Effectiveness of community based physical activity on step count and sedentary behaviour in people with Rheumatoid Arthritis within the first five years of diagnosis

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Abstract

Background: Rheumatoid Arthritis (RA) is associated with increased risk of cardiovascular disease (CVD). Physical inactivity is a modifiable risk factors of CVD and frequently associated with impaired functional status and health related quality of life.

Objectives: This single blind randomised controlled trial investigated the impact of a pedometer-supported walking and education programme (Walk for RA-WARA) on PA, sedentary time, PA self-efficacy, disease activity, functional capacity, quality of life and cardiovascular (CV) risk in people with RA.

Methods: Seventy-six individuals, aged 56 (±15) years and within 5 years from RA diagnosis were randomly assigned to either the WARA intervention group (six weekly group education sessions and two booster sessions at 3 and 6 months) or the control group (single session). Demographic data were recorded and Body Mass Index (BMI), Waist-Hip ratio (WHR), Waist-Height ratio (WHtR), and blood pressure were measured. The primary outcomes were objectively measured PA profiles, daily step counts and time spent sedentary, using an activPAL™ and self-reported using international physical activity questionnaire (IPAQ). Functional status was assessed with six-minute walk test (6MWT), health assessment questionnaire (HAQ), and hand grip strength. Rheumatoid arthritis quality of life (RAQoL) and PA Self-efficacy were evaluated. Blood samples were taken and the 10-year risk of CVD scores were calculated, using the Scottish Intercollegiate Guidelines Network (ASSIGN). Data were analysed descriptively and mixed generalised linear models (GLM) were used incorporating restricted maximum likelihood (REML) and post-hoc analyses. Interviews were undertaken with 10 people from the intervention and data were analysed thematically using the framework approach and NVivo 11 software.

Results: The intervention group showed a significantly greater increase than the control group in steps/day at 3 months (by 3413 (1835-4990) steps/day, mean (95%CI)) ($P<0.001$), and 6 months (3599 (2135-5062) steps/day) ($P<0.001$) and a significant reduction in IPAQ weekday ($P=0.014$) and weekend sitting time ($P=0.046$). There were significant improvements in 6MWT ($P<0.001$), PA self-efficacy ($P=0.008$), systolic blood pressure ($P=0.002$) and ASSIGN scores ($P<0.001$) in the intervention group. Participants found education sessions,

booster sessions, hand-outs, pedometer, PA diaries were important factors in increasing their step counts. In addition, they stated that WARA programme was enjoyable and helpful in terms of raising their knowledge regarding their condition. They also reported they felt much healthier and their mood had improved.

Conclusions: The 6-month WARA intervention was effective in promoting PA, PA self-efficacy, physical function, and reducing the 10-year risk of CVD. The WARA programme may be a useful adjunct to current clinical practice in rheumatology.

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Author's Declaration

I hereby declare that explicit reference is made to the contribution of other, that this dissertation is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institutions.

Signature_____

Printed name _____

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Definitions/Abbreviations

ACPA	Anti-Citrullinated Protein Antibody
ACR	American College of Rheumatology
ADL	Activities of Daily Living
ALT	Alanine aminoTransferase
ASMP	Arthritis Self-Management Program
ASSIGN	Assessing cardiovascular risk using SIGN (Scottish Intercollegiate Guidelines Network)
AST	Aspartate aminoTransferase
B	Baseline
BCTs	Behavioural Change Techniques
BMI	Body Mass Index
CARRE	CARdiovascular research and RhEumatoid arthritis
CCMR	Clustered CardioMetabolic Risk
CDAI	Clinical Disease Activity Index
CG	Control Group
Chol	Cholesterol
CI	Confidence Interval
cm	centimeter
COS	Core Outcome Sets
COXIBS	Cyclo-Oxygenase Inhibitors
CTD	Connective Tissue Disease
CVD	Cardiovascular Disease
CV	Cardiovascular
CRP	C Reactive Protein
DAS	Disease Activity Score
DINE	Modified Dietary Instrument for Nutrition Education
DM	Diabetes Mellitus
DMARD	Disease Modifying Anti-Inflammatory Drug
DBP	Diastolic Blood Pressure
EULAR	European League Against Rheumatism
ESR	Erythrocyte Sedimentation Rate
FACET	Five-A-day Community Evaluation Tool
FFQ	Food Frequency Questionnaire
FGF	Fibroblast Growth Factor
GGT	Gamma-Glutamyl Transpeptidase
GLM	Generalised Linear Models
GPAQ	Global Physical Activity Questionnaire
GSE	General Self-Efficacy scale
HBA1c	Glycated Haemoglobin
HC	Hip Circumference
HBC	Health Behaviour Change
HDL	High Density Lipoprotein
HR	Hazard Ratio
HRQoL	Health-Related Quality of Life
hrs	hours
HRT	Hormonal Replacement Therapy
HTN	Hypertension

HLA	Human Leukocyte Antigen
HDL	High Density Lipoprotein
HAQ	Health Assessment Questionnaire
Ig	Immunoglobulin
IG	Intervention Group
IHD	Ischemic Heart Disease
IL	Interleukin
IPAQ	International Physical Activity Questionnaire
kg	kilogram
LDL	Low Density Lipoprotein
LDCs	Low Dose Corticosteroid
M	Months
m	meter
MET	Metabolic Equivalent of Task
mmHG	millimeter of mercury
MICD	Minimal Clinically Important Differences
Min	Minutes
mg	milligram
mmol/L	millimole per litre
µIU/mL	micro litre unite per millimole
MTX	Methotrexate
n	number
NA	Not Applicable
ADL	Activities of Daily Living
NSAIDS	Non-Steroidal Anti-Inflammatory Drug
OR	Odds Ratio
PA	Physical Activity
PDGF	Platelet-Derived Growth Factor
PTPN22	Protein Tyrosine Phosphatase, Non-receptor type 22
QUEST-RA	Questionnaires in standard monitoring of people with RA
RA	Rheumatoid Arthritis
RAQoL	Rheumatoid Arthritis Quality of Life questionnaire
RF	Rheumatoid Factor
RCT	Randomised Control Trial
REML	Restricted Maximum Likelihood
ROM	Range Of Motion exercise
RR	Relative Risk
SB	Sedentary Behaviour
SBP	Systolic Blood Pressure
SCT	Social Cognitive Theory
SDAI	Simplified Disease Activity Index
SD	Standard Deviation
SE	Standard Error
Sig	Significant
SLE	Systemic Lupus Erythematous
SMART goals	Specific, Measurable, Achievable, Realistic and Time-bound
6MWT	Six Minute Walk Test

TGF-β	Transforming Growth Factor Beta
TNF-α	Tumour Necrosis Factor Alpha
Trig	Triglyceride
U/L	Units/Litre
VAS	Visual Analogue Scale
WHR	Waist-Hip Ratio
WHtR	Waist-Height Ratio
WC	Waist Circumference
WARA	Walk for Rheumatoid Arthritis
yrs	years

1 Introduction

1.1 Problem statement

Rheumatoid Arthritis (RA) is a chronic auto-immune disease of unknown aetiology. It affects 0.5-1% of the UK population, and is most prevalent among people aged 40–60 years (Cooney et al., 2011, Panel., 2004). The risk of developing RA is two to three times higher among women than men (Henchoz et al., 2012, Plasqui, 2008, Sokka et al., 2008). Despite, the aetiology of RA being unknown, there are many factors implicated in the development of the disease, and the interaction of genetics, the immune system and environment factors may contribute to the development of RA (Aho and Heliovaara, 2004, Sugiyama et al., 2010).

RA is characterized by inflammation of the joints resulting in progressive musculoskeletal damage and also extra articular manifestation such as pericarditis, neuropathy, ophthalmological manifestation and glomerulonephritis (John et al.,2011; Plasqui.,2008; Metsios et al.,2007; Turesson et al., 2003; Riemsa et al.,2003). The pathological process of RA may lead to a severe degree of articular destruction, loss of function, accelerated loss of muscle mass, restricted mobility and deformities (Cooney et al., 2011, Metsios et al., 2008). As a consequence of RA, people may suffer from severe joint pain, swelling, stiffness, muscle weakness, loss of bone density and general functional limitation in performing daily physical tasks (Avina-Zubieta et al., 2008, Cooney et al., 2011, Esbensen et al., 2015).

Several disease-modifying antirheumatic drugs (DMARDs), such as methotrexate, sulfasalazine, leflunomide, hydroxychloroquine and azathioprine and biological drugs, such as infliximab, adalimumab and rituximab, have been shown to be effective in the control of disease activity, in minimising structural damage and in promoting longer life (Inui and Koike, 2016). Some recommend a ‘treat-to-target’ (T2T) approach for RA, in order to achieve remission, or at least low disease activity (Smolen *et al.*, 2016). Although modern technology may be used to help diagnose RA earlier, and new approaches using anti-rheumatic treatment regimens have improved the outcome of the disease, those with RA still suffer

from progressive, long term disability (Avina-Zubieta et al., 2008, Cooney et al., 2011).

It is well established that RA is associated with increased morbidity and mortality compared with general population (Pieringer and Pichler, 2011). People with RA have an increased risk of cardiovascular (CV) mortality of up to 50% (Choy et al., 2014, Kerola et al., 2013, Metsios et al., 2008, Siebert et al., 2016). Specifically, RA is associated with increased risk of cardiovascular disease (CVD) such as myocardial infarction, ischemic heart disease and heart failure; (Houri Levi et al., 2016, Kerola et al., 2013, Metsios et al., 2008, Pieringer and Pichler, 2011). However, increased risk of CVD among people with RA is not fully explained by traditional cardiovascular risk factors (Cooney et al., 2011, Houri Levi et al., 2016, Kerola et al., 2013, Zegkos et al., 2016). Clinical epidemiological observations suggest that low grade inflammation plays an important role in accelerating atherosclerosis and CVD (Avina-Zubieta et al., 2008, Cooney et al., 2011, Kremers et al., 2008, Sattar et al., 2003).

Metsios et al. (2008) reported a significantly greater CV risk profile among physically inactive people with RA (as determined by higher systolic pressure, elevated total cholesterol and low-density lipoprotein levels) compared with physically active RA people. People with RA may have inactive lifestyles for a number of reasons, including joint pain and stiffness, psychological disturbances or even fear of aggravating their disease, that could raise the CV risk profile (Zegkos et al., 2016).

RA guidelines emphasise the role of regular physical activity (PA) which is associated with improved health outcomes both physical and mental, and reduced the risk of all-cause mortality by 30% (Knittle et al., 2015, Sokka et al., 2008). It has been identified that over two-thirds of people with RA in the UK are physically inactive in comparison with the healthy population (Cooney et al., 2011, Esbensen et al., 2015). PA plays an important role in the management of the disease, as it has a fundamental role in maintaining muscle strength, endurance, range of motion, decreasing inflammation and pain, and improving function and a sense of well-being (Baillet et al., 2012, Hakkinen et al., 2001, Plasqui, 2008, Prioreschi et al., 2013).

Behavioural interventions and patient education are fundamental components in the management of chronic disease and several studies strongly recommend their use in lifestyle interventions (Greaves et al., 2011, John et al., 2011a, Knittle et al., 2015). Changing patient behaviour is one of the important challenges of healthcare (Michie et al., 2012). Systemic reviews and meta-analyses have indicated that behavioural interventions show a significant positive effect on self-efficacy for PA, which is associated with a change in PA behaviour (John et al., 2011a, Olander et al., 2013).

Systematic reviews by Olander et al. (2013) and Michie et al. (2012) showed behavioural change techniques, including self-monitoring and goal setting, are effective in increasing self-efficacy for PA, and that interventions which aim to increase PA should also promote social support. Any educational and lifestyle modification programme to increase knowledge should provide an explanation of the relevance of CVD, modification of lifestyle and encouragement of long-term relevant behavioural modification (Knittle et al., 2015, Olander et al., 2013). It is uncertain; however, whether behavioural change interventions can promote PA among people with RA, and further study of this is recommended (Cramp et al., 2013, Larkin et al., 2015a).

John et al. (2011a) and Riemsma et al. (2004) evaluated the effectiveness of education programmes to manage RA, based on a systematic review of the evidence from randomised controlled trials. It concluded that any successful education programmes for people with RA, with the aim of promoting PA, would need to be designed in the format of group education, as this improves the participants' compliance and adherence to programmes.

In particular, it has been suggested that healthy lifestyle education programmes such as those aimed at increasing PA and reducing sedentary behaviour for people with RA should be provided during the early stage of the disease to maximise the potential for appropriate behaviours to be implemented and maintained (National Institute for Health and Care Excellence, 2015, Riemsma et al., 2003). There is a lack of education programme in routine clinical settings regarding lifestyle modification for people with RA (Zegkos et al., 2016). Thus, the outcomes that emerge from this study may help in developing new

approaches to patient education programme regarding PA and improve the health outcomes of people with RA.

1.2 The purpose of the study

The overall aim of this single blind randomised control trial (RCT) study was to investigate the effectiveness of a six-month, community based, pedometer supported, walking programme, along with an education programme incorporating behavioural change techniques (Walk for Rheumatoid Arthritis – WARA) on objectively measured physical activity (step count) and sedentary time, disease activity, functional capacity, quality of life, self-efficacy for PA and cardiovascular risk of people within the first five years of being diagnosed with RA.

1.3 Objectives of the study

This study had three objectives:

To examine the effectiveness of a six-month community based, pedometer supported, walking programme, to increase PA and reduce sedentary time in people with RA within the first five years of diagnosis and to compare the results with a group of people (control) receiving usual care.

To investigate the effectiveness of the programme in terms of cardiovascular risk, disease activity, quality of life, functional capacity and self-efficacy for physical activity.

To explore the relationship between changes in physical activity, time spent sedentary and disease activity, quality of life, functional capacity, self-efficacy for physical activity and cardiovascular risk.

1.4 Overview of the study

The single blind RCT was approved by the West of Scotland Research Ethics Committee and was conducted in accordance with declaration of Helsinki between November 2014 and March 2016. The participants were recruited from

rheumatology clinics at Gartnavel General Hospital, Stobhill Hospital and Glasgow Royal Infirmary in Glasgow, UK.

Participants who were randomised to the Walk for Rheumatoid Arthritis (WARA) intervention, received six weekly, one-hour small group interactive education sessions with plus two booster sessions at 3 and 6 months combined with pedometer based walking programme. The education sessions were delivered by an experienced physiotherapist. The control group received a one-hour group education session.

The primary outcome measure was the changes in daily step count and sedentary time from baseline to six months (end of the intervention) which was obtained using an activPAL^{TM} worn for 7 consecutive days. The outcome measures (at baseline, 3, 6 months and one year) were self-reported questionnaires and physiological assessments (see Chapter 4). The principle investigator who performed all assessments was blind to the group allocation. To explore participant views regarding the WARA intervention at the end of the programme (6 months) 10 participants from the intervention group took part in a semi structured telephone interview.

1.5 Thesis layout

Chapter Two reviews the current literature on the prevalence and epidemiological trends in RA, its clinical features and extra articular manifestations, the risk factors for RA, the diagnostic criteria and course of RA, the epidemiology of CVD in RA, the risk factors of CVD in RA, its possible mechanisms and the pattern of CVD in people with RA. It also reviews PA, the benefits of PA, PA in RA, the definition of sedentary behaviour and the consequences of being sedentary in the general population and in those with RA.

Chapter Three presents a definition of complex interventions discusses physical activity interventions as lifestyle interventions, the theoretical underpinning of the integral behavioural change, the behavioural change techniques (BCTs) and their effectiveness in changing the behaviour of people with RA in terms of physical activity. It also presents the content and mode of delivery of the WARA intervention.

Chapter Four presents a rationale for the chosen outcome measures in the form of a literature review, including discussion of the reliability and validity of the outcome measures.

