significance level, $p < 0.05$.

3.4.6 Data analysis

3.4.6.1 Effect size calculation

Meta-analysis was performed using Comprehensive Meta-Analysis (Version 3.0 for Windows: Biostat, Englewood, Colorado, USA). The effect size for each study was calculated as the difference in the mean change in body weight in the multi-component intervention minus the mean change in body weight in the control or comparator intervention (Borenstein, Hedges, Higgins, & Rothstein, 2009). In the studies that reported mean change in body and SD of the change, these values were included directly in the meta-analysis. For studies that reported pre and post data on body weight, the SD of the mean change was calculated using the following equation:

- $SD\ change = \sqrt{(SD_{pre}^2 + SD_{post}^2 - (2 \times r \times SD_{pre} \times SD_{post}))}$

To calculate the SD, a correlation coefficient (r) of 0.98 was used based on studies where data on the variance of pre and post intervention mean body weight and mean change in body weight were reported (Beeken *et al.*, 2013; Beeken *et al.*, 2015; Bergström, Hagströmer, Hagberg, & Elinder, 2013; Fox, Haniotes, & Rotatori, 1984; McDermott *et al.*, 2012).

- $r = (SD_{pre}^2 + SD_{post}^2 - SD_{change}^2) / (2 \times SD_{pre} \times SD_{post})$

The pooled effect size WMD for studies comparing a multi-component intervention to a non-active control group and studies comparing the multi-component intervention to an active comparator are analysed and reported separately using a random effects meta-analysis (DerSimonian & Laird, 1986).

3.4.6.2 Assessment of heterogeneity

Cochrane's Q statistic was used to assess heterogeneity, with a significance level of $p < 0.05$ indicating evidence of statistical heterogeneity. The I^2 statistic was also used to assess the degree of heterogeneity, with $I^2 \geq 50\%$ indicating substantial heterogeneity (Higgins, Thompson, Deeks, & Altman, 2003).

3.4.6.3 Clinical effectiveness

Defining changes in weight loss is important to determine if the magnitude of the change is consistent with clinical improvements in health. For the purpose of this review and throughout this thesis, a clinically important weight loss will be defined as a weight loss of $\geq 5\%$ of initial body weight. A weight loss of less than 3% will be considered a small weight fluctuation following the recommendation by Stevens, Truesdale, McClain, & Cai, (2006). Successful weight maintenance will be achieved if participants maintain $\pm 2.9\%$ of their weight loss achieved at the end of the weight loss phase.

3.5 Results

3.5.1 Literature search

The search resulted in a total of 3008 studies. Duplicates (401 studies) were removed and the remaining studies titles and abstracts were screened. Two thousand, five hundred and sixty-seven studies were excluded as they were obviously irrelevant (i.e., did not implement a multi-component intervention, were single stranded studies or did not include participants with intellectual disabilities). Forty potentially relevant studies were assessed for their eligibility. Thirty-three studies were excluded due to the reasons illustrated in Figure .1 and nine studies were included for discussion in this review.

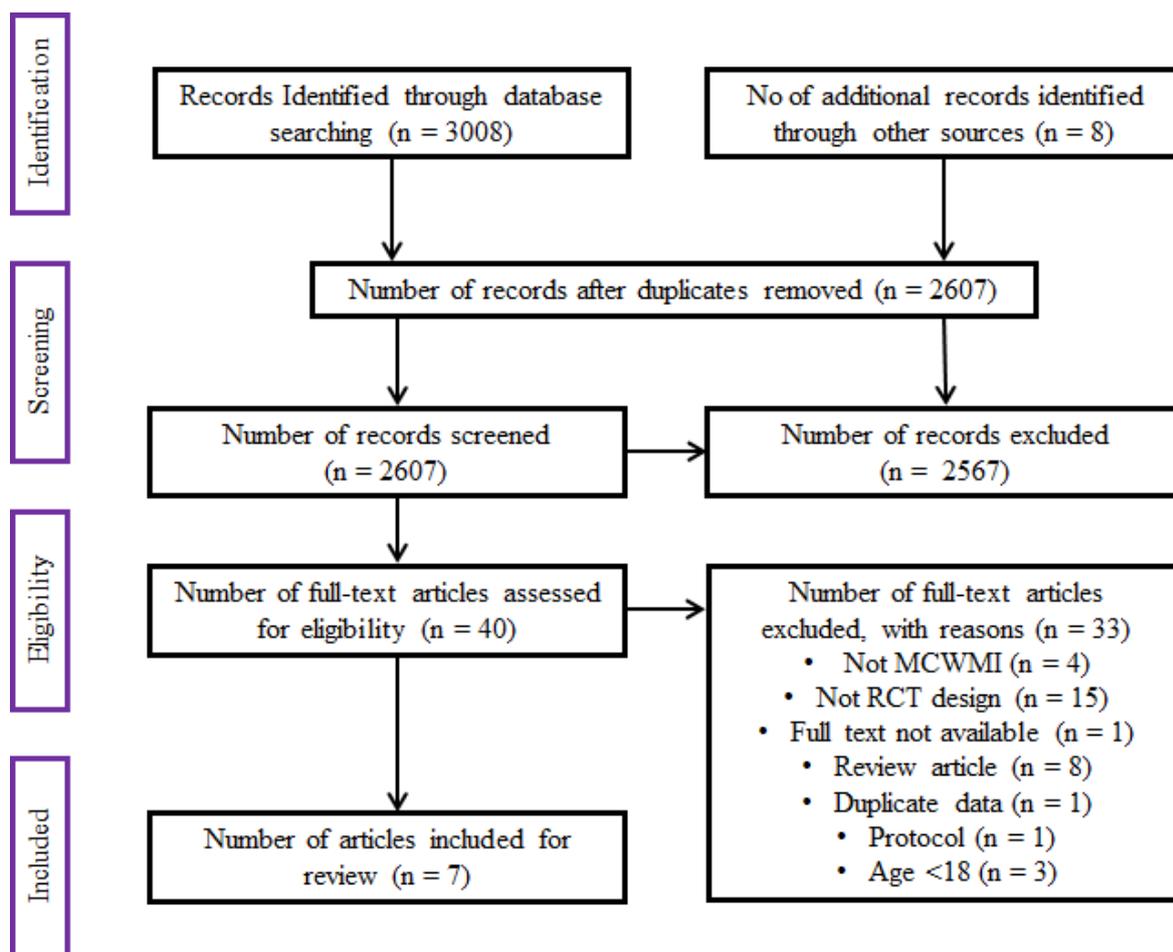


Figure 3.1. Study search results and selection process.

MCWMI = Multi-component weight management intervention; RCT = Randomised controlled trial

3.5.2 Study characteristics

Of the seven studies, five studies were conducted in the USA (Fox *et al.*, 1984; Fisher, 1986; McDermott *et al.*, 2012; Marks, Sisirak, & Chang, 2013; Pett, Clark, Eldredge, Cardell, Jordan, Chambless, & Burley, 2013), one study in Sweden (Bergström *et al.*, 2013), and one study in the UK (Beeken *et al.*, 2013; Beeken *et al.*, 2015). The mean duration of the active intervention period across studies was 4.5 months (range: 2-15 months), with participant follow ups scheduled at three, six and 12 month time points. Two studies did not conduct further follow ups after post intervention measures (Bergström *et al.*, 2013; Marks *et al.*, 2013). Sessions lasted between 60 and 90 minutes and were conducted between one and three times per week. All studies were conducted in a group setting with small numbers of participants led by health professionals including dietitians (Beeken *et al.*, 2013; Beeken *et al.*, 2015), recreation specialists (Fox *et al.*, 1984) and a health educator (McDermott *et al.*, 2013). Carers and community staff also received training and delivered intervention components (Bergström *et al.*, 2013; Marks *et al.*, 2013; Pett *et al.*, 2013). A summary of the study characteristics are presented in Table 3.1.

Table 3.1. Summary of study characteristics of multi-component weight management interventions

Reference	Study Population		Duration of active intervention (follow up)	Interventions	Attrition
Beeken <i>et al.</i>, (2013/2015)	Shape UP-LD intervention N = 25 Age: ≥ 18 years BMI: ≥ 25 kg/m ² ID: Mild/Moderate	Control Treatment as usual N = 25 Age: ≥ 18 years BMI: ≥ 25 kg/m ² ID: Mild/Moderate	12 weeks (3 months/6 months)	Session duration: 90 minutes Session frequency: 1/week Delivery: Sessions conducted in groups by a health professional	Shape UP-LD Enrolled: N = 25 Completed: N = 22 Control: Enrolled: N = 25 Completed: N = 17 Attrition rate: 22%

Bergström et al., (2013)	Intervention N = 73 Age: 36.2 (10.1) years BMI: 30.0 (7.6) kg/m ² Gender: Male n = 27 (42.2%) Female n = 37 (57.8%) ID: Mild/Moderate	Control Waiting list control N = 66 Age: 39.4 (11.3) years BMI: 28.5 (6.6) kg/m ² Gender: Male n = 29 (43.9%) Female n = 37 (56.1%) ID: Mild/Moderate	12-15 months	Session duration: 90 minutes Session frequency: Not specified Delivery: Sessions conducted by care staff after a period of training	Intervention Enrolled: N = 73 Completed: N = 63 Control Enrolled: N = 66 Completed: N = 66 Attrition rate: 7.2%
Fisher et al., (1986)	Behaviour Self-control plus physical activity intervention N = 8 Age: ≥ 20	Behaviour Self-control intervention Comparator intervention N = 9 Age: ≥ 20	8 weeks (4 weeks)	Session duration: 60 minutes Session frequency: 2/week	Attrition rate: 0%

	Weight status: Obese, 20% above desired weight for height	Weight status: Obese, 20% above desired weight for height		Delivery: Sessions were delivered in groups.	
	Gender: Female	Gender: Female			
	ID: Mild/Moderate	ID: Mild/Moderate			
Fox et al., (1984)	Behaviour Therapy + Buddy Reinforcement N = 8 Age: 27.5 (5.4) years Weight status: % overweight 34.7 (18.5) % Gender: Male n = 4 (50%) Female n = 4 (50%) IQ: 46.3 (12.1)	Behaviour Therapy Comparator intervention N = 8 Age: 29.5 (7.2) years Weight status: % overweight 44.4 (35.4) % Gender: Male 3 Female 5 IQ: 42.1 (8.4)	15 weeks (12 months)	Session duration: 60 minutes Session frequency: 2/week for 10 weeks weight loss, followed by 1/week for 5 weeks weight maintenance	Attrition rate: 0%
				Delivery: Sessions conducted in groups by a recreational therapist	

Marks <i>et al.</i>, (2013)	Intervention N = 32 Age: 42.6 (7.4) years Weight status: Underweight-Obese Gender: Male N = 16 (50%) Female N = 16 (50%) ID: Mild/Moderate	Control No treatment N = 35 Age: 47.6 (7.0) years Weight status: Gender: Male N = 16 (46%) Female N = 19 (54%) ID: Mild/Moderate	12 weeks	Session duration: 60 minutes Session frequency: 3/week Delivery: Sessions were conducted in groups by community based organisation staff.	Total Enrolled: 67 Total Completed: 60 (1 drop out, 6 not complete specified number of sessions) Attrition rate: 10.4%
McDermott <i>et al.</i>, (2012)	STYH intervention N = 216 Age: 39 (range: 19-65) years BMI: 32.5 (range: 18.5 - 71.3) kg/m ²	Control No treatment N = 216 Age: 39 (range: 19-65) years BMI: 32.5 (range: 18.5 -71.3) kg/m ²	8 weeks (12 months)	Session duration: 90 minutes Session frequency: 1/week.	Total Enrolled: 443 Total Completed: 196

	Gender: Male n = 218 (49.2%) Female n = 225 (50.8%) ID: Mild/Moderate	Gender: Male n = 218 (49.2%) Female n = 225 (50.8%) ID: Mild/Moderate		Delivery: Sessions were conducted in groups by a health educator.	Attrition rate: 55.8%
Pett et al., (2013)	Intervention with young adults N = 12 Age: 23.6 (3.1) years BMI: 39.0 (8.0) kg/m ² Gender: Male n = 4 (36.4%) Female n = 7 (63.6%) ID: Mild/Moderate	Intervention with young adults + parents Comparator intervention N = 11 Age: 25.6 (4.8) years BMI: 37.3 (5.2) kg/m ² Gender: Male n = 5 (45.5%) Female n = 6 (54.5%) ID: Mild/Moderate	12 weeks (3 months)	Session duration: 90 minutes Session frequency: 2/week Delivery: Sessions were conducted in groups by recreational centre staff	Young adults Enrolled: 12 Completed: 11 Young adults + parents Enrolled: 11 Completed: 11 Attrition rate: 4.3%

Change in body weight was a primary outcome in four studies (Fox *et al.*, 1984; Fisher, 1986; Beeken *et al.*, 2013; Beeken *et al.*, 2015; Pett *et al.*, 2013). McDermott *et al.*, (2012) included BMI as a primary outcome, aiming to limit weight gain and Bergström *et al.*, (2013), and Marks *et al.*, (2013) included BMI as a secondary outcome. As BMI is calculated from the following equation; body weight (kg) divided by height² (m) and due to the limited number of studies providing quantitative data on changes in BMI for analysis, the authors reporting BMI were contacted to request data on change in body weight. This allowed inclusion of these studies in the meta-analysis on body weight. All studies focused on reduction in weight and only one study included a weight maintenance period following weight loss (Fox *et al.*, 1984).

Four studies compared the efficacy of the weight management treatment against no treatment, control intervention (Beeken *et al.*, 2013; Beeken *et al.*, 2015; Bergström *et al.*, 2013; McDermott *et al.*, 2012; Marks *et al.*, 2013) and three studies used an active comparator intervention to examine the efficacy of the intervention (Fox *et al.*, 1984; Fisher, 1986; Pett *et al.*, 2013). These foregoing studies included additional components to the intervention for example a more comprehensive physical activity programme (Fisher, 1986), or the addition of social support from carers (Fox *et al.*, 1984; Pett *et al.*, 2013). The studies that had the most comprehensive intervention component were used to subtract the mean change on body weight of the less-inclusive comparator intervention in order to calculate the effect size (see section 3.4.6.1 Effect size calculation).

3.5.3 Participant characteristics

A total of 755 participants were randomised into the studies. The sample size of studies ranged from 12 to 443 participants. The mean age range of participants was from 20 to 45 years. Four studies included adults with overweight and obesity, BMI ≥ 25 kg/m² (Fox *et al.*, 1984; Fisher, 1986; Beeken *et al.*, 2013; Beeken *et al.*, 2015; Pett *et al.*, 2013). Three studies included participants with varying weight status, classified as underweight, normal weight, overweight, and obese (Bergström *et al.*, 2013; McDermott *et al.*, 2012; Marks *et al.*, 2013). The authors of the studies by Bergström *et al.*, (2013) and McDermott *et al.*, (2012) provided raw data and therefore, meta-analysis of participants with obesity only was conducted. The majority of participants in the study reported by Marks *et al.*, (2013) were reported as overweight (40.5%) and obese (36.7%). The gender distribution of studies included male and female participants with the exception of one study including female participants only (Fisher, 1986). Studies included participants diagnosed with mild to moderate levels of

intellectual disabilities. One study included participants with Down syndrome (Pett *et al.*, 2013). A summary of study and participant characteristics is presented in Table 3.2.

Table 3.2. Summary of multi-component weight management intervention components

Reference	Intervention components			Control/Comparator intervention
	Diet	Physical Activity	Behaviour change	
Beeken <i>et al.</i>, (2013/2015)	Health education – food groups/ portions, eating 3 meals & healthy snacks, shopping & cooking.	Health education	<p>Behaviour change theories:</p> <p>Social cognitive theory, control theory</p> <p>Behaviour change techniques:</p> <p>6. Goal setting (outcome)</p> <p>8. Barrier identification/problem solving</p> <p>11. Prompt review of outcome goals</p> <p>16. Prompt self-monitoring of behaviour</p> <p>21. Provide instruction on how to perform the behaviour</p> <p>26. Prompt practice</p> <p>35. Relapse prevention/coping planning</p>	<p>Control</p> <p>Usual care, 1 off session 30-45 minutes duration, plus health booklet and healthy eating and exercise DVD.</p>

			36. Stress management/emotional control training	
			39. General communication skills training	
Bergström et al., (2013)	Health Education plus opportunity to try foods	Health Education plus opportunity to try physical activity	<p>Behaviour change theories:</p> <p>Social cognitive theory</p> <p>Behaviour change techniques:</p> <p>1. Provide information on consequences of behaviour in general</p> <p>26. Prompt practice</p>	Waiting list control
Fisher (1986)	Health education – healthy balanced diet, portion control, reducing snacking.	Walking – 10 minute target at the beginning of the intervention, increase by 5 minutes every 2	<p>Behaviour change theories:</p> <p>Control theory</p> <p>Behaviour change techniques:</p> <p>7. Action planning</p>	Diet identical to Behaviour Self-control plus physical activity intervention.
				Behaviour change techniques:

Eating techniques – practice eating slowly	weeks until a target of 30 minute was achieved).	<p>13. Provide rewards contingent on successful behaviour</p> <p>16. Prompt self-monitoring of behaviour</p> <p>17. Prompt self-monitoring of behavioural outcome</p> <p>19. Provide feedback on performance</p> <p>21. Provide instruction on how to perform the behaviour</p> <p>22. Model/demonstrate the behaviour</p> <p>26. Prompt practice</p> <p>29. Plan social support/social change</p>	<p>13. Provide rewards contingent on successful behaviour</p> <p>16. Prompt self-monitoring of behaviour</p> <p>17. Prompt self-monitoring of behavioural outcome</p> <p>19. Provide feedback on performance</p> <p>21. Provide instruction on how to perform the behaviour</p> <p>22. Model/demonstrate the behaviour</p> <p>26. Prompt practice</p> <p>29. Plan social support/social change</p>	
Fox et al., (1984)	Health education – healthy balanced diet,	Calisthenics (e.g., jumping jacks) and aerobic exercises at least two	<p>Behaviour change theories:</p> <p>Control theory</p>	<p>Behaviour Therapy intervention</p>

portion control, reducing snacking.	times a day. Lifestyle activities (e.g., walk instead of riding to work; using stairs).	Behaviour change techniques: 5. Goal setting (behaviour) 6. Goal setting (outcome) 7. Action planning 8. Barrier identification/problem solving 9. Set graded tasks 10. Prompt review of behavioural goals 11. Prompt review of outcome goals 12. Prompt rewards contingent on effort or progress 13. Provide rewards contingent on successful behaviour 14. Shaping 16. Prompt self-monitoring of behaviour 17. Prompt self-monitoring of behavioural outcome	Diet and physical activity components and behaviour change techniques identical in both interventions.
Eating techniques – practice eating slowly			

-
19. Provide feedback on performance
 20. Provide information on where and when to perform behaviour
 21. Provide instruction on how to perform the behaviour
 22. Model/demonstrate the behaviour
 24. Environmental restructuring
 26. Prompt practice
 27. Use of follow-up prompts
 29. Plan social support/social change
 40. Stimulate anticipation of future rewards

Additional social support from peers with intellectual disabilities.

Marks <i>et al.</i>, (2013)	Knowledge of healthy foods, meals and snacks	Review importance of physical activity components including flexibility, strength, endurance	<p>Behaviour change theories: Social cognitive theory</p> <p>Behaviour change techniques:</p> <ol style="list-style-type: none"> 1. Provide information on consequences of behaviour in general 2. Provide information on consequences of behaviour to the individual 5. Goal setting (behaviour) 6. Goal setting (outcome) 7. Action planning 8. Barrier identification/problem solving 9. Set graded tasks 10. Prompt review of behavioural goals 11. Prompt review of outcome goals 	Control: No treatment
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12. Prompt rewards contingent on effort or progress
 13. Provide rewards contingent on successful behaviour
 16. Prompt self-monitoring of behaviour
 17. Prompt self-monitoring of behavioural outcome
 20. Provide information on where and when to perform behaviour
 21. Provide instruction on how to perform the behaviour
 22. Model/demonstrate the behaviour
 24. Environmental restructuring
 26. Prompt practice
 29. Plan social support/social change
 35. Relapse prevention/coping planning
-

39. General communication skills training

McDermott et al., (2012)	Health education – emphasise on fruit, vegetables, wholegrains and portion sizes. Provided healthy snacks.	Health education plus optional brisk walk.	<p>Behaviour change theories:</p> <p>Social cognitive theory</p> <p>Behaviour change techniques:</p> <p>1. Provide information on consequences of behaviour in general</p> <p>8. Barrier identification/problem solving</p> <p>18. Prompting focus on past success</p> <p>21. Provide instruction on how to perform the behaviour</p> <p>26. Prompt practice</p> <p>36. Stress management/emotional control training</p> <p>39. General communication skills training</p>	<p>Control:</p> <p>Participants attended the same number of sessions. Content not centred on healthy lifestyle, focussed on hygiene and safety.</p>
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Pett <i>et al.</i>, (2013)	Health education – healthy eating, emphasised increased fruit and vegetable intake based on American Dietary guidelines (Dietary Guidelines Advisory Committee, 2005)	Physical activity based on guidelines by American College of Sports Medicine (American College of Sports Medicine, 2006) Mode: aerobic activity, muscle strength and endurance, and flexibility (activities such as walking or jogging outdoors or on a treadmill, stationary cycling, weight lifting and stretching Duration: 45 minutes Intensity: Based on individual fitness levels	Behaviour change theories: Social cognitive theory/ Transtheoretical Model Behaviour change techniques: 5. Goal setting (behaviour) 7. Action planning 8. Barrier identification/problem solving 10. Prompt review of behavioural goals 18. Prompting focus on past success 22. Model/demonstrate the behaviour 24. Environmental restructuring 26. Prompt practice 29. Plan social support/social change	Behaviour change techniques: 7. Action planning 8. Barrier identification/problem solving 18. Prompting focus on past success 26. Prompt practice 36. Stress management/emotional control training
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**36. Stress
management/emotional control
training**

NOTE: Techniques colour coded in blue were consistent across both interventions.

3.5.4 Risk of bias

An overview of the risk of bias for each domain, categorised per study is presented in Figure 3.2. Selection bias was assessed by studies fulfilling the criteria on reporting sequence generation and allocation concealment. Three studies provided adequate details on sequence generation (Beeken *et al.*, 2013; Bergström *et al.*, 2013; Marks *et al.*, 2013) and were judged as a low risk of bias. The remaining studies did not provide sufficient information to assess the risk of bias domain as high or low risk and were judged as unclear risk (Fox *et al.*, 1984; Fisher, 1986; McDermott *et al.*, 2012; Pett *et al.*, 2013). The methods of concealment of random allocation were in general reported as unclear with only two studies reporting adequate details to be judged as low risk of bias (Beeken *et al.*, 2013; Bergström *et al.*, 2013). One study was classified as high risk of bias as the community based organisations that delivered the intervention performed the randomisation of participants into the multi-component intervention or waiting list control (Marks *et al.*, 2013).

All of the studies failed to report clear methods of blinding of participants, researchers, and personnel involved in the trial, with the exception of Marks *et al.*, (2013) which was judged as high risk of bias for this domain. In the study by Marks *et al.* the carers were involved in conducting the randomisation process and therefore unblinded to the group allocation. Across studies detection bias was in general uncertain as there was either inadequate information reported, from which high or low risk of bias could be assessed. Two studies involved independent researchers, unaware of the intervention treatments to assess the outcome measures (Bergström *et al.*, 2013; Marks *et al.*, 2013). These studies are assessed as having a low risk of bias.

Attrition bias was assessed as low risk of bias in five out of the seven studies. McDermott *et al.*, (2012) received a high risk of bias rating, with an attrition rate of 55.8% and in the study by Marks *et al.*, (2013) although only 10.4% of participants with intellectual disabilities did not complete the intervention and were excluded from the analysis, 22.7% of staff participants withdrew from the study thus increasing the total attrition. Two studies reported no drop outs (Fox *et al.*, 1984; Fisher, 1986).

The study by Beeken *et al.*, (2015) had to be assessed as unclear risk of bias for reporting bias as data were obtained from publication of the abstract and full results are yet to be published. However, a study protocol has been published and contact with the author provided details on the change in body weight to calculate the WMD. Therefore, it is

believed that this will be low on receipt of full publications. The remaining studies were judged as low risk of bias with the exception of one study which was subject to reporting bias, by not reporting all outcome measures and/or not providing adequate information on outcome results (Fisher, 1986).

The study by Prett *et al.*, (2013) was considered to be at potential risk of other sources of bias. This was in relation to the study design as only two out of the three intervention groups were randomised. A further potential source of bias which was not accounted for in the majority of studies with the exception of (Fisher, 1986; Fox *et al.*, 1984; McDermott *et al.*, 2012; Pett *et al.*, 2013) was the lack of justification of the sample sizes of studies. This may result in underpowered studies and or certainly studies with unknown power.

Reference	Random sequence generation (selection data)	Allocation concealment (selection bias)	Blinding of participants and researchers (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome bias (attrition bias)	Selective outcome reporting (reporting bias)	Other bias
Beeken (2013/2015)	+	?	?	+	+	?	+
Bergstorm (2013)	+	+	?	?	+	+	+
Fisher (1986)	?	?	?	?	+	-	+
Fox (1984)	?	?	?	?	+	+	+
Marks (2013)	+	-	-	+	-	+	+
McDermott (2012)	?	?	?	?	-	+	+
Pett (2013)	?	?	?	?	+	+	-

Figure 3.2. Risk of bias assessment of studies included in the review of multi-component weight management interventions for adults with intellectual disabilities and obesity.

Adapted from the Cochrane Handbook (Higgins *et al.*, 2011).  represents low risk of bias;  represents unclear risk of bias and  represents high risk of bias.

3.5.5 Publication bias

As only seven studies, four with a control and three with an active comparator intervention were identified, funnel plots asymmetry was not determined due the limited number of studies to provide adequate power of reliability test for presence of publication bias (Higgins & Green, 2011).

3.5.6 Intervention components

3.5.6.1 Diet

The majority of studies were focussed on a health education approach, providing general information on healthy balanced diet including for example food groups, portion sizes, and healthy meals and snacks. The information was conveyed in a number of formats from images to food games (Beeken *et al.*, 2013), demonstrations and tasting of foods (Bergström *et al.*, 2013).

3.5.6.2 Physical activity

Three studies provided structured physical activity programmes as part of their intervention, involving aerobic activities, stretches to improve flexibility and strength and muscular endurance based activities (Marks *et al.*, 2013; Pett *et al.*, 2013). Participants were instructed to perform these activities two-three times per week. The intensity that these activities were to be performed at was not reported. Three studies focussed on lifestyle physical activity such as walking (Fisher, 1986; Fox *et al.*, 1984; McDermott *et al.*, 2012), with Fisher, prescribing daily walking targets ranging from 10 minutes at the beginning of the intervention to 30 minutes by the end of the intervention period. Fox *et al.*, (1984) included calisthenics (e.g., jumping jacks) and aerobic exercise performed twice a week. These studies also provided advice on increasing energy expenditure through changes in daily activities such as taking the stairs, housework, and dancing. The studies by Beeken *et al.*, (2013); Bergström *et al.*, (2013) and McDermott *et al.*, (2012) mainly focussed on increasing physical activity through a health education approach with Bergström *et al.*, (2013) providing participants with the opportunity to try new physical activities.

3.5.6.3 Behaviour change techniques

In total 26 out of the 40 behaviour change techniques from the CALO-RE taxonomy were coded as being utilised across interventions. The mean number of techniques used was 11

(range: 2-21). The techniques identified as consistently reported in the interventions were: prompt practice; provide instruction on how to perform the behaviour; barrier identification/problem solving; action planning; model/demonstrate the behaviour; plan social support/social change; and prompt self-monitoring of behaviour. The techniques used in each intervention are also presented in summary Table 3.2 and the frequency of each technique across studies in Table 3.3. The 14 techniques not identified as being utilised in studies were: provide information about others' approval; provide normative information about others' behaviour; prompting generalisation of a target behaviour; teach to use prompts/cues; agree behavioural contract; facilitate social comparison; prompt identification as role model/position advocate; prompt identification as role model/position advocate; prompt anticipated regret; fear arousal; prompt self-talk; prompt use of imagery; motivational interviewing; time management; stimulate anticipation of future rewards

.

Table 3.3. Frequency of behaviour change techniques used in the studies comparing the multi-component to a control or active comparator intervention.

Behaviour Change Technique	Control		Active Comparator	
	N	%	N	%
26. Prompt practice	4	100	3	100
21. Provide instruction on how to perform the behaviour	3	75	2	67
8. Barrier identification/problem solving	3	75	2	67
7. Action planning	1	25	3	100
16. Prompt self-monitoring of behaviour	2	50	2	67
22. Model/demonstrate the behaviour	1	25	3	100
29. Plan social support/social change	1	25	3	100
5. Goal setting (behaviour)	1	25	2	67
6. Goal setting (outcome)	2	50	1	33
10. Prompt review of behavioural goals	1	25	2	67
13. Provide rewards contingent on successful behaviour	1	25	2	67
17. Prompt self-monitoring of behavioural outcome	1	25	2	67
24. Environmental restructuring	1	25	2	67
11. Prompt review of outcome goals	2	50	1	33
36. Stress management/emotional control training	2	50	1	33
1. Provide information on consequences of behaviour in general	3	75	0	0
39. General communication skills training	3	75	0	0
19. Provide feedback on performance	0	0	2	67
9. Set graded tasks	1	25	1	33
12. Prompt rewards contingent on effort or progress towards behaviour	1	25	1	33
18. Prompting focus on past success	1	25	1	33
20. Provide information on where and when to perform behaviour	1	25	1	33
35. Relapse prevention/coping planning	2	50	0	0
14. Shaping	0	0	1	33
27. Use of follow-up prompts	0	0	1	33

2. Provide information on consequences of behaviour to the individual	1	25	0	0
3. Provide information about others' approval	0	0	0	0
4. Provide normative information about others' behaviour	0	0	0	0
15. Prompting generalisation of a target behaviour	0	0	0	0
23. Teach to use prompts/cues	0	0	0	0
25. Agree behavioural contract	0	0	0	0
28. Facilitate social comparison	0	0	0	0
30. Prompt identification as role model/position advocate	0	0	0	0
31. Prompt anticipated regret	0	0	0	0
32. Fear arousal	0	0	0	0
33. Prompt self-talk	0	0	0	0
34. Prompt use of imagery	0	0	0	0
37. Motivational interviewing	0	0	0	0
38. Time management	0	0	0	0
40. Stimulate anticipation of future rewards	0	0	0	0

The detail in which behaviour change techniques were reported varied greatly across studies as did the description of intervention components (i.e., diet and physical activity) which made it difficult to code techniques and in some cases, it was unclear if a technique was present due to insufficient detail reported. For example, two studies (Fox *et al.*, 1984; Fisher, 1986) examined the efficacy of the multi-component weight management intervention originally developed by Rotatori & Fox (1981). The original intervention comprised of 14 weeks focusing on weight loss, with participants meeting three times per week; followed by an additional weight maintenance period, with two sessions per week. The sessions focussed on healthy eating such as increased awareness of environmental conditions related to eating, (i.e. sitting at the dining room table and not watching television during eating), and reducing the rate and amount of food eaten by chewing food completely. Although both the studies by Fox *et al.*, (1984) and Fisher, (1986) were founded on the study by Rotatori & Fox (1981), it was not clear whether the intervention content delivered in the original sessions was replicated. In particular, Fox *et al.*, (1984) investigated the efficacy of a streamlined version of the weight management programme by reducing the intervention period to 10 weeks with meetings occurring twice per week and five further weeks of weekly maintenance meetings.

This was achieved by eliminating some of the behaviour change techniques. Furthermore, both studies made adaptations to the original intervention. Fox *et al.*, (1986) aimed to compare two formats of the group based intervention, with and without planned social support from peers in the form of a ‘buddy system’. Fisher (1986) also examined a deviation of the original intervention in assessing the effects of the intervention to a comparator intervention with a more involved physical activity component. In addition to the lifestyle physical activity (i.e., taking the stairs) by Rotatori & Fox, (1981), Fisher, (1986) provided daily walking targets. In order to prevent inaccurate assumptions of the application of the techniques originally used by Rotatori & Fox, (1981) the only behaviour change techniques reported by Fox and colleagues (1984) and Fisher (1986) were coded. The difference in detail of reporting of techniques is illustrated as the studies were coded as utilising 21 and nine techniques, respectively.

3.5.7 Carer involvement

All of the studies with the exception of Fisher, (1986) and McDermott *et al.*, (2012) involved the support of carers in the intervention. The level of support provided was of varying degrees. For example, two studies included a specifically designed component of the intervention for carers, which generally aimed to increase their knowledge of healthy lifestyle routines (Bergström *et al.*, 2013; Pett *et al.*, 2013). Bergstrom and colleagues specifically designed their complex intervention to simultaneously target adults with intellectual disabilities and their carers. The aim of the intervention was to improve diet and physical activity of adults with intellectual disabilities through increasing the knowledge of both the service users and staff. The intervention components directed towards improving the carers’ knowledge and skills included the appointment of a ‘health ambassador’ in each residential setting where the intervention took place and the involvement of a staff study circle. The role of a health ambassador is a common occurrence in residences in Sweden, which was built upon and involved relaying health information to colleagues and organisation of the health promotion activities. The study circle was based on ‘Focus Health’ a newly piloted manual and the principles of peer education. The manual consisted of 10 themes which aimed to improve the carers’ knowledge and skill regarding health and health determinants for individuals with intellectual disabilities: 1) Health and quality of life; 2) Autonomy and ethics; 3) National recommendations concerning diet and health and information in society; 4) Healthy dietary habits; 5) Physical activity for health; 6) Availability and accessibility; 7) Habits and attitudes; 8) Motivation and support for

behavioural change; 9) Cooperation; and 10) How to sustain good work (Bergström *et al.*, 2013).

In the study by Pett *et al.*, (2013) parents received intervention sessions which aimed to improve healthy lifestyle behaviours in terms of physical activity habits of the young adults also participating in separate intervention sessions. Three studies also provided training for carers prior to the delivery of the intervention with service users in order to provide carers with knowledge about the intervention and to help support the participants during the intervention (Fox *et al.*, 1984; Beeken *et al.*, 2013; Beeken *et al.*, 2015; Marks *et al.*, 2013).

3.5.8 Efficacy of the interventions

3.5.8.1 Multi-component weight management intervention versus control intervention

The summary estimates of the meta-analyses are presented in Figures 2.3 to 2.5. Four studies examined the efficacy of a multi-component weight management intervention against a control intervention (Beeken *et al.*, 2013; Beeken *et al.*, 2015; Bergström *et al.*, 2013; McDermott *et al.*, 2012; Marks *et al.*, 2013). Two studies reported BMI as their primary outcome, however, data were provided from the authors of these studies and therefore were included in the meta-analysis. The within group change in body weight was not significant in the multi-component interventions with only one study reporting a change in body weight of -1.86 kg (SD 4.40 kg) (Marks *et al.*, 2013). The remaining studies reported minimal changes (less than 1 kg) which could be attributed to fluctuations in body weight. Body weight remained unchanged in the control intervention (less than 1 kg change in body) with the exception of the study by Bergström *et al.*, (2013) reporting weight gain of 2.36 kg (SD 4.26 kg) in adults with intellectual disabilities and obesity. There was no significant difference in body weight between the multi-component interventions and control interventions post intervention (WMD: -0.92 kg; 95% CI -2.11 kg to 0.28 kg; $p = 0.13$). Statistical heterogeneity was not present ($Q(3) 5.3$, $p = 0.15$; $I^2 = 43.4\%$). The study by Marks *et al.*, (2013) reported a significant between group effect size (-2.13 kg; 95% CI -4.03 kg to -0.23 kg), illustrating that the multi-component intervention was more effective than no treatment.

Reference	Intervention		Control		Mean difference (95% CI)
	Mean (SD)	N	Mean (SD)	N	
Beeken <i>et al.</i> (2013)	0.00 (2.79)	21	0.30 (3.49)	19	-0.30 (-2.25 to 1.65)
Bergström <i>et al.</i> (2013)	-0.85 (7.53)	26	2.36 (4.26)	18	-3.21 (-7.06 to 0.64)
Marks <i>et al.</i> (2013)	-1.86 (4.40)	32	0.27 (3.52)	86	-2.13 (-4.03 to -0.23)
McDermott <i>et al.</i> (2012)	-0.13 (2.76)	106	0.04 (3.38)	35	-1.17 (-1.03 to 0.70)
Pooled Estimate (Random Effect)		185		158	-0.92 (-2.11 to 0.28)
Tests for heterogeneity: $p = 0.15$, $I^2 = 43.4\%$					

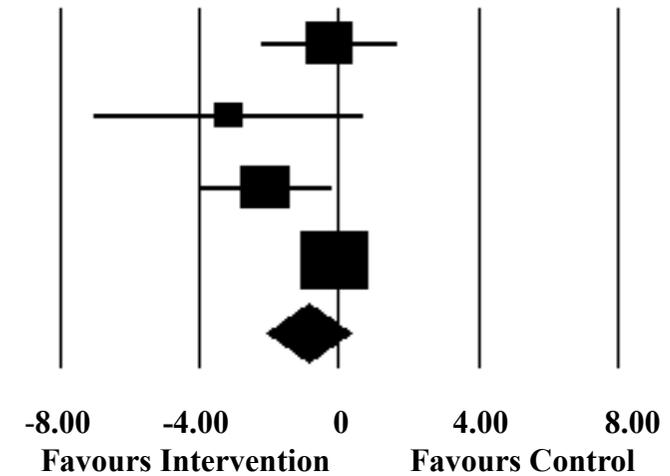


Figure 3.3. Weighted mean difference in body weight (kg) between the multi-component interventions and control interventions (Post intervention).

Reference	Intervention		Control		Mean difference (95% CI)
	Mean (SD)	N	Mean (SD)	N	
Bergström <i>et al.</i> (2013)	-0.85 (7.53)	26	2.36 (4.26)	18	-3.21 (-7.06 to 0.64)
McDermott <i>et al.</i> (2012)	-0.58 (5.33)	56	-0.57 (4.26)	49	0.00 (-1.87 to 1.86)
Pooled Estimate (Random Effect)		82		67	-1.15 (-4.15 to 1.86)
Tests for heterogeneity: $p = 0.14$, $I^2 = 53.5\%$					

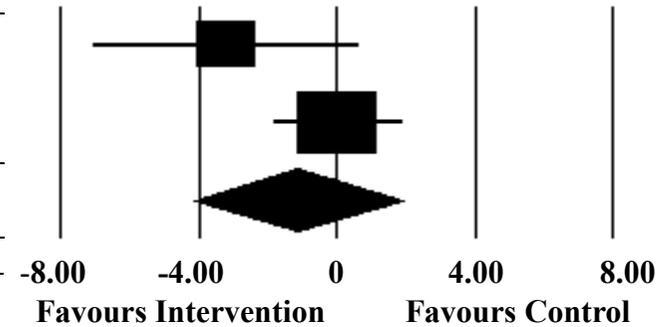


Figure 3.4. Weighted mean difference in body weight (kg) between the multi-component interventions and control interventions (12 month follow up).

Two studies examined the long term efficacy of the intervention at 12 months (Bergström *et al.*, 2013; McDermott *et al.*, 2012). Within group change in body weight in the multi-component weight management interventions was again minimal with a change of approximately less than 1 kg in each intervention. The WMD was -1.15 kg (95% CI -4.15 kg to 1.86 kg; $p = 0.45$). Statistical heterogeneity was present ($Q (1) 2.2$, $p = 0.14$; $I^2 = 53.5\%$).

3.5.8.2 Multi-component weight management intervention versus active comparator intervention

Three studies utilised an active comparator intervention to investigate the efficacy of the multi-component interventions (Fox *et al.*, 1984; Fisher, 1986; Pett *et al.*, 2013). The studies included a more comprehensive intervention with additional intervention components in comparison to a less intense multi-component intervention. Three studies included additional behaviour change techniques, which primarily provided increased social support either from peers or carers (Fox *et al.*, 1984; Pett *et al.*, 2013) and one study investigated the effect of a more structured physical activity programme with graded targets (Fisher, 1986). The WMD was 0.55 kg (95% CI -2.94 kg to 2.05 kg; $p = 0.70$) post intervention. Statistical heterogeneity in effect sizes ($Q (2) 0.7$, $p = 0.69$; $I^2 = 0.0\%$). Studies reported no between group differences, however, the within group changes in body weight in the study by Fox *et al.*, (1984) illustrated that both interventions were effective in changing body weight, with a weight change of -4.77 kg in both interventions. Exploration of no between intervention effect was primarily due to minimal changes in weight loss in both multi-component interventions (Fisher, 1986) and also a greater weight loss favouring the comparator intervention (Pett *et al.*, 2013).

Reference	Intervention		Control		Mean difference (95% CI)
	Mean (SD)	N	Mean (SD)	N	
Fisher, (1986)	-0.60 (2.10)	8	-1.00 (2.20)	9	0.40 (-1.65 to 2.45)
Fox <i>et al.</i> (1984)	-4.77 (3.08)	8	-4.77 (2.56)	8	0.00 (-2.78 to 2.78)
Pett <i>et al.</i> (2013)	-0.82 (3.72)	11	-2.72 (4.66)	11	1.90 (-1.62 to 5.42)
Pooled Estimate (Random Effect)		27		28	0.55 (-0.94 to 2.05)
Tests for heterogeneity: $p = 0.69$, $I^2 = 0.0\%$					

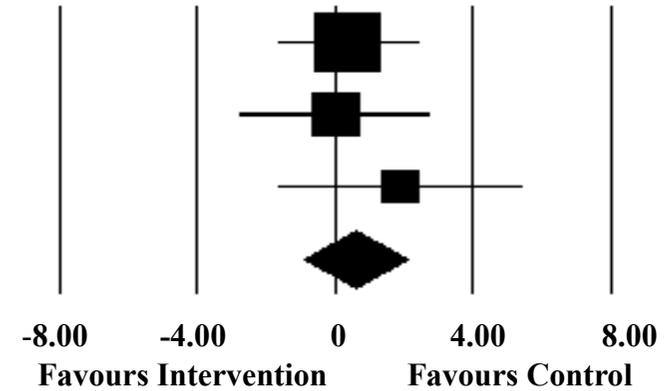


Figure 3.5. Weighted mean difference in body weight (kg) between the multi-component interventions and the active comparator interventions (Post intervention).

Follow up of the long term efficacy of the interventions at 12 months was only investigated in one study by Fox *et al.*, (1984). Results therefore could not be pooled in a meta-analysis, although the within group, pre-post results revealed that participants in the multi-component intervention had maintained changes ($\pm 3\%$) in body weight from baseline with a weight loss of -1.87 kg (SD 6.55 kg) and in the active comparator -0.79 kg (3.39 kg).

3.5.8.3 Clinical effectiveness

None of the studies reported if participants achieved a weight loss associated with clinical benefits (5-10%) of initial body weight. Changes in percentage body weight pre-post intervention were reported for only one study, which achieved a mean clinically significant weight loss at the end of the active intervention period (Fox *et al.*, 1984). Fox and colleagues reported that at the end of the weight maintenance phase participants in both interventions had achieved an average weight loss of -6.1% (SD 3.3%) and -5.9% (SD 3.0%) in the multi-component intervention and comparator intervention, respectively. However, this was not maintained at 12 months, questioning the sustainability of the benefits of the intervention.

3.6 Discussion

The purpose of this study was to systematically review the available evidence on the effects of randomised controlled trials of weight management interventions on body weight loss in adults with intellectual disabilities. The identification of the successful components of multi-component weight management interventions from high quality randomised controlled trials can help to inform the development of future studies. Consistent with previous reviews (Hamilton *et al.*, 2007; Jinks *et al.*, 2011; Spanos *et al.*, 2013a), this study found that there are few studies designed to reduce obesity in adults with intellectual disabilities.

3.6.1 Efficacy of the interventions

The meta-analysis found that overall current studies of multi-component interventions do not significantly reduce body weight in comparison to no treatment control intervention. One multi-component intervention by Marks *et al.*, (2013) however, did report a significant effect size in comparison to no treatment (-2.13 kg; 95% CI -4.03 kg to -0.23 kg). This is unexpected considering the limited effect of the other interventions which have been shown to be homogeneous in intervention components, primarily opting for a health education approach and the inclusion of similar behaviour change techniques. Closer inspection of the

primary study revealed that although the between group change in body weight was significant this was not reported as a key finding which raises concern over the validity of this result. A difference of 9.48 kg was present between the intervention group and control group at baseline. Although, this was not reported in the primary study to be a significant between group difference, it is thought that this may have confounded the results. It would be expected that participants with a higher baseline weight would lose more weight due to regression to the mean (McQueen, Cohen, St John-Smith, & Rampes, 2009). Furthermore, results were presented for incomplete data without justification, illustrating presence of attrition bias. Therefore, this result should be interpreted cautiously. The study by Bergström *et al.*, (2013) contributed to the pooled effect size favouring the multi-component intervention in comparison to no treatment. However, the results of this study do not report a significant effect of the intervention on weight loss, with a minimal within group weight change of -0.85 kg (SD 7.53 kg) and thus not considered an effective weight management intervention for adults with intellectual disabilities and obesity. On the contrary, this multi-component intervention may be considered as an approach to prevention of weight gain, as the participants in the control intervention gained weight. Prevention of weight gain is an alternative strategy to tackling the obesity epidemic and research has shown that this is also a priority and under researched area in adults with intellectual disabilities (Harris, Hankey, Murray, & Melville, 2015).

3.6.2 Clinically important weight loss

Clinical guidelines for the management of obesity recommend that for individuals with a BMI between 25-35 kg/m² a 5-10% weight loss is required to reduce health risks associated with obesity (SIGN 2010; NICE 2014). Clinically important weight losses were not reported in the studies included in this review. Only one study reported to have a mean percentage weight loss greater than 5% in participants at the end of the 15 week intervention period (Fox *et al.*, 1984). However, a clinically important weight loss was not maintained in the study by Fox *et al.*, (1984) 12 months from baseline.

3.6.3 Comparison of intervention components with clinical recommendations on weight management

3.6.3.1 Diet

None of the studies met the recommendations of the inclusion of an EDD, instead opting for a health education approach. This in part may explain the limited weight loss reported in

studies. A health education approach is based on non-quantitative dietary advice, which is not prescriptive and therefore open to more interpretation by the individual or their carer. Future studies should aim to examine the feasibility and acceptability of offering an EDD to adults with intellectual disabilities and obesity, and examine the efficacy of this approach in order to provide insight into the optimum approach to weight management interventions in this population group.

3.6.3.2 Physical activity

Physical activity is an integral component of the management of obesity due to its role in affecting energy balance, and the regulation of body weight through an increase in energy expenditure (Berk, Hubert, & Fries, 2006; Kavouras, Panagiotakos, Pitsavos, Chrysohoou, Anastasiou, Lentzas, & Stefanadis, 2007; McTiernan *et al.*, 2007). Evidence based guidelines support an energy expenditure of 1200 to 2000 kcal per week. This is achieved through participation in 150-250 minutes of moderate to vigorous physical activity per week and is required to achieve a steady weight loss (SIGN 2010; NICE 2014). Increased levels of physical activity is associated with the long term maintenance of body weight loss (Catenacci & Wyatt, 2007; SIGN 2010; NICE 2014). The physical activity components of studies in this review varied from a structured physical activity plan including aerobic, flexibility, and strength based activities to a health education approach and advice on lifestyle physical activity such as taking the stairs, and walking. The 'dose' of physical activity prescribed could only be quantified in three studies (Fisher, 1986; McDermott *et al.*, 2012; Pett *et al.*, 2013). The weekly amount of physical activity in these studies varied from 70 minutes to 210 minutes per week. Only one study in this review achieved the current physical activity recommendations for weight loss (Fisher, 1986). Adults with intellectual disabilities and obesity are consistently reported to have low levels of physical activity (Fernhall & Unnithan, 2002) with one study reporting engagement levels of only 13.1 (SD 16.2) minutes per day in moderate to vigorous physical activity (Melville *et al.*, 2011). It should be considered that the current guidelines might not be achievable for some adults with intellectual disabilities and obesity. Future studies should aim at looking at new ways to reduce the amount of time spent in sedentary behaviours and aim to gradually increase participation in physical activity over time to reach the amount of physical activity required to lose weight. This is in accordance with new consensus guidelines for beginners to exercise and may be applicable for this population group (O'Donovan *et al.*, 2010).

3.6.3.3 Behaviour change techniques

The importance of the incorporation of behaviour change techniques into weight management interventions has been shown to be effective in supporting changes in attitudes and adoption of practices of healthier lifestyle habits (SIGN 2010; NICE 2014). The number of behaviour change techniques included in this review varied between studies, with the most common techniques incorporated including prompt practice; provide instruction on how to perform the behaviour; barrier identification/problem solving; action planning; model/demonstrate the behaviour; plan social support/social change; and prompt self-monitoring of behaviour. To the author's knowledge, this study is the first to utilise the CALO-RE taxonomy to assess behaviour change techniques in multi-component weight management interventions in adults with intellectual disabilities. However, the taxonomy has been applied in recent systematic reviews related to changing lifestyle habits in the general population and therefore relevant to draw comparison with this study. For example, the taxonomy has been applied to interventions improving dietary intake in older adults (Lara *et al.*, 2014); increasing physical activity in obese adults (Olander, Fletcher, Williams, Atkinson, Turner, & French, 2013) and promoting weight loss (Hartmann-Boyce, Johns, Jebb, & Aveyard, 2014). There is no clear evidence of the optimum number of behaviour change techniques with recent research in the general population reporting conflicting results. Lara *et al.*, (2014) examined the effectiveness of behaviour change techniques in dietary interventions in older adults, and reported a significant trend towards greater fruit and vegetable intake with increased number of behaviour change techniques per study. Whereas, Michie and colleagues, (Michie, Abraham, Whittington, McAteer, & Gupta, 2009) prior to the development of the CALO-RE taxonomy reported that effectiveness was not increased with increased number of behaviour change techniques.

Direct comparison of studies that included a more comprehensive intervention with a comparator intervention revealed insignificant results, suggesting that perhaps these techniques were not of significant magnitude to effect changes in body weight. In addition, goal setting and providing feedback on performance, which in the general population have been shown to be an effective technique in supporting weight loss, were infrequently implemented in the interventions (Michie *et al.*, 2009; SIGN, 2010; NICE, 2014). However, it is important to note that caution is warranted over the interpretation of any comparisons of effective behaviour change techniques in the general population with those applied in adults with intellectual disabilities. As this population group may not be able to apply specific techniques due to limitations in their cognitive abilities and level of understanding.

For example, provide information on the consequences of behaviour in general has been shown to be an effective technique in increasing physical activity in obese adults (Dombrowski, Sniehotta, Avenell, Johnston, MacLennan, & Araújo-Soares, 2012). However previous randomised controlled trials of weight management interventions in adults with intellectual disabilities reported that some participants did not have the capacity to understand the health implications of not engaging in healthy lifestyle habits (Bergström *et al.*, 2013). This was further explored by Spanos *et al.*, (2013b) investigating the acceptability of the single stranded TAKE 5 intervention. Carers reported that adults with intellectual disabilities had difficulties in understanding the health risks of obesity and healthy eating messages such as quantifying portion sizes. Therefore, this technique may not be applicable to this population group. Indeed, there has been an inconsistency in the effective techniques supporting behaviour change between population groups and even between obese and non-obese adults (Olander *et al.*, 2013). Behaviour change techniques associated with increasing physical activity in adults without obesity (Williams & French, 2011) were not shown to be effective in obese adults by Olander *et al.*, (2013). Only four techniques across the two reviews were associated with increased physical activity, these included; provide information on consequences of behaviour in general, prompt rewards contingent on effort or progress towards behaviour, provide instruction on how to perform the behaviour and facilitate social comparison. In order to elucidate the effective techniques for weight management in adults with intellectual disabilities future studies are required that actively report the behaviour change techniques and facilitate direct comparison of intervention components.

3.6.3.4 Weight maintenance intervention

Weight maintenance is recognised as an integral component to the management of obesity, illustrating that individuals who have lost a significant amount of weight through substantial lifestyle changes are able to maintain changes in body weight and prevent future weight gain or health risks (NICE 2014; SIGN 2010). This review illustrated that research on weight maintenance interventions for adults with intellectual disabilities is limited. This is consistent with the research in the general population with studies primarily focusing on the development and evaluation of weight loss initiatives (Loveman *et al.*, 2011). The effectiveness of weight maintenance interventions in adults with intellectual disabilities has not been extensively investigated. Only one study included in this review included a weight maintenance period (Fox *et al.*, 1984). This was five weeks in duration and arguably not really a weight maintenance intervention as participants were encouraged to continue to lose

weight. Therefore, technically it differed little from the weight loss phase. The long term effects of a multi-component weight maintenance interventions require further investigation in adults with intellectual disabilities and obesity.

3.6.3.5 Long term follow up

Few studies investigated the long term effects of the weight management interventions at 12 months (Fox *et al.*, 1984; Bergström *et al.*, 2013; McDermott *et al.*, 2012). The meta-analysis illustrated no significant weight loss at 12 months post intervention in the studies comparing the long term effects of multi-component weight management intervention to no treatment control intervention. Research in the general population shows that the trend in weight change for most adults in the following a period of initial weight loss, is weight regain over time (Avenell *et al.*, 2004). Clinical guidelines advocate a minimum 12 month study period (including the intervention and follow up) to examine the efficacy of the intervention. Therefore, future studies are required to assess the long term effect of the intervention.

3.6.4 Support from carers

It has been highlighted in previous reviews that carers play an integral role in motivating participants to make healthy lifestyle choices (Hamilton *et al.*, 2007; Spanos *et al.*, 2013a). The level of carer involvement in the studies included in this review varied from carers attending each of the intervention sessions, to individual components of the intervention specifically designed to involve carers to help the participants they support to achieve healthy lifestyle changes and ultimately weight loss. Two studies compared the effect of increased social support from carers on weight loss, and found insignificant results (Fox *et al.*, 1984; Pett *et al.*, 2013). Although both interventions in the study by Fox *et al.*, (1984) were shown to both be effective, the addition of a buddy system involving increased social support from peers did not provide any additive effect. Exploring the results of the study by Pett *et al.*, (2013) in further detail revealed that the additional involvement of support from carers did not significantly support participants with intellectual disabilities to lose weight. However, this study was limited by a small sample size, and was an underpowered study. Furthermore, the authors reported that only eight of the carers out of 18 parent carers who inquired about the parent group took part. It was speculated by the authors that this was due to participant burden and lack of time; therefore, these reasons may have also been present in the carers who participated, and could be a potential explanation to the limited weight loss in comparison to the participant with intellectual disabilities only intervention. There was

also an imbalance between the number of participants with Down syndrome in the comparator intervention. The authors of this study reported that the presence of Down syndrome was a predictor of weight loss and therefore may have resulted in the increased weight loss in the comparator intervention. Overall, this review illustrated that there is insufficient evidence from direct comparisons of studies comparing the efficacy and thus quantifying the effect of increased support from carers on change in body weight. Clinical guidelines have advocated that multi-component interventions should be individualised, both in terms of the type of treatment suggested (with resources adapted to the cognitive abilities of service users) and the level of support provided (SIGN 2010; NICE 2014). Interventions should therefore continue to recognise the important influence carers have on the lives of adults with intellectual disabilities. Interventions should aim to actively involve the carers in implementing session with study participants and also aim to enhance their knowledge and skills, in order to help facilitate healthy lifestyle choices for this population group.

3.6.5 Intervention delivery

All the studies delivered the intervention in a group format, with the involvement of 4-8 participants. The effectiveness of the delivery of weight management interventions are uncertain and are unexplored in this population. Evidence in the general population is equivocal on the optimum delivery to support individuals to lose weight. A recent systematic review by Greaves, Sheppard, Abraham, Hardeman, Roden, Evans, & Schwarz, (2011) on the evidence synthesis of reviews of intervention components associated with effective dietary and physical activity interventions reported high quality randomised controlled trials (Avenell *et al.*, 2004; Dombrowski *et al.*, 2012; Ogilvie, Foster, Rothnie, Cavill, Hamilton, Fitzsimons, & Mutrie, 2007) provided evidence for individual, group and a mixture (both group and individual) mode of delivery in changing diet and /or physical activity behaviours. Furthermore, the interventions were delivered by a variety of providers, from carers to health professionals in physical activity and dietitians. There is a lack of evidence distinguishing between the effect of the delivery of the intervention between providers (Greaves *et al.*, 2011). Individual randomised controlled trials have provided evidence for the delivery of physical and dietary interventions by a variety of providers including dietitians/nutritionists, doctors and nurses and physical activity specialists (Greaves *et al.*, 2011). However, a recent review of weight management interventions in the general population, provided evidence for a strong association with weight loss when interventions were delivered by a dietitian (-1.5

kg; 95% CI -2.9 kg to -0.2 kg) (Hartmann-Boyce *et al.*, 2014). This is further supported by evidence of the effective role of dietitians in delivering a weight management intervention in the general population (Laws, 2004). These data suggest a slight advantage for dietitians in terms of weight loss. However, future studies of multi-component weight management interventions should investigate the efficacy in adults with intellectual disabilities and weigh up the cost-effectiveness of the additional resource required to employ a full time dietitian over the potential benefit in terms of efficacy of the intervention.

Adults with intellectual disabilities experience difficulties with communication, understanding, and adaptive behaviour and require varying levels of support. The studies in this review only included participants with mild to moderate level of intellectual disabilities. Obesity is not exclusive to this group of people with intellectual disabilities, it affects individuals with all levels of intellectual disabilities. Therefore, future studies should aim to take into consideration the context and experience of all adults with intellectual disabilities and obesity. However, this may justify a carer based approach in some cases, or an individual mode of delivery. A one-to-one approach could allow the inclusion of all adults with intellectual disabilities, however it would be resource intensive. Furthermore, it has been reported that adults with intellectual disabilities can experience difficulties in accessing services due to transportation issues, and may rely heavily on their carers for support. An individualised intervention may be able to accommodate the needs specific to this population group and engage carers in the implementation of the intervention. The cost-effectiveness of this type of delivery would be required before implementation into routine practice (NICE, 2014). None of the studies in this review conducted an economic evaluation of the study and therefore no information was available on the cost-effectiveness of multi-component interventions in this population group. Economic evaluation can provide an important insight into considerations regarding the design of the components and resources required to implement an intervention. Therefore, future trials should consider evaluating the cost effectiveness of an intervention alongside outcome evaluations (MRC, 2008).

3.6.6 Quality assessment

The internal validity of the studies was assessed by the Cochrane Collaboration risk of bias assessment tool. Differences in the risk of bias can help to understand the variation in the results of studies, with more rigorous studies (i.e., studies with a low risk of bias) more likely to produce results that are true. The majority of risk of bias assessment across domains for studies was considered as low risk. However, this was closely followed by the reporting that

showed an unclear risk for domains. Due to this lack of reporting of information on the methodology of studies, it was not possible to grade or categorise studies on their level of potential bias. Inclusion of these studies in this review was justified on the basis that including studies that had low risk of bias for all domains would have resulted in the exclusion of all studies. Furthermore, excluding solely studies of high risk of bias would produce a summary effect that was imprecise due to only a very limited number of quality trials considered to be eligible.

Adequate description and randomisation of participants is essential to prevent an imbalance in participant characteristics between the intervention groups. This is particularly pertinent when participants are allocated to a no treatment arm / treatment as usual arm of a randomised controlled trial. Researchers aware of and not concealed from may enrol participants into the more 'appropriate intervention.' All the studies reported either low risk of bias or unclear risk of bias for this domain with the exception of Marks *et al.*, (2013). High risk of bias was assessed by this study due to the fact that community based organisations conducting the randomisation could potentially have influenced the sequence of participants entered into the interventions.

Blinding of participants, researchers and others involved in the study (performance bias), particularly those involved in the outcome assessment (detection bias) can reduce the risk of the identity of the intervention treatment and the potential of influencing the trial outcomes, respectively. The majority of studies did not address or provide sufficient details on performance bias. However, it is unlikely that participants/carers were blinded as this is usually difficult for a lifestyle intervention. Attempts at blinding cannot ensure successful concealment of the treatment under investigation, and is especially obvious to personnel if the comparator intervention is no treatment. Detection bias is more important as the unblinding of the intervention allocation has been shown to exaggerate the intervention effect (Hróbjartsson *et al.*, 2012). Only two studies reported blinding of outcome assessors (Beeken *et al.*, 2013; Beeken *et al.*, 2015; Marks *et al.*, 2013), therefore future trials should aim to include more rigorous attempts to prevent detection bias by including single blinded study designs.

Rates of attrition were reported in all studies. Weight management interventions in the general population often report high attrition rates of 30-60% (Douketis, Macie, Thabane, & Williamson, 2005). Only one study in this review had attrition rates comparable with the

highest attrition rates (55.8%) (McDermott *et al.*, 2013). However, this study, although it included a randomisation process and under the definition by Cochrane Collaboration (Higgins & Green, 2011) met the criteria for inclusion in this review, the study design was more like that of a cohort study. With the exception of the above study, the attrition rates of included studies were much lower than studies of weight management interventions in the general population with two studies reporting no drop outs. The mean attrition rate for the studies was 14.2% (range: 0% to 55.8%). This low attrition rate may also be due to the duration of studies with the mean duration of 4.5 months. Investigations of weight management interventions in the general population include longer term interventions of 12 month duration. Moreover, the low attrition may also be the result of interventions being delivered with the involvement of others, such as carers, who may be influential in securing attendance of participants at appointments. Future studies of longer duration are required to examine the acceptability of long term weight management interventions and their retention of participants. A further potential source of bias which was not accounted for in the majority of studies with the exception of (Fisher, 1986; Fox *et al.*, 1984; McDermott *et al.*, 2012; Pett *et al.*, 2013) was the lack of justification of the sample sizes of studies. This may result in underpowered studies and or certainly studies with unknown power.

3.6.7 Strengths and limitations

To the authors knowledge, this is the first review to synthesis and quantify the effect of the available evidence of multi-component weight management interventions on change in body weight in adults with intellectual disabilities and obesity. The inclusion of randomised controlled trials provides a more valid and reliable estimate of the effect of the intervention, by aiming to reduce methodological errors of non-randomised trials such as imbalances between participant characteristics under investigation, and also un-measurable confounding factors and reverse causality often associated with observation studies. Furthermore, the behaviour change techniques were systematically identified against a standardised taxonomy.

Sample heterogeneity in terms of the weight status of participants limits the interpretation of the results as one of the studies included participants across a range of BMI, classified as underweight, normal weight, overweight and obese (Marks *et al.*, 2013). Although, the aim of this review was to examine the effect of multi-component interventions in adults with intellectual disabilities and obesity, the study was included in this review as a high proportion of participants with overweight and obesity participated. Due to the limited number of

studies further analysis of subgroups such as age, BMI categories of severity of obesity, and risk of bias could not be explored to assess the effects of these characteristics on body weight.

Finally, regarding the reporting of the intervention components some of the included studies did not clearly define the behaviour change techniques. This made it difficult to extract the active techniques which were implemented to evoke the change in lifestyle. Additionally, different labels were used across studies which reflect the same techniques (i.e., self-monitoring, completion of diaries). The MRC guidelines for developing and evaluating complex interventions have further highlighted this issue stating that clear reporting on the components of interventions are necessary with standard definitions to classify behaviour change techniques (MRC, 2008).

3.7 Conclusion

In conclusion, there is a paucity of available evidence on the management of obesity in adults with intellectual disabilities. The current weight management interventions did not adhere to clinical recommendations on the inclusion of an EDD, inclusion of a weight maintenance period or provided adequate follow up to examine the efficacy of the intervention. In general interventions were based on a health education approach, were underpowered and produced small insignificant effects on weight loss. The meta-analysis revealed that multi-component weight management interventions did not significantly reduce body weight in comparison to no treatment (control intervention) post intervention or at 12 months follow up. One study produced a significant between group effect, post intervention, in comparison to the control intervention. However, large variation in baseline weights between groups, with higher baseline body weight in the multi-component intervention, meant that under the principle of regression to the mean, greater weight loss is expected.

The direct effect of intervention components was assessed by studies including an active comparator study design. Three studies compared two active weight management interventions, however there was no significant difference in change in body weight between multi-component weight management interventions. Difficulties in isolating the active ingredients of the weight management interventions due to lack of adequate reporting of behaviour change techniques and homogeneity of techniques utilised in the interventions limited exploration into the active processes supporting weight loss.

The current evidence base raises questions over the efficacy of the health education approach to weight management. Future studies of multi-component weight management interventions should aim to meet clinical guidelines recommended by NICE and SIGN on weight management, in particular the inclusion of an EDD and social support from carers. Long term studies including an active weight maintenance period of at least six months duration and comprising a minimum 12 months intervention period overall are required to investigate the efficacy of this approach to weight management in supporting sustainability of weight loss in adults with intellectual disabilities and obesity.

Chapter 4: Methods

4.1 Introduction

This chapter will outline the rationale for conducting the pilot randomised trial and include the details of the feasibility, potential efficacy, and process outcomes which will be evaluated. This chapter consists of a mixed method design, utilising predominantly quantitative research methods, and enhanced by qualitative methods to explore in-depth the processes involved in conducting a randomised trial. A systematic description of the ‘active ingredients’ of the intervention components will also be discussed. This chapter concludes with a detailed statistical analysis plan (SAP).

4.2 Study design

Defining the optimum study design in behavioural change research can cause considerable debate, and decision balancing is often required between different methodological concepts. One of the major influencing factors in the choice of an active comparator intervention in this study was the ethical considerations of offering participants with obesity and at increased risk of health inequalities (Guh, Zhang, Bansback, Amarsi, Birmingham, & Anis, 2009; Whitlock *et al.*, 2009) no treatment or withholding treatment for a 12 month period.

There are few studies of randomised trials examining the efficacy of a multi-component weight management intervention in comparison to an active comparator intervention (chapter two). Therefore, there was limited evidence available on which to base a best alternative comparator intervention.

Treatment as usual (TAU) in most areas in the UK for adults with intellectual disabilities and obesity is inconsistent, ranging from no treatment intervention to community group based lifestyle interventions, such as Waist Winners Too [(WWToo); Jones, Melville, Tobin, & Gray 2015]. This variability in treatment options was also thought to affect the validity of the study design, as providing a no treatment, control intervention would limit the differentiation between the effects of taking part in the research project and specific treatment effects of the intervention (McQueen *et al.* 2013). For the purpose of the study

TAU was therefore defined as an active comparator intervention, WWToo. Moreover, an active comparator intervention was justified as this is a relatively novel study design in adults with intellectual disabilities and with the feasibility of recruitment and retention uncertain, it was considered that recruitment and retention would be negatively affected by offering no treatment as an intervention.

The outline of the study design is illustrated in Figure 4.1. Participants were randomised to either intervention for a 12 month period; a six month weight loss period (comprising of 9-12 sessions designed to take place at between two – three weekly intervals) followed by a six month weight maintenance period (comprising of six sessions taking place once a month). At the end of the weight loss phase, if participants lost a clinically significant weight loss of 5% of initial body weight they continued onto the six month weight maintenance phase. However, if participants did not reach this weight loss target of 5% at the end of the weight loss period, they were advised to continue on the weight loss plan for a further three months, followed by a condensed three month weight maintenance period. This allowed a 12 month “intervention period” for all participants and mirrored the procedures conducted by the GCWMS. In order to prevent detection bias, outcomes measures were assessed by the researcher (LH) who was blinded to study group allocation at three time points, baseline, six months (post weight loss phase) and 12 months at the end of the intervention period.

4.3 Ethical approval

The study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki and consistent with the principles of Good Clinical Practice. Ethical approval was received from the Scotland A Research Ethics committee on the 16th of December 2013 (reference number: 13/SS/0229. Appendix ii).

4.4 Recruitment

Recruitment is an integral part in the process of conducting a randomised controlled trial as poor recruitment can result in an underpowered study and therefore any results that may be clinically important without adequately achieving the sample size may be statistically inconclusive. One of the main aims of this study was to investigate the feasibility of conducting a full-scale, multi-centre trial. Therefore, essential procedures necessary to coordinate a full-scale trial such as recruitment and retention to the trial were piloted.

There is a lack of a clear framework to inform the recruitment into intervention studies in the general population (Foster, Brennan, Matthews, McAdam, Fitzsimons, & Mutrie, 2011). Furthermore, research in adults with intellectual disabilities is made more complex due to ethical procedures including procedures with informed consent and the inability to directly approach potential participants (Cleaver, Ouellette-Kuntz, & Sakar, 2010; Lennox, Taylor, Rey-Conde, Bain, Purdie, & Boyle, 2005). To attempt to overcome the barriers often faced with involving participants with intellectual disabilities in research (Oliver, Piachaud, Done, Regan, Cooray, & Tyrer, 2002) this study utilised a multi-point recruitment strategy which has shown to be successful in research recruiting adults with intellectual disabilities to a physical activity intervention (Melville *et al.*, 2015). This strategy was originally postulated in research recruiting participants into walking interventions (Foster *et al.*, 2011). The framework was adapted to facilitate recruitment to this study based on the four primary stages.

- **Stage 1: Identification of potential participants**

An initial planning stage involving identification of potential participants to be recruited to the study. Participants were recruited from multiple organisations, from specialist intellectual disabilities services, provider organisations and local day centres. A researcher (LH) visited staff working in these settings to explain the study and ask if their organisation would be willing to support recruitment to the study.

- **Stage 2: Invitation to participate in the study**

If organisations and their staff were engaged and supported the study, they were provided with study information packs in which they were invited to disseminate to service users they deemed would be interested in taking part in the study. One hundred and ninety-five information packs were distributed between two day centres, four specialist intellectual disabilities services, and one provider organisation and the GCWMS. The information packs comprised an invitation to participate in the study and separate information sheets for participants, carers and relatives/welfare guardians (see appendix iii). In order to prevent identification of numerous potentially ineligible participants, staff were informed of the inclusion and exclusion criteria (although final assessment of eligibility into the study was made by the researcher after informed consent). On the back of the participant information sheet, a tear off slip was provided in which potential participants could complete, where appropriate supported by carers, to indicate they were interested in taking part in the study. Potential participants replied to the invitation to the study by FREEPOST using the self-

addressed envelope provided, indicating whether they would like to meet the researcher to find out more about the study.

- **Stage 3: Response to invitation and assessment of eligibility**

If the participant indicated they would like to find out more information about the study, the researcher then made first contact with the individual to arrange an initial visit to further discuss the study, at a convenient time and location to the individual. This was following the suggestions by Foster *et al.* (2011) on enhancing the recruitment process by meeting participants face-to-face. It was also felt that this approach would provide a better rapport with the researcher and the recruited participants (Banks-Wallace, Enyart, & Johnson, 2004). At this appointment, more information about the study was discussed and potential participants and carers and/or relative/welfare guardians were given the opportunity to ask questions about the study. If the individual was willing to participate they provided informed consent (see section 4.5) or another meeting was scheduled to give participants time to think about the decision of participating. On completion of informed consent participants were screened for eligibility and baselines measurements obtained.

- **Stage 4: Initiation into intervention**

Participants were assessed individually for their eligibility, however, if participants were identified as living together and/or supported by the same carer, participants were randomised to the TAKE 5 or WWToo intervention as a cluster to prevent contamination between the two interventions. Participants were then contacted by the research dietitian to arrange their first appointment (the randomisation process is discussed further in section 4.7).

In order to evaluate the effectiveness of the recruitment process a record was kept of the number of potential participants who contacted the researcher from each of the recruitment points. Individuals consenting to participate in the study (based on the information slips returned and liaising with staff at the organisation sites) were recorded.

4.5 Informed consent

A detailed protocol of consent was implemented prior to any protocol specific procedures being carried out. An information sheet was read to the potential participant and adequate verbal explanation about the study provided to them. Potential participants were given the opportunity to ask questions and to clarify anything they did not understand. They were also

given the opportunity to decline to take part in the research study and it was emphasised that the participant may withdraw their consent at any time and to decline to take part in any particular aspect without loss of benefits to which they otherwise would be entitled. Before informed consent was obtained the decision of an individual to participate in the research study was based on a clear understanding of what the study was about and what was involved. The process of obtaining consent was conducted in accordance with the Adults with Incapacity Act, 2000 (Scottish Executive 2000). A carer or someone known to the participant, independent from the research team was witness to the consent. In circumstances where a participant did not have the capacity to consent to participation in the research study, written informed consent to participate was provided from the nearest relative or welfare guardian. Ongoing consent was also checked and assessed throughout the study period.

4.6 Sample size

There are few studies of randomised trials of weight management interventions involving adults with intellectual disabilities. Therefore, there is limited data on which to model a sample size calculation. The study sample size calculation of 66 participants (33 participants to each treatment intervention) is based on the following considerations:

- To determine the probable variance of study outcomes in order to power a larger randomised trial. If 50 participants provide 12 month outcome data, a 90% confidence interval for each variance estimate will have a width of approximately 70% of the estimate (i.e. -29% to + 41%)
- To provide sufficient insight into recruitment and retention rates, which will have a 95% confidence interval of no more than $\pm 10\%$ and help inform the development of a full-scale trial
- To account for clustering of individuals (discussed in more detail in section 4.7 Randomisation) – potential participants identified may live together and/or be supported by the same family or paid carers which could lead to some contamination between treatments and clustering of outcomes. However, there were few cluster randomised trials to base the likely degree of clustering, therefore the following assumptions were made (a conservative intra-class correlation coefficient of 0.1, and an average of 2 participants per cluster) to increase the sample size by 10% to give a sample size calculation of 56 participants

- To account for attrition - drop outs during the clinical trials can lead to insufficient data to be able to detect significant differences in outcomes. To account for this, studies inflate the number of participants required to prevent the trial from being underpowered. Review of the multi-component weight management interventions in adults with intellectual disabilities (chapter 3) reported variable study attrition rates, mean 13% (range 0% to 55.8%). Evidence from the single stranded reports of the TAKE 5 and WWToo studies also reported marked differences in the rate of attrition, 5% and 48%, respectively (Jones *et al.*, 2015; Melville *et al.*, 2011). Therefore, taking the attrition rates into consideration, and differences in the delivery of the intervention (individual delivery in the TAKE 5 intervention versus group based interventions in the other studies) the sample size of this study was increased to allow a conservative attrition rate of 20%. This provided a final sample size calculation of 66 participants.

4.7 Randomisation

In theory, if participants are randomised individually to a trial, there is potential that contamination of intervention specific information may occur between participants in different intervention groups. Risk of potential contamination in this study were believed to exist if participants had a close relationship, for example if they lived together or, due to the major role of social support from carers in this study, if participants were supported by the same carer. Thus, cluster randomisation was used in this study to prevent contamination between interventions, clustering of outcomes and to minimise imbalance between study groups.

As previously discussed in chapter one, in large clinical trials the randomisation process is designed to prevent systematic differences in participant characteristics between intervention groups. However, when trials are conducted with small sample sizes, intervention groups may result in an unequal distribution of participant characteristics due to chance. In order to ensure that participant characteristics, which are likely to affect the relationship between the treatment and outcome, a statistical analysis technique, stratification, can be performed. In the single stranded feasibility study, subgroup analysis revealed that there was a trend in participants with Down syndrome (OR 3.50; 95% CI 0.90 to 13.66; $p = 0.071$) or more mild to moderate level of intellectual disabilities to lose weight (OR 4.08; 95% CI 0.97 to 17.21, $p = 0.055$) although results were not statistically significant (Melville *et al.*, 2011). To

prevent any imbalances in this study stratification and therefore analysed with adjustment for presence of Down syndrome, level of intellectual disabilities and number of participants within a cluster was incorporated into the randomisation algorithm.

Randomisation was implemented using an interactive voice response system (IVRS). This was hosted by the Robertson Centre for Biostatistics, University of Glasgow a separate department from the researcher. The researcher was blinded to participant group allocation by registering each participant via telephone call, providing details including the participant's screen number, level of intellectual disabilities and presence of Down syndrome. Subsequent to registering a participant in the study, the system notified the principal investigator via email of the group allocation (TAKE 5 intervention or WWToo intervention).

4.8 Study population

Eligibility of participants was based on the following inclusion and exclusion criteria.

Inclusion criteria:

- Diagnosed with intellectual disabilities (Mild/Moderate/Severe/Profound)
- Adults ≥ 18 years of age (no upper age limit was set in keeping with specialist intellectual disabilities health services in the National Health Service Greater Glasgow & Clyde and in accordance with the GCWMS)
- BMI ≥ 30 kg/m²
- Ambulatory - able to walk (with or without a walking aid) for 10 minutes at a time based on self/carer report
- Not currently on a prescribed or restricted diet e.g. for phenylketonuria or diabetes
- Not intentionally lost weight of >3 kg in the previous three months.

Exclusion criteria:

- Presence of the following genetic syndromes; Prader Willi syndrome, Cohen syndrome or Bardet- Biedl syndrome, due to more intensive weight management support required
- Currently activity involved in any other research study
- Taking medication for the purpose of losing weight (either prescribed or over the counter)

- Individuals who were pregnant or who conceive during the study will be excluded.

4.9 Interventions

4.9.1 Intervention delivery

The TAKE 5 and WWToo interventions were delivered by a dietitian or a health professional trained for the purpose of this study (the health professional received one and a half days of training, including instruction on the intervention content and shadowing the dietitian on participant appointments). Henceforth, the dietitian and the health professional will be denoted by the name research dietitians. The research dietitians delivered both interventions. To minimise contamination between the interventions, research dietitians followed a pre-set protocol and manual for each intervention session. The intervention sessions were delivered one-to-one over a 12 month period, 9-12 sessions in the weight loss phase and six sessions in the weight maintenance phase. This was to allow appointments to be organised flexibly in order to maximise the consistent involvement of family and paid carers. Each session was scheduled to last approximately 40 - 60 minutes. This was to account for individual needs and abilities of participants. If for example the session content was too intense for an individual, the sessions were designed flexibly to allow the content to perhaps be delivered over shorter additional sessions to help carers and participants develop a better understanding of the intervention information. Additional sessions were recorded in the research dietitian's clinical notes.

4.9.2 Communication and resources

Clinical guidelines advocate that the success of behaviour change interventions is dependent on them being tailored to the specific needs and context experienced by the individual (NICE 2014). Adults with intellectual disabilities have difficulties with communication and understanding of information, therefore in order for participants to understand the content on the intervention and to express their choices during the intervention, appropriate methods and techniques were used to facilitate augmentative communication e.g. talking mats and pictorial explanations (Murphy & Cameron, 2008).

The resources used in both interventions had previously been piloted in the TAKE 5 single stranded feasibility study and in the evaluation of the WWToo intervention (Melville *et al.*, 2011; Jones *et al.*, 2015) and have shown to be acceptable for adults with intellectual

disabilities. These resources are designed to be used flexibly for all adults with varying levels of intellectual disabilities and carers where appropriate.

The resources were adapted to meet guidelines on images and easy read text for adults with intellectual disabilities (National Equalities Partnership, 2005; Department of Health, 2010). These included recommendations for the wording and layout, font size, and colour. Examples of resources for the TAKE 5 intervention and WWToo intervention are illustrated in appendix v.

4.9.3 Carer involvement

The important role of carers in supporting weight loss is highlighted by previous research (Fox *et al.*, 1985; Hamilton *et al.*, 2007; Spanos *et al.*, 2013a). Participants were invited to be supported throughout the intervention by family and/or paid carers. Carers were offered additional one hour training session with the research dietitians on any of the components of the intervention. Carers were invited to attend sessions with the research dietitians to help with communication or where necessary behavioural change techniques for example goal setting and self-monitoring of the participants' physical activity or dietary intake.

4.9.4 Systematic identification of active intervention components

In order to conduct a systematic evaluation of the effect and processes of an intervention, it is important to be able to identify the 'active ingredients' of an intervention (Abraham, Kelly, West, & Michie, 2009; MRC, 2008; Michie, 2008). The process of extracting the components of interventions in particular behaviour change techniques can be facilitated using standard terminology and definitions (Abraham & Michie, 2008; Michie *et al.*, 2011). Evaluation of the behaviour change techniques utilised in the TAKE 5 and WWToo interventions was conducted to explore the effective components and causal mechanisms resulting in clinically important outcomes such as weight loss and whether these behaviour changes were maintained long term. Furthermore, this aimed to provide a detailed insight into refining the interventions for future studies and allow the comparison of intervention components to previous literature on weight management interventions. The components of each intervention are discussed in further detail below and illustrated in Figure 3.3. The behaviour change techniques are coded using the CALO-RE taxonomy due to its reliability and applicability to dietary and physical activity interventions (Michie *et al.*, 2011).

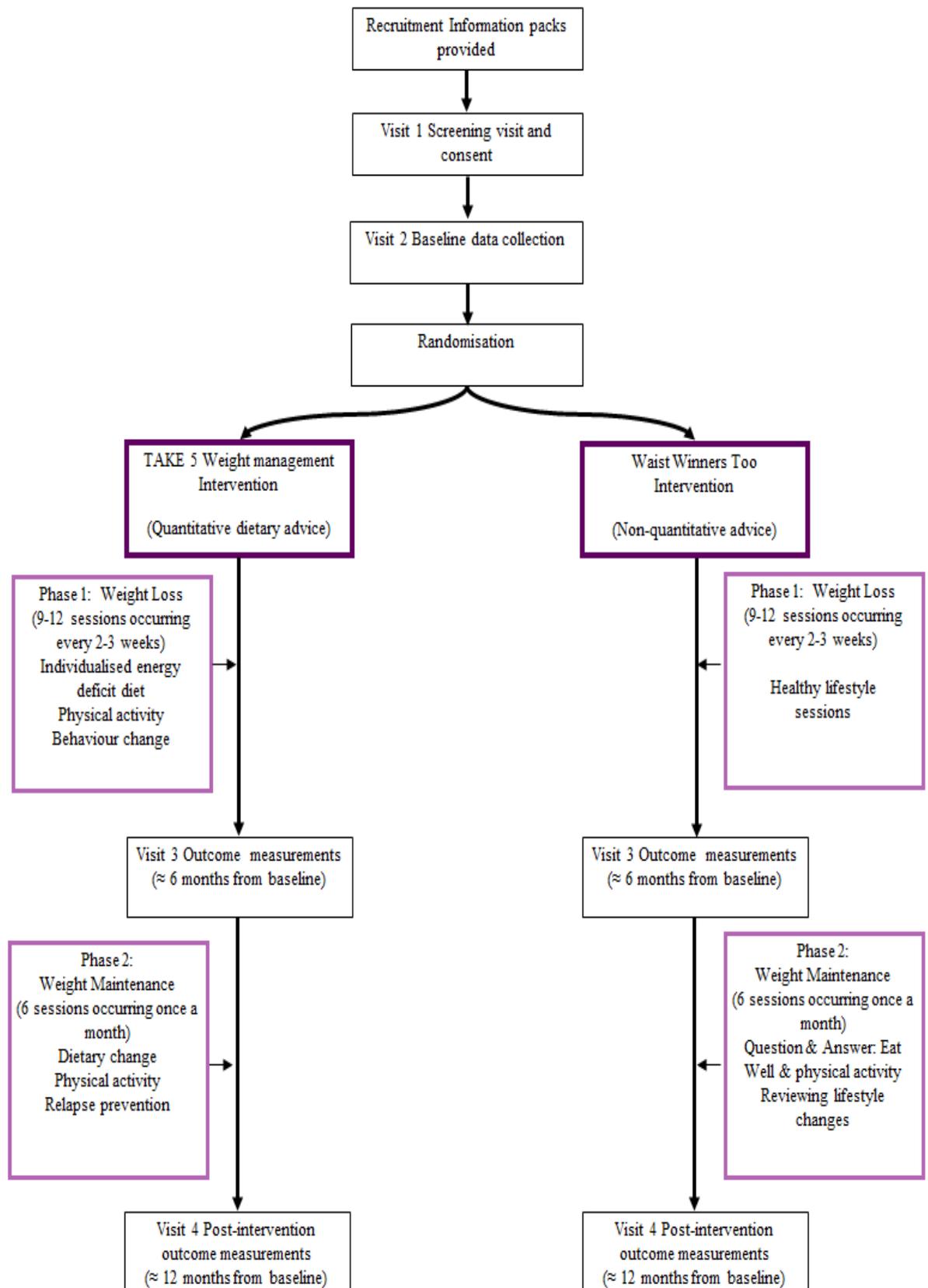


Figure 4.1. Study Design (Adapted from Harris *et al.*, 2015).

4.10 TAKE 5 weight management intervention

As described in chapter one, diet and physical activity are key components recommended by clinical guidelines (NICE 2014; SIGN 2010). To facilitate these healthy lifestyle changes, behaviour change techniques are also incorporated into weight management interventions. Recommendations advocate interventions should include self-monitoring, goal setting, problem solving, relapse prevention, and social support. Research development in behaviour change has led to systematic reviews and meta-analysis providing strong evidence for the causal mechanism of change in behaviour (Michie *et al.*, 2009). The clarity in understanding the process of behaviour change has also been facilitated by standardisation of behaviour change taxonomies (Abraham & Michie, 2008; Michie *et al.*, 2011). A meta-analysis of effective techniques in healthy eating and physical activity interventions, demonstrated that interventions were more effective when they included self-monitoring and at least one other technique from Control Theory (Carver & Scheier, 1982) in comparison to interventions not including these techniques (Michie *et al.*, 2009). Control Theory proposes that the following techniques are fundamental to self-management and control of behaviour: goal setting, reviewing goals, and providing feedback on performance (Carver & Scheier, 1982). Therefore, evidence from clinical guidelines, and the meta-analysis of behaviour change techniques based on Control Theory informed the development of the TAKE 5 multi-component weight management intervention.

The TAKE 5 intervention comprises two discrete phases:

- Phase one – an initial weight loss phase of approximately six months
- Phase two – a weight maintenance phase of approximately six months (or an additional three month weight loss period if participants don't achieve a clinically significant weight loss of 5% of initial body weight followed by three months weight maintenance).

The key themes of the TAKE 5 weight loss and weight maintenance intervention phases are illustrated in Tables 3.1 and 3.2. Each session consists of a:

- Weight measurement
- Diet discussion point
- Physical activity discussion point
- Behavioural discussion point
- Target setting

- Summary

Repetition is essential to facilitate learning and understanding for adults with intellectual disabilities therefore reoccurring messages are implemented into each session.

4.10.1 TAKE 5 intervention components

4.10.1.1 Phase 1: Weight loss

4.10.1.1.1 Diet

To facilitate a healthy sustainable weight loss of 0.5-1 kg per week, an energy deficit of 600 kcal per day deficit through modification of dietary intake is advocated by clinical guidelines (NICE 2014; SIGN 2010). This recommendation is supported by high quality evidence from a systematic review and meta-analysis of randomised controlled trials of dietary interventions (NICE 2006). Interventions were included if they had a minimum 12 months duration and were conducted in overweight and obese adults (BMI range 27.9 kg/m² to 34.0 kg/m²). The effect size was reported for studies categorised as including either a 600 kcal EDD or a low fat diet due to limitations in the reporting of primary studies, preventing a clear distinction between dietary approaches. Twelve studies were included and found that the WMD at 12 months between studies utilising a 600 kcal EDD or low fat diets and control was -5.31 kg (95% CI -5.86 kg to - 7.77 kg).

Participants' individual EDD was calculated as the estimated total energy expenditure (TEE) of each participant minus an energy deficit of 600kcal per day. TEE for each participant was calculated using the following equations:

- $TEE = \text{Basal metabolic rate (BMR)} \times \text{physical activity level (PAL)}$

BMR was calculated based on age, gender, weight and height (Mifflin *et al.*, 1990):

- Females: $BMR = 10 \times \text{weight (kg)} + 6.25 \times \text{height (cm)} - 5 \times \text{age (years)} - 161.$
- Males: $BMR = 10 \times \text{weight (kg)} + 6.25 \times \text{height (cm)} - 5 \times \text{age (years)} + 5.$

The equation by Mifflin and colleagues (Mifflin, St Jeor, Hill, Scott, Daugherty, & Koh, 1990) was used as it has been shown to more accurately estimate BMR in comparison to

other prediction equations when applied in overweight and obese adults (Weijis & Vansant, 2010).

A PAL of 1.3 was used as results from the pilot single stranded study of the TAKE 5 multi-component intervention reported that individuals with intellectual disabilities and obesity are extremely sedentary and engage in low levels of physical activity, engaging on average 13.1 (SD 6.2) minutes per day in moderate-to-vigorous-intensity physical activity (Melville *et al.*, 2011). Thus, it is believed that the PAL of 1.4 used in the single stranded study may have overestimated total energy requirements. To account for this, a PAL of 1.3 was used in this study which is consistent with the available evidence of another randomised controlled trial in the general population, examining the efficacy of a 600kcal EDD in comparison to a generalised 1500 kcal low-calorie diet in overweight and obese participants (Leslie, Lean, Baillie & Hankey, 2002).

The EDD provides daily energy intake from a specified number of daily portions individually calculated for each participant by the research dietitians. This is based on the five food groups in the *Eatwell* plate: starchy foods such as bread, rice, potatoes and pasta; meat/fish and alternatives; fruit and vegetables; milk and dairy products; foods high in sugar and fat [Food Standards Agency (FSA), 2009].

The amount of energy intake of each individual was dependent on the variables above, gender, age, height and weight. Therefore, larger participants consumed more calories on their EDD in comparison to someone of a lesser body weight. To ensure nutrient adequacy (NICE, 2014) the energy intake was limited to between 1200 and 3000 kcal per day.

An example EDD prescribed for participants on 1500kcal energy intake and 3000 kcal energy intake is illustrated in Figure 4.2. This figure also presents an example of the images used for participants with intellectual disabilities in the TAKE 5 intervention. The five segments of the eat well plate indicate the amount of portions to be consumed from the diet, with fruit and vegetables (~30-40% of energy intake) and starchy foods (~30%) being the largest, followed by milk and dairy products (~10-20% of energy intake) and meat fish and alternatives (~10-15% of energy intake) and the smallest intake from foods high in fat and sugar (~5-10% of energy intake). This is based on recommendations of energy intake from macronutrients in the form of 50% of energy intake from carbohydrates, less than 35% from fat and 20% from protein (Department of Health, 1991).

The EDD was designed to be used flexibly with participants and carers, portions could be swapped for alternatives and extra kcal allowances were provided, for example to provide energy intake for treats at the weekend.

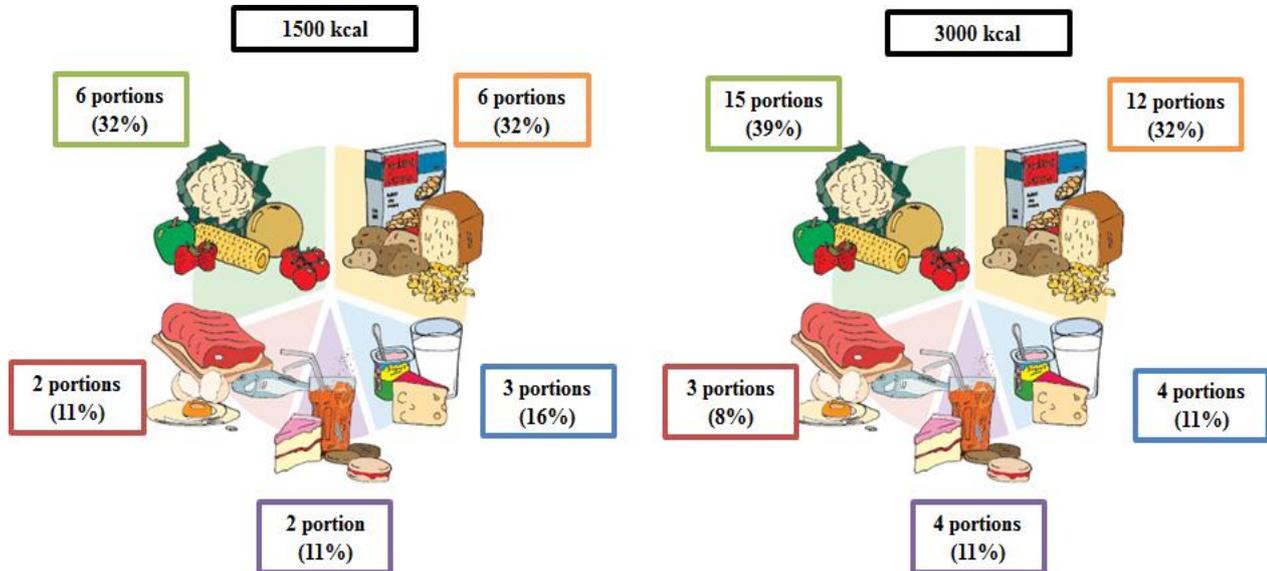


Figure 4.2. Example of energy intake from the five food groups of participants on an energy prescription of 1500 kcal and 3000 kcal. *Eatwell* plate images from the TAKE 5 resources.

4.10.1.1.2 Physical activity

The physical activity component was based on health education of the benefits of being physically active and followed consensus guidelines on physical activity interventions for beginners (O'Donovan *et al.*, 2010). The guidelines focus on supporting people to gradually increase their participation in physical activity and work towards achieving health recommendations on the duration and intensity of physical activity (Department of Health 2004; NHS Health Scotland 2009).

Participants' physical activity patterns were assessed at the start of the intervention and individualised physical activity plans made, primarily focussing on the following physical activities:

- 1) Lifestyle physical activity: Physical activity that could be performed in the home environment such as housework, walking up stairs and following the interactive **You Can Do It** DVD

- 2) Walking: based on baseline average steps per day, individuals were encouraged to set targets to progressively increase walking behaviour and used pedometers to monitor step counts
- 3) Sport and exercise: information was given to each participant on local leisure facilities and clubs with accessible sports and exercise groups/classes (Melville *et al.*, 2011).

Since many adults with learning disabilities have been shown to live sedentary lifestyles and to be less physically active compared to the general population (McGuire *et al.* 2007; Temple & Walkley, 2007), a major focus of this intervention component was also to interrupt time spent inactive and engaged in sedentary behaviours. This was achieved throughout the intervention, by assessing the participants' lifestyle habits such as watching television and sitting for long periods, and encouraging activity during add breaks when watching television such as walking or dancing when music is played.

In order to discourage the participants from being physically active by overloading them with unachievable goals, activity was gradually increased particularly in the early stages, by setting achievable goals in order to build confidence and increase the participants' motivation to being physically active. Furthermore, small increases in physical activity have shown to have health benefits independent of weight loss (NICE, 2014).

4.10.1.1.3 Behaviour change techniques

As previously mentioned the success of behaviour change interventions is dependent on them being tailored to the individual's needs (NICE 2014). Following recommendations by clinical guidelines (SIGN 2010; NICE 2014) and based on the evidence on behaviour change techniques based on Control Theory (Carver & Scheier, 1982), goal setting, self-monitoring, review of goals and feedback on performance are considered to be successful techniques in supporting healthy lifestyle changes (Michie *et al.*, 2009), therefore these were used in every session.

However, it is noted that due to the cognitive abilities of individuals with intellectual disabilities some of these techniques may be challenging for this population group. Therefore, other techniques were designed to be incorporated flexibly in relation to the needs

of the individual participants and included relapse prevention/coping planning and barrier identification/problem solving. For a full list of the behaviour change techniques utilised in the TAKE 5 intervention see Figure 4.3. The principal techniques are discussed in more detail below:

4.10.1.1.3.1 Goal setting

The primary goal for participants was to achieve a clinically significant weight loss of 5-10% body weight. This was communicated with participants at the start of the intervention period and subsequent goals made in relation to this overall aim throughout. This was achieved by setting smaller achievable weight loss goals of 0.5-1kg per week. This is in accordance with clinical guidance (SIGN 2010; NICE 2014). Goals were set at the end of each session (and reviewed at the following session) and focused on dietary habits and physical activity. Goals were Specific, Measurable, Achievable, Relevant and Time specific [SMART] (Doran, 1981) to each individual.

4.10.1.1.3.2 Self-monitoring

Participants were encouraged to monitor their food intake with support from carers, to the specified number of portions of the EDD. Participants were provided with food and physical activity diaries and asked to record their food intake by putting a dot by the food group when they had consumed it. In addition, participants were given a pedometer and asked with support from carers to note the number of steps they performed per day and any other physical activities they had engaged with.

4.10.1.1.3.3 Provide feedback on performance

At the start of each session participants were weighed and the research dietitians provided participants with a record of their body weight.

4.10.1.1.3.4 Relapse prevention/ coping planning

Participants were prepared to deal with small lapses such as increases in weight gain throughout the intervention as and when the research dietitians felt appropriate. Coping strategies were rehearsed to prepare the participant to deal with uncertain situations such as eating out and when faced with unfamiliar foods. In addition, session eight devoted a focus to relapse prevention of weight gain.

4.10.1.1.3.5 Barrier identification/ problem solving

Due to the one to one interaction with the research dietitians in the TAKE 5 intervention, this allowed exploration of the participants' individual context and environment. Any issues that prevented the participant from eating healthily or participating in physical activity were attempted to be resolved such as, engaging in physical activity due to difficulty accessing physical activity facilities. A solution provided was examples of lifestyle physical activity that can be conducted in the participant's home environment.

4.10.1.1.3.6 Stress management

At each session participant's dietary intake and physical activity were reviewed. At this point cues, internal or external were identified that positively or negatively influenced the participant's behaviour. Any positive cues were encouraged and negative cues discussed to find strategies to overcome these. For example, avoiding cues that would facilitate over-eating such as watching television and participating in sedentary behaviour.

4.10.1.1.3.7 Prompt reward contingent on effort or progress towards behaviour

Motivation was achieved through reinforcement of the diet and physical activity messages, and encouragement when a participant achieved a lifestyle goal or weight loss.

Table 4.1. TAKE 5 key themes for weight loss

	Theme	Sub-theme
Session 1	Benefits of losing weight and motivation towards a healthy lifestyle	Introduction to TAKE 5 booklets
		Introduction to food groups that make up healthy balanced diet
		Set first weight loss goal
Session 2	Introduction to individualised energy deficit diet and the importance of physical activity	Food portions
		Benefits and ways to being active
Session 3	Principles of healthy eating and improving physical activity levels	Taking control of diet
		Meals, snacks and fluid
		Introduction to physical activity diaries and pedometer
Session 4	Healthy ways to cook and healthy shopping lists	Menu planning
		Emotions and overeating
Session 5	Changing behaviour and stopping “bad habits”	Disadvantages of eating out and take-aways
Session 6	Coping with cravings and evaluating knowledge of physical activity	Techniques to help with cravings
		Physical activity quiz
Session 7	Motivation to being active	New ways to motivate physical activity
		Diet myths
Session 8	Relapse prevention	Lapses and ways to prevent them
		Coping with setbacks
		Getting support from others
Session 9	Review	Evaluate success in the programme
		Review healthy balanced diet and physical activity

4.10.1.2 Phase 2: Weight maintenance

4.10.1.2.1 Diet

Dietary intake for the weight maintenance phase was modified based on the six month weight loss during the weight loss phase. If participants had lost a clinical weight loss of 5% of initial body weight, they were offered a personalised energy prescription diet to maintain their body weight. The diet followed the same dietary principles used in the weight loss phase, without an energy deficit of 600 kcal per day. It was aimed to ensure a eucaloric dietary prescription and intake. If participants did not achieve a weight loss of 5% they were offered the option of continuing on their current EDD for a three month period followed by three months of a eucaloric energy prescribed diet to maintain their body weight.

4.10.1.2.2 Physical activity

The importance of physical activity was highlighted in the maintenance phase as it plays an important role in sustaining any reductions in body weight (Catenacci & Wyatt, 2007; SIGN 2010; NICE 2014). Individuals were encouraged to build on the levels of physical activity they achieved in phase one and continued to aim to meet clinical recommendations.

4.10.1.2.3 Behaviour change techniques

To maintain body weight loss participants were encouraged with support from carers where appropriate to maintain the healthy lifestyle habits from phase one. Behavioural strategies used in the weight loss phase were continued to be used flexibly. Specific approaches, in particular, relapse prevention/ coping planning and barrier identification/ problem solving were used to prevent large fluctuations in increased body weight and a negating of any benefits of the weight lost from baseline. In addition to self-monitoring of key lifestyle behaviours of food intake and habitual physical activity, participants were encouraged to self-monitor their body weight as this has been shown to help with weight maintenance (Wing & Phelan, 2005) and also aimed to help to imbed this as part of their routine and facilitate weight maintenance after the intervention has finished.

Table 4.2. TAKE 5 key themes for weight maintenance intervention

	Theme	Sub-theme
Session 1	Weight maintenance and new individualised maintenance dietary plan	Importance of not regaining the weight loss
Session 2	Importance of being active and adopting regular eating patterns	New diet plan Meal planning Maintaining motivation for physical activity and new options to be active
Session 3	Regular self-monitoring	Importance of food diaries and monitoring physical activity (e.g. step counts)
Session 4	Overview of barriers to healthy eating and physical activity	Introduction to self-weighing Strategies to choose healthy meal options and saying no to unhealthy food Finding time to be active
Session 5	Snacking, lapses, eating out/social activities	Healthy snack options Not returning to bad / old habits
Session 6	Healthy menu plan and review of principles of weight maintenance	Healthy menu choices from restaurants Overview of programme Healthy meal plan for the future Importance of regular self-monitoring of body weight

4.10.1.2 TAKE 5 resources

The TAKE 5 intervention included four information booklets, specifically designed to support adults with intellectual disabilities to lose weight with support from their carers. The acceptability and utility of the booklets was investigated in the qualitative study with family and paid carers (Spanos *et al.*, 2013b) and found to be a useful source of information and suitable to the developmental needs of adults with intellectual disabilities. The use of images was highly regarded by carers who reported that all adults with intellectual disabilities could engage with the books irrespective of their ability to read. Further details on the title and aim of the booklets have been described below:

Booklet 1: Eat well- Feel well: The aim of the booklet was to provide basic information regarding healthy eating based on the “Eat Well” plate (FSA, 2009).

Booklet 2: You can do it: The aim of the booklet, accompanied by a DVD, aimed to motivate participants to improve their physical activity

Booklet 3: How to help someone lose weight: The aim of the booklet was to motivate the carers to support participants who were attempting to lose weight

Booklet 4: Get help with losing weight: The aim of the booklet was to introduce the importance of losing weight and the need of involving other people in this difficult process

Additional resources included for the TAKE 5 intervention sessions were:

- Food diaries – based on the *Eatwell* plate
- Physical activity diaries
- Hand-outs for each session

4.11 WWToo comparator intervention

WWToo was developed by a partnership group of health professionals, NHS Dietitians, Learning Disabilities Nursing, and Glasgow Council (Health Improvement and Glasgow Life). The aim of the intervention was to provide information and support on how to lose weight and adopt a healthier lifestyle. WWToo was developed from the original mainstream Waist Winners weight management programme designed to be used in adults. The content and resources was adapted to a more accessible format specifically for adults with intellectual disabilities (Jones *et al.*, 2015).

WWToo was originally developed and delivered as a community group intervention with eight, one hour sessions delivered over seven weeks. A retrospective evaluation of the WWToo reported change in body weight post intervention at seven weeks, and 13 weeks (follow up) from baseline. Participants significantly decreased body weight -1.67 kg (95% CI -2.65 kg to -0.69 kg; $p = 0.002$) and -2.48 kg (95% CI -4.70 kg to -0.25 kg; $p = 0.032$), respectively. Five participants (36%) out of the 29 participants achieved a clinically important weight loss at the 13 week follow up appointment. Significant reductions in the health risk factors BMI and waist circumference were also illustrated at follow up time points (waist circumference was only measured at seven weeks). Furthermore, investigation into process measures demonstrated that the intervention was found to be acceptable to adults with intellectual disabilities and their carers.

For the purpose of this research study the delivery was modified to an individualised intervention, delivered on a one-to-one basis. Participants in this comparator intervention received the same number of sessions as participants in the TAKE 5 intervention. To retain participants to the study for the same duration period as those allocated to TAKE 5, a weight maintenance phase for WWToo was developed.

4.11.1 WWToo intervention components

4.11.1.2 Phase 1: Weight loss

4.11.1.2.1 Diet

The dietary component to the intervention focused on a health education approach. This was based on the principles of a health balanced diet based on the *Eatwell* plate (FSA, 2009). Food and drink was categorised as ‘healthy’ such as fruit and vegetables, ‘unhealthy’ such as food high in fat and sugar and other ‘healthy’ foods such as starchy foods and dairy products but to be had in portion controlled amounts. To facilitate understanding of categorisation of ‘healthy’ and ‘unhealthy’ foods, foods were coded by three colours: Red = unhealthy, Green = healthy and Orange = healthy but limit intake of these foods. These food sheets were also used to help self-monitor food intake between sessions. An overview of the themes of the intervention session is illustrated in Table 4.3.

4.11.1.2.2 Physical activity

Physical activity was discussed based on current public health recommendations on increasing activity and reducing sedentary behaviour (NICE 2014). Session seven was devoted to education on the benefits of physical activity and at each session participants reviewed their current participation in physical activity and set new goals to increase physical activity levels.

4.11.1.2.2 Behaviour change techniques

The main focus of the intervention session was to provide educational information on healthy lifestyle behaviours. This was achieved by the inclusion of behaviour change techniques. The primary techniques included in each session were goal setting, self-monitoring and feedback on performance. A full list of the behaviour change techniques used is presented in Figure 4.3.

4.11.1.2.2.1 Goal setting

Participants set either a physical activity related goal or a dietary goal each week. These were based on the SMART principles (Doran, 1981).

4.11.1.2.2.2 Self-monitoring

Self-monitoring of food intake was encouraged between sessions participants recorded their food intake by marking a green, orange or red dot on the food sheets to indicate the unhealthy and healthy foods consumed.

4.11.1.2.2.3 Provide feedback on performance

At the start of each session participants were weighed and the research dietitians provided participants with a record of their body weight. The research dietitian also reviewed participant's food charts and provided information about their food intakes and whether or not they had achieved a healthy or unhealthy diet. In both cases approaches to improve quality and quantity of the participants overall dietary intake was provided.

4.11.1.3 Phase 2: Weight maintenance

After the initial nine sessions focussing on weight loss, participants met with the research dietitians a further six times. Each meeting was a session and it focussed on assisting the retention of knowledge delivered in the first phase of the intervention. Support was also provided for participants to continue to monitor their diet, physical activity and body weight. At each session, an opportunity for questions related to maintaining body weight was offered and any queries addressed.

Table 4.3. WWT00 key themes for weight management

	Theme	Sub-theme
Session 1	Introduction to health and weight	Food Groups – Good and bad food Energy balance Food diaries
Session 2	Planning Meals and importance of physical activity	Food groups Portion sizes Healthy/unhealthy snacks
Session 3	Food labelling and fats	Choosing healthy food options when shopping Identifying high fat food and healthier alternatives
Session 4	Food labelling salt and sugar	Recognising supermarkets healthy labelling range of foods Identifying high sugar foods and healthier alternatives
Session 5	Shopping, budgeting, snacks, eating out and take-aways	Healthy food options in restaurants and take-aways
Session 6	Alcohol and other drinks	Healthy and unhealthy drink options Importance of drink enough Effects of alcohol on weight gain
Session 7	Benefits of exercise	Different types of physical activity Incorporate physical activity in daily routine
Session 8	Review	Review healthy food and physical activity
Session 9	*Evaluate what has been learned	Evaluate knowledge Questions and feedback
Weight Maintenance	Weight maintenance question and answer session	Address any questions regarding diet and physical activity

*Additional session to maintain the same number of sessions as TAKE 5

4.11.1.4 WWToo resources

The WWToo intervention was centred around diet sheets which illustrated how foods were split into red (unhealthy), yellow (healthy in moderation) and green (healthy) groups. These resources were piloted in the retrospective evaluation by Jones *et al.*, (2015). Process evaluation with carers revealed that these diet sheets were popular and acted as a good visual aid.

4.11.2 TAKE 5 vs WWToo intervention components

Guidelines set out by the MRC for developing and evaluating complex interventions highlight it is important to establish the effective or ineffective components of an intervention (MRC, 2008). The two multi-component interventions under investigation are both made up of a diet, physical activity and behaviour change component. However, the distinct difference between the two interventions was based on the inclusion of the quantitative EDD of the TAKE 5 intervention. Based on the principles of energy balance this aimed to facilitate a 0.5-1 kg per week weight loss (if full compliance was achieved). Whereas, the diet component in the WWToo intervention is dietary advice, compliance with which cannot be quantified. The physical activity component of the TAKE 5 intervention is more comprehensive in that it included the use of pedometers and finally the behaviour change techniques utilised in the TAKE 5 intervention to facilitate weight loss through changes in diet and physical activity are more numerous and used more flexibly to meet the individual participants needs. Comparison of the two interventions has been illustrated in Figure 3.3.

TAKE 5	Quantitative Dietary Advice	WWT00	Non-quantitative Dietary Advice
	<p>EDD of 600 kcal/day</p> <p>Individually specified number of food portions</p>		<p>Information on healthy and unhealthy food choices</p>
	<p>Physical activity</p> <p>Physical activity goals set at every session</p> <p>Aim to gradually increase lifestyle physical activity and reduce sedentary behaviour</p> <p>Pedometers encourage walking</p>		<p>Physical activity</p> <p>Physical activity goals set at every session</p> <p>Aim to gradually increase lifestyle physical activity and reduce sedentary behaviour</p>
	<p>Behaviour change techniques</p> <ol style="list-style-type: none"> 1. Provide information on consequences of behaviour in <i>general</i> 2. Provide information on consequences of behaviour <i>to the individual</i> 5. Goal setting (behaviour) 6. Goal setting (outcome) 8. Barrier identification/problem solving 9. Set graded tasks 10. Prompt review of behavioural goals 11. Prompt review of outcome goals 13. Provide rewards contingent on successful behaviour 15. Prompting generalisation of a target behaviour 16. Prompt self-monitoring of behaviour 17. Prompt self-monitoring of behavioural outcome 18. Prompting focus on past success 19. Provide feedback on performance 20. Provide information on <i>where and when</i> to perform behaviour 21. Provide instruction on how to perform the behaviour 23. Teach to use prompts/cues 27. Use of follow-up prompts 29. Plan social support/social change 35. Relapse prevention/coping planning 36. Stress management/emotional control training 38. Time management 39. General communication skills training 		<p>Behaviour change techniques</p> <ol style="list-style-type: none"> 1. Provide information on consequences of behaviour in <i>general</i> 5. Goal setting (behaviour) 10. Prompt review of behavioural goals 15. Prompting generalisation of a target behaviour 17. Prompt self-monitoring of behavioural outcome 18. Prompting focus on past success 19. Provide feedback on performance 20. Provide information on <i>where and when</i> to perform behaviour 22. Model/demonstrate the behaviour 26. Prompt practice 27. Use of follow-up prompts

Figure 4.3. Comparison of intervention components between groups. The components consistent across both interventions are colour coded in blue.

4.12 Outcomes

4.12.1 Primary outcome

The primary outcome measure was the difference in body weight at twelve months from baseline between the two treatment groups.

4.12.2 Secondary outcomes

Secondary outcomes include:

- Weight loss of five percent or more of initial body weight,
- Change in BMI, waist circumference and percentage body fat.
- Mean percentage time per day spent engaged in moderate-vigorous intensity physical activity; light intensity physical activity and engagement in sedentary behaviour.
- Change in health related Quality of Life.

Change from baseline at the end of the weight loss intervention period (6 months) and end the intervention (12 months) will be analysed for each secondary outcome.

4.13 Outcome measurements

4.13.1 Demographic and health questionnaires

Data on the following demographics and health were collected at baseline on the clinical reporting forms for the study.

- Demographics [age (years), sex, marital status, ethnicity, Scottish Index of Multiple Deprivation (SIMD) decile and social support (Scottish Government, 2012)]
- Physical and mental health questionnaires (Epilepsy, vision, hearing, mental health and problem behaviours).

4.13.2 Level of intellectual disabilities

The level of intellectual disabilities of participants, in keeping with the ICD-10 definition, was calculated from the ability and development questionnaire . The questionnaire measures development level through assessing participants' ability and need for support in five key areas of functioning: eating and drinking, intimate care, personal safety, communication and decision making. A total score between 5 and 25 was obtained from the sum of the five

individual questions, which was then used to categorise level of intellectual disabilities, based on the following scores:

- Mild: 5-8
- Moderate: 9-13
- Severe: 14-19
- Profound: 20-25

Total scores assessed by the ability and development questionnaire have shown to be highly associated with the Vineland's Adaptive Behaviour Scale a validated assessment of functioning and ability level (Sparrow, Balla, & Cicchetti, 1984) and the questionnaire has been previously used as a measure of level of intellectual disabilities (Cooper, 1997; Melville *et al.*, 2008).

4.13.3 Anthropometric outcomes

The accurate assessment of body composition is necessary to provide valid results on the efficacy of the weight management interventions. The criterion methods for measuring body composition are considered to be complex. These include lab based methodologies such as doubly labelled water and dual energy X-ray absorptiometry (DEXA) (Stewart, Bramley, Heighton, Green, Horsman, Losowsky, & Smith, 1993; Lean Han & Deurenberg, 1996). These methodologies are also considered to be invasive and not commonly used in clinical studies. Other measures of body composition are inherently subject to methodological limitations and error due to the indirect nature however often offer a more practical and less time intensive approach (Lee & Gallagher, 2008). Anthropometric measurements provide an alternative methodology which are more routinely used in clinical practice. The reliability of anthropometric measurements is dependent on the standardisation of anatomical sites on the body and also the skill level of the researcher undertaking the measurements (Wang Thornton Kolesnik & Pierson, 2000). To ensure accuracy and reliability of measurements the researcher measuring outcomes undertook training to level one of the international society of anthropometry and kinesiology (ISAK) (Marfell-Jones, Olds, Stewart, & Carter, 2006).

Measurements of participants' weight, height, waist circumference and triceps skinfold thickness measured were conducted. Measurements were made with the participant wearing light clothes without shoes. All measurements were made in duplicate and the final value

calculated as the mean of the two measurements. Weight in kilograms (kg), was measured to the nearest 100 grams (g), using SECA877 scales (SE approval class III; SEA Germany). Height in meters (m) was measured to the nearest 1mm (mm) using the SECA Leicester stadiometer (SECA, Germany).

BMI has been utilised as an indicator of health (Sohler, Lubetkin, Levy, Soghomonian, & Rimmerman, 2009) and previously in randomised trials of weight management interventions in adults with intellectual disabilities (Bergström *et al.*, 2013; Pett *et al.*, 2013). BMI is widely used to assess weight status and categorise participants as underweight, normal weight, overweight and obese (WHO, 2004). BMI was calculated using the following equation: $BMI = \text{weight}/\text{height}^2$ (kg/m²). However, BMI is limited as it cannot distinguish between fat and fat free mass (Romero-Corral *et al.*, 2008). Therefore, the combination of other anthropometric measurements girths and percentage body fat can provide additional information on body composition changes. Another commonly used anthropometric technique recommended as a measure of health and weight status is waist circumference (WHO, 2004). Waist circumference is a measure of the central abdominal fatness and may be particularly useful as a measure in adults with Down syndrome who have been reported to have large amounts of central adiposity (González-Agüero, Vicente-Rodríguez, Ara, Moreno, & Casajús, 2011).

Waist circumference was measured to the nearest 0.5 centimetre (cm) at the midpoint between the iliac crest and the lowest rib, in full expiration whilst the participant is standing (WHO, 2008). This deviated from the ISAK procedure on assessment of waist circumference, due to difficulties in finding the midpoint on the natural contours of the body in adults with obesity and to allow comparison with previous research utilising the method by the WHO.

Skinfold measurements can be used to calculate percentage body fat which has been shown to be a valid estimate of body composition in adults with obesity in the general population (Lean *et al.*, 1996). Percentage body fat was calculated using the triceps skinfold thickness (mm) measured to the nearest 1 mm, waist circumference (cm) and age (years) of the participant. Separate regression equations for male and female participants, developed by Lean *et al.* (1996) were used to predict body density and percentage body fat.

Men

- Body density = $1.1554 - (0.000761 \times \text{waist}) - (0.00170 \times \text{triceps}) - (0.000532 \times \text{age})$
- Percentage body fat = $(0.353 \times \text{waist}) + (0.756 \times \text{triceps}) + (0.235 \times \text{age}) - 26.4$

Women

- Body density = $1.1062 - (0.000482 \times \text{waist}) - (0.00140 \times \text{triceps}) - (0.000453 \times \text{age})$
- Percentage body fat = $(0.232 \times \text{waist}) + (0.657 \times \text{triceps}) + (0.215 \times \text{age}) - 5.5$

4.13.4 Physical activity outcome

Physical activity was objectively measured by accelerometers, worn by participants prior to the start of the intervention and at the six and 12 month data collection time points. Accelerometers used were small devices which measured the acceleration of the body during movement (Chen & Bassett, 2005). These accelerations are then converted into activity counts which are interpreted by cut points or equations to provide information on the frequency, intensity and duration of physical activity (Hinckson & Curtis, 2013). Accelerometers are considered the gold standard methodology for measuring habitual physical activity (Lee *et al.*, 2015) and have been used previously in studies involving adults with intellectual disabilities, further illustrating them to be a reliable measure of levels of physical activity (Temple *et al.*, 2000; Temple & Walkley 2003).

Participants were invited to wear the Actigraph GT3X+ (Manufacturing Technology inc., Florida), worn at the hip, attached to a belt worn round the waist and worn for a seven day period at each time point. Participants were instructed to wear the Actigraph during all waking hours; except when showering, bathing or swimming.

In order to ensure the validity of the accelerometer data, the minimum data requirement was set at six hours of data, on at least three days from seven (Penpraze, Reilly, MacLean, Montgomery, Kelly, Paton, & Grant, 2006). If this requirement was not met, the accelerometer data were considered invalid and excluded in the analysis. The accelerometers were set to record activity over 15 second intervals (epochs). The activity counts for four consecutive epochs summed to give activity counts per minute (cpm). This was categorised as four levels of activity intensity based on recommendations from previous studies (Atkin *et al.*, 2012):

- sedentary behaviour 0 – 99 cpm
- light intensity activity 100 – 1951 cpm

- moderate intensity activity 1952 – 5724 cpm
- vigorous intensity activity greater than 5725 cpm.

The accelerometer data were used to calculate the mean time (minutes), and the percentage time per day, spent in each level of activity.

4.13.5 Health related quality of life

The EQ-5D questionnaire was used to measure health related quality of life (Brooks, 1996). The EQ-5D consists of two parts the EQ-5D descriptive systems and the visual analogue scale (EQ VAS). The descriptive system was based on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants were required to rate each domain based on three levels: no problems, some problems or extreme problems. The EQ VAS requires participants to self-report their health on a vertical scale ranging from ‘worst imaginable health state’ to ‘best imaginable health state’. The EQ-5D has been shown to be reliable, valid and sensitive to change in adults with obesity (Sach, Barton, Doherty, Muir, Jenkinson, & Avery, 2007).

Due to the difficulties adults with intellectual disabilities are reported to experience in terms of communication and level of understanding the youth version of the EQ-5D was used as it is aimed at young people aged seven years and older, which corresponded approximately to the developmental level of adults with mild/ moderate intellectual disabilities.

Carers were also asked to rate their opinion of the participant’s health on the five domains of the EQ-5D and the EQ VAS. This was then compared with the responses of participants classified as having mild intellectual disabilities and the level of agreement between the two responses assessed.

4.13.6 Process evaluation measures

There are a number of frameworks and methodological approaches to conducting process evaluations. There is overlap between process evaluation frameworks, for example, the measure of fidelity or implementation is commonly measured (Moore *et al.*, 2015). Other frameworks recommended by the MRC guidelines exist, including the RE-AIM framework (Glasgow *et al.*, 1999). However, the aim of this framework was to support translation of research into practice (Glasgow *et al.*, 1999) which is not consistent with the aim of this

study at this stage of the research process. Process evaluation components were guided by the framework of Linnan & Steckler., (2002) as this has been shown to be the most comprehensive process evaluation including seven key process domains and is particularly relevant to measuring the feasibility and fidelity of complex interventions. Research questions were developed in accordance with each of the seven key process evaluation components: context, reach, dose delivered, dose received, fidelity, implementation and recruitment. As this process evaluation was designed subsequent to the start of the intervention, data collection methods were selected on their feasibility within the scope of the trial. Both qualitative and quantitative methods are used in combination to provide a detailed insight into the above processes (Moore *et al.*, 2015). The key components and the data collection methods used for analysis discussed in more detail below. There is some similarity and overlap of the definitions of the process evaluation components, in particular the reach, dose delivered and fidelity.

4.13.6.1 Context

Context related to environmental factors that may have affected the implementation of the intervention. It also incorporates contextual aspects which may have influenced study outcomes such as the setting in which the intervention was delivered. To explore this domain, information on participants' geographical location and level of social deprivation was obtained from the case reporting forms. A record of the location of the delivery of the sessions was also recorded from the therapists' notes. Furthermore, investigation into contextual barriers was explored in the qualitative interviews with the research dietitians.

4.13.6.2 Reach

Reach is a measure of the extent of which the intended population, adults with intellectual disabilities and obesity participate in the intervention. This is measured by attendance at the intervention based on the research dietitians' session attendance records for participants. Barriers to participants participating in the intervention were also explored in the qualitative interviews with the research dietitians.

4.13.6.3 Fidelity

Fidelity is defined as the extent to which the intervention was implemented by the research dietitians as intended. Information on the research dietitians delivering the information in

terms of qualifications, relevant experience and training needs was captured by the qualitative interviews.

Fidelity of the intervention was explored by post-evaluation of the intervention session manuals. The research dietitians were directed to at the end of each session complete a checklist of the components delivered in each session. They also noted any deviation from the manual for example if content was left out or if new information was provided with rationale. This method is reported as a more feasible approach to monitoring fidelity (Linnan & Steckler, 2002) and was selected over the criterion method of direct observation (Hill, Maucione, & Hood, 2007) as it was felt that having additional unknown researchers would negatively affect the relationship between the participant and research dietitians which is fundamental to the delivery of the intervention. Furthermore, in the qualitative interviews, adaptations to the intervention and challenges faced with implementation the intervention as planned were explored.

4.13.6.4 Dose delivered

Dose delivered is the number of intended sessions that were delivered to the participants and the number of each intervention component delivered. This is a measure of the research dietitians' efforts to deliver the intervention. Data were obtained from the attendance records and checklists.

4.13.6.5 Dose received

Dose delivered is the extent to which participants engage with the content of the intervention they received. This includes materials or resources and the extent to which they implement these as they are intended. This was explored in the qualitative interviews to assess if the content of the intervention and mode of delivery worked for this population group. As described above attendance records were obtained by the research dietitians. In addition, the research dietitians recorded clinical notes at the end of each session, detailing what parts of the session were well received and any difficulties experienced.

4.13.6.6 Implementation

Implementation represented a combination of the extent to which the intervention was delivered as intended (fidelity) and received by participants (dose received).

4.13.6.7 Recruitment

Recruitment related to the procedures and strategies used to approach and identify potential participants to enrol in the study. Recruitment strategies have been reported from a narrative perspective by the researcher (LH) from information provided through liaising with health professionals, community organisations and day centre staff during the multi-point recruitment strategy. Furthermore, information was collected through receipt of invitations to participate in the intervention. A record of participants was kept from each recruitment site. Information on retention rates was noted when participants dropped out from the intervention.

4.14 Data analysis

4.14.6 Quantitative data analysis

4.14.6.1 Analysis principles

The primary analysis in this thesis were conducted as a completers intention to treat (ITT) analysis and exploratory analysis was conducted as per-protocol analysis. ITT is considered the gold standard statistical approach in clinical trials (Gupta, 2011; Hollis & Campbell, 1999). ITT aimed to eliminate potential bias associated with drop outs, missing data or deviations from the initial sample size calculation. ITT analysis was defined as analysing participants according to initial randomisation, irrespective of what happened to the participant after this point, i.e., whether they complied with the intervention or dropped out from the study). There are several advantages to ITT as it aims to emulate the effects of treatments in the 'real world' (Gupta, 2011). Thus, it provides a more realistic estimate of the intervention effect as it allowed for dropouts and non-compliance of interventions which occurred in everyday life. Furthermore, ITT analysis, maintained the integrity of the randomisation process and thus the validity of the results. This allowed interpretation of any post-treatment differences between interventions to be attributed to the treatments and not due to differences in participant characteristics.

An additional analytic approach in clinical trials is per-protocol analysis. This can be defined as participants considered to have complied with the intervention protocol and further defined as having adhered to a specific dose of the intervention, i.e. attendance at 75% of intervention sessions. Participants were defined as completing the intervention if they attended 75% of the total sessions. This statistical approach can be used to further explore

the efficacy of the interventions, by examining the difference in treatment effects under conditions which participants fully adhered to the intervention. Descriptive statistics were used for participant demographics and all outcome measures. Results have been presented as means and SD for baseline continuous variables (Anthropometric outcomes, physical activity outcomes and health related quality of life) and frequencies and percentages (%) for categorical variables (Demographics, Ability and development, Health conditions).

Mixed linear models were used to examine the potential efficacy of primary and secondary outcomes. Mixed linear models were selected due to their capabilities over general linear models as mixed models may have accounted for correlated data or data with unequal variances which can arise from hierarchical data. For example, and relevant to this study mixed models can analyse data for individuals who have been selected from a cluster of participants.

To differentiate the proportion of the variance that is due to between cluster variation an interclass correlation (ICC) was calculated. The ICC was calculated as the proportion of total variance that is due to between cluster variation from the following equation:

$$\sigma b^2 / (\sigma b^2 + \sigma w^2)$$

Where σb^2 is the variance due to differences between clusters and σw^2 is the variance due to differences between individuals within clusters. An ICC of less than 5% indicates there is no meaningful difference between clusters (Tabecjnick & Fidell, 2007).

Analysis was conducted to assess normal distributions of the data. Each variable was assessed graphically using a histogram with normal distribution curves, boxplots and Q-Q residual plots. In addition to visual inspection of these plots for normal distribution, skewness and kurtosis were tested using z-scores with < 1.96 representing normally distributed data. In circumstances that data were considered not normally distributed, factors affecting this were explored. Outliers were identified by examining residual Q-Q plots. Data points classified as outliers were assessed for their potential to influence results and therefore study conclusions. Sensitivity analyses were conducted to compare results with and without outlier(s). Discrepancies between the two analyses are reported and discussed in chapters five and six. In addition to examining the data with and without outliers, in some cases transformation of the data were assessed using logarithmic and square root transformations and normality reassessed.

All statistical analyses were carried out in accordance with a pre-specified SAP. The objective of the SAP was to provide detailed analysis of each outcome; this is presented in Appendix vii. All statistical data were analysed using SPSS 21 IBM statistical package (SPSS IBM, New York, NY, USA).

4.14.6.2 Primary outcomes

A mixed effects model was used to determine the mean difference in weight loss at the end of the intervention period (~12 months) from baseline, between TAKE 5 and WWToo. The mixed effects model accounted for the effects of clustering of participants (stratified by level of intellectual disability, number of participants within a cluster and presence of Down syndrome) and was adjusted for baseline weight. Within group analysis was also investigated from the mixed models. The ICC, adjusted mean difference (95% confidence interval (CI) and p-value are reported.

4.14.6.3 Secondary outcomes

Continuous secondary outcomes were analysed and reported similarly as described above. A logistic regression model was fitted for the categorical outcome, weight loss of 5% or more of initial body weight taking account of clustering and baseline adjustments listed above.

4.14.6.4 Process outcomes

Descriptive statistics were used to assess process measures such as attendance to sessions for each treatment group. Independent sample t-tests were performed to determine if there were any differences between the treatment groups.

4.14.6.5 Serious adverse events

Serious adverse events (SAE) were defined as an adverse event (an injury or newly diagnosed health condition) that induced hospitalisation or prolonged hospitalisation, results in persistent/significant disability or incapacity or is life-threatening or fatal. SAE were recorded after baseline visits by the researcher at follow up visits. Incidence of SAE were recorded for each treatment group.

4.14.7 Qualitative data analysis

In addition to the quantitative data collection methods, qualitative interviews were conducted with the research dietitians. The interviews with the dietitians were conducted retrospectively on completion of delivery of the intervention sessions and 12 month data collection. The interviews were conducted by an independent researcher with experience in conducting qualitative research and not otherwise involved in the study. The main aim of the qualitative interviews was to elicit the research dietitian's views of the interventions, the practicalities of delivering the intervention and any challenges to implementing the intervention as intended. The interview consisted of semi-structured questions and is presented in appendix vii. The interviews were audio-recorded using Olympus DSS player 2300. The interviews lasted between 45 minutes and one hour. The interviews were transcribed and analysed guided by the thematic analysis framework by Braun & Clarke, (2006). This consists of an outline of the following six steps:

1. Familiarisation of transcribed data:

The researcher familiarised oneself with the data through repetition of reading the transcribed data and noting initial ideas that emerged.

2. Initial coding of data:

Initial coding of data, identifying relevant data extracts to support codes

3. Theme searches:

The data were grouped together into potential themes and sub-themes with supporting evidence.

4. Theme revisions

Themes were reviewed against codes and relevant themes were modelled in relation to each other in a thematic map.

5. Theme definitions

The specifics of each theme were defined, themes were discarded if no longer relevant in order to form a coherent collection of themes.

6. Final analysis:

Confirmation of data extracts were selected for evidence of themes. Reflection of the research question, analysis and coding of results.

Chapter 5: Results

5.1 Introduction

The primary aim of this study was to investigate the feasibility of a full-scale clinical trial of a multi-component weight management intervention (TAKE 5) in comparison to an active comparator intervention (WWToo). The main results from the completers ITT analysis and exploratory analysis (per-protocol) are presented in this thesis chapter.