Chapter Five describes the materials and method used in the study, including the study design, ethical approval, study setting, patient recruitment and selection method, method of allocating participants to the intervention and control groups. It also discusses, the sample and sample size, control group intervention, piloting of the study, data management, the quantitative data collection tools and processes, and the qualitative data collection (telephone interview). Additionally, it presents the methods of data analysis (quantitative and qualitative) applied.

Chapter Six presents the results of the study and offers comparisons between the intervention and control groups at baseline, three and six months, in terms of PA, CVD risk, quality of life, functional capacity and participants' self-efficacy for PA. It includes the results of PA and sedentary behaviour of both groups at one year (6 months follow up).

Chapter Seven presents the facilitators and barriers of the WARA intervention including all of the identified themes and subthemes. It includes a summary of the results and integrates the findings of both studies (quantitative and qualitative).

Chapter Eight is the discussion chapter where the results of the study are discussed in relation to previous literature. It discusses the strengths and limitations of the study.

Chapter Nine offers a summary of the study, considers the implications for future research, and offers recommendations for clinical practice. It also presents the conclusions of the study and detail of the current study makes a novel and original contribution to the existing evidence base in this field.

2 Literature Review

This chapter describes the current literature related to rheumatoid arthritis (RA), cardiovascular disease (CVD), physical activity (PA), and sedentary behaviour providing the background and justification for the study. The section will begin with a description of the key features of RA and CV risk factors associated with RA. Also, it will explain PA guidelines and sedentary behaviour, and specifically discuss the role of PA on quality of life, functional capacity, disease activity and the risk of CVD in people with RA. The literature in relation to the outcome measures applied in this study will be presented in Chapter 4.

2.1 Rheumatoid arthritis (RA)

2.1.1 Epidemiology and prevalence

Several epidemiological studies demonstrate that the incidence and prevalence of RA across the world shows considerable geographical variation (Alamanos and Drosos, 2005, Tobon et al., 2010). The estimated incidence of RA in North Europe and North America ranges from 20 to 50 cases per 100,000 of the population; in Southern Europe, this is 9 to 24 cases per 100,000 of the population (Tobon et al., 2010). The prevalence is about 0.5-1.1% in Northern Europe and North America, with a lower prevalence at around 0.3-0.7% in Southern Europe (Tobon et al., 2010). In developing countries, the prevalence is 0.1-0.5%; however, no data was available about the number of cases/population (Alamanos and Drosos, 2005, Silman and Pearson, 2002, Tobon et al., 2010). In the large population-based UK Biobank cohort study the prevalence of reported RA was higher among participants from South Asia 1.35% compared to black participants 0.90% and Chinese 0.50% (Siebert et al., 2016).

RA is the most common form of chronic joint inflammation. It is more prevalent among women, for example, the rates are two to three times higher in women than in men in the UK, where RA affects 0.5-1% of the population (Rodriguez et al., 2009). Rodriguez et al. (2009) reported that the RA incidence in the UK was 0.15 per 1000 person-years; this was slightly lower than in previous reports from North American and northern European populations, where it was 0.20–0.50 per 1000 person-years.

In addition, RA occurs at any age, however the prevalence of disease for both genders increases with age and the peak incidence of RA is between 50-60 years of age (Alamanos and Drosos, 2005, Tobon et al., 2010).

It revealed that people with RA have shortened life expectancy by 3-10 years, with most people dying from CVD, infections, or haematological, gastrointestinal and pulmonary complications (Cooney et al., 2011, Dougados et al., 2014, John et al., 2011a, Sattar et al., 2003). CVD accounts for 50% of excess mortality in RA (Cooney et al., 2011, John et al., 2011a, Choy et al., 2014). It has been demonstrated that the RA mortality rate is relatively constant for both male and female at 2.4/100 person-years and 2.5/100 person-years respectively. The wider mortality gap between people with RA and those without RA may be due to improvement in survival among the general population (Gonzalez et al., 2007).

2.1.2 Time trends in the epidemiology of rheumatoid arthritis

A number of epidemiological studies have documented that after 1960s the incidence and prevalence of RA decreased (Alamanos and Drosos, 2005, Tobon et al., 2010, Turesson et al., 2003). The average annual incidence of RA in Rochester, Minnesota during the period 1950 through to 1974 was 28.1 per 100,000 for males and of 65.7 per 100,000 for females. A population study undertaken by Doran et al. (2002) using part of the cohort of Rochester, Minnesota demonstrated that there was a decrease in the incidence of RA from 61.2/100,000 in 1955 to 32.7/100,000 in 1994. In 1975, prevalence rates were 5.8 per 1000 for males and 13.4 for females (Linos et al., 1980). However, Symmons et al. (2002) reported that, from the 1950s the prevalence of RA in women in the UK may have fallen, but not among men. These changes may be due to changes in study methodology and case ascertainment criteria as some data collection was carried out before 1987/American College of Rheumatology (ACR) classification criteria, which added more precise diagnostic criteria, were published (Arnett et al., 1988).

In 1956, RA was sub classified into definite RA that required at least 5 criteria out of 11 and 6 weeks of joint symptoms, or probable RA which required at least 3 criteria and 4 weeks of joints symptoms. In 1958, classic RA was added (which

required patients to have 7 out of 11 criteria), and the duration of joint symptoms in probable RA was increased from 4 weeks to 6 weeks. However, data from the last decade indicates that the incidence of RA may be rising again after four decades of decline (Gonzalez et al., 2007, Tobon et al., 2010). In a population based the US, it was reported that the estimated incidence of RA appeared to increase more in women compared to men during the period of 1995-2007. The incidence of RA appeared to increase by 2.5% per year from 1995 to 2007 in women (95% CI: 0.3%, 4.7% per year, P=0.02), but not in men where the incidence declined 0.5% per year (95% CI: −3.6%, 2.7%; P=0.74) (Myasoedova et al., 2010).

2.1.3 Pathophysiology of rheumatoid arthritis

RA is a chronic inflammatory autoimmune disease, primarily affecting the synovium of the joint, and is characterized by disabling, symmetrical, polyarthritis and erosive synovitis (Cojocaru et al., 2010, Gibofsky, 2012). RA usually affects smaller, distal joints, which leads to progressive destruction of joint margins and articular cartilage. Joint pain, swelling and morning stiffness are the dominant features (Cooney et al., 2011), see Figure 2-1. RA also affects a number of organs, such as the heart, lung and eyes (Cojocaru et al., 2010).

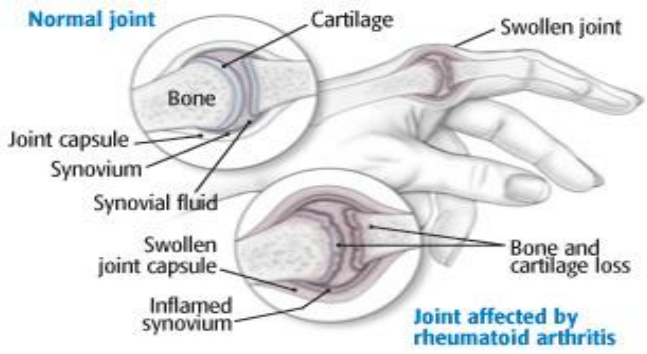

Figure 2-1 Joint affected by rheumatoid arthritis.
http://www.drugs.com/health-guide/rheumatoid-arthritis.html, 09/05/2016 09:30 pm

The synovium is the central area of pathology in a number of inflammatory joint diseases, including RA (Smith, 2011). The synovium is a soft tissue lining the joints, tendon sheaths and bursae. It consists of two parts, the surface layer is the intima and the underlying tissue is the sub intima (Smith, 2011).

The pathophysiology of RA is a complex phenomenon consisting of inflammation, abnormal production of certain inflammatory mediators such as cytokines and chemokines of numerous types, tumor necrosis factor alpha (TNF-α), interleukin-1 (IL-1), IL-6, IL-8, transforming growth factor beta (TGF-ß), fibroblast growth factor (FGF) and platelet-derived growth factor (PDGF) (Gibofsky, 2012, Siebert et al., 2015). RA is distinguished by inflammation of the synovium, elevated pro inflammatory cytokines such as; tumour necrosis factor alpha (TNF-α), interleukin 1b and C reactive protein about 3 to 100 times. Proliferation of synovium occurs and gives rise to destruction of several tissues, which include cartilage, tendon, bone, blood vessels and ligament (Gibofsky, 2012, Siebert et al., 2015), see Figure 2-2. A hyperplastic synovium with cartilage damage is the main manifestation in RA (Smith, 2011).

In people with RA the intimal lining layer is usually markedly thickened, due to a number of processes, with macrophage influx from the vascular compartment, under cytokine and cell adhesion molecule control, being the dominant process (Cooney et al., 2011). The circulating level of cytokines reflects the level of inflammation and activity of disease, it also plays an important role in systemic effects of the disease such as vascular and rheumatoid cachexia (Cooney et al., 2011, Smith, 2011). The rise of circulating inflammatory cytokines leads to damage of tendon and collagen and results in disorganisation of the tendon structure and gradual loss of elasticity and stiffness, particularly if the individual does not perform exercise regularly (Cooney et al., 2011).

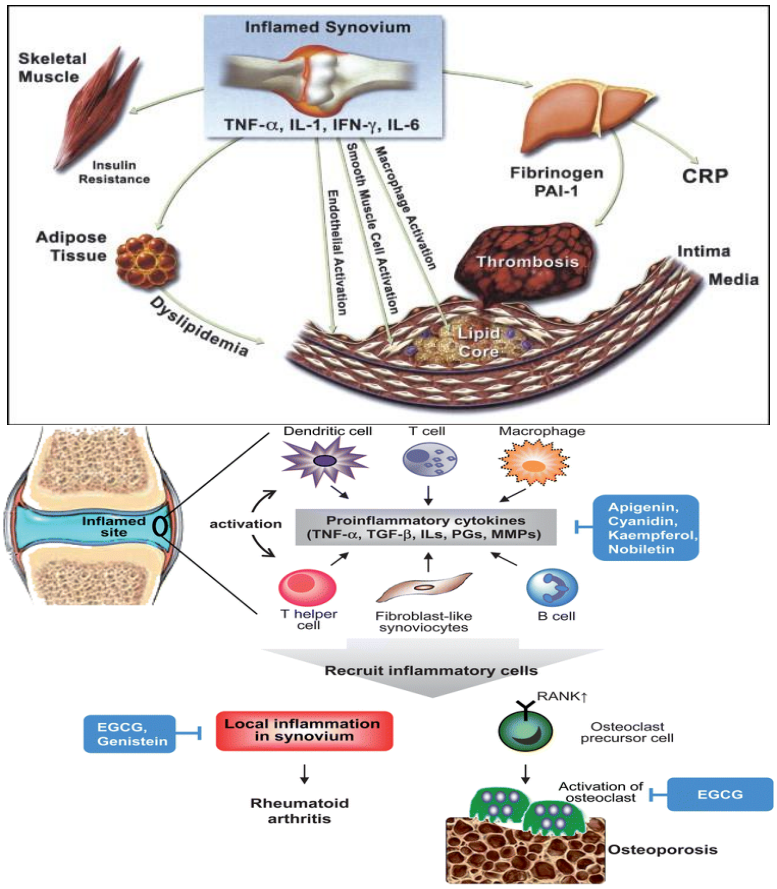

Figure 2-2 The mechanism of inflammation associated pathogenesis in rheumatoid arthritis and osteoporosis
http://pubs.rsc.org/services/images/RSCpubs.ePlatform.Service.FreeContent.ImageService.svc/ImageService/Articleimage/2010/FO/c0fo00103a/c0fo00103a-f6.gif, 08/05/2016 11 am

Bone erosion affects 80% of people with RA (Smith, 2011). Synovial cytokines enhance osteoclast invasion and differentiation of the periosteal surface adjacent to articular cartilage. Deep resorption pits result from destroyed mineralized tissue due to effects of acidic enzymatic machinery of osteoclasts; the pits then become filled with inflammatory tissue. Also, inflammation of bone marrow happens as result of breach of cortical bone and synovial access to bone marrow (Freemont, 1996, Smith, 2011), see Figure 2-3.

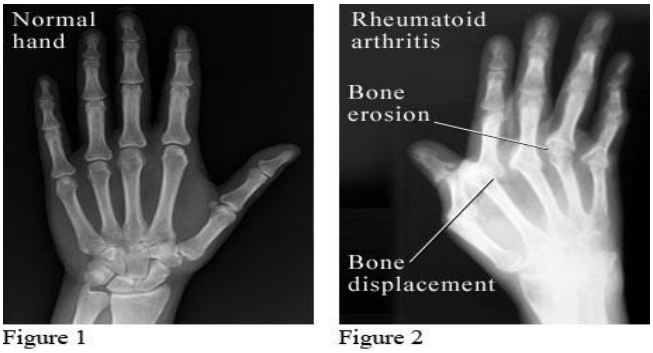

Figure 2-3 Anterior Posterior radiographic views of normal and rheumatoid arthritis hand
http://img.webmd.com/dtmcms/live/webmd/consumer_assets/site_images/media/medical/hw/h9991226.jpg, 09/05/2016 08pm

In addition, RA is associated with increased overall morbidity and mortality compared with the general population particularly due to CVD (Agca et al., 2016, Houri Levi et al., 2016, Metsios et al., 2014). The following section explains the current evidence in terms of the risk of CVD in people with RA.

2.1.4 Diagnostic criteria for rheumatoid arthritis

The classification of RA is dependent on several criteria to facilitate the definition of cases in clinical and epidemiological research. The recent criteria were developed by the American College of Rheumatology (ACR) in 1987 and the European League Against Rheumatism (EULAR) 2010 (Aletaha et al., 2010). The subsets of RA are based on the presence or absence of rheumatoid factor (RF) and anti-cyclic citrullinated peptide antibodies (ACPA) which can precede the clinical manifestation of RA by many years. The presence of ACPA is positive for RA (Alamanos and Drosos, 2005, Sugiyama et al., 2010). RF is an autoantibody that binds the Fc region of the immunoglobulin G molecule (IgG) and serves as a diagnostic and prognostic marker (Aletaha et al., 2010, Pratt et al., 2009). The production of RF results from a response to an antigen/antibody complex such as in immunisation and infections. However, it has been demonstrated that 5% of healthy subjects have positive RF, but RF is retained as a criterion for RA (Aletaha et al., 2010, Pratt et al., 2009). RA patients with positive RF have a higher frequency of extra articular manifestations than those with negative RF (Cojocaru et al., 2010).

The criteria for the classification of Rheumatoid Arthritis (RA) 1987 American College of Rheumatology and the revised criteria from 2010 European League Against Rheumatism are shown in Table 2-1. The new criteria focus on diagnosis of RA at an early stage, rather than at a late stage and rely on features, such as persistent and/or erosive disease, rather than late stage features (Aletaha *et al.*, 2010).

Table 2-1 Criteria for the classification of rheumatoid arthritis 1987 and the revised criteria 2010

	1987 Criteria		2010 Criteria	
Criteria	**Description**	**Score**	**Description**	**Score**
Morning Stiffness	In and around joints for at least 1 hour	1	Clinical synovitis/swelling in at least 1 joint not explained by another disease	NA
Joint involvement	Physician observed soft tissue swelling or fluid in 3 of 14 possible joints	1	1 large joint 2-10 large joints 1-3 small joints (with or without large joint) 4-10 small joints (with or without large joint) > 10 joints (at least 1 small)	0 1 2 3 5
Arthritis of hand joints	At least 1 swollen hand or wrist area	1	NA	NA
Symmetric arthritis	Simultaneous bilateral involvement	1	NA	NA
Rheumatoid nodules	Subcutaneous nodules over body prominences, extensor surfaces, or in juxtra-articular regions observed by physician	1	NA	NA
Serology	Positive RF serum test	1	Negative RF and negative ACPA Low-positive RF or ACPA High-positive RF or ACPA	0 2 3
Radiographic changes	Erosions-or unequivocal bony decalcification in or adjacent to the involved joints, but not consistent with osteoarthritis	1	NA	NA
Acute-phase reactants	CRP or ESR	NA	Normal CRP and ESR Abnormal CRP or ESR	0 1
Duration of symptoms	First 4 criteria must be present for at least 6 weeks	NA	< 6 weeks >6 weeks	0 1
Criteria score required		> 4/7		>6/10

Adapted from Aletaha et al. (2010), Symmons et al. (2002).Arnett et al. (1988). ACPA= Anti Circullinated Protein Antibody, CRP =C Reactive Protein, ESR= Erythrocyte Sedimentation Rate, NA =Not Applicable, RF= Rheumatoid Factor.