5.2 Participant characteristics

Fifty adults (Mean age: 42 years; range: 18-71 years) with intellectual disabilities and obesity (Mean BMI: 40.7 kg/m², range 30.7-65.8 kg/m²) were randomised to the study. Participants' level of intellectual disabilities were mild (28.0 %), moderate (42.0 %), severe (22.0 % and profound (8.0 %). Eight participants had Down syndrome as their diagnosis of intellectual disabilities and two participants were diagnosed with Fragile X Syndrome.

Participants demographic and health characteristics are presented in Table 5.1, by intervention group and overall. In addition to obesity, participants were reported to have other chronic conditions and health issues including type II diabetes; high blood pressure; asthma; rheumatoid arthritis; underactive thyroid and depression.

Table 5.1. Baseline characteristics of participants by randomised group and overall (ITT).

Characteristic	TAKE 5 (n = 26)	WWTOO (n = 24)	Total (n = 50)
Age (years) Mean (SD)	40.6 (15.0)	43.6 (14.0)	42.0 (14.5)
Gender n (%)			
Males	8 (30.8)	10 (41.7)	18 (36.0)
Females	18 (69.2)	14 (58.3)	32 (64.0)
Ethnicity n (%)			
Caucasian	26 (100.0)	22 (91.7)	48 (96.0)
Other Asian Background	0 (0.0)	2 (8.3)	2 (4.0)
Marital Status n (%)			
Married/Live with a	1 (3.8)	0 (0.0)	1 (2.0)
Separated/Divorced	1 (3.8)	0 (0.0)	1 (2.0)
Single	24 (92.3)	24 (100.0)	48 (96.0)
SIMD (% living in quintiles)			
1 (most deprived)	12 (46.2)	9 (37.5)	21 (42.0)
2	6 (23.1)	5 (20.8)	11 (22.0)
3	2 (7.7)	4 (16.7)	6 (12.0)
4	5 (19.2)	5 (20.8)	10 (20.0)
5 (least deprived)	1 (3.8)	1 (4.2)	2 (4.0)
Social Support n (%)			
Lives Independently	10 (28.4)	8 (33.3)	18 (36.0)
Family Carer	8 (30.8)	8 (33.3)	16 (32.0)
Paid Carer		8 (33.3)	16 (32.0)
Level of Intellectual Disabilities n (%)			
Mild	8 (30.8)	6 (25.0)	14 (8.0)
Moderate	11 (42.3)	10 (41.7)	21 (42.0)
Severe	4 (15.4)	7 (29.2)	11 (22.0)
Profound	3 (11.5)	1 (4.2)	4 (8.0)
Down Syndrome n (%)	4 (15.4)	4 (16.7)	8 (16.0)
Health n (%)			
Epilepsy, Seizures or Fits	6 (23.1)	5 (20.8)	11 (22.0)
Vision impairment	16 (61.5)	9 (37.5)	25 (50.0)
Hearing Impairment	6 (23.1%)	3 (12.5%)	9 (18.0%)
Mental Health Problems	6 (23.1)	3 (12.5)	9 (18.0)
Problem Behaviour	10 (38.5)	9 (37.5)	19 (38.0)
High Blood Pressure	12 (46.2)	11 (45.8)	23 (46.0)
Type II Diabetes	1 (3.8%)	3 (12.5%)	4 (8.0%)
EQ-5D index	0.8 (0.3)	0.7 (0.3)	0.7 (0.3)

Values represent number (%), means (SD). SIMD; Scottish Index of Multiple Deprivation.

5.3 Feasibility outcomes

5.3.1 Recruitment

Recruitment of participants to the study was conducted between February to October 2014. A total of 76 participants returned an information slip expressing their interest in finding out more information about the study. Six individuals returned the slip indicating they did not want to find out further information. No contact with these individuals was made by the researcher. Of the 76 individuals, 69 were assessed for their eligibility to participate. Four participants expressed interest after the target sample size was reached and therefore were not assessed for eligibility and three participants were excluded as they were identified as a cluster after a participant had been randomised and therefore their participation would have been exempt from inclusion in the analysis. Of the individuals screened, eight did not meet the inclusion criteria, three declined to participate and eight reported other reasons such as commitment issues to the project and illness that prevented them from participating in the study. Fifty participants in total of the 69 individuals screened met the eligibility criteria, provided informed consent, baseline measures and were enrolled in the study. Study screening, recruitment and retention is illustrated in Figure 5.1. Participants were recruited using a multi-point recruitment strategy from a primary health care service, the GCWMS (n = 4); specialist intellectual disabilities health services across GG&C (n = 24); community provider organisation (n = 4) and day centres for adults with intellectual disabilities (n = 15). Participants were also identified as a cluster upon a screening visit for another participant involved in the study (n = 3). There were five clusters in total, with two participants in each (two cluster of siblings, two clusters of participants living in the same household, and one cluster of individuals with intellectual disabilities supported by the same carer; SAP Table 1.5). The recruited of 50 participants is short of the projected sample size calculated of 66 participants. The recruitment period was not extended to achieve the full sample size due to the limited demand capacity of the research dietitians in terms of scheduling participant appointments. Further time restrictions to the recruitment period were introduced due to the time constraints of the author of this thesis PhD restrictions, in completing the study within a set timeframe (4 years including recruitment, data collection, interpretation, and write up of results).

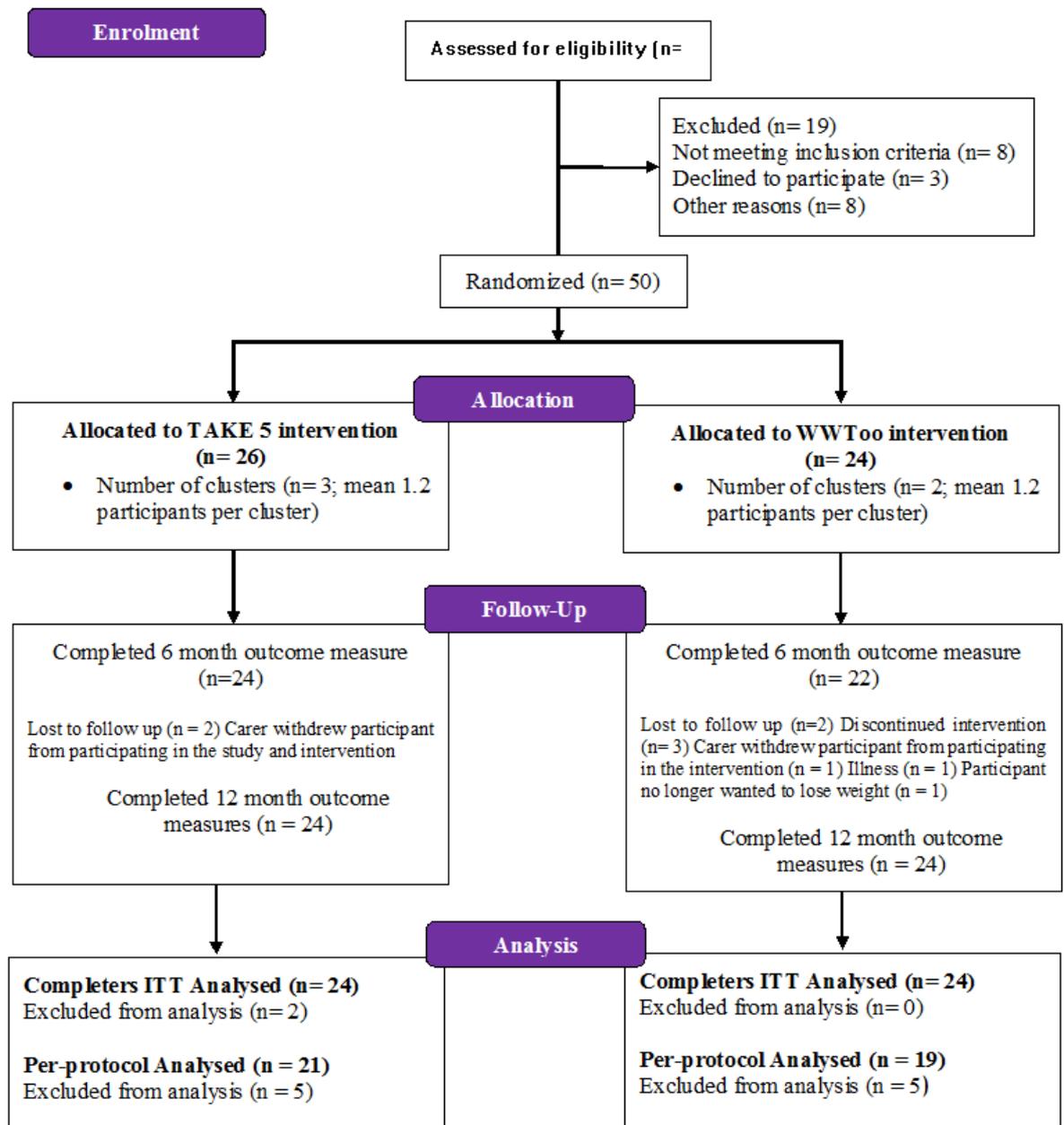


Figure 5.1. Study screening, recruitment and retention.

5.3.2 Retention

Retention to the 12 month interventions was high with 45 (90%) out of the 50 participants randomised to the study, completing both interventions. During the study period only five (10%) participants withdrew from taking part in the interventions. All five participants withdrew before the six month follow up due to the following reasons, one did not want to lose weight, one withdrew due to illness and three participants were withdrawn at the discretion of their carers. Of the five participants who dropped out of the interventions (TAKE 5 n = 2; WWToo n = 3), only two were considered lost to follow up and outcome data were not available for these participants at six and 12 months. In the WWToo intervention, two participants were lost to follow up at six months and outcome assessments were not taken due to concerns over ethical considerations in measuring outcomes if the participants were no longer involved in the intervention. This was clarified with ethics committee and protocol of consent and participants who were happy to continue to take part in the study outcomes were assessed at 12 months. Primary outcome measurements were collected for 46 participants (92%) at six months and for 48 participants (96%) at 12 months.

5.3.3 Adherence

Overall adherence to intervention sessions was high in both interventions in those who had not withdrawn, with session adherence $\geq 75\%$ in both interventions (range: 75% - 100%). Attendance at each intervention sessions is presented in the SAP Table 1.3 (Appendix vii). Attendance rate decreased slightly in the first weight maintenance session after the weight loss phase (82.2%) overall, and increased to 93.3% at the end of the intervention. The average attendance rate was 86.4% in both intervention groups. Excluding those who dropped out of the intervention 26.7% attended all intervention sessions, 31.1% attended 90% and 80% of the sessions, with 2.2% attending 70% of the intervention. The lowest attendance recorded was an attendance rate of 60% with 8.9% of the participants attending 9 out of the 15 sessions. Session attendance by intervention group is illustrated in Table 5.2.

Table 5.2. Number of participants attending all sessions, by randomized group and overall.

Percentage attendance at all appointments	TAKE 5 (n=24)	WWTOO (n=21)	TOTAL (n=45)
100%	7 (29.1%)	5 (23.8%)	12 (26.7%)
90%	6 (25.0%)	8 (38.1%)	14 (31.1%)
80%	8 (33.3%)	6 (28.6%)	14 (31.1%)
70%	1 (4.2%)	0 (0.0%)	1 (2.2%)
60%	2 (8.3%)	2 (9.5%)	4 (8.9%)

Note: Percentage of attendance of participants excluding participants who dropped out of the intervention.

Participants were defined as completing the intervention if they attended 75% of the total. Ten (20%) participants did not meet this definition and were considered non-completers. The baseline characteristics of participants defined as completers and non-completers by treatment group are presented in the SAP Tables 2.1.1-2.1.2. (appendix vii). There was no significant difference in continuous outcomes (age or anthropometric characteristics) between the two groups (independent sample t-tests; $p > 0.05$). Baseline categorical outcomes (gender, level of intellectual disabilities, ethnicity, marital status, SIMD and level of social support) were also not significantly different between completers and non-completers (Fisher's exact test; $p > 0.05$).

5.4 Potential Efficacy outcomes (ITT)

The baseline outcome measurements, anthropometry and physical activity, are illustrated in Tables 5.3-5.4. Health related quality of life, as measured by the EQ-5D index are presented in Table 5.1.

Table 5.3. Baseline anthropometric outcomes by group and overall (ITT).

Anthropometric Outcomes	TAKE 5 (n = 26)	WWTOO (n = 24)	Total (n = 50)
Weight (kg)	102.3 (25.4)	104.1 (28.9)	103.1 (26.9)
Height (cm)	158.4 (10.6)	158.5 (13.7)	158.4 (12.1)
BMI (kg/m ²)	40.2 (6.8)	41.2 (8.1)	40.7 (7.4)
Waist Circumference (cm)*	121.9 (14.0)	122.2 (16.1)	122.0 (14.9)
Percentage Body Fat (%)*	49.3 (9.1)	51.7 (8.5)	50.3 (8.4)

Values represent mean (SD) BMI; Body Mass Index.

*Waist circumference TAKE 5 n = 24 WWTOO n = 23 Total n = 47

*Percentage Body Fat TAKE 5 n = 24 WWTOO n = 19 Total n = 43

Table 5.4. Baseline objectively measured physical activity by group and overall (ITT)

Physical activity/Sedentary behaviour outcome	TAKE 5 (n = 25)	WWTOO (n = 22)	Total (n = 47)
Average Wear Time (minutes/day)	677.9 (130.9)	713.5 (208.0)	694.5 (170.3)
CPM	276.9 (122.9)	292.0 (155.7)	284.0 (137.9)
Step Count (per day)	4880 (2185)	4875 (2315)	4877 (2222)
Light PA (minutes/day)	147.9 (47.0)	159.6 (77.2)	153.4 (62.5)
Light PA (% time spent/day)	21.8 (6.2)	22.3 (8.0)	22.1 (7.0)
MVPA (minutes/day)	28.8 (16.9)	31.6 (22.5)	30.1 (19.6)
MVPA (% time spent/day)	4.5 (2.7)	4.7 (3.8)	4.6 (3.2)
Total PA (minutes/day)	176.8 (53.3)	191.2 (85.1)	183.5 (69.6)
Total PA (% time spent/day)	26.3 (7.6)	27.0 (9.7)	26.7 (8.6)
Sedentary Behaviour (minutes/day)	501.1 (125.9)	522.3 (165.3)	511.0 (144.4)
Sedentary Behaviour (% time spent/day)	73.7 (7.6)	73.0 (9.7)	73.3 (8.6)

Values represent means (SD) CPM; Counts per minute, MVPA; Moderate to vigorous physical activity, PA; Physical activity

The primary efficacy analysis was an ITT analysis conducted using a mixed model, adjusting for baseline variables and accounting for clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). This was a completers ITT analysis (only participants providing outcome data at follow up assessments were included) as no missing data were imputed in any of the analysis. Exploratory analysis was also conducted to further investigate the potential efficacy of the weight management interventions when full compliance is achieved. This was completed for all outcomes. The results for the participants who completed the intervention sessions (per-protocol analysis: attendance at greater than 75% of sessions) are presented in tables alongside the main analysis to facilitate comparison. The results are presented as within and between group mean change in outcome variables with 95% CI and adjusted for the covariates above. Absolute mean values at all time points baseline, six and 12 months are presented in the SAP Tables (3.1.1-3.18.1).

5.4.1 Primary outcome

The primary outcome for this study was change in mean weight change post intervention, 12 months from baseline (Table 5.5). The weight loss pre-post intervention at 12 months in TAKE 5 was significantly different from baseline (-3.55 kg 95% CI -5.59 kg to -1.52 kg), however there was no significant difference in body weight in the comparator intervention, WWT00 (-1.66 kg 95% CI -3.69 kg to 0.38 kg). Although, participants in the TAKE 5 intervention achieved a significant weight loss at 12 months, there was no significant difference in weight loss between participants in the TAKE 5 intervention in comparison to participants in the WWT00 intervention (mean difference in weight loss between groups -1.90 kg; 95% CI -4.80 kg to 1.01 kg; $p = 0.195$). There was no evidence of clustering (ICC = 0.000).

Table 5.5. Change in anthropometric outcomes from baseline (ITT)

Anthropometric outcomes	TAKE 5 (n = 26)		WWTOO (n = 24)		Difference between groups		
	N	Mean (95% CI) *	N	Mean (95% CI) *	Mean (95% CI) *	p-value	ICC
Change in weight (kg)							
6 months	24	-2.93 (-4.42 to -1.44)	22	-1.26 (-2.82 to 0.30)	-1.67 (-3.84 to 0.50)	0.126	0.059
12 months	24	-3.55 (-5.59 to -1.52)	24	-1.66 (-3.69 to 0.38)	-1.90 (-4.80 to 1.01)	0.195	0.000
Change in BMI (kg/m²)							
6 months	24	-1.19 (-1.77 to -0.62)	22	-0.46 (-1.06 to 0.15)	-0.74 (-1.58 to 0.11)	0.085	0.000
12 months	24	-1.48 (-2.29 to -0.66)	24	-0.59 (-1.41 to 0.23)	-0.89 (-2.05 to 0.28)	0.134	0.000
Change in waist circumference (cm)							
6 months	22	-3.15 (-4.91 to -1.40)	20	-1.45 (-3.29 to 0.40)	-1.71 (-4.28 to 0.86)	0.186	0.176
12 months	22	-3.60 (-5.99 to -1.21)	21	-1.83 (-4.24 to 0.58)	-1.77 (-5.20 to 1.67)	0.304	0.267
Change in percentage body fat (%)							
6 months	22	-1.79 (-3.08 to -0.50)	18	-1.02 (-2.45 to 0.41)	-0.77 (-2.72 to 1.19)	0.430	0.187
12 months	22	-2.23 (-3.95 to -0.51)	18	-0.65 (-2.56 to 1.26)	-1.58 (-4.21 to 1.05)	0.231	0.000

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence interval; ICC = Interclass correlation coefficient.

5.4.2 Secondary anthropometric outcomes

Secondary outcomes included change in body weight and other anthropometric variables, physical activity outcomes and health related quality of life are reported six months and 12 months from baseline. The results are presented in the following Tables 4.5-4.9.

5.4.2.1 Weight (six months)

The pattern in weight loss within each intervention, replicated similar effects at six months as observed at 12 months, in that participants in the TAKE 5 intervention lost a significant amount of weight from baseline (-2.93 kg; 95% CI -4.42 kg to -1.44 kg), whereas as participants in the WWTOO intervention did not (-1.26 kg; -2.82 kg to 0.30 kg). The between intervention effect at six months, did not result in a significant effect on body weight (-1.67 kg; 95% CI -3.48 kg to 0.50 kg; $p = 0.126$). Although there was no indication of clustering in change in body weight, 12 months from baseline, there was some evidence of clustering in change in body weight at six months ($ICC = 0.059$).

5.4.2.2 Percentage weight change

Table 5.6 illustrates the number of participants achieving a clinically significant weight loss at six months and 12 months, between the intervention groups. Based on the definitions for weight loss maintenance by Stevens *et al.*, (2006) (chapter two, section 2.4.6 clinical effectiveness), the participants' percentage weight change from phase one (end of the weight loss phase) to phase two (end of the weight the weight maintenance phase and end of the 12 month intervention period) have been reported. This was categorised into weight loss ($\geq 3\%$), weight maintenance ($\pm 2.99\%$) and weight gain ($\geq 3\%$). There was no difference in the number of participants achieving 5% weight loss between intervention groups at six months (OR 2.70; 95% CI 0.44 to 16.59; $p = 0.275$). At 12 months more participants in the TAKE 5 intervention (50.0%) achieved a clinically important weight loss than the comparator intervention (20.8%) (OR 3.76; 95% CI 0.92 to 15.30; 0.064). During the weight maintenance phase the majority of participants in both interventions maintained their weight (58.3%, 68.2%, TAKE 5 and WWToo respectively) within $\pm 3\%$ of initial body weight. Seven (29.2%) participants in the TAKE 5 intervention and four participants in the WWToo intervention (18.2%) continued to lose weight and three participants in both intervention groups gained weight. There was no significant difference in percentage weight change in the weight maintenance phase between intervention groups.

Table 5.6. Secondary outcome: Change in percentage weight change at 6 and 12 months from baseline. Odds ratio (95% confidence interval) and p-value (ITT).

Percentage weight change	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)	Odds ratio (95% CI)*	p-value
Weight loss phase (0-6 months)					
Weight loss >5%	5 (20.8)	2 (9.1)	7 (15.2)	2.70 (0.44 to 16.59)	0.275
Weight loss <5%	19 (79.2)	20 (90.9)	39 (84.8)	Referent	
Weight maintenance phase (6 -12 months)					
Weight loss >3%	7 (29.2)	4 (18.2)	11 (23.9)	1.57 (0.18 to 13.90)	0.679
Weight maintenance	14 (58.3)	15 (68.2)	29 (63.0)	0.92 (0.14 to 5.91)	0.924
Weight gain >3%	3 (12.5)	3 (13.6)	6 (13.0)	Referent	
Post intervention (12 months)					
Weight loss >5%	12 (50.0)	5 (20.8)	17 (35.4)	3.76 (0.92 to 15.30)	0.064
Weight loss <5%	12 (50.0)	19 (79.2)	31 (64.6)	Referent	

Note: At 6 months from baseline TAKE n = 24, WWTOO n = 22, TOTAL n = 46

At 12 months from baseline TAKE 5 n = 24, WWTOO n = 24, TOTAL n = 48

*Results are presented as adjusted Odds Ratio (OR) for effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

5.4.2.3 BMI

The analysis on BMI was performed similarly to the model fitted for the primary analysis on change in body weight using a mixed effects model, adjusting for baseline BMI. Change in BMI at six and 12 months from baseline revealed that, participants in the TAKE 5 intervention, had a significant reduction in BMI pre-post intervention at both six months (-1.19 kg/m²; 95% CI -1.77 kg/m² to -0.62 kg/m²) and 12 months (-1.48 kg/m²; -2.29 kg/m² to -0.66 kg/m²). There was not a significant reduction reported for change in BMI for participants in the WWToo intervention at either time points (6 months -0.46 kg/m²; 95% CI -1.06 kg/m² to 0.15 kg/m² and 12 months -0.59 kg/m²; 95% CI -1.41 kg/m² to 0.23 kg/m²). Despite the significant effect of the TAKE 5 intervention on the reduction in BMI, there was no significant intervention effect between participants in the TAKE 5 and WWToo intervention (six months: -0.74 kg/m²; 95% CI -1.58 kg/m² to 0.11 kg/m²; $p = 0.085$ and 12 months: -0.89 kg/m²; 95% CI -2.05 kg/m² to 0.28 kg/m²; $p = 0.134$). There was no effect of clustering on change in BMI at either six or 12 months (ICC = 0.000).

5.4.2.4 Waist circumference

Participants in both interventions had a significant reduction in waist circumference at six months. Participants in the TAKE 5 intervention lost -3.15 cm (95% CI -4.91 cm to -1.40 cm) and participants in the WWToo intervention lost -1.45 cm (95% CI -3.29 cm to 0.40 cm). However, this significant difference was only maintained in participants in the TAKE 5 (-3.60 cm; 95% CI -5.99 cm to -1.21 cm) intervention at 12 months, with no significant difference in the WWToo intervention (-1.83 cm; 95% CI -4.24 cm to 0.58 cm). Adjusting for baseline waist circumference, there was no significant difference between the two interventions at six months (-1.71 cm; 95% CI -4.28 cm to 0.86 cm; $p = 0.186$) and 12 months (-1.77 cm; 95% CI -5.20 cm to 1.67 cm; $p = 0.304$). There was some effect of clustering on waist circumference at both six months and 12 months (ICC = 0.176 and ICC = 0.267, respectively).

5.4.2.5 Percentage body fat

Percentage body fat was significantly reduced in participants in the TAKE 5 intervention at both six months (-1.79%; 95% CI -3.08% to -0.50%) and 12 months (-2.23%; 95% CI -3.95% to -0.51%). Participants in the WWToo intervention showed no significant change in percentage body fat at either time point (six months -1.02%; 95% CI -2.45% to 0.41% and 12 months -0.65%; 95% CI -2.56% to 1.26%). There was no significant between intervention

effect in change in percentage body fat at either six or 12 months (-0.77%; 95% CI -2.72% to 1.19%; $p = 0.430$ and -1.58%; 95% CI -4.21% to 1.05%; $p = 0.231$, respectively). There was some indication of clustering on change in percentage body fat at six months from baseline (ICC = 0.147), however, this was not evident at 12 months (ICC = 0.000).

5.4.3 Physical activity outcomes

Valid measure of physical activity through accelerometer data collection was available for 35 participants and 29 participants at 6 months and 12 months, respectively. Of the five participants who dropped out, only one participant wore the accelerometer at all three time points. The remaining missing data were due to five participants not having worn the accelerometer for the minimum duration of three days and six hours for valid data (Penpraze *et al.*, 2006); nine participants did not wear the accelerometer (one at baseline, seven at six months and nine at 12 months); and three monitors did not collect data due to a fault with the monitor.

The average wear time significantly decreased in the TAKE 5 intervention at six (-53.4 minutes; 95% CI -96.8 minutes to -9.9 minutes) and 12 months (-88.3 minutes; 95% CI -145.8 minutes to -31.4 minutes) and in the WWToo intervention at 12 months (-65.0 minutes; 95% CI -126.1 minutes to -3.8 minutes). Therefore, the time spent in light, MVPA, total physical activity and sedentary behaviour also decreased from baseline and should be considered when interpreting the results for change in physical activity data in time spent in minutes/day. To adjust/account for the difference in accelerometer wear time, percentage time spent in physical activity at different intensities and percentage time spent in sedentary behaviour has been reported. Objective physical activity outcomes are presented in Table 5.7 and change in sedentary behaviour in table 5.8 for the primary ITT.

Table 5.7. Change in objectively measured sedentary behaviour from baseline (ITT)

Sedentary behaviour outcomes	TAKE 5	WWTOO	Difference between groups		
	Mean (95% CI) *	Mean (95% CI) *	Mean (95% CI) *	p-value	ICC
Sedentary behaviour (minutes/day)					
6 months	-27.64 (-66.48 to 11.20)	21.69 (-22.33 to 65.70)	-49.33 (-108.78 to 10.12)	0.100	0.547
12 months	-64.72 (-108.24 to -21.19)	-46.42 (-93.19 to 0.35)	-18.30 (-83.70 to 47.10)	0.568	0.961
Sedentary behaviour (% time spent/day)					
6 months	-2.08 (-4.43 to 0.27)	-2.00 (-4.67 to 0.67)	-0.09 (-3.67 to 3.50)	0.962	0.450
12 months	-0.91 (-4.05 to 2.24)	1.05 (-2.33 to 4.42)	-1.95 (-6.61 to 2.70)	0.394	0.994

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). 6 months TAKE 5 n = 20 WWTOO n = 15; 12 months TAKE 5 n = 16 WWTOO n = 13. CI = Confidence interval; ICC = Interclass correlation coefficient.

Table 5.8. Change in objectively measured physical activity from baseline (ITT)

Physical activity outcomes	TAKE 5	WWTOO	Difference between groups		
	Mean (95% CI) *	Mean (95% CI) *	Mean (95% CI) *	p-value	ICC
Average Wear Time (minutes/day)					
6 months	-53.35 (-96.78 to -9.92)	10.90 (-39.66 to 61.46)	-64.25 (-132.72 to 4.21)	0.065	0.000
12 months	-88.34 (-145.28 to -31.40)	-64.97 (-126.14 to -3.81)	-23.37 (-108.84 to 62.11)	0.576	0.979
CPM					
6 months	-11.33 (-51.16 to 28.50)	-27.83 (-72.59 to 16.94)	16.50 (-43.49 to 76.48)	0.58	0.924
12 months	7.71 (-30.62 to 46.03)	-0.82 (-42.03 to 40.40)	8.53 (-48.33 to 65.38)	0.76	0.910
Step count (per day)					
6 months	-652 (-1291 to -13)	-556 (-1298 to 185)	-95 (-1080 to 899)	0.846	0.000
12 months	-454 (-1466 to 558)	-580 (-1666 to 505)	126 (-1371 to 1624)	0.863	0.997
Light PA (minutes/day)					
6 months	-23.84 (-37.28 to -10.39)	-5.00 (-20.64 to 10.63)	-18.83 (-39.91 to 2.25)	0.078	0.000
12 months	-14.93 (-42.53 to 12.66)	-22.71 (-52.31 to 6.88)	7.78 (-33.15 to 48.71)	0.697	0.999
Light PA (% time spent/day)					
6 months	-1.79 (-3.69 to 0.11)	-1.22 (-3.40 to 0.96)	-0.57 (-3.50 to 2.35)	0.692	0.164
12 months	0.79 (-2.22 to 3.81)	-0.92 (-4.15 to 2.31)	1.71 (-2.75 to 6.17)	0.434	0.994
MVPA (minutes/day)					

6 months	-4.26 (-8.49 to -0.03)	-6.00 (-10.75 to -1.25)	1.74 (-4.62 to 8.11)	0.579	0.999
12 months	-1.85 (-9.16 to 5.46)	-3.59 (-11.49 to 4.30)	1.74 (-9.16 to 12.64)	0.744	0.871
MVPA (% time spent/day)					
6 months	-0.32 (-1.17 to 0.54)	-0.81 (-1.77 to 0.15)	0.50 (-0.79 to 1.78)	0.434	0.895
12 months	0.10 (-0.94 to 1.13)	-0.17 (-1.28 to 0.95)	0.26 (-1.28 to 1.80)	0.726	0.818
Total PA (minutes/day)					
6 months	-28.76 (-43.84 to -13.69)	-10.76 (-28.29 to 6.76)	-18.00 (-41.64 to 5.64)	0.130	0.000
12 months	-17.05 (-48.53 to 14.44)	-25.55 (-59.34 to 8.25)	8.50 (-38.26 to 55.26)	0.710	0.994
Total (% time spent/day)					
6 months	2.08 (-0.27 to 4.43)	2.00 (-0.67 to 4.67)	0.09 (-3.50 to 3.60)	0.962	0.449
12 months	0.91 (-2.24 to 4.05)	-1.05 (-4.42 to 2.33)	1.95 (-2.70 to 6.61)	0.39	0.994

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). 6 months TAKE 5 n = 20 WWTOO n = 15; 12 months TAKE 5 n = 16 WWTOO n = 13. CI = Confidence Interval; ICC = Interclass Correlation Coefficient; CPM = Counts per minute; MVPA = Moderate to vigorous physical activity; PA = Physical activity.

5.4.3.1 Sedentary behaviour

Participants with intellectual disabilities in this study engaged in high levels of physical inactivity and time spent a majority of time in sedentary behaviour. At baseline, all participants spent on average 511.0 minutes (SD 144.4 minutes) and 73.7% (SD 7.63%) of their time sedentary. Participation in either weight management intervention did not have a significant effect on decreasing time spent in sedentary behaviour at the end of the weight loss phase (TAKE 5 -27.6 minutes; 95% CI -66.5 minutes to 11.2 minutes; WWToo 21.7 minutes; 95% CI -22.3 minutes to 65.7 minutes). However, at the end of the weight maintenance phase, participants in the TAKE 5 intervention significantly decreased time spent sedentary by -64.7 minutes (95% CI -108.2 minutes to -21.2 minutes). Although there was a trend for participants in the WWToo intervention also to decrease time spent sedentary this was not significant -46.4 minutes (95% CI -93.2 minutes to 0.4 minutes). There was no significant between group differences as six or 12 months (-49.3 minutes; 95% CI -108.8 minutes to 10.1 minutes; $p = 0.100$ and -18.3 minutes; 95% CI -83.7 minutes to 47.1 minutes; $p = 0.568$, respectively). There was an effect of clustering on time spent in sedentary behaviour at both six months (IC = 0.547) and 12 months (ICC = 0.961). It is important to note that although time spent in sedentary behaviour in minutes was significantly reduced after completion of the TAKE 5 intervention at 12 months, this finding was not replicated when accounting for time spent wearing the physical activity monitor and has been reported as percentage time spent/day (-0.9%; 95% CI -4.1% to 2.2%).

5.4.3.2 Light intensity physical activity

Participation in light physical activity was the most common form of physical activity in adults with intellectual disabilities and obesity. At baseline, participants engaged in 153.4 minutes (SD 62.5 minutes) per day which is equivalent to 22.1% (SD 7.0%) of monitor wear time. The aim of the intervention was to examine the potential efficacy of the weight management interventions on increasing physical activity and in particular aiming to increase and build on levels of light intensity physical activity which is believed to be more feasible for this population group. Participation in either weight management intervention did not significantly increase light intensity physical activity in minutes per day (TAKE 5 -23.8 minutes; 95% CI -37.3 minutes to -10.4 minutes; WWToo -5.0 minutes; 95% CI -20.6 minutes to 10.6 minutes) or percentage time spent in light intensity physical activity (TAKE 5 1.8%; 95% CI -3.7% to 0.1%; WWToo -1.2%; 95% CI -3.4% to 1.0%) at the end of the

weight loss phase. The pattern of no significant change in time spent in light physical activity was also evident at 12 months for both interventions (TAKE 5 -14.9 minutes 95% CI -42.7 minutes to 12.7 minutes; WWToo -22.7 minutes; 95% CI -52.3 minutes to 6.9 minutes). Adjusting for wear time also did not result in any significant results for the TAKE 5 intervention (0.8% 95% CI -2.2% to 3.8%) or the WWToo intervention (-0.9%; 95% CI -4.2% to 2.3%). There was no between group effect sizes with comparisons at six months or 12 months (table 5.8). There was evidence of clustering for all comparisons with the exception of change in time spent (minutes) in light physical activity at six months.

5.4.3.3 Moderate to vigorous intensity physical activity

At baseline mean time spent in moderate to vigorous physical activity for all participants was 30.1 minutes (SD 19.5 minutes) per day. Participants engaged in physical activities of moderate to vigorous less frequently than light intensity physical activity, 4.6% (SD 3.2%) of wear time per day. At six months, participants in the TAKE 5 intervention significantly decreased time spent in moderate to vigorous physical activity (-4.3 minutes; 95% CI -8.5 minutes to -0.0 minutes). A decrease in time spent in moderate to vigorous physical activity was also found in participants in the WWToo intervention at the end of the weight loss phase (-6.0 minutes; 95% CI -10.8 minutes to -1.3 minutes). However, adjusting for wear time, these significant reductions were not replicated in percentage time spent in moderate to vigorous physical activity at six months (TAKE 5 -0.3%; 95% CI -1.2% to 0.5%; WWToo -0.8% 95% CI -1.8% to 0.2%). There was no between group difference in time spent in minutes (1.7 minutes; 95% CI -4.6 minutes to 8.1 minutes; $p = 0.579$) and percentage time spent at six months (0.5%; 95% CI -0.8% to 1.8%; $p = 0.434$). At the end of the intervention period at 12 months, although time spent in both interventions was shown to decrease, this was not significant in either the TAKE 5 intervention (1.9 minutes; 95% CI -9.2 minutes to 5.5 minutes) or the WWToo intervention (-3.6 minutes; 95% CI -11.5 minutes to 4.3 minutes). There was also no between group effect 1.7 minutes (95% CI -9.2 minutes to 12.6 minutes; $p = 0.871$). There was evidence of clustering for all moderate to vigorous physical between group comparisons (ICC = 0.818 to 0.999).

5.4.3.4 Total physical activity

At baseline participants engaged in an accumulation of light and moderate to vigorous physical activity to achieve an average of 183.5 minutes (SD 69.6 minutes) per day in total. This is equivalent to only 26.5% (SD 8.6%) of wear time per day. Participants in the TAKE

5 intervention significantly decreased the time spent in total physical activity per day at six months (-28.8 minutes; 95% CI -43.8 minutes to -13.7 minutes). At 12 months participants in the TAKE 5 intervention continued to report a reduction on accumulated total physical activity, however, this was not a significant change (-17.1 minutes; 95% CI -48.5 minutes to 14.4 minutes). Due to the reduction in wear time across time points as previously reported, adjustment for this did not support a significant reduction in total physical activity. Change in percentage time spent in total physical activity was in contrast to time spent in minutes as this was increased by 2.1% (95% CI -0.3% to 4.4%), however, this was not a significant change. Participants in the WWToo intervention, demonstrated a reduction in time spent in total physical activity at both six (-10.8 minutes; 95% CI -28.2 minutes to 6.8 minutes) and 12 months (-25.6 minutes; 95% CI -59.3 minutes to 8.3 minutes), however, this was not a significant reduction. There was no between group effect on change in total physical activity at six months (-18.0 minutes; 95% CI -41.6 minutes to 5.6 minutes; $p = 0.130$) or 12 months (8.5 minutes; 95% CI -38.3 minutes to 55.3 minutes; $p = 0.710$).

5.4.4 Health related quality of life

Health related quality of life was assessed by the EQ-5D questionnaire. The results are presented as the EQ-5D index which is a summary index of the five health domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression; baseline values are presented in the SAP table 2.10). Presentation as a single index value allowed comparison with previous research measuring health related quality of life in adults with intellectual disabilities (Melville *et al.*, 2015). A high proportion of participants reported to be in a good health state (EQ-5D index for all participants 0.7 (SD 0.3). There was no change in health related quality of life at six months from baseline in either the TAKE 5 (0.07; 95% CI -0.03 to 0.17) intervention or the WWToo intervention (0.04; 95% CI -0.07 to 0.14). Completion of the 12 month weight management interventions also did not change health related quality of life in adults with intellectual disabilities from (TAKE 5: 0.00; 95% CI -0.14 to 0.14; WWToo: -0.04; -0.18 to 0.10).

Table 5.9. Change in health related quality of life from baseline (ITT)

		TAKE 5 (n = 26)		WWTOO (n = 24)		Difference between groups	
EQ-5D outcomes	N	Mean (95% CI)*	N	Mean (95% CI) *	Mean (95% CI)*	p-value	ICC
Change in EQ-5D index							
6 months	24	0.07 (-0.03 to 0.17)	22	0.04 (-0.07 to 0.14)	0.03 (-0.12 to 0.18)	0.652	0.118
12 months	24	0.00 (-0.14 to 0.14)	24	-0.04(-0.18 to 0.10)	0.04 (-0.16 to 0.24)	0.675	0.000

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval; ICC = Interclass Correlation Coefficient.

5.5 Exploratory analysis

5.5.1 Per-protocol analysis

To investigate the effect of the weight management intervention under ideal circumstances, per-protocol analysis was conducted when participants adhered to the intervention (defined as attendance at 75% of intervention sessions). The baseline outcome measurements for completers (anthropometry, physical activity and health related quality of life) are illustrated in Tables 5.10-5.11. Baseline health related quality of life, is presented in the SAP (Table 2.11.1), as this did not differentiate from the ITT results

Table 5.10. Baseline anthropometric outcomes by group and overall (Completers).

Anthropometric	TAKE 5	WWTOO	Total
Outcomes	(n = 21)	(n = 19)	(n = 40)
Weight (kg)	102.7 (25.1)	101.9 (18.1)	102.3 (21.8)
Height (cm)	158.2 (10.4)	157.0 (13.9)	157.7 (12.0)
BMI (kg/m ²)	40.6 (7.1)	41.5 (6.2)	41.0 (6.6)
Waist Circumference (cm)*	121.7 (14.1)	121.0 (13.3)	121.4 (13.5)
Percentage Body Fat (%)*	49.3 (10.0)	51.0 (5.8)	50.1 (8.4)

Values represent mean (SD) BMI = Body Mass Index.

*Waist circumference Completers TAKE 5 n = 19 WWTOO n = 18 Total n = 37

*Percentage Body Fat Completers TAKE 5 n = 19 WWTOO n = 15 Total n = 34

Table 5.11. Baseline objectively measured physical activity by group and overall (Completers)

Physical activity/Sedentary behaviour outcome	TAKE 5 (n = 20)	WWTOO (n = 17)	Total (n = 47)
Average Wear Time (minutes/day)	686.1 (142.2)	716.5 (227.6)	700.1 (184.2)
CPM	276.7 (123.6)	265.6 (134.2)	271.6 (126.9)
Step Count (per day)	4974 (2066)	4416 (2311)	4718 (2170)
Light PA (minutes/day)	150.9 (51.9)	159.4 (87.0)	154.8 (69.3)
Light PA (% time spent/day)	21.9 (6.6)	22.1 (9.0)	22.0 (7.7)
MVPA (minutes/day)	28.9 (17.1)	27.9 (19.8)	28.4 (18.1)
MVPA (% time spent/day)	4.5 (2.7)	4.0 (2.9)	4.3 (2.8)
Total PA (minutes/day)	179.7 (57.5)	187.3 (96.0)	183.2 (76.5)
Total PA (% time spent/day)	26.4 (7.8)	26.1 (10.0)	26.2 (8.8)
Sedentary Behaviour (minutes/day)	506.4 (133.5)	529.1 (173.8)	516.8 (151.6)
Sedentary Behaviour (% time spent/day)	73.6 (7.8)	73.9 (10.0)	73.8 (8.8)

Values represent means (SD) CPM = Counts per minute; MVPA = Moderate to vigorous physical activity; PA = Physical activity

5.5.1.1 Primary outcome

The results of the per-protocol analysis for the primary outcome, change in body weight at 12 months from baseline are in agreement with the ITT results. Participants in the TAKE 5 intervention demonstrated a significant reduction in body weight pre-post intervention (-3.75 kg; 95% CI -6.06 kg to -1.45 kg). There was no significant change in body weight in the WWToo intervention (-1.30 kg; 95% CI -3.72 kg to 1.13 kg). As in the ITT analysis, despite the significant change in body weight in the TAKE 5 intervention, there was no significant between group differences for participants defined as adhering to the intervention in full (-2.46 kg; 95% -5.84 kg to 0.93 kg; $p = 0.150$). There was no evidence of clustering (ICC = 0.000). Per-protocol results for the primary outcome and secondary anthropometric outcomes are illustrated in Table 5.12.

Table 5.12. Change in anthropometric outcomes from baseline (Completers).

Anthropometric outcomes	TAKE 5 (n = 21)		WWT00 (n = 19)		Difference between groups		
	N	Mean (95% CI) *	N	Mean (95% CI) *	Mean (95% CI) *	p-value	ICC
Change in weight (kg)							
6 months	21	-3.24 (-4.93 to -1.54)	19	-1.35 (-3.13 to 0.44)	-1.89 (-4.38 to 0.59)	0.130	0.096
12 months	21	-3.75 (-6.06 to -1.45)	19	-1.30 (-3.72 to 1.13)	-2.46 (-5.84 to 0.93)	0.150	0.000
Change in BMI (kg/m²)							
6 months	21	-1.34 (-2.00 to -0.67)	19	-0.47 (-1.17 to 0.23)	-0.87 (-1.84 to 0.11)	0.078	0.078
12 months	21	-1.56 (-2.49 to -0.63)	19	-0.50 (-1.48 to 0.49)	-1.06 (-2.44 to 0.31)	0.125	0.000
Change in waist circumference (cm)							
6 months	19	-3.54 (-5.48 to -1.59)	17	-1.48 (-3.54 to 0.59)	-2.06 (-4.93 to 0.81)	0.152	0.194
12 months	19	-3.87 (-6.56 to -1.18)	16	-1.37 (-4.25 to 1.51)	-2.49 (-6.48 to 1.49)	0.211	0.263
Change in percentage body fat (%)							
6 months	19	-1.94 (-3.38 to -0.51)	15	-1.23 (-2.86 to 0.39)	-0.71 (-2.91 to 1.49)	0.512	0.177
12 months	19	-2.16 (-4.09 to -0.24)	14	-0.49 (-2.75 to 1.77)	-1.68 (-4.72 to 1.36)	0.268	0.000

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval; ICC = Interclass Correlation Coefficient.

5.5.1.2 Secondary anthropometric outcomes

The exploratory analysis on other anthropometric outcomes including change in body weight at six months and BMI, waist circumference and percentage body fat (at six and 12 months) resulted in similar effect sizes for within group and between group analysis. Participants defined as completers in the TAKE 5 intervention had a significant reduction in all of the above anthropometric outcomes at six and 12 months from baseline, whereas participation in the WWToo intervention had no significant effect on the anthropometric outcomes of adults with intellectual disabilities. These results provide further evidence of the potential efficacy for the TAKE 5 intervention, illustrating under ‘real life’ and full adherence that participants can achieve significant improvements in weight, BMI, waist circumference and percentage body fat.

5.5.1.3 Sedentary behaviour

Change in physical activity and sedentary behaviour was assessed in individuals who adhered to the intervention. The primary finding of the per-protocol analysis was that there was a significant between group effect in time spent per day in sedentary behaviour at six months (-71.88 minutes; 95% CI -136.40 minutes to -7.37 minutes; $p = 0.031$). This resulted as the between group effect size for the TAKE 5 intervention further reduced time spent sedentary from -27.64 minutes (95% CI -66.48 minutes to 11.20 minutes) in the ITT analysis to -38.60 minutes (-79.75 minutes to 2.49 minutes) in the per-protocol analysis, with a concomitant increase in time spent sedentary in the WWToo intervention from 21.69 minutes (95% CI -22.33 minutes to 65.70 minutes) to 33.25 minutes (95% CI -71.88 minutes (-136.40 minutes to -7.37 minutes), ITT analysis and per-protocol analysis, respectively. The between group effects in sedentary behaviour were not significant. Caution over the interpretation of these results is warranted as these findings are not adjusted for wear time and not replicated in the change in percentage time spent in sedentary behaviour. Indeed, the per-protocol analysis resulted in between group differences for TAKE 5 and WWToo, although not statistically significant, illustrate an increase in percentage time spent in sedentary behaviour. This suggests that full adherence to either weight management intervention was not effective in interrupting the lifestyle habits of adults with intellectual disabilities in terms of reducing time spent sedentary.

5.5.1.4 Physical activity outcomes

Investigation into whether participants adhered to the intervention, did not result in any significant within group or between group difference in change in physical activity outcomes. Results of the per-protocol analysis for objectively measured physical activity outcomes and sedentary behaviour are illustrated in Tables 5.13-5.14.

5.5.1.5 Health related quality of life

Data analysis from the 40 participants who adhered to the intervention had no effect on health related quality of life. Change in the EQ-5D index between group or within group at six or 12 months was not different from the ITT analysis. The results for the per-protocol analysis on EQ-5D index are presented in Table 5.15.

Table 5.13. Change in objectively measured sedentary behaviour from baseline (Completers)

Sedentary behaviour outcomes	TAKE 5	WWTOO	Difference between groups		
	Mean (95% CI) *	Mean (95% CI) *	Mean (95% CI) *	p-value	ICC
Sedentary behaviour (minutes/day)					
6 months	-38.60 (-79.75 to 2.49)	33.25 (-14.68 to 81.18)	-71.88 (-136.40 to -7.37)	0.031	0.525
12 months	-80.00 (-127.27 to -31.74)	-43.03 (-95.93 to 9.88)	-36.98 (-110.95 to 37.00)	0.305	0.934
Sedentary behaviour (% time spent/day)					
6 months	1.76 (-1.05 to 4.57)	2.32 (-0.95 to 5.59)	2.09 (-4.90 to 3.78)	0.792	0.481
12 months	-0.44 (-3.93 to 3.05)	-0.60 (-4.42 to 3.21)	2.46 (-5.05 to 5.37)	0.949	0.994

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). 6 months TAKE 5 n = 17 WWTOO n = 12; 12 months TAKE 5 n = 13 WWTOO n = 10. CI = Confidence Interval; ICC = Interclass Correlation Coefficient.

Table 5.14. Change in objectively measured physical activity from baseline (Completers)

Physical activity outcomes	TAKE 5	WWT00	Difference between groups		
	Mean (95% CI) *	Mean (95% CI) *	Mean (95% CI)*	p-value	ICC
Average Wear Time (minutes/day)					
6 months	-64.34 (-110.20 to -18.47)	23.34 (-31.95 to 78.64)	-87.68 (-162.04 to -13.32)	0.023	0.000
12 months	-105.15 (-170.16 to -40.14)	-52.59 (-123.76 to 18.58)	-52.56 (-151.41 to 46.30)	0.276	0.972
CPM					
6 months	5.95 (-41.78 to 53.69)	-30.10 (-64.86 to 24.66)	35.18 (-36.89 to 109.00)	0.317	0.942
12 months	2.38 (-39.80 to 44.56)	36.68 (-9.21 to 82.57)	29.86 (-97.80 to 29.21)	0.268	0.935
Step count (per day)					
6 months	-458 (-1229 to 313)	-399 (-1323 to 526)	594 (-1287 to 1169)	0.922	0.000
12 months	-187 (-1473 to 1100.00)	-264 (-1668 to 1141)	904 (-1837 to 1991)	0.933	1.000
Light PA (minutes/day)					
6 months	-26.61 (-41.91 to -11.32)	-5.07 (-23.56 to 13.32)	-21.55 (-46.13 to 3.04)	0.083	0.000
12 months	-18.66 (-52.03 to 14.72)	-17.36 (-53.81 to 19.06)	-1.28 (-51.14 to 48.58)	0.957	1.000
Light PA (% time spent/ day)					
6 months	-1.95 (-4.16 to 0.25)	-1.53 (-4.13 to 1.08)	1.67 (-3.89 to 3.04)	0.801	0.133
12 months	-18.66 (-52.03 to 14.72)	-17.38 (-53.81 to 19.06)	-1.28 (-51.14 to 48.58)	0.957	0.994

MVPA (minutes/day)					
6 months	-2.43 (-7.58 to 2.73)	-5.10 (-11.01 to 0.82)	2.67 (-5.17 to 10.51)	0.487	1.000
12 months	-1.18 (-9.81 to 7.44)	1.24 (-8.19 to 10.66)	6.05 (-15.30 to 10.46)	0.695	0.719
MVPA (% time spent/day)					
6 months	0.06 (-0.94 to 1.06)	-0.74 (-1.89 to 0.41)	0.75 (-0.75 to 2.35)	0.296	0.904
12 months	-0.10 (-1.17 to 0.97)	0.79 (-0.38 to 1.96)	0.76 (-0.73 to 2.51)	0.260	0.732
Total PA (minutes/day)					
6 months	-29.65 (-47.20 to -12.09)	-10.08 (-31.16 to 11.01)	13.59 (-47.68 to 8.54)	0.163	0.000
12 months	-19.12 (-57.84 to 19.60)	-15.99 (-58.30 to 26.32)	27.25 (-60.96 to 54.70)	0.910	0.995
Total PA (% time spent/day)					
6 months	-1.76 (-4.57 to 1.05)	-2.32 (-5.59 to 0.95)	2.09 (-3.78 to 4.90)	0.792	0.481
12 months	0.44 (-3.05 to 3.93)	0.60 (-3.21 to 4.42)	2.46 (-5.37 to 5.05)	0.949	0.994

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). 6 months TAKE 5 n = 17 WWTOO n = 12; 12 months TAKE 5 n = 13 WWTOO n = 10. CPM = CI = Confidence Interval; ICC = Interclass Correlation Coefficient; Counts per minute; MVPA = Moderate to vigorous physical activity; PA = Physical activity.

Table 5.15. Change in health related QOL from baseline (Completers)

EQ-5D outcomes	TAKE 5 (n = 26)		WWTOO (n = 24)		Difference between groups		
	N	Mean (95% CI)*	N	Mean (95% CI) *	Mean (95% CI)*	p-value	ICC
Change in EQ-5D index							
6 months	24	0.08 (-0.04 to 0.1)	22	0.07 (-0.11 to 0.13)	0.07 (-0.10 to 0.24)	0.393	0.341
12 months	24	-0.03 (-0.19 t 0.13)	24	-0.05 (-0.22 to 0.11)	0.02 (-0.21 to 0.25)	0.851	0.059

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval; ICC = Interclass Correlation Coefficient.

5.6 Sensitivity analysis

Mixed models were selected due to their advantages over general linear models (see section 4.16.1.1). For these models to produce valid results, data must meet the assumption of a normal distribution. Undertaking the analysis revealed that in some circumstances outliers (identified based on visual inspection of normality plots and Q-Q plots) affected the distribution of the data. Data points classified as outliers were assessed for their potential to influence results and therefore study conclusions. Sensitivity analysis was conducted to compare results with and without outlier(s). Important discrepancies between the two analyses are reported and full results of the sensitivity analysis can be found in the SAP in appendix vii. In circumstances where data were affected by multiple data points deviating from the normal distribution curve, transformation of the data were assessed using logarithmic and square root transformations to try and improve the distribution.

5.6.1 Primary outcomes ITT

The baseline distribution of body weight was considered to be normally distributed, however, one participant had a higher baseline weight which was classified as an outlier (212 kg). This participant's body composition in terms of BMI, waist circumference and percentage body fat was also considered to be outside the normal distribution of the remaining participants (the effect on secondary anthropometric outcomes will be discussed below). To test the effects of this participant on the analysis of change in body weight at 12 months, mixed linear models were run with (Between group effect: -1.90 kg; 95% CI -4.80 kg to 1.01 kg; $p = 0.195$) and without (Between group effect: -2.16 kg; 95% CI -5.08 kg to 0.76 kg; $p = 0.143$; SAP table 3.1.1.1) the inclusion of the participant. The exclusion of this participant did not result in a significant between group effect and thus did not change the study conclusion for the primary outcome. Further analysis revealed that although the participant discussed above was considered an outlier at baseline, this was not evident in change in body weight at six months from baseline (SAP Tables 3.2.1.1 to 3.5.3.1).

Outliers in change in body weight at 12 months were also investigated. At twelve months a participant in the WWToo intervention lost -15.10 kg (mean -1.6 kg; SD 5.03 kg) and was also identified as an outlier. Analysis without this participant (SAP Table 3.1.2.1) resulted in a significant between group effect -3.26 kg (95% CI -6.42 kg to -0.10 kg; $p = 0.044$). Further, investigation through the process evaluation revealed that this participant had lost

weight following a serious adverse event unrelated to participation in the study. It was noted in the research dietitian's clinical notes that they were advised to consume a liquid diet and therefore, it can be assumed that the weight loss may not have been due to participating in the intervention. This provides further support for the potential efficacy of the TAKE 5 weight management intervention.

5.6.2 Secondary anthropometric outcomes ITT

The participant defined as an outlier at baseline with a body weight of 212 kg in comparison to the mean body weight of the remaining participants, also extended to other body composition measurements including BMI, waist circumference and percentage body fat. However, exclusion of this participant from the analysis did not result in any significant differences in change in body composition measurements at six and 12 months. However, exclusion of both participants described as outliers above resulted in a significant between group effect for change in BMI at 12 months (-1.29 kg/m^2 ; 95% CI -2.35 kg/m^2 to -0.24 kg/m^2 ; $p = 0.018$). Another participant in the WWToo intervention, at six months lost -11 kg, which was distinct from the mean weight loss of -1.4 kg (SD 3.60 kg). Analysis with and without this participant (plus the participant identified as an outlier at baseline) resulted in a between group difference tending to be in favour of the TAKE 5 intervention, however this did not reach statistical significance (Between group difference: -2.02 kg (95% CI -4.13 kg to 0.08 kg; $p = 0.059$). This change in body weight was not evident at 12 months when the participant regained the weight loss.

Sensitivity analyses were also completed to assess the validity of the per-protocol results. Similar outliers arose in terms of deviations from the mean change in outcome variable. At 12 months, change in weight and BMI was considered not normally distributed by the same participant described in section 5.6.1 above and who lost -15.10 kg and received and liquid diet. Between group differences for change in body weight (-3.26 kg ; 95% CI -6.42 to -0.10 kg ; $p = 0.044$) and BMI (-1.39 kg/m^2 ; -2.63 kg/m^2 to -0.16 kg/m^2 ; $p = 0.028$) were statistically significant at 12 months from baseline. This provided further evidence of the potential efficacy of the TAKE 5 intervention under conditions in which participants adhered to 75% or more of the intervention.

This was repeated for all anthropometric outcome measures, however, exclusion of outliers did not affect the interpretation or conclusion of the results. Full details of the analysis are presented in the SAP (Tables 3.1.1.1 to 3.5.4.1) in appendix vii.

5.6.3 Physical activity outcomes

The classification of participants as outliers, affected the normal distribution of accelerometer data in some cases at baseline and for change in the physical activity variable at six and 12 months. Differences in physical activity measured were considered outliers when for example, participants completed a higher or lower than average level of time spent engaged in physical activity. These values however, were not removed from the analysis for the following reasons: results were due to naturally occurring variation in physical activity and sedentary behaviour as the data were not spurious or subject to measurement error (data were double entered), and the small sample size meant that normal distribution can be hard to determine and thus fulfil the statistical test assumptions. Another approach in analysis of clinical trial data can be to use transformation of data to facilitate inclusion of all data points. Attempts at using logarithmic and square root transformations were conducted however, this did not improve the overall fit of the data and compromised variables in the mixed model which was originally normally distributed. Therefore, based on the above justification and to facilitate comparison between intensities of physical activity results are presented as ITT and per-protocol above using parametric mixed models.

5.6.4 Health related quality of life

The results for the change in EQ-5D were also considered to be not normally distributed. This was primarily due to kurtosis in the distribution of data, resulting from a lack of change in health related quality of life. Standard transformations did not improve the fit of the data, therefore, to examine the validity of no significant change in EQ-5D index, change in the domains that make up this health profile were explored. The improvement of each of the health domains; mobility, self-care, usual activities, pain/discomfort and anxiety/depression was categorised as improved or no improvement/deteriorated. The findings are in support of no change in the EQ-5D index with no significant change in outcomes at six months or 12 months. The results for the dichotomous outcomes are reported in the SAP Tables 3.19 and 3.20.

5.7 Adverse events

Eleven serious adverse events in total were reported (four in the TAKE intervention and seven in the WWToo intervention), seven recorded in the weight loss phase and a further four in the weight maintenance phase. Four were due to exacerbation of pre-existing health conditions, two were surgical procedures (one routine), two were presentations of new medical conditions, two were the result of falls and one was an adverse reaction to change in medication. The weight management interventions are considered as safe as none of the above serious adverse events were considered to be the result of taking part in the study.

5.8 Process evaluation outcomes

To enhance understanding of the quantitative results, exploration of key processes including the fidelity of the intervention, implementation and effective and ineffective components are presented below. The results are collated from a number of methodologies including, clinical notes, case reporting forms, checklists and enriched from qualitative interviews with the research dietitians with experience and insight into weight management in this population group. A summary of the key themes identified in the qualitative interviews with the research dietitians are presented in Table 5.16.

Table 5.16. Key themes and subthemes from interviews with research dietitians

Key themes	Subthemes
Intervention delivery	Participant appointments and logistics Fidelity
Intervention content	Abstraction and complexity of behaviour change techniques
Mediators of weight management	Professional motivation Support from carers Barriers to behaviour change
Context	Socio environmental barriers and facilitators

5.8.1 Dose delivered

The intervention was delivered by a dietitian and a health professional. Both had experience working with adults with intellectual disabilities. The dietitian had experience in obesity management and had a previous employment role at the Glasgow Clyde and Weight Management Service, which TAKE 5 has been adapted from. Furthermore, the dietitian devised and delivered the WWToo intervention in its original group format. Therefore, the dietitian had extensive experience in the delivery of both interventions. The health professional was also qualified to degree level, in the area of health and physical activity. The health professional had experience as a lifestyle counsellor on a number of physical activity intervention studies and therefore both were suitably qualified for the role.

Research dietitians delivered both interventions on a one-to-one basis to the participants and/or carers where applicable. The research dietitians were asked about the feasibility of delivering the intervention, their demand capacity to facilitate delivery and any challenges they experienced in delivering the intervention.

Both research dietitians were employed on a 0.5 full time equivalent contract. At the start of the intervention only one dietitian was employed until it was highlighted that to complete the intervention within the desired time frame (February 2014- October 2015) additional resource was required.

'I was employed two and a half days per week so at the beginning that was full and I probably did a bit more than two and half days a week because we didn't know how much time would be taken up. So the first three or four months it was more like full time, maybe four or five days at the beginning and then we managed to get RD2 on so that helped a lot, so then it went down to two and half days.' RD1

The decision to recruit another research dietitian reduced the workload for the first research dietitian, however both research dietitians continued to report pressure in delivering the volume of appointments to participants, particularly during the weight loss phase where appointments were scheduled for every two-three weeks.

'The time pressure in the beginning was stressful.' RD1

However, the flexibility of the working hours also suited the research dietitians as they could organise appointments around their schedule.

'Although there were days I was doing a lot, but perhaps that was because I wanted to do a lot on those days as well. It could have been more spread out, no I found it was fine I didn't find it a problem at all.' RD2

The research dietitians were asked to identify any challenges to delivering the intervention. The practicalities of delivering the intervention sessions to participants who were recruited from different geographical locations across GG&C was reported as challenging.

'The actual practicalities are one thing that would help if we did do things in the same postcodes. I figured that out in a couple of months because we had people in different areas at the time we were going from the East End to Barrhead, so I was booking appointments to suit the people, which might mean 9 o'clock in the East End and 11 o'clock in Barrhead and 1 o'clock East End a total pain, so very soon I realised not to do that and I would do my mornings in East End and afternoons in Barrhead so that wouldn't happen and people fitted into that fine.' RD1

5.8.2 Fidelity

The fidelity for the duration of the intervention sessions was not met at the start of the intervention where sessions were delivered by only one research dietitian and had to be condensed to meet the demands of the number of participants. Although the duration of the intervention sessions was reduced to regulate the demand from participants, the recruitment of a second research dietitian resolved this issue and it was found that in fact the time to deliver the content of each session did not require the full time allocated.

'Duration was much more rushed, and where RD2 made it easier and things could be longer it was rare especially with WWToo that was an hour session for a group so quite often not so much discussion but you would need that one to one. With Take 5 the first few sessions were longer so the first few sessions were maybe needing a good hour but after that the sessions were shorter.' RD1

Despite deviations in the duration of the intervention fidelity of the intervention content was ensured as the intervention sessions were manualised. This meant that the intervention content was not compromised and delivered as intended.

'I found it fine before I went in I always had my files ready. I would know what I was going to be presenting, I would run through the protocols as I went through... I would always be looking at my book any way to check I had covered everything.' RD2

Adherence to the delivery of the content was measured on completing of a checklist of the intervention content. Fidelity was reported to be high, with the only deviations from the intervention were due to unnecessary delivery of session content such as the exclusion of information on alcohol intake due to the participant not engaging reporting consuming alcohol. Adaptations also arose when session content was moved between sessions to facilitate the needs of participants. For example, it was identified in the clinical notes and from the qualitative interviews that one participant had problems with binge eating. Binge eating was an element within session seven and was moved to an earlier session (session three) as the problem was identified. Barrier identification/problem solving and stress management/emotional control training were behaviour change techniques used to help alleviate this issue.

'I would sometimes swap sessions around so when Laura for example went on holiday in session two she talked about she used to binge eat a lot so we covered binge eating, which wasn't meant to be covered until way late in Session seven or eight so we covered that in Session two it would have been silly to wait months when there was an issue there.' RD1

5.8.3 Context

This was an individualised intervention and the majority of sessions were conducted in participants' homes (92.0%). In four cases participants met with the research dietitians at another location convenient to them. This was the community day centre where the participants attended. One participant had to be weighed at the GCWMS to allow accurate assessment of their body weight which was in excess of 200 kg and thus exceeded the limits of the scales used for measurement of body weight used in this study. To ensure valid and reliable measures of this participants' body weight, all measurements were conducted (research dietitian and researcher conducting outcome assessments) at this site.

In cases where the research dietitians reflected on any negative cases, i.e. cases where participants did not meet their goals, it was reported that in some circumstances participants were limited by contextual factors such as the area they lived in. Setting goals around the most popular activity, walking, for this population was limited as the area in which participants lived was considered unsafe/not suitable. The SIMD scores are presented in table 5.1. It has been documented that participants 42.0% lived in the most deprived areas.

'He couldn't walk around because it was a bad area. That has been an issue for a lot of people where they live and they can't go walks.' RD2

5.8.4 Dose received

The research dietitians provided an insight into how each of the interventions were received and highlighted the successful and unsuccessful components. Both interventions were reported to be well received by participants and carers. It was noted in particular, that the structured format of the TAKE 5 session and the reputability of the TAKE 5 intervention was highly regarded by carers.

'I think carers liked the structure, TAKE 5 was very structured and I told them as well that this what they would be getting if they didn't have intellectual disabilities and that it was the same programme as the Weight Management Service. So I think a lot liked that because they felt they weren't getting a dampened down version it was equal.' RD1

Successful receipt of the components of the intervention was dependent on the resources and methods of communication being tailored to the individual needs of participants. A method of communication utilised and found to be effective in both interventions, was the use of visual aids, in particular in the TAKE 5 intervention the use of fat and sugar models to illustrate the quantities in food products was considered a powerful technique in facilitating understanding of key nutrition messages.

'I think the sugar test tubes and the fat test tubes to me they were just a godsend people would say "have you got your test tubes again" They would go "I can't believe that a McDonalds has got so much fat in it and it's all visual stuff. I know a lot of them will still think about that.' RD2

5.8.5 Intervention components

There is a degree of overlap between the components of both interventions (see figure 4.3). The successful components identified in both interventions were discussed by the research dietitians.

5.8.5.1 Diet

In both interventions participants with support from carers were asked to complete food diaries. The format of the food diaries were different across interventions. In TAKE 5 this was in the form of ticking off food portions based on the *EatWell* plate and in WWToo this was based on the traffic light system (Detailed description of food diaries is discussed in the methods sections 4.10; 4.11). Both formats were reported to be successful for some participants.

'They liked doing the diaries, writing it down, showing people, and showing me and the carers, well these were the ones who could do it and I think it probably opens up conversation that they would be able to discuss their weight or being a point of interest to them, and something that is theirs.' RD1

The research dietitians were asked to identify any aspects of the intervention sessions that were considered as challenging or ineffective. The absence of quantitative dietary advice in WWToo was highlighted by one research dietitian as an issue in that it was harder to monitor participants' dietary changes and progress.

'There were no proper amounts of calories that weren't worked out for example. So it was harder for me to see improvements or to see where things could change.' RD1

5.8.5.2 Physical activity

Support to increase physical activity was well received and changes in this behaviour were observed. Although it was reported that small changes in physical activity did occur, they might not have been sufficient to have a significant effect on the outcomes of the study.

'Other things that I observed was a lot more exercise, people dancing in their bedroom that seems to be really really good for a lot of people, which is fab. That was mostly in Take 5 with the pedometers so they could record their steps, so were trying to reach a given step count.' RD2

'Physical activity definitely increased and everybody changed something a little bit. Maybe it wasn't enough but they did change something and again I think that comes down to support and care'. RD2

5.8.5.3 Behaviour change techniques

A key component to the weight management interventions was the incorporation of behaviour change techniques goal setting and self-monitoring of diet and physical activity. The techniques included were adapted from mainstream interventions, however it was uncertain whether adults with intellectual disabilities had the cognitive abilities and skills to understand, reflect and implement these techniques.

'At the moment I am not convinced they were self-monitoring.' RD1

'The only thing about being weighed was it was positive whatever. There were very few who understood a number as being higher or lower than a previous number.' RD1

Participants with mild to moderate intellectual disabilities were more able to implement these behaviour change techniques and it was reported that this was an effective component and was often used as a source of discussion at subsequent appointments.

'Goal setting worked, they liked doing goals they weren't SMART goals by any sense but they were goals and most time they would remember their goals the next week when I would speak to them.' RD1

'Being weighed definitely helped people like that, everyone liked that regardless, more than mainstream groups way more.' RD1

Participants with more severe or profound intellectual disabilities were reported to be unable to monitor their own behaviour and were therefore reliant on carers in supporting weight loss. These are preliminary findings, but highlight that not all individuals have the ability to

self-monitor their behaviour which is a key consideration when implementing weight management interventions in this population group.

5.8.5.4 Implementation

Factors affecting the implementation of the weight management interventions were explored. The research dietitian highlighted the role of carers as a key facilitator in implementing the behaviour changes techniques and supporting healthy lifestyle choices, diet and physical activity, to facilitate the weight loss. Participants supported by consistent and engaged carers were associated with greater weight loss

'She was a success on Take 5 and it was totally down to the staff and they stuck to their guns and they didn't have to. They could have given her chocolate for an easy life and they made her walk round the block despite her throwing big tantrums about it so that was good. RD1 She did well solely because staff were good.' RD1

'The ones with the most support I would say probably lost the most weight but that was the same with physical activity as well.' RD2

On the contrary, challenges that were identified in the implementation of the intervention sessions included the lack of support from carers. Adults with less severe intellectual disabilities although have the autonomy to make decisions and lived independently, it was observed that the additional support from carers would have been beneficial. Indeed, the lack of engagement from carers was identified as a barrier to achieving successful weight loss.

'I have got a few I used to go and see and there was no support and it made it more difficult'. RD2

'There was some people that had a mild intellectual disability but could have still done with carer support so sometimes I would turn up and they would be in charge of their own lives and how they arranged it but maybe they would have a carer once a week who would pop in and visit them.' RD1

'So some carers weren't that supportive and some family wasn't supportive in that denying all knowledge of them having anything apart from fruit and veg, yet he was one of our

heaviest people his weight was 107kilos and he lost no weight despite his mum being adamant he wasn't eating and there was clearly something going wrong.' RD1

It was also highlighted that a lack of consistency in support due to multiple carer involvement was perceived as a barrier.

'It was difficult when there was more than one carer involved, so sometimes I had a main carer who was on the ball and there from the beginning and other carers came in later on in the programme they didn't know about it, it was always offered to go over but sometimes the carers weren't that bothered any way. It was always a possibility that you could speak and do extra carer sessions if they needed it but most didn't want that.' RD1

In addition to the social support from carers both research dietitians agreed that their presence and company (professional support) at sessions was a motivational factor for participants to lose weight.

'The support and me turning up and the lady called Sarah, again pleasing me was quite a big one.' RD1

'They just liked the company and wanted us to come round.' RD2

The dietitians were also used as motivation by carers in between appointments.

'And staff would use that RD1 is going to be cross with you and what would RD1 say if you ate that chocolate bar?' RD1

Chapter 6: Discussion

6.1 Introduction

The management of obesity is an international health concern, particularly for adults with intellectual disabilities who have equivalent or greater rates of obesity in comparison to the general population (Melville *et al.*, 2007; Rimmer & Yamaki, 2006). The health risks associated with obesity have shown to have a negative impact on the health of adults with intellectual disabilities, exacerbating already prevalent health conditions in this population and further reducing their life expectancy (Cooper *et al.*, 2004). The level of evidence for the management of obesity for this population group has been identified as insufficient in comparison to the available literature in the general population. This is supported by evidence from national clinical guidelines (SIGN, 2010; NICE, 2014) and previous systematic reviews (Hamilton *et al.*, 2007; Jinks *et al.*, 2011; Spanos *et al.*, 2013a) in recognising that more research is required to provide equality of service provision in the treatment of obesity for adults with intellectual disabilities. This thesis aimed to fulfil current gaps in the research by examining the effectiveness of multi-component weight management interventions for adults with intellectual disabilities and piloting and evaluating a randomised controlled trial of a multi-component weight management intervention consistent with clinical recommendations on the treatment of obesity. This chapter will provide an overview of the principal findings of the studies conducted for this thesis. The outcomes of the pilot randomised trial will be discussed in terms of feasibility and acceptability to participants, potential efficacy of outcomes, and key findings will be discussed in relation to previous research. In addition to the outcome evaluation, evaluation of the study processes including fidelity, implementation and exploring the effective and ineffective components will also be discussed. This chapter will conclude with recommendations and areas for future research.

6.2 Summary of principal findings

6.2.1 Systematic review of multi-component weight management interventions in adults with intellectual disabilities

The systematic review identified that current randomised controlled trials of multi-component weight management interventions in adults with intellectual disabilities do not meet current clinical recommendations on the management of obesity. The current available evidence elicited a small insignificant effect on weight loss in comparison to no treatment and no studies reported whether participants achieved clinically important results of 5-10% weight loss. The interventions primarily focussed on a health education approach, and although one intervention appeared to potentially be efficacious, issues regarding reporting bias and confounding factors including differences in baseline characteristics prevented interpretation of results. The sustainability of changes in body weight has not been extensively explored in the management of obesity in adults with intellectual disabilities, therefore longer term studies with a distinct weight maintenance phase were recommended. Direct comparison of the active ingredients of multi-component weight management interventions revealed non-significant results. This was primarily due to the homogeneity of behaviour change techniques used in the interventions and also challenges with the identification of the active ingredients of the intervention, due to limited reporting on intervention components. Therefore, due to the uncertainty over the efficacy of interventions founded on a health education approach, recommendations from this review were for future weight management interventions to adhere to current UK clinical recommendations, in particular including an EDD, support to increase physical activity and support from carers in the implementation of the intervention (NICE, 2014; SIGN, 2010). The results of this review are in contrast to the abundance of interventions on weight management in the general population (Avenell *et al.*, 2004; Loveman *et al.*, 2011; Hartman-Boyce *et al.*, 2014). Evidence in the general population provides support for the EDD approach in the treatment of obesity. The disparity in the evidence between the two population groups is concerning and may be attributed to the limited funding and resources in research involving adults with intellectual disabilities.

6.2.2 Pilot randomised controlled trial of the TAKE 5 multi-component weight management intervention in comparison with an active comparator intervention.

This is the first ever study of a randomised controlled trial of a weight management intervention in adults with intellectual disabilities which satisfies clinical recommendations on the management of obesity: including an EDD, adequate weight maintenance component and provided 12 month follow up to examine the potential efficacy of the intervention (NICE 2014; SIGN 2010). This study overcame the barriers to involving adults with intellectual disabilities in research and demonstrated the successful recruitment and retention of adults with intellectual disabilities to a randomised controlled trial of two weight management interventions. The principal findings of this study are that an EDD approach to weight management is acceptable and effective when tailored to the specific needs of adults with intellectual disabilities. This study adds to the limited evidence of weight management interventions in this population group and provides preliminary evidence that an EDD approach to weight management may be efficacious in the treatment of obesity. Furthermore, this study provides additional evidence that current practice based on a health education approach is ineffective in the treatment of obesity in adults with intellectual disabilities.

6.3 Feasibility of the pilot randomised controlled trial

The TAKE 5 multi-component weight management intervention was originally developed by a multi-disciplinary team of researchers and health professionals to reflect the recommendations for weight management advocated by UK clinical guidelines. The GCWMS largely implemented this guidance and their service (Morrison *et al.*, 2012; Logue *et al.*, 2014) was a useful model for developing the TAKE 5 intervention. TAKE 5 met clinical guidelines for multi-component weight management interventions, including an EDD, support to increase physical activity and behaviour change techniques (SIGN, 2010; NICE, 2014). An evaluation of the single stranded TAKE 5 intervention was conducted by Melville and colleagues (2011; Spanos *et al.*, 2015), and demonstrated that it led to significant improvements in health risk factors including body weight, BMI, waist circumference and an increase in physical activity and reduced time spent in sedentary behaviour. Therefore, the benefits of the pilot intervention, provided the foundation on which this thesis was built and following research guidance on developing and evaluating complex interventions (MRC 2000; 2008). To provide a reliable and accurate investigation of the

potential efficacy of the TAKE 5 multi-component weight management intervention, a randomised controlled trial was required. This is a fairly novel design in intellectual disabilities research, as few randomised controlled trials of weight management interventions previously have been conducted (Hamilton *et al.*, 2007; Spanos *et al.*, 2013a). Therefore, prior to a full-scale trial this thesis aimed to address questions over the feasibility of key processes including recruitment of adults with intellectual disabilities, acceptability of outcomes and provide data for sample size calculations to determine whether or not a full-scale trial could be justified.

6.3.1 Recruitment

The recruitment strategy was found to be effective and fifty participants were randomised to either intervention group. The successful recruitment to this study was better than anticipated. Previous research has reported minimal participation of adults with intellectual disabilities in research (Iacono, 2006) and is evident by the small sample sizes of weight management interventions in this population group identified in chapter two and previous systematic reviews (Hamilton *et al.*, 2007; Jinks *et al.*, 2011; Spanos *et al.*, 2013a). This was in contrast to the evidence on weight management interventions in the general population. The small sample sizes may reflect the limited resources and funding available to researchers in this field (Lennox *et al.*, 2005) and the challenges reported to recruiting adults with intellectual disabilities (Cleaver *et al.*, 2010; Lennox *et al.*, 2005). Recruitment in this trial was shown to be feasible and acceptable to adults with intellectual disabilities. This study utilised a multi-point recruitment strategy developed by Foster and colleagues (2011) based on the success of recruitment of adults with intellectual disabilities to a walking intervention (Mitchell *et al.*, 2013; Melville *et al.*, 2015). This strategy overcame the barriers and challenges often reported previously to recruitment such as ethical procedures consistent with the inability to have direct contact with participants and procedures of taking informed consent (Cleaver *et al.*, 2010; Lennox *et al.*, 2005). Barriers were overcome by utilising the advice from Lennox *et al.*, (2005) and identification of a key worker/carer known to the potential participant with intellectual disabilities was a priority. The personal approach to recruitment, achieved by meeting participants and carers in person to build up a rapport with participants, aimed to eliminate potential barriers to participating in a research study (Foster *et al.*, 2011). Although the final sample of 50 participants were successfully recruited in this study, this was short of the original target sample size of 66 participants. The decision made

to stop recruitment at 50 participants was justified based on following reasons; the demand capacity of the research dietitians was near maximum and therefore, enrolling additional participants was believed to potentially threaten the validity of the delivery of the interventions; as this was a pilot trial extending the recruitment period would require additional resources for the researcher and the research dietitians which was not feasible and would prohibit completion of the trial in the desired timeframe; finally, one of the aims of this study was to provide sufficient insight into the feasibility of the recruitment and retention rates to inform a full-scale trial and not to provide sufficient power to determine the efficacy of the between group differences in outcomes. This aim of this study was achieved by demonstrating the successful recruitment of participants from multiple organisations.

It was difficult to compare the effectiveness of the recruitment strategy of this study with previous trials of weight management interventions as the majority of studies did not report how participants were recruited (chapter two). With the exception of Beeken *et al.*, (2013), reporting that their recruitment strategy was based on self-referral or referral by carers or health professionals in response to advertisements through posters in services and day care facilities utilised by adults with intellectual disabilities. Fifty participants were recruited to this study over a 12 month period, and short of the target original sample size of 60 participants. Full results of this study have as yet not been reported, therefore reasons for the shortfall in the target sample size remain unclear. However, it is postulated that this may be mainly due to the difficulties in recruitment as discussed above.

Feasibility issues of recruitment to randomised controlled trials were also prevalent in clinical trials in the general population (Campbell, Snowdon, Francis, Elbourne, McDonald, Knight, & Grant, 2007; McDonald, Knight, Campbell, Entwistle, Grant, Cook, & Snowdon, 2006). For example, a recent review investigating recruitment strategies to enrolment in randomised controlled trials, revealed that of the 114 trials of lifestyle interventions included in this review, only 31% achieved their original target and furthermore, 45% achieved less than 80% of the calculated sample size (McDonald *et al.*, 2006). In summary, it is recommended that clinical trials aiming to recruit participants with intellectual disabilities should implement a pre-planned recruitment strategy. Future trials of multi-component weight management interventions should build upon the successful recruitment of this study in order to provide sufficient sample sizes to ensure statistically significant results for clinically important effects.

6.3.2 Retention

Acceptability of the intervention was evident by the retention rates which were extremely high in this study, 90% at six months and 12 months. The retention rates were similar in both interventions (92.3% and 87.5%, TAKE 5 and WWToo, respectively). The retention rates in this study are comparable to the high retention rates in the feasibility studies of the weight loss (Melville *et al.*, 2011) and weight maintenance phases (Spanos *et al.*, 2015). As these were conducted separately and eligibility criteria into the second phase re-assessed, retention rates were 87% and 90% for the two discrete phases at six months and 18 months from baseline. The high retention rates are in contrast to the single stranded evaluation of the WWToo intervention by Jones *et al.*, (2015), which reported only half (52%) of the participants enrolled in the study completed the intervention. It is speculated that this could be due to the group delivery of the intervention and the need to attend the sessions outside the home or with support from carers. Comparison of the long term retention to multi-component weight management interventions in adults with intellectual disabilities is limited as only two studies examined retention rates at 12 months (Fox *et al.*, 1984; Bergström *et al.*, 2013). The results of this study and the above randomised controlled trials of multi-component weight management interventions in adults with intellectual disabilities compare favourably with the retention rates of studies conducted in the general population. Comparison of drop-outs with weight management interventions for adults with obesity were 30-60% at 12 months (Douketis *et al.*, 2005). Retention rates were higher for adults with intellectual disabilities and obesity in this study in comparison to clinical trials of weight management interventions in the general population.

6.3.3 Adherence

Acceptability of the intervention was also measured by attendance at the intervention sessions. Adherence to the intervention was high with greater than 75% during the weight loss phase and weight maintenance phase in both interventions. The one-to-one delivery of this intervention and the option to conduct the sessions at the participants' location of choice may explain the high attendance levels. However, previous research in intellectual disabilities has not evaluated adherence and the process of the delivery of the intervention in depth. The majority of studies on weight management interventions in adults with intellectual disabilities delivered the interventions in a group setting and a set location, therefore comparison with other evaluations remains difficult (Chapter two). The high

attendance rate is in agreement with an individualised multi-component weight maintenance intervention conducted in the general population. Process evaluation with the therapists delivering the intervention reported that the one-to-one delivery of the intervention in person was higher than when the intervention was delivered by telephone and also that the individual delivery in the participant's home environment prevented poor adherence to the intervention sessions (Simpson *et al.*, 2015).

6.4 Acceptability of outcomes

In order to detect clinically important changes in outcomes, it is important that outcomes are acceptable to participants and can be measured accurately and reliably. The main outcomes under investigation in this study were anthropometric variables, objective assessment of physical activity and health related quality of life.

6.4.1 Anthropometric outcomes

Measurement of body composition was well received by participants, overall compliance to measurements ranged between 86% and 100% of all measurements. Body weight and height measurements to calculate BMI were acceptable to all participants with intellectual disabilities. Waist circumference could not be measured accurately in three participants with severe/profound intellectual disabilities at baseline due to difficulties with them moving or refusing to take off an outer layer of clothing by one participant. Percentage body fat was the most challenging methodological assessment in terms of acceptability to participants and accuracy of measurement. The level of compliance with the measurement was reported to be lower in comparison to other anthropometric assessments (86%). For example, at baseline seven participants reported that they did not want this measurement to be taken or the researcher had issues in accurately measuring triceps skinfold. Percentage body fat could not be measured in one participant due to clothing restrictions. It was noted that a greater proportion of adults with severe or profound intellectual disabilities had difficulty with the acceptability of this measurement technique.

The results of this study on the feasibility and acceptability of anthropometric measurements are consistent with the available literature. For example, a study by Verstraelen and colleagues (Verstraelen, Maaskant, Knijff-Raeven, Curfs, & van Schroyen Lantman-de Valk, 2009) investigated the feasibility of BMI, waist circumference and skinfold

measurements in 76 adults (age range 19 to 72 years) with intellectual disabilities. Participants were classified as underweight (14%), normal weight (50%), overweight (18%) and obese (18%). BMI and waist circumference were shown to be feasible in all participants, whereas skinfold measurements were slightly less acceptable with five participants reported to not be able to tolerate this measurement due to fear of the skinfold callipers. This study, however, did not report level of intellectual disabilities and therefore it is unclear if the lack of acceptability in some participants was limited to a specific subgroup of adults with intellectual disabilities. Furthermore, Temple & Walkley, & Greenway, (2010) investigated the accuracy of BMI in measuring adiposity in adults with intellectual disabilities against a criterion measure, DEXA. Data from 46 adults (age range 19 to 60) with mild to moderate intellectual disabilities was obtained. Participants again varied in their weight status from normal weight to morbidly obese (Mean BMI 27.7 kg/m²; range 18.4 kg/m² to 42.3 kg/m²). Linear regression analysis was used to investigate the association between the two measurement techniques. BMI was strongly associated with direct assessment of adiposity ($R^2 = 0.83$) and therefore shown to be a reliable measure of adults with intellectual disabilities.

The feasibility of anthropometric measurements in the above research included adults with mild to moderate intellectual disabilities or as in the study by Vestraelen *et al.*, (2009) the level of intellectual disabilities was not reported. In the current study, body composition was assessed in adults with all levels of intellectual disabilities and it was found that skinfold measurements were not feasible in adults with severe intellectual disabilities. This is in agreement with a previous study in adults with severe intellectual (weight status: underweight 4%; normal weight 65%; overweight 27% and obese 4%) and sensory disabilities (Waninge, Van der Weide, Evenhuis, Van Wijck, & Van der Schans, 2009). Waninge *et al.*, (2009) also examined the feasibility of BMI and waist circumference with high levels of feasibility ($\geq 95\%$) whereas skinfold measurements were found to be feasible in 82% of measurements. An explanation for the lower level of acceptability to this population was due to a proportion of participants becoming agitated during the measurement and being unable to remain still upon feeling the pinch of the callipers. This limited accurate assessment of the measurement as it takes two seconds, with the callipers in place, before a reading of a skinfold thickness can be taken. In this current study the researcher was aware of these potential effects on anxiety and agitation and did not want to provoke these symptoms. Any signs of discomfort with the suggestion of the measurement or occurrence when performing the measurement, resulted in the measurement not being

conducted. Due to the enhanced impairment in cognitive abilities of adults with severe or profound intellectual disabilities, barriers with understanding their environment and/or the measurements being taken may limit the feasibility of skinfold measurements. Future research is warranted in the assessment of body fat for this subgroup of adults with intellectual disabilities.

6.4.2 Physical activity outcomes

Objective assessment of physical activity by accelerometers was shown to be acceptable to adults with intellectual disabilities. Compliance with the accelerometers was reported to be extremely high at baseline (94%), however, this decreased to 76% and 63% at six and 12 months, respectively. As data were analysed retrospectively on completion of the study, issues regarding compliance were not identified and reasons for non-compliance were not formally explored. Compliance strategies were conducted throughout the study with weekly telephone calls facilitating as a reminder to participants and carers to encourage maximum wear time (Trost, McIver, & Pate, 2005). However, it was noted by the researcher that, in some circumstances there may have been resistance from carers to the participants wearing the monitors. This could perhaps be due to a lack of understanding of the importance of the monitors or carer's making assumptions about the participants' willingness to wear accelerometers. Since carers play an integral role in supporting this population with decision making, future studies should aim to educate the carers and participants on the importance of capturing physical activity levels through accelerometer wear. Indeed, compliance strategies shown to be effective in the general population include providing more education on the accelerometer so participants know why they are wearing them (i.e. explaining the output from the accelerometer) (Trost *et al.*, 2005) and getting participants to complete an activity monitor log. Future studies should aim to implement these strategies with both participants and carers in order to maintain high rates of compliance and provide more valid physical activity data.

6.4.3 Health related quality of life

Due to the lack of burden to participants all questions asked in the process of this trial, all were found to be acceptable to adults with intellectual disabilities and their carers. The five dimensions of the EQ-5D were answered by all individuals or by proxy responses from carers (i.e. with participants with more, severe profound intellectual disabilities). However,

the majority of participants were unable to answer the EQ VAS. Participants who could answer the EQ VAS had predominantly mild intellectual disabilities. In the original analysis, it was proposed that ratings from individuals with mild intellectual disabilities and their carers would be compared. However, challenges in the interview setting in that carers would in some circumstances want to answer for the individual independent of level of intellectual disabilities meant that in some cases due to acquiescence of participants, their responses matched carers and vice versa. Few studies have examined the acceptability of the EQ-5D questionnaire in adults with intellectual disabilities. One study by Melville *et al.*, (2015) also reported that participants were unable to complete the EQ-VAS and did not report the results of participants who were able to complete the scale, therefore comparison with other studies is limited. The difficulties arose in this study due to proxy response and the turnover of staff meant in some case measurements at all three time points were not completed by the same carer.

6.5 Potential efficacy of interventions

The primary efficacy analysis for this study was completers ITT, as this maintained the original treatment random allocation to the TAKE 5 intervention and the WWToo intervention, therefore, minimising any confounding biases such as differences between baseline characteristics that may influence the outcome. Exploratory analysis was conducted to examine the potential efficacy of the intervention under ‘ideal’ conditions in which participants were defined as adhering to the intervention and finally sensitivity analysis was also conducted to examine the validity of the results. The main discussion and conclusion on the potential efficacy of the TAKE 5 and WWToo interventions was based on the results of the completers ITT analysis, as this reflects what would happen in clinical practice. However, where relevant, per-protocol results and results of the sensitivity analysis will also be discussed.

6.5.1 Weight management

The primary results of this study provide preliminary evidence that the TAKE 5 intervention may be an effective weight loss strategy. The within group analysis revealed that participants in the TAKE 5 intervention achieved significant reductions in body weight, BMI, waist circumference and percentage body fat at six months and 12 months which were not found in participants completing the WWToo intervention. Although there was no between intervention effect of the TAKE 5 intervention in comparison to the WWToo intervention,

this was due to the small sample size of this study which was not sufficiently powered to detect between group differences. At 12 months the proportion of participants achieving a clinically important weight loss, although not statistically significant, was 50% of participants in the TAKE 5 intervention in comparison to 21% of the proportion of participants in the WWToo intervention. This finding is extremely influential in terms of effective weight management approaches for adults with intellectual disabilities and provides preliminary evidence of the potential efficacy of the EDD as an alternative approach to weight management over current practice of health education interventions.

6.5.1.1 Comparison with single stranded studies

Comparison of the interventions used in this study with the original pilot investigations is important to determine if progress has been made in terms of the development of the intervention and the potential efficacy. Comparison of the weight loss results of this study of the TAKE 5 intervention at the end of the weight loss phase (-2.93 kg 95% CI -4.42 kg to -1.44 kg) with the original pilot study by Melville and colleagues (2011), (-4.47 kg 95% CI -5.91 kg to -3.03 kg), revealed a slightly lower absolute weight loss and clinically important weight loss of 5-10% of initial body weight (20.5% vs 36.2%, respectively). However, adhering to clinical recommendations, the true time point to examine the efficacy of an intervention is at 12 months. At the end of the weight maintenance phase and end of the intervention, participants in the TAKE 5 intervention in this study had continued to lose weight, (overall weight change from baseline at 12 months: -3.55 kg; -5.59 kg to -1.52 kg). This may reflect the design of the study, as if participants had not achieved a clinically significant weight loss of 5% at six months they were offered the option to continue to lose weight for a further three months, followed by three months of weight maintenance. This compares favourably to the changes in body weight in the single stranded weight maintenance phase in which participants did not maintain a significant reduction in body weight, -0.6 kg (SD 5.5 kg; $p = 0.5$). Based on the definitions by Stevens *et al.*, (2006), fifty-eight percent of participants maintained their weight loss in this study in comparison to 50% of participants in the single stranded study (Spanos *et al.*, 2015). Moreover, fewer participants gained weight (13% vs 29%) and a higher percentage of participants continued to lose weight (29% vs 21%) in this study. Although, these results should be interpreted cautiously due to the differences in the duration of the weight maintenance period by Spanos *et al.*, (2015) which was 12 months in comparison to the six months weight maintenance

phase in this study, the results suggest that TAKE 5 can achieve sustainable clinically important changes in body weight.

Comparison of the WWToo intervention with the retrospective evaluation by Jones *et al.*, (2015) is difficult as the two interventions under investigation are distinct. The WWToo utilised in this study was adapted from the original format in terms of the delivery of the intervention, from a group based to an individual based intervention with one-to-one contact with a dietitian; the addition of the involvement of family and paid carers in supporting participants to make healthy lifestyle choices; addition of a weight maintenance sessions and finally the increased number of sessions and duration of the intervention from eight to fifteen sessions and 13 weeks to 12 months. In the original group based intervention, participants were reported to have significant reductions in weight, BMI, waist circumference and 26% of participants lost 5-10% of initial body weight. It is important to take into consideration limitations of the single stranded observational study of the WWToo intervention when interpreting these results. Firstly, this study is subject to a high risk of detection bias as researchers collecting outcome measures were not blinded and it has been shown in clinical trials that unblinding of study outcomes can exaggerate the treatment effect (Hróbjartsson *et al.*, 2012). Secondly, the duration of the study was very short therefore, the sustainability of the change in outcomes is uncertain and does not meet clinical recommendations on examining the efficacy of interventions for weight management. Re-evaluation of interventions at the feasibility and piloting stage is central to informing and justifying a full-scale clinical trial. Based on the results of this study, it appears that even in a more intensive format of the WWToo intervention in terms of delivery with increased frequency of sessions and level of support on a one to one basis, does not support the findings of the original study as a potential approach to weight management in adults with intellectual disabilities.

6.5.1.2 Comparison with randomised controlled trials in adults with intellectual disabilities

This thesis identified a paucity of randomised controlled trials of weight management interventions in adults with intellectual disabilities. The current available evidence did not meet current clinical recommendations on the management of obesity and elicited small non-significant effects on weight loss in comparison to no treatment. Furthermore, the quality of the current evidence base, is subject to poorly conducted trials which in general have small samples sizes and were not adequately powered. Furthermore, current studies have

methodological limitations and risk of biases including confounding factors, selective reporting and attrition bias which limit the efficacy of results. This is the first ever randomised controlled trial to adhere to clinical recommendations. This study was carried out using robust methods which aimed to provide an unbiased assessment of the effect of the intervention. Furthermore, this is the first study to illustrate the acceptability of an EDD in adults with intellectual disabilities and report clinically important weight loss. Future studies, should aim to emulate the high-quality design of this study, in order to evolve the field of weight management in adults with intellectual disabilities.

6.5.2 Physical activity and sedentary behaviour

The results of this study are consistent with previous research in that adults with intellectual disabilities are at increased health risk due to the adoption of sedentary lifestyles and lack of engagement in physical activity (Bartlo & Klein., 2011; Temple & Walkley, 2003). Participants in both interventions were reported to participate in 153.4 minutes/day (SD 62.5) of light and 30.1 minutes/day (SD 19.6) of moderate to vigorous physical activity. The baseline results of the physical activity levels in this study are higher than the physical activity levels reported in the single-stranded feasibility study, with baseline moderate to vigorous physical activity double the level reported by Melville *et al.*, (2011). However, this is still low in comparison to the evidence of physical activity in the general population and consistent with previous research for adults with intellectual disabilities (Phillips *et al.*, 2011).

At 12 months the study found no effect in time spent in physical activity at either light, moderate or vigorous intensity or time spent sedentary. This replicated the findings found at the end of the weight maintenance period in the TAKE 5 weight maintenance study by Spanos *et al.*, (2015). Furthermore, few of the randomised controlled trials of multi-component weight management interventions measured the effect of the intervention using objective assessment of physical activity. Only one study measured physical activity by accelerometer (McDermott *et al.*, 2012). Another study utilised pedometers to measure physical activity (Bergström *et al.*, 2013), on the basis they had shown high agreement with accelerometer-measured physical activity (Le Masurier & Tudor-Locke 2003; Tudor-Locke, Ainsworth, B. Thompson, & Matthews 2002). McDermott *et al.*, (2012) reported consistent finding with this study in that participants engaged in high levels of sedentary behaviour (87.4% of accelerometer wear time spent sedentary). The main physical activity outcome

was solely focussed on moderate to vigorous physical activity. This was shown to not to be significantly increased at 12 months from baseline in comparison to the control intervention. However, in contrast participants in the study by Bergström and colleagues (2013), reported a significant increase in step count at 12 months their multi-component intervention in comparison to no treatment control intervention (1608 steps per day; 95% CI 42 to 3137; $p = 0.045$). Although a significant increase in step count is reported this is not of significant magnitude to have any clinical benefits from change in physical activity levels. However, difficulties in making direct comparisons with the single stranded study and previous research due to different models of accelerometers used, different cut points used to categorise intensities of physical activities and uni-axial, multiple-axial devices used are some of the challenges in comparing data (Rothney, Apker, Song, & Chen, 2008; Thompson, Batterham, Markovitch, Dixon, Lund, & Walhin, 2009).

Irrespective of the methodology issues in comparing objective measures of physical activity across studies, adults with intellectual disabilities and obesity engage in low levels of physical activity. The reported low levels of physical activity and adoption of sedentary lifestyles in this population group is largely due to the increased barriers individuals with intellectual disabilities face in leading physically active lifestyles. Barriers commonly reported for adults with intellectual disabilities include; a reduced cognitive ability to understand the benefits of engaging in regular physical activity and a lack of awareness of available physical activity options, limited time capacity and support from carers to assist engagement in physical activity (i.e. taking a service user for a walk) and limitations in transportation (Hawkins & Look, 2006; Bodde & Seo, 2009). Although, this study did not explore barriers to engagement in physical activity directly, it was reported in the process evaluation that contextual factors and the engagement of carers were influential in changing this behaviour. It was reported in the qualitative interviews with the research dietitians that physical activity goals were not achieved in some participants due to the environment and concerns over safety in performing physical activity outside the home. The negative impact of the environment can be further illustrated as 42.0% of participants lived in the most deprived areas of Glasgow. This is in agreement with previous research discussing the barriers and facilitators to engagement in physical activity by a recent study by Melville *et al.*, (2015). Melville *et al.*, (2015) attributed the ineffectiveness of their walking intervention in part to the unsupportive environment. If the environment in which the participants are resident is not supportive of physical activity, more emphasis should be placed in future studies on feasible home based activities and interrupting sedentary behaviour.

6.5.3 Health related quality of life

The between group differences in change in health related quality of life were negligible, with this pattern in small insignificant changes also evident pre-post at six months and 12 months from baseline in both interventions. Comparison of changes in weight loss on health related quality of life is limited as few studies have utilised the EQ-5D in adults with intellectual disabilities (Riemsma, Forbes, Glanville, Eastwood, & Kleijnen, 2001). Only one of the multi-component weight management interventions reviewed in chapter two included a measure of the EQ-5D index, however, this study has not published full results and therefore, comparison with this study is not possible. A recent study of a physical activity/walking programme also found that there was no significant change in health related quality of life, however the intervention also had no effect on its primary outcome of change in physical activity (Melville *et al.*, 2015). The limited change in this study may be due to a high proportion of participants reporting no problems in health profiles at baseline and therefore, the EQ-5D itself might not be sensitive to changes in a population classifying themselves or from proxy respondents as in general having no health problems. This is in agreement with a recent study of a weight maintenance intervention in the general population (Simpson *et al.*, 2015), illustrated that participants with intellectual disabilities have equivalent self-reported health states as overweight and obese adults in the general population.

In a study undertaking practice nurse health checks, the authors reported that the health dimensions measured which are considered important for the general population may not be regarded as health priorities for adults with intellectual disabilities (Cooper *et al.*, 2014). Another useful tool to measure health related quality of life in weight management interventions in the general population is the short Form questionnaire-12 items (SF-12). This may provide an alternative approach to capture changes in health related quality of life. There are also obesity specific research tools to capture changes in health related quality of life following weight loss, however, the validity and interpretability of these questionnaires is uncertain (Duval *et al.*, 2006). Furthermore, their applicability to the cognitive needs and abilities of adults with intellectual disabilities requires further investigation. As proxy response is an integral component to both conducting research and clinical practice involving adults with intellectual disabilities (Finlay & Lyons, 2001), it is important that future research investigates valid questionnaires or self-report/proxy response measures to

accurately and reliably measure health related quality of life in adults with intellectual disabilities.

6.6 Validity of principal findings

Validity of the results was conducted based on the sensitivity analysis. The eligibility criteria in this study included no upper limit on weight status ($BMI \geq 30 \text{ kg/m}^2$) mirroring the procedures in clinical practice at the GCWMS (Morrison *et al.*, 2012; Logue *et al.*, 2014). Due to the small sample size of this study one participant was identified as an outlier with a weight of 212 kg and distinct from the study population mean. The effect of this participant increased the average body weight and body composition measurement at baseline, therefore analysis was conducted with and without this participant. Analysis without this participant did not affect the overall conclusion and interpretation of the results. Indeed, it is important that this participant is included in the results of the intervention as morbid obesity is shown to further increase the risk of health inequalities associated with obesity and therefore, weight loss for this population group is imperative.

An important finding of the sensitivity analysis is that one participant in the WWToo intervention was shown to lose a substantial amount of weight loss of -15 kg which was not replicated by other participants completing this intervention at 12 months. Exploration of reasons into this substantial change in body weight revealed that this was due to medical reasons and likely not a result of taking part in the intervention. Following the procedures of conducting analysis excluding outliers, the results revealed a mean weight change in the WWToo intervention of -0.5 kg (SD 3.5kg) and resulted in a significant between group difference (TAKE 5 – WWToo). This provides further evidence that the TAKE 5 intervention may be an effective approach to treat obesity.

6.7 Comparison with the GCWMS

Clinical services often judge the success of their intervention based on participants defined as completing the intervention. The GCWMS conducted a recent analysis of the efficacy of their tier three weight management programme at 12 months (Logue *et al.*, 2014). A high proportion of missing data were reported in this study; therefore, analysis was conducted by last observation carried forward (LOCF) and for completers (defined as attending 50% of the sessions in each phase). One thousand eight hundred and thirty-eight patients were

included in the LOCF analysis, reporting a weight loss of -3.6 kg (95% CI -3.9 kg to -3.3 kg) at 12 months from baseline. For completers, weight was measured directly for the participants who started the intervention and the absolute weight loss revealed a change of -7.2 kg (95% CI -8.1 kg to -6.3 kg). Furthermore, comparison of the number of participants achieving a clinically important weight loss increased from 24% (LOCF) to 51% for participants completing the intervention. The difference in results suggests that participants who adhere to the intervention produce greater effect sizes on change in body weight and clinically important weight losses. However, the interpretation of these results may be misleading as only 21.7% of participants had direct measurement of body weight at 12 months and therefore it is reported that confirmation of clinically important weight losses can only be assured for only 12% of the patients at 12 months. This raises questions over the validity of their completers analysis and may ask questions about the effectiveness of the current service.

The results of the TAKE 5 intervention compare favourably to the results in the GCWMS offered to the general population. Firstly, in terms of adherence to the intervention, a higher proportion of adults with intellectual disabilities attended the intervention sessions. Only 20% of adults with intellectual disabilities were defined as having not completed the intervention in this study, which was based on a higher acceptability rate of 75% attendance at intervention sessions. The absolute weight loss independent of analysis conducted (completers ITT or per-protocol) in this study is equivalent to the LOCF analysis reported in the GCWMS, and results for clinically important weight losses were reported for approximately 50% of the participants in TAKE 5. This illustrates that adults with intellectual disabilities can achieve significant weight losses comparable to the general population. This is in agreement with the study by Spanos, Hankey, Boyle, & Melville, (2014) comparing the single stranded weight loss study of the TAKE 5 intervention with 'matched participants' (based on gender, BMI and age) in the general population completing the GCWMS. The conclusions of the study reported that the TAKE 5 multi-component intervention was equally effective as the GCWMS in the general population. Although this thesis did not match participants and therefore direct comparison is limited, it appears to reiterate the results of Spanos *et al.*, (2014) that adults with intellectual disabilities can lose an equivalent amount of weight comparable to the general population and that a personalised dietary approach of an EDD is an acceptable and efficacious approach to weight management in this population group.

6.8 Process evaluation

The process evaluation was implemented to understand some of the feasibility measures such as recruitment and retention to the intervention, delivery and implementation of the intervention and the identification of effective and ineffective components. Investigation into these outcomes is essential to evolve intervention design and resolve any challenges or barriers to the research process or implementation of the intervention which might have the potential to be extrapolated on conducting a full-scale trial. A mixed methods design was utilised to address the above research questions, which were guided by the process evaluation framework designed by Linnan & Steckler, (2000).

6.8.1 Fidelity of the intervention

The intervention was delivered successfully by two trained health professionals (a dietitian and lifestyle counsellor). In general, the intervention was implemented as intended. Issues with study resources and capacity, at the start of the study due to the employment of only one research dietitian meant that in some circumstances sessions did not adhere to the time allocation for appointments set at 1 hour in the protocol. Delivery of session content was not compromised and this was resolved quickly with the appointment of a second research dietitian. Furthermore, it was noted that the delivery of session content did not require the full duration and no participants requested additional appointments to help facilitate understanding of session information. Duration of the intervention sessions varied depending on the intervention content. At the start of the TAKE 5 intervention in particular, sessions required the full hour to effectively communicate the information to participants. However, coverage of session content in other sessions did not require the full time allocated, and sessions lasted approximately 40 minutes. This was also found to be the case in the WWToo intervention, as delivering the intervention content on a one-to-one basis required less time than in the pilot group base study that the intervention was adapted from (Jones *et al.*, 2015). One of the reasons of conducting a pilot randomised trial was to work out the practicalities of delivering the weight management intervention. Lessons learnt from this study are that a whole time equivalent dietitian is required to deliver the weight management intervention and that appointments should be consolidated to geographical regions to maximise the research dietitian's time to see participants.

The fidelity of the delivery of the intervention sessions was good across both interventions and the research dietitians only on occasion deviated from the protocol to meet the needs of a participant such as rearranging session content design to be delivered later in the intervention to an earlier session in which it was required. Justification for changes were noted and within the scope of the intervention. This mirrored what would happen in clinical practice at the GCWMS, which the intervention aimed to replicate. As both research dietitians delivered both interventions, there is potential for contamination in crossing over of intervention content to the opposite intervention. This is a limitation of this study was that fidelity of the intervention was not recorded by a criterion method of direct observation (Hill *et al.*, 2007). However, research has shown that professionals alter the way they interact and respond when being observed and this has shown to provide an inaccurate estimate of implementation fidelity (Breitenstein, Gross, Garvey, Hill, Fogg, & Resnick, 2010). This can present, for example, either in terms of being over adherent to the protocol or if anxiety is provoked, this can lead to diminishing effects on protocol adherence and/or competency in implementing the intervention. It was also felt that either reaction would negatively affect the interaction between the participant and research dietitian which as previously discussed is shown to be a contributing factor to the successful delivery of the intervention. To maximise the fidelity of the intervention other measures including providing research dietitians with a manual of each intervention sessions and adherence to a set pre-specified protocol were implemented and checklists of the components delivered at each session (Hill *et al.*, 2007; Linnan & Steckler, 2002). A future full scale randomised controlled trial would however require multiple professionals to deliver the intervention. Therefore, to ensure fidelity, audio recording of a selection of the sessions or alternatively having different research dietitians deliver each intervention would further reduce the risk of contamination between interventions.

6.8.2 Implementation of the intervention

One of the integral components of this study was the influence of social support from carers in supporting participants to lose weight. Successful strategies associated with improvements in healthy lifestyle habits in particular included, carers supporting participants to increase their physical activity by encouraging them to go walking or interrupt sedentary time by encouraging engagement in enjoyable activities such as dancing. Furthermore,

advising on portion control and consumption of healthy food options also played an integral role in helping to achieve participants weight loss targets. This is in agreement with previous research identifying the role of social support from carers in supporting individuals with intellectual disabilities (Matthews *et al.*, 2016; Spanos *et al.*, 2013b).

The multi-component weight management interventions were based on behaviour change techniques recommended by clinical guidelines (NICE 2014; SIGN 2010) and research from high quality meta-analysis on supporting healthy eating and physical activity in the general population (Michie *et al.*, 2009). However, it was identified that in some circumstances behaviour change techniques shown to be effective in the general population may not be easily implemented in adults with intellectual disabilities due to limitations in levels of understanding and cognitive skills. The primary behaviour change techniques utilised in the interventions were goal setting and self-monitoring. Preliminary results demonstrated that adults with severe or profound intellectual disabilities were not able to self-monitor lifestyle behaviours. For example, self-monitoring of physical activity involves a process of identification of the number of steps, reflection and understanding on the amount and interpretation of the results as to whether this has improved or decreased since the last time. The three self-monitoring behaviours changes were diet, physical activity and body weight. It was reported that the food diaries were more easily interpretable to adults with intellectual disabilities than pedometers. In circumstances where adults with intellectual disabilities could not process the behaviour change techniques it was associated from the research dietitians that carers were influential in implementing the technique. This highlighted the importance of consistent and continued support from carers in helping all adults with intellectual disabilities to lose weight. Furthermore, although adults with mild to moderate intellectual disabilities have shown to have more autonomy, it was proposed by the research dietitians that additional support from carers would have been beneficial and resulted in further success in changing participants' behaviour. Previous trials reported in chapter two excluded adults with severe or profound intellectual disabilities. Therefore, this is the first study to provide weight management for all adults with intellectual disabilities and highlights with support from carers, this population group irrespective of severity of intellectual disabilities, can achieve improvements in body weight and composition.

In addition, to overcome barriers in providing complex health information and to be inclusive of all adults with intellectual disabilities the intervention included adapted methods of communication such as visual aids, drawings and games. This was highlighted as another

key facilitator in implementing the intervention. This is supported by previous research illustrating that participants learn more from visual and sensory methods of communication rather than written exercises or solely discussions (Spanos *et al.*, 2012; Holly & Sharp, 2014).

6.8.3 Effective and ineffective components

In addition to the feasibility of the implementation of the intervention, the systematic coding and identification of behaviour change techniques allowed insight into the active ingredients of the intervention. The findings of this study provide exploratory information on the process of behaviour change in supporting participants with intellectual disabilities to lose weight. This study provides support for the utility of an EDD in adults with intellectual disabilities. The research dietitians reported that quantitative dietary advice from the EDD was easier to monitor and observe progress in dietary habits. Furthermore, due to the limited effect on increasing physical activity, the main active component in the TAKE 5 intervention can be attributed to the EDD along with successful implementation of behaviour change techniques such as feedback, goal setting, self-monitoring and social support from carers.

A limiting component of this study was the lack of effect of the intervention on increasing physical activity or reducing sedentary behaviour. Investigation into the barriers and facilitators to implementation of the intervention components with the research dietitians provided an insight into why the process of this intervention component failed to elicit an effect. One explanation for this could be due to a lack of carer knowledge and education on the benefits of physical activity and current physical activity recommendations (Melville *et al.*, 2009). Although carers were involved in the implementation of the intervention, the main focus was on education and engaging the participants with intellectual disabilities. Future trials should focus on developing further resources targeting carers to improve their knowledge on the benefits of physical activity and effectively engage adults with intellectual disabilities to improve this lifestyle behaviour. The lack of change could also be related in addition to socioeconomic factors discussed previously, and the challenges in adapting complex interventions for the needs of this population group. The behaviour change techniques implemented to support increases in physical activity were feedback, goal setting and self-monitoring. Although shown to be effective in changing dietary habits, they may not have been of significant magnitude to change levels of physical activity. Evidence in increasing physical activity in obese adults in the general population suggests that effective

behaviour change techniques include self-efficacy, teach to use prompts/cues, prompt practice, and prompt rewards contingent on process or effort (Olander *et al.*, 2014). Future implementation of the intervention should take on lessons learnt from this thesis which included, reinforcing the strategy for engaging carers in the implementation of the intervention, refining the physical activity component by utilising other effective behaviour change techniques such as incorporating practice of physical activity into the sessions, providing prompts cues to stimulate increased physical activity between sessions and encourage peers and family and friends to engage in this lifestyle behaviour. Enhancement of these intervention components, in particular the support to increase physical activity in addition to the already positive changes achieved in diet, could provide a larger effect size on weight loss.

6.9 Strengths and limitations

A key strength of this research is in aiming to address the lack of evidence on the management of obesity in an underrepresented population in adults with intellectual disabilities. This thesis followed a programme of research in accordance with best practice guidance on examining and developing complex interventions (MRC 2000; 2008). This included providing an updated review of current knowledge through systematically reviewing the evidence base on weight management interventions in adults with intellectual disabilities, followed by the evaluation of a multi-component weight management intervention which fully adhered to clinical guidelines (NICE 2014, SIGN 2010). This consisted of examining the feasibility of essential processes to conducting clinical trials including recruitment and retention, examining the implementation and fidelity of the intervention and also provided insight into the mechanisms supporting behaviour change. Furthermore, a consistent strength throughout the studies in this thesis was reviewing and conducting research based on the gold standard, randomised controlled trial study design and finally, and most importantly providing weight management support inclusive of all adults with varying severity of intellectual disabilities.

The pilot randomised controlled trial was conducted rigorously and aimed to reduce potential risks of bias identified in previous studies. However, this was a pilot study and the small sample size prevented any significant between group findings and prevents firm conclusions over the efficacy of the intervention being made. Although this study aimed to adhere to guidelines of examining the feasibility of complex interventions, this study did not conduct

pilot investigation into the cost-effectiveness of the future trial. The delivery of the intervention was by a highly trained and educated dietitian and health professional based on the evidence that these professionals can have a slight improvement on increased efficacy of weight loss in weight management in the general population (Hartmann-Boyce *et al.*, 2014; Laws, 2004). However, the cost-effectiveness of employing dietitians to deliver weight management in adults with intellectual disabilities is uncertain. Furthermore, due to the limited funding and resources available to this population group, delivery of the intervention by dietitians may not be feasible on a larger scale. A future research area based on the results of this study in the association of successful implementation of the intervention by carers may include whether or not carers could be trained to effectively deliver the intervention. Future studies should undertake an economic evaluation of the TAKE 5 multi-component weight management intervention to provide evidence on whether or not the TAKE intervention is viable for implementation into practice.

As the process evaluation was conducted prior to the start of the randomised controlled trial as an additional exploratory study, there are limitations in understanding some of the process of participating in a randomised controlled trial. In particular, a lack of the measure of compliance with intervention components such as the EDD, carers experiences of supporting individuals with intellectual disabilities in the intervention and barriers and facilitators to implementing the intervention. Other limitations in conducting the process evaluation of the study include a lack of measurement of fidelity of the behaviour change techniques implemented throughout the sessions, as these were not recorded. This has importance to gain insight into whether the intervention was implemented as planned and in identifying the active ingredients of the intervention. Finally, although the qualitative interviews with the research dietitians enriched the data to provide insight into the effective and ineffective components of the interventions and the implementation of the interventions, further insight could have been achieved by interviewing participants and carers. Participants who were successful or unsuccessful in terms of their compliance with the regime and weight loss may report differently.

6.10 Research implications

Currently in the UK, there is no formal treatment pathway within the national health service for the treatment of obesity for adults with intellectual disabilities. Although services exist

for weight management in the general population, difficulties with communication, level of understanding and additional support needs means that these services are not easily accessible or even ineffective for adults with intellectual disabilities. The disparity in the provision of health services available for adults with intellectual disabilities is recognised by clinical guidelines as a major health priority (NICE 2007). It is recognised that individuals with intellectual disabilities need access to health services tailored specifically to their cognitive and communication needs, and that training of health professionals to facilitate effective communication and appropriate resources designed to meet the level of intellectual disabilities is required in order to make services more accessible to this population group. This study of the TAKE 5 weight management intervention has provided evidence to facilitate the next step of a programme of research to examine the effectiveness of the intervention. This is consistent with the MRC guidelines on developing and evaluating health interventions. Further research is necessary to provide strong support for the future implementation of this intervention as a service and reduce the inequalities adults with intellectual disabilities receive in terms of service provision for weight management.

In order to tackle the obesity epidemic in adults with intellectual disabilities, alternative strategies may also need to be considered. Prevention of obesity is often considered a desirable strategy as it is shown to be easier to prevent weight gain than to lose weight. Body weight has shown to increase over time (Anderson, Konz, Frederich, & Wood, 2001; Heitmann, & Garby, 1999) and therefore intervention strategies in the prevention of obesity should aim to tackle this problem at an earlier age. In the general population, the transition from adolescence to adulthood has been identified as a high risk period for weight gain (Gordon-Larsen, Nelson, & Popkin, 2004). There is also anecdotal evidence from health professionals that this is also a time for increased weight gain in individuals with intellectual disabilities. Strategies to tackle an increase in body weight vary in terms of intervention components (diet, physical activity and behaviour change) and there is no gold standard approach. Physical activity has shown to be an effective approach in preventing weight gain due to its role in energy balance through increased energy expenditure (Kavouras *et al.*, 2007; McTiernan *et al.*, 2007), improved appetite control and reduced energy intake (Chaput, Klingenberg, Rosenkilde, Gilbert, Tremblay, & Sjodin, 2011; Stubbs & Tolcamp, 2006). In order to develop such an intervention to prevent weight gain in young adults with intellectual disabilities, it is important that the current evidence base is evaluated. An additional research question addressed by this thesis was to systematically assess the literature on randomised controlled trials on the effects of physical activity interventions to

prevent weight gain in young adults with intellectual disabilities (Harris *et al.*, 2015). This review highlighted, consistent with the evidence for weight management in adults with intellectual disabilities, the paucity of interventions to prevent weight gain. None of the interventions identified had a specific focus to prevent adverse increases in body weight and meta-analysis reported that the physical activity interventions included did not prevent weight gain (WMD: -0.17 kg, 95% CI, -1.04 kg to 0.72 kg) or improve body composition. No effect of the interventions was found due to limitations in inadequate dose of the intervention with only two out of the six studies included meeting current physical activity recommendations to prevent weight gain. Furthermore, the duration of the interventions was short with the mean duration 15.3 weeks (range 10-21 weeks). This was designed to facilitate physiological adaptations and improvements in central aspects of fitness such as cardiorespiratory fitness and metabolic health, however, it was insufficient to investigate adaptations in body weight and no intervention adhered to clinical recommendations to examine the efficacy of the intervention on changes in body weight. Based on this evidence synthesis of single component physical activity interventions, future research recommendations were established, in terms of advocating longer term physical activity interventions and follow up period (duration 12 months) to elucidate the effects of physical activity interventions on the prevention of weight gain and body composition in young adults with intellectual disabilities.

6.11 Recommendations for implementing a full-scale randomised controlled trial

Future research into the development of a full-scale trial of the TAKE 5 multi-component weight management intervention has been detailed throughout this thesis. This section aims to summarise these recommendations and provide a comprehensive list of recommendations to evolve the programme of research in examining the effectiveness of the intervention.

6.11.1 Sufficiently powered study

As this study was underpowered to investigate the true efficacy of the intervention, a future full-scale study needs to be adequately powered. Decisions over the most appropriate comparator intervention need to be deliberated based on the justification which formed this study (section 4.2 study design). For a full-scale randomised controlled trial, utilising a TAU comparator intervention, 56 participants per group would be required to have 90% power at the 5% (two-sided) significance level. Attrition in this pilot study was 10%, however, to take

account of a TAU design a 20% attrition rate would be required for a full-scale trial, increasing the sample size to 68 per group. The majority of participants in this study were randomised as individuals with an average cluster size of 1.11. Assuming a conservative ICC of 0.2 the final recommended sample size is 140.

6.11.2 Intervention components

Future replication of this study should refine the development of the physical activity component. Based on the high levels of physical inactivity and the barriers discussed with changing this behaviour, a prescriptive physical activity component focussed on home based physical activity and interrupting sedentary behaviour is recommended.

6.11.3 Key role of carers

As carers have been highlighted as having a fundamental role in supporting behaviour change in relation to weight loss for adults with intellectual disabilities, adaptations are recommended to the intervention resources. Currently the intervention resources are solely developed for adults with intellectual disabilities (with the exception of one booklet; How to help someone lose weight). Although adults with intellectual disabilities should remain the main focus of the intervention, additional resources specific for carers are believed to be beneficial. In particular, information and resources to increase carers' knowledge on the importance and benefits of physical activity are recommended. As carers were also shown to be key facilitators in implementing the intervention, investigation into the delivery of the intervention by carers who already work with adults with intellectual disabilities is recommended. This would be after an initial training period from health professionals.

6.11.4 Sustainability of weight loss

As this was a pilot study which was conducted over a 12 month period, the sustainability of long term changes in body weight is uncertain. Previous research of multi-component weight management interventions have not been conducted for longer than 15 months. It is recommended that future studies, should provide long term follow up measures which would provide valuable insight into whether the short term changes in body weight and secondary outcomes persist over time. This would provide findings which are more generalizable to real world situations, and therefore provide evidence to support the implementation of TAKE 5 as a weight management programme in clinical practice.

6.11.5 Compliance of intervention components

It is recommended that compliance to the components of the weight management interventions, in particular the EDD, should be monitored. Methods to inform compliance to the EDD include self-monitoring in diaries completed by participants with support from carers. Although this was used as a behaviour change technique in the weight management intervention, this was not recorded as an outcome. This would identify if the components are received as intended.

6.11.6 Fidelity of the intervention

To ensure fidelity of the interventions it is recommended that audio recording of a selection of intervention sessions be used. This would allow a more accurate measure of the implementation of the intervention as intended by research dietitians and bring to light any deviations in the protocol or contamination between delivering the interventions. Furthermore, although the behaviour change techniques were mapped out at the start of the intervention, investigation into measuring the frequency and use of these techniques could help identify the active ingredients in supporting weight loss in this population group.

6.11.7 Qualitative research

To understand why there was a lack of change in physical activity, it is recommended that qualitative interviews with carers should be conducted. This would provide insight into their attitudes towards physical activity and the barriers and facilitators to engaging adults with intellectual disabilities in this component of the intervention.

6.12 Future research

The overall findings of this thesis are that there is a disparity of evidence based weight management interventions designed for adults with intellectual disabilities and that interventions based on clinical recommendations in the general population are acceptable to adults with intellectual disabilities. The findings of this thesis add considerably to the limited evidence base on the management of obesity in adults with intellectual disabilities and also provide new potential research areas to be considered in the future:

- Investigation into the importance of contextual factors formed by the social ecological model to assist the understanding of physical activity behaviour change and weight loss in adults with intellectual disabilities
- Investigation into the development of interventions to reduce the high levels of sedentary behaviour in adults with intellectual disabilities
- Investigation into alternative strategies to tackle the obesity epidemic in adults with intellectual disabilities. This should include strategies to prevent weight gain
- Investigation into the applicability of behaviour change techniques in adults with intellectual disabilities. For example, identifying if adults with intellectual disabilities can self-monitor diet or physical activity behaviours.

6.13 Conclusions

This thesis has investigated an area of clinical need. It has contributed to closing the gap between research and providing accessible weight management services for adults with intellectual disabilities. This thesis has provided an update on the current evidence using robust systematic review techniques and demonstrated the feasibility and process of conducting high quality randomised controlled trials of weight management interventions. The principal findings offer promise in the treatment of obesity and benefits to the health of this underrepresented population group.

Appendices

Appendix i: Systematic review search strategy

Medline search strategy used to identify multi-component weight management interventions in adults with intellectual disabilities and obesity.

1. exp Intellectual Disability/
2. exp Mentally Disabled Persons/
3. (intellectual* adj (disab* or disorder* or handicap* or impair* or deficien* or subnorm*)).tw.
4. (learning adj (disab* or disorder* or impair* or difficult*)).tw.
5. (development* adj (disab* or disorder* or handicap* or impair* or delay*)).tw.
6. (Mental* adj (disab* or disorder* or handicap* or impair* or deficien* or subnorm* or retard*)).tw.
7. 1 or 2 or 3 or 4 or 5 or 6

8. exp Exercise/
9. exp Exercise Therapy/
10. exp Physical Fitness/
11. exp Motor Activity/
12. exp Sports/
13. exp "Physical education and training"/
14. (fit* adj (regime* or program*)).tw.
15. ((moderate or vigorous*) adj3 activ*).tw.
16. (physic* adj5 (fit* or train* or activ* or endur* or intervention*)).tw.
17. (exercis* adj5 (aerobic* or train* or fit* or activ* or endur* or intervention*)).tw.
18. (gym* or circuit* or aqua* or walk* or jog* or run* or swim*).tw.
19. (weight lift* or strength train* or resistance train* or circuit train* or aerob* train*).tw.
20. ((lifestyle or life-style) adj5 (activ* or physic*)).tw.
21. Exercise*.tw.
22. Physical Activ*.tw.
23. exp Diet/
24. exp Diet Therapy/
25. exp Caloric Restriction
26. exp Diet, Fat-Restricted/ or exp Diet/ or exp Diet, Carbohydrate-Restricted/
27. exp Nutrition Therapy/
28. exp Nutritional Support/
29. (nutrition* or food or carbohydrate* or protein or fat*).ti,ab.
30. ((diet or dieting) adj5 (health* or weight*)).tw.
31. (calorie adj3 (control or reduc* or restriction)).tw.
32. Nutrition education.tw.
33. diet*.tw.
34. exp Behavior therapy/
35. exp cognitive therapy/
36. exp psychotherapy/

- 37. exp family therapy/
- 38. (behavio* adj3 (therap* or technique* or modif* or intervention*)).tw.
- 39. (cognit* adj3 (therap* or technique* or modif* or intervention*)).tw.
- 40. CBT.tw.
- 41. (psychotherapy* or pyscho-therapy*).tw.
- 42. exp Health Promotion/
- 43. (health* adj3 (promot* or educ* or lifestyle)).tw.
- 44. OR 8-43

3

- 45. exp Obesity/
- 46. exp Body Weight/
- 47. exp Body Weight Changes/
- 48. exp Weight Gain/
- 49. exp Weight Loss/
- 50. exp Body Mass Index/
- 51. obes*.tw.
- 52. ("weight gain" or "weight loss").tw.
- 53. (overweight or "over weight" or over-weight).tw.
- 54. (weight adj2 (loss or lost or losing or reduc* or change*)).tw.
- 55. (body weigh* or bodyweigh* or body mass* or bodymass or body fat* or bodyfat*).tw.
- 56. (bmi or "body mass index").tw.
- 57. ((bmi or "body mass index") adj2 (gain or loss or change*)).tw.
- 58. body composition.tw.
- 59. OR 45-58

- 60. exp Intervention studies/
- 61. exp Evaluation studies/
- 62. Randomized controlled trial.pt.
- 63. Controlled clinical trial.pt.
- 64. Clinical trial.pt.
- 65. (randomized or randomised).ti,ab.
- 66. Randomly.ti,ab.
- 67. Trial.ti,ab.
- 68. Groups.ti,ab.
- 69. OR 60-68
- 70.7 AND 44 AND 59 AND 69

Appendix ii: Ethical Approval

Scotland A Research Ethics Committee

Research Ethics Service
2nd Floor Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone: 0131 465 5680
Fax: 0131 465 5789
www.nres.nhs.uk



Dr Craig Melville
Senior Lecturer in Learning Disabilities
Psychiatry
University of Glasgow
Mental Health & Wellbeing
Gartnavel Royal Hospital
Glasgow
G12 0XH

Date: 16 December 2013
Your Ref:
Our Ref: 13/SS/0229
Enquiries to: Walter Hunter
Extension: 35680
Direct Line: 0131 465 5680
Email: walter.hunter@nhslothian.scot.nhs.uk

Dear Dr Melville

Study title: Weight loss in learning disabilities and obesity (WELLDO); a pilot, randomised-controlled trial of a weight management intervention for adults with learning disabilities and obesity.

REC reference: 13/SS/0229

IRAS project ID: 134936

The Scotland A Ethics Committee reviewed the above application at the meeting held on 12 December 2013. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mr Walter Hunter, walter.hunter@nhslothian.scot.nhs.uk.

Ethical opinion

The Committee noted the intention to include adults lacking capacity and adults who could give their own informed consent. The study follows on from the potential benefits found in the earlier feasibility study. The Committee considered whether it was necessary to include adults lacking capacity in this pilot study. In considering the justification for including adults lacking capacity the Committee examined the following specific issues:

- 1. Justification of inclusion of adults not able to consent for themselves:** This was a pilot study, looking at feasibility and likely attrition, in order to inform the

Chairman Dr Ian Zealley
Vice-Chairman Dr Colin Selby



design of a larger study. The argument for inclusion was that it would be difficult to develop and test a weight loss programme suitable for all adults with learning difficulties, without adults lacking capacity as well as those who were more able. Given the diverse nature of 'adults with learning difficulties' the Committee was unsure whether a programme could be designed that was suitable for all; but perhaps this would be ultimately found out when the outcomes were analysed.

2. **Is the research on the condition that renders adults not capable or on the treatment for this condition?** The Committee expressed reservations but noted the researchers had presented evidence that those with learning difficulties were more likely than the general population to be over-weight. The issue therefore for this population group was whether they were over-weight as an indirect consequence of having a learning difficulty, and therefore this study was looking at a consequence of a condition that renders potential participants incapable?
3. **Risk/burden:** The Committee agreed that the risk for this population group was pretty minimal, but that the burden was probably greater for the carers, rather than the adults themselves, which had been made clear in the carers' information sheet. The Committee recognised that the researchers had done all they could to minimise the burden on participants by arranging to see them at home, or somewhere else of the participants' choosing.
4. **Optimising capacity:** The Committee noted that the researcher would be trained in assessing capacity (assessing each individual on a case by case basis). The Committee therefore assumed that all those who were capable would be asked to give consent themselves and only those deemed not sufficiently able would be consented by a welfare guardian/nearest relative. The application did not explicitly say how the researchers would maximise capacity e.g. the use of Makaton or other communication tools; however given the research group involved the expectation was that they would have a number of tools at their disposal.
5. **Consent from welfare guardian/nearest relative:** The information sheet for the welfare guardian/nearest relative was clear about why they were being asked and what they should consider in making the decision.
6. **What if an adult with incapacity seems to object?** The Committee identified that the researchers were assuming that would not be the case but the Committee recognised that the researchers to comply with the law they were obliged to withdraw the participant if s/he objects. The Committee was unclear though how they would determine that someone was objecting to participation?

The Committee in reaching a decision on the justification for including adults lacking capacity retained some reservations about this study covering both participants with capacity and those without capacity. However if the researchers were confident that this



was feasible option the Committee agreed that on balance the inclusion of adults lacking capacity was justified.

The Committee in commenting on the other issues raised by the application recognised the involvement of a dietician as a positive step and that the role of the carer was not simply about giving consent but to be actively involved. The Committee expressed some concern that the qualitative study was underspecified, for example the absence of a topic guide, planned duration of the interview and procedures should participants become distressed. The Committee was also unclear given the lack of an essential guide how the findings would be analysed. The Committee was also unclear about the differences between the two programmes. The participant information sheet attempted to make a distinction but it was still not clear. The Committee welcomed the positive aspect that all participants would be offered access to a programme even for some this would not be normal care. The Committee also wondered if the changes to the participant's diet would cost more than they were presently spending and if so this would have to be mentioned in the information sheet.