2.1.5 Risk factors for rheumatoid arthritis

The epidemiological data on the risk factors of RA suggest that the variation in incidence and prevalence of RA reflects the complexity of predisposing factors (Rodriguez et al., 2009). The specific cause of RA is yet unknown, however the occurrence and expression of RA predisposition may be due to the interaction of genetic and environmental factors (Alamanos and Drosos, 2005, Tobon et al., 2010). The environmental factor of infections, smoking, pollutants and dietary factors also play a role (Alamanos and Drosos, 2005, Sugiyama et al., 2010). However, the impact of these factors in developing and expression of the disease are not yet proven (Alamanos and Drosos, 2005). The following sections describe the risk factors that may influence the development of RA or the course and severity of the condition.

1 Genetic Factors

Epidemiological evidence suggests that genetic factors play an important role in the risk of RA (Tobon et al., 2010). In recent years, further evidence of the impact and nature of the genetic factors involved in RA has become available, although the relationship between the genetic factors and risk of developing RA, as well as the severity of the disease, is still uncertain (Alamanos and Drosos, 2005, Tobon et al., 2010). Studies reported that genetic factors account for 50-60% of the risk of developing RA and that the main gene associated with RA is the human leukocyte antigen (HLA)- class II alleles and particularly with sub types HLA-DRB104 (HLA-DR4) which accounts for one third of the genetic susceptibility to RA (Aho and Heliovaara, 2004, Scott et al., 2013). The main genetic factors associated with development of RA are HLA-DRBI and protein tyrosine phosphatase, non-receptor type 22 (PTPN22) (Tobon et al., 2010). Genetic predisposition is suggested as homozygous twins are at a higher risk of developing RA due to a shared epitope (epitope is the antibody binding site on an antigen) (Aho and Heliovaara, 2004, Combe, 2009). Family and twin studies found the risks for developing RA in relatives of affected individuals to be approximately 50-60% (Alamanos and Drosos, 2005, Pratt et al., 2013, Silman and Pearson, 2002).

2 Gender and Age

RA is more common in females than males. The female to male ratio reported in studies varies from about 2:1 to 3:1; however the underlying reasons is unknown (Kvien et al., 2006, Scott et al., 2013). The higher risk of developing RA among females suggests the role of hormonal factors in disease susceptibility. Late menarche, 15 years and older, was found to be associated with an increased risk of RA (Pedersen et al., 2006). Pregnancy in RA is associated with remission of the disease, while in the post-partum period RA may flare up (Aho and Heliovaara, 2004, Silman and Pearson, 2002, Tobon et al., 2010).

There is an increased risk of developing RA in the post-partum period with an odds ratio (OR) of 5.6 (95% CI 1.8-17.6) (Alamanos and Drosos, 2005, Scott et al., 2013). A few studies suggest that the use of oral contraceptives and hormonal replacement therapy (HRT) after menopause may be associated with a reduced risk of developing RA. However, the role of hormones whether in occurrence of RA or as a protective mechanism remain uncertain (Alamanos and Drosos, 2005, Tobon et al., 2010).

3 Socioeconomic Factors

Socioeconomic status; occupation, level of education, marital status and social group are associated with the course and outcome of the disease more than with the risk of developing RA (Ahlstrand et al., 2012, Combe, 2009). Low socioeconomic status has been associated with rheumatoid factor (RF) positive and poor outcomes of the disease in both genders (Pedersen et al., 2006, Scott et al., 2011).

4 Ethnicity

Several studies reported a difference in susceptibility, clinical expression and occurrence of the disease between ethnic and racial groups, which may be related to differences in the interactions and distributions of genetic and environmental factors including life style (Alamanos and Drosos, 2005, Tobon et al., 2010). The risk of RA is high in Native Americans compared with Europeans (Molokhia and McKeigue, 2000). In addition, lower prevalence of RA has been identified among those from Mediterranean countries, South Asia, China and

Japan (Aho and Heliovaara, 2004, Gibofsky, 2012). Migrant studies demonstrated low occurrence of RA in migrant populations of African origin living in UK and they concluded that the genetic factors were important in predisposing individuals to the disease (Silman and Pearson, 2002). However, the role of genetic factors in disease susceptibility and severity is not fully explained, the variation of the incidence and prevalence of RA in different ethnic is only explained partly by genetic variation in the HLA region (Aho and Heliovaara, 2004, Alamanos and Drosos, 2005, Scott et al., 2013).

5 Lifestyle factors

Lifestyle factors such as smoking, alcohol consumption, diet and obesity have been found to be associated with an increased risk of RA. The following lifestyle factors may influence the development or the course and severity of RA.

a Smoking

Smoking is considered to be the main environmental factor associated with RA. It has been shown in different cohort studies that smoking unequivocally increases the risk of seropositive RA (Scott et al., 2011). The risk of RA increases among current smokers, compared to non-smokers, and is also directly related to the number of packs smoked per year (Boyer et al., 2011, Hoovestol and Mikuls, 2011). Smoking influences the course and the risk of developing RA, and is also associated with severity and outcome of RA (Combe, 2009).

Cigarette smoking duration has a role in disease progression through its relationship with rheumatoid factor and radiographic erosion and nodule (Combe, 2009). Gene-environment interaction studies reveal an increased risk of RA with HLA DR4 alleles susceptibility, in smokers, and those exposed to some form of bronchial stress such as Silica (Aho and Heliovaara, 2004, McInnes and Schett, 2011).

b Alcohol

The association between alcohol and severity of RA is still unclear (Frampton, 2011). Studies revealed that consumption of alcohol may be protective against RA (Hoovestol and Mikuls, 2011, Scott et al., 2011). The risk of developing RA is

reduced by half in individuals who drink relatively small amount of alcohol (five or less alcoholic drinks/week) compared to those with no alcohol consumption (Hoovestol and Mikuls, 2011, Kallberg et al., 2009). In addition, Lu et al. (2014) reported that functional status improved with moderate alcohol consumption. Conversely, some studies reported no association between the consumption of alcohol and presence of RA (Huidekoper et al., 2013). A systematic review by Scott et al. (2013) demonstrated that ACPA-positive RA but not ACPA-negative RA was inversely associated with alcohol intake.

c Dietary factors

Epidemiological studies suggest that lifelong consumption of fish, cooked vegetables and olive oil has a protective effect against RA (Tobon et al., 2010). Studies indicated that the Mediterranean diet reduces the risk of RA (Aho and Heliovaara, 2004, Alamanos and Drosos, 2005). Omega 3 long chain polyunsaturated fatty acids from fish and oleic acid from olive oil produce anti-inflammatory effects that were attributed to their protective role. These observations could explain the possible relation between diet and RA, and also partly explain the geographical variation of disease occurrence and severity (van Breukelen-van der Stoep et al., 2013).

In addition, low risk of RA has been associated to a high intake of vitamins D and C, while vitamin K associated with decreases severity of inflammation in RA (Tobon et al., 2010). Retrospective studies found that antioxidant micronutrients play an important role in protecting against RA (Aho and Heliovaara, 2004, Hoovestol and Mikuls, 2011). An observational study reported that coffee intake was associated with higher risk of developing RA (Pedersen et al., 2006).

d Obesity

Obesity is associated with increased risk of developing RA and this risk is higher in those with morbid obesity (BMI more than 30) (Crowson et al., 2013, Scott et al., 2011). The risk of developing anti-citrullinated protein antibodies (ACPAs) at age 55 years and younger was (hazard ratio 1.45, 1.03-2.03) for overweight women and (1.65, 1.34-2.05) for obese women ($P \leq 0.001$) (Lu et al., 2014).

6 Environmental factors

Genetic and environment interaction plays an important role in the development of RA (Pratt et al., 2009, Scott et al., 2011, Hoovestol and Mikuls, 2011). The following environmental factors may also influence the development or the course and severity of RA.

a Pollutants

There is a reported increased risk of RA among women living within 50 meters of a road, in comparison to those living 200 meters or more away from the road (Gabriel and Michaud, 2009). Exposure to traffic pollution may therefore be an environmental risk of developing RA (Shapira et al., 2010).

b Early environmental factors and birth weight

Early environmental factors could influence the risk of developing RA, for example, birth weight greater than 4.54 kg has been associated with a two-fold increase risk of developing RA (Scott et al., 2011). Breast-feeding and infections in infancy were found to be protective against RA (Scott et al., 2011, Tobon et al., 2010). In addition, breast feeding duration was found to be inversely related to RA risk (Scott et al., 2011). The meta-analysis of Chen et al. (2015) suggests that breastfeeding is associated with a lower risk of RA, regardless of whether the duration is shorter or longer than 12 months.

c Infectious agents

Infectious agents have been identified as risk factors of RA; however the underlying mechanism is unknown (McInnes and Schett, 2011). Immune complex formation in periods of infection may play a role in the induction of Rheumatoid Factor (RF). In addition, recent evidence suggests that gastrointestinal microbiomes influence the development of autoimmunity and emergence of RA (Alamanos and Drosos, 2005, McInnes and Schett, 2011). Epstein-Barr virus, borrelia, burgdorferi, rubella, parvovirus, and some bacteria, such as proteus and mycoplasma are infectious agents that have been implicated in RA disease development (Gibofsky, 2012, Silman and Pearson, 2002, Tobon et al., 2010). Porphyromonas gingivalis is a bacterial pathogen causing periodontal disease and

it has been reported that periodontal disease is more common in people with RA (Hoovestol and Mikuls, 2011, Scott et al., 2011).

2.1.6 Clinical features of rheumatoid arthritis

The most common symptoms of RA are symmetric swelling of the small joints associated with pain and/or morning stiffness of more than 30 minutes (Combe, 2009, Knittle et al., 2011). Typically RA presents with joint pain and stiffness in multiple joints with the proximal interphalangeal joints, metacarpo-phalangeal joints and wrists most commonly involved (Wasserman, 2011). In addition, patients may suffer from fatigue; psychological stress and disability, which affect their ability to perform their normal activities of daily living (ADL) and work (Ahlstrand et al., 2012, Combe, 2009). Other presentations include polymyalgia like onset (polymyalgia is an inflammatory condition that causes pain and stiffness; it mostly affects the shoulders and neck),low grade fever, weight loss and malaise which can be associated with extra-articular manifestations (Young and Huizinga, 2009) such as pulmonary fibrosis, vasculitis, Sjögren's syndrome, and pulmonary nodules (Cojocaru et al., 2010).

2.1.7 Differential diagnosis of rheumatoid arthritis

There is a wide spectrum of disease characterized by joint swelling, and it is often difficult to distinguish early RA from other arthritis related conditions such as SLE (Systemic Lupus Erythematous) and psoriatic arthritis. A detailed history which includes joint assessments, laboratory and imaging findings are required to reach a diagnosis of RA (Aletaha et al., 2010, Pratt et al., 2009), Figure 2-4 shown the classification of arthritis.

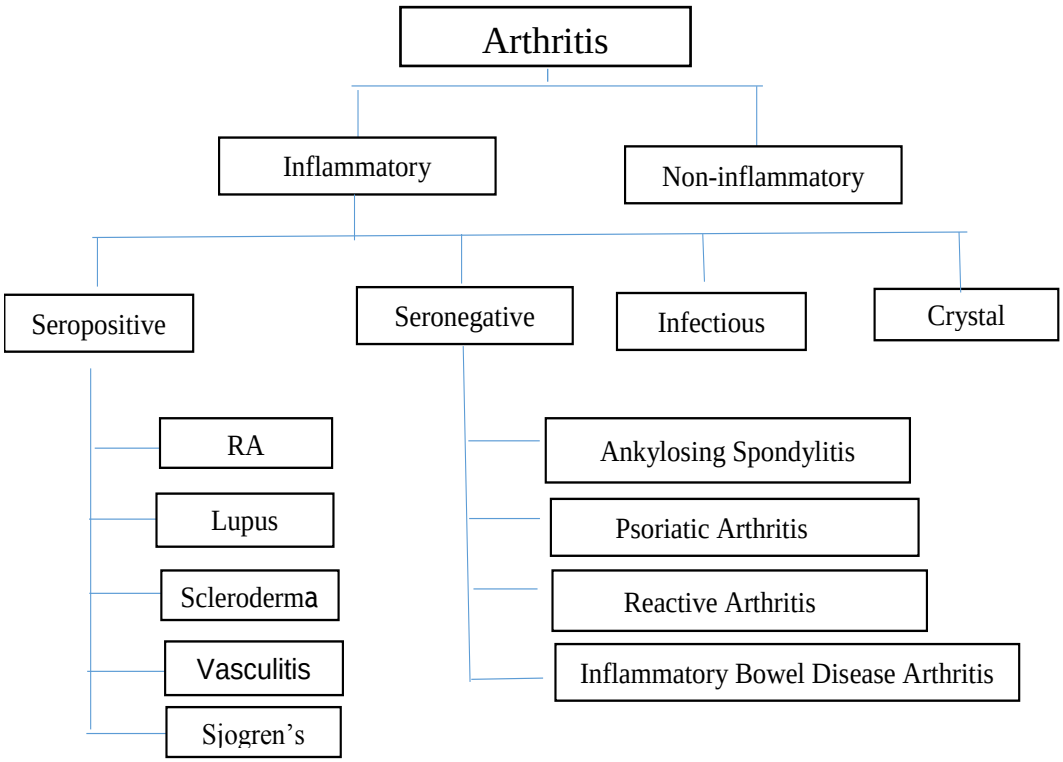

Figure 2-4 Classification of arthritis
http://doctorsgates.blogspot.co.uk/2010/12/classification-of-inflammatory.html, 14/02/2017 08:18 pm

2.1.8 The course of rheumatoid arthritis

The clinical course of RA is characterized by the remission and flare-up of disease. The follow-up of patients with radiological and laboratory investigations can indicate the disease process and also help to predict the outcome of the disease. Adequate treatment and early diagnosis may alter the disease (Combe, 2009, Young and Huizinga, 2009). Identification and treatment of RA at an earlier stage can affect the disease course and the outcomes. It prevents the development of joint erosions or retards the progression of erosive disease (Heidari, 2011). In addition, the Scottish early RA study reported that those newly diagnosed with RA showed significant improvements in disease activity, functional ability and quality of life after treatment (Dale et al., 2016). However, people with RA may experience high rates of psychiatric morbidity such as anxiety and depression and also employment rates reduced after diagnosis (Dale et al., 2016). Thus, RA affects people in many domains of life such as physical, psychological and social, therefore early diagnosis and management of RA needs to include these aspects (Al-Fadl et al., 2014).

2.2 Cardiovascular risk in rheumatoid arthritis

Studies have reported that the risk of heart failure, myocardial infarction and CV death among people with RA is 2-3 fold greater than the general population (Boyer et al., 2011). The high levels of CVD are not fully explained by traditional CV risk factors (Houri Levi et al., 2016, Kaplan, 2006, Kremers et al., 2008) and further studies have been recommended in order to develop an accurate estimation of CV risk in people with RA (Liao and Solomon, 2013). A large population-based cohort study using data from the UK Biobank found that participants who reported RA were more likely to have CVD than non-RA participants (OR 1.52, 95% CI 1.39 to 1.67) (Siebert et al., 2016).