Dr Melville and Miss Harris attended to discuss the study. The researchers were asked to clarify how they would know that a potential participant had expressed a willingness to participate. Dr Melville explained that information provided from the research dietician and evidence obtained from previous studies would be an indicator. Dr Melville recognised that the carer also had a role to play and if they were not motivated this would make it more difficult. Dr Melville also indicated that some of the participants would have some ability to make it clear that they wanted to take part. On being asked about how they would identify signs that a participant wanted to withdraw from the study Dr Melville said that any changes in behaviour would be noticeable to the carers. Miss Harris was asked about the differences to the two programmes. She explained that one was a diet based programme and the other was a healthy eating programme. The researchers wanted to find out which was the best approach. Dr Melville also added that the expectation was that participating in the study would not cost participants any more money as portions would be smaller and the TAKE5 costs should not be excessive. When asked about the intention to include both adults lacking capacity and adults with capacity Dr Melville said it was an open feasible study and they were looking to solve a problem in a situation where there was no chemical intervention. He recognised that it may or may not work for both groups but as it was an open study it did not look at that question. Dr Melville mentioned that people with obesity had lower levels of energy. He did concede that the burden on carers was greater but the amount of activity was probably in the region of 5-10 minutes per day. Dr Melville was asked to clarify the relationship between the carer and the participant. He said this had not been looked at explicitly but the carers had short term contracts and there



was no requirement for them to be able to cook. In response to where the carers became involved he said the carer was the person who supported the participant in the home environment. When asked if there was any evidence of carers expressing guilt and/or regrets he confirmed he had never encountered this in the past. Dr Melville was asked if there were any cultural elements in the different interventions but indicated this had not been a factor in designing the study. On being asked analysing the results Dr Melville said that he was experienced in working with this type of study. Dr Melville was asked about the potential for having to disclose situations where abuse has arisen. The position was for anyone coming across this type of situation to discuss with a senior member of the research team.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Adults with Incapacity (Scotland) Act 2000

I confirm that the Committee has approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is satisfied that the requirements of section 51 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.



Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. A stratified analysis and randomisation was required for adults lacking capacity.
2. The study design needs to be more clearly defined with a more structured approach to the questions.
3. The welfare guardian/nearest relative information sheet should:
 1. in the invitation paragraph say something along the lines 'we are asking you to provide consent on behalf of the person with learning difficulties, having considered what you think they would want to do.'
 2. at the top of page 2 it should be made clear who was giving consent i.e. say something along the lines 'If the adult is not able, it is the nearest relative or WG who will be asked to provide consent not the adult themselves.'
4. Approval for the qualitative dimension of the study would be withheld until further details were provided and should be submitted as a substantial amendment.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be



sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		12 November 2013
REC application: IRAS Form 3.5		07 November 2013
Protocol	1.0	04 November 2013
Investigator CV: Dr Melville		
Investigator CV: Miss Harris		



Letter of invitation to participant	1.0	04 November 2013
Participant Information Sheet: Participant	1.0	04 November 2013
Participant Consent Form: Participant	1.0	04 November 2013
Participant Information Sheet: Welfare Guardian/Nearest Relative	1.0	04 November 2013
Participant Consent Form: Welfare Guardian/Nearest Relative	1.0	04 November 2013
Participant Information Sheet: Carer	1.0	04 November 2013
Participant Consent Form: Carer	1.0	04 November 2013
GP/Consultant Information Sheets	1.0	04 November 2013
Interview Schedules/Topic Guides	1.0	11 November 2013
Questionnaire: EQ-5D		
Questionnaire: IPAQ-S		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study



The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

REC reference number: 13/SS/0229-Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'I. Zealley', written in a cursive style.

Dr Ian Zealley
Committee Chairman

*cc: Dr Erica Packard, NHS Greater Glasgow and Clyde, Research and Development
Miss Leanne Harris*



Scotland A REC

Attendance at Committee meeting on 12 December 2013

Committee Members:

Name	Profession	Present	Notes
Dr Fiona C Denison	Senior Lecturer and Honorary Consultant in Maternal and Fetal Health	No	
Dr Bridget Harris	Clinical Research Specialist	Yes	
Mrs Fiona Mack	Clinical Pharmacist	Yes	
Dr Mary Joan Macleod	Clinical Pharmacologist/Consultant Physician	No	
Mrs Katherine McGuigan	Nurse	No	
Canon Matt McManus	Parish Priest	Yes	
Dr Craig Melville	Senior Lecturer in Learning Disabilities Psychiatry	Yes	Declared an interest
Dr Zoe Morrison	Research Fellow, Centre for Population Health Sciences	Yes	
Mrs Wendy Nganasurian	Retired	Yes	
Dr Anthony Pottage	retired Physician/Clinical Pharmacologist	Yes	
Dr Richard Quigley	General Practitioner	No	
Dr Colin Selby	Consultant Physician	Yes	
Dr Rachel Smith	MRC Programme Manager (Training and Partnerships)	No	



Mrs Mary Sweetland	Statistician	Yes	
Mrs Margaret Thomson	Retired	Yes	
Professor Nigel Webster	Chair of Anaesthesia & Intensive Care	Yes	
Dr Ian Zealley	Consultant	Yes	

Also in attendance:

Name	Position (or reason for attending)
Dr Alex Bailey	Scientific Officer
Mr Walter Hunter	Committee Coordinator

Written comments received from:

Name	Position
Dr Mary Joan Macleod	Clinical Pharmacologist/Consultant Physician
Dr Rachel Smith	MRC Programme Manager (Training and Partnerships)

Appendix iii: Study invitation and information sheets

Version 1.0 04.11.2013



Direct Line: 0141 211 0213

E-mail: l.harris.1@research.gla.ac.uk

15 November 2016

Dear

we would like to invite you to take part in a research project. We have sent you some information about this project. You are being invited to take part because you are using the learning disabilities services and someone who knows you thinks you might like to lose some weight.

You do not have to take part in the project. It is OK to say 'No'. If you would like to find out more I can come and meet with you. This meeting would give you a chance to ask questions. I will then invite you to choose whether you would like to take part in the project, or not. Please fill in the reply slip. Send this back in the FREEPOST envelope.

If we do not receive the reply slip an NHS secretary will phone you in two weeks. This is to check you still have the information about the project. The secretary can send another information pack. If you do not want to find out about the project, please let the secretary know.

Thank you for taking the time to read this letter.

Yours sincerely

Leanne Harris

Learning Disabilities Research Group

Mental Health and Wellbeing, University of Glasgow

Academic Centre, Mental Health and Wellbeing, Gartnavel Royal Hospital,
1055 Great Western Road, Glasgow, G12 0XH
The University of Glasgow, charity number SC004401



WEIGHT LOSS AND LEARNING DISABILITIES

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in a research project. The project is to find ways to help people lose weight. The information sheet tells you about the project. Please read the information sheet, or ask someone to read it with you. This information sheet is for you to keep.

You can talk to your family and friends about the project. Ask them what they think about it.

What is the research project about?

The aim of this project is to help people lose weight.

This project will use two weight loss programs:

- TAKE 5
- Waist Winners Too

Previous research projects found that TAKE 5 and Waist Winners Too were able to help support people to lose weight. We would like to see which program is better at helping people to lose weight.

The weight loss programs will try and help people lose weight by making healthy lifestyle choices such as eating a balanced diet and becoming more active. People who lose weight have been shown to:

- feel better
- sleep better
- have more energy
- have a lower risk of getting health problems.

Why do you want me to take part?

We are inviting you to take part because you are using the learning disabilities services. Someone who knows you thinks you might be interested in losing weight. We would like 60 people who want to lose weight to take part.

What will the research project involve?

If you want to find out more a researcher will contact you and ask to visit you. You do not have to meet the researcher. Please let us know if you do not want to see the researcher.

You can ask the researcher questions about the project. The researcher will invite you to decide if you want to take part in the research project. If you say yes, you will be asked to sign a form. You can keep a copy of the consent form.

If you choose to take part, the researcher will visit you three times over 12 months. The meetings will be at a place that is suitable for you. Each meeting will last about one hour. The researcher will ask questions about:

- ✓ Yourself and the things you do**
- ✓ What you like to eat and any physical activity you do**
- ✓ How you feel about losing weight.**

The researcher will also ask to measure your weight, height, waist circumference and body fat.

You will be asked to wear a special belt for one week at the beginning, middle and at the end of the project. This measures how active you are.

We will ask you if we can tell your GP that you are taking part in the project.

After you meet with the researcher a dietician will meet you. The dietician will talk to you about starting a weight loss program. You will either get the TAKE 5 weight loss program or the Waist Winners Too weight loss program. The program that you get will be decided by a process called randomisation, which is like the toss of a coin. You have an equal chance of taking part in the TAKE 5 or Waist Winners Too. Both programs last 12 months. The first six months is a weight loss phase. After that there is a six month weight maintenance phase.

We would like to find out what people think about the weight loss program they received. At the end of the 12 months the researcher will ask to meet you and ask you questions about the weight loss program. We want to know if you think it helped you. You can also suggest ways to make the weight loss program better. This meeting with the researcher will last about one hour. The researcher will make notes of the things you said and also record what you said during the meeting. If you give permission we will also ask a carer what they think about the weight loss program.

What do the weight loss programs involve?

In both programs a dietician will meet you:

- Phase 1: Nine times, every two-three weeks**
- Phase 2: Six times, every month**

A carer can support you in these sessions. The carer will be invited to help you make a note of your diet and activities. They can also help you plan the changes you want to make.

TAKE 5

Phase 1: Weight loss

The meetings in the first phase of this program are to help you find ways to lose weight. These sessions will focus on:

- **Dietary change:** The dietician will help you chose ways to make healthy changes to your diet. They will give you a Personalised Dietary Plan to help you to lose weight
- **Physical Activity:** You will discuss activities that you like to do. The dietician will support you to increase your physical activity levels
- **Behaviour Change:** You will be encouraged to set goals and keep a note of your weight and waist circumference.

Phase 2: Weight maintenance

The meetings in the second phase are to help you to learn new skills to keep the weight off. These sessions will focus on:

- Behavioural methods to maintain lifestyle changes
- Keeping a note of your body weight and food intake
- Staying active.

Waist Winners Too

Phase 1: weight loss

The meetings in the first phase of this program are to give you advice on healthy eating and how you can achieve a steady weight loss by making changes to your diet and lifestyle. These sessions will focus on:

- Eating a balanced healthy diet – based on the *Eatwell* plate
- Importance of physical activity and current recommendations
- Goal setting and keeping a note of your weight and daily food intake.

Phase 2: Weight maintenance

The meetings in the second phase are to help you to remember what you learned in the first phase and to support you to continue to monitor your diet and weight. You will be able to ask questions about the healthy lifestyle information you received and discuss positive changes you have been able to make and any barriers you experience to making these changes.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this if you wish to complain about any aspect of the way you have been treated during the course of this project, the normal National Health Service complaints mechanism will be available to you.

Has ethical approval been granted for this project?

This project has been granted ethical approval by the Scotland A Research Ethics Committee.

When will the project take place?

This project will take place during 2014-2016. You would be involved for a maximum of twelve months.

Will taking part in the project help me?

If you decide to take part in the project it might help you lose weight. You might feel better or have more energy. However, taking part might not help. We want to find out if the weight loss programs work.

The results of this project may help other people lose weight. All researchers are fully trained and qualified. We will provide feedback to you at the end of the project.

What will happen if I decide not to take part in the project?

You do not have to take part in this research project. It is OK to say no. If you do not want to take part, this will not affect the care and support you receive.

What if I change my mind and do not want to take part during the project?

You can change your mind about taking part, or stop, at any time. You do not have to give a reason. If you change your mind this will not affect the care and support you receive.

Where would the interviews take place?

If it is OK with you, the researcher will arrange to see you at your home. If you want the researcher can arrange to see you somewhere else.

What will happen to the information the researcher collects?

All the information about you is kept safe. It will be treated with strict confidence. It will be kept secret. The research team will not tell anyone your name. The information will be kept safely on a computer. Only members of the research team and the sponsor for

the research project will have access to the information. The sponsor may access the information for audit purposes only. The Data Protection Act will be followed at all times.

What will happen to the results of the project?

When the research project is finished, the research team will write to you about the research findings. They will also write reports about the research. Your name will not be used in the reports. They may write about the things you said but no one will be able to tell from the reports that you took part in the research. The information will also be used as part of a PhD student project.

Who is organising and funding the research?

This project is organised by the researchers at the University of Glasgow. The money to pay for the project was provided by the Equally Well Fund.

How can I find out more about the project?

You can ask the researcher questions about the project. The name and telephone number of the researchers are shown below.

You can contact them at any time to ask questions.

You might like to speak to someone who is not a member of the research group. Andrew Jahoda can be contacted on the telephone. His number is 0141 211 3878. Andrew will try and answer any questions you have.

What do I do now?

It is up to you to choose whether you want to take part in the project.

Please fill out the reply slip on the last page. Write your name, address and telephone number. Let us know if you want to find out more about the project by ticking one of the boxes.

Please send the reply slip back in the FREEPOST envelope.

If you tick the YES box we will contact you.

If you tick the NO box we will not contact you again.

Thank you for reading this information sheet.

Researcher**Leanne Harris****Mental Health and Wellbeing****Admin Building, Gartnavel Royal****Hospital, 1055 Great Western Road,****Glasgow, G12 0XH.****Telephone: 0141 211 0213****Research Team****Dr. Craig Melville, Senior Lecturer in Learning Disabilities,
University of Glasgow. Telephone: 0141 211 3878****Dr Catherine Hankey, Senior Lecturer in Human Nutrition, University of
Glasgow. Telephone: 0141 211 5443****Mrs Heather Murray, Senior Statistician, University of Glasgow. Telephone:
0141 330 4744****Dr Susan Boyle, Consultant Clinical Psychologist, Glasgow and Clyde Weight
Loss Service. Telephone: 0141 211 1296****Dr Carol Pert, Consultant Clinical Psychologist, Learning Disabilities
Psychology NHS GG&C. Telephone: 0141 276 2300**

WEIGHT LOSS AND LEARNING DISABILITIES

Name

Address

.....

.....

Telephone Number

I would like to find out more about the project

Yes

No

Please return this form in the FREEPOST envelope to:

Researcher name: Leanne Harris
Mental Health and Wellbeing

Admin Building, Gartnavel Royal

Hospital, 1055 Great Western Road,

Glasgow, G12 0XH.

Telephone: 0141 211 0213



WEIGHT LOSS AND LEARNING DISABILITIES

Carer Information Sheet

We would like to invite the person with learning disabilities whom you support to take part in a research project. Please keep this information sheet. Before the person you support decides it is important to understand why the research is being done and what it will involve. You may be able to help the person you support decide whether they want to take part. You will not be asked to be a participant in the project. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

What will the research project find out?

The aim of this project is to compare two weight loss programs; TAKE 5 and Waist Winners Too, to see if they can help adults with learning disabilities lose weight. The weight loss programs will try and help adults with learning disabilities lose weight through making healthy lifestyle choices such as eating a balanced diet and becoming more physically active. This approach has been shown to work for adults who do not have learning disabilities.

People who lose weight and are of a healthy weight have been shown to feel better, sleep better, have more energy, and have a lower risk of developing certain diseases (heart disease, cancer, bone diseases and diabetes).

Why do you want the person I support to take part?

The person with learning disabilities whom you support has been invited to take part in the project because he/she is using the learning disabilities services and someone thinks they might be interested in losing weight. We would like 60 individuals who want to lose weight to take part. We will look at whether this approach helps the person you support lose and maintain weight loss over a 12 month period.

What will the project involve?

If the person you support wants to find out more about the project a researcher can contact them to arrange a time to meet. This meeting would be to discuss the project, and answer any questions about the project. If the person you support does not want to meet the researcher, please let us know. Some people with learning disabilities are unable to consent to participation in research. If this is the case, under the procedures of the Adults with Incapacity (Scotland) Act a relative, or welfare guardian can be asked to consider providing consent to participation.

If the person you support chooses to meet the researcher, they will explain the project to them, and answer any questions. The person with learning disabilities you

support will be invited to choose whether to take part in the project. They will be given a copy of the consent form to keep. The person you support does not have to take part in the project it is OK to say 'no' and this will not affect the care that the person you support receives from learning disabilities services.

If the person you support chooses to take part in the project, they would be involved in the project for about 12 months. The researcher would like to arrange three meetings, over the 12 months. Each meeting will last about one hour. If this seems too long, the person can choose shorter meetings. At each meeting, the researcher would like to ask questions about:

- The person and the things they do
- What the person likes to eat and any physical activity they do
- How the person feels about losing weight.

The researcher will also ask to measure the person's weight, height, waist circumference and body fat. The person you support will be asked to wear a special belt each day for one week at the beginning, middle and end of the project. It measures how active people are.

The researcher will also ask for specific consent to speak to carers about the person with learning disabilities life and the support they receive.

After the first meeting with the researcher, a research dietician will arrange to meet the person you support to talk about starting a weight loss program. The person you support will either get the TAKE 5 weight loss program or the Waist Winners Too weight loss program. The program that they get will be decided by a process called randomisation, which is like the toss of a coin. They will have an equal chance of taking part in the TAKE 5 or Waist Winners Too programs. Both programs last 12 months are split into two phases:

- six month weight loss phase
- six month weight maintenance phase.

We would like to find out what people think about the weight loss program they receive. If the person you support decides to take part the researcher will ask to meet them and ask them questions about the weight loss program. We want to know if they think it helped them. They can also suggest ways to make the weight loss program better. This meeting with the researcher will last about one hour. The researcher will make notes of the things the person you support said and also audio record what is said during the meeting. If the person you support gives permission we would also like to ask carers what they think about the weight loss program.

What do the weight loss programs involve?

TAKE 5 and Waist Winners Too have both been developed and piloted in Glasgow. Both programs have both been shown to be acceptable to adults with learning disabilities and shown to be effective in helping them to lose weight.

In both programs a dietician will meet the person you support:

- Phase 1: Nine times, every two-three weeks
- Phase 2: Six times, every month

If the participant wants a carer can be involved in these sessions.

TAKE 5

Phase 1: Weight loss

The meetings in the first phase of this program are to help the person you support find ways to lose weight. The research dietician will help the person you support to choose ways to make changes to their diet and give them a personalised dietary plan to help them eat less to lose weight. The person you support will also be encouraged to set goals and monitor their progress by measuring their own weight and how active they are. The research dietician will also try and help the person you support find ways to increase their activity.

Phase 2: Weight maintenance

The meetings in the second phase are to help the person you support to find ways to maintain any weight loss and help prevent weight regain. The person you support will learn ways to help them maintain the important changes they have made to their lifestyle, to monitor their food intake and weight and also ways to continue to be more active.

Waist Winners Too

Phase 1: Weight loss

The meetings in the first phase of this program are to give the person you support advice on healthy eating and how they can achieve a steady weight loss by making changes to their diet and lifestyle. The research dietician will talk about eating a balanced diet and the person you support will learn to make better food choices. They will also learn about the importance of physical activity. The research dietician will help the person you support set goals and monitor their progress in making healthy lifestyle choices.

Phase 2: Weight maintenance

The meetings in the second phase are to help the person you support maintain any weight loss, they will review the important topics that they have already learned in phase one and be given support to continue monitoring of their diet and weight.

If the person you support is harmed by taking part in this research project, there are no special compensation arrangements. If they are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this if you, or the person you support, wish to complain about any aspect of the way you have been treated during the course of this project, the normal National Health Service complaints mechanism will be available.

What is the role of carers in the project?

If the person with learning disabilities decides to take part they will be invited to choose if they want carers to support them. The carers could be asked to support the person with learning disabilities during the research interviews and during the sessions with the research dietician. Family carers and paid carers can be involved in supporting the person.

There are some questionnaires for carers to complete. These ask the carer their views on weight loss, healthy eating and physical activities of the person with learning disabilities.

During the 12 month period the carers will be invited to support the person with learning disabilities to gradually lose weight. As well as giving general support to the person with learning disabilities, the carers will be asked to help them answer the questions, make a note of their activities and help make choices about how to eat healthier.

Will taking part in the project help me, or the person I support?

If the person you support decides to take part, they may benefit from losing weight. Other studies have found that losing weight helps people feel better. However, there is no guarantee the weight loss program will help the person you support do lose weight. We want to find out if the weight loss programs work.

What will happen if the person I support decides not to take part in the project?

The person with learning disabilities whom you support does not have to take part in this research project. It is OK to say 'no'. If he/she decides not to take part in the project this will not affect the care that the person you support receives from anybody who provides care or support to that person.

What if the person I support changes his/her mind about taking part during the project?

The person you support can change his/her mind about taking part, or stop, at any time. He/she does not have to give a reason for changing their mind. If he/she changes their mind about taking part in the project this will not affect the care the person you support receives from the services.

Where will the sessions take place?

The researcher, and research dietician, will arrange to meet with the person with learning disabilities at a place that is convenient for them. He/she can choose where they want to meet with the researcher, and research dietician. The researcher, and research dietician, could meet at the home of the person you support. If this is not suitable, the researcher, and research dietician, will arrange to meet somewhere that is suitable for the person you support. The person you support will be invited to choose if they would like someone to support them during the interviews.

What will happen to the information the research team collect?

The research team will keep all the information provided in strict confidence. Only members of the research team and the sponsor of the research project will have access to the information provided. The sponsor may access the information for the

purpose of audit only. The information will be kept very safely on a computer database. The Data Protection Act will be adhered to at all times.

Who is organising and funding the research?

This research project is organised by researchers at the University of Glasgow. The research team have organised other studies that adults with learning disabilities have participated in. The money to pay for the project was provided by the Equally Well Fund.

Has ethical approval been granted for this project?

This project has been granted ethical approval by the Scotland A Research Ethics Committee.

When will the project take place?

This project will take place in 2014-2016 but the involvement of the person you support will only be for 12 months.

What will happen to the results of the project?

After the project is finished, we will post out information about the findings of this research project to everyone who takes part. Findings of this project will also be given to managers of learning disabilities health and social work services. The research findings will be written into reports which will be published. Quotes from the interviews may also be published. It will not be possible to identify any of the individuals who take part in the project from the reports, as all the information will be anonymised, with information from many individuals grouped together. The information will also be used as part of a PhD student project.

How can I find out more about this project?

If you would like to discuss any aspect of this project, or wish to ask any questions please ask the researcher, or contact members of the research team, at any stage of the project.

If you want to talk to someone independent of the research project please contact Professor Andrew Jahoda (Telephone: 0141 211 3878). Professor Jahoda will try and answer any questions you have about the project.

Thank you for taking the time to read this information sheet.

Researcher

Leanne Harris

Mental Health and Wellbeing

Admin Building, Gartnavel Royal

Hospital, 1055 Great Western Road,

Glasgow, G12 0XH.

Telephone: 0141 211 0213

Research Team

Dr. Craig Melville, Senior Lecturer in Learning Disabilities,
University of Glasgow. Telephone: 0141 211 3878

Dr Catherine Hankey, Senior Lecturer in Human Nutrition, University of Glasgow.
Telephone: 0141 211 5443

Mrs Heather Murray, Senior Statistician, University of Glasgow. Telephone: 0141
330 4744

Dr Susan Boyle, Consultant Clinical Psychologist, Glasgow and Clyde Weight Loss
Service. Telephone: 0141 211 1296

Dr Carol Pert, Consultant Clinical Psychologist, Learning Disability Psychology
NHS GG&C. Telephone: 0141 276 2300





WEIGHT LOSS AND LEARNING DISABILITIES

RELATIVE/ WELFARE GUARDIAN INFORMATION SHEET

We would like to invite the person with learning disabilities whom you support to take part in a research project. We do not think that this person has the capacity to consent to participate in research. However, under the provisions of the Adults with Incapacity (Scotland) Act you are able to provide consent. We are inviting you to provide consent on behalf of the person with learning disabilities, having considered what you think they would want you to do. Before you make your decision about whether to give consent for them to participate in this project, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with the person with learning disabilities whom you support, and others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please keep this information sheet. Thank you for reading this information sheet.

What will the research project find out?

The aim of this project is to compare two weight loss programs; TAKE 5 and Waist Winners Too, to see if they can help adults with learning disabilities lose weight. The weight loss programs will try and help adults with learning disabilities lose weight through making healthy lifestyle choices such as eating a balanced diet and becoming more physically active. This approach has been shown to work for adults who do not have learning disabilities.

People who lose weight and are of a healthy weight have been shown to feel better, sleep better, have more energy, and have a lower risk of developing certain diseases (heart disease, cancer, bone diseases and diabetes).

Why do you want the person I support to take part?

The person with learning disabilities whom you support has been invited to take part in the project because he/she is using the learning disabilities services and someone thinks they might be interested in losing weight. We would like 60 individuals who want to lose weight to take part. We will look at whether this approach helps the person you support lose and maintain weight loss over a 12 month period.

What will the project involve?

If the person you support wants to find out more about the project a researcher can contact them to arrange a time to meet. This meeting would be to discuss the project, and answer any questions about the project. If the person you support does not want to meet the researcher, please let us know. Some people with learning disabilities are unable to consent to participation in research.

If the person with learning disabilities is not able to consent a nearest relative or welfare guardian can be asked to provide consent not the adult themselves, under the Adults with Incapacity (Scotland) Act.

If the person you support chooses to meet the researcher, they will explain the project to them, and answer any questions. The person with learning disabilities you support will be invited to choose whether to take part in the project. They will be given a copy of the consent form to keep. The person you support does not have to take part in the project it is OK to say 'no' and this will not affect the care that the person you support receives from learning disabilities services.

If the person you support chooses to take part in the project, they would be involved in the project for about 12 months. The researcher would like to arrange three meetings, over the 12 months. Each meeting will last about one hour. If this seems too long, the person can choose shorter meetings. At each meeting, the researcher would like to ask questions about:

- The person and the things they do
- What the person likes to eat and any physical activity they do
- How the person feels about losing weight.

The researcher will also ask to measure the person's weight, height, waist circumference and body fat. The person you support will be asked to wear a special belt each day for one week at the beginning, middle and end of the project. It measures how active people are.

The researcher will also ask for specific consent to speak to carers about the person with learning disabilities life and the support they receive.

After the first meeting with the researcher, a research dietician will arrange to meet the person you support to talk about starting a weight loss program. The person you support will either get the TAKE 5 weight loss program or the Waist Winners Too weight loss program. The program that they get will be decided by a process called randomisation, which is like the toss of a coin. They will have an equal chance of taking part in the TAKE 5 or Waist Winners Too programs. Both programs last 12 months are split into two phases:

- six month weight loss phase
- six month weight maintenance phase.

We would like to find out what people think about the weight loss program they receive. If the person you support decides to take part the researcher will ask to meet them and ask them questions about the weight loss program. We want to know if they think it helped them. They can also suggest ways to make the weight loss program better. This meeting with the researcher will last about one hour. The researcher will make notes of the things the person you support said and also audio record what is said during the meeting. If the person you support gives permission we would also like to ask carers what they think about the weight loss program.

What do the weight loss programs involve?

TAKE 5 and Waist Winners Too have both been developed and piloted in Glasgow. Both programs have both been shown to be acceptable to adults with learning disabilities and shown to be effective in helping them to lose weight.

In both programs a dietician will meet the person you support:

- Phase 1: Nine times, every two-three weeks
- Phase 2: Six times, every month

If the participant wants a carer can be involved in these sessions.

TAKE 5

Phase 1: Weight loss

The meetings in the first phase of this program are to help the person you support find ways to lose weight. The research dietician will help the person you support to choose ways to make changes to their diet and give them a personalised dietary plan to help them eat less to lose weight. The person you support will also be encouraged to set goals and monitor their progress by measuring their own weight and how active they are. The research dietician will also try and help the person you support find ways to increase their activity.

Phase 2: Weight maintenance

The meetings in the second phase are to help the person you support to find ways to maintain any weight loss and help prevent weight regain. The person you support will learn ways to help them maintain the important changes they have made to their lifestyle, to monitor their food intake and weight and also ways to continue to be more active.

Waist Winners Too

Phase 1: Weight loss

The meetings in the first phase of this program are to give the person you support advice on healthy eating and how they can achieve a steady weight loss by making changes to their diet and lifestyle. The research dietician will talk about eating a balanced diet and the person you support will learn to make better food choices. They will also learn about the importance of physical activity. The research dietician will help the person you support set goals and monitor their progress in making healthy lifestyle choices.

Phase 2: Weight maintenance

The meetings in the second phase are to help the person you support maintain any weight loss, they will review the important topics that they have already learned in phase one and be given support to continue monitoring of their diet and weight.

If the person you support is harmed by taking part in this research project, there are no special compensation arrangements. If they are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this if you, or the person you support, wish to complain about any aspect of the way you have been treated during the course of this project, the normal National Health Service complaints mechanism will be available.

What is the role of carers in the project?

If the person with learning disabilities decides to take part they will be invited to choose if they want carers to support them. The carers could be asked to support the person with learning disabilities during the research interviews and during the sessions with the research dietician. Family carers and paid carers can be involved in supporting the person.

There are some questionnaires for carers to complete. These ask the carer their views on weight loss, healthy eating and physical activities of the person with learning disabilities.

During the 12 month period the carers will be invited to support the person with learning disabilities to gradually lose weight. As well as giving general support to the person with learning disabilities, the carers will be asked to help them answer the questions, make a note of their activities and help make choices about how to eat healthier.

Will taking part in the project help me, or the person I support?

If the person you support decides to take part, they may benefit from losing weight. Other studies have found that losing weight helps people feel better. However, there is no guarantee the weight loss program will help the person you support do lose weight. We want to find out if the weight loss programs work.

What will happen if the person I support decides not to take part in the project?

The person with learning disabilities whom you support does not have to take part in this research project. It is OK to say 'no'. If he/she decides not to take part in the project this will not affect the care that the person you support receives from anybody who provides care or support to that person.

What if the person I support changes his/her mind about taking part during the project?

The person you support can change his/her mind about taking part, or stop, at any time. He/she does not have to give a reason for changing their mind. If he/she changes their mind about taking part in the project this will not affect the care the person you support receives from the services.

Where will the sessions take place?

The researcher, and research dietician, will arrange to meet with the person with learning disabilities at a place that is convenient for them. He/she can choose where they want to meet with the researcher, and research dietician. The researcher, and research dietician, could meet at the home of the person you support. If this is not suitable, the researcher, and research dietician, will arrange to meet somewhere that is suitable for the person you support. The person you

support will be invited to choose if they would like someone to support them during the interviews.

What will happen to the information the research team collect?

The research team will keep all the information provided in strict confidence. Only members of the research team and the sponsor of the research project will have access to the information provided. The sponsor may access the information for the purpose of audit only. The information will be kept very safely on a computer database. The Data Protection Act will be adhered to at all times.

Who is organising and funding the research?

This research project is organised by researchers at the University of Glasgow. The research team have organised other studies that adults with learning disabilities have participated in. The money to pay for the project was provided by the Equally Well Fund.

Has ethical approval been granted for this project?

This project has been granted ethical approval by the Scotland A Research Ethics Committee.

When will the project take place?

This project will take place in 2014-2016 but the involvement of the person you support will only be for 12 months.

What will happen to the results of the project?

After the project is finished, we will post out information about the findings of this research project to everyone who takes part. Findings of this project will also be given to managers of learning disabilities health and social work services. The research findings will be written into reports which will be published. Quotes from the interviews may also be published. It will not be possible to identify any of the individuals who take part in the project from the reports, as all the information will be anonymised, with information from many individuals grouped together. The information will also be used as part of a PhD student project.

How can I find out more about this project?

If you would like to discuss any aspect of this project, or wish to ask any questions please ask the researcher, or contact members of the research team, at any stage of the project.

If you want to talk to someone independent of the research project please contact Professor Andrew Jahoda (Telephone: 0141 211 3878). Professor Jahoda will try and answer any questions you have about the project.

Thank you for taking the time to read this information sheet.

Researcher

Leanne Harris

Mental Health and Wellbeing

Admin Building, Gartnavel Royal

Hospital, 1055 Great Western Road,

Glasgow, G12 0XH.

Telephone: 07554316255



Research Team

Dr. Craig Melville, Senior Lecturer in Learning Disabilities,
University of Glasgow. Telephone: 0141 211 3878

Dr Catherine Hankey, Senior Lecturer in Human Nutrition, University of Glasgow.
Telephone: 0141 211 5443

Mrs Heather Murray, Senior Statistician, University of Glasgow. Telephone: 0141
330 4744

Dr Susan Boyle, Consultant Clinical Psychologist, Glasgow and Clyde Weight Loss
Service. Telephone: 0141 211 1296

Dr Carol Pert, Consultant Clinical Psychologist, Learning Disability Psychology
NHS GG&C. Telephone: 0141 276 2300

Appendix iv: Study Consent Forms



WEIGHT LOSS AND LEARNING DISABILITIES

PARTICIPANT CONSENT FORM

This form asks if I will take part in a research project.

A researcher will ask me questions about my diet, physical activity and health.

The researcher will measure my height, weight, waist circumference and body fat.

I will work with a dietician to try and lose weight.

It might help me lose weight.

It might help me be healthier.

It might help me be more active.

The researchers will keep my information confidential (secret) and safe.

Please tick the box if you agree with what it says.

I have been given an information sheet about the project **YES**

I have asked all the questions I want to **YES**

I have been given enough answers to my questions. **YES**

I know it is OK to say 'No' to taking part in the project. I don't have to take part. I don't have to say why. **YES**

Saying 'No' will not affect my care or support in any way. **YES**

I know I can change my mind and say 'No' later on. **YES**

I know the research team will write about the project results. I know the results will not include my name. No one will be able to identify me from the results. **YES**

The research team will let my GP know I am taking part. **YES**

I agree to taking part in the research project

YES

Participant signature of consent

Signed

Name

Date

Witness signature

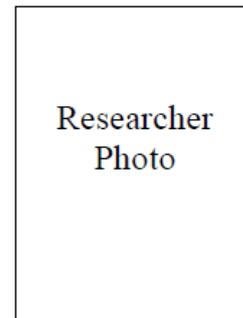
Signed

Name

Date

Researcher

Leanne Harris
Mental Health and Wellbeing
Admin Building, Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH.
Telephone: 0141 211 0213



Researcher signature

Signed

Name

Date



WEIGHT LOSS AND LEARNING DISABILITIES

CARER CONSENT FORM

This form asks if I will support the person named below to take part in a research project of a weight loss intervention. I know that I am not providing consent for the person with learning disabilities I support to take part in the project.

Name of participant.....

I am completing this form as the carer that the participant has chosen to support them during the weight loss project. Other carers will also support the individual.

My relationship to the participant is (please tick):

family carer

paid carer

other, please specify.....

I know that I am not a participant in the project so I will not be asked for information about my own lifestyle, or invited to lose weight.

I will be asked to support the participant to collect information about their dietary intake and physical activity. I will also be involved in supporting the participant to try and lose weight.

The researchers will keep all the information confidential. Only members of the research team will have access to the information I discuss.

I understand that participation in the research project might help the person with learning disabilities I support.

Please initial the box to show you agree with each statement

I have been given an information sheet about the project **YES**

I have asked all the questions I want to **YES**

I am satisfied that my questions have been thoroughly answered **YES**

I know it is OK to say 'no' to supporting the person to take part in the project. **YES**

I don't have to take part. I don't have to say why.

If I say 'no', I know it will not affect the future health care, or support, that the person I support receives **YES**

I know the research team will write about the project results. However, the results will not include my name, or the name of the person I support. No one will be able to identify me, or the person with learning disabilities I support, from the results. **YES**

I agree to supporting the person I support to take part in the research project **YES**

Signed

Name

Date

Researcher

Leanne Harris
Mental Health and Wellbeing
Admin Building, Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH.
Telephone: 0141 211 0213



Researcher signature

Signed

Name

Date



WEIGHT LOSS AND LEARNING DISABILITIES

RELATIVE, WELFARE GUARDIAN CONSENT FORM

This form asks if I will consent to my relative, or the person I support taking part in a research project.

I have been asked to do this as my relative, or the person I support, does not have the capacity to consent to participation in research. I understand that under the provisions of the Adults with Incapacity (Scotland) Act 2000, I can provide consent to the person participating in the research project.

If I provide consent to my relative, or the person I support participating in the project, a researcher will ask questions about the health and lifestyle of the person I support.

The researchers will keep all the information confidential. Only members of the research team will have access to the information I discuss.

I understand that if I provide consent, participation in the research project might help the person with learning disabilities I support.

I am completing this form as the nearest relative/welfare guardian. (Delete as appropriate)

My relationship to the participant is

As the nearest relative, I confirm that there is no welfare guardian or nearer relative **YES**

Please initial the box to show you agree with each statement

I have been given an information sheet about the project **YES**

I have asked all the questions I want to **YES**

I am satisfied that my questions on behalf of the person I support have been thoroughly answered **YES**

I know it is OK to say 'no' to the person I support taking part in the project. I don't have to consent to their taking part. I don't have to say why. **YES**

If I say 'no', I know it will not affect the future health care, or support, that the person I support receives **YES**

If I decide that the person I support can take part in the project, I know I can still change my mind and say 'no' later on. **YES**

I know the research team will write about the project results. However, the results will not include my name, or the name of the person I support. No one will be able to identify me, or the person with learning disabilities I support, from the results. **YES**

I know the research team will let the GP know that the person I support is taking part in the project **YES**

I agree to my relative, or the person I support taking part in the research project **YES**

Nearest relative/ welfare guardian signature of consent

Signed

Name

Date

Researcher

Leanne Harris
Mental Health and Wellbeing
Admin Building, Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 0XH.
Telephone: 0141 211 0213



Researcher signature

Signed

Name

Date

Appendix v: TAKE 5 and WWToo Resources

TAKE 5 Resources

What activities can I do?

At home on my own



With other people



Classes or sports or groups



What?
When?
Where?

Coping with Cravings

Sometimes we went to eat something but we are not really hungry.

We may even get a craving after we have eaten a meal.



Cravings you think about in your head



You feel hungry in your tummy

If you get a craving try to:

- Do something else for 20 minutes. What could you do? _____
- Look at your target sheet
- Talk to someone about it

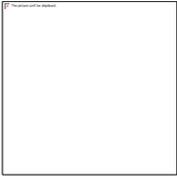
Practical tips

How many of these tips can you try?
Tick them off as you do them.

- 1. Make a healthy packed lunch or healthy snack every day for a week
- 2. Use less or no oil or butter in your meals
- 3. Freeze or bin leftovers
- 4. Use a smaller plate
- 5. Have fruit or vegetables rather than crisps
- 6. Plan the next day's food
- 7. Make a healthy shopping list and go shopping
- 8. Do a new activity
- 9. Cover half your dinner plate with salad or vegetables
- 10. Add frozen vegetables to your meals

WWToo Resources

Food versus Exercise

100		=	30 mile	
		=	30 minute	
		=	40 minute	
		=	10 minute	
		=	50 minute	
		=	70 minute	 
		=	45 minute	



= 20 minute



How to use up 100 calories



15 minutes



20 minutes



10 minutes



15 minutes



10 minutes

Appendix vi: Process evaluation semi-structured interview

Interview schedule for staff implementing the weight management interventions

The aim of this interview is to gain an insight into what worked well and did not work well with the WELLDO study. Any insight that you have about the positive and negative aspects of the study could help inform future trials.

1. Could you briefly summarise your role in the implementation of the weight management interventions used in this trial?
2. Can you briefly summarise your qualifications and experience relevant to your role?
3. What was your demand capacity to deliver the intervention?
4. Did you have any training needs to be able to deliver the interventions? If yes, how were these met?
5. What did you think of the standard of training you received to deliver the weight management interventions? How fully did it meet your needs? Were there any gaps or anything unnecessary delivered?
6. Could you have been supported in any other way to improve the delivery of the intervention?

Implementation

7. What were the practicalities of implementing the planned interventions (TAKE 5/WWToo) in practice?
8. Were any adaptations to the interventions required or did it go to plan? If so why were the adaptations required?
9. Were there any additional training needs of people supporting participants (i.e. day centre staff/ family or paid carers)? How did you address these?
10. Could participants/carers have been supported in any other way to improve the intervention?

11. There are no formal results as yet, but what in your opinion are the changes in outcomes you have observed overall in the participants you have seen?
12. Are there any positive cases (participants you regard as achieving their targets) you can describe? Why do you think it worked for the participant(s)?
13. Are there any negative cases (participants you regard as not achieving their targets) you can describe? Why do you think it didn't work for the participant(s)?

Weight management sessions (TAKE 5/ WWT00)

We would like to find out more about how well the two interventions were received, starting with TAKE 5 followed by the same question repeated for WWT00.

14. What is your general insight into how well the intervention sessions were received?
15. What components (Diet/PA/Behaviour change techniques) worked well within the sessions?
16. Where there any challenges to delivering the sessions?
17. What types of communication techniques were used most often to communicate with this population group?
18. Are carers actively involved in the intervention sessions? If so how do they help facilitate the session?
19. Did any aspect of the sessions not work well with most of this group of participants?
20. Did sessions adhere to the content, duration and quality as initially set out in the protocol? If not, why did this deviate? How often did this deviation take place and how did you manage any deviations?
21. Can you describe any adaptations that were required to the sessions?
22. Where and when was flexibility needed?

General

The aim of this interview is to gain an insight into specific positive and negative issues about the WELLDO project in order to inform future trials.

23. What if anything do you think could be done for future studies to improve the implementation of the weight management interventions?
24. Finally, do you have any additional comments you would like to add based on your experience of taking part in this trial and delivery of the interventions?

Appendix vii: Statistical Analysis Plan

WEight Loss in Learning Disabilities and Obesity Study (WELLDO)

Statistical Analysis Plan (SAP)

Study Title:	Weight Loss in Learning Disabilities and Obesity (WELLDO): A single-blind randomised trial of a weight loss intervention for adults with learning disabilities and obesity.
Short Title:	WELLDO
Trial Registration:	ISRCTN52903778
Sponsors:	NHS Greater Glasgow and Clyde
Funded by:	Scottish Government, The Equally Well Fund
Protocol Version:	1.2
SAP Version:	Final 1.0

Abbreviations

BMI	Body Mass Index
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
EQ-5D-Y	EuroQol (Youth)
ICC	Intraclass correlation
IVRS	Interactive Voice Response System
RCB	the Robertson Centre for Biostatistics
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SIMD	Scottish Index of Multiple Deprivation
SD	Standard Deviation
VAS	Visual Analogue Scale

1.0 Introduction

1.1. Background

Individuals with intellectual disabilities have consistently reported to have higher rates of obesity than the general population. Despite the negative impact of obesity on health there is a limited evidence base to inform the management of obesity in this population. Clinical guidelines recommend multi-component weight management interventions to support individuals who are overweight or obese to achieve a clinically significant weight loss. The aim of this study is to add to the limited evidence base by examining the feasibility of a full-scale clinical trial of the TAKE 5 multi-component weight management intervention in comparison with an active comparator intervention.

1.2 Purpose of Analysis

The objective of this SAP is to describe the statistical analysis to be carried out for the WELLDO study.

1.3 Study Objectives

1. Can adults with intellectual disabilities and obesity be recruited to a randomised study of the TAKE 5 intervention versus a health education control intervention?
2. What attrition rates are observed at 6 and 12 months post-randomisation?
3. Are the patient centred outcome measures acceptable to the participants and can they be measured reliably to detect clinically important changes?

2.0 Study Methods

2.1 Study Design

This study was a single-centre, randomised trial. Participants were randomised in clusters to a multi-component weight management (TAKE 5) intervention or an active comparator intervention (WWT00) (Figure 1).

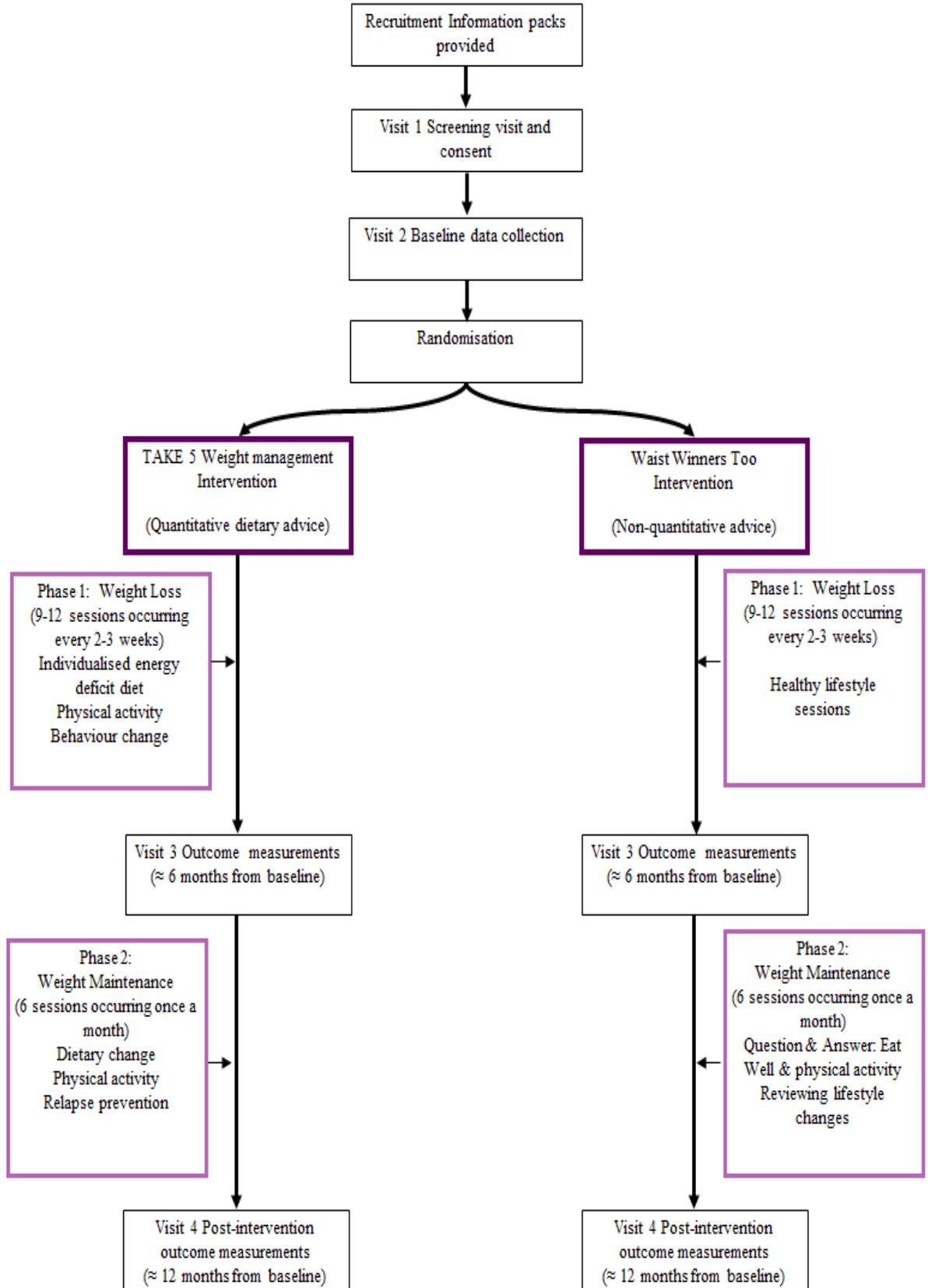


Figure 1. Study Design (Adapted from Harris *et al.*, 2015).

2.2 Study Population

The target population for this study is adults with intellectual disabilities and obesity (BMI ≥ 30 kg/m²). A multi-point recruitment strategy will be used to identify potential participants from adults with intellectual disabilities:

- attending local authority day centres
- receiving support from provider organisations
- using services provided by Area Intellectual Disabilities Teams, in the catchment area of NHS Greater Glasgow and Clyde.

Participants will be considered eligible to take part in the study if they are adults (≥ 18 years) with intellectual disabilities, obese (BMI ≥ 30 kg/m²), ambulatory (able to walk with or without a walking aid for 10 minutes), not currently on a prescribed or restricted diet e.g. for phenylketonuria or diabetes and not intentionally lost weight of >3 kg in the previous three months. Participants will be excluded if they have the following genetic syndromes; Prader Willi syndrome, Cohen syndrome or Bardet- Biedl syndrome, taking medication for the purpose of losing weight (either prescribed or over the counter) and individuals who are pregnant or who conceived during the study will be excluded.

2.3 Randomisation and Blinding

Once informed consent is obtained, participants will undergo baseline assessments. For clusters of participants, the baseline data for all participants in the cluster will be collected before randomisation. Participants will be allocated to one of the two study groups, using a mixed randomisation/minimisation approach.

The researcher will telephone an Interactive Voice Response System (IVRS) created and maintained by the Robertson Centre for Biostatistics (RCB). The researcher will log onto the system with a user ID and PIN, and provide the screening number and age of the participant for identification, as well as level of intellectual disabilities and presence of Down Syndrome for use in the adaptive minimisation algorithm (designed to ensure that none of these factors is imbalanced between the two study groups). The IVRS will not reveal the random allocation to the researcher, but notified the study coordinator, who will contact the research dietitians to arrange subsequent study visits. The researcher will be blinded to study group allocation.

2.4 Sample Size and Power

There is limited data from controlled trials of weight management involving adults with intellectual disabilities on which to base a sample size calculation. This study is designed to estimate recruitment and retention rates for a full-scale clinical trial; it is not powered to detect a difference between study groups. Sixty-six participants will be recruited (33 to each treatment arm). This will provide sufficient insight into recruitment and retention rates, which will have a 95% confidence interval of no more than $\pm 10\%$. The sample size will allow for a possible attrition rate of 20%. This study also aims to determine likely variance of study outcomes in order to power a larger randomised trial; if 50 participants provide outcome data at 12 months, a 90% confidence interval for each variance estimate will have a width of approximately 70% of the estimate (i.e. -26% to $+44\%$).

2.5 Study Variables

Outcome variables will be measured at three time points (table 1), baseline, ≈ 6 and 12 months from baseline.

Table 1: Schedule of outcome measure assessments

Outcome measure	Baseline	Time 1 (\approx 6 months from baseline)	Time 2 (\approx 12 months from baseline)
Demographic & health questionnaires	x	X	X
Height, weight, waist circumference, and triceps skinfold thickness	x	X	X
Quality of life measures	x	X	X

- Age, physical activity objective accelerometer data – Items measured on a continuous scale
- Anthropometric variables – Items measured on a continuous scale. Items will be measured twice and the average for each item reported as the summary statistic
- Demographics, marital status, ethnicity, social support, lifestyle habits, physical activity and mental health
- SIMD is calculated from participants' postcodes. Items are ordered categorically into quintiles for which 1 = most deprived and 5 = least deprived
- Ability and development – Items are measured on a 1-5 ordered categorical scale for which 1 = total independent, 2 = minimum assistance, 5 = regular supervision, 4 = 1:1 support and 5 = totally dependent. A total score 5-25 is calculated from the 5 questions
- Quality of life (EQ-5D-Y) – Items are measured on a 1-3 categorical scale for which 1 = no problems, 2 = some problems and 3 = extreme problems for each dimension
- Quality of life (EQ VAS) – Items are measured on a 0-100 visual analogue scale (VAS) for which 0 = worst imaginable health state and 100 = the best imaginable health state
- EQ-5D index.

2.6 General Considerations

Analysis is based on the intention to treat (ITT) principle. Per-protocol analyses, including only those participants who engaged with the programme, will also be used to test the sensitivity of the ITT results.

Analysis will be conducted to assess normal distributions of the data. Each variable will be assessed graphically using a histogram with normal distribution curves, boxplots and Q-Q residual plots. In addition to visual inspection of these plots for normal distribution, skewness and kurtosis will be tested using z-scores with < 1.96 representing normally distributed data. In circumstances if data are considered not normally distributed, factors affecting this will be explored. Outliers will be identified by examining residual Q-Q plots. Data points classified as outliers will be assessed for their potential to influence results and therefore study conclusions. Sensitivity analysis will be conducted to compare results with and without outlier(s). Any discrepancies between the two analyses will be reported and discussed. In addition to examining the data with and without outliers, transformation of the

data will be assessed using logarithmic and square root transformations and normality reassessed.

Descriptive statistics will be used for participant demographics and all outcome measures. Results will be presented as means and standard deviations (SD) for continuous variables (Anthropometric outcomes, physical activity outcomes) and frequencies and percentages (%) for categorical variables (Demographics, Ability and development, Health, QOL).

2.7 Primary Outcome

The primary outcome measure is the mean difference in body weight (kilograms (kg)) at twelve months from baseline between the two treatment groups.

2.8 Secondary Outcomes

Secondary outcomes include:

- Weight loss of five percent or more of initial body weight,
- Change in BMI, waist circumference and percentage body fat.
- Mean percentage time per day spent engaged in moderate-vigorous intensity physical activity; light intensity physical activity and engagement in sedentary behaviour.
- Change in health related Quality of Life.

Change from baseline at the end of the weight loss intervention period (6 months) and end the intervention (12 months) will be analysed for each secondary outcome.

2.9 Derived Variables

BMI will be calculated by the equation weight/height^2 (kg/m²).

Percentage body fat will be calculated using the triceps skinfold thickness (mm) measured to the nearest 1 mm, waist circumference (cm) and age (years) of the participant. Separate regression equations for male and female participants, developed by Lean *et al.* (1996) will be used to predict body density (BD) and percentage body fat (BF%).

Men

$$\text{BD} = 1.1554 - (0.000761 \times \text{waist}) - (0.00170 \times \text{triceps}) - (0.000532 \times \text{age})$$

$$\text{BF\%} = (0.353 \times \text{waist}) + (0.756 \times \text{triceps}) + (0.235 \times \text{age}) - 26.4$$

Women

$$\text{BD} = 1.1062 - (0.000482 \times \text{waist}) - (0.00140 \times \text{triceps}) - (0.000453 \times \text{age})$$

$$\text{BF\%} = (0.232 \times \text{waist}) + (0.657 \times \text{triceps}) + (0.215 \times \text{age}) - 5.5$$

Level of intellectual disabilities will be calculated by the adding the scores (total score 5-25) from the five key areas of functioning: eating and drinking, intimate care, personal safety, communication and decision making.

3.0 Analysis

All statistical data will be analysed using SPSS 21 IBM statistical package (SPSS IBM, New York, NY, USA).

3.1 Participant Disposition

A summary of the characteristics of the participants randomised to each treatment group (TAKE 5 or WWT00) and lost to follow-up will be provided overall and by randomised

group. This will be illustrated following Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 2).

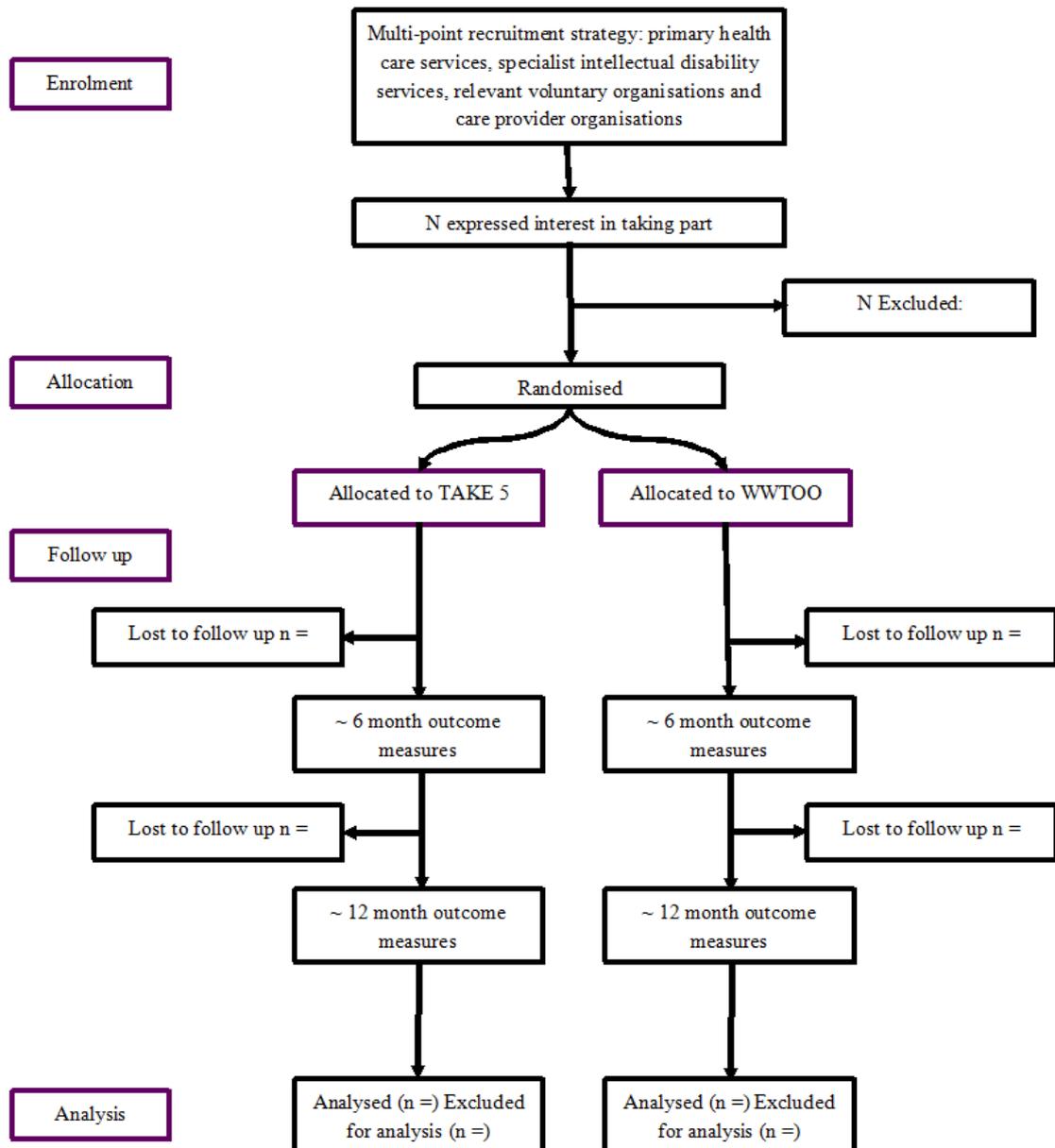


Figure 2. CONSORT flow diagram.

3.2 Baseline Characteristics

A summary of baseline characteristics for each randomised treatment group and overall will be reported:

- Demographics (age (years), sex, marital status, ethnicity, SIMD decile and social support)
- Anthropometry measurements (weight (kg), height (cm), body mass index (BMI) (kg/m^2) and, waist circumference (cm) and percentage body fat (%))
- Ability and development
- Physical and mental health questionnaires
- Lifestyle habits

- Physical activity (Accelerometer data)
- Quality of life (EQ-5D-Y)

3.3 Concurrent Illness and Medical Conditions

Physical and mental health conditions: Epilepsy, vision, hearing, mental health and problem behaviours will be reported as in accordance with the summary statistics. Further health problems such as diabetes and high blood pressure will be added from health problems or diagnosis questionnaire.

3.4 Treatment Compliance

Treatment compliance will be assessed by attendance to the intervention sessions.

3.5 Potential efficacy Analysis

3.5.1 Primary Outcome

A mixed effects model will be used to determine the mean difference in weight change at the end of the intervention period (~12 months) from baseline, between TAKE 5 and WWT00. The mixed effects model will take into account of clustering of participants (stratified by level of intellectual disabilities, number of participants in a cluster and presence of Down syndrome) and will adjust for baseline weight. The Interclass correlation coefficient (ICC), adjusted mean difference ((95% confidence interval (CI)) and p-value will be reported.

3.5.2 Secondary Outcome

Continuous secondary outcomes will be analysed and reported similarly as described above. A logistic regression model will be fitted for the categorical outcome, weight loss of 5% or more of initial body weight taking account of clustering and baseline adjustments listed above.

3.6 Process Measures

Descriptive statistics will be used to assess process measures such as attendance to sessions for each treatment group. Independent sample t-tests will be performed to determine if there are any differences between the treatment groups.

3.7 Missing Data

Missing data will not be imputed for any of the analysis.

3.8 Serious Adverse Events

Serious adverse events (SAE) are defined as an adverse event (an injury or newly diagnosed health condition) that induced hospitalisation or prolonged hospitalisation, results in persistent/significant disability or incapacity or is life-threatening or fatal. SAE will be recorded after baseline visits by the researcher at follow up visits. Incidence of SAE will be recorded for each treatment group.

4.0 Listing of Tables and Figures

Table 1.1. Subject disposition and reasons for withdrawal.

Table 1.2. Number of participants attending each visit, by randomised group and overall.

Table 1.3. Number of participants attending each intervention session, by randomised group and overall.

- Table 1.4.** Number of participants attending all sessions, by randomised group and overall.
- Table 1.5.** Summary of clusters, by randomised group and overall.
- Table 2.1.** Summary of demographic and baseline characteristics, by randomised group and overall (ITT).
- Table 2.1.1.** Summary of demographic and baseline characteristics, by randomised group and overall (Completers).
- Table 2.1.2.** Summary of demographic and baseline characteristics, by randomised group and overall (Non-completers).
- Table 2.2.** Summary of baseline anthropometry measurements, by randomised group and overall (ITT).
- Table 2.2.1.** Summary of baseline anthropometry measurements, by randomised group and overall (Completers).
- Table 2.2.2.** Summary of baseline anthropometry measurements, by randomised group and overall (Non-completers).
- Table 2.3.** Summary of baseline ability and development, by randomised group and overall (ITT).
- Table 2.3.1.** Summary of baseline ability and development, by randomised group and overall (Completers).
- Table 2.3.2.** Summary of baseline ability and development, by randomised group and overall (Non-completers).
- Table 2.4.** Summary of baseline level of intellectual disabilities, by randomized group and overall (ITT).
- Table 2.4.1.** Summary of baseline level of intellectual disabilities, by randomized group and overall (Completers).
- Table 2.4.2.** Summary of baseline level of intellectual disabilities, by randomized group and overall (Non-completers).
- Table 2.5.** Summary of baseline physical and mental health, by randomised group and overall (ITT).
- Table 2.5.1.** Summary of baseline physical and mental health, by randomised group and overall (Completers).
- Table 2.6.** Summary of baseline lifestyle habits, by randomised group and overall (ITT).
- Table 2.6.1.** Summary of baseline lifestyle habits, by randomised group and overall (Completers).
- Table 2.7.** Summary of baseline accelerometer data (minutes/day), by randomised group and overall (ITT).

Table 2.7.1. Summary of baseline accelerometer data (minutes/day), by randomised group and overall (Completers).

Table 2.8. Summary of baseline accelerometer data (percentage time spent/day), by randomised group and overall (ITT).

Table 2.8.1. Summary of baseline accelerometer data (percentage time spent/day), by randomised group and overall (Completers).

Table 2.9. Summary of baseline EQ domain, by randomised group and overall (ITT).

Table 2.9.1. Summary of baseline EQ domain, by randomised group and overall (Completers).

Table 2.10. Summary of baseline EQ-5D-Y index, by randomised group and overall (ITT).

Table 2.10.1. Summary of baseline EQ-5D-Y index, by randomised group and overall (Completers).

Table 3.1.1. Primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.1.1.1. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.1.1.2. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.1.2. Primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.1.2.1. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.2.1. Secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.2.1.1. Sensitivity analysis - secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.2.1.2. Sensitivity analysis - secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.2.2. Secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.3.1. Secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.3.1.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.3.2. Secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.3.3. Secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.3.3.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.3.3.2. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.3.4. Secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.3.4.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.4.1. Secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.4.1.1. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.4.1.2. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.4.2. Secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.4.2.1. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.4.3. Secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.4.3.1 Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.4.4. Secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.5.1. Secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.1.1. Sensitivity analysis -secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.1.2 Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.2. Secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.5.2.1 Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.5.3. Secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.3.1. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.3.2. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.5.4. Secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.5.4.1. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.6. Secondary outcome: Change in percentage weight change at 6 and 12 months from baseline. Odds ratio (95% confidence interval) and p-value (ITT).

Table 3.6.1. Secondary outcome: Change in percentage weight change at 6 and 12 months from baseline. Odds ratio (95% confidence interval) and p-value (Completers).

Table 3.7. Secondary outcome: Change in average step count at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.7.1. Secondary outcome: Change in average step count at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.8. Secondary outcome: Change in average step count at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.8.1. Secondary outcome: Change in average step count at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.9. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.9.1. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.9.2. Secondary outcome: Change in percentage time spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.9.3 Secondary outcome: Change in percentage time spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.10. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.10.1. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.10.2. Secondary outcome: Change in percentage time spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.10.3 Secondary outcome: Change in percentage time spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.11. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.11.1. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.11.2. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.11.3 Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.12. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.12.1. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.12.2. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.12.3 Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.13. Secondary outcome: Change in average number of minutes spent in any physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.13.1. Secondary outcome: Change in average number of minutes spent in any physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.13.2. Secondary outcome: Change in percentage time spent in any physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.13.3 Secondary outcome: Change in percentage time spent in any physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.14. Secondary outcome: Change in average number of minutes spent in any physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.14.1. Secondary outcome: Change in average number of minutes spent in any physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.14.2. Secondary outcome: Change in percentage time spent in any physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.14.3 Secondary outcome: Change in percentage time spent in any physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.15. Secondary outcome: Change in average number of minutes spent in sedentary behaviour physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.15.1. Secondary outcome: Change in average number of minutes spent in sedentary behaviour physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.15.2. Secondary outcome: Change in percentage time spent in sedentary behaviour physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.15.3 Secondary outcome: Change in percentage time spent in sedentary behaviour physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.16. Secondary outcome: Change in average number of minutes spent in sedentary behaviour physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.16.1. Secondary outcome: Change in average number of minutes spent in sedentary behaviour physical activity per day at 12 months from baseline, by intervention group and

overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.16.2. Secondary outcome: Change in percentage time spent in sedentary behaviour physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.16.3 Secondary outcome: Change in percentage time spent in sedentary behaviour physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.17. Secondary outcome: Change in average EQ-5D index at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.17.1 Secondary outcome: Change in average EQ-5D index at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.18. Secondary outcome: Change in average EQ-5D index at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Table 3.18.1 Secondary outcome: Change in average EQ-5D index at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Table 3.19. Secondary outcome: Change in EQ-5D-Y domain at 6 months from baseline. Adjusted odds ratio (95% confidence interval) and p-value (ITT).

Table 3.20. Secondary outcome: Change in EQ-5D-Y domain at 12 months from baseline. Adjusted odds ratio (95% confidence interval) and p-value (ITT).

4.1 Figures

No figures with exception of the skeleton CONSORT flow diagram was documented in this SAP.

5.0 Tables

Table 1.1. Subject disposition and reasons for withdrawal.

Disposition	TAKE 5	WWTOO	TOTAL
Screened participants	N/A	N/A	69
Randomised participants	26	24	50 (100.0%)
Completed study	24 (92.3%)	21 (87.5%)	45 (90.0%)
Withdrawals from study	2 (7.7%)	3 (12.5%)	5 (10.0%)
Reasons for withdrawal			
Adverse event (non-serious)	0 (0.0%)	1 (33.3%)	1 (20.0%)
Participant unwilling to continue in study activities	0 (0.0%)	1 (33.3%)	1 (20.0%)
Participant withdrew consent	0 (0.0%)	0 (0.0%)	0 (0.0%)
Participant withdrew on advice of investigator	0 (0.0%)	0 (0.0%)	0 (0.0%)
Carer or next of kin withdrew consent	1 (50.0%)	1 (33.3%)	2 (40.0%)
Participant lost to follow-up	1 (50.0%)	0 (0.0%)	1 (20.0%)
Inclusion / exclusion criteria not met	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 1.2. Number of participants attending each visit, by randomised group and overall.

Visit	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Screening	26 (100.0%)	24 (100.0%)	50 (100.0%)
Baseline	26 (100.0%)	24 (100.0%)	50 (100.0%)
6 months	24 (92.3%)	22 (91.7%)	46 (92.0%)
12 months	24 (92.3%)	24 (100.0%)	48 (96.0%)

Table 1.3. Number of participants attending each intervention session, by randomised group and overall.

TAKE 5 session	N	TAKE 5 (n=26)	N	WWTOO (n=24)	N	TOTAL (n=50)
Weight Loss 1	26	26 (100.0%)	24	24 (100.0%)	50	50 (100.0%)
Weight Loss 2	26	26 (100.0%)	24	19 (79.2%)	50	45 (90.0%)
Weight Loss 3	26	24 (92.3%)	24	20 (83.3%)	50	44 (88.0%)
Weight Loss 4	26	24 (92.3%)	23	19 (82.6%)	49	43 (87.8%)
Weight Loss 5	26	20 (76.9%)	23	23 (100.0)	49	43 (87.8%)
Weight Loss 6	25	22 (88.0%)	23	18 (78.3%)	48	40 (83.3%)
Weight Loss 7	25	22 (88.0%)	22	21 (95.5%)	47	43 (91.5%)
Weight Loss 8	24	23 (95.8%)	21	18 (85.7%)	45	41 (91.1%)
Weight Loss 9	24	22 (91.7%)	21	20 (95.2%)	45	42 (93.3%)
Weight Maintenance 1	24	18 (75.0%)	21	19 (90.5%)	45	37 (82.2%)
Weight Maintenance 2	24	20 (83.3%)	21	16 (76.2%)	45	36 (80.0%)
Weight Maintenance 3	24	21 (87.5%)	21	18 (85.7%)	45	39 (86.7%)
Weight Maintenance 4	24	19 (79.2%)	21	19 (90.5%)	45	38 (84.4%)
Weight Maintenance 5	24	20 (83.3%)	21	18 (85.7%)	45	38 (84.4%)
Weight Maintenance 6	24	21 (87.5%)	21	21 (100.0%)	45	42 (93.3%)

Table 1.4. Number of participants attending all sessions, by randomized group and overall.

Percentage attendance at all appointments	TAKE 5 (n=24)	WWTOO (n=21)	TOTAL (n=45)
100%	7 (29.1%)	5 (23.8%)	12 (26.7%)
90%	6 (25.0%)	8 (38.1%)	14 (31.1%)
80%	8 (33.3%)	6 (28.6%)	14 (31.1%)
70%	1 (4.2%)	0 (0.0%)	1 (2.2%)
60%	2 (8.3%)	2 (9.5%)	4 (8.9%)

Note: Percentage of attendance of participants excluding participants who dropped out of the intervention.

Table 1.5. Summary of clusters, by randomised group and overall.

		TAKE 5	WWTOO	TOTAL
Number of clusters		3	2	5
Size of clusters	N	26	24	50
	Mean	1.2	1.2	1.2
	Std Dev	0.43	0.38	0.40
	Median	1.0	1.0	1.0
	Min-Max	1-2	1-2	1-2
Interquartile range		1	1	1

Table 2.1. Summary of demographic and baseline characteristics, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Age (years)	N	26	24	50
	Mean	40.6	43.6	42.0
	Std Dev	14.98	13.99	14.45
	Median	42.5	45.5	44.5
	Min-Max	18-71	23-66	18-71
	Interquartile range	26-53	29-54	29-53
Gender	Missing	0	0	0
	N	26	24	50
	Male	8 (30.8%)	10 (41.7%)	18 (36.0%)
	Female	18 (69.2%)	14 (58.3%)	32 (64.0%)
Marital status	Missing	0	0	0
	N	26	24	50
	Married/live in partner	1 (3.8%)	0 (0.0%)	1 (2.0%)
	Separated/ divorced	1 (3.8%)	0 (0.0%)	1 (2.0%)
	Single	24 (92.3%)	24 (100.0%)	48 (96.0%)
	Widow/er	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity	Missing	0	0	0
	N	26	24	50
	White	26 (100.0%)	22 (91.7%)	48 (96.0%)
	Asian	0 (0.0%)	2 (8.3%)	2 (4.0%)
	Black	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Mixed	0 (0.0%)	0 (0.0%)	0 (0.0%)
SIMD decile (% living in quintiles)	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
	N	26	24	50
	1 (most deprived)	12 (46.2%)	9 (37.5%)	21 (42.0%)
	2	6 (23.1%)	5 (20.8%)	11 (22.0%)
	3	2 (7.7%)	4 (16.7%)	6 (12.0%)
Where does participant live?	4	5 (19.2%)	5 (20.8%)	10 (20.0%)
	5 (least deprived)	1 (3.8%)	1 (4.2%)	2 (4.0%)
	Missing	0	0	0
	N	26	24	50
	Parents home	7 (26.9%)	7 (29.2%)	14 (28.0%)
	Other family carers home	1 (3.8%)	1 (4.2%)	2 (4.0%)
	Lives independently +/- children	1 (3.8%)	3 (12.5%)	4 (8.0%)
	Lives independently with spouse	1 (3.8%)	0 (0.0%)	1 (2.0%)
	Lives independently with paid support	8 (30.8%)	5 (20.8%)	13 (26.0%)
	Supported group living	5 (19.2%)	6 (25.0%)	11 (22.0%)
If supported, how much?	Supported living - individual	2 (7.7%)	1 (4.2%)	3 (6.0%)
	Residential care	1 (3.8%)	1 (4.2%)	2 (4.0%)
	Nursing home	0 (0.0%)	0 (0.0%)	0 (0.0%)
	NHS accommodation	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
	N	16	13	29
	Part-time support (less than daily)	3 (18.8%)	0 (0.0%)	3 (10.3%)

	Part-time support (daily)	6 (37.5%)	3 (23.1%)	9 (31.0%)
	24 hour support, sleep-in nights	7 (43.8%)	10 (76.9%)	17 (58.6%)
	24 hour support, including wake at night	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.1.1. Summary of demographic and baseline characteristics, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Age (years)	N	21	19	40
	Mean	40.9	42.6	41.7
	Std Dev	13.54	13.91	13.57
	Median	44.0	45.0	44.5
	Min-Max	18-61	23-65	18-65
	Interquartile range	28-53	29-52	29-52
Gender	Missing	0	0	0
	N	21	19	40
	Male	7 (33.3%)	7 (36.8%)	14 (35.0%)
	Female	14 (66.7%)	12 (63.2%)	26 (65.0%)
Marital status	Missing	0	0	0
	N	21	10	40
	Married/live in partner	1 (4.8%)	0	1 (2.5%)
	Separated/ divorced	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Single	20 (95.2%)	19 (100%)	39 (97.5%)
	Widow/er	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity	Missing	0	0	0
	N	21	19	40
	White	21 (100%)	17 (89.5%)	38 (95.0%)
	Asian	0 (0.0%)	2 (10.5%)	2 (5.0%)
	Black	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Mixed	0 (0.0%)	0 (0.0%)	0 (0.0%)
SIMD decile (% living in quintiles)	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
	N	21	19	40
	1 (most deprived)	7 (33.3%)	8 (42.1%)	15 (37.5%)
	2	6 (28.6%)	5 (26.3%)	11 (27.5%)
	3	2 (9.5%)	0 (0.0%)	2 (5%)
Where does participant live?	4	5 (23.8%)	5 (26.3%)	10 (25.0%)
	5 (least deprived)	1 (4.8%)	1 (5.3%)	2 (5.0%)
	Missing	0	0	0
	N	21	19	40
	Parents home	5 (23.8%)	6 (31.6%)	11 (27.5%)
	Other family carers home	1 (4.8%)	1 (5.3%)	2 (5.0%)
Where does participant live?	Lives independently +/- children	1 (4.8%)	2 (10.5%)	3 (7.5%)
	Lives independently with spouse	1 (4.8%)	0 (0.0%)	1 (2.5%)
	Lives independently with paid support	6 (28.6%)	4 (21.1%)	10 (25.0%)
	Supported group living	5 (23.8%)	5 (26.3%)	10 (25.0%)
	Supported living - individual	1 (4.8%)	0 (0.0%)	1 (2.5%)
	Residential care	1 (4.8%)	1 (5.3%)	2 (5.0%)
	Nursing home	0 (0.0%)	0 (0.0%)	0 (0.0%)
	NHS accommodation	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

If supported, how much?	N	13	10	23
	Part-time support (less than daily)	1 (7.7%)	0 (0.0%)	1 (4.3%)
	Part-time support (daily)	6 (46.2%)	2 (20.0%)	8 (34.8%)
	24 hour support, sleep-in nights	6 (46.2%)	8 (80.0%)	14 (60.9%)
	24 hour support, including wake at night	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.1.2 Summary of demographic and baseline characteristics, by randomised group and overall (Non-completers).

Variable	Statistic	TAKE 5 (n=5)	WWTOO (n=5)	TOTAL (n=10)
Age (years)	N	5	5	10
	Mean	39.2	47.6	43.4
	Std Dev	21.97	15.14	18.33
	Median	32.0	50.0	46.5
	Min-Max	19-71	25-66	19-71
	Interquartile range	21-62	34-60	24-57
Gender	Missing	0	0	0
	N	5	5	10
	Male	1 (20.0%)	3 (60.0%)	4 (40.0%)
	Female	4 (80.0%)	2 (40.0%)	6 (60.0%)
Marital status	Missing	0	0	0
	N	5	5	10
	Married/live in partner	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Separated/ divorced	1 (20.0%)	0 (0.0%)	1 (10.0%)
	Single	4 (80.0%)	5 (100.0%)	9 (90.0%)
	Widow/er	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity	Missing	0	0	0
	N	5	5	10
	White	5 (100.0%)	5 (100.0%)	10 (100.0%)
	Asian	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Black	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Mixed	0 (0.0%)	0 (0.0%)	0 (0.0%)
SIMD decile (% living in quintiles)	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N	5	5	10
	1 (most deprived)	5 (100.0%)	1 (20.0%)	6 (60.0%)
	2	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	4 (80.0%)	4 (40.0%)
Where does participant live?	4	0 (0.0%)	0 (0.0%)	0 (0.0%)
	5 (least deprived)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
	N	5	5	10
	Parents home	2 (40.0%)	1 (20.0%)	3 (30.0%)
	Other family carers home	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Lives independently +/- children	0 (0.0%)	1 (20.0%)	1 (10.0%)
	Lives independently with spouse	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Lives independently with paid support	2 (40.0%)	1 (20.0%)	3 (30.0%)
	Supported group living	0 (0.0%)	1 (20.0%)	1 (10.0%)
If supported, how much?	Supported living - individual	1 (20.0%)	1 (20.0%)	2 (20.0%)
	Residential care	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Nursing home	0 (0.0%)	0 (0.0%)	0 (0.0%)
	NHS accommodation	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
	N	3	3	6

	Part-time support (less than daily)	2 (66.7%)	0 (0.0%)	2 (33.3%)
	Part-time support (daily)	0 (0.0%)	1 (33.3%)	1 (16.7%)
	24 hour support, sleep-in nights	1 (33.3%)	2 (66.7%)	3 (50.0%)
	24 hour support, including wake at night	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.2. Summary of baseline anthropometry measurements, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Height (cm)	N	26	24	50
	Mean	158.4	158.5	158.4
	Std Dev	10.64	13.65	12.05
	Median	157.5	157.5	157.5
	Min-Max	137-175	132-181	1322-181
	Interquartile range	151-167	149-172	150-168
Weight (kg)	Missing	0	0	0
	N	26	24	50
	Mean	102.3	104.1	103.1
	Std Dev	25.40	28.86	26.85
	Median	102.3	100.4	100.7
	Min-Max	59-149	72-212.	59-212
BMI (kg/m ²)	Interquartile range	84-126	87-111	867-122
	Missing	0	0	0
	N	26	24	50
	Mean	40.2	41.2	40.7
	Std Dev	6.84	8.14	7.43
	Median	40.4	39.0	39.6
Waist circumference (cm)	Min-Max	31-54	32-66	31-66
	Interquartile range	33-45	34-46	34-45
	Missing	0	0	0
	N	24	23	47
	Mean	121.9	122.2	122.0
	Std Dev	14.02	16.12	14.92
Percentage body fat (%)	Median	121.5	121.1	121.1
	Min-Max	95-143	98-171	95-171
	Interquartile range	111-136	109-130	110-132
	Missing	2	1	3
	N	24	19	43
	Mean	49.3	51.7	50.3
Percentage body fat (%)	Std Dev	9.11	8.55	8.84
	Median	48.9	49.6	49.5
	Min-Max	33-68	41-79	33-79
	Interquartile range	45-55	47-55	46-55
	Missing	2	5	7

Note: Summaries are the average of two measurements taken for each participant.

Table 2.2.1 Summary of baseline anthropometry measurements, by randomised group and overall (Completers)

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Height (cm)	N	21	19	40
	Mean	158.2	157.0	157.7
	Std Dev	10.37	13.85	12.00
	Median	157.9	156.2	157.2
	Min-Max	137-175	132-181	132-181
	Interquartile range	151-165	147-168	149-166
	Missing	0	0	0
Weight (kg)	N	21	19	40
	Mean	102.7	101.9	102.3
	Std Dev	25.10	18.05	21.77
	Median	100.5	100.9	100.7
	Min-Max	59-149	72-145	59-149
	Interquartile range	87-126	88-112	87-119
	Missing	0	0	0
BMI (kg/m ²)	N	21	19	40
	Mean	40.6	41.5	41.0
	Std Dev	7.06	6.19	6.59
	Median	39.6	42.9	40.4
	Min-Max	31-54	32-52	31-54
	Interquartile range	34-46	35-46	35-46
	Missing	0	0	0
Waist circumference (cm)	N	19	18	37
	Mean	121.7	121.0	121.4
	Std Dev	14.11	13.28	13.53
	Median	120.5	121.4	121.1
	Min-Max	95-143	98-149	95-149
	Interquartile range	111-136	109-130	110-133
	Missing	2	1	3
Percentage body fat (%)	N	19	15	34
	Mean	49.3	51.0	50.1
	Std Dev	10.02	5.79	8.35
	Median	49.9	51.3	50.1
	Min-Max	33-68	41-61	33-68
	Interquartile range	40-55	47-55	46-55
	Missing	2	4	6

Note: Summaries are the average of two measurements taken for each participant.

Table 2.2.2 Summary of baseline anthropometry measurements, by randomised group and overall (Non-completers)

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Height (cm)	N	5	5	10
	Mean	159.0	164.2	161.6
	Std Dev	13.04	12.55	12.37
	Median	157.1	162.7	159.9
	Min-Max	139-173	150-180	139-180
	Interquartile range	148-171	152-177	154-174
Weight (kg)	Missing	0	0	0
	N	5	5	10
	Mean	100.4	112.2	106.3
	Std Dev	29.58	56.73	43.11
	Median	104.1	86.8	95.3
	Min-Max	65-132	77-212	65-212
BMI (kg/m ²)	Interquartile range	70-129	79-158	77-127
	Missing	0	0	0
	N	5	5	10
	Mean	38.9	40.3	39.6
	Std Dev	6.40	14.37	10.51
	Median	42.2	34.3	35.3
Waist circumference (cm)	Min-Max	31-44	32-66	31-66
	Interquartile range	32-44	32-51	33-44
	Missing	0	0	0
	N	5	5	5
	Mean	122.5	126.3	124.4
	Std Dev	15.26	25.52	19.92
Percentage body fat (%)	Median	128.6	118.4	120.0
	Min-Max	105-141	105-171	105-171
	Interquartile range	107-135	111-146	108-132
	Missing	0	0	0
	N	5	4	9
	Mean	49.2	54.3	51.4
Percentage body fat (%)	Std Dev	5.05	16.46	11.03
	Median	48.1	47.3	48.1
	Min-Max	45-58	44-79	44-79
	Interquartile range	46-53	44-71	45-54
	Missing	0	1	1

Note: Summaries are the average of two measurements taken for each participant.

Table 2.3. Summary of baseline ability and development, by randomised group and overall (ITT).

How much support does the participant need with	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Eating and drinking	N	26	24	50
	Totally independent	18 (69.2%)	16 (66.7%)	34 (68.0%)
	Minimum assistance	3 (11.5%)	7 (29.2%)	10 (20.0%)
	Regular prompting/supervision	3 (11.5%)	1 (4.2%)	4 (8.0%)
	1:1 support required	2 (7.7%)	0 (0.0%)	2 (4.0%)
	1:1 support required and special equipment	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
Intimate care	N	26	24	50
	Fully independent	10 (38.5%)	9 (16.7%)	19 (38.0%)
	Minimum assistance	7 (26.9%)	4 (16.7%)	11 (22.0%)
	Regular prompting/supervision	3 (11.5%)	2 (8.3%)	5 (10.0%)
	1:1 support required	5 (19.2%)	8 (33.3%)	13 (26.0%)
	1:1 support required and totally dependent	1 (3.8%)	1 (4.2%)	2 (4.0%)
Missing	0	0	0	
Personal safety	N	26	24	50
	Totally independent	6 (23.1%)	5 (20.8%)	11 (22.0%)
	Minimum assistance	6 (23.1%)	5 (20.8%)	11 (22.0%)
	Some awareness/supervision	8 (30.8%)	5 (20.8%)	13 (26.0%)
	Constant supervision	3 (11.5%)	4 (16.7%)	7 (14.0%)
	Totally dependent	3 (11.5%)	5 (20.8%)	8 (16.0%)
	Missing	0	0	0
Communication	N	26	24	50
	Totally independent	14 (53.8%)	12 (50.0%)	26 (52.0%)
	Reasonably clearly, sign/aids	4 (15.4%)	3 (12.5%)	7 (14.0%)
	Staff support	2 (7.7%)	4 (16.7%)	6 (12.0%)
	Time required understand	3 (11.5%)	1 (4.2%)	4 (8.0%)
	Extremely limited	3 (11.5%)	4 (16.7%)	7 (14.0%)
	Missing	0	0	0
Decision making	N	26	24	50
	Totally independent	4 (15.4%)	3 (12.5%)	7 (14.0%)
	Minimum support	9 (34.6%)	6 (25.0%)	15 (30.0%)
	Some choices/decisions	8 (30.8%)	12 (50.0%)	20 (40.0%)
	Support required	3 (11.5%)	1 (4.2%)	4 (8.0%)
	Totally dependent	2 (7.7%)	2 (8.3%)	4 (8.0%)
Missing	0	0	0	

Table 2.3.1. Summary of baseline ability and development, by randomised group and overall (Completers).

How much support does the participant need with	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Eating and drinking	N	21	19	40
	Totally independent	15 (71.4%)	13 (68.4%)	28 (70.0%)
	Minimum assistance	3 (14.3%)	5 (26.3%)	8 (20.0%)
	Regular prompting/supervision	1 (4.8%)	1 (5.3%)	2 (5.0%)
	1:1 support required	2 (9.5%)	0 (0.0%)	2 (5.0%)
	1:1 support required and special equipment	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
Intimate care	N	21	19	40
	Fully independent	8 (38.1%)	7 (36.8%)	15 (37.5%)
	Minimum assistance	6 (28.6%)	3 (15.8%)	9 (22.5%)
	Regular prompting/supervision	3 (14.3%)	1 (5.3%)	4 (10.0%)
	1:1 support required	4 (19.0%)	7 (36.8%)	11 (27.5%)
	1:1 support required and totally dependent	0 (0.0%)	1 (5.3%)	1 (2.5%)
	Missing	0	0	0
Personal safety	N	21	19	40
	Totally independent	5 (23.8%)	4 (21.1%)	9 (22.5%)
	Minimum assistance	6 (28.6%)	4 (21.1%)	10 (25.0%)
	Some awareness/supervision	6 (28.6%)	3 (15.8%)	9 (22.5%)
	Constant supervision	2 (9.5%)	4 (21.1%)	6 (15.0%)
	Totally dependent	2 (9.5%)	4 (21.1%)	6 (15.0%)
	Missing	0	0	0
Communication	N	21	19	40
	Totally independent	12 (57.1%)	9 (47.4%)	21 (52.5%)
	Reasonably clearly, sign/aids	4 (19.0%)	3 (15.8%)	7 (17.5%)
	Staff support	0 (0.0%)	3 (15.8%)	3 (7.5%)
	Time required understand	2 (9.5%)	1 (5.3%)	3 (7.5%)
	Extremely limited	3 (14.3%)	3 (15.8%)	6 (15.0%)
	Missing	0	0	0
Decision making	N	21	19	40
	Totally independent	3 (14.3%)	2 (10.5%)	5 (12.5%)
	Minimum support	8 (38.1%)	5 (26.3%)	13 (32.5%)
	Some choices/decisions	6 (28.6%)	9 (47.4%)	15 (37.5%)
	Support required	3 (14.3%)	1 (5.3%)	4 (10.0%)
	Totally dependent	1 (4.8%)	2 (10.5%)	3 (7.5%)
	Missing	0	0	0

Table 2.3.2. Summary of baseline ability and development, by randomised group and overall (Non-completers).

How much support does the participant need with	Statistic	TAKE 5 (n=5)	WWTOO (n=5)	TOTAL (n=10)
Eating and drinking	N	5	5	10
	Totally independent	3 (60.0%)	3 (60.0%)	6 (60.0%)
	Minimum assistance	0 (0.0%)	2 (40.0%)	2 (20.0%)
	Regular prompting/supervision	2 (40.0%)	0 (0.0%)	2 (20.0%)
	1:1 support required	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1:1 support required and special equipment	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
Intimate care	N	5	5	10
	Fully independent	2 (40.0%)	2 (40.0%)	4 (40.0%)
	Minimum assistance	1 (20.0%)	1 (20.0%)	2 (20.0%)
	Regular prompting/supervision	0 (0.0%)	1 (20.0%)	1 (10.0%)
	1:1 support required	1 (20.0%)	1 (20.0%)	2 (20.0%)
	1:1 support required and totally dependent	1 (20.0%)	0 (0.0%)	1 (10.0%)
Missing	0	0	0	
Personal safety	N	5	5	10
	Totally independent	1 (20.0%)	1 (20.0%)	2 (20.0%)
	Minimum assistance	0 (0.0%)	1 (20.0%)	1 (10.0%)
	Some awareness/supervision	2 (40.0%)	2 (40.0%)	4 (40.0%)
	Constant supervision	1 (20.0%)	0 (0.0%)	1 (10.0%)
	Totally dependent	1 (20.0%)	1 (20.0%)	2 (20.0%)
Missing	0	0	0	
Communication	N	5	5	10
	Totally independent	2 (40.0%)	3 (60.0%)	5 (50.0%)
	Reasonably clearly, sign/aids	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Staff support	2 (40.0%)	1 (20.0%)	3 (30.0%)
	Time required understand	1 (20.0%)	0 (0.0%)	1 (10.0%)
	Extremely limited	0 (0.0%)	1 (20.0%)	1 (10.0%)
Missing	0	0	0	
Decision making	N	5	5	10
	Totally independent	1 (20.0%)	1 (20.0%)	2 (20.0%)
	Minimum support	1 (20.0%)	1 (20.0%)	2 (20.0%)
	Some choices/decisions	2 (40.0%)	3 (60.0%)	5 (50.0%)
	Support required	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Totally dependent	1 (20.0%)	0 (0.0%)	1 (10.0%)
Missing	0	0	0	

Table 2.4. Summary of baseline level of intellectual disabilities, by randomized group and overall (ITT).

Variable	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Mild	8 (30.8%)	6 (25.0%)	14 (28.0%)
Moderate	11 (42.3%)	10 (41.7%)	21 (42.0%)
Severe	4 (15.4%)	7 (29.2%)	11 (22.0%)
Profound	3 (11.5%)	1 (4.2%)	4 (8.0%)

Table 2.4.1. Summary of baseline level of intellectual disabilities, by randomized group and overall (Completers).

Variable	TAKE 5	WWTOO	TOTAL
Mild	6 (28.6%)	5 (26.3%)	11 (27.5%)
Moderate	11 (52.4%)	7 (36.8%)	8 (45.0%)
Severe	2 (9.5%)	6 (31.6%)	8 (20.0%)
Profound	2 (9.5%)	1 (5.3%)	3 (7.5%)

Table 2.4.2 Summary of baseline level of intellectual disabilities, by randomized group and overall (Non-completers).

Variable	TAKE 5	WWTOO	TOTAL
Mild	2 (40.0%)	1 (20.0%)	3 (30.0%)
Moderate	0 (0.0%)	3 (60.0%)	3 (30.0%)
Severe	2 (40.0%)	1 (20.0%)	3 (30.0%)
Profound	1 (20.0%)	0 (0.0%)	1 (10.0%)

Table 2.5. Summary of baseline physical and mental health, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Epilepsy	N	26	24	50
	Yes	6 (23.1%)	5 (20.8%)	11 (22.0%)
	No	20 (76.9%)	19 (79.2%)	39 (78.0%)
	Missing	0	0	0
Vision	N	26	24	50
	Yes	16 (61.5%)	9 (37.5%)	25 (50.0%)
	No	10 (38.5%)	14 (58.3%)	24 (48.0%)
	Don't know	0 (0.0%)	1 (4.2%)	1 (2.0%)
	Missing	0	0	0
Hearing	N	26	24	50
	Yes	6 (23.1%)	3 (12.5%)	9 (18.0%)
	No	20 (76.9%)	21 (87.5%)	41 (82.0%)
	Missing	0	0	0
Mental Health Issues	N	26	24	50
	Yes	10 (38.5%)	9 (37.5%)	19 (38.0%)
	No	15 (57.7%)	14 (58.3%)	29 (58.0%)
	Not sure	1 (3.8%)	1 (4.2%)	2 (4.0%)
	Missing	0	0	0
Problem behaviours	N	26	24	50
	Yes	12 (46.2%)	11 (45.8%)	23 (46.0%)
	No	14 (53.8%)	13 (54.2%)	27 (54.0%)
	Missing	0	0	0
High Blood Pressure	N	26	24	50
	Yes	5 (19.2%)	2 (8.3%)	7 (14.0%)
	No	21 (80.8%)	22 (91.7%)	43 (86.0%)
	Missing	0	0	0
Type II Diabetes	N	26	24	50
	Yes	1 (3.8%)	3 (12.5%)	4 (8.0%)
	No	25 (96.2%)	21 (87.5%)	46 (92.0%)
	Missing	0	0	0
Underactive Thyroid	N	26	24	50
	Yes	2 (7.7%)	1 (4.2%)	3 (6.0%)
	No	24 (92.3%)	23 (95.8%)	47 (94.0%)
	Missing	0	0	0
Rheumatoid Arthritis	N	26	24	50
	Yes	3 (11.5%)	2 (8.3%)	5 (10.0%)
	No	23 (88.5%)	22 (91.7%)	45 (90.0%)
	Missing	0	0	0
Asthma	N	26	24	50
	Yes	4 (15.4%)	3 (12.5%)	7 (14.0%)
	No	22 (84.6%)	21 (87.5%)	43 (86.0%)
	Missing	0	0	0
Depression	N	26	24	50
	Yes	3 (11.5%)	3 (12.5%)	6 (12.0%)
	No	23 (88.5%)	21 (87.5%)	44 (88.0%)
	Missing	0	0	0

Table 2.5.1. Summary of baseline physical and mental health, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Epilepsy	N	21	19	40
	Yes	4 (19.0%)	3 (15.8%)	7 (17.5%)
	No	17 (81.0%)	16 (84.2%)	33 (82.5%)
	Missing	0	0	0
Vision	N	21	19	40
	Yes	11 (52.4%)	7 (36.8%)	18 (45.0%)
	No	10 (47.6%)	12 (63.2%)	22 (55.0%)
	Don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hearing	N	21	19	40
	Yes	6 (28.6%)	2 (10.5%)	8 (20.0%)
	No	15 (71.4%)	17 (89.5%)	32 (80.0%)
	Missing	0	0	0
Mental Health Issues	N	21	19	40
	Yes	8 (38.1%)	7 (36.8%)	15 (37.5%)
	No	12 (57.1%)	11 (57.9%)	23 (57.5%)
	Not sure	1 (4.8%)	1 (5.3%)	2 (5.0%)
Problem behaviours	N	21	19	40
	Yes	10 (47.6%)	8 (42.1%)	18 (45.0%)
	No	11 (52.4%)	11 (57.9%)	22 (55.0%)
	Missing	0	0	0
High Blood Pressure	N	21	19	40
	Yes	4 (19.0%)	2 (10.5%)	6 (15.0%)
	No	17 (81.0%)	17 (89.5%)	34 (85.0%)
	Missing	0	0	0
Type II Diabetes	N	21	19	40
	Yes	1 (4.8%)	1 (5.3%)	2 (5.0%)
	No	20 (95.2%)	18 (94.7%)	38 (95.0%)
	Missing	0	0	0
Underactive Thyroid	N	21	19	40
	Yes	2 (9.5%)	1 (5.3%)	3 (7.5%)
	No	19 (90.5%)	18 (94.7%)	37 (92.5%)
	Missing	0	0	0
Rheumatoid Arthritis	N	21	19	40
	Yes	1 (4.8%)	2 (10.5%)	3 (7.5%)
	No	20 (95.2%)	17 (89.5%)	37 (92.5%)
	Missing	0	0	0
Asthma	N	21	19	40
	Yes	3 (14.3%)	2 (10.5%)	5 (12.5%)
	No	18 (85.7%)	17 (89.5%)	35 (87.5%)
	Missing	0	0	0
Depression	N	21	19	40
	Yes	3 (14.3%)	3 (15.8%)	6 (15.0%)
	No	18 (85.7%)	16 (84.2%)	34 (85.0%)
	Missing	0	0	0

Table 2.6. Summary of baseline lifestyle habits, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Hours watching TV, DVDs or videos	N	26	24	50
	Does not watch TV	2 (7.7%)	0 (0.0%)	2 (4.0%)
	1-3 hours month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1 hour a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2-4 hours a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	5-6 hours a week	0 (0.0%)	1 (4.2%)	1 (2.0%)
	1 hour a day	2 (7.7%)	3 (12.5%)	5 (10.0%)
	2-3 hours a day	10 (38.5%)	5 (20.8%)	15 (30.0%)
	4-5 hours a day	7 (26.9%)	8 (33.3%)	15 (30.0%)
	6+ hours a day	5 (19.2%)	7 (29.2%)	12 (24.0%)
	Missing	0	0	0
Hours using computers	N	26	24	50
	Does not use computers	10 (38.5%)	14 (58.3%)	24 (48.0%)
	1-3 hours month	3 (11.5%)	2(8.3%)	5 (10.0%)
	1 hour a week	2 (7.7%)	4 (16.7%)	6 (12.0%)
	2-4 hours a week	1 (3.8%)	1 (4.2%)	2 (4.0%)
	5-6 hours a week	1 (3.8%)	0 (0.0%)	1 (2.0%)
	1 hour a day	2 (7.7%)	1 (4.2%)	3 (6.0%)
	2-3 hours a day	7 (26.9%)	0 (0.0%)	7 (14.0%)
	4-5 hours a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	6+ hours a day	0 (0.0%)	2 (8.3%)	2 (4.0%)
	Missing	0	0	0
Number of cigarettes smoked	N	26	24	50
	None, does not smoke	26 (100.0%)	21 (87.5%)	47 (94.0%)
	Less than 1 cigarette a month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-3 cigarettes a month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-6 cigarettes a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-3 cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	4-10 cigarettes a day	0 (0.0%)	1 (4.2%)	1 (2.0%)
	11-20 cigarettes a day	0 (0.0%)	2 (8.3%)	2 (4.0%)
	21-39 cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	40+ cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.6.1. Summary of baseline lifestyle habits, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Hours watching TV, DVDs or videos	N	21	19	40
	Does not watch TV	2 (9.5%)	0 (0.0%)	2 (5.0%)
	1-3 hours month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1 hour a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2-4 hours a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	5-6 hours a week	0 (0.0%)	1 (5.3%)	1 (2.5%)
	1 hour a day	2 (9.5%)	3 (15.8%)	5 (12.5%)
	2-3 hours a day	10 (47.6%)	4 (21.1%)	14 (35.0%)
	4-5 hours a day	3 (14.3%)	6 (31.6%)	9 (22.5%)
	6+ hours a day	4 (19.0%)	5 (26.3%)	9 (22.5%)
	Missing	0	0	0
Hours using computers	N	21	19	40
	Does not use computers	9 (42.9%)	10 (52.6%)	19 (47.5%)
	1-3 hours month	3 (14.3%)	2 (10.5%)	5 (12.5%)
	1 hour a week	2 (9.5%)	3 (15.8%)	5 (12.5%)
	2-4 hours a week	1 (4.8%)	1 (5.3%)	2 (5.0%)
	5-6 hours a week	1 (4.8%)	0 (0.0%)	1 (2.5%)
	1 hour a day	1 (4.8%)	1 (5.3%)	2 (5.0%)
	2-3 hours a day	4 (19.0%)	0 (0.0%)	4 (10.0%)
	4-5 hours a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	6+ hours a day	0 (0.0%)	2 (10.5%)	2 (5.0%)
	Missing	0	0	0
Number of cigarettes smoked	N	21	19	40
	None, does not smoke	21 (100.0%)	17 (89.5%)	38 (95.0%)
	Less than 1 cigarette a month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-3 cigarettes a month	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-6 cigarettes a week	0 (0.0%)	0 (0.0%)	0 (0.0%)
	1-3 cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	4-10 cigarettes a day	0 (0.0%)	1 (5.3%)	1 (2.5%)
	11-20 cigarettes a day	0 (0.0%)	1 (5.3%)	1 (2.5%)
	21-39 cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	40+ cigarettes a day	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.8. Summary of baseline accelerometer data (minutes/day), by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Steps	N	25	22	47
	Mean	4880	4875	4877
	Std Dev	2184.72	2315.32	2222.06
	Median	4652	5077	4705
	Min-Max	1422-10062	1246-9207	1246-10062
	Interquartile range	3578-6371	2757-6591	3055-6490
	Missing	1	2	3
Light PA (minutes/day)	N	25	22	47
	Mean	147.9	159.6	153.4
	Std Dev	47.01	77.19	62.51
	Median	141.9	143.7	141.9
	Min-Max	49-268	75-382	49-382
	Interquartile range	124-180	101.3-194.8	105-183
	Missing	1	2	3
MVPA (minutes/day)	N	25	22	47
	Mean	28.8	31.6	30.1
	Std Dev	16.90	22.52	19.56
	Median	23.5	23.0	23.5
	Min-Max	2-64	5-89	2-89
	Interquartile range	17-42	17-39	17-40
	Missing	1	2	3
Total PA (minutes/day)	N	25	22	47
	Mean	176.8	191.2	183.5
	Std Dev	53.25	85.09	69.55
	Median	175.2	184.0	176.9
	Min-Max	68-331	93-420	68-420
	Interquartile range	145-203	112-229	136-212
	Missing	1	2	3
Sedentary Behaviour	N	25	22	47
	Mean	501.1	522.3	511.0
	Std Dev	125.88	165.29	144.41
	Median	475.7	496.6	479.6
	Min-Max	353-945	268-915	268-945
	Interquartile range	411-583	410-671	412-593
	Missing	1	2	3

Table 2.8.1. Summary of baseline accelerometer data (minutes/day), by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Steps	N	20	17	37
	Mean	4974	4416	4718
	Std Dev	2066.43	2311.27	2169.62
	Median	4673	3939	4652
	Min-Max	1599-10062	1246-8130	1246-10062
	Interquartile range	3752-6426	2360-6671	2982-6562
	Missing	1	2	3
Light PA (minutes/day)	N	20	17	37
	Mean	150.9	159.4	154.8
	Std Dev	51.85	86.97	69.28
	Median	150.7	118.9	144.7
	Min-Max	49-268	75-382	49-382
	Interquartile range	127-183	95-210	103-187
	Missing	1	2	3
MVPA (minutes/day)	N	20	17	37
	Mean	28.9	27.9	28.4
	Std Dev	17.09	19.81	18.14
	Median	21.5	22.2	22.2
	Min-Max	4-64	5-89	4-89
	Interquartile range	17-43	16-37	17-39
	Missing	1	2	3
Total PA (minutes/day)	N	20	17	37
	Mean	179.7	187.3	183.2
	Std Dev	57.47	96.04	76.54
	Median	176.1	170.1	175.2
	Min-Max	68-331	93-420	68-420
	Interquartile range	150-219	108-239	122-219
	Missing	1	2	3
Sedentary Behaviour	N	20	17	37
	Mean	506.4	529.1	516.8
	Std Dev	133.54	173.84	151.57
	Median	459.3	479.6	475.7
	Min-Max	374-945	268-915	268-945
	Interquartile range	416-586	407-684	412-609
	Missing	1	2	3

Table 2.9. Summary of baseline accelerometer data (percentage time spent/day), by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Light PA (% time)	N	25	22	47
	Mean	21.8	22.3	22.1
	Std Dev	6.22	8.01	7.04
	Median	21.2	20.2	20.9
	Min-Max	10-38	12-39	10-39
	Interquartile range	18-26	16-29	17-26
	Missing	1	2	3
MVPA (% time spent)	N	25	22	47
	Mean	4.5	4.7	4.6
	Std Dev	2.73	3.78	3.23
	Median	4.1	3.8	3.9
	Min-Max	0-9	1-15	0-15
	Interquartile range	2-6	2-6	2-6
	Missing	1	2	3
Total PA (% time spent)	N	25	22	47
	Mean	26.3	27.0	26.7
	Std Dev	7.63	9.72	8.6
	Median	25.5	25.0	25.5
	Min-Max	14-47	15-45	14-47
	Interquartile range	21-30	19-32	20-31
	Missing	1	2	3
Sedentary Behaviour (%)	N	25	22	47
	Mean	73.7	73.0	73.3
	Std Dev	7.63	9.72	8.58
	Median	74.5	75.0	74.5
	Min-Max	53-86	55-85	53-86
	Interquartile range	70-79	68-81	69-80
	Missing	1	2	3

Table 2.9.1. Summary of baseline accelerometer data, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5	WWTOO	TOTAL
Light PA (% time)	N	20	17	37
	Mean	21.9	22.1	22.0
	Std Dev	6.62	8.96	7.67
	Median	21.3	17.2	20.6
	Min-Max	10-38	12-39	10-39
	Interquartile range	18-26	15-30	16-27
	Missing	1	2	3
MVPA (% time spent)	N	20	17	37
	Mean	4.5	4.0	4.3
	Std Dev	2.70	2.91	2.77
	Median	3.6	3.4	3.4
	Min-Max	0-9	0-14	0-14
	Interquartile range	2-6	2-5	2-6
	Missing	1	2	3
Total PA (% time spent)	N	20	17	37
	Mean	26.4	26.1	26.2
	Std Dev	7.80	10.03	8.77
	Median	25.3	20.6	25.1
	Min-Max	14-47	15-44	14-47
	Interquartile range	22-30	18-33	20-31
	Missing	1	2	3
Sedentary Behaviour (%)	N	20	17	37
	Mean	73.6	73.9	73.8
	Std Dev	7.80	10.03	8.77
	Median	74.7	79.4	74.9
	Min-Max	53-86	56-85	53-86
	Interquartile range	70-78	67-82	69-80
	Missing	1	2	3

Table 2.10. Summary of baseline EQ-5D-Y domain, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
EQ-5D Dimension				
Mobility	N	26	24	50
	No problems	21 (80.8%)	16 (66.7%)	37 (74.0%)
	Some problems	3 (11.5%)	7 (29.2%)	10 (20.0%)
	Extreme problems	2 (7.7%)	1 (4.2%)	3 (6.0%)
	Missing	0	0	0
Self-care	N	26	24	50
	No problems	18 (69.2%)	15 (62.5%)	33 (66.0%)
	Some problems	5 (19.2%)	2 (8.3%)	7 (14.0%)
	Extreme problems	3 (11.5%)	7 (29.2%)	10 (20.0%)
	Missing	0	0	0
Usual activities	N	26	24	50
	No problems	23 (88.5%)	22 (91.7%)	45 (90.0%)
	Some problems	3 (11.5%)	2 (8.3%)	5 (10.0%)
	Extreme problems	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
Pain/discomfort	N	26	24	50
	No problems	21 (80.8%)	19 (79.2%)	40 (80.0%)
	Some problems	4 (15.4%)	4 (16.7%)	8 (16.0%)
	Extreme problems	1 (3.8%)	1 (4.2%)	2 (4.0%)
	Missing	0	0	0
Anxiety/depression	N	26	24	50
	No problems	21 (80.8%)	20 (83.3%)	41 (82.0%)
	Some problems	5 (19.2%)	4 (16.7%)	9 (18.0%)
	Extreme problems	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.10.1. Summary of baseline EQ-5D-Y domain, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
EQ-5D Dimension				
Mobility	N	21	19	40
	No problems	17 (81.0%)	13 (68.4%)	30 (75.0%)
	Some problems	2 (9.5%)	5 (26.3%)	7 (17.5%)
	Extreme problems	2 (9.5%)	1 (5.3%)	3 (7.5%)
	Missing	0	0	0
Self-care	N	21	19	40
	No problems	15 (71.4%)	12 (63.2%)	27 (67.5%)
	Some problems	4 (19.0%)	2 (10.5%)	6 (15.0%)
	Extreme problems	2 (9.5%)	5 (26.3%)	7 (17.5%)
	Missing	0	0	0
Usual activities	N	21	19	40
	No problems	20 (95.2%)	18 (94.7%)	28 (95.0%)
	Some problems	1 (4.8%)	1 (5.3%)	2 (5.0%)
	Extreme problems	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0
Pain/discomfort	N	21	19	40
	No problems	18 (85.7%)	16 (84.2%)	34 (85.0%)
	Some problems	2 (9.5%)	3 (15.8%)	5 (12.5%)
	Extreme problems	1 (4.8%)	0 (0.0%)	1 (2.5%)
	Missing	0	0	0
Anxiety/depression	N	21	19	40
	No problems	17 (81.0%)	17 (89.5%)	34 (85.0%)
	Some problems	4 (19.0%)	2 (10.5%)	6 (15.0%)
	Extreme problems	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Missing	0	0	0

Table 2.11. Summary of baseline EQ-5D-Y index, by randomised group and overall (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
EQ-5D Index	N	26	24	50
	Mean	0.8	0.7	0.7
	Std Dev	0.27	0.32	0.29
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	0	0	0

Table 2.11.1. Summary of baseline EQ-5D-Y index, by randomised group and overall (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
EQ-5D Index	N	21	19	40
	Mean	0.8	0.8	0.8
	Std Dev	0.28	0.28	0.28
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	0	0	0

Table 3.1.1. Primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT)

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	24	48
	Mean	101.3	104.1	102.7
	Std Dev	26.02	28.86	27.22
	Median	98.0	100.4	100.2
	Min-Max	59-149	72-212	59-212
	Interquartile range	78-126	87-111	86-119
	Missing	2	0	2
12 months	N	24	24	48
	Mean	97.7	102.4	100.1
	Std Dev	26.65	26.88	26.59
	Median	97.7	97.1	97.2
	Min-Max	58-149	73.5-199.4	58.3-199.4
	Interquartile range	74-122	85.8-107.9	85.5-113.1
	Missing	2	0	2
Change at 12 months	N	24	24	48
	Mean	-3.6	-1.6	-2.6
	Std Dev	5.16	5.03	5.14
	Median	-4.3	-0.8	-1.7
	Min-Max	-13-5	-15-4	-15-5
	Interquartile range	-7-1	-5-2	-6-2
	Missing	2	0	2
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-1.90 (-4.80 to 1.01)	p = 0.195	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.1.1.1. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	23	47
	Mean	101.3	99.4	100.3
	Std Dev	26.02	17.82	22.16
	Median	98.0	99.8	99.8
	Min-Max	59-149	72-145	59-149
	Interquartile range	78-126	87-110	86-114
	Missing	2	1	1
12 months	N	24	23	47
	Mean	97.7	98.2	97.9
	Std Dev	26.65	17.60	22.43
	Median	97.7	97.0	97.2
	Min-Max	58-149	74-146	58-149
	Interquartile range	74-122	86-107	96-113
	Missing	2	1	1
Change at 12 months	N	24	23	47
	Mean	-3.6	-1.1	-2.4
	Std Dev	5.16	4.55	4.97
	Median	-4.3	-0.4	-1.5
	Min-Max	-13-5	-15-4	-15-5
	Interquartile range	-7-1	-3-2	-6-2
	Missing	2	1	1
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.16 (-5.08 to 0.76)	p = 0.143	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.1.1.2. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	22	46
	Mean	101.3	99.3	100.3
	Std Dev	26.02	18.24	22.41
	Median	98.0	96.5	97.7
	Min-Max	59-149	72-145	59-149
	Interquartile range	78-126	86-110	86-116
	Missing	2	2	4
12 months	N	24	22	46
	Mean	97.7	98.8	98.2
	Std Dev	26.65	17.80	22.61
	Median	97.7	97.1	97.2
	Min-Max	58-149	74-146	58-149
	Interquartile range	74-122	86-107	85-113
	Missing	2	2	4
Change at 12 months	N	24	22	46
	Mean	-3.6	-0.5	-2.1
	Std Dev	5.16	3.46	4.65
	Median	-4.3	0.1	-1.4
	Min-Max	-13-5	-8-4	-13-5
	Interquartile range	-7-1	-2-2	-6-2
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.93 (-5.65 to -0.20)	p = 0.036	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.1.2. Primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	19	40
	Mean	102.7	101.9	102.3
	Std Dev	25.10	18.05	21.77
	Median	100.5	100.9	100.7
	Min-Max	59-149	72-145	59-149
	Interquartile range	87-126	88-112	87-119
	Missing	0	0	0
12 months	N	21	19	40
	Mean	98.9	100.7	99.8
	Std Dev	25.48	18.22	22.07
	Median	98.3	97.3	97.8
	Min-Max	58-149	74-146	58-149
	Interquartile range	83-120	86-108	86-113
	Missing	0	0	0
Change at 12 months	N	21	19	40
	Mean	-3.8	-1.2	-2.6
	Std Dev	5.40	4.71	5.18
	Median	-4.9	-0.4	-1.4
	Min-Max	-13-5	-15-4	-15-5
	Interquartile range	-8-1	-2-2	-6-2
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-2.46 (-5.84 to 0.93)	p = 0.150	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.1.2.1. Sensitivity analysis - primary outcome: Change in average weight (kg) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	18	39
	Mean	102.7	102.0	102.4
	Std Dev	25.10	18.57	22.05
	Median	100.5	100.5	100.5
	Min-Max	59-149	72-145	59-149
	Interquartile range	87-126	88-113	87-121
	Missing	0	1	1
12 months	N	21	18	39
	Mean	98.9	101.5	100.1
	Std Dev	25.48	18.37	22.2
	Median	98.3	99.0	98.3
	Min-Max	58-149	74-146	58-149
	Interquartile range	83-120	86-109	86-113
	Missing	0	1	1
Change at 12 months	N	21	18	39
	Mean	-3.8	-0.5	-2.3
	Std Dev	5.40	3.4	4.83
	Median	-4.9	0.1	-1.3
	Min-Max	-13-5	-8-4	-13-5
	Interquartile range	-8-1	-2-2	-6-2
	Missing	0	1	1
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-3.26 (-6.42 to -0.10)		
	P-value		p = 0.044	
	ICC			0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.2.1. Secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	22	46
	Mean	101.3	105.1	103.1
	Std Dev	26.02	29.78	27.63
	Median	98.0	100.4	100.2
	Min-Max	59-149	72-212	59-212
	Interquartile range	78-126	87-113	87-122
	Missing	2	2	4
6 months	N	24	22	46
	Mean	98.4	103.7	101.0
	Std Dev	26.75	28.77	27.6
	Median	95.6	98.8	98.1
	Min-Max	58-144	71-211	58-211
	Interquartile range	77-122	86-109	85-119
	Missing	2	2	4
Change at 6 months	N	24	22	46
	Mean	-2.8	-1.4	-2.1
	Std Dev	3.76	3.34	3.60
	Median	-2.4	-1.4	-1.6
	Min-Max	-12-5	-11-6	-12-6
	Interquartile range	-6-0	-3-1	-4-0
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-1.67 (-3.84 to 0.50)	p = 0.126	0.059

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.2.1.1. Sensitivity analysis - secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	21	45
	Mean	101.3	100.0	100.7
	Std Dev	26.02	18.22	22.47
	Median	98.0	99.8	99.8
	Min-Max	59-149	72-145	59-149
	Interquartile range	78-126	87-111	86-118
	Missing	2	3	5
6 months	N	24	21	45
	Mean	98.4	98.7	98.5
	Std Dev	26.75	16.50	22.31
	Median	95.6	98.6	97.6
	Min-Max	58-144	71-135	58-144
	Interquartile range	77-122	86-107	85-114
	Missing	2	3	5
Change at 6 months	N	24	21	45
	Mean	-2.8	-1.4	-2.1
	Std Dev	3.76	3.42	3.64
	Median	-2.4	-1.4	-1.7
	Min-Max	-12-5	-11-6	-12-6
	Interquartile range	-6-0	-3-1	-4-0
	Missing	2	3	5
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-1.55 (-3.76 to 0.66)	p = 0.162	0.072
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.2.1.2. Sensitivity analysis - secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	20	44
	Mean	101.3	97.8	99.7
	Std Dev	26.02	15.41	21.68
	Median	98.0	96.5	97.7
	Min-Max	59-149	72-130	59-149
	Interquartile range	78-126	87-108	86-114
	Missing	2	4	6
6 months	N	24	20	44
	Mean	98.4	96.9	97.7
	Std Dev	26.75	14.68	21.88
	Median	95.6	98.1	96.9
	Min-Max	58-144	71-129	58-144
	Interquartile range	77-122	86-105	84-110
	Missing	2	4	6
Change at 6 months	N	24	20	44
	Mean	-2.8	-0.9	-2.0
	Std Dev	3.76	2.78	3.45
	Median	-2.4	-0.9	-1.6
	Min-Max	-12-5	-6-6	-12-6
	Interquartile range	-6-0	-3-1	-4-0
	Missing	2	4	6
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.02 (-4.13 to 0.08)	p = 0.059	0.033
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.2.2. Secondary outcome: Change in average weight (kg) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	19	40
	Mean	102.7	101.9	102.3
	Std Dev	25.10	18.05	21.77
	Median	100.5	100.9	100.7
	Min-Max	59-149	72-145	59-149
	Interquartile range	87-126	88-112	87-119
	Missing	0	0	0
6 months	N	21	19	40
	Mean	99.6	100.5	100.0
	Std Dev	25.98	16.29	21.66
	Median	96.2	99.0	98.7
	Min-Max	58-144	71-135	58-144
	Interquartile range	85-121	86-108	87-116
	Missing	0	0	0
Change at 6 months	N	21	19	40
	Mean	-3.1	-1.4	-2.3
	Std Dev	3.91	3.48	3.76
	Median	-3.6	-1.4	-2.0
	Min-Max	-12-5	-11-6	-12-6
	Interquartile range	-6-0	-3-0	-4-0
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-1.89 (-4.38 to 0.59)	p = 0.130	0.096

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.1. Secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	22	46
	Mean	40.0	41.8	40.8
	Std Dev	7.06	8.29	7.64
	Median	39.6	41.3	39.6
	Min-Max	31-54	32-66	31-66
	Interquartile range	33-45	35-46	34-46
	Missing	2	2	4
6 months	N	24	22	46
	Mean	38.8	41.3	40.0
	Std Dev	7.53	8.21	7.88
	Median	38.5	40.8	39.6
	Min-Max	27-55	32-65	27-65
	Interquartile range	33-45	34-46	33-45
	Missing	2	2	4
Change at 6 months	N	24	22	46
	Mean	-1.2	-0.5	-0.8
	Std Dev	1.57	1.20	1.43
	Median	-1.1	-0.6	-0.7
	Min-Max	-5-2	-3-2	-5-2
	Interquartile range	-2-0	-1-0	-2-0
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-0.74 (-1.58 to 0.11)	p = 0.085	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.1.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	21	45
	Mean	40.0	40.6	40.3
	Std Dev	7.06	6.47	6.73
	Median	39.6	39.6	39.6
	Min-Max	31-54	32-52	31-54
	Interquartile range	33-45	35-46	34-46
	Missing	2	3	5
6 months	N	24	21	45
	Mean	38.8	40.2	39.4
	Std Dev	7.53	6.36	6.97
	Median	38.5	40.4	39.6
	Min-Max	27-55	32-52	27-55
	Interquartile range	33-45	34-45	33-45
	Missing	2	3	5
Change at 6 months	N	24	21	45
	Mean	-1.2	-1.0	-0.8
	Std Dev	1.57	1.23	1.45
	Median	-1.1	-0.7	-0.7
	Min-Max	-5-2	-3-2	-5-2
	Interquartile range	-2-0	-1-0	-2-0
	Missing	2	3	5
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-0.74 (-1.61 to 0.12)		
	P-value			p = 0.090
	ICC			0.006

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.2. Secondary outcome: Change in average BMI (kg/m²) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	19	40
	Mean	40.6	41.5	41.0
	Std Dev	7.06	6.19	6.59
	Median	39.6	42.9	40.4
	Min-Max	31-54	32-52	31-54
	Interquartile range	34-46	35-46	35-46
	Missing	0	0	0
6 months	N	21	19	40
	Mean	39.3	41.0	40.1
	Std Dev	7.63	6.11	6.92
	Median	39.1	41.1	39.6
	Min-Max	27-55	32-52	27-55
	Interquartile range	34-46	35-45	34-45
	Missing	0	0	0
Change at 6 months	N	21	19	40
	Mean	-1.3	-0.5	-0.9
	Std Dev	1.63	1.24	1.50
	Median	-1.3	-0.7	-0.8
	Min-Max	-5-2	-3-2	-5-2
	Interquartile range	-3-0	-1-0	-2-0
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.87 (-1.84 to 0.11)	p = 0.078	0.078

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.3. Secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	24	48
	Mean	40.0	41.2	40.6
	Std Dev	7.06	8.14	7.56
	Median	39.6	39.0	39.6
	Min-Max	31-54	32-66	31-66
	Interquartile range	33-45	35-46	34-46
	Missing	2	0	2
12 months	N	24	24	48
	Mean	38.5	40.7	39.6
	Std Dev	7.30	7.73	7.51
	Median	38.2	38.2	38.2
	Min-Max	27-50	32-62	27-62
	Interquartile range	32-44	35-46	33-45
	Missing	2	0	2
Change at 12 months	N	24	24	48
	Mean	-1.5	-0.6	-1.0
	Std Dev	2.06	1.97	2.04
	Median	-1.8	-0.3	-0.7
	Min-Max	-6-2	-7-2	-7-2
	Interquartile range	-3-0	-2-1	-2-1
	Missing	2	0	2
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-0.89 (-2.05 to 0.28)	p = 0.134	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.3.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	23	47
	Mean	40.0	40.2	40.1
	Std Dev	7.06	6.37	6.66
	Median	39.6	38.3	39.5
	Min-Max	31-54	32-52	31-54
	Interquartile range	33-45	34-46	34-45
	Missing	2	1	3
12 months	N	24	23	47
	Mean	38.5	39.7	39.1
	Std Dev	7.30	6.41	6.83
	Median	38.2	37.6	37.9
	Min-Max	27-50	32-52	27-52
	Interquartile range	32-44	35-45	33-44
	Missing	2	1	3
Change at 12 months	N	24	23	47
	Mean	-1.5	-0.4	-1.0
	Std Dev	2.06	1.88	2.02
	Median	-1.8	-0.2	-0.5
	Min-Max	-6-2	-7-2	-7-2
	Interquartile range	-3-0	-1-1	-2-1
	Missing	2	1	3
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI) P-value ICC	-1.00 (-2.15 to 0.20)	p = 0.100	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.3.2. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	22	46
	Mean	40.0	39.9	40.0
	Std Dev	7.06	6.40	6.68
	Median	39.6	38.2	38.9
	Min-Max	31-54	32-52	31-54
	Interquartile range	33-45	34-45	34-45
	Missing	2	2	4
12 months	N	24	22	46
	Mean	38.5	39.8	39.1
	Std Dev	7.30	6.55	6.91
	Median	38.2	37.5	37.7
	Min-Max	27-50	32-52	27-52
	Interquartile range	32-44	34-45	33-45
	Missing	2	2	4
Change at 12 months	N	24	22	46
	Mean	-1.5	-0.1	-0.8
	Std Dev	2.06	1.29	1.84
	Median	-1.8	0.0	-0.5
	Min-Max	-6-2	-3-2	-6-2
	Interquartile range	-3-0	-1-1	-2-1
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-1.29 (-2.35 to -0.24)	p = 0.018	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.4. Secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	19	40
	Mean	40.6	41.5	41.0
	Std Dev	7.06	6.19	6.59
	Median	39.6	42.9	40.4
	Min-Max	31-54	32-52	31-54
	Interquartile range	34-46	35-46	35-46
	Missing	0	0	0
12 months	N	21	19	40
	Mean	39.0	41.0	40.0
	Std Dev	7.2	6.29	6.79
	Median	38.5	40.4	39.6
	Min-Max	27-50	32-52	27-52
	Interquartile range	33-46	35-47	35-46
	Missing	0	0	0
Change at 12 months	N	21	19	40
	Mean	-1.6	-0.5	-1.1
	Std Dev	2.15	1.97	2.11
	Median	-2.3	-0.2	-0.5
	Min-Max	-6-2	-7-2	-7-2
	Interquartile range	-3-0	-1-0	-3-1
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-1.06 (-2.44 to 0.31)	p = 0.125	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.3.4.1. Sensitivity analysis - secondary outcome: Change in average BMI (kg/m²) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	18	39
	Mean	40.6	41.3	40.9
	Std Dev	7.06	6.29	6.63
	Median	39.6	41.3	39.6
	Min-Max	31-54	32-52	31-54
	Interquartile range	34-46	35-46	35-46
	Missing	0	1	1
12 months	N	21	18	39
	Mean	39.0	41.1	40.0
	Std Dev	7.2	6.46	6.87
	Median	38.5	40.5	40.4
	Min-Max	27-50	32-52	27-52
	Interquartile range	33-46	35-47	35-47
	Missing	0	1	1
Change at 12 months	N	21	18	39
	Mean	-1.6	-0.2	-0.9
	Std Dev	2.15	1.27	1.91
	Median	-2.3	0.0	-0.5
	Min-Max	-6-2	-3-2	-6-2
	Interquartile range	-3-0	-1-1	-3-1
	Missing	0	1	1
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI) P-value ICC	-1.39 (-2.63 to -0.16)	p = 0.028	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.1. Secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	20	42
	Mean	121.2	123.7	122.4
	Std Dev	14.49	16.30	15.24
	Median	120.0	121.4	120.8
	Min-Max	95-143	103-171	95-171
	Interquartile range	110-136	109-131	110-135
	Missing	4	4	8
6 months	N	22	20	42
	Mean	118.5	121.9	120.1
	Std Dev	14.94	15.34	15.05
	Median	117.2	120.6	118.4
	Min-Max	91-142	102-170	91-170
	Interquartile range	108-132	110-125	109-131
	Missing	4	4	8
Change at 6 months	N	22	20	42
	Mean	-2.8	-1.8	-2.3
	Std Dev	4.35	3.65	4.01
	Median	-1.9	-1.5	-1.6
	Min-Max	-11-5	-12-4	-12-5
	Interquartile range	-6-0	-4-0	-5-0
	Missing	4	4	8
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-1.71 (-4.28 to 0.86)	p = 0.186	0.176

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.1.1. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	19	41
	Mean	121.2	121.2	121.2
	Std Dev	14.49	12.34	13.37
	Median	120.0	121.1	120.5
	Min-Max	95-143	103-149	95-149
	Interquartile range	110-136	109-130	109-133
	Missing	4	5	9
6 months	N	22	19	41
	Mean	118.5	119.4	118.9
	Std Dev	14.94	10.63	12.97
	Median	117.2	119.9	118.2
	Min-Max	91-142	103-140	91-142
	Interquartile range	108-132	109-125	109-130
	Missing	4	5	9
Change at 6 months	N	22	19	41
	Mean	-2.8	-1.9	-2.4
	Std Dev	4.35	3.74	4.05
	Median	-1.9	-1.6	-1.7
	Min-Max	-11-5	-12-4	-12-5
	Interquartile range	-6-0	-4-0	-5-0
	Missing	4	5	9
Statistical Analysis				
Mixed effects model (Sensitivity analysis)	Intervention effect (95% CI)	-1.48 (-4.05 to 1.09)	p = 0.249	0.147
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.1.2. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	18	40
	Mean	121.2	119.7	120.6
	Std Dev	14.49	10.65	12.77
	Median	120.0	120.6	120.3
	Min-Max	95-143	103-139	95-143
	Interquartile range	110-136	109-128	109-132
	Missing	4	6	10
6 months	N	22	18	40
	Mean	118.5	118.4	118.4
	Std Dev	14.94	10.00	12.80
	Median	117.2	119.2	118.0
	Min-Max	91-142	103-140	91-142
	Interquartile range	108-132	109-125	109-128
	Missing	4	6	10
Change at 6 months	N	22	18	40
	Mean	-2.8	-1.3	-2.1
	Std Dev	4.35	2.93	3.80
	Median	-1.9	-1.5	-1.6
	Min-Max	-11-5	-6-4	-11-5
	Interquartile range	-6-0	-3-1	-4-0
	Missing	4	6	10
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.00 (-4.48 to 0.47)	p = 0.109	0.179
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.2. Secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	19	17	36
	Mean	121.7	122.4	122.0
	Std Dev	14.11	12.33	13.12
	Median	120.5	121.7	121.4
	Min-Max	95-143	103-149	95-149
	Interquartile range	111-136	109-130	111-134
	Missing	2	2	4
6 months	N	19	17	36
	Mean	118.6	120.5	119.5
	Std Dev	14.59	10.62	12.73
	Median	117.9	121.3	119.2
	Min-Max	91-142	103-140	91-142
	Interquartile range	109-132	110-125	109-130
	Missing	2	2	4
Change at 6 months	N	19	17	36
	Mean	-3.1	-1.9	-2.5
	Std Dev	4.58	3.73	4.19
	Median	-2.5	-1.6	-1.7
	Min-Max	-12-5	-12-4	-12-5
	Interquartile range	-7-0	-4-0	-5-0
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI)	-2.06 (-4.93 to 0.81)		
	P-value		p = 0.152	
	ICC			0.194