Studies have revealed strong positive associations between high BMI measurements and CVD risk factors, such as diastolic hypertension and hypercholesterolemia in RA patients (Summers et al., 2008, Paniagua et al., 2008). Conversely, a low BMI in people with RA is an important indicator of the high risk of CVD mortality in people with RA, possibly due to high systemic inflammatory activity among people with low BMI (Kremers et al., 2008). This finding supports the hypothesis which states that inflammation is the key to CV mortality among people with RA (Escalante et al., 2005, Zegkos et al., 2016).

van Halm et al. (2009) compared the prevalence of CVD among 294 people with RA with normal fasting glucose levels from a CARRE´ study with 194 individuals with type II diabetes mellitus (DM) and 258 people without diabetes (control) in the Hoorn study. The results demonstrated that the mean WHR was lower in individuals with RA 0.88 (SD± 0.08) compared with the non-diabetic controls 0.89 (SD± 0.08). It is also significantly higher in the diabetic population 0.95 (SD± 0.08) compared to those with RA. The odds ratio (OR) risk of developing CVD among individuals with RA is three times higher than that for non-diabetics and 2.5 times that of individuals with Type II DM (van Halm et al., 2009).

The European League Against Rheumatism taskforce recommended screening and identification of CVD for all people with RA at least once every 5 years. It also recommended a CVD prediction model such as Systematic Coronary Risk Evaluation and Framingham (Agca et al., 2016). EULAR attempted to adjust the prediction models for RA by a 1.5 multiplication factor when certain RA disease

characteristics were present (if two of the three criteria are fulfilled: (1) RA disease duration >10 years, (2) presence of RF or ACPA and (3) presence of severe extra-articular manifestations) (Agca et al., 2016). However, several studies found that the EULAR recommendations were ineffective. The CV risk score in RA seems to be underestimated even after the correction is applied (Corrales et al., 2014, Karpouzas G., 2013).

It has been reported that despite an increased incidence of CVD among people with RA, health providers fail to identify CVD risk (Bartels et al., 2016). Further prospective studies have been recommended in order to evaluate the impact of traditional risk factors on the CV risk in RA, and also to identify the most appropriate management of CVD among RA sufferers (Zegkos et al., 2016).

A cohort of 603 people with RA with a mean age of 58 years, of which 73% were female, were followed up for 15 years. During that time period, 176 patients died from CVD. Multivariable Cox regression analyses, controlled for cardiovascular risk factors and comorbidities, were used to estimate the risk of CV death, which was found to be significantly higher among people with RA vasculitis (HR 2.41, 95% CI 1.00-5.81) and RA lung disease (HR 2.32, 95% CI 1.11-4.84) (Maradit-Kremers et al., 2005).

People with RA sometimes manifest with CVD even before they fulfil the criteria for RA (Kremers et al., 2008). They are at double the risk of sudden death compared to the general population. Therefore, asymptomatic people with RA, who are at high risk may be potentially benefit from primary prevention (Cooney et al., 2011, Kaplan, 2006). Kremers et al. (2008) reported that CV risk is high in people with newly diagnosed RA; and one aim of management should be to detect and prevent CV disease as early as possible. However, Innala et al. (2011) reported that the CV events in early RA could explain by modifiable risk factors (explained below). Risk factors can be defined as any factors that increase the likelihood of developing a disease or injury, and can be modifiable or non-modifiable (World Heart Federation, 2017a). The following are the modifiable and non-modifiable risk factors that could influence the risk of developing CVD in general population as well as RA.

2.2.1 Modifiable risks factors for cardiovascular disease

Modifiable risk factors are defined as factors that increase the risk of morbidity and mortality where the means to reduce them are known and can be controlled (World Health Organization, 2009). Physical inactivity, sedentary behaviour, smoking and diets rich in saturated fats, are examples of modifiable risk factors that need to be mitigated by preventive action (Maruthur et al., 2009, World Heart Federation, 2017a). The seven risk factors are discussed below.

1 Low levels of physical activity

Reduced physical activity is the key risk factor for a chronic condition such as CVD, and other conditions such as diabetes and dyslipidemia, and it is one of the top 10 leading risk factors for mortality worldwide (World Health Organization, 2015). Efforts to promote PA have led to significant improvement in health outcomes and have reduced relative risk of CVD by 20-35 % in the general population (Kokkinos, 2012, Warburton et al., 2006). Regular PA can reduce the risks of morbidity and mortality associated with numerous conditions such as CVD, hypertension and DM and also may help to improve joints and maintain muscle strength in the general population (UK physical activity guidelines, 2011). Adherence to a regular PA is associated with a low risk of sudden cardiac death (Chiuve et al., 2011, Greenland et al., 2010).

2 Unhealthy diet

High dietary intake of saturated fat, salt, and low intake of fruit and vegetables are linked to cardiovascular risk, with a strong relationship between the quality of diet and the risk of CVD in the general population (Dehghan et al., 2012, World Health Organization, 2014). A diet rich with fruit and vegetable reduced the risk of recurrent CVD events in people aged 55 years or over who were diagnosed with CVD (Dehghan et al., 2012). There is an association between the Mediterranean diet (high fruit, vegetables, legumes and cereals consumption, less red meat, more fish and olive oil or vegetable oil) and a reduction in the risk of CVD in the general population (Agca et al., 2016). Although there is a lack of evidence regarding the role of diet on CVD in RA, a healthy diet is recommended as part of a healthy lifestyle (Agca et al., 2016).

3 Smoking

As early as the 1950s studies reported that there is strong association between cigarette smoke exposure and heart disease. Consuming more than 20 cigarettes daily leads to a 2- to 3-fold increase in heart disease (Rea et al., 2002). Smoking is considered one of the modifiable risk factors that increase the risk of CVD in the general population (Liao and Solomon, 2013), in both women and men (Huxley and Woodward, 2011). Although the evidence suggests that smoking increases the risk of CVD in the general population, the effect of smoking in those with RA remains uncertain. A meta-analysis data of 4 studies out of 10 found an association between smoking and CV risk in people with RA (RR 1.50, 95% CI 1.15, 1.84), indicating a 50% increased risk of a CV event in smokers with RA compared to non-smoking RA patients (Baghdadi et al., 2015). However, the causal link between smoking and CV events in RA has not yet been identified.

4 Obesity

Obesity is associated with elevated vascular risk in population studies. Those with a body mass index (BMI) >30kg/m^2 (van Halm et al., 2009) or low BMI<20kg/m^2 are at increased risk of developing heart disease compared with health individuals (del Rincon et al., 2001, Kremers et al., 2008). Also, a high waist-to-hip ratio (WHR) could increase the risk of CVD in people with RA (van Halm et al., 2009). Abnormal body fat composition can lead to increased levels of CRP in RA adipose tissue; this is considered to be a source of inflammatory cytokines that induce the hepatic production of CRP (Liao and Solomon, 2013).

A review by Baghdadi et al. (2015) reported a 16% higher incidence of CV morbidity in obese RA people compared to non-obese RA people. In addition, obesity is a major predicator of CV events and type II diabetes mellitus (DM) in non-RA patients. However, people with RA and with a low BMI are also at risk of CVD due to loss of body cell mass, known as rheumatoid cachexia which is frequently accompanied by inflammatory disease activity, excess production of cytokines and increased risk of CVD (Boyer et al., 2011, Zegkos et al., 2016).

5 Hypertension

Hypertension is defined as an average systolic blood pressure (SBP) ≥140 mmHg, an average diastolic blood pressure(DBP) ≥90 mmHg, or taking medication for elevated blood pressure (Centers for Disease Control and prevention, 2016a). In the Framingham Heart Study, even high-normal blood pressure (which was defined as a SBP of 130-139 mmHg, DBP of 85-89 mmHg, or both or taking medication for elevated blood pressure levels) increased the risk of CVD 2-fold, compared with healthy individuals (Kannel, 2009). Hypertension contributes to the increases risk of CVD in the general population as well as in RA (Liao and Solomon, 2013). Individuals with RA and hypertension (RR of 2.24, 95% CI 1.42-3.06) are at two times greater risk of CVD than non-hypertensive individuals (Baghdadi et al., 2015, Innala et al., 2011). Siebert et al. (2016) reported participants with RA were more likely to have hypertension than people without RA (OR 1.19, 95% CI 1.21-1.27).

6 Metabolic syndrome

Metabolic syndrome is characterized by a group of medical conditions that contribute to the risk for both heart disease and type II DM. In the Kuopio ischemic heart disease risk factor study, people with metabolic syndrome had significantly higher rates of CVD, coronary, and all-cause mortality (Grundy et al., 2005, Lakka et al., 2002). There is an increased prevalence of metabolic syndrome in people with long term RA of about 43% more than the general population (Pamuk et al., 2006) and greater insulin resistance among RA people who carotid plaques (La Montagna et al., 2007). It has been reported that the use of some medications such as antihypertensive drugs and glucocorticoids, were correlated with glucose metabolism effect in people with RA (Dessein et al., 2006).

7 Diabetes

Diabetes mellitus (DM) is defined as fasting plasma glucose >7 mmol/L or treatment with hypoglycaemic agents (Howard et al., 2002). People with diabetes are 2-8 times more likely to experience CV events than age-matched and ethnically matched individuals without diabetes (Howard et al., 2002). The

risk of CV events was increased among people with RA who have type II DM (RR 1.94, 95% CI 1.58-2.30) (Baghdadi et al., 2015).

2.2.2 Non modifiable risk factors for cardiovascular disease

Non-modifiable risk factors can be defined as factors that increase the risk of mortality and morbidity from disease; however, they cannot be changed or controlled (World Heart Federation, 2017a). The non- modifiable risk factors for CVD are discussed below.

1 Age

The risk of developing heart disease increases with age in RA (Kaplan, 2010). Men aged over 45 years and women greater than 55 years are at risk of developing CVD in general population (del Rincon et al., 2001, Kremers et al., 2008).

2 Gender

There is an increased risk of developing CVD among men compared to pre-menopausal women in general population. However, women tend to develop CVD later in life than men (Peters et al., 2016). This is likely to be due to sex-specific biological factors, such as hormones and fat distribution, as well as behavioural, social and cultural factors related to risk behaviours, and gender disparities in access and usage of health services (Peters et al., 2016).

3 Family history of early heart disease

A family history of heart disease is considered one of the risk factors in increasing the risk of developing CVD in the general population (del Rincon et al., 2001, Kremers et al., 2008). A first-degree family history of CVD or stroke before the age of 55 years for men or 65 years for women increases the risk of CVD in the general population (World Heart Federation, 2017b).

4 Race

It has been noted that the risk of CVD is higher among African Americans diagnosed with RA (29.7%) than other connective tissue disease (CTD) (14.7%) (Alenghat, 2016).

The clinical manifestation of atherosclerosis is mainly CVD and coronary heart disease. The following are possible mechanisms that may explain the high prevalence of atherosclerosis in people with RA.

2.2.3 Possible mechanisms of atherosclerosis in rheumatoid arthritis

1 Chronic systemic inflammation on vascular endothelium

Inflammation in RA centres around the synovium which may play an indirect role through spill of inflammation mediators into the systemic circulation which can then interact with endothelial cells, altering their function and leading to atherosclerosis (Cooney et al., 2011). Inflammation in RA is associated with high concentrations of interleukin IL-1, IL-6 and tumor necrosis factor alpha (TNFα), two of the central cytokines resulting in high C reactive protein (CRP). The effects of these cytokines on endothelial cells may enhance the atherosclerotic process; increase their permeability, facilitating migration of inflammatory cells to vessel walls and up regulating inflammatory response to express adhesion molecules (del Rincon et al., 2001, Metsios et al., 2009, Pieringer and Pichler, 2011).

2 Atherogenic side effects of some anti-rheumatic medications

In addition, to the inflammatory phenomena, some anti-rheumatic treatment may play a role in predisposing individuals to atherosclerosis. For example, disease modifying anti-inflammatory drugs (DMARDs) such as Methotrexate (MTX) could lead to high plasma homocysteine (hyperhomocysteinemia) (van Ede et al., 2002), which is associated with atherothrombosis (Boers, 2000). However, studies by Nurmohamed (2009), Westlake et al. (2010) & Marks and Edwards (2012) demonstrate that MTX use is associated with a reduced risk of CVD morbidity and mortality in people with RA and may also reduce atherosclerosis. Glucocorticoids affect glucose metabolism and could contributed to the higher

prevalence of metabolic disorder in people with RA (Boyer et al., 2011). EULAR guidelines recommend the prescribing the lowest dose of glucocorticoids for the shortest duration (Peters et al., 2010).

However, the questionnaires in standard monitoring of people with RA (QUEST-RA) undertaken by Naranjo et al. (2008), which analysed data from 15 countries and 4363 participants demonstrated that even long-term use of medication such as sulfasalazine, leflunomide, and methotrexate is associated with a lower risk of CV disease among people with RA. The risk of CVD was reduced in people with RA treated with TNFα blocking agents, while controlling inflammation and decreasing risk of plaque formation (Solomon et al., 2013). However, the beneficial effects of the use of biological drugs such as anti-TNF-α therapy should be administered with caution in people who have been diagnosed with moderate or severe heart failure, as it could worsen the condition (Listing et al., 2008).

In addition, non-steroidal anti-inflammatory (NSAIDS) and cyclo-oxygenase inhibitors (COXIBS) are associated with a twofold increased risk of CV risk (especially myocardial infarction) (Nurmohamed, 2009, van Breukelen-van der Stoep et al., 2013).

Nevertheless, the findings of studies investigating the association between CV events and corticosteroid use are contradictory, since some studies have been unable to demonstrate an association between steroid use and CV mortality among people with RA (del Rincon et al., 2001). A systematic review carried out by Ruyssen-Witrand et al. (2011) included 1138 screened reports and 37 items of literature assessing the risk of CV in low dose corticosteroid (LDCs) to treat RA. LDCs were associated with major CV events in four studies out of six.

2.2.4 Pattern of CVD in patients with rheumatoid arthritis

Studies have suggested that the rate of myocardial infarction and stroke is doubled and the rate of sudden death increased in people with RA (Gonzalez et al., 2007, Kremers et al., 2008, Liao et al., 2015). The prevalence of ischemic heart disease (IHD) was higher among people with RA in comparison to healthy control (Gonzalez et al., 2007, Kremers et al., 2008, Liao et al., 2015).

In addition, the absolute risk of CV events such as myocardial infarction and heart failure among people with RA was found to be 49.5 per 1000 person-years and among non-RA was 31.7 per 1000 person-years in populations which were age and sex matched (Kremers et al., 2008). It has been reported that the CVD events in people with RA is higher in young adults and those without known have prior CVD events (Solomon et al., 2006).

People with RA who are physically inactive have a worse CVD profile than people with RA who are physically active (Metsios et al., 2009). European league against Rheumatism.(2009) recommended healthy lifestyle with promotion of PA among people with RA in order to reduce the risk of CVD and improve the health outcomes (Zegkos et al., 2016). The following section discusses physical activity, guidelines, benefits and its effects generally and in people with RA.

2.3 Physical activity (PA)

2.3.1 Definition of physical activity

Physical activity is defined as “any type of bodily movement produced by muscles that results in energy expenditure”(World Health Organization, 2015). Housework, gardening, walking, climbing stairs are examples of PA (Public Health England, 2016, Miles and British Nutrition Foundation, 2007). PA includes all body movement produced by skeletal muscles to improve functional ability, retain quality of life or slow deterioration of health (Plasqui, 2008). Exercise is a specific form of PA in that it is planned, structural and repetitive bodily movement, performed with the intention of acquiring fitness, such as swimming, and yoga (World Health Organization, 2015).

2.3.2 The benefits of physical activity in the general population and in people with rheumatoid arthritis

1 The benefits of physical activity in the general population

There is good evidence to show that PA plays an important role in improving health outcomes and reducing morbidity and mortality in the general population (Warburton et al., 2006). The UK physical activity guidelines (2011) demonstrate that PA is the key determinant for preventing and reducing the consequences of

non-communicable diseases. PA is important for reducing and preventing a number of conditions such as hypertension, diabetes, coronary heart disease, depression, hip fracture, cancers and all-cause mortality (Hamilton et al., 2008, Macera et al., 2003). Regular PA plays an important role in reducing the risk of hip fractures by up to 68%, depression 30%, CVD 35% and all causes of mortality 30% (Public Health England, 2016). PA is an essential component of a healthy life, and it also has a role in improving mental health and mood (Hamilton et al., 2008).

PA is characterized and described in terms of frequency, intensity and duration. Frequency is defined as the number of times an activity is performed in a given time frame (Hamilton et al., 2008, Macera et al., 2003). Duration refers to total amount of time which the activity is performed either accumulative or continuously over specified of time. Intensity is defined as that energy expenditure during specific activity and usually is measured in metabolic equivalents (METs) (Khoja et al., 2016). A study involving 77,782 participants followed up healthy women for 24 years in relation to their lifestyle including moderate, vigorous and low levels of PA, and showed that 1790 died from CVD and 4527 died from cancer; 47% to 62% of the deaths were correlated with being overweight, physically inactive and having an unhealthy diet (van Dam et al., 2008).

Moreau et al. (2001) demonstrated that over a 24-week walking programme, women who increased their step count by 4330 steps/day above baseline reduced their systolic blood pressure (SBP) by 11mmHg and body mass reduced by 1.3 kg. A study carried out by Teh et al. (2015) on healthy individuals found that SBP levels were negatively associated with PA levels ($P = 0.032$) but not diastolic blood pressure (DBP) levels. However, no dose response was found between PA and blood pressure. A reduction in SBP and DBP was seen at 12 weeks and 12 months in men in the intervention group in an RCT conducted by Hunt et al. (2014). The participants of Hunt et al.' study took part in a walking programme delivered as part of a healthy lifestyle programme at professional football clubs.

A RCT by Baker et al. (2008a), involved 16 healthy men and 63 women, the mean age was 49.2 years ± 8.8. The intervention group received a PA consultation and

a 12-week pedometer-based walking programme with no programme for the control group. The results demonstrated an increased step count in the intervention group from baseline (6802 ± 3212) to (9977 ± 4669) steps/day (46.7%) at 12 weeks (P<0 .001) and time spent in leisure walking (P=0.02). In addition, the weekday and weekend sedentary times were reduced, as measure by the self-reported method international physical activity questionnaires (IPAQ). However, no changes were noted in health outcome measures in either group. This could be due to intensity of walking being too low, or the duration of study (12 weeks) being insufficient for physiological changes to take place.

It revealed that PA plays an important role in improving CV profile. In studies by Loprinzi and Ramulu (2013) and Healy et al. (2015), a significant association was found between light-intensity PA, low inflammatory markers and blood glucose in adults with diabetes mellitus. A cross-sectional study of Teh et al. (2015) reported a significant dose response between blood glucose and PA (P= 0.04). Also, a large cohort study carried out in the United States among more than 70,000 healthy women aged 40-65 years reported that brisk walking and more vigorous exercise were associated with a 25% reduction in diabetes incidence (Hu et al., 1999).

2 The benefits of physical activity in people with rheumatoid arthritis

An increase in PA may be beneficial to those with RA, as previous evidence has revealed that people with RA are less active than the general population (Cooney et al., 2011, Esbensen et al., 2015). Increasing PA in those with RA may help with symptoms such as muscle weakness, poor mobility and physical function, without damaging the joints or exacerbating rheumatoid disease activity (Cooney et al., 2011). People with RA who are physically active have improved RA symptoms such as pain and fatigue, which conversely are considered the primary barriers to PA in RA sufferers (Veldhuijzen van Zanten et al., 2015).

A study by Khoja et al. (2016) on RA reported that very light, light and moderate intensity PA was significant associated with lower functional disability, SBP, DBP, and BMI, and improved insulin sensitivity and HDL (P < 0.05). A study done by Stavropoulos-Kalinoglou et al. (2013) reported that CVD was reduced in RA

cohorts who participated in programmes of 6 months of high intensity exercise. Another study showed a reduction in risk of CVD by 20-30% among women and men who engaged in high levels of leisure time PA, while moderate leisure time PA decreased CVD risk by 10-20% (Li and Siegrist, 2012). A review of RCTs by Metsios et al. (2009) demonstrated a reduced risk of developing CVD and improved functional capacity in RA cohorts who were physically active. Thus, physical activity may play a role in reducing CVD in people with RA; however, walking is a simple and inexpensive PA. There is a lack of studies that examine the effect of walking on CVD risk, therefore the WARA intervention was designed.

The most important factors for maintaining health and improving physical function in people with RA are aerobic physical exercise and muscle strength training, along with psychosocial factors (Tierney et al., 2012). Exercise whether aerobic or strengthening has positive effect on RA disease progress, range of motion, muscle mass quality of life and functional capacity (Plasqui, 2008). The combination of increased PA and effective medication may help to inhibit disease progression, improve quality of life and health outcomes (Metsios et al., 2011).

The benefits of PA were identified from both quantitative and qualitative studies that reported improvements in joint function, pain relief, a feeling of independence and taking control (van Zanten et al., 2015).

It was concluded that PA is important for improving arthritis symptoms and mental health, and reducing the risk of CVD. It was recommended that support was given to people with RA to overcome their PA barriers. Support from friends, family and health providers was found to be an important facilitator of PA, as was education about the importance and benefits of being physically active for people with RA (van Zanten et al., 2015).

2.3.3 Physical activity guidelines

According to the UK physical activity guidelines (2011), Public Health England (2016), Start active stay active (2011) it is recommended that adults (19 to 64 years) and older adults (65 years and more), undertake 150 minutes of moderate

intensity PA per week (equivalent to 2½ hours of moderately intense PA of 10 minutes bouts or more, which could be achieved with 30 minutes' exercise 5 days per week), for general health and to reduce the risk of cardio-metabolic disease. However, for older adults any amount of PA is better than none, and greater PA results in better physical and cognitive function. In addition, the physical activity guidelines recommended undertaking PA to improve muscle strength on at least two days of the week (UK physical activity guidelines, 2011). This is particularly important in the context of RA to help preserve muscle mass and function (Plasqui, 2008).

For adults a target of 10,000 steps per day has been widely adopted as a reasonable estimate of an appropriate level of daily activity (Hardeman et al., 2009). Studies reveal that 10,000 steps/day are associated with good health (Choi et al., 2007, Tudor-Locke and Bassett, 2004, Tudor-Locke and Rowe, 2012). Moderate intensity walking is approximately 1000 steps in 10 minutes i.e. a cadence of 100 steps/ minute (Harris et al., 2013). However, 10,000 steps per day may not be possible for older adults and people who have chronic conditions (Tudor-Locke and Bassett, 2004), therefore, any amount of PA is better than none (UK physical activity guidelines, 2011).

The 2015 update of the 2009 EULAR recommendations for CVD risk management (Nurmohamed, 2015)in inflammatory joint disease (IJD) recommended a healthy lifestyle for people with RA, with an emphasis on the benefits of a healthy diet, regular exercise and smoking cessation. To date, there is no evidence that exercise has any detrimental effects on people with RA and it should be encouraged in people with RA (Agca et al., 2016).

2.4 Habitual physical activity in rheumatoid arthritis

This section will present an overview of physical activity levels in people with RA. It will then present a critical appraisal of interventional studies aiming to increase PA in people with RA.

Many studies have been carried out to examine the level of PA in people with RA either objective, subjective or both. Observational data reports that over two-thirds of people with RA in the UK are physically inactive in comparison with the

healthy population (Cooney et al., 2011, Esbensen et al., 2015). It has been identified that RA has negative consequences on individual lives, both physically and psychologically, and exercise programmes for people with RA should include strengthening and stretching exercises, as well as exercises of moderate intensity (Cooney et al., 2011). When PA was encouraged in people with RA in the lowest quartile in terms of physical function, the highest physical improvements were noted (Feinglass et al., 2012).

A cross-sectional study used data from two RA cohorts collected from two research studies carried out at the University of Pittsburgh between 2007 and 2013. PA was measured using Sensewear Armband accelerometers (Khoja et al., 2016). Ninety-eight participants mean age 58 ± 9 years with disease duration ranging from 6 to 22 years were included in the study, 85% of which were female. Sedentary behaviour was defined as activities that needed up to 1 metabolic equivalents (METs); very light intensity represented activities that required between 1.1 and 1.9 METs, light intensity was activities between 2.0 and 2.9 METs, whereas moderate intensity represented activities ≥3.0 METs. Watching TV, reading, or working at a computer were examples of sedentary behaviour; washing dishes, cleaning windows, or folding laundry were the examples of very light intensity; lawn-mowing, vacuuming, and slow walking were examples of light intensity; and swimming, brisk walking, or playing golf were examples of moderate intensity (Khoja et al., 2016).

The results showed that 17% were physical active (as defined by ≥150 minutes/week of moderate PA in 10-minute bouts), and that the mean sedentary time across the cohort was 9.8 hours/day. Participants spent on average 3.5 hours/day engaged in very light PA, light PA 2.1 hours/day, and 35 minutes/day engaged in moderate PA. It concluded that people with RA were mainly active at light and very light intensities PA.

In addition, a cross-sectional study was conducted by Paul et al. (2014) involving 19 people with RA and 19 controls, matched in terms of age, sex and BMI. The mean age of RA group was 51 ± 12.5 years and the control group was 49.6 ± 12.5 years, the disease duration was 13.6 ± 9.3 years. PA monitoring was undertaken for five days using an activPAL™ device. It was demonstrated that people with RA exhibited significantly longer periods of sedentary behaviour than the control

group of community dwelling volunteers (P=0.029) with significantly lower levels of walking-related PA (6052 ± 1955 steps/day) compared with the control group (11,045 ± 4329 steps/day) (P< 0.001).

A cross-sectional study was carried out with 47 individuals with RA and a mean age 56.5 ± 7.0 years. The mean disease duration was 14.3 ± 8.4. PA was objectively measured by the Sensewear for 10 consecutive days. It was found that the average steps/day were (7151 ± 2637) (Piva et al., 2010). The average number of steps/day in Piva et al.'s study was higher than Paul et al.'s study. Although both studies were similar in the disease duration and age of the participants, the difference in the step results in both studies may be related to the cohort sample as Piva et al. only recruited women and also although both studies measured PA objectively, the activPAl™ is more accurate and valid than the Sensewear in assessing PA (Mahendran et al., 2016).

Furthermore, a case control study of 110 people with RA with disease duration 9.3 ±7.6 years and 440 age and sex matched controls used a self-reported PA frequency questionnaire to assess the energy expenditure of participants (Henchoz et al., 2012). Sedentariness was defined as spending less than 10% of total energy expenditure in moderate or high PA. People with RA had lower energy expenditure (2392kcal/day) compared with controls (2494 kcal/day) (P=0.003), resulting from engaging in less moderate-intensity PA (P=0.015). Sedentariness was also associated with poor clinical scores in RA (Henchoz et al., 2012). The result of Henchoz et al.'s study supported the findings of Khoja et al as discussed above. People with RA spend less time on moderate-intensity PA; however, the studies differed in their way of measuring PA as Khoja et al. assessed it with an objective measure and Henchoz et al used a subjective measure.

Additionally, although there was a difference in the mean disease duration of Wikstrom et al.'s study (less than 6 years) and Henchoz et al.'s study (up to 16.9 years) both studies measured PA subjectively and PA has been found to be lower in RA irrespective of the disease duration.

A review aimed to examine the PA level, energy expenditure and aerobic capacity of people with RA (Munsterman et al., 2012). The review included 12

studies, 10 cross-sectional studies and 2 cohort studies. PA levels were assessed with self-reported questionnaires, either the Paffenbarger questionnaire, modified versions of the Paffenbarger Questionnaire, or the Short Questionnaire to Assess Health Enhancing PA (SQUASH). Aerobic capacity was measured with VO_{2Max} and PA energy expenditure (PAEE) was also calculated. People with RA were less physically active compared with healthy people, and had significantly lower energy expenditure, lower aerobic capacity than the normative values and also they spent less time on vigorous PA than the healthy controls (Munsterman et al., 2012). Thus, people with RA were less physically active compared with the controls and promotion of PA in people with RA was recommended.

Despite the differences in methodology, sample size, disease duration and the outcome measures, all studies found that, compared to healthy controls, people with RA had lower levels of PA, whether in terms of taking few steps, lower energy expenditure, lower aerobic capacity or spend less time on moderate and vigorous intensity PA. People with RA therefore do not meet the PA guidelines (≥150 minutes/week of moderate PA) (UK physical activity guidelines, 2011) and the 2015 update of the 2009 EULAR recommendations of regular exercise and healthy lifestyle (Agca et al., 2016). Therefore, promoting PA in people with RA is recommended in order to improve health outcomes and to reduce the risk of comorbidity, particularly CVD (Cooney et al., 2011).

2.5 Physical activity/ Exercise interventions in rheumatoid arthritis

The following section reviews and describes the evidence for physical activity/ exercise interventions in people with RA. The review focuses on studies where the intervention mainly promotes PA and aerobic exercise, particularly walking and strengthening exercises, and where the primary outcome measure is PA. This review was not concerned with other types of exercises such as balance or flexibility exercises, or studies where the primary outcome measures are not physical activity, for example interventions that aim to manage the symptoms of RA. This review was undertaken to identify the effectiveness of PA/exercise in people with RA and also to highlight the limitations and evidence gaps in this area. The information from this review helped to inform the design of the present study.

2.5.1 Search strategy

A literature review provides the background and justification for the research and it allows a comparison of past research on PA/exercise for those with RA. In order to review literature regarding the effectiveness of PA programmes in people with RA on the primary outcome measure (PA behaviour), relevant research was identified by searching relevant databases for publications from 2006 through to 2017. The main search covered the most recent papers; however older papers of interest were also included. Relevant papers were also identified by reviewing the reference lists (Figure 2-5).

The key articles were obtained primarily from PubMed, Medline, Google Scholar, Cochrane Library, and Web Sciences. In order to ensure that relevant studies were not missed, the search terms remained broad. These were rheumatoid arthritis, physical activity, exercise, walking then these terms were combined with the Boolean operator AND “rheumatoid arthritis AND physical activity”, “rheumatoid arthritis AND exercise”, “rheumatoid arthritis AND walking”, “rheumatoid arthritis AND aerobic exercise”.

2.5.2 Inclusion and exclusion criteria in the literature review

To focus the literature review, only randomised clinical trials and controlled trials on PA-based interventions or exercise interventions were reviewed. Any studies that included balance or flexibility exercises were not included in this review. Full articles were retrieved for assessment to determine whether the abstract fulfilled the criteria, Figure 2-5 shows the prisma diagram. The following criteria were adopted for the exclusion of studies from this literature review: Any study involving people diagnosed with arthritis other than rheumatoid arthritis; however, if the study examined a mixed population where the data from the RA group was reported, it was not excluded.

Publications in other languages than English

Trials which were not randomised controlled trials or controlled trials

Primary outcome other than physical activity/exercise

Inaccessible/unpublished studies

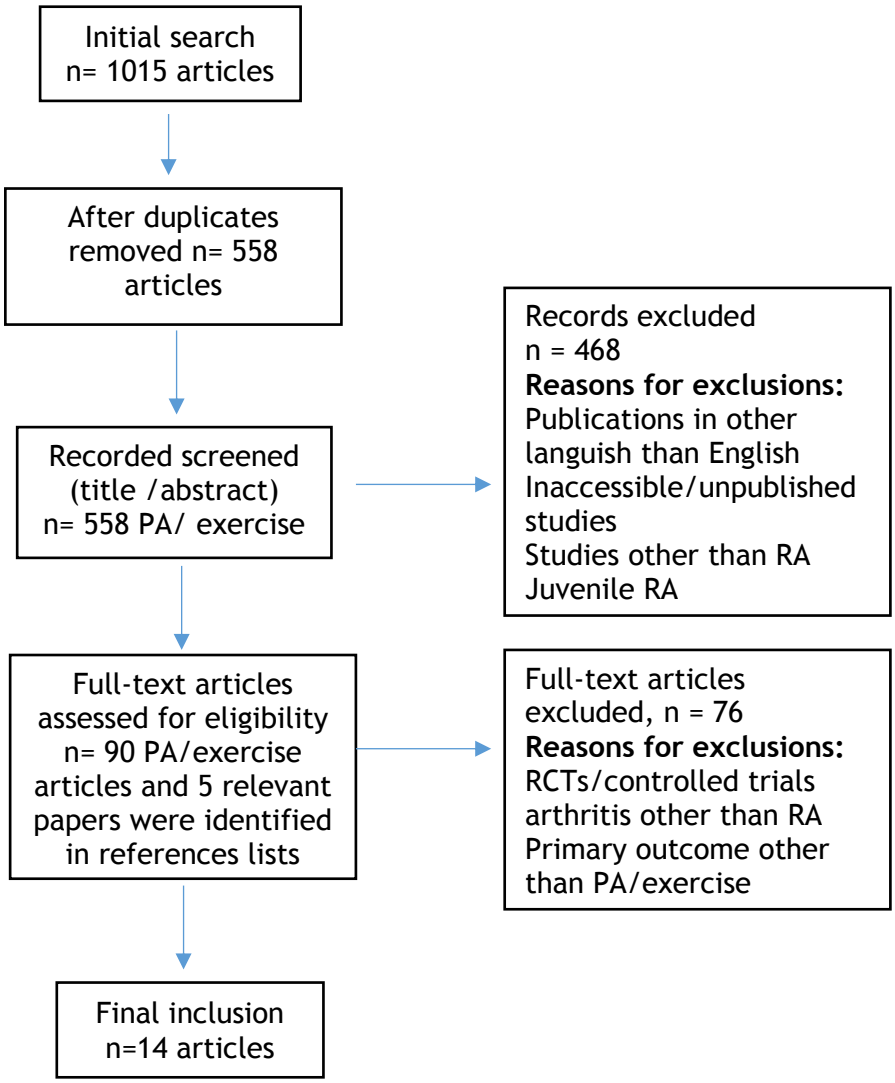

Figure 2-5 Prisma diagram of the literature seach
Adopted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7) (Moher et al., 2009)

Table 2-2 summarises the 14 articles included in this review. The review of previous studies helped to understand the role of PA/exercise intervention in terms of the health outcomes, the gap in the research and also the safety of exercise in people with RA. In addition, in order to understand the key methods, the contradictory findings between studies, their limitations and recommendations were also examined. This helped to design the study and justify the findings of this thesis. The following information was extracted from each article and is included in Table 2-2: study citation, study population, age, disease duration, intervention, outcome measures, results and limitations of the studies. Although the main searching the databases for publications was from

2006 through to 2017, one study of interest from 2001 was included. The studies were published between 2001 and 2017.

Table 2-2 Physical activity / Exercise intervention studies in rheumatoid arthritis

Author and design	Participants	Key methods	Outcome measure	Findings	Limitations
Hakkinen et al. (2001) RCT, 2yrs	70 RA patients Mean age: 49 ± 10yrs DD: <2yrs 62 completed the study	IG: Strength training with elastic band 2times/week also patients encouraged to perform PA such as walking, cycling, &swimming 2–3 times/ week for 30–45 minutes. IG minimally supervised at-home CG: ROM (without resistance) 2times/week Both groups completed diaries (bimonthly)	Assessed at 0,6,12,18 months Grip strength: dynamometer FC: HAQ DA: DA score Walk time: the number of seconds /30m	Improved Muscle strength in both groups IG=15-59% CG=1-31% Improved DA, HAQ and walking speed in IG No negative effect of exercise	The participants were low disease activity none of participants were treated with DMARDs
van den Berg et al. (2006) RCT, 12 months	160 RA patients Mean age: IG 49.5 ±12.9 yrs &CG 49.8±13.9yrs DD: IG 7.6yrs & CG 5.5yrs 152 completed the study	IG: Muscle strengthening, range of motion and cycling, 5 times/week on 5 days, also an online discussion forum &face-to-face group meetings were held every 3 months CG: Training delivered on a website without additional support	Assessed at 0, 3, 6, 9 and 12 months PA assessed with study questionnaire and with activity monitor (Actilog V3.0) Number of days participating in vigorous exercise for 20-minute HAQ, RAQoL &DAS28 was collected	Greater proportion of people in the IG were physically active than in the CG (38% v 22%) at 6 months increasing the number of days (at least 3 days) participating in vigorous intensity PA for 20 minutes in IG There were no	Using self-reported questionnaires were developed specifically for the study and not validated for sensitivity to change and construct validity

				significant differences between groups regarding HAQ, RAQoL or DAS28	
Neuberger et al. (2007) RCT, 12 weeks	310 RA patient Mean age: 55.5yrs 40-70yrs DD: not mentioned 220 completed the study	IG: Class exercise, home exercise using a videotape (Warm-up, low-impact aerobics, strengthening, and cool-down exercises) CG: Usual care	Assessed at 0, 6 & 12 weeks Grip strength: portable sphygmomanometer Walk time: the number of seconds 50 feet & $VO2_{max}$	Improved Grip strength, walk time, self-efficacy, and Self-efficacy influenced exercise participation, no negative effect of exercise	Convenience sample
Mayoux-Benhamou et al. (2008) RCT, 12 months	208 RA patients mean age: 54.7 ± 13.1yrs DD: 12.7 ± 9.8yrs 189 completed the study	IG: Education programme (8 weekly sessions, totalling 5 hours) including training on home-based exercises and guidelines for leisure PA CG: Usual care	Assessed at 0,6 &12 months Baecke questionnaire was used to compare PA at the baseline and follow-up	Increase adherence with PA (particularly leisure PA) at 6 months programmes but not 12 months	Most of the participants had a long disease duration and had received education before the programme
de Jong et al. (2009) RCT,2yrs	150 RA patients Aged:20-70yrs DD: 6yrs 118 completed the study	IG: Supervised high intensity exercise programme, 1.25hrs/session CG: Physical therapy (usual care)	Assessed at 0 ,6,12 &24 months Muscle strength with dynamometer DAS44, disability questionnaires	Participants in IG Increased muscle strength, physical fitness & function and reduce disease activity	Participants in the IG more motivated with better experience with exercise and physical function

Flint-Wagner et al. (2009) RCT, 16weeks	24 RA patients Mean age: NA DD: NA 24 completed the study	IG: Supervised exercise programme 3times/week CG: Usual care	Assessed at 0, 8 and16 weeks Muscle strength with dynamometer, VAS, HAQ & 50 feet walk time	Muscle strength improved, hand grip however reduced in CG, improved 50 feet walk time & HAQ & reduced in pain	Small sample size
Hurkmans et al. (2010) RCT, follow up study 24 months	152 RA patients Mean age: IG 49.5 ±12.9yrs & CG 49.8±13.9yrs DD: IG 7.6 & CG 5.5yrs 110 completed the study	IG: Individual guidance on PA through the website, a bicycle ergometer and also group contact CG: Received general information regarding PA by Email and the website	Assessed at 24 months The PA levels were investigated with two questionnaires HAQ & RAQoL was also assessed	More participants met the public health recommendation of moderate-intensity PA in the IG than CG at 24 months (19% and 24% retrospectively, P< 0.05), improved RAQoL in IG; no improvement in HAQ	Self-reported questionnaires, which might lead to under or overestimation Selection bias in the study as only people who had access to the internet were selected
Breedland et al. (2011) RCT, 9 weeks	34 RA patients Mean age:48 ±11.3yrs DD: IG 9.7& CG 5.9yrs 32 completed the study	IG: Supervised aerobic (cyclic, jogging) & strength exercise plus education sessions (joint pain, fatigue, disease activity, sleep disturbance, self-efficacy) 60 minutes/weekly session CG: Usual care	Assessed at 0,9,13 & 22 follow-up) weeks $VO2_{max}$, muscle strength, arthritis self-efficacy scale	Improvement of $VO2_{max}$, physical training with self-management education would increase physical performance, improved self-efficacy	Small sample size
Brodin et al. (2008)	228 RA patients	IG: Individual coaching by a physiotherapist	Assessed at regular medical check-ups	There was a significant	Convenience sample

RCT 12 months' data Sjoquist et al. (2011) RCT, 24 months	Mean age: IG 55±14.0yrs &CG 57±113.9yrs DD: IG 33±4.5 &CG 34±4.4 months 157 completed the study	during the first year with telephone support monthly for 12 months CG: Usual care	Self-reported PA questionnaires, visual analogue scale to assess pain, HAQ & DAS28	difference between groups in terms of PA after the one-year intervention (54% versus 44%) (P< 0.05), improvement in muscle strength No difference in VAS, HAQ&DAS28 at 24 months in both groups	
Dogu et al. (2013) RCT, 6weeks	52 female RA patients Aged:40-70yrs DD:6.51-10.65yrs 47 completed the study	IG 1: Supervised isotonic exercise IG2: Supervised isometric exercise	Assessed at 0 & 6 weeks Muscle strength with dynamometer VAS, DAS28, RAQoL	Both isotonic and isometric increased muscle strength, quality of life and reduce pain & disease activity	Short term study
Stavropoulos-Kalinoglou et al. (2013) RCT,6months	40 RA patients Mean age: 53.9±9.9yrs DD: 6.0 (4.0–10.0)yrs 36 completed the study	IG: Individualised aerobic and resistance high intensity exercise, 3times/week plus walk on treadmill, cycle and resistance training leg, shoulder & chest press. CG: Advice on exercise benefits and lifestyle changes	Assessed at 0,3 and 6 months IPAQ, $VO2_{max}$, DAS28, HAQ&CVD risk	Improved IPAQ, $VO2_{max}$, blood pressure, lipid profile, HAQ, DAS28 & reduce CVD risk	Convenience sample
Knittle et al. (2015).	78 RA patients	IG: 5-week motivation and behaviour	Assessed at 0,6 & 32 weeks	A significant interaction effect	PA was assessed with

RCT, 32 weeks	Mean age: IG60.7 ±11.9yrs &CG 64.7±11.5yrs DD: not mentioned 67 completed the study	programme combined with education session, one motivational interview and two self-regulation coaching sessions CG: Single education session about PA exercise	short questionnaire to assess health-enhancing PA and number of days participating in Self-efficacy assessed with an 18-item questionnaire from Badura, (2006); RA disease activity index and HAQ	between the IG&CG A significant increase in leisure time PA in IG by 84 minutes (P=0.022), also an increase in days/week of 30 minutes PA (P=0.016) and self-efficacy (P=0.001); no significant difference in HAQ or disease activity in either group	self-reported questionnaires only
Orlova et al. (2015) RCT,6 months	51 RA patients Aged:18-53yrs DD:2-17months 66.&% of IG1 completed study 57.1% of IG2 completed study	IG1: High-intensity dynamic exercises using gym apparatus at hospital. IG2: Muscle-strengthening at hospital, therapeutic exercises (45 min) under the supervision of a trainer CG: At outpatient exercises 3 times/week a week drug therapy	Assessed at 0,6 Average power of knee extension and ankle flexion, VAS, ESR, DAS28,HAQ	Efficacy of the intensive gym exercises was higher than the therapeutic exercises Improved VAS, HAQ	Young age participants, early stage of RA, participants with low disease activity
Seneca et al. (2015) RCT,12 weeks	51 RA patients Aged:23-79yrs DD: ≤ 5yrs	IG: Six-week supervised, progressive, high-intensity exercise	Assessed at 0, 6 &12 weeks $VO2_{max}$, DAS28, HAQ, muscle strength	No significant differences between groups in terms of muscle strength,	Small sample size with a number of dropout in

	36 completed the study	programme followed by a six-week self-administered exercise programme CG: A 12-week self-administered exercise programme. Both groups: Exercises 3times/week		physical fitness, pain or HAQ, there was a significant differences in DAS28 score	remission and early disease, short term study

IG= intervention group, CG= Control Group, RAQoL= Rheumatoid Arthritis Quality of Life, HAQ= Health Assessment Questionnaire, ROM=Range of Motion Exercise, yrs=years, m=meter, NA= Not Available, DD=Disease Duration, CRP= C - Reactive Protein, DA=Disease Activity, DAS= Disease Activity Score, VAS=Visual Analogy Scale, RCT= Randomised Clinical Trial, DMARD=Disease Modifying Anti-Rheumatic Drug.

Generally, sample size varied across the studies. Some studies had a small sample size, such as Flint-Wagner et al. (2009) with only 24 RA participants, whereas Neuberger et al. (2007) RA cohort numbered 310.

There were differences in population demographics. Some studies included younger participants, such as Orlova et al. (2015) where the participants were aged between 18 and 53 years old. The mean age of Hakkinen et al. (2001) study was 49 ± 10yrs, and in comparison other studies such as Seneca et al. (2015) included participants up to the age of 79 years.

There was also a different in disease duration between studies. For example, Orlova et al. (2015) included participants in the early stage of RA, less than 2 years from diagnosis, while others included participants with disease duration up to 22 years (Mayoux-Benhamou et al., 2008). Many different outcome measures have been used across the studies. For example, some studies measured PA with self-reported questionnaires developed specifically for the study, while others used standard questionnaires, making comparisons difficult.

The majority of the studies found improvement in PA regardless of the duration of the intervention or the intensity of the exercise. The level of description of the interventions varied throughout the studies, especially in terms of describing the type of exercise included. However, they all agree that exercise (aerobic/ strengthening exercise) is effective for people with RA.

Generally, all studies assessed the participants before and after the intervention and a few studies included follow-up after the period of the intervention (12 months follow-up). However, these studies had high loss to follow-up; for example, in Sjoquist et al. (2011) the loss to follow-up was 31% and in Hurkmans et al. (2010) it was 28%.

In general, the intervention was delivered face-to-face and in a few studies the intervention was delivered via the internet, as in van den Berg et al. (2006) and Hurkmans et al. (2010).

The majority of the studies were non-blinded RCTs, either assessor or participants or both, and this may increase the risk of bias in the results. Most

studies made a comparison between the intervention and usual care, with a few studies having an attentional control programme for the control group, such as a self-administered exercise programme. In the majority of studies, the interventions/exercise programmes were done under supervision, and the programmes consisted of different types of exercise such as strengthening, stretching and aerobic exercises. Therefore, it is difficult to identify the particular type and intensity of exercise that helps to improve the PA outcome. And also the programmes were delivered to people with RA at different stages of disease and disability.

Almost all of the studies that included strengthening exercises in their intervention showed an improvement in muscle strength and hand grip. A few studies reported improvement in disease activity; however these studies had a small sample size and included early RA patients (Seneca et al., 2015).

A few studies demonstrated improvement in functional capacity (HAQ). They were studies where the examined cohort was in the early stage of RA and had low disease activity (Hakkinen et al., 2001) or the programme was supervised with intensive intervention and the participants were young, aged between 18 and 53 years old (Orlova et al., 2015). It seems that PA programmes for people with early RA (less than 2 years' duration) were more effective in improving functional capacity.

Whilst there are a number of studies on the efficacy and effectiveness of exercise (resistance, stretching and strengthening exercises) among those with RA, and a number of internet-based interventions, there was a lack of group education sessions based on behaviour change theory and BCT. Although the effectiveness of walking has been revealed and recommended by PA guidelines, there is a lack of studies where the intervention was based mainly on a walking programme.

From the 14 studies summarised in Table 2-2, seven studies aimed to promote PA in people with RA using mainly physical activity and aerobic exercise, particularly walking/strengthening exercises. These are discussed in detail in the following section.

2.5.3 Physical activity interventions in rheumatoid arthritis

Physical activity includes all body movement that results in energy expenditure such as housework, gardening and walking (Plasqui, 2008). It is important to improve functional capacity and health and wellbeing in people with RA (Cooney et al., 2011).

Exercise is a key modifiable factor which may be undertaken alone or in combination with other lifestyle changes, to help reduce the risk of a number of chronic diseases, such as CVD (From et al., 2013). There are many different types of exercise, such as aerobic including walking, strengthening or stretching exercises. The most appropriate PA for RA joints is aerobic exercise such as walking. It can enhance cartilage integrity and joint lubrication, increase range of motion and flexibility in people suffering from RA (Cooney et al., 2011, Pal et al., 2009).

Walking is a perfect PA for the general population, as well as people with RA. It is popular, convenient for all ages, requires no specialist skills and has little risk of injury (Baxter et al., 2016, Kassavou et al., 2013, Ogilvie et al., 2007). Walking can prevent premature mortality and contributes to a healthy lifestyle as well as good quality of life in people with RA (Tudor-Locke and Rowe, 2012).

A randomised control trial was carried out by Baxter et al. (2016) involving 33 RA patients and 22 control individuals. The intervention group had instructions on a walking route and had to complete the walking circuit three or four times per week, while the control group undertook a nutrition education session. The intervention group showed improvements in their self-efficacy for PA and wellbeing and experienced less pain symptoms compared with the control group; as such, it was recommended that walking appeared to be safe, feasible and acceptable for people with RA (Baxter et al., 2016).

Additionally, strengthening exercises can improve the strength of connective tissues and increase tendon stiffness (Cooney et al., 2011, Pal et al., 2009). Metsios et al. (2008) reported that the combination of aerobic and strengthening exercises has been used in an RA exercise regimen to achieve effective outcomes.

Strengthening exercise is a type of physical exercise that requires the use of resistance to induce muscle contraction (Gois et al., 2014). While, stretching exercise involves slow and controlled movements through a range of muscle and joint motion in order to enhance and maintain range of motion (Page, 2012).

The following sections discuss seven studies on PA/aerobic exercise in detail. An intervention targeting PA in people with RA was undertaken by Mayoux-Benhamou et al. (2008). The study investigated the effect of education on the exercise habits of people with RA. The intervention consisted of an education programme (8 weekly sessions, totalling 5 hours) including training on home-based exercises and guidelines for leisure PA. The content of the first 4 sessions was information about RA and its medical management. The other 4 sessions discussed the PA programme. These sessions aimed to enhance the positive attitudes and beliefs related to PA, and they were conducted by health professionals. Also, discussed in the sessions were individual physical and psychological barriers to PA, and instruction for the participants on how to incorporate moderate intensity PA into their daily lives. All of the participants received a booklet about the home-based exercise programme and leisure PA recommendations.

Two hundred and eight participants were followed up after 6 and 12 months. The adherence with leisure PA was defined by whether the leisure PA increased by 20% or more above their baseline. The Baecke questionnaire score was used to assess PA. The paper suggested that education programmes for people with RA may increase adherence with PA (particularly leisure PA) (Mayoux-Benhamou et al., 2008).

A multicentre RCT investigated the effectiveness of an internet-based PA intervention for people with RA (van den Berg et al., 2006). A sample of 160 participants was randomised into an intervention group (IG) (n=82) and a control group (CG) (n=78). The disease duration of the IG was 7.6 years and CG was 5.5 years. The IG programme was an individual weekly schedule with feedback from a physiotherapist through a website PA programme. Both groups were eligible to participant in the study if they had a computer with Internet facilities and they were able to cycle on a bicycle ergometer.

The programme consisted of muscle strengthening exercise, range of motion exercises and cycling exercises, 5 times/week on 5 days. The exercises were performed in sitting, standing and lying positions in 3 sets of 10 repetitions per set; for some exercises, an elastic band was used. Also, there was an online discussion forum that enabled the participants to discuss the PA programme with other participants. Additionally, face-to-face group meetings were held every 3 months for a year. The CG programme was training delivered on a website without additional support. The intervention (training group) was given individual guidance on PA through the website, a bicycle ergometer and also group contact. The control group received general information regarding PA by Email and the website. The participants were assessed at baseline, and at 3, 6, 9 and 12 months. The PA level, the primary outcome measure, was measured with a questionnaire developed specifically for the study. The participants were asked regarding the days participating in moderate and vigorous intensity PA in order to identify the proportion of participants who were meeting the Dutch public health recommendations for PA. The secondary outcome measure was objectively measured PA, which involved an activity monitor (Actilog V3.0) worn around the ankle for 5 consecutive days, assessing the number of days spent participating in vigorous exercise for 20 minutes.

Functional capacity was assessed with the HAQ, RA quality of life was assessed with RA quality of life questionnaire (RAQoL) and disease activity measured with the DAS28. The main finding was that a greater proportion of people in the IG were physically active people than in the CG (38% versus 22%) ($P< 0.05$) at 6 months and 35% versus 11% respectively ($P< 0.05$) at 9 months. Significant differences in PA were observed between the IG and the CG with the IG increasing the number of days participating in vigorous intensity PA for 20 minutes compared to the CG. There were no significant differences between groups regarding HAQ, quality of life or disease activity. However, the questionnaires were not validated for sensitivity to change and construct validity, which could lead to bias in the results. Also, the study did not utilise specific health behaviour change theory, despite including goal setting and social support (van den Berg et al., 2006).

The 24 months follow data of van den Berg et al. (2006) was reported by Hurkmans et al. (2010). Of 152 participants who completed the 1-year internet based PA intervention, 110 participants were available at follow-up study at 24 months. The PA levels were investigated with two questions according to public health recommendations of PA 30 min for at least 5 days/week; or vigorous physical activity, 20 min for at least 3 days/week. The first question asked how many days/week people performed moderate PA, which was defined as PA that causes a small increase in heart rate or breathing, such as gardening or brisk walking, in the past 3 months. The second question was how many days/week they performed vigorous PA, which was defined as exercise causing a large increase in heart rate or breathing, such as running, in the past 3 months.

Functional capacity was also assessed at 24 months with the HAQ and quality of life with the RAQoL questionnaire. The number of participants who met the public health recommendation of moderate-intensity PA was significantly higher in the intervention group at 24 months compared with the control ($P< 0.05$). Only RAQoL was significantly improved at 24 months in the intervention group; no improvement in functional capacity (HAQ) was noted in either group. The study concluded that both general and individual internet-based PA programmes were effective for increasing moderate PA intensity up to 12 months' post-intervention in people with RA. However, the study used self-reported questionnaires, which might lead to under or overestimation of PA levels, and there was no description of the behaviour change theory underpinning the development and delivery of the intervention, or if they used such theory. Therefore, it is difficult to explain and understand the success of the study. In addition, there was the potential for selection bias in the study as only people who had access to the internet were selected; those people may have higher levels of self-efficacy to perform exercise. As a result, those participants may have better self-management skills and therefore need less face-to-face contact (Hurkmans et al., 2010).

A multicentre RCT was carried out in Sweden over 24 months. It involved 228 participants, with an intervention group (n=94) and control group (n=134) with early RA (within 2 years of diagnosis) (Sjoquist et al., 2011). The intervention consisted of individual coaching by a physiotherapist during the first year in

order to adopt health-enhancing PA levels (defined as 30 minutes/day of moderate intensity PA more than 4 days/week) with telephone support monthly for 12 months. This was followed by no coaching during the subsequent year. The participants were assessed with self-reported PA questionnaires, visual analogue scale to assess pain, HAQ and DAS28. It was reported that 69% of the participants in the intervention group and 69% of those in the control group completed the study (2 years). There was a significant difference between groups in terms of PA at the baseline (the intervention group 47% versus the control group 51%) and after the one-year intervention (the intervention group 54% versus the control group 44%) ($P< 0.05$).

There was also an improvement in the intervention group in muscle strength, measured by the timed stand test ($P< 0.001$) and hand grip strength ($P=0.03$),12 months data published by Brodin et al. (2008). Despite the observed different pattern in PA behaviour in both groups, there was no significant difference between groups in any measurement at the end of the second year of the study (Sjoquist et al., 2011). The sampling method used was convenience sampling, and the questionnaire used to assess PA was developed specifically for the study and validated. The programme may have been unable to cause long-term behaviour change because important behavioural elements that facilitate the maintenance of PA behaviour, such as enhancing self-efficacy, or behaviour theory such as SCT were not included.

An RCT evaluated motivation and behaviour change in a 5-week programme of combined education sessions, one motivational interview and two self-regulation coaching sessions in people with RA (Knittle et al 2015). Seventy-eight participants were randomised into an intervention group (n=38) and a control group (n=40) (Knittle et al., 2015). In the first week, both groups received a small group education session led by a physiotherapist. The education session topic was the importance of PA for people with RA and the recommended guidelines for PA. Also, the participants were motivated to choose PA, to start with comfortable intensity and duration of activity and then to increase it gradually. The participants were provided with a list of exercises suitable for people with arthritis. The control group received no further intervention. The intervention received a workbook developed for study of exercise instructions. In

weeks 2 and 3, the intervention group received a one-to-one motivational interview carried out by a physiotherapist for 45 minutes, discussing PA long-term goals and PA lifestyle. At the end of the interview, PA diaries were given out. In weeks 4 and 5, one-to-one sessions were carried out lasting 40 to 60 minutes by a rheumatology nurse. In order to enhance the intervention, the participants were advised to follow the structure of the workbook and their PA diaries were reviewed. The participants received feedback on their progress, set a PA goal, engaged in action planning, identifying PA barriers and how to overcome them, all encouraged by social support.

The main outcome was health-enhancing PA measured with a short questionnaire, and the number of days per week they were involved in leisure time PA for at least 30 minutes at moderate intensity PA was recorded. Self-efficacy was assessed with an18-item questionnaire from Badura, (2006); disease activity was assessed with the RA disease activity index and functional capacity with the HAQ. All outcomes were assessed at 6 weeks and at follow-up, 32 weeks after the baseline. Over the 32 weeks of the study, there was a significant interaction effect between the intervention and control groups. In the intervention group there was a significant increase in leisure time PA by 84 minutes (P=0.022), also an increase in days/week of 30 minutes PA (P=0.016) and self-efficacy (P=0.001); however, there was no significant difference in HAQ or disease activity in either group. Although the programme successfully increased PA in the target population, PA was assessed with self-reported questionnaires only and also the programme consisted of multiple components, so it is difficult to isolate the component that led to the change of PA behaviour (Knittle et al., 2015).

An RCT carried out by Stavropoulos-Kalinoglou et al. (2013) included 40 RA patients with a mean age of 53.9±9.9 years. The disease duration ranged from 4.0 to 10.0 years. The participants were randomly allocated to the intervention or control group. The intervention group had a programme consisting of individualised aerobic exercise. They were asked to perform 3-4 different exercises such as walking on a treadmill and cycling for 3-4 minutes; each session was 50-60 minutes including 10 minutes warm up and 5-10 minutes cool down. This programme was for the first 3 months and thereafter some resistance

training was added such as leg press, shoulder press, chest press and pull ups. They were required to complete three sets of 12–15 repetitions during each exercise session. The control group received advice on exercise benefits and lifestyle changes. The participants were assessed at baseline, 3 and 6 months. The outcome measures were PA assessed with self-reported questionnaire (IPAQ), and aerobic capacity assessed with $VO2_{max}$. Disease activity was measured with DAS28, functional capacity with HAQ, blood pressure was measured and total and high density lipoprotein (HDL) cholesterol was evaluated. The 10-year CVD event probability was established using the Heart Score programme (http://www.heartscore.org) of the European Society of Cardiology. The results showed improved physical activity, aerobic capacity ($VO2_{max}$) and also systolic and diastolic blood pressure. Additionally, lipid profile, HAQ, DAS28 & CVD risk were improved (Stavropoulos-Kalinoglou et al., 2013). However, the intervention was intensive, and the sample was small (40 participants), 36 completed the study.

Another study included 34 RA patients with a mean age of 48±11.3 years (Breedland et al., 2011). The mean disease duration was 7 years. The study was an RCT which aimed to evaluate the effect of group-based education and an exercise programme on physical aerobic capacity. The outcome assessor was blinded to the group allocation of the participants. The participants were randomly divided into a control group and an intervention group where the intervention consisted of a supervised physical exercise programme in order to improve aerobic capacity and muscle strength, plus an educational programme. The supervised aerobic exercise was muscle exercise circuit, cyclic and aqua jogging for 3 hours per week on 2 separate days. Strengthening exercises were done in a circuit which included leg press, leg extension, leg curl, rowing, chest press and abdominal trainer. Each training session consisted of 3 sets of 20 contractions. The education sessions were lasted 60 minutes a week and covered joint pain, fatigue, disease activity, sleep disturbance and self-efficacy.

The participants were assessed at baseline, 9, 13 & 22 weeks. Aerobic capacity was assessed with $VO2_{max}$, muscle strength was assessed by hand grip strength and the self-reported health status of the participants was assessed using the Dutch version of the Arthritis Impact Measurement Scales-2. The control group

was usual care. The results showed a significant improvement of aerobic capacity in the intervention group (12.1%) however the control group declined (-1.7%). Although there were significant changes within the groups in terms of muscle strength and health status, no difference was noted between groups regarding these outcomes (Breedland et al., 2011). However, the study sample was small and also the programme was supervised and intensive.

Although the success of the aforementioned studies in increasing PA levels was evident, the PA outcome was measured by self-reported questionnaires. Only the study of van den Berg et al. (2006) used an objective measure (Actilog V3.0), and this was as a secondary outcome measure. However, the current study assessed PA using both objective and subjective methods, whilst also being built upon behaviour change theory and behaviour change techniques.

There were differences in the duration of the interventions and programmes; some studies had programmes of 6 -12 months, and in these the loss during follow-up was lower, e.g. Stavropoulos-Kalinoglou et al. (2013) where loss during follow-up was 10% and van den Berg et al. (2006) were loss during follow-up was 5%. However, in other studies with follow-up of 24 months, such as Hurkmans et al. (2010), loss during follow-up was 27.6%.

The intervention in some studies was intensive and under supervision and these studies were able to improve the lipid profile and HAQ, and reduce CVD, as in Stavropoulos-Kalinoglou et al. (2013). However, no behavioural theory or behavioural change techniques were included. This means that it is difficult to understand the results and also it is unclear whether these studies were able to motivate people and maintain their PA levels after the intervention.

Only the follow-up study of Hurkmans et al. (2010) reported improving the quality of life of people with RA at 24 months. This may be explained by the fact that the people who were motivated and physically active completed the 24-month assessment or it may be related to other factors such as disease activity controlled by treatment or pain and fatigue further study is needed. None of the other studies showed any improvement in RAQoL.

2.5.4 Summary

There is growing body of literature regarding physical activity/exercise in RA and this has been discussed in relation to aerobic, strengthening, stretching or combined exercises. The literature varied in methodology and quality and it has been summarised in Table 2-2. Overall, all of the studies were able to improve PA levels and also muscle strength if they included strengthening exercises. None of the studies reported injuries related to exercise or PA.

Physical activity and exercise has been found to be beneficial for people with RA; however, there is a need for further research to evaluate:

The effect of aerobic exercise, particularly walking, on RA. Walking is simple, inexpensive and feasible for all ages.

To assess physical activity as a primary outcome measure with both subjective and objective measures. This will allow an assessment of the actual activity and the context of this activity.

To assess the effectiveness of group education sessions based on behavioural change theory and behavioural change techniques on RA outcomes.

To examine the effectiveness of a walking programme and education sessions on RA disease and comorbidities such as CVD risk.

To improve research methodology used in studies of PA in RA in order to reduce the risk of bias.

Therefore, the WARA intervention was designed based on the limitations and the gaps in the evidence in this area.

To promote PA effectively, the evidence suggested the use of some devices such as pedometers. The following section presents the evidence for pedometer-supported walking programmes in healthy people and those with RA.

2.6 Walking based pedometer support programme

A pedometer is small device which may provide information about the number of steps taken, time spent walking and distance covered (Fitzsimons et al., 2008). Pedometers have been widely used in the assessment and promotion of PA in clinical studies (Mansi et al., 2013). Studies suggest that pedometers can promote walking effectively with a significant association between increase in PA and pedometer use (Fitzsimons et al., 2008, Pal et al., 2009). Studies have demonstrated that interventions using pedometers that provide feedback to users and assist in self-monitoring PA behaviour are one of the most effective approaches that can be used to increase PA (Baker et al., 2008a, Mansi et al., 2013, Pal et al., 2009). Studies by Bravata et al. (2007) and Pal et al. (2009) concluded that the immediate feedback from a pedometer and the use of step goals, can lead to a significant improvement in PA levels among obese women.

The study, Walking for Wellbeing in the West, demonstrated that pedometer based walking for 12 weeks with PA consultation is an effective way to increase walking and encourage and motivate people who do not meeting the current PA recommendation (Baker et al., 2008a). A systematic review demonstrated that the use of a pedometer can increase PA level by 27% and daily step count by 2000-3000 steps (Tudor-Locke et al., 2011b).

A pilot study by Stovitz et al. (2005) included 94 participants from a family medicine clinic and aimed to investigate the role of the pedometer in physician counselling that may help patients to increase their ambulatory activity. The participants were assigned to two groups; both groups received a brief physician endorsement of regular PA, education material on the benefits of a healthy lifestyle, three contacts with a health educator. However, the intervention group received a pedometer, were instructed how to use it and were asked to record their step count daily over the 9-weeks of the study. The mean step count in the intervention group increased from (6779 steps/day) at baseline to (8855 steps/day) at 9 weeks (pedometer step count was assessed for the intervention group only).

A 16 week pedometer-based workplace intervention was carried out with 154 employees at two work places (Baghianimoghaddam et al., 2016). The

participants were instructed to wear a pedometer and were told how to use the pedometer and the PA log. The participants submitted weekly logs to the researcher. Participants in the intervention workplace were encouraged to develop teams, and each team was motivated to complete at least 30 minutes of continuous, brisk walking every workday. They were given a map of walks around the campus and instructions on how to increase PA throughout the intervention phase. The instructions included increasing their step count by 500 steps/week, and training to overcome their PA barriers. Furthermore, the participants were told about the role of social support. They were advised to use the staircase instead of the lift, to use their break times to walk, and to parking their cars farther away from the building.

Pedometer-based and self-reported PA using the IPAQ from one work place (intervention) was compared with another work place (control group). A significant improvement was observed in step count from baseline to 16 weeks among the intervention group (8279 ± 2759 steps/day) compared with the control group (4118 ± 1136 steps/day). A significant increase in the leisure time PA was reported by women in the intervention group but not in the control group (Baghianimoghaddam et al., 2016).

A systematic review was carried out of 14 RCTs examined the effect of PA intervention on objectively measured PA using accelerometers or pedometers in people with chronic musculoskeletal pain, such as osteoarthritis and low back pain (Oliveira et al., 2016). It found no significant difference between the intervention groups and those with no or minimal intervention in objectively-measured PA in short-term (≤3 months), intermediate (>3 months and <12 months), and long-term (≥12 months) (Oliveira et al., 2016). The sample size of the included trials ranged from 38 to 293 participants. Interventions to promote PA varied across the trials, and included a cognitive-behavioural PA intervention, a web-based PA intervention programme, a pedometer-based walking programme, general exercise group classes and therapeutic exercises. Education/advice was the type of comparator most commonly used, followed by self-management. Five trials used accelerometers to assess PA, 2 trials used pedometers and 1 trial used both. The PA measures used as outcomes were step

count, time spent in various intensities of PA, and total vector magnitude (counts) (Oliveira et al., 2016).

The authors suggested that future research is warranted to clarify whether inactive people with chronic musculoskeletal pain respond better to PA interventions than more active people. The included studies had limitations such as combined study populations and also the use of a variety of outcome measures to asses PA e.g. pedometers or accelerometers. The authors recommended that future trials should investigate the long-term effects of PA interventions in people with chronic musculoskeletal pain. They also recommended that dropout rates and the blinding of the assessor should be considered in future studies (Oliveira et al., 2016).

A weakness of the available literature is the use of different data-processing techniques, as well as the variability of outcomes reported. No behaviour theories were mentioned in any of the trials included and this could explain the reason for their failure to promote PA in the target population (Oliveira et al., 2016).

Although a number of studies evaluated pedometer-supported programmes in healthy individuals, only one study conducted by Katz et al. (2015), published as an abstract, used a pedometer with people with RA. Ninety-six participants were included in the study; the mean age was 54 ±13 years, and 88% were female. The disease duration was 14 ±13 years (Katz et al., 2015). The participants completed baseline questionnaires and received activity-monitoring devices which were used to gather baseline PA data over one week. After one week, the participants were randomised into an education group or a control group. The latter only received education regarding PA.

The intervention group either received a pedometer and step diary, or pedometer, step diary, and step targets. The step target was based on the step count of the baseline value with the goal of increasing 10% every two weeks. The intervention groups received phone calls every two weeks to collect step diary information. The participants were assessed at week 10 (by phone) and week 21 (in person). The study by Katz et al. showed a positive change in step count from the baseline to 21 weeks (2132 ± 2698 steps/day) by 92% ± 125 in the

intervention group, who used a pedometer and PA diary. When a step target was included in addition to the pedometer and diary, the step count increased by (1299 ± 2389 steps/day) (P=0.02) by 188% ± 506. In the control group, the step count increased by (-327 ± 2429 steps/day) (P=0.53) by 3% ± 56 (Katz et al., 2015). The result suggests that prescribing pedometers to people with RA can be effective in promoting PA and adding a step target is actually less beneficial than using a pedometer and PA diary (Katz et al., 2015). No other study evaluated pedometer-supported programmes in people with RA.

As a result of the increase in use of pedometers and through research aimed to motivate PA, Tudor-Locke et al. (2004) evaluated the popular health recommendation of 10,000 steps/day, as well as the available evidence regarding pedometer-based indices. It has been reported that 10,000 steps/day is a reasonable estimate of daily PA, providing health benefits among healthy individuals. However, there was some evidence to suggest that this value was not suitable for some groups, such as old people and people who have chronic conditions. In addition, there was concern about the use of 10,000 steps/day as a universal goal as it is considered low for children and also as a target against obesity. There was some evidence demonstrating the health benefits relating to incremental improvement in baseline value.

People who were involved in daily physical activity which totalled less than 500 steps/day were considered as having a sedentary lifestyle (Tudor-Locke et al., 2004). While, people who performed more than 10,000 steps/day were classified as having an active lifestyle. Tudor-Locke et al. (2004) has classified pedometer-determined PA in healthy adults, as shown in Table 2-3.

Table 2-3 Classify pedometer-determined physical activity in healthy adult

Steps/day	Activity index
<5000	Sedentary lifestyle
5000-7499	Low active
7500-9999	Somewhat active
≥10,000	Active
>12,500	Highly active

Adapted from how many steps are enough (Tudor-Locke et al., 2004).

Based on the aforementioned evidence on the role of pedometers in self-monitoring and feedback, showing that they encourage and motivate PA behaviour, the pedometer was chosen for self-monitoring of PA as part of the intervention in the current study. The pedometer-supported walking with a weekly goal will be discussed in (Section 3.8.2).

2.7 Qualitative studies on facilitators and barriers of physical activity in rheumatoid arthritis

Qualitative research methods include interviews and focus groups, and allow a wider interpretation and in-depth examination of the barriers and facilitators of PA in people with RA.

A study by Withall et al. (2016) conducted focus groups with people with RA: 15 females and 4 males with a mean age of 59.9 ± 10.3 years and mean disease duration of 44 ±34 months. They identified that group-based education as part of a PA programme supported by health care workers positively influenced the recruitment and adherence to the programme as it facilitated social support from other members of the group and motivated them. Withall et al found a PA programme which consisted of 5 education sessions over 12 weeks (4 group sessions and 1 individual session with guided exercise) was acceptable. The findings of the focus group suggested that the participants would have preferred a less intense programme with less contact and more flexibility. While, a programme of 6 months' duration with twice-weekly education sessions for six weeks was considered to be a significant commitment for participants.

People with RA have a fear that exercise may worsen their condition, and also that pain and RA disease activity are main barriers to PA in people with RA (Withall et al., 2016).The majority of people with early RA who participated in a focus group requested group education with information regarding RA, along with discussions and sharing thoughts with other people with RA (Withall et al., 2016).Therefore, the education of people with RA regarding the benefits of PA on disease activity, functional capacity and cardiovascular health is recommended.

A qualitative study examined the experience of an exercise programme which aimed to maintain physical ability in people with RA. Semi-structured interviews were carried out with 16 physically active people with RA with a mean age of 50 years and average disease duration of 21 years. It demonstrated that PA maintenance in people with RA was understood as meaning resisting disability and taking responsibility for their life, health and wellbeing (Loeppenthin et al., 2014).

A focus group conducted by Crowley and Kennedy (2009) involving 12 people with RA found that the factors that enhanced adherence to exercise include disease activity (remission), and environmental (social support) and personal factors (individual motivation). It reported that people with RA preferred the exercise sessions to take place on common ground (a comfortable place that is available to people with good transportation and facilities) and people with RA liked to receive exercise instructions. It identified pain and fatigue as barriers to exercise but also identified fear of falling and the psychological effects of RA as other barriers to PA (Crowley and Kennedy, 2009).

Eight females with RA undertook semi structured interviews via telephone in order to examine the perceived barriers and attitudes to PA among women with RA. Fear for safety and fear of unknown and social support were the main barriers to PA. Walking 3-4 times/week was reported as an acceptable programme for people with RA (Baxter et al., 2015).

Ten women and 5 men aged 23 to 73 years with RA disease duration from 4 -27 years were interviewed with a semi-structured interview technique in their homes, in order to discover how people with RA describe their sedentary behaviour (Thomsen et al., 2015). Content analysis was used to analyse the data. People with RA mentioned that during a flare-up of the disease they spent a lot of time being sedentary and that also they cancelled social activities as a result of fatigue. They found a day of having pain isolating. They also said that RA forced them to sit, and that they had more sitting breaks between day-to-day activities. It was concluded that people with RA see pain and fatigue as barriers to their mobility, and that also personal and social factors lead them to spend more time sitting down (Thomsen et al., 2015).

A review of qualitative studies done by van Zanten et al. (2015) regarding the barriers, facilitators and benefits of PA in people with RA found 453 articles; however only 26 studies, quantitative and qualitative, fulfilled the inclusion criteria of the study. It was found that there was a lack of knowledge regarding the amount and type of exercise and PA suitable for people with RA. Also, there was a fear of PA aggravating their condition. Pain and fatigue were identified as the barriers to PA, plus a lack of advice from health care providers regarding PA. The most effective facilitators were identified as support from instructors and health care providers, and social support for PA. Conversely, the lack of this support was reported as a barrier.

In addition, knowledge and awareness regarding CVD can influence a patient's choice in adopting a healthy lifestyle behaviour including PA (Koniak-Griffin and Brecht, 2015). A study interviewed 10 people with RA, ranging from 23-81 years of age 70% of whom were female, in order to evaluate CVD preventive care (lipid testing and hypertension diagnosis) including promotion of healthy lifestyle (Bartels et al., 2013). Almost all of the participants were not aware of the increased risk of CVD in people with RA. In addition, the majority of the participants who were interviewed reported that they received no consistent CVD preventive care. It is recommended that rheumatologists should consider interventions to overcome the CVD preventive care gap in clinics.

Thus, the majority of the studies suggested that physically active people with RA might not be different from inactive people with RA in terms of their perceived barriers to PA, but that PA interventions are able to help physically active people to manage or overcome these barriers more effectively than inactive people.

Although the studies varied in their ways of collecting data (some used focus groups and others semi-structured interviews) fear of PA aggravating their condition, pain and fatigue seems to be the most common PA barrier of people with RA. In addition, group-based education sessions and social support appeared to be the most important facilitators of PA programmes in people with RA.

UK physical activity guidelines (2011), Start active stay active (2011) not only recommended an increase in PA, but also emphasise that adults should reduce the time spent being sedentary. The following is a discussion of sedentary behaviour in general and in people with RA.

2.8 Sedentary behaviour

2.8.1 Definition of sedentary behaviour

Sedentary behaviour is defined as the amount of time spent sitting or lying down and includes behaviours such as viewing TV, other screen- time behaviour (computer, video), being a passenger in a car or other forms of transport (Ford and Caspersen, 2012, Khoja et al., 2016).

Also, sedentary behaviour has been defined in terms of energy expenditure. "Sedentary behaviour is defined as any waking behaviour characterised by an energy expenditure of 1.5 METS or less, while in a sitting or reclining posture" (Sedentary Behaviour Research Network, 2012).

2.8.2 Sedentary behaviour in rheumatoid arthritis

Objectively measured sedentary behaviour in people with RA using activPAL™ found that people with RA had higher sedentary times than the control group by 1 hour (P = 0.029) (Paul et al., 2014). Subjective measures of sedentary behaviour using a self-reported questionnaire also concluded that there was a higher sedentary time in those with RA than in the control (Henchoz et al., 2012). Similarly, it reported that women with RA were spending more time sedentary than healthy controls (Tourinho et al., 2008). However, it is unclear how sedentarism was defined in these studies.

2.8.3 Consequences of sedentary behaviour in general population as well as rheumatoid arthritis

Sedentary behaviour has a negative impact on health and wellbeing (Mutrie et al., 2012). Evidence suggests that sedentary time is an independent risk factor for ill health (Mutrie et al., 2012, Thorp et al., 2011).

Sedentary behaviour might lead to suppression of lipoprotein lipase activity of skeletal muscle (LPL) due to loss of local contractile stimulation. LPL is the enzyme engaged in the uptake of free fatty acids and triglycerides into skeletal muscle and high density lipoprotein (HDL) (Hamilton et al., 2008). In addition, lack of local muscle contraction may reduce glucose uptake. Elevated levels of triglyceride, free fatty acids and glucose in circulation could lead to excess free radicals and trigger inflammation, endothelial dysfunction and increased sympathetic pathway activity that is conductive to the development of coronary heart disease and CV risk (O'Keefe et al., 2012).

Dunstan et al. (2010) revealed that the length of time spent viewing television was correlated with increased risk of CVD as well as all-cause mortality. Their research examined 880 adults and followed them up over 58,087 person-years, and found 284 deaths (87 CVD deaths, 125 cancer deaths). They found that 1 hour/day of time spent viewing television has a hazard ratio (HR; 1.11 95% CI 1.03 -1.20) for CVD mortality, (1.09 95% CI 0.96 - 1.23) for cancer mortality and (1.18 95% CI 1.03- 1.35) for all-cause mortality (Dunstan et al., 2010). A review by Ford and Caspersen (2012) revealed that sedentary behaviour is significantly associated with increased risk of CVD, and also overweight/obesity, hypertension, diabetes, high cholesterol, metabolic syndrome (Healy et al., 2008), and cancers such as ovarian, colon and endometrial in general population.

A few studies investigated the consequences of sedentary behaviour in people with RA. Sixty-one individuals with RA, with a mean age of 54.9 years, were included in a cross-sectional study (Fenton et al., 2017). Fasted blood samples were taken and sedentary behaviour (sedentary time, sedentary bouts and sedentary breaks) and also level of PA were objectively assessed using GT3X accelerometers (Actigraph) for 7 consecutive days. The ten-year CVD risk was computed (Q-risk-score2), and functional disability was measured using self-reported questionnaire. The participants spent about 8 to 9 hrs/day being sedentary and 4.5 hrs/day engaged in low levels of PA. There was a significant positive association between sedentary time and number of sedentary bouts/day ≥20 min and CVD risk in people with RA. There was also a reverse association between low levels of PA (1.6 – 2.9 METS) and CVD risk in people with RA. However, this association was independent of engagement in moderate intensity

PA. Promoting low levels of PA and reducing sedentary bouts to <20 min were recommended in order to reduce CVD risk in people with RA. There was a non-significant association between sedentary