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.2.1. Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	19	16	35
	Mean	121.7	120.7	121.3
	Std Dev	14.11	10.59	12.46
	Median	120.5	121.4	121.1
	Min-Max	95-143	103-139	95-143
	Interquartile range	111-136	109-129	111-132
	Missing	2	3	5
6 months	N	19	16	35
	Mean	118.6	119.5	119.0
	Std Dev	14.59	10.04	12.54
	Median	117.9	120.6	118.6
	Min-Max	91-142	103-140	91-142
	Interquartile range	109-132	110-125	109-129
	Missing	2	3	5
Change at 6 months	N	19	16	35
	Mean	-3.1	-1.3	-2.3
	Std Dev	4.58	2.79	3.93
	Median	-2.5	-1.5	-1.7
	Min-Max	-12-5	-6-4	-12-5
	Interquartile range	-7-0	-3-0	-5-0
	Missing	2	3	5
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.64 (-5.38 to 0.10)		
	P-value		p = 0.059	
	ICC			0.224

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.3. Secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	21	43
	Mean	121.2	123.4	122.3
	Std Dev	14.49	15.96	15.08
	Median	120.0	121.6	120.5
	Min-Max	95-143	103-171	95-171
	Interquartile range	110-136	109-130	110-134
	Missing	4	3	7
12 months	N	22	21	43
	Mean	117.9	121.4	119.6
	Std Dev	15.05	14.17	14.56
	Median	117.4	118.9	118.3
	Min-Max	93-145	106-156	93-156
	Interquartile range	105-129	110-126	109-128
	Missing	4	3	7
Change at 12 months	N	22	21	43
	Mean	-3.4	-2.0	-2.7
	Std Dev	5.65	5.59	5.60
	Median	-3.3	-1.2	-2.5
	Min-Max	-15-6	-15-9	-15-9
	Interquartile range	-8-1	-5-1	-6-1
	Missing	4	3	7
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-1.77 (-5.20 to 1.67)	p = 0.304	0.267

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.3.1 Sensitivity analysis - secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	20	42
	Mean	121.2	121.0	121.1
	Std Dev	14.49	12.06	13.22
	Median	120.0	120.9	120.3
	Min-Max	95-143	103-149	95-149
	Interquartile range	110-136	109-129	110-133
	Missing	4	4	8
12 months	N	22	20	42
	Mean	117.9	119.7	118.8
	Std Dev	15.05	12.09	13.59
	Median	117.4	118.6	118.0
	Min-Max	93-145	106-150	93-150
	Interquartile range	105-129	110-125	108-127
	Missing	4	4	8
Change at 12 months	N	22	20	42
	Mean	-3.4	-1.3	-2.4
	Std Dev	5.65	4.89	5.34
	Median	-3.3	-0.9	-2.2
	Min-Max	-15-6	-11-9	-15-9
	Interquartile range	-8-1	-4-2	-6-1
	Missing	4	4	8
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-2.08 (-5.48 to 1.32)	p = 0.223	0.163
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.4.4. Secondary outcome: Change in average waist circumference (cm) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	19	16	35
	Mean	121.7	122.5	122.1
	Std Dev	14.11	12.73	13.31
	Median	120.5	123.0	121.7
	Min-Max	95-143	103-149	95-149
	Interquartile range	111-136	109-131	111-134
	Missing	2	3	5
12 months	N	19	16	35
	Mean	118.1	120.9	119.4
	Std Dev	14.06	13.18	13.54
	Median	117.7	120.0	118.4
	Min-Max	93-142	106-150	93-150
	Interquartile range	109-128	108-127	109-128
	Missing	2	3	5
Change at 12 months	N	19	16	35
	Mean	-3.6	-1.5	-2.7
	Std Dev	5.87	5.09	5.55
	Median	-2.7	-0.9	-2.0
	Min-Max	-15-6	-11-9	-15-9
	Interquartile range	-8-1	-4-2	-8-1
	Missing	2	3	5
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-2.49 (-6.48 to 1.49)	p = 0.211	0.263

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.1. Secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	18	40
	Mean	49.5	51.8	50.5
	Std Dev	9.52	8.78	9.15
	Median	49.7	49.4	49.7
	Min-Max	33-68	41-79	33-79
	Interquartile range	44-56	46-55	45-55
	Missing	4	6	10
6 months	N	22	18	40
	Mean	47.9	50.5	49.1
	Std Dev	9.22	8.87	9.04
	Median	48.9	49.4	48.9
	Min-Max	28-66	40-78	28-78
	Interquartile range	44-55	44-54	44-55
	Missing	4	6	10
Change at 6 months	N	22	18	40
	Mean	-1.5	-1.3	-1.4
	Std Dev	2.92	2.82	2.84
	Median	-1.6	-0.9	-1.2
	Min-Max	-11-4	-10-3	-11-4
	Interquartile range	-3-0	-3-0	-3-0
	Missing	4	6	10
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-0.77 (-2.72 to 1.19)	p = 0.430	0.187

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.1.1. Sensitivity analysis -secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	17	39
	Mean	49.5	50.2	49.8
	Std Dev	9.52	5.84	8.03
	Median	49.7	47.4	49.5
	Min-Max	33-68	41-61	33-68
	Interquartile range	44-56	46-55	45-55
	Missing	4	7	11
6 months	N	22	17	39
	Mean	47.9	48.9	48.3
	Std Dev	9.22	5.82	7.84
	Median	48.9	48.4	48.7
	Min-Max	28-66	40-59	28-66
	Interquartile range	44-55	44-53	44-54
	Missing	4	7	11
Change at 6 months	N	22	17	39
	Mean	-1.5	-1.3	-1.4
	Std Dev	2.92	2.91	2.88
	Median	-1.6	-1.1	-1.3
	Min-Max	-11-4	-10-3	-11-4
	Interquartile range	-3-0	-3-0	-3-0
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-0.64 (-2.61 to 1.33)	p = 0.510	0.140
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.1.2 Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	21	16	37
	Mean	48.7	49.5	49.0
	Std Dev	9.10	5.26	7.60
	Median	49.5	47.3	48.4
	Min-Max	33-68	41-59	33-68
	Interquartile range	42-55	45-55	45-55
	Missing	5	8	13
6 months	N	21	16	37
	Mean	47.6	48.7	48.1
	Std Dev	9.35	5.97	7.98
	Median	48.7	47.8	48.4
	Min-Max	28-66	40-59	28-66
	Interquartile range	43-55	44-54	44-54
	Missing	5	8	13
Change at 6 months	N	21	16	37
	Mean	-1.1	-0.8	-1.0
	Std Dev	2.10	2.02	2.04
	Median	-1.5	-0.8	-1.1
	Min-Max	-5-4	-4-3	-5-4
	Interquartile range	-2-2	-3-0	-2-0
	Missing	5	8	13
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-0.61 (-2.08 to 0.85)		
	P-value			p = 0.399
	ICC			0.112

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.2. Secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	19	15	34
	Mean	49.3	51.0	50.1
	Std Dev	10.02	5.79	8.35
	Median	49.9	51.3	50.1
	Min-Max	33-68	41-61	33-68
	Interquartile range	40-55	47-55	46-55
	Missing	2	4	6
6 months	N	19	15	34
	Mean	47.6	49.5	48.4
	Std Dev	9.63	5.76	8.10
	Median	49.1	50.4	49.5
	Min-Max	28-66	40-59	28-66
	Interquartile range	43-55	45-54	44-54
	Missing	2	4	6
Change at 6 months	N	19	15	34
	Mean	-1.7	-1.5	-1.6
	Std Dev	3.11	2.76	2.92
	Median	-2.0	-1.1	-1.4
	Min-Max	-11-4	-10-2	-11-4
	Interquartile range	-3-0	-3-0	-3-0
	Missing	2	4	6
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.71 (-2.91 to 1.49)	p = 0.512	0.177

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.2.1 Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	18	14	32
	Mean	48.5	50.2	49.2
	Std Dev	9.57	5.22	7.90
	Median	49.7	49.4	49.7
	Min-Max	33-68	41-59	33-68
	Interquartile range	39-55	47-55	46-55
	Missing	3	5	8
6 months	N	18	14	32
	Mean	47.3	49.3	48.2
	Std Dev	9.79	5.94	8.27
	Median	48.9	48.8	48.9
	Min-Max	28-66	40-59	28-66
	Interquartile range	41-55	44-54	44-55
	Missing	3	5	8
Change at 6 months	N	18	14	32
	Mean	-1.2	-0.9	-1.1
	Std Dev	2.24	1.65	1.98
	Median	-1.8	-0.8	-1.2
	Min-Max	-5-4	-4-2	-5-4
	Interquartile range	-3-0	-2-0	-2-0
	Missing	3	5	8
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI) P-value ICC	-0.60 (-2.16 to 0.95)	p = 0.432	0.113

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.3. Secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	18	40
	Mean	49.5	51.8	50.5
	Std Dev	9.52	8.78	9.15
	Median	49.7	49.4	49.7
	Min-Max	33-68	41-79	33-79
	Interquartile range	44-56	46-55	45-55
	Missing	4	6	10
12 months	N	22	18	40
	Mean	47.6	50.9	49.1
	Std Dev	9.47	8.38	9.04
	Median	48.2	50.2	48.6
	Min-Max	27-65	39-70	27-70
	Interquartile range	42-56	44-57	43-56
	Missing	4	6	10
Change at 12 months	N	22	18	40
	Mean	-1.9	-1.0	-1.5
	Std Dev	3.98	4.04	3.98
	Median	-2.2	-0.6	-1.3
	Min-Max	-14-4	-9-6	-14-6
	Interquartile range	-4-1	-4-2	-3-1
	Missing	4	6	10
Statistical Analysis				
Mixed effects model (ITT)	Intervention effect (95% CI) P-value ICC	-1.58 (-4.21 to 1.05)	p = 0.231	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.3.1. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	22	17	39
	Mean	49.5	50.4	49.9
	Std Dev	9.52	5.79	8.02
	Median	49.7	49.6	49.6
	Min-Max	33-68	41-61	33-68
	Interquartile range	44-56	46-55	45-55
	Missing	4	7	11
12 months	N	22	17	39
	Mean	47.6	49.8	48.5
	Std Dev	9.47	7.14	8.50
	Median	48.2	49.7	48.2
	Min-Max	27-65	39-62	27-65
	Interquartile range	42-56	44-56	43-55
	Missing	4	7	11
Change at 12 months	N	22	17	39
	Mean	-1.9	-0.6	-1.3
	Std Dev	3.98	3.64	3.84
	Median	-2.2	-0.5	-0.7
	Min-Max	-14-4	-7-6	-14-6
	Interquartile range	-4-1	-3-2	-3-1
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Sensitivity-analysis)*	Intervention effect (95% CI)	-1.76 (-4.39 to 0.87)	p = 0.182	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.3.2. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	21	17	38
	Mean	48.7	50.4	49.5
	Std Dev	9.10	5.79	7.74
	Median	49.5	49.6	49.6
	Min-Max	33-68	41-61	33-68
	Interquartile range	42-55	46-55	45-55
	Missing	5	7	12
12 months	N	21	17	38
	Mean	47.4	49.8	48.5
	Std Dev	9.68	7.14	8.61
	Median	48.2	49.7	48.2
	Min-Max	27-65	39-62	27-65
	Interquartile range	42-56	44-56	43-55
	Missing	5	7	12
Change at 12 months	N	21	17	38
	Mean	-1.3	-0.6	-1.0
	Std Dev	2.89	3.64	3.22
	Median	-2.0	-0.5	-0.7
	Min-Max	-5-4	-7-6	-7-6
	Interquartile range	-3-1	-3-2	-3-1
	Missing	5	7	12
Statistical Analysis				
Mixed effects model (Sensitivity-analysis)*	Intervention effect (95% CI)	-1.00 (-3.28 to 1.28)	p = 0.378	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.4. Secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	19	14	33
	Mean	49.3	51.3	50.2
	Std Dev	10.02	5.90	8.46
	Median	49.9	51.9	50.4
	Min-Max	33-68	41-61	33-68
	Interquartile range	40-55	47-55	46-55
	Missing	2	5	7
12 months	N	19	14	33
	Mean	47.4	50.5	48.7
	Std Dev	9.72	7.50	8.85
	Median	48.2	50.2	49.0
	Min-Max	27-65	39-62	27-65
	Interquartile range	43-55	44-57	43-56
	Missing	2	5	7
Change at 12 months	N	19	14	33
	Mean	-3.9	-0.8	-1.5
	Std Dev	4.19	3.52	3.90
	Median	-2.0	-0.2	-0.7
	Min-Max	-14-4	-7-6	-14-6
	Interquartile range	-4-0	-4-2	-4-1
	Missing	2	5	7
Statistical Analysis				
Mixed effects model (Per-protocol)	Intervention effect (95% CI)	-1.68 (-4.72 to 1.36)	p = 0.268	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.5.4.1. Sensitivity analysis - secondary outcome: Change in average percentage body fat (%) at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	18	14	32
	Mean	48.5	51.3	49.7
	Std Dev	9.57	5.90	8.17
	Median	49.7	51.9	50.1
	Min-Max	33-68	41-61	33-68
	Interquartile range	39-55	47-55	46-55
	Missing	3	5	8
12 months	N	18	14	32
	Mean	47.2	50.5	48.7
	Std Dev	9.97	7.50	8.99
	Median	48.2	50.2	48.6
	Min-Max	27-65	39-62	27-65
	Interquartile range	41-56	44-57	43-56
	Missing	3	5	8
Change at 12 months	N	18	14	32
	Mean	-1.2	-0.8	-1.0
	Std Dev	2.97	3.52	3.17
	Median	-1.3	-0.2	-0.6
	Min-Max	-5-4	-7-6	-7-6
	Interquartile range	-4-1	-4-2	-3-1
	Missing	3	5	8
Statistical Analysis				
Mixed effects model (Sensitivity analysis)*	Intervention effect (95% CI)	-0.71 (-3.29 to 1.86)	p = 0.575	0.000
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.6. Secondary outcome: Change in percentage weight change at 6 and 12 months from baseline. Odds ratio (95% confidence interval) and p-value (ITT).

Percentage weight change	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)	Odds ratio (95% CI)*	P-value
Weight loss phase (6 months)					
>5%	5 (20.8)	2 (9.1)	7 (15.2)	2.70 (0.44 to 16.59)	0.275
<5%	19 (79.2)	20 (90.9)	39 (84.8)	Referent	
Weight maintenance phase (6 months – 12 months)					
Weight loss >3%	7 (29.2)	4 (18.2)	11 (23.9)	1.57 (0.18 to 13.90)	0.679
Weight maintenance	14 (58.3)	15 (68.2)	29 (63.0)	0.92 (0.14 to 5.91)	0.924
Weight gain >3%	3 (12.5)	3 (13.6)	6 (13.0)	Referent	
Post intervention (12 months)					
>5%	12 (50.0)	5 (20.8)	17 (35.4)	3.76 (0.92 to 15.30)	0.064
<5%	12 (50.0)	19 (79.2)	31 (64.6)	Referent	

Note: At 6 months from baseline TAKE n = 24, WWTOO n = 22, TOTAL n = 46

At 12 months from baseline TAKE 5 n = 24, WWTOO n = 24, TOTAL n = 48

*Results are presented as adjusted Odds Ratio (OR) for effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval.

Table 3.6.1. Secondary outcome: Change in percentage weight change at 6 and 12 months from baseline. Odds ratio (95% confidence interval) and p-value (Completers).

Percentage weight change	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)	Odds ratio (95% CI)*	P-value
Weight loss phase (6 months)					
>5%	5 (23.8%)	2 (10.5%)	7 (17.5%)	2.84 (0.39 to 20.56)	0.291
<5%	16 (76.2%)	17 (89.5%)	33 (82.5%)	Referent	
Weight maintenance phase (6 months – 12 months)					
Weight loss >3%	3 (14.3%)	3 (15.8%)	6 (15.0%)	1.37 (0.13 to 14.64)	0.788
Weight maintenance	13 (61.9%)	13 (68.4%)	26 (65.0%)	0.97 (0.14 to 6.69)	0.972
Weight gain >3%	5 (23.8%)	3 (15.8%)	8 (20.0%)	Referent	
Post intervention (12 months)					
>5%	10 (47.6%)	3 (15.8%)	13 (32.5%)	4.93 (0.95 to 25.58)	0.057
<5%	11 (52.4%)	16 (84.2%)	27 (67.5%)	Referent	

*Results are presented as adjusted Odds Ratio (OR) for effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval.

Table 3.7. Secondary outcome: Change in average step count at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	5002	5311	5135
	Std Dev	2319.90	2308.58	2286.10
	Median	4673	5584	4882
	Min-Max	1422-10062	1850-9207	1422-10062
	Interquartile range	3752-6783	3055-6892	3751-6892
	Missing	6	9	15
6 months	N	20	15	35
	Mean	4304	4817	4524
	Std Dev	2311.59	1894.16	2128.30
	Median	4245	4757	4421
	Min-Max	1249-8293	2001-7361	1249-8293
	Interquartile range	2022-5831	2914-7126	2452-5869
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-697	-495	-611
	Std Dev	1637.73	1446.41	1540
	Median	-847	-769	-769
	Min-Max	-3024-4083	-3574-2164	-3574-4083
	Interquartile range	-1767-92	-1321-704	-1761-208
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)	Intervention effect (95% CI) P-value ICC	-95.48 (-1089.66 to 898.69)	p = 0.846	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.7.1. Secondary outcome: Change in average step count at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	4940	4805	4884
	Std Dev	2173.11	2215.02	2151.88
	Median	4652	5090	4695
	Min-Max	1599-10062	1850-8130	1599-10062
	Interquartile range	3753-6348	2318-6782	3534-6671
	Missing	4	7	11
6 months	N	17	12	29
	Mean	4355	4587	4451
	Std Dev	2387	1991.10	2197
	Median	4105	4589	4384
	Min-Max	1249-8293	2001-7361	1249-8293
	Interquartile range	2053-6233	2568-6757	2284-6233
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-585	-218	-433
	Std Dev	1682.93	1475.74	1583.65
	Median	-709	-483	-497
	Min-Max	-3024-4083	-3574-2164	-3024-4083
	Interquartile range	-1765-157	-1055-789	-1447-410
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)	Intervention effect (95% CI) P-value ICC	-59.10 (- 1287.03 to 1168.83)	p = 0.922	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.8. Secondary outcome: Change in average step count at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	4710	5211	4935
	Std Dev	2354.11	2469.19	2376.16
	Median	4342	5584	4705
	Min-Max	1422-10062	1850-9207	1422-10062
	Interquartile range	3426-5969	2564-7183	3186-6583
	Missing	10	11	21
12 months	N	16	13	29
	Mean	4157	4505	4313
	Std Dev	2450.50	2295.81	2346.65
	Median	3451	3741	3595
	Min-Max	1076-8951	1857-9314	1076--9314
	Interquartile range	2276-5643	2631-6905	2344-6372
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	-553	-707	-622
	Std Dev	1673.48	2087.43	1836.78
	Median	-395	-526	-438
	Min-Max	-3578-2774	-5090-3730	-5090-3730
	Interquartile range	-1815-258	-2136-78	-1957-176
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	126.40 (-1371.07 to 1623.87)	p = 0.863	0.997

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.8.1. Secondary outcome: Change in average step count at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	4563	4574	4567
	Std Dev	2147.57	2363.71	2191.19
	Median	4033	4322	4033
	Min-Max	1599-10062	1850-8130	1599-10062
	Interquartile range	3534-5383	2064-7037	3055-5675
	Missing	8	9	17
12 months	N	13	10	23
	Mean	4121	4325	4210
	Std Dev	2617.42	2509.44	2514.70
	Median	3441	3531	3441
	Min-Max	1076-8951	1857-9314	1076-9314
	Interquartile range	2340-6104	2212-6898	2221-6882
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-441	-249	-358
	Std Dev	1609.11	2188.54	1838.82
	Median	-438	-142	-351
	Min-Max	-2675-2774	-5090-3730	-5090-3730
	Interquartile range	-1709-240	-892-452	-1288-203
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	76.93 (- 1837.01 to 1990.88)	p = 0.933	1.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.9. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	150.7	172.7	160.2
	Std Dev	49.27	84.77	66.61
	Median	150.7	149.9	149.9
	Min-Max	49-268	80-382	49-3812
	Interquartile range	127-181	104-233	122-183
	Missing	6	9	15
6 months	N	20	15	35
	Mean	128.5	165.6	144.4
	Std Dev	41.55	72.24	58.83
	Median	124.3	141.6	131.2
	Min-Max	46-224	78-318	46-318
	Interquartile range	105-153	111-242	111-160
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-22.3	-7.1	-15.8
	Std Dev	29.16	36.22	32.76
	Median	-16.3	-7.4	-9.7
	Min-Max	-91-13	-81-34	-91-34
	Interquartile range	-39 to -3	-32-30	-33-8
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-18.83 (-39.91 to 2.25)	p = 0.078	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.9.1. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	152.6	178.7	163.4
	Std Dev	53.03	94.51	72.71
	Median	156.7	150.0	150.1
	Min-Max	49-268	80-382	49-382
	Interquartile range	129-182	98-152	111-1187
	Missing	4	7	11
6 months	N	17	12	29
	Mean	128.0	170.9	145.7
	Std Dev	44.61	78.37	63.35
	Median	125.3	136.4	131.2
	Min-Max	46-224	78-318	46-318
	Interquartile range	96-151	112-256	108-167
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-24.7	-7.8	-17.7
	Std Dev	30.83	37.57	34.19
	Median	-19.4	-7.8	-13.3
	Min-Max	-91-13	-81-34	-91-34
	Interquartile range	-46 to -5	-29-30	-38-9
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-21.55 (- 46.13 to 3.04)	p = 0.083	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.9.2. Secondary outcome: Change in percentage time spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	22.4	23.5	22.9
	Std Dev	6.10	8.85	7.30
	Median	21.3	22.0	21.3
	Min-Max	10-38	12-39	10-39
	Interquartile range	20-26	16-29	17-27
	Missing	6	9	15
6 months	N	20	15	35
	Mean	20.7	22.1	21.3
	Std Dev	5.50	6.97	6.12
	Median	20.6	19.9	20.4
	Min-Max	10-34	11-38	10-38
	Interquartile range	16-24	18-25	18-25
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-1.7	-1.4	-1.6
	Std Dev	3.80	5.63	4.60
	Median	-1.7	-0.1	-0.9
	Min-Max	-12-5	-20-3	-20-5
	Interquartile range	-4-0	-2-2	-4-1
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-0.57 (-3.50 to 2.35)	P = 0.692	0.164

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.9.3 Secondary outcome: Change in percentage time spent in light physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	22.4	23.3	22.8
	Std Dev	6.36	9.78	7.80
	Median	21.3	20.2	21.3
	Min-Max	10-38	12-39	10-39
	Interquartile range	20-26	15-33	17-27
	Missing	4	7	11
6 months	N	17	12	29
	Mean	20.5	21.6	21.0
	Std Dev	5.51	7.53	6.32
	Median	20.5	19.3	19.9
	Min-Max	10-34	11-38	10-38
	Interquartile range	16-24	18-25	17-24
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-1.9	-1.7	-1.8
	Std Dev	3.89	6.28	4.92
	Median	-1.8	-0.4	-1.0
	Min-Max	-12-5	-20-3	-20-5
	Interquartile range	-4-0	-3-2	-4-1
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.43 (-3.89 to 3.04)	p = 0.801	0.133

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.10. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	151.8	169.9	159.9
	Std Dev	52.05	89.62	70.55
	Median	157.4	148.2	150.1
	Min-Max	49-268	81-382	49-382
	Interquartile range	123-181	100-222	111-182
	Missing	10	11	21
12 months	N	16	13	29
	Mean	137.0	145.0	140.6
	Std Dev	54.94	71.90	62.04
	Median	131.4	133.5	132.3
	Min-Max	61-261	44.8-291.1	44.8-291.1
	Interquartile range	91-162	87-197	87-164
	Missing	10	11	21
12 months Change	N	16	13	29
	Mean	-14.7	-24.8	-19.3
	Std Dev	42.17	71.66	56.39
	Median	-25.4	-9.4	-16.6
	Min-Max	-75-69	-228-57	-228-69
	Interquartile range	-39-19	-26-9	-33-11
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	7.78 (-33.15 to 48.71)	p = 0.697	0.999

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.10.1. Secondary outcome: Change in average number of minutes spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	154.5	176.2	163.9
	Std Dev	57.30	102.4	78.77
	Median	158.1	134.5	156.7
	Min-Max	49-268	80-382	49-382
	Interquartile range	115-182	95-267	103-186
	Missing	8	9	17
12 months	N	13	10	23
	Mean	137.1	155.3	145.0
	Std Dev	60.57	74.42	65.97
	Median	130.6	143.8	133.5
	Min-Max	61-261	72-291	61-291
	Interquartile range	86-160	87-229	87-65
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-17.4	-21.0	-19.0
	Std Dev	43.93	77.56	59.30
	Median	-30.0	-8.9	-9.4
	Min-Max	-75-69	-228-57	-228-69
	Interquartile range	-55-17	-23-17	-36-12
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-1.28 (-51.14 to 48.58)	p = 0.957	0.999

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.10.2. Secondary outcome: Change in percentage time spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	22.4	22.3	22.3
	Std Dev	6.30	8.37	7.16
	Median	21.0	20.9	20.9
	Min-Max	10-38	12-39	10-39
	Interquartile range	19-26	15-29	17-27
	Missing	10	11	21
12 months	N	16	13	29
	Mean	22.2	22.1	22.1
	Std Dev	8.29	9.35	8.62
	Median	21.8	23.8	22.2
	Min-Max	123-45	8-37	8-45
	Interquartile range	15-24	13-31	15-27
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	-0.2	-0.2	-0.2
	Std Dev	6.03	5.48	5.69
	Median	2.1	0.7	1.8
	Min-Max	-12-7	-13-9	-13-9
	Interquartile range	-5-5	-3-3	-4-4
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	1.71 (-2.75 to 6.17)	P = 0.434	0.993

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.10.3 Secondary outcome: Change in percentage time spent in light physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=29)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	22.4	21.8	22.1
	Std Dev	6.69	9.34	7.76
	Median	21.3	17.2	20.6
	Min-Max	10-38	12-39	10-39
	Interquartile range	19-26	15-30	16-26
	Missing	8	9	17
12 months	N	13	10	23
	Mean	21.8	22.3	22.0
	Std Dev	8.55	9.06	8.57
	Median	21.3	22.5	21.3
	Min-Max	13-45	12-37	12-45
	Interquartile range	15-24	14-30	15-26
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-0.6	0.5	-0.1
	Std Dev	6.28	4.47	5.48
	Median	2.1	0.0	0.7
	Min-Max	-12-7	-6-9	-12-9
	Interquartile range	-5-3	-2-3	-4-3
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI)	0.55 (-4.32 to 5.42)	p = 0.814	0.994
	P-value			
	ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.11. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	28.4	33.7	30.6
	Std Dev	17.97	19.77	18.67
	Median	21.5	33.2	23.5
	Min-Max	2-64	11-83	2-83
	Interquartile range	17-43	20-39	17-42
	Missing	6	9	15
6 months	N	20	15	35
	Mean	24.4	26.6	25.4
	Std Dev	16.37	13.75	15.13
	Median	21.0	26.2	23.7
	Min-Max	2-62	4-60	2-62
	Interquartile range	11-36	19-31	14-31
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-3.9	-7.1	-5.3
	Std Dev	9.50	10.45	9.89
	Median	-1.9	-7.7	-5.7
	Min-Max	-24-19	-23-8	-24-19
	Interquartile range	-10-2	-15-3	-13-2
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	1.74 (-4.62 to 8.12)	p = 0.579	0.999

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.11.1. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)	
Baseline	N	17	12	29	
	Mean	28.0	27.2	27.7	
	Std Dev	17.46	12.42	15.33	
	Median	19.4	22.3	22.2	
	Min-Max	4-64	11-52	4-64	
	Interquartile range	17-42	18-38	17-39	
6 months	Missing	4	7	11	
	N	17	12	29	
	Mean	25.1	22.1	23.8	
	Std Dev	16.77	8.73	13.89	
	Median	21.0	25.2	21.2	
	Min-Max	6-62	4-32	4-62	
Change at 6 months	Interquartile range	12-38	15-28	13-30	
	Missing	4	7	11	
	N	17	12	29	
	Mean	-3.0	-5.1	-3.9	
	Std Dev	9.4	10.30	9.67	
	Median	-0.6	-6.8	-3.3	
Statistical Analysis	Min-Max	-24-19	-21-8	-24-19	
	Interquartile range	-9-2	-13-7	-11-2	
	Missing	4	7	11	
	Mixed effects model (Per-protocol)*	Intervention effect (95% CI)	2.67 (-5.17 to 10.51)	p = 0.487	1.000
		P-value			
		ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.11.2. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	4.4	4.9	4.6
	Std Dev	2.80	3.58	3.11
	Median	3.6	3.7	3.7
	Min-Max	0-9	2-16	0-16
	Interquartile range	2-6	3-6	3-6
	Missing	6	9	15
6 months	N	20	15	35
	Mean	4.1	3.9	4.0
	Std Dev	2.88	2.92	2.86
	Median	3.6	3.3	3.4
	Min-Max	0-12	1-11	0-12
	Interquartile range	2-5	2-4	2-5
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-0.3	-1.0	-0.6
	Std Dev	1.91	1.70	1.83
	Median	-0.2	-0.8	-0.7
	Min-Max	-4-5	-4-1	-4-5
	Interquartile range	-2-1	-2-1	-2-1
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	0.50 (-0.79 to 1.78)	p = 0.434	0.895

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.11.3. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	4.3	3.6	4.0
	Std Dev	2.63	1.49	2.23
	Median	3.2	3.1	3.2
	Min-Max	0-9	2-6	0-9
	Interquartile range	2-6	2-5	2-6
	Missing	4	7	11
6 months	N	17	12	29
	Mean	4.3	2.9	3.7
	Std Dev	2.97	1.21	2.47
	Median	3.5	3.0	3.4
	Min-Max	1-12	1-5	1-12
	Interquartile range	2-6	2-4	2-5
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-0.1	-0.7	-0.3
	Std Dev	1.89	1.54	1.76
	Median	-0.2	-0.8	-0.6
	Min-Max	-4-5	-4-1	-4-5
	Interquartile range	-1-1	-2-1	-1-1
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	0.80 (-0.75 to 2.35)	p = 0.296	0.904

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.12. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)	
Baseline	N	16	13	29	
	Mean	25.2	33.5	28.9	
	Std Dev	18.05	21.34	19.68	
	Median	18.5	22.4	20.2	
	Min-Max	2-64	11-83	2-83	
	Interquartile range	16-42	19-46	17-41	
12 months	Missing	10	11	21	
	N	16	13	29	
	Mean	24.3	26.7	25.4	
	Std Dev	22.86	13.77	19.04	
	Median	13.4	22.9	18.0	
	Min-Max	4-78	8-52	4-78	
Change at 12 months	Interquartile range	8-41	15-39	11-40	
	Missing	10	11	21	
	N	16	13	29	
	Mean	-0.9	-6.8	-3.6	
	Std Dev	12.85	15.75	14.28	
	Median	-2.6	-5.8	-4.5	
Statistical Analysis	Min-Max	-18-35	-31-20	-31-35	
	Interquartile range	-9-4	-17-4	-11-3	
	Missing	10	11	21	
	Mixed effects model (ITT)*	Intervention effect (95% CI)	1.74 (-9.16 to 12.64)	p = 0.744	0.871
		P-value			
		ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.12.1. Secondary outcome: Change in average number of minutes spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	24.0	25.7	24.8
	Std Dev	17.19	13.17	15.26
	Median	17.8	21.2	19.4
	Min-Max	4-64	11-52	4-64
	Interquartile range	16-33	17-39	16-39
	Missing	8	9	17
12 months	N	13	10	23
	Mean	23.5	24.1	23.7
	Std Dev	24.03	12.98	19.60
	Median	12.4	20.4	15.0
	Min-Max	5-78	8-44	5-78
	Interquartile range	9-34	14-37	11-36
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-0.6	-1.6	-1.0
	Std Dev	13.96	12.96	13.23
	Median	-3.0	-5.6	-3.4
	Min-Max	-18-35	-24-21	-24-35
	Interquartile range	-9-4	-9-9	-8-4
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-2.42 (-15.30 to 10.46)	p = 0.695	0.823

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.12.2. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	3.9	4.8	4.3
	Std Dev	2.87	3.85	3.31
	Median	3.1	3.4	3.2
	Min-Max	0-9	2-15	0-16
	Interquartile range	2-6	2-5	2-6
	Missing	10	11	21
12 months	N	16	13	29
	Mean	4.1	4.2	4.2
	Std Dev	3.87	2.46	3.26
	Median	2.2	3.5	2.7
	Min-Max	1-13	2-10	1-13
	Interquartile range	1-8	2-6	2-6
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	0.2	-0.6	-0.2
	Std Dev	2.10	2.03	2.06
	Median	-0.1	-0.5	-0.2
	Min-Max	-2-7	-5-2	-5-7
	Interquartile range	-1-1	-1-1	-1-0
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	0.26 (-1.28 to 1.80)	p = 0.726	0.818

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.12.3. Secondary outcome: Change in percentage time spent in moderate to vigorous physical activity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	3.7	3.2	3.5
	Std Dev	2.63	1.31	2.13
	Median	3.0	2.8	2.9
	Min-Max	0-9	2-6	0-9
	Interquartile range	2-5	2-4	2-4
	Missing	8	9	17
12 months	N	13	10	23
	Mean	3.8	3.4	3.7
	Std Dev	3.89	1.75	3.09
	Median	2.1	2.8	2.2
	Min-Max	1-13	2-6	1-13
	Interquartile range	1-6	2-6	2-6
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	0.1	0.2	0.2
	Std Dev	2.34	1.11	1.87
	Median	-0.3	-0.2	-0.2
	Min-Max	-2-7	-1-2	-2-7
	Interquartile range	-1-1	-1-1	-1-1
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.89 (-2.51 to 0.73)	p = 0.260	0.732

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.13. Secondary outcome: Change in average number of minutes spent in physical activity of any intensity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	179.1	206.4	190.8
	Std Dev	56.94	93.80	74.99
	Median	177.0	185.9	180.6
	Min-Max	68-331	94-420	68-420
	Interquartile range	150-206	124-266	141-226
	Missing	6	9	15
6 months	N	20	15	35
	Mean	152.9	192.2	169.7
	Std Dev	48.98	76.19	64.20
	Median	146.0	167.8	159.6
	Min-Max	68-274.0	88-346	68-346
	Interquartile range	124-180	137-267	129-187
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-26.2	-14.2	-21.0
	Std Dev	31.10	43.94	37.05
	Median	-23.1	-18.1	-21.9
	Min-Max	-90-30.0	-99-42	-99-42
	Interquartile range	-45 to -2	-54-29	-45-2
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-18.00 (41.64 to 5.64)	p = 0.130	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.13.1 Secondary outcome: Change in average number of minutes spent in physical activity of any intensity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	180.7	205.9	191.1
	Std Dev	60.02	105.01	80.93
	Median	177.0	178.0	177.0
	Min-Max	68-331	94-420	68-420
	Interquartile range	150-211	116-289	133-227
	Missing	4	7	11
6 months	N	17	12	29
	Mean	153.1	193.0	169.6
	Std Dev	52.27	84.12	68.86
	Median	146.3	163.8	159.6
	Min-Max	68-274	88-346	68-346
	Interquartile range	118-178	135-286	126-184
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-27.6	-12.9	-21.5
	Std Dev	33.16	46.31	39.05
	Median	-22.1	-11.2	-18.1
	Min-Max	-90-30	-99-42	-99-42
	Interquartile range	-49 to -3	-48-34	-49-4
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-19.57 (- 47.68 to 8.54)	p = 0.163	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.13.2 Secondary outcome: Change in percentage time spent in physical activity of any intensity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	26.8	28.4	27.5
	Std Dev	7.63	10.83	9.03
	Median	26.0	28.1	26.4
	Min-Max	15-47	15-45	15-47
	Interquartile range	22-30	19-40	20-32
	Missing	6	9	15
6 months	N	20	15	35
	Mean	24.8	26.0	25.3
	Std Dev	6.86	8.43	7.48
	Median	23.8	24.2	23.9
	Min-Max	15-41	13-42	13-42
	Interquartile range	20-28	20-31	20-28
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	-2.1	-2.3	-2.2
	Std Dev	4.67	6.82	5.60
	Median	-2.7	-1.1	-1.9
	Min-Max	-12-10	-24-4	-24-10
	Interquartile range	-5-0	-4-2	-5-1
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-0.09 (-3.6 to 3.50)	p = 0.962	0.449

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.13.3 Secondary outcome: Change in percentage time spent in physical activity of any intensity per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	26.8	26.9	26.8
	Std Dev	7.61	10.99	8.97
	Median	25.5	24.3	25.5
	Min-Max	15-47	15-44	15-47
	Interquartile range	22-30	17-38	20-31
	Missing	4	7	11
6 months	N	17	12	29
	Mean	24.8	24.5	24.7
	Std Dev	6.93	8.21	7.34
	Median	23.9	21.9	23.8
	Min-Max	15-41	13-42	13-42
	Interquartile range	20-28	20-27	20-27
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-2.0	-2.4	-2.2
	Std Dev	4.81	7.63	6.01
	Median	-2.3	-1.5	-1.9
	Min-Max	-12-10	-24-4	-24-10
	Interquartile range	-5-0	-4-3	-5-1
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	0.56 (-3.78 to 4.90)	p = 0.792	0.481

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.14. Secondary outcome: Change in average number of minutes spent in physical activity of any intensity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	177.0	203.4	188.8
	Std Dev	58.50	99.63	79.16
	Median	176.1	182.1	176.9
	Min-Max	68-331	94-420	68-420
	Interquartile range	139-206	119-269	130-218
	Missing	10	11	21
12 months	N	16	13	29
	Mean	161.4	171.7	166.0
	Std Dev	62.04	81.68	70.35
	Median	159.5	151.4	156.8
	Min-Max	72-308	67-335	67-335
	Interquartile range	106-188	104-243	107-208
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	-15.6	-31.7	-22.8
	Std Dev	44.01	80.73	62.43
	Median	-29.1	-22.3	-22.45
	Min-Max	-78-86	-251-72	-251-86
	Interquartile range	-40-18	-40-3	
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	8.50 (-38.26 to 55.26)	p = 0.710	0.994

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.14.1. Secondary outcome: Change in average number of minutes spent in physical activity of any intensity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	178.5	201.9	188.7
	Std Dev	62.91	114.09	87.31
	Median	175.2	155.6	174.5
	Min-Max	68-331	94-420	68-420
	Interquartile range	142-211	111-309	124-226
	Missing	8	9	17
12 months	N	13	10	23
	Mean	160.5	179.4	168.7
	Std Dev	69.27	85.56	75.52
	Median	151.1	158.5	151.1
	Min-Max	72-308	80-335	72-335
	Interquartile range	102-206	107-267	104-222
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-18.0	-22.5	-20.0
	Std Dev	45.48	88.25	65.72
	Median	-34.7	-14.6	-22.3
	Min-Max	-78-86	-251-72	-251-86
	Interquartile range	-49-14	-31-28	-37-17
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-3.13 (-60.96 to 54.70)	p = 0.910	0.995

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.14.2. Secondary outcome: Change in percentage time spent in physical activity of any intensity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)	
Baseline	N	16	13	29	
	Mean	26.3	27.1	26.7	
	Std Dev	7.67	10.66	8.97	
	Median	24.4	25.7	25.1	
	Min-Max	15-47	15-45	15-47	
	Interquartile range	22-30	18-36	20-32	
12 months	Missing	10	11	21	
	N	16	13	29	
	Mean	26.3	26.3	26.3	
	Std Dev	10.15	11.11	10.39	
	Median	24.2	27.5	24.3	
	Min-Max	14-53	12-43	12-53	
Change at 12 months	Interquartile range	20-31	15-36	17.5-32.3	
	Missing	10	11	21	
	N	16	13	29	
	Mean	0.0	-0.8	-0.4	
	Std Dev	5.89	5.8	5.77	
	Median	1.5	-1.8	0.4	
Statistical Analysis	Min-Max	-12-8	-14-11	-14-11	
	Interquartile range	-4-5	-3-2	-3-3	
	Missing	10	11	21	
	Mixed effects model (ITT)*	Intervention effect (95% CI)	1.95 (-2.70 to 6.61)	p = 0.394	0.994
		P-value			
		ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.14.3. Secondary outcome: Change in percentage time spent in physical activity of any intensity per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	26.1	25.0	25.6
	Std Dev	7.64	10.44	8.76
	Median	23.7	20.0	23.7
	Min-Max	15-47	15-44	15-47
	Interquartile range	22-29	17-34	19-30
	Missing	8	9	17
12 months	N	13	10	23
	Mean	25.6	25.7	25.6
	Std Dev	10.27	10.51	10.14
	Median	24.3	24.8	24.3
	Min-Max	14-53	13-42	13-53
	Interquartile range	18-31	15-34	17-32
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-0.5	0.7	0.0
	Std Dev	6.06	4.90	5.50
	Median	1.0	0.1	1.0
	Min-Max	-12-8	-5-11	-12-11
	Interquartile range	-5-3	-3-3	-3-3
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.16 (-5.37 to 5.05)	p = 0.949	0.994

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.15. Secondary outcome: Change in average number of minutes spent on sedentary behaviour per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)	
Baseline	N	20	15	35	
	Mean	485.5	533.7	506.1	
	Std Dev	89.69	184.02	137.93	
	Median	482.5	513.7	489.3	
	Min-Max	353.1-662.2	267.5-915.4	267.5-915.4	
	Interquartile range	404.8-571.9	412.5-705.7	411.6-588.0	
6 months	N	20	15	35	
	Mean	464.2	550.9	501.4	
	Std Dev	91.84	159.73	130.81	
	Median	466.4	556.0	492.1	
	Min-Max	316.5-605.2	323.8-926.2	316.5-926.2	
	Interquartile range	388.1-555.2	432.5-639.2	393.8-592.5	
Change at 6 months	N	20	15	35	
	Mean	-21.2	17.2	-4.8	
	Std Dev	85.32	82.77	85.21	
	Median	-26.3	20.4	-9.4	
	Min-Max	-173.9-129.5	-109.2-178.0	-173.9-178.0	
	Interquartile range	-74.2-51.0	-37.8-66.9	-57.6-61.4	
Statistical Analysis	Missing	6	9	15	
	Mixed effects model (ITT)*	Intervention effect (95% CI)	-49.33 (-108.78 to 10.12)	p = 0.100	0.547
		P-value			
		ICC			

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.15.1 Secondary outcome: Change in average number of minutes spent in sedentary behaviour per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	489.0	562.4	519.4
	Std Dev	90.41	190.26	142.29
	Median	475.7	521.9	489.3
	Min-Max	374-662	268-915	268-915
	Interquartile range	407-583	425-708	412-613
	Missing	4	7	11
6 months	N	17	12	29
	Mean	462.3	584.4	512.8
	Std Dev	91.07	147.41	130.46
	Median	460.0	580.4	500.0
	Min-Max	317-605	399-926	317-926
	Interquartile range	390-554	464-667	413-586
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	-26.6	22.0	-6.5
	Std Dev	86.27	83.28	87.02
	Median	-27.4	15.6	-21.6
	Min-Max	-174-130	-99-178	-174-178
	Interquartile range	-88-41	-36-61	-48-52
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-71.88 (- 136.40 to - 7.37)	p = 0.031	0.525

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.15.2. Secondary outcome: Change in percentage time spent in sedentary behaviour per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	20	15	35
	Mean	73.2	71.6	72.5
	Std Dev	7.63	10.83	9.03
	Median	74.04	71.9	73.6
	Min-Max	53-86	55-85	53-86
	Interquartile range	70-78	60-81	68-80
	Missing	6	9	15
6 months	N	20	15	35
	Mean	75.2	74.0	74.7
	Std Dev	6.86	8.43	7.48
	Median	76.2	75.8	76.1
	Min-Max	59-85	58-87	58-87
	Interquartile range	72-80	69-80	72-80
	Missing	6	9	15
Change at 6 months	N	20	15	35
	Mean	2.1	2.3	2.2
	Std Dev	4.67	6.82	5.60
	Median	2.7	1.1	1.9
	Min-Max	-10-12	-4-24	-10-24
	Interquartile range	0-5	-2-4	-1-5
	Missing	6	9	15
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	0.09 (-3.50 to 3.67)	p = 0.962	0.449

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.15.3. Secondary outcome: Change in percentage time spent in sedentary behaviour per day at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	17	12	29
	Mean	73.2	73.1	73.2
	Std Dev	7.61	10.99	8.97
	Median	74.5	75.7	74.5
	Min-Max	53-86	56-85	53-86
	Interquartile range	70-78	62-83	69-80
	Missing	4	7	11
6 months	N	17	12	29
	Mean	75.2	75.5	75.3
	Std Dev	6.93	8.21	7.34
	Median	76.1	78.1	76.2
	Min-Max	59-85	58-87	58-87
	Interquartile range	72-80	73-80	73-80
	Missing	4	7	11
Change at 6 months	N	17	12	29
	Mean	2.0	2.4	2.2
	Std Dev	4.81	7.63	6.01
	Median	2.3	1.5	1.9
	Min-Max	-10-12	-4-24	-10-24
	Interquartile range	0-5	-3-4	-1-5
	Missing	4	7	11
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-0.56 (-4.90 to 3.78)	p = 0.792	0.481

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.16. Secondary outcome: Change in average number of minutes spent on sedentary behaviours per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	493.4	554.7	520.9
	Std Dev	96.96	187.65	145.24
	Median	489.9	526.3	492.3
	Min-Max	353.1-662.2	267.5-915.4	267.5-915.4
	Interquartile range	404.8-585.7	422.7-707.2	412.0-612.6
	Missing	10	11	21
12 months	N	16	13	29
	Mean	458.7	479.0	467.8
	Std Dev	108.40	102.93	104.60
	Median	475.9	456.1	470.0
	Min-Max	234.5-602.9	295.4-648.3	234.5-648.3
	Interquartile range	390.4-558.6	420.9-547.4	403.6-551.9
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	-34.7	-75.8	-53.1
	Std Dev	73.57	149.36	113.55
	Median	-21.6	-57.6	-28.4
	Min-Max	-192.1-70.8	-469.5-156.4	-469.5-156.4
	Interquartile range	-102.4-32.1	-129.9-7.3	-99.8-12.7
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-18.30 (-83.70 to 47.10)	p = 0.568	0.961

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.16.1. Secondary outcome: Change in average number of minutes spent in sedentary behaviours per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	499.8	595.5	541.4
	Std Dev	98.95	189.77	149.75
	Median	489.3	596.20	513.7
	Min-Max	374-662	268-915	268-915
	Interquartile range	407-593	463-721	412-662
	Missing	8	9	17
12 months	N	13	10	23
	Mean	462.3	508.3	482.3
	Std Dev	95.58	87.82	93.18
	Median	470.0	489.7	470.0
	Min-Max	269-603	418-648	269-648
	Interquartile range	392-558	428-572	418-556
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	-37.5	-87.2	-59.1
	Std Dev	72.28	169.69	123.55
	Median	-23.8	-59.0	-28.4
	Min-Max	-192-46	-470-156	-470-156
	Interquartile range	-100-24	-190-17	-105-17
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	-36.98 (- 110.95 to 37.00)	p = 0.305	0.946

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.16.2. Secondary outcome: Change in percentage time spent in sedentary behaviours per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	16	13	29
	Mean	73.7	72.9	73.3
	Std Dev	7.67	10.66	8.97
	Median	75.6	74.3	74.9
	Min-Max	53-86	55-85	53-86
	Interquartile range	70-78	64-82	69-80
	Missing	10	11	21
12 months	N	16	13	29
	Mean	73.7	73.7	73.7
	Std Dev	10.15	11.11	10.39
	Median	75.8	72.5	75.7
	Min-Max	47-86	57-88	47-88
	Interquartile range	69-80	64-85	68-83
	Missing	10	11	21
Change at 12 months	N	16	13	29
	Mean	0.0	0.8	0.4
	Std Dev	5.89	5.83	5.77
	Median	-1.5	1.8	-0.4
	Min-Max	-8-12	-11-14	-11-14
	Interquartile range	-4-4	-2-3	-3-3
	Missing	10	11	21
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	-1.95 (-6.61 to 2.70)	p = 0.394	0.994

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.16.3. Secondary outcome: Change in percentage time spent in sedentary behaviours per day at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	13	10	23
	Mean	73.9	75.0	74.4
	Std Dev	7.64	10.44	8.76
	Median	76.3	80.0	76.4
	Min-Max	53-86	56-85	53-86
	Interquartile range	71-78	66-83	70-81
	Missing	8	9	17
12 months	N	13	10	23
	Mean	74.4	74.3	74.4
	Std Dev	10.27	10.51	10.14
	Median	75.7	75.2	75.7
	Min-Max	47-86	58-87	47-87
	Interquartile range	70-82	66-85	68-83
	Missing	8	9	17
Change at 12 months	N	13	10	23
	Mean	0.5	-0.7	0.0
	Std Dev	6.06	4.90	5.50
	Median	-1.0	-0.1	-1.0
	Min-Max	-8-12	-11-5	-11-12
	Interquartile range	-3-5	-3-3	-3-3
	Missing	8	9	17
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	0.16 (-5.05 to 5.37)	p = 0.949	0.994

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.17. Secondary outcome: Change in average EQ-5D index at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	Total (n=50)
Baseline	N	24	22	46
	Mean	0.8	0.7	0.8
	Std Dev	0.27	0.33	0.29
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	2	2	4
6 months	N	24	22	46
	Mean	0.8	0.8	0.8
	Std Dev	0.29	0.25	0.27
	Median	1.0	0.8	0.9
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	1-1	1-1
	Missing	2	2	4
Change at 6 months	N	24	22	46
	Mean	0.1	0.0	0.1
	Std Dev	0.28	0.32	0.29
	Median	0.0	0.0	0.0
	Min-Max	-1-1	-1-1	-1-1
	Interquartile range	0-0	0-0	0-0
	Missing	2	2	4
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	0.03 (-0.12 to 0.18)	p = 0.652	0.118

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.17.1. Secondary outcome: Change in average EQ-5D index at 6 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	Total (n=40)
Baseline	N	21	19	40
	Mean	0.8	0.8	0.8
	Std Dev	0.28	0.28	0.28
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	0	0	0
6 months	N	21	19	40
	Mean	0.9	0.8	0.8
	Std Dev	0.30	0.26	0.28
	Median	1.0	0.8	0.9
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	0	0	0
Change at 6 months	N	21	19	40
	Mean	0.1	0.0	0.0
	Std Dev	0.28	0.23	0.26
	Median	0.0	0.1	0.0
	Min-Max	-1-1	-1-0	-1-1
	Interquartile range	0-1	0-0	0-0
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	0.07 (-0.10 to 0.24)	p = 0.393	0.341

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 6 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.18. Secondary outcome: Change in average EQ-5D index at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (ITT).

Variable	Statistic	TAKE 5 (n=26)	WWTOO (n=24)	TOTAL (n=50)
Baseline	N	24	24	48
	Mean	0.8	0.7	0.8
	Std Dev	0.27	0.32	0.29
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	2	0	2
12 months	N	24	24	48
	Mean	0.8	0.7	0.7
	Std Dev	0.39	0.30	0.35
	Median	1.0	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	2	0	2
Change at 12 months	N	24	24	48
	Mean	-0.0	-0.0	-0.0
	Std Dev	0.39	0.37	0.38
	Median	0.0	0.0	0.0
	Min-Max	-1-1	-1-1	-1-1
	Interquartile range	0-0	0-0	0-0
	Missing	2	0	2
Statistical Analysis				
Mixed effects model (ITT)*	Intervention effect (95% CI) P-value ICC	0.04 (-0.16 to 0.24)	p = 0.675	0.000

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.18.1. Secondary outcome: Change in average EQ-5D index at 12 months from baseline, by intervention group and overall. Adjusted mean difference (TAKE 5-WWTOO), 95% confidence interval, p-value and ICC (Completers).

Variable	Statistic	TAKE 5 (n=21)	WWTOO (n=19)	TOTAL (n=40)
Baseline	N	21	19	40
	Mean	0.8	0.8	0.8
	Std Dev	0.28	0.28	0.28
	Median	0.8	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	1-1
	Missing	0	0	0
12 months	N	21	19	40
	Mean	0.8	0.7	0.7
	Std Dev	0.41	0.31	0.36
	Median	1.0	0.8	0.8
	Min-Max	0-1	0-1	0-1
	Interquartile range	1-1	0-1	0-1
	Missing	0	0	0
Change at 12 months	N	21	19	40
	Mean	0.0	0.0	0.0
	Std Dev	0.41	0.28	0.35
	Median	0.0	0.0	0.0
	Min-Max	-1-1	-1-0	-1-1
	Interquartile range	0-0	0-0	0-0
	Missing	0	0	0
Statistical Analysis				
Mixed effects model (Per-protocol)*	Intervention effect (95% CI) P-value ICC	0.02 (-0.21 to 0.25)	p = 0.851	0.059

CI= Confidence Interval; ICC = Intraclass correlation.

Data only reported for participants with data at both baseline and 12 months

*Results are presented as adjusted means for baseline variable and effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome).

Table 3.19. Secondary outcome: Change in EQ-5D-Y domain at 6 months from baseline. Odds ratio (95% confidence interval) and p-value (ITT).

EQ-5D Domain	Change in EQ-5D Domain	TAKE 5 (n=24)	WWTOO (n=22)	TOTAL (n=46)	Odds ratio (95% CI)*	P-value
Mobility	Improvement	3 (12.5%)	7 (31.8%)	10 (21.7%)	0.34 (0.07 to 1.67)	0.179
	No improvement/Deteriorated	21 (87.5%)	15 (68.2%)	36 (78.3%)	Referent	
Self-care	Improvement	2 (8.3%)	3 (13.6%)	5 (10.9%)	0.63 (0.09 to 4.41)	0.633
	No improvement/Deteriorated	22 (91.7%)	19 (86.4%)	41 (89.1%)	Referent	
Usual activities	Improvement	1 (4.2%)	1 (4.5%)	2 (4.3%)	0.92 (0.07 to 12.17)	0.951
	No improvement/Deteriorated	23 (95.8%)	21 (95.5%)	44 (95.7%)	Referent	
Pain discomfort	Improvement	3 (12.5%)	4 (18.2%)	7 (15.2%)	0.66 (0.11 to 4.02)	0.646
	No improvement/Deteriorated	21 (87.5%)	18 (81.8%)	39 (84.8%)	Referent	
Anxiety/depression	Improvement	3 (12.5%)	4 (18.2%)	7 (15.2%)	0.58 (0.09 to 3.72)	0.555
	No improvement/Deteriorated	21 (87.5%)	18 (81.8%)	39 (84.8%)	Referent	

*Results are presented as adjusted Odds Ratio (OR) for effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval.

Table 3.20. Secondary outcome: Change in EQ-5D-Y domain at 12 months from baseline. Odds ratio (95% confidence interval) and p-value (ITT).

EQ-5D Domain	Change in EQ-5D Domain	TAKE 5 (n=24)	WWTOO (n=24)	TOTAL (n=48)	Odds ratio (95% CI)*	P-value
Mobility	Improvement	3 (12.5%)	5 (20.8%)	8 (16.7%)	0.65 (0.11 to 3.87)	0.630
	No improvement/Deteriorated	21 (87.5%)	19 (79.2%)	40 (83.3%)	Referent	
Self-care	Improvement	2 (8.3%)	4 (16.7%)	6 (15.2%)	0.58 (0.09 to 3.80)	0.562
	No improvement/Deteriorated	22 (91.7%)	20 (83.3%)	42 (91.3%)	Referent	
Usual activities	Improvement	1 (4.2%)	2 (8.3%)	3 (6.3%)	0.57 (0.08 to 5.70)	0.626
	No improvement/Deteriorated	23 (95.8%)	22 (91.7%)	45 (97.8%)	Referent	
Pain discomfort	Improvement	3 (12.5%)	3 (12.5%)	6 (12.5%)	0.98 (0.16 to 5.93)	0.985
	No improvement/Deteriorated	21 (87.5%)	21 (87.5%)	42 (91.3%)	Referent	
Anxiety/depression	Improvement	3 (12.5%)	4 (16.7%)	7 (14.6%)	0.65 (0.10 to 4.11)	0.637
	No improvement/Deteriorated	21 (87.5%)	20 (83.3%)	41 (89.1%)	Referent	

*Results are presented as adjusted Odds Ratio (OR) for effect of clustering of participants (stratified by number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI = Confidence Interval.

Appendix VIII: Publications arising from this thesis

STUDY PROTOCOL

Open Access

A single-blind, pilot randomised trial of a weight management intervention for adults with intellectual disabilities and obesity: study protocol

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Abstract

Background: The prevalence of obesity in adults with intellectual disabilities has consistently been reported to be higher than the general population. Despite the negative impact of obesity on health, there is little evidence of the effectiveness of weight management interventions for adults with intellectual disabilities and obesity. Preliminary results from a single-stranded feasibility study of a multi-component weight management intervention specifically designed for adults with intellectual disabilities and obesity (TAKE 5) and that satisfied clinical recommendations reported that it was acceptable to adults with intellectual disabilities and their carers. This study aims to determine the feasibility of a full-scale clinical trial of TAKE 5.

Methods: This study will follow a pilot randomised trial design. Sixty-six obese participants (body mass index (BMI) ≥ 30 kg/m²) will be randomly allocated to the TAKE 5 multi-component weight management intervention or a health education 'active' control intervention (Waist Winners Too (WWToo)). Both interventions will be delivered over a 12-month period. Participants' anthropometric measures (body weight, BMI, waist circumference, percentage body fat); indicators of activity (levels of physical activity and sedentary behaviour) and well-being will be measured at three time points: baseline, 6 and 12 months. The researcher collecting outcome measures will be blind to study group allocation.

Conclusions: The data from this study will generate pilot data on the acceptability of randomisation, attrition rates and the estimates of patient-centred outcomes of TAKE 5, which will help inform future research and the development of a full-scale randomised clinical trial.

Trial registration: ISRCTN52903778.

Keywords: Intellectual disability, Weight management, Obesity, TAKE 5

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Background

Intellectual disability is defined as the 'disability characterised by significant limitations both in intellectual functioning and in adaptive behaviour, which covers everyday social and practical skills. The disability originates before the age of 18 years [1]'. Individuals with intellectual disabilities have consistently been reported to have higher rates of obesity than the general population [2-6]. Obesity, defined as a body mass index (BMI) of 30 kg/m² or greater, is known to have a negative impact on health, associated with chronic diseases such as cardiovascular disease [7], some cancers [8] and type II diabetes [9]. Being overweight or obese has shown to further exacerbate the health needs and already reduced life expectancy of adults with intellectual disabilities [10]. Despite the negative impact of obesity on health, there is a limited evidence base to inform the management of obesity in this population [11].

Clinical guidance on the management of obesity advocates that adults who are overweight or obese should aim for a clinically important, sustainable weight loss of 5%–10% of initial body weight [12,13]. To achieve this multi-component weight management, interventions are recommended which include as follows:

1. Dietary changes to create an energy deficit diet (EDD) of 2,510 kilojoules (kJ)/day (600 kilocalories (kcal)/day).
2. Support to increase physical activity levels and decrease inactivity.
3. Incorporation of behaviour change strategies to facilitate dietary and activity changes.
4. A weight maintenance phase encouraging sustained behaviour changes in healthy eating, increased physical activity and reduced sedentary behaviour.
5. A minimum 12-month study period (including the intervention and follow up) to examine the efficacy of the intervention.

Multi-component interventions have been used in the general population to successfully support individuals to lose a clinically important weight [14]. However, there are no published randomised controlled trials of weight management interventions meeting clinical recommendations in adults with intellectual disabilities.

Prior to this study, a single-stranded feasibility study was carried out to examine the efficacy of TAKE 5; a multi-component weight management intervention specifically designed for adults with intellectual disabilities and obesity [15,16]. TAKE 5 was developed in collaboration with National Health Service (NHS) Greater Glasgow & Clyde Weight Management Service (GCWMS) [14] and modelled on their multi-component intervention, which incorporates diet and activity advice underpinned by behaviour

change approaches and based on clinical guidelines [12,13]. Full results from the TAKE 5 feasibility study have been published previously [15,16]. The feasibility study found that TAKE 5 was acceptable to adults with intellectual disabilities, and carers, and reported clinically important reductions in body weight which were comparable to those achieved in adults with no reported intellectual disability following the GCWMS multi-component intervention [17]. Furthermore, clinically important reductions in risk factors associated with chronic diseases, such as waist circumference and increased physical activity levels, were also observed [15,16,18].

This study will add to the limited evidence base of controlled trials which have examined the efficacy of weight management interventions for adults with intellectual disabilities by piloting an intervention meeting current UK clinical recommendations on weight management. This study will compare the effects of a multi-component weight management intervention, TAKE 5 with a health education control intervention which does not include quantitative dietary advice to generate an individualised energy deficit, Waist Winners Too (WWToo). The design and rationale of the study with detail on the components of both interventions will be reported in this protocol.

Aim

The overall aim of this pilot randomised trial is to examine the feasibility of a full-scale clinical trial of the TAKE 5 multi-component weight management intervention in comparison with a health education control intervention.

The key research questions to determine the feasibility of a full-scale randomised clinical trial are the following:

1. Can adults with intellectual disabilities and obesity be recruited to a randomised study of the TAKE 5 intervention versus a health education control intervention?
2. What attrition rates are observed at 6 and 12 months post-randomisation?
3. Are the patient centred outcome measures acceptable to the participants and can they be measured reliably to detect clinically important changes?
4. What are the sample size requirements for a full-scale clinical trial powered at 90% to determine a clinically important difference in body weight?

Methods

The study will be conducted in accordance with the ethical principles of the Declaration of Helsinki and consistent with the principles of Good Clinical Practice. Ethical approval has been received from the Scotland A Research Ethics committee. In accordance with the Adults with Incapacity (Scotland) Act 2000, a detailed protocol of

consent was implemented. This included seeking consent from individuals with intellectual disabilities with the capacity to provide informed consent and seeking consent from the nearest relative or welfare guardian in circumstances where the individual was unable to provide informed consent. Written informed consent was obtained from all participants or nearest relative or welfare guardian. Participants will have the right to withdraw from the study at any time and to decline to take part in any particular aspect or measure. This will be explained to them whilst seeking consent and their on-going consent will be checked and assessed throughout the intervention.

Design

This study is a single-centre, single-blind pilot randomised trial. It consists of two active intervention arms: TAKE 5 multi-component weight management intervention versus treatment as usual (TAU), health educational intervention, WWToo. TAU in most areas in the UK for adults with intellectual disabilities and obesity is inconsistent—ranging from no intervention to the WWToo health education approach. An ‘active’ control intervention is preferred to the traditional non-intervention control group as due to the health risks associated with obesity [19,20]; the research group believe it to be unethical to offer participants to be randomised to the control group with no intervention, for a 12-month period. Sixty-six participants will be randomised to the study (33 to each treatment arm) for a 12-month period; a 6-month weight loss period (comprising of 9–12 sessions designed to take place between two and three weekly intervals) followed by a 6-month weight maintenance period (comprising of six sessions taking place once a month). If the participants have not lost a clinically relevant weight loss of 5% of initial body weight at the end of the weight loss period, they will be advised to continue on the weight loss plan for a further 3 months, followed by a condensed 3-month weight maintenance period, mirroring the procedures conducted by the GCWMS and allowing a 12-month ‘intervention period’ for all participants. The study design is illustrated in Figure 1.

Study population

Participants will be invited to take part in the study if they meet the eligibility criteria presented in Table 1.

Recruitment

One aim of the proposed study is to examine recruitment and retention to a randomised trial design and inform recruitment strategies that could be used in the development of a full-scale, multi-centre trial. Therefore, this pilot randomised trial will use a multi-point recruitment strategy, involving primary health care services, specialist

intellectual disability services, relevant voluntary organisations and care provider organisations. A record will be kept of the numbers of potential participants, and individuals consenting to participate in the study, identified from each of the recruitment points.

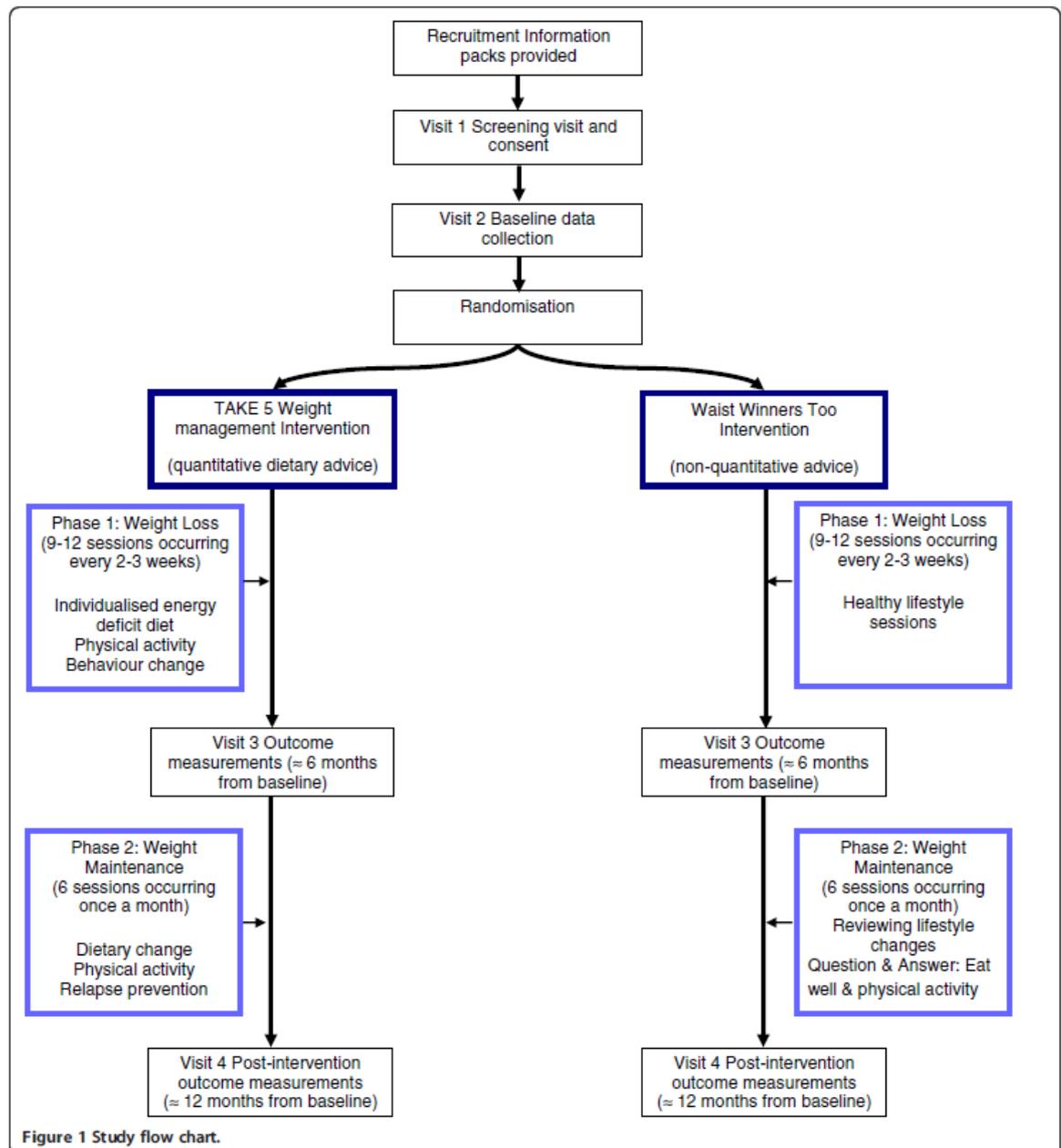
The research team will visit staff working in these settings to explain the study and ask if their organisation would be willing to support recruitment to the study. For those staff willing to support recruitment to the study, a supply of study information packs will be provided, comprising information about the study including an invitation for potential participants to participate. Staff will be invited to distribute these packs to service users who they think would fulfil the study inclusion criteria and potentially be willing to take part. Potential participants, who reply to the invitation to the study by post using the self-addressed envelope provided, will indicate whether they would like to meet the researcher to find out more about the study. The researcher (LH) will then contact participants to arrange a visit, at a convenient location to the participant, to discuss the study. Individuals recruited to the study may live together and/or be supported by the same family or paid carers. These factors could make it difficult to randomise people to the different treatment interventions of the study and lead to some contamination between treatments and clustering of outcomes. Cluster randomisation, stratified by (and therefore analysed with adjustment for) the number of individuals within a randomised cluster, level of intellectual disabilities and presence of Down Syndrome will account for the clustering of outcomes and minimise imbalance between study groups.

Sample size

There is limited data from controlled trials of weight management involving adults with intellectual disabilities on which to base a sample size calculation. This study is designed to estimate recruitment and retention rates for a full-scale clinical trial; it is not powered to detect a difference between study groups. Sixty-six participants will be recruited (33 to each treatment arm). This will provide sufficient insight into recruitment and retention rates, which will have a 95% confidence interval of no more than $\pm 10\%$. The sample size will allow for a possible attrition rate of 20%. This study also aims to determine likely variance of study outcomes in order to power a larger randomised trial; if 50 participants provide outcome data at 12 months, a 90% confidence interval for each variance estimate will have a width of approximately 70% of the estimate (i.e. -26% to $+44\%$).

Procedure

Participant eligibility will be assessed by the researcher based on the inclusion and exclusion criteria (Table 1) at an initial screening visit. Participants will also be asked to



complete the Physical Activity Readiness Questionnaire (PARQ) [21] in order to identify any potential contraindications to increasing their physical activity levels. If participants score positively, they will be advised to consult their doctor about whether they should participate in the study.

After obtaining informed consent, the researcher will arrange a visit to collect baseline outcome measures.

Participants' level of intellectual disability will be assessed with questions assessing an individual's level of ability and need for support in five key areas of functioning: eating and drinking, intimate care, personal safety, communication and decision making. A total score (range 5–25) is obtained by adding together the scores from the five individual questions. This will be used to categorise the level of intellectual disability as mild, moderate, severe or

Table 1 Participant eligibility, inclusion and exclusion criteria

Criteria	
Inclusion	
Intellectual disability	Any level of intellectual disability
Age	Adults ≥ 18 years old (there is no upper age limit, in keeping with the GCWMS and specialist intellectual disability health services in NHS GGC)
Weight status	BMI ≥ 30 kg/m ²
Ambulatory	Ability to walk (with or without a walking aid) for 10 min at a time based on self/carer report
Diet	Not currently on a prescribed or restricted diet, e.g. for phenylketonuria or diabetes
Weight stability	No intentional weight loss >3 kg over the previous 3 months
Exclusion	
Genetic intellectual disability	Participants with Prader Willi syndrome, Cohen syndrome or Bardet-Biedl syndrome as they require specific support to lose weight
Research	Currently taking part in any other research study
Medication	Taking medication; either prescribed or over the counter, designed for weight loss
Pregnancy	Individuals who are pregnant will be excluded from the study and anyone who conceived during the study will be excluded.

profound. The cut-offs corresponding to the four categories of intellectual disabilities were derived in a previous study [22] and shown to have a good level of agreement with a validated structured assessment of functioning and ability level, the Vineland's Adaptive Behaviour Scale [23]. Participants will then be randomised into the TAKE 5 intervention or WWToo intervention. The researcher will telephone an interactive voice response system (IVRS), hosted by the Robertson Centre for Biostatistics, University of Glasgow. The researcher will register each participant in the study, by giving the participants' cluster number, the number of individuals within the cluster, level of intellectual disabilities and presence of Down Syndrome. After registering each participant, the system will notify the principal investigator of the allocation (TAKE 5 intervention or WWToo intervention). During post randomisation, participants will be contacted by the research dietitian delivering the interventions and arrangements will be made for their first session. Intervention sessions will take place in a participant's own home or, if an individual prefers, in out-patient facilities located in the local learning disabilities team base, or other NHS Greater Glasgow & Clyde setting. The researcher collecting the data will be blind to group allocation. After the first 6 months of weight loss phase and at 12 months, all outcome measures will be repeated. These data will be used to determine whether any changes in outcome measures have been maintained.

Interventions

Both interventions will be delivered by a research dietitian. The session frequency (9–12 sessions in the weight loss phase and six sessions in the weight maintenance phase) is to allow appointments to be organised flexibly to maximise the consistent involvement of family and paid carers.

Previous research has shown that the involvement of family and paid carers contributes to the effectiveness of weight management interventions for adults with intellectual disabilities [24,25]. Each session will last approximately 40–60 min duration. This is to allow some flexibility in the session content, required to take account of the individual needs and abilities of participants. For example, some participants and carers may prefer to have shorter sessions or have extra sessions to develop an understanding of the information. This study will use appropriate methods and techniques for augmentative communication, e.g. talking mats and pictorial explanations that aim to enable participants to express their choices during the intervention [26]. Accessible resources, appropriate to the developmental levels of adults with intellectual disabilities were developed during the TAKE 5 feasibility study and will be used to support participants in both intervention arms. Supporting resources are designed to be used flexibly with adults with all levels of learning disabilities, involving family and paid carers where appropriate.

TAKE 5

TAKE 5 is an individualised intervention involving family or paid carers to support participants, where appropriate. It was adapted specifically for use with adults with intellectual disabilities in that it is designed to be delivered on a one-to-one basis with support from carers in the individual's home environment instead of a group setting as in the GCWMS intervention [13].

TAKE 5 intervention components

The main themes discussed at each session for weight loss and weight maintenance are illustrated in Tables 2 and 3, respectively. Each session will focus on a discussion point

Table 2 Intervention key themes underpinning weight loss sessions

Session	TAKE 5	Waist Winners Too
1	Benefits of losing weight and motivation towards a healthy lifestyle	Introduction to health and weight
2	Introduction to individualised energy deficit diet and the importance of physical activity	Planning meals
3	Principles of healthy eating and improving physical activity levels Introduction to physical activity diaries and pedometer	Food labelling and fats
4	Healthy ways to cook, meal planning and shopping lists Emotions and overeating	Food labelling salt and sugar
5	Disadvantages of eating out and take-aways Using behaviour change to alter 'bad habits'	Shopping, budgeting, snacks, eating out and take-aways
6	Coping with cravings and evaluating knowledge of physical activity	Alcohol and other drinks
7	Diet myths and introduction to new ways to motivate participation in physical activity	Benefits of exercise
8	Relapse prevention	Review
9	Evaluate success up to now	What have we learned

on diet and physical activity and incorporate behavioural change techniques (Table 2).

Diet

Phase 1—weight loss

To achieve a healthy sustainable weight loss of 0.5–1.0 kg per week, a daily EDD of 600 kcal is recommended [11,12]. Each individual's daily energy deficit will be calculated based on the estimate of their total energy expenditure –2,510 kJ (600 kcal). Basal metabolic rate (BMR) will be calculated with gender, age, height and weight using the Mifflin St Jeor equation [27]. Total energy expenditure is estimated from BMR multiplied by a physical activity level of 1.3 [28].

The EDD provides daily caloric intake from a specified number of daily portions from the five food groups in the *Eatwell* plate: starchy foods such as bread, rice, potatoes and pasta; meat/fish and alternatives; fruit and vegetables; milk and dairy products; foods high in sugar and fat [29]. The EDD also gives specific advice on portion sizes and alternatives to energy dense food stuffs.

Table 3 TAKE 5 key themes underpinning weight maintenance sessions

Session	Theme
1	Weight maintenance and new individualised maintenance dietary plan
2	Importance of being active and adopting regular eating patterns
3	Regular self-monitoring of weight and food intakes
4	Overview of barriers to healthy eating and physical activity
5	Snacking, lapses, eating out/social activities
6	Healthy menu plan and review of principles of weight maintenance

Phase 2—weight maintenance

In the weight maintenance phase, dietary intake will continue to be based on the principles of portions from the five food groups from the *Eatwell* plate [29]. However, this will not incorporate a daily EDD approach to include a deduction of 600 kcal. Instead, each individual's energy requirements will be calculated to maintain energy balance.

Physical activity

Phase 1—weight loss

Results from the single-stranded feasibility study of TAKE 5 reported that individuals with intellectual disabilities and obesity have very sedentary lifestyles and have low levels of physical activity spending an average of 13.1 (SD 16.2) min per day in moderate-to-vigorous-intensity physical activity [15]. The majority of physical activity recommendations advocate 30 min of moderate-to-vigorous physical activity on most days of the week [30,31]. This may be unrealistic and unattainable for some individuals with intellectual disabilities. Therefore, consensus guidelines on physical interventions for beginners [32] will be adhered to, initially aiming to support participants to progressively increase regular participation in physical activity and reduce time spent being sedentary.

In each session, physical activity goals will be negotiated and set based on the individual's current level of physical activity, physical ability and individual's expressed preference, with the overall aim to gradually work towards current physical activity recommendations advocated for all adults.

Participants will be encouraged to reduce the time spent sedentary, i.e. watching TV, by accumulating bouts of physical activity over the course of the day. Current activity across three types of physical activity will be reviewed with each participant and carer:

- Activity at home as a replacement for sedentary behaviour, e.g. housework and gardening
- Walking—based on baseline average steps per day, individuals will be encouraged to set targets to progressively increase walking behaviour and use pedometers to monitor step counts
- Sport and exercise—information will be given to each participant on local leisure facilities and clubs with disability accessible sports and exercise groups/classes.

Phase 2—weight maintenance

The importance of physical activity will be highlighted in the maintenance phase as it plays an important role in sustaining any reductions in body weight [12,13]. Individuals will be encouraged to build on the levels of physical activity they achieved in phase 1 and continue to aim to meet clinical recommendations.

Behaviour change techniques

Phase 1—weight loss

It is recommended that behaviour change techniques are incorporated into weight management interventions to support and maintain changes in attitudes and behaviour in relation to healthy lifestyle patterns such as healthy eating, increased physical activity and a decrease in sedentary behaviour [12,13]. The techniques incorporated into the TAKE 5 intervention are based on the recommendation of clinical guidelines and will include self-monitoring, goal setting, management of eating behaviours, relapse prevention, stimulus control, cue avoidance, reinforcement and social assertion [15,18]. There are recognised challenges to supporting behaviour change in adults with intellectual disabilities. Therefore, TAKE 5 uses support from family or paid carers to provide encouragement and motivation for behaviour change and the behavioural methods above flexibly in keeping with the needs and ability of levels of participants [33].

Goal setting and dietary self-monitoring are key aspects of behaviour change [13]. Short-term goals incorporating dietary change and physical activity will be set by participants at the end of each session and reviewed subsequently. Participants and carers will be provided with daily diaries to facilitate monitoring of dietary intakes and level of participation in physical activity. These will be reviewed at each session and used to monitor progress towards goals, identify potential barriers to change and discuss means to achieve goals. This information is used as part of the intervention and will not be used as a source of data for formal statistical analyses. When an individual's level of abilities allows additional behavioural change, techniques will be included within the TAKE 5 intervention, such as problem solving and assertiveness.

Phase 2—weight maintenance

To maintain a healthy body weight, behavioural strategies used in the weight loss phase will continue to be used flexibly. Specific approaches, such as problem solving and lapse and relapse prevention, are particularly relevant to discuss and use during maintenance sessions. Participants will be encouraged with support from carers where appropriate to maintain the healthy lifestyle habits from phase 1. Furthermore, they will be encouraged to regularly self-monitor their body weight, food intake and habitual physical activity. Goal setting will be used at the end of each session (Table 3).

Control intervention (WWT00)

WWT00 is a health education intervention developed by a partnership group consisting of NHS dietitians, intellectual disability nurses, health improvement specialists and representatives from Glasgow Life, responsible for delivering community leisure facilities. WWT00 was adapted from a mainstream Waistwinners programme into an accessible format for adults with intellectual disabilities. The Waistwinners programme aims to increase knowledge and skills to improve behaviour related lifestyle habits such as healthy eating, weight management and physical activity. The programme is a group-based intervention delivered over eight weekly sessions.

For the purpose of this research study, the delivery of the WWT00 intervention has been modified to an intervention delivered on a one-to-one basis. Participants in this control intervention will receive the same number of face-to-face sessions as participants in the TAKE 5 intervention. To retain participants to the study for the same duration as TAKE 5, a weight maintenance phase to WWT00 was developed.

WWT00 intervention components

Phase 1—weight loss

Diet Dietary change will be based on non-quantitative advice based on the food groups from the *Eatwell* plate [29]. Participants will not be given quantitative dietary advice but will be provided with knowledge about healthy and unhealthy food groups to assist them to make an informed decision on optimal food choice.

Physical activity

The physical activity component will follow the same guidelines set out for the participants in the TAKE 5 intervention. However, participants will not be encouraged to self-monitor or increase their daily step counts using a pedometer.

Behaviour change techniques

The behaviour change technique goal setting and self-monitoring will be incorporated into the intervention

purely with respect to dietary targets and physical activity. Participants will be invited to set a general dietary or a physical activity goal for each session and to self-monitor their food intake and physical activity.

Phase 2—weight maintenance

At each session, the dietitian will weigh the participant and discuss their weight in the context of sustaining any weight change. The opportunity for participants or carers to ask any questions relevant to diet and physical activity will be available at every session.

Outcome measures

A researcher (LH) who is blind to study group allocation is responsible for collecting all outcome measures. Demographic, health questionnaires and all other outcome measures will be completed at baseline, at 6 months and at 12 months.

Primary outcome

The primary outcome measure will be the mean difference in body weight (kilograms (kg)) at 12 months from baseline between the two treatment groups.

Secondary outcome

Secondary outcomes include weight loss of 5% or more of initial body weight, change in BMI, waist circumference and percentage body fat. Mean percentage time per day spent engaged in moderate-vigorous intensity physical activity, light intensity physical activity and engagement in sedentary behaviour.

Anthropometric outcomes

Participants will be invited to have their weight, height, waist circumference and triceps skinfold thickness measured. Measurements will be made with the participant wearing light clothes without shoes. All measurements will be made in duplicate and the final value calculated as the mean of the two measurements. Weight in kilograms will be measured to the nearest 100 grams (g), using SECA877 scales (SE approval class III; SEA Germany). Height in metres (m) will be measured to the nearest 1 mm using the SECA Leicester stadiometer (SECA, Germany). The height (m) and weight (kg) will be used to calculate BMI using the formula $BMI = \text{weight}/\text{height}^2$ (kg/m^2).

Waist circumference will be measured to the nearest 0.5 cm at the midpoint between the iliac crest and the lowest rib, in full expiration whilst the participant is standing [34].

Due to the invasive nature of skinfold measurements and the issue of level of compliance of adults with intellectual disabilities, percentage body fat will be calculated using only the triceps skinfold thickness (mm) measured to the nearest 1 mm, waist circumference (cm) and age

(years) of the participant. Separate regression equations for male and female participants, developed by Lean et al. [35] will be used to predict body density and percentage body fat.

Physical activity outcome

To objectively measure physical activity, all participants will be invited to wear accelerometers for 7 days on three occasions, at baseline, 6 and 12 months. Accelerometers have been used in studies involving adults with intellectual disabilities and shown to be well utilised by this group and to be a reliable and effective measure of levels of physical activity [36,37].

Actigraph GT3X+ accelerometers (Manufacturing Technology Inc., Florida) will be worn at the hip, attached to a belt worn round the waist. Participants will be invited to wear the actigraph GT3X+ over a 7-day period. Instructions will be given to wear the actigraph during all waking hours, except when showering, bathing or swimming.

In keeping with guidelines on the validity of accelerometer data, the minimum data requirement will be set at 6 h of data, on at least 3 days from seven [38]. If this requirement is not met, the accelerometer data will be discarded and not be included in the analysis. The number of participants who fail to record sufficient records of physical activity will be recorded. The accelerometers will be set to record activity over 15-s intervals (epochs), with activity counts of four consecutive epochs summed to give activity counts per minute (cpm). Based on recommendations from previous studies [39], four categories of activity intensity will be defined:

- Sedentary behaviour 0–499 cpm.
- Light intensity activity 500–1,951 cpm.
- Moderate intensity activity 1,952–5,724 cpm.
- Vigorous intensity activity greater than 5,725 cpm.

The accelerometer data will then be used to calculate the mean time (minutes) and the percentage time per day, spent in each level of activity.

In addition, physical activity levels will also be measured subjectively by administering the International Physical Activity Questionnaire-Short (IPAQ-S). This will provide information about the types of physical activity they participated in.

Health-related quality of life

To allow comparison with weight loss studies that do not include adults with intellectual disabilities as participants, the EQ-5D [40] will be used to measure health-related quality of life. The EQ-5D has been shown to be reliable, valid and sensitive to change in adults with obesity [41].

Completion of generic measures, like the EQ-5D, can be difficult for adults with intellectual disabilities because of the levels of communication and abstraction required. The EQ-5D has been used as a proxy-measure of health-related quality of life in studies involving adults with cognitive impairments due to dementia [42,43] and stroke [44]. In this study, carers will be asked to complete the EQ-5D as a rating of the carer views of the five domains in the EQ-5D, rather than as proxy-rating. Individuals with mild intellectual disabilities will also be asked to complete the EQ-5D and the level of agreement with carer ratings examined. The wording from the youth version of the EQ-5D will be used as it is aimed at young people aged 7 years and older and is appropriate to the of verbal comprehension of adults with mild/moderate intellectual disabilities.

Process measures

An in-depth process evaluation of the interventions will be conducted as a separate study on completion of the study. Process measures will be collected as part of the treatment protocol, as the research dietitian will also complete written clinical notes at the end of each intervention session, noting the success of components of the interventions, and ways they adapted the approach (in accordance with the manual) to individual need and circumstances. The research dietitian will also collect routine data on the number of sessions attended, participants' body weight and information about the participants' dietary habits, physical activity and their success in using the behaviour change techniques. Analysis of process evaluation data will provide insight into multiple aspects of the interventions and will capture experiences gained with delivering the interventions and the fidelity of the interventions which will be used to help inform the development of a full-scale clinical trial.

Data analysis

The main analysis of the pilot study will include descriptive statistics of feasibility outcomes, including recruitment rates and the acceptability of randomisation (recorded from attrition rates). This analysis will help inform the development of a full-scale trial. Additional analysis of patient-centred outcomes will be carried out according to a detailed pre-specified statistical analysis plan. The primary efficacy analysis, change in body weight at the end of the intervention period (\approx 12 months) from baseline will use a linear regression (random effects) model to take into account clustering and will be adjusted for randomised group, baseline weight and variables used in the minimisation algorithm (level of intellectual disabilities and presence of Down Syndrome). Similar linear regression models will be fitted for each continuous secondary outcome measure. A logistic regression model

will be fitted for the categorical outcome, weight loss of 5% or more of initial body weight taking account of clustering and baseline adjustments listed above. Further analyses may assess the effects of baseline characteristics on outcomes and investigate the evidence for interactions with treatment effects using regression models.

Analyses will be conducted according to the intention to treat (ITT) principle. Per-protocol analyses, including only those participants who engaged with the programme, will also be used to test the sensitivity of the ITT results. Analyses will initially be performed using only those individuals for whom outcome data are available. Participants, who are lost to follow-up, will be assessed to see if they were different at baseline to those included in these analyses. As this is a pilot trial, the level of missing data will be recorded, but no value imputation for outcome variables will be conducted.

Discussion

The increase prevalence of obesity and health inequalities in adults with intellectual disabilities is further accentuated by the limited access to evidence-based health care in meeting the equality legislation and addressing the health needs of this population group [45]. The need for research on the management of obesity for adults with intellectual disabilities has been emphasised as a priority for research and an important step towards addressing this issue [12,13].

This pilot study will examine the feasibility of conducting a full-scale trial. The trial will help provide valuable insight into the feasibility of key issues such as the acceptability of randomisation and the fidelity of the intervention delivery.

Both arms of this trial are active interventions designed to support adults to make healthier lifestyle choices, with particularly focussed on supporting weight loss. This study will compare the two dietary strategies, an individualised EDD with quantitative dietary advice against a health education approach without quantitative dietary advice. Both interventions include support to increase physical activity and incorporate behaviour change techniques. Thus, comparing the two interventions will allow the identification of the essential and any superfluous components of the intervention which will be used to inform the optimal management approach to take forward in designing a full-scale clinical trial to address the obesity epidemic in adults with intellectual disabilities.

This study will make important contributions to the available evidence in this field, by piloting an intervention that fully satisfies UK clinical obesity guidelines on weight management. In a recent review of weight management interventions for adults with intellectual disabilities and obesity, it was reported that there are relatively few published studies and that the evidence available is subject to

methodological limitations including recruiting small samples sizes with inadequate statistical power, and with only a few studies implementing a randomised controlled design [11]. None of the interventions met current recommendations from UK clinical guidelines on the use of multi-component interventions with an EDD for weight loss [12,13]. Studies instead include combinations of a component relevant to supporting individuals to increase levels of physical activity, a dietary advice/health education components or a component with a focus on behavioural change. Furthermore, only a few studies were able to demonstrate a clinically significant weight loss of 5%–10% of initial body weight and met the recommended minimum follow-up period of 12 months to examine the effectiveness of a weight loss intervention.

Current guidelines on weight management interventions recommend weight maintenance as an integral component, illustrating that individuals who have lost a clinically significant weight loss and are able to maintain this weight have made substantial lifestyle changes that will prevent future weight gain or health risks [12,13]. However, research for weight management in the general population and adults with intellectual disabilities has mainly focused on the development and evaluation of weight loss strategies and has not examined extensively the effectiveness of weight maintenance interventions that immediately follow a weight loss phase [46]. Only four studies involving participants with intellectual disabilities offered a structured weight loss maintenance intervention [24,25,47,48]. Of these, only one study, reported the long-term effects of a 6-month weight maintenance intervention [45], illustrating that after 6 months, most adults with intellectual disabilities were able to sustain the clinically significant weight lost in phase 1 or continue further to lose weight. This study will therefore add to the evidence base by piloting a structured weight maintenance phase.

The controlled design is a key strength of this study, as it is considered the optimal design to evaluate complex interventions [49] and will add to the limited evidence of controlled studies of weight management interventions of adults with intellectual disabilities and obesity. There is limited evidence on which to base a best alternative control intervention. An 'active' control intervention is selected for this study over a non-intervention control; as in addition to the ethical issues discussed previously, the research group believes that this design would threaten the validity of the study by not taking into consideration the specific treatment effects of the intervention. In addition, it is believed that offering participants no intervention would have a negative effect on study recruitment and retention of participants. Receiving information on the importance of weight management may influence participants receiving a non-intervention control to change their behaviour

and seek out other resources available in order to make healthier lifestyle choices. This could potentially cause individuals to drop out from the study and/or make it difficult to follow individuals up when offering them no intervention. The findings of this study will provide clear direction on this key issue and guide future experimental designs.

It is recognised that specific challenges are likely to arise when conducting research with adults with intellectual disabilities due to their cognitive and communication needs. In particular, it is noted that recruitment of adults with intellectual disabilities to research studies is challenging and is evident from the small sample sizes reported in previous research [11]. A review by Cleaver et al. [50] reported that ethical procedures which are consistent with this study such as the inability to contact potential participants directly and the procedures of taking consent may lead to poor participation in studies involving adults with intellectual disabilities. This study will assess the feasibility of recruiting and retaining adults with intellectual disabilities to a randomised design of a weight management intervention using a multi-point recruitment strategy which will collect information from recruitment sites such as organisations and services for adults with intellectual disabilities. This will be used to identify potential barriers and facilitators to recruitment which will help inform other controlled trials of weight management interventions and also be influential in informing the development a full-scale multi-centre clinical trial.

Conclusion

There is limited access to evidence-based health care for adults with intellectual disabilities. Currently, no published controlled studies of weight management interventions for adults with intellectual disabilities meet clinical obesity recommendations. This pilot randomised trial will examine the acceptability of randomisation and attrition rates and provide pilot data on the estimates of patient-centred outcomes of TAKE 5 compared to the health education control intervention. If this study design is acceptable to adults with intellectual disabilities and shows a significant effect on outcome measures, this protocol can serve as a framework or model on which development of a full-scale clinical trial can be based.

Trial status

Recruitment commenced in February 2014 and is projected to be complete by November 2014.

Abbreviations

BMR: Basal metabolic rate; BMI: Body mass index; cpm: Counts per minute; EDD: Energy deficit diet; FSA: Food Standards Agency; GCWMS: Glasgow & Clyde Weight Management Service; ITT: Intention to treat; IVRS: Interactive voice response system; IPAQ-S: International Physical Activity Questionnaire-Short version; NHS: National Health Service; MRC: Medical Research Council;

WWToo: Waist Winners Too; PARQ: Physical Activity Readiness Questionnaire; TAU: Treatment as usual.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

LH, CM and CH led the drafting and editing of the manuscript. NJ is the research dietitian on the study. CP, SB and HM were all involved in the original application and the design in the study. JT and FG developed the WWToo programme. All authors read and approved the final manuscript.

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Review

The effects of physical activity interventions on preventing weight gain and the effects on body composition in young adults with intellectual disabilities: systematic review and meta-analysis of randomized controlled trials

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Summary

The aim of this study was to examine the literature on randomized controlled trials examining the efficacy of physical activity interventions to prevent weight gain and the effects on body composition in young adults with intellectual disabilities. A systematic search of Medline, Embase, CINAHL, PsychINFO, Cochrane library and ERIC was conducted from 1946 to September 2014. Eligibility criteria included; randomized controlled trials of a physical activity intervention: objective measure of body weight and body composition; young adults (age range 16–24 years) with intellectual disabilities. Six studies met the eligibility criteria. The interventions varied in their prescription of physical activity including aerobic and strength-based activities. The mean duration of the interventions was 15.3 (range 10–21 weeks). There was no significant effect of physical activity interventions on body weight (weighted mean difference: -0.17 kg, 95% confidence interval, -1.04 kg to 0.72 kg) and body composition outcomes. The meta-analysis showed that physical activity interventions did not prevent weight gain in young adults with intellectual disabilities. Published studies are inadequate to form firm conclusions. Future longer term studies of interventions specifically designed for this population group are required to elucidate the effects of physical activity interventions on body composition and the prevention of weight gain in young adults with intellectual disabilities.

Keywords: Intellectual disabilities, physical activity, meta-analysis, weight gain.

Introduction

The prevention of obesity is a major public health priority internationally (1). There is clear evidence of the negative impact of excess body weight on health, increasing the risk of chronic diseases such as cardiovascular disease (2), some cancers (3) and type II diabetes (4). The transition from

adolescence to young adulthood is recognized as a particularly high-risk period for weight gain (5). This period is associated with unhealthy lifestyle characteristics such as a decline in diet quality and decreased physical activity levels (6). This is of concern as once adoption of these unhealthy lifestyle patterns and obesity is established, it is shown to continue into adulthood and increase early mortality (7).

Young adults with intellectual disabilities, defined as significant limitations both in intellectual functioning and in adaptive behaviour (including everyday social and practical skills), with onset before the age of 18 years (8), have continuously been reported to have high rates of overweight and obesity (9–11), be less physically active and adopt more sedentary lifestyles than the general population (12). In a population-based study, the prevalence of obesity in young adults with intellectual disabilities aged 16–24 was reported to be 28.1%, compared with 10.5% in a comparison sample of young adults who did not have intellectual disabilities (odds ratio = 3.37, 95% confidence interval [CI] 2.12, 5.37) (9). The prevention of unhealthy weight gain and obesity is therefore a priority for health care and particularly important for young adults with intellectual disabilities (13).

Physical activity is considered an important strategy to prevent weight gain because of its pivotal role in energy balance and the regulation of body weight, through increased energy expenditure (14–16), improved appetite control and reduced energy intake (17,18). However, despite the negative impact of obesity on health, there is a limited evidence base to inform the management of obesity in individuals with intellectual disabilities (19). The available evidence on physical activity research in individuals with intellectual disabilities has primarily focussed on addressing cardiorespiratory fitness (12,20,21). The effects of physical activity interventions on body weight and composition have been recently reviewed; however, these studies included heterogeneous populations including studies involving children adolescents and adults and studies with varying methodological design (22,23).

In order to provide an evidence base of the effects of physical activity interventions and provide insight into the development of future studies within the field, it is important that reviews are based on quality randomized controlled trials which aim to eliminate bias and provide an accurate estimate of the intervention effect (24). The main aim of this review is to systematically assess the literature on randomized controlled trials on the effects of physical activity interventions to prevent weight gain in young adults with intellectual disabilities. Specific objectives also include the evaluation of the effect of physical activity interventions on body composition outcomes (body mass index [BMI], waist circumference, percentage body fat, fat mass and lean mass) in young adults with intellectual disabilities.

Methods

This study was conducted in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (25).

Search strategy

A literature search of the following six electronic databases was conducted from the inception (1946) to and including September 2014: Medline, Embase, CINAHL, PsychINFO, Cochrane library and ERIC. Key words included intellectual disabilities, mental retardation, physical activity, obesity, body weight changes. For the full Medline search strategy, which was adapted for other databases, please see Appendix A. The literature search also included hand searching of reference lists of retrieved studies, key journals and systematic reviews.

Eligibility criteria

The study selections for this review were assessed as eligible by the following inclusion criteria:

- Participants diagnosed with intellectual disabilities;
- Physical activity as a single component intervention;
- Randomized controlled trial study design;
- Included young adults across the age range 16–24 years;
- Studies had to report a specific objective measure of body weight and could include measures of body composition (i.e. BMI, waist circumference, percentage body fat at baseline and follow-up).

Studies not published in English-language journals were not included for consideration in this review.

Study selection

The first author performed the literature search and removed the duplicates. The titles and abstracts were screened and potentially relevant studies were identified. Articles were obtained in full text and were assessed by all reviewers for inclusion. Consensus on included studies was agreed and the final list of studies included in this review.

Data extraction

Relevant data from studies was extracted by one reviewer (LH) for assessment of methodology quality and data synthesis. Study details included

- Author, title, year of publication
- Participants' characteristics
- Research question
- Intervention (i.e. mode of physical activity, frequency, intensity and duration)
- Outcome measures (anthropometric outcomes, i.e. body weight, BMI, waist circumference, percentage body fat, fat mass and lean mass)

- Results (pre-post means \pm standard deviation [SD] for each outcome measure).

Rating of methodology quality

Assessment of methodological quality of included studies was performed using the Physiotherapy Evidence Database (PEDro) scale (26,27). The PEDro scale was developed to assist clinical decision making by identifying studies that are more likely to be valid (26). The PEDro Scale consists of an 11-item checklist designed to score the quality of randomized controlled trials. The first item is a measure of a study's external validity. This is not included in the final calculation of the PEDro score of the study. Internal validity is determined by the remaining 10 items. These items are rated as either a yes or no score. The total 'yes' score out of 10 determines the overall PEDro score of that study. The individual items rated for each study were as follows (i) specified eligibility criteria; (ii) random allocation of participants; (iii) concealment of participant allocation; (iv) baseline similarity between groups; (v) blinding of all participants; (vi) blinding of all therapists administering the intervention; (vii) blinding of all assessors who measured at least one key outcome; (viii) measurement of at least one key outcome being obtained by more than 85% of the participants; (ix) following up on intention to treat analysis; (x) reporting of results of between group statistical comparisons for at least one key outcome and (xi) providing both point measures and measures of variability for at least one key outcome. The papers were rated independently by two authors (LH, CM) who then compared ratings and discussed any discrepancies with the second author (CH) to come to a consensus and final score.

Data synthesis and analysis

The effect size for each outcome was calculated as the difference in the mean change in the outcome (e.g. body weight) in the intervention group minus the mean change in the outcome in the control group (28). All main authors on the primary studies were contacted. Two studies provided their raw data on individual participants for all relevant outcomes (29,30). Their data were used to calculate a correlation coefficient from the variance of pre- and post-intervention data and the variance of the mean change in outcome variable. In studies which included more than one treatment group, groups were combined (sample size, mean and standard deviation from both groups to form a single group) to create a single pair-wise comparison, and to prevent multi-comparisons and a unit-of-analysis error. Sensitivity analysis was performed varying the correlation coefficient from 0.5 to 0.98 to examine the validity of the results. The study findings for each outcome were pooled using the random effects model (31). Statistical heterogeneity for each outcome was assessed by Cochrane's Q

statistic, with $P < 0.05$ indicating evidence of statistical heterogeneity. The degree of heterogeneity was measured by the I^2 statistic, with $I^2 \geq 50\%$ indicating substantial heterogeneity (32). Meta-analysis was performed using Comprehensive Meta-Analysis (Version 2.0 for Windows: Biostat, Englewood, Colorado, USA).

Results

Literature search

Figure 1 illustrated the results of the search strategy and process of study selection. A total of 2371 studies were initially identified, 587 duplicated were removed and 1770 articles excluded on reviewing the title and abstract as they were obviously irrelevant, i.e. did not study participants with intellectual disabilities, did not implement a physical activity intervention. Of the remaining full text articles ($n = 14$), six met the inclusion criteria and are presented in this review.

Study characteristics

A summary of study characteristics of included studies are presented in Table 1. All the included studies were published after the year 2000. Three studies were conducted in Spain (29,30,35), two studies in Belgium (33,34), and one in Portugal (36). A total of 178 participants were recruited across the six studies, with a mean total sample size of 30 (range 16–54) participants. Participants' ages ranged from 10 to 30 years and were classified as normal weight to overweight and obese across studies. Participants were diagnosed with mild to moderate level of intellectual disabilities. Four studies included participants with Down syndrome only (29,30,35,36). Two studies did not exclude individuals with Down syndrome, but none of the participants in the study were diagnosed with Down syndrome (33,34).

Methodological quality

Table 1 illustrates the PEDro scores for the studies included in this review ($n = 6$). Five studies were considered to have high methodology quality (a score of six or above) and one study was considered to have fair methodology quality. Only two studies provided the eligibility criteria of the participants (30,36). Allocation concealment method and blinding of subjects and therapists who delivered the intervention were not fulfilled in any study. All studies provided information on following up with intention to treat, between group comparisons and point estimates and variability. In addition to the criteria assessed by the PEDro scale, none of the studies reported a sample size calculation and consisted of small samples which may affect the power of the analysis.

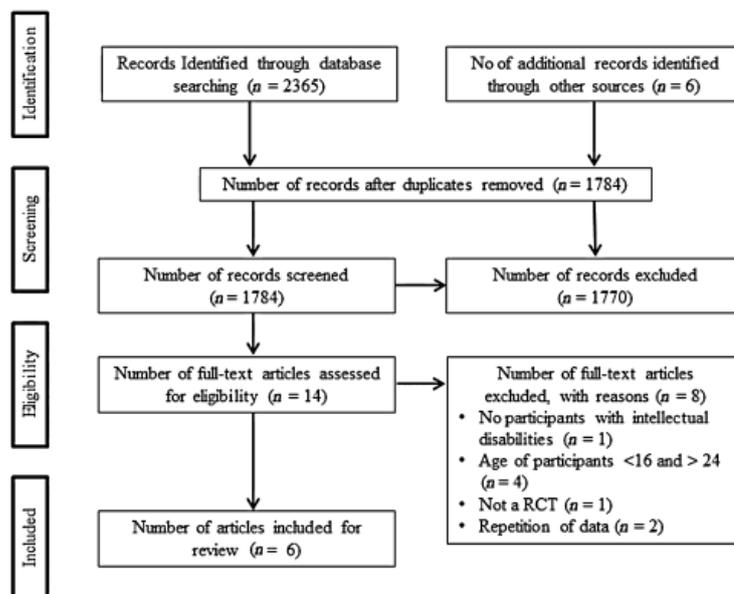


Figure 1 Study selection process.

Physical activity interventions

Seven types of interventions were prescribed in the included studies, including a bicycle ergometer intervention and an aerobic training program (33); strength and endurance training intervention (34); conditioning and plyometric jumps training (29); whole body vibration, which included isometric exercise (30); an aerobic treadmill ergometer intervention (35) and an aerobic rowing ergometer intervention (36). The mean duration of intervention programs was 15.3 weeks (range 10–21 weeks). The frequency of physical activity sessions was two to three sessions per week for a duration range of 5–65 min across studies. The aerobic training component of the interventions was predominately performed at moderate to vigorous intensities (55–75% heart rate reserve or peak heart rate). Strength/conditioning based exercise was performed only in two studies. The intensity varied between individuals based on a participant's capacity (29), to a set intensity of 60–80% of 1RM for three sets of 10 repetitions (34).

Effects of physical activity interventions

The effect sizes and weighted mean difference (WMD) are presented in Table 2. The random effects model was used to estimate the effect size for all outcomes of body weight and body composition.

Body weight

All studies assessed the effect of physical activity on body weight. Five studies were included in the meta-analysis. In

these studies, physical activity interventions had no effect on body weight (WMD -0.17 kg, 95% CI -1.04 kg to 0.72 kg; $P = 0.71$), in comparison with the control group (Fig. 2). There was no statistical heterogeneity in body weight ($I^2 = 24.19\%$).

Sensitivity analysis

Estimates of the effect sizes were calculated using an estimated correlation coefficient for each outcome. Varying the correlation coefficient from 0.5 to 0.98 (correlation coefficient used for the estimate for body weight) did not result in any statistical difference ($P = 0.36$) between the summary effect (WMD -0.19 kg; 95% CI -4.26 to 03.89) to (WMD -0.17 kg, 95% CI -1.04 kg to 0.72 kg), respectively. This was repeated for all outcomes, with no significant change in the estimate of the weighted effect size ($P > 0.05$).

BMI

Four studies investigated BMI as an outcome. The pooled effect size illustrated that physical activity had no effect on BMI (-0.07 kg m^{-2} , 95% CI -0.64 kg m^{-2} to 0.51 kg m^{-2} ; $P = 0.82$) in comparison with the control group. This results is statistically heterogeneous ($I^2 = 75.05\%$).

Body composition outcomes

Measures of body composition reported in the included studies were waist circumference, percentage body fat, fat

Table 1 Summary of randomised controlled trials of physical activity interventions

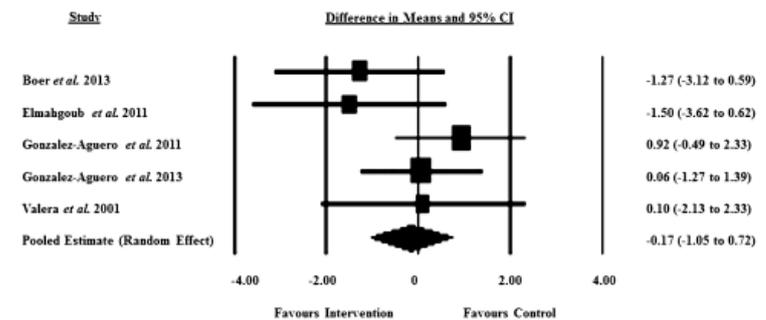
Reference	Study population	Intervention	Anthropometric outcomes	Quality rating (PEDro scale)	
Boer <i>et al.</i> (33)	<i>N</i> = 54 adolescent and young adults BMI: 27.7 ± 3.7 kg m ⁻² Age: 17 ± 3.0 years ID: IQ 59 ± 8.6	SIT: <i>N</i> = 17 Mode: Cycle ergometer Intensity: Weeks 1–7: Sprint bouts (>100 r per min) of 15 s at a resistance matching the ventilatory threshold (VT _R), 45 s relative rest (50 r per min at VT _R) Weeks 8–15: Sprint bouts and relative rest increased up to 110% of VT _R . Duration: 40 min Frequency: Two times a week, 15 weeks CAT: <i>N</i> = 15 Mode: Aerobic exercises (cycling/walking/stepping) Intensity: Weeks 1–7: HR similar to HR at VT (60 r per min) Weeks 8–15: Increased to HR at 110% of VT. Duration: 40 min Frequency: Two times a week, 15 weeks	Control: <i>N</i> = 15 Participated in usual everyday scholar activities without supervised exercise training.	Mean change in: Weight BMI WC %BF	7
Elmahgoub <i>et al.</i> (34)	<i>N</i> = 45 adolescents, Age: 14–22 years BMI: 23–48 kg m ⁻² ID: IQ 45–70	CET3: <i>N</i> = 15 Mode: Strength and endurance exercises (bicycles and cross trainers) Intensity: Endurance – 60% – 75% HRR Strength – 60% – 80% 1 RM Duration: 50 min Frequency: Three times a week, 10 weeks CET2: <i>N</i> = 15 Mode: strength and endurance exercises (bicycles and cross trainers) Intensity: Endurance – 60% – 75% HRR Strength – 60% – 80% 1 RM Duration: 50 min Frequency: Two times a week, 15 weeks	Control: <i>N</i> = 15 Participated in the daily school activities, including physical education lessons	Mean change in: Weight BMI WC Fat mass Fat-free mass	6
Gonzalez-Aguero <i>et al.</i> (29)	<i>N</i> = 26 children and adolescents Age: 10–19 years ID: Down syndrome	<i>N</i> = 13 Mode: Conditioning and plyometric jumps training Intensity: Based in individual capacity Duration: 20–25 min Frequency: Two times a week, 21 weeks	<i>N</i> = 15 Control: No training	Mean change in: Weight BMI %BF Fat mass Fat-free mass	6
Gonzalez-Aguero <i>et al.</i> (30)	<i>N</i> = 30 adolescents Age: 12–18 years ID: Down syndrome	<i>N</i> = 13 Mode: Isometric exercises (squat position) Intensity: Duration: 15–20 min Frequency: Three times a week, 20 weeks	<i>N</i> = 11 Control: No training	Mean change in: Weight BMI Fat mass Fat-free mass	5
Ordóñez <i>et al.</i> (35)	<i>N</i> = 20 women Age: 18–30 years ID: IQ 50–69, Down syndrome	<i>N</i> = 11 Mode: Treadmill ergometer Intensity: 55–65% of peak HR increasing by 2.5% every 2 weeks Duration: 45–65 min Frequency: Three times a week, 10 weeks	<i>N</i> = 9 Control: No training	Mean change in: WC WHR %BF	6
Valera <i>et al.</i> (36)	<i>N</i> = 16 young adults Age: 21.4 ± 3.0 years ID: DS with mild to moderate ID	<i>N</i> = 8 Mode: Rowing ergometer Intensity: 55–70% peak VO ₂ Duration: 25–45 min Frequency: Three times a week, 16 weeks	<i>N</i> = 8 Control: No training	Mean change in: Weight %BF	6

%BF, percentage body fat; 1RM, 1 maximum repetition; BMI, body mass index; CAT, continuous aerobic training; CET2, combined training twice a week; CET3, combined training three times a week; COM, combined training; HR, heart rate; HRR, heart rate reserve; ID, intellectual disabilities; IQ, intelligent quotient; SIT, sprint interval training; VO₂, oxygen consumption; WC, waist circumference.

Table 2 Pooled random effects analysis of effect size (WMD) of outcomes

Outcome	K	WMD	SE	95% CI		Heterogeneity		
				Lower limit	Upper limit	Q	I ²	P-value
Weight (kg)	5	-0.17	0.45	-1.04	0.72	5.28	24.19	0.26
BMI (kg m ⁻²)	4	-0.07	0.29	-0.64	0.51	12.02	75.05	0.01
Waist circumference (cm)	4	-1.14	1.47	-4.03	1.75	15.24	80.32	0.002
Percentage body fat (%)	4	-0.44	0.81	-2.03	1.15	32.40	90.74	0.001
Fat mass (kg)	3	-0.26	0.68	-1.60	1.08	9.48	78.92	0.01
Lean mass (kg)	3	0.77	0.43	-0.08	1.62	5.52	63.79	0.06

CI, confidence interval; I², index of heterogeneity beyond within-study sampling error; K, number of studies; Q, heterogeneity statistic to test homogeneity; SE, standard error; WMD, weighted mean difference.

Figure 2 WMD in body weight (kg) between the intervention groups and the control groups.

mass and lean mass. The overall findings for effects of physical activity interventions were insignificant for all outcomes (Table 2). Substantial heterogeneity was found for outcomes waist circumference, percentage body fat and fat-mass ($I^2 \geq 50$). For forest plots of BMI and all body composition outcomes, see Appendix C.

The difference in mean change in body composition outcomes within-groups (intervention and control) are presented in Table 3. For the purpose of this review, clinically significant weight loss and weight maintenance is defined using the recommendation by Stevens *et al.* (37), as greater than 5% and less than 3% change in body weight, respectively. The participants in the physical activity interventions for all studies maintained their body weight over the intervention period. The participants in the control group also maintained their body weight over the study period.

Discussion

This study reviewed the effects of physical activity interventions on the prevention of weight gain and effects on body composition in young adults with intellectual disabilities. Overall, relatively few published studies were designed to engage young adults in physical activity. None of the studies identified through systematic searching of the available evidence and the studies included in this review were specifically designed to prevent weight gain.

The meta-analysis indicates that physical activity interventions did not significantly change body weight or BMI in young adults with intellectual disabilities. Possible explanations for the limited effects of physical activity interventions could be attributed to the 'dose' of physical activity prescribed in some interventions. The weekly amount of physical activity prescribed in the randomized controlled trials included varied from 80 to 195 min per week. Evidence-based guidelines recommends that physical activity of 150–250 min per week with an energy equivalent of 1200 to 2000 kcal per week is effective to prevent weight gain (38). Only two studies included in this review met current physical activity recommendations (34,35). This is consistent with the available evidence in that adults with intellectual disabilities engage in low levels of physical activity (20,39). The barriers reported for participation in physical activity for individuals with intellectual disabilities include a lack of understanding of the benefits or regular physical activity, a lack of awareness of available physical activity options, financial limitations and limited transport and staffing (40,41). It is important that future studies are developed that take into consideration these barriers and aim to overcome the difficulties for adults with intellectual disabilities in participating in regular physical activity.

In addition, the physical activity interventions were relatively short in duration, average duration of 15.3 (SD 4.0) weeks. This may be typical in exercise science research, as

Table 3 Changes in weight and body composition of included studies

Reference	Exercise mode	Study length (weeks)	Intervention					Control										
			N	ΔWeight (kg)	ΔWeight (%)	ΔBMI (kg m ⁻³)	ΔWC (cm)	Δ%BF (%)	ΔFM (kg)	ΔLM (kg)	N	ΔWeight (kg)	ΔWeight (%)	ΔBMI (kg m ⁻³)	ΔWC (cm)	Δ%BF (%)	ΔFM (kg)	ΔLM (kg)
Boer et al. (33)	SIT	15	17	-0.8	-1.0	-0.7	-4.3*	-3.8*	-	-	14	+0.7	+0.9	0	+0.9	0	-	-
Elmahgoub et al. (34)	CAT	15	15	-0.3	-0.4	-0.6	-2.5*	-1.0*	-	-	15	0	0	-0.4	-1.0	-	-1.0	-1.0
	CET2	10	15	-1.0	-1.3	-0.3	-4.0	-	-	15	0	0	-0.4	-1.0	-	-	-	-
Gonzalez-Aguero et al. (29)	CET3	15	15	-2.0*	-2.4	-1.0*	-4.0*	-	-	15	0	0	-0.4	-1.0	-	-	-	-
	PLY	21	13	+1.7	+4.2	+0.6	+1.2	+0.1	+0.4	13	+0.8	+1.6	-0.2	-0.9	-0.9	-0.3	+0.4	+0.4
Gonzalez-Aguero et al. (30)	WBV	20	11	+0.7	+1.5	+0.1	-0.2	-0.2	0	+0.6	+1.2	0	0	-0.8	-0.6	-0.1	+0.5	
Ordonez et al. (35)	AEROBIC	10	11	-	-	-	-3.2**	-3.9**	-	9	-	-	-	-	-	-	-	
	ROWING	16	8	+0.4	+0.5	-	-	-0.6	-	8	+0.3	-0.5	-	-	-0.1	-	-	

*Significant difference between intervention vs. control. **Significant difference pre-post-intervention. CAT, continuous aerobic training; CET2, combined training twice a week; CET3, combined training three times a week; COM, combined training; PLY, conditioning plus plyometric jump training; SIT, sprint interval training; WBV, whole body vibration training.

approximately 12 weeks duration or less is sufficient for physiological adaptations and improvements in central aspects of fitness such as cardiorespiratory fitness and metabolic health (42). However, this duration is insufficient in terms of altering body weight. It is recommended by clinical guidelines that a 1 year intervention period is necessary to examine weight maintenance and the efficacy of an intervention (43,44). None of the included studies examined long-term follow-up measurements.

Participants in both the treatment and control group were clinically defined as maintaining their body weight (± 3% of initial body weight) for the study period. Therefore, the first research question, do physical activity interventions prevent weight gain in young adults with intellectual disabilities cannot be addressed by the current available evidence because of the limited changes in body weight gain in the control group. However, research in the general population has shown that participants not receiving any intervention will gain weight over time (45,46). This is generally accepted to occur at a rate of 0.5–1 kg per year. Therefore, it can be assumed that changes in increasing body weight reported in young adults with intellectual disabilities in the control groups (not statistically significant) in this short time period are likely to continue if examined over a longer duration. The importance of participating in regular physical activity to maintain body weight should therefore be encouraged as this is associated with a reduction in other health risk factors aside from excess body weight (47,48).

The effects of physical activity interventions on other measures of body composition were inconsistent. Although subgroup analysis was not performed because of the limited number of studies and inadequate quantity of data to calculate the effect size to explore heterogeneity in a meaningful way, these differences in part may be explained by differences in the mode of physical activity. The mode of physical activity investigated across studies, included aerobic-based interventions, combinations of strength and endurance, plyometric and conditioning and isometric exercises. Significant improvements were seen when studies included aerobic-based physical activity in their intervention (33,34). However, these were negated when predominantly resistance-based studies (29,30) were included in the weighted analysis. This is consistent with the available literature that suggests that resistance type physical activity plays a limited role in maintaining body weight (38).

The heterogeneity in results may be further explained by the measurement techniques applied to estimate body composition outcomes. Percentage body fat, fat and lean mass were estimated using bio-electrical impedance analysis (33–35), dual energy X-ray absorptiometry (29,30) and by anthropometric techniques (36). The heterogeneity in results caused by the different methodology used is in agreement with the reviews by Casey & Rasmussen (22),

reporting the effects of physical activity on percentage body fat in individuals with intellectual disabilities, and Maiano and colleagues (49) investigating the effect of lifestyle interventions on body composition in youth with intellectual disabilities.

It was interesting that the majority of studies identified included only participants with Down syndrome. Individuals with Down syndrome have been reported to have suboptimal levels of cardiorespiratory fitness (50), reduced muscle mass and increased adiposity (51) that could affect their participation in physical activity and thus the effectiveness of physical activity interventions (52). However, individuals with Down syndrome make up only a small proportion of young adults with intellectual disabilities. Many young adults with intellectual disabilities who do not have Down syndrome experience high rates of obesity and low levels of physical activity. Therefore, physical activity researchers need to have a broader interest in the health and well-being of all young adults with intellectual disabilities.

This review is primarily focussed on the effects of physical activity interventions on body weight and composition; however, it is important to note that the included studies reported improvements in central aspects of fitness such as cardiorespiratory fitness and metabolic health (33–35). This is particularly pertinent to young adults with intellectual disabilities who have reported to have lower levels of cardiorespiratory fitness (53,54) and increased health needs in comparison to the general population (55).

Strengths and limitations

To our knowledge, this is the first review to address a strategy for weight gain prevention research in individuals with intellectual disabilities. A key strength of this review is the inclusion of randomized control trials only. Observational studies of physical activity are often affected by methodological issues. These comprise measurement errors of physical activity, unmeasurable confounding factors and reverse causality. Furthermore, this meta-analysis adds to the available evidence on the efficacy of physical activity interventions on body composition by providing a more reliable estimate of the effect size of physical activity interventions than existing narrative reviews.

This review is limited in that articles not published in English were not included, therefore potentially excluding studies fulfilling the eligibility criteria. The heterogeneity of the sample population in age range limits the generalizability of results specific to young adults aged 16–24. None of the studies specifically targeted young adults, instead including a wide range from children to older adults. This makes it difficult to draw conclusions specifically for this target population, as children included around the ages nine and 11 years of age (girls and boys,

respectively) will be going through the pubertal growth spurt and subject to changes in body composition aside from any effects from physical activity. Furthermore, interventions targeted at this age group such as school-based physical activity interventions may not be appropriate to young adults who are experiencing a change in their lifestyle including environmental and social settings. In addition, it is unlikely that interventions developed for older adults will be transferable to young adults with intellectual disabilities.

Sample heterogeneity of the included studies also extends to the weight status of the participants. Studies included participants classified clinically as normal weight, overweight and obese. It is therefore difficult to compare studies as obese individuals may require a distinct approach in the prescription of physical activity. Obese individuals are likely to have lower levels of physical fitness and require an alternative strategy to tackle unhealthy weight gain, through a treatment approach in the reduction of body weight. A combination of physical activity plus a dietary intervention may need to be considered to help them lose weight as the role of physical activity on its own for weight loss in individuals with intellectual disabilities, as for other adults from the general population, is only modest (19).

Implications for future research

Because of the high rates of overweight and obesity and the low levels of physical activity observed in young adults with intellectual disabilities, there is a need for research to examine whether interventions can support young adults to be more active and maintain a healthy body weight. The studies presented in this review are structured physical activity interventions, which consist of a repetitive set format, which is heavily dependent on trained experts to supervise and deliver the intervention. Because of the barriers discussed previously, long-term adherence to such interventions is generally considered not to be sustainable in everyday life for individuals with intellectual disabilities. For example, Cluphf *et al.* (56) reported following their aerobic-based interventions (6 weeks duration), participants did not continue to participate in regular physical activity. An alternative format of physical activity is lifestyle physical activity, which can include all activities an individual can perform during the course of a day, with accumulating effects on increased energy expenditure (42). Research has shown that higher levels of lifestyle physical activity can prevent initial weight gain (42). Thus, considering the reported barriers to participation in regular physical activity and the poor attrition rates reported in some studies (29), this should be considered as an alternative approach to meet the needs of adults with intellectual disabilities and engage them in regular physical activity participation.

Conclusion

This review has illustrated the lack of evidence of physical activity interventions specifically designed for young adults with intellectual disabilities. The meta-analysis found that physical activity interventions in young adults with intellectual disabilities did not prevent weight gain or improve body composition. This is due to limitations of the published studies, implementing inadequate duration and dose of the interventions. Although there was no significant effect of physical activity on body weight, physical activity interventions improved health risk factors, which is important for this population group to prevent health inequalities in later life. Future high-quality, adequately powered randomized controlled trials, with a long-term intervention and follow-up period are required to elucidate the effects of physical activity interventions on the prevention of weight gain and body composition in young adults with intellectual disabilities.

Conflict of Interest Statement

No conflict of interest was declared.

Authors' contributions

LH carried out the review and drafted the manuscript. LH, CH and CM reviewed the full text of studies for inclusion. LH and CM rated the studies for methodology quality and reviewed any discrepancies with CH to come to a consensus. All authors read and approved the final manuscript.

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Appendix A

Medline Search Strategy

1. (intellectual* adj (disab* or disorder* or handicap* or impair* or deficien* or subnorm*)).tw.
2. (learning adj (disab* or disorder* or impair* or difficult*)).tw.
3. (development* adj (disab* or disorder* or handicap* or impair* or delay*)).tw.
4. (mental* adj (disab* or disorder* or handicap* or impair* or deficien* or subnorm* or retard*)).tw.
5. exp Intellectual Disability/
6. exp Mentally Disabled Persons/
7. Or/1–6
8. exp Exercise/
9. exp Physical Fitness/
10. exp Sports/
11. (fit* adj (regime* or program*)).tw.

12. ((moderate or vigorous*) adj3 activ*).tw.
13. (physic* adj5 (fit* or train* or active* or endur* or intervention*)).tw.
14. (exercis* adj5 (aerobic* or train* or fit* or activ* or endur or intervention*)).tw.
15. ((leisure or fitness) adj5 (centre* or center* or facility*)).tw.
16. (gym* or circuit* or aqua* or walk* or jog* or run* or swim*).tw.
17. ((cycle or cycling) adj5 (school* or work or work-place or commut* or travel* or equipment* or facility*)).tw.
18. pilates.tw.
19. weight lift* or strength train* or resistance train* or circuit train* or aerobic* train*).tw.
20. ((lifestyle or life-style) adj5 (activ* or physic*)).tw.
21. Or/8–20
22. exp Obesity/
23. exp Body Weight Changes/
24. exp Weight Gain/
25. Weight Loss/
26. obes*.tw.
27. ('weight gain' or 'weight loss').tw.
28. (overweight or 'over weight' or 'over-weight).tw.
29. (weight adj2 change*).tw.
30. (bmi or 'body mass index').tw.
31. ((bmi or 'body mass index') adj2 (gain or loss or change*)).tw.
32. body composition.tw.
33. Or/22–32
34. 7 and 21 and 33
35. limit 34 to (English language and humans)

Appendix B

Rating of Methodology Quality (PEDro Score)

Table B1 Quality assessment (PEDro score) of included studies

Criteria	1	2	3	4	5	6	7	8	9	10	11	Total score
Boer <i>et al.</i> (33)	○	●	○	●	○	○	●	●	●	●	●	7
Elmahgoub <i>et al.</i> (34)	○	○	○	●	○	○	●	●	●	●	●	6
Gonzalez-Aguero <i>et al.</i> (29)	○	●	○	●	○	○	○	●	●	●	●	6
Gonzalez-Aguero <i>et al.</i> (30)	●	●	○	●	○	○	○	○	●	●	●	5
Ordonez <i>et al.</i> (35)	○	●	○	●	○	○	○	●	●	●	●	6
Valera <i>et al.</i> (36)	●	●	○	●	○	○	○	●	●	●	●	6
Total by criteria	2	5	0	7	0	0	3	6	7	7	7	

Notes: ●, fulfils PEDro criteria for the item; ○, does not fulfil PEDro criteria for that item. For full list of each item, please refer to methods section.

Appendix C

Forest plots of body mass index and body composition outcomes

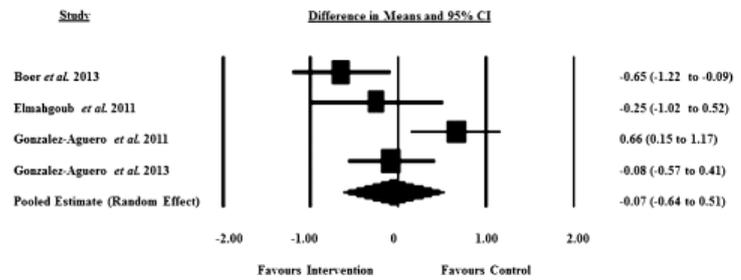


Figure C1 WMD in BMI (kg m^{-2}) between the intervention groups and the control groups.

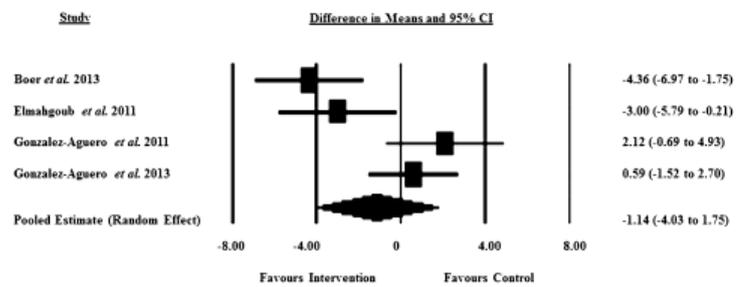


Figure C2 WMD in waist circumference (cm) between the intervention groups and the control groups.

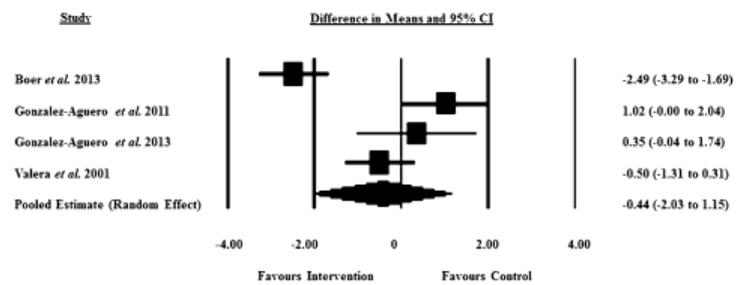


Figure C3 WMD in percentage body fat (%) between the intervention groups and the control groups.

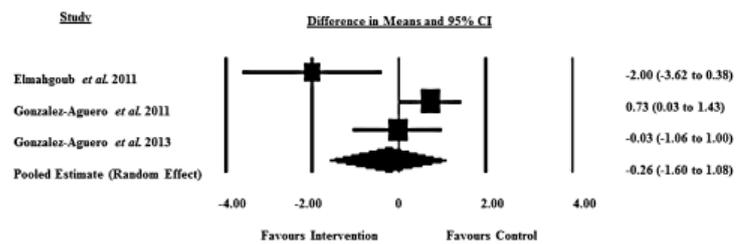


Figure C4 WMD in fat mass (kg) between the intervention groups and the control groups.

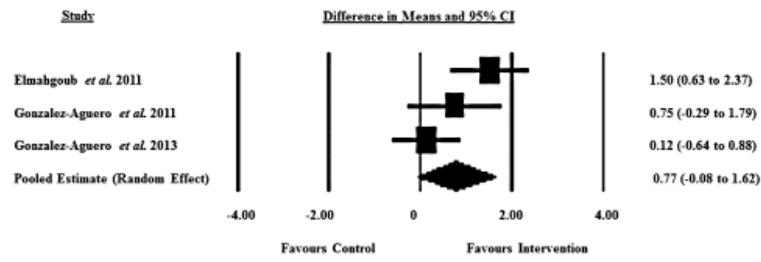


Figure C5 WMD in lean mass (kg) between the intervention groups and the control groups.

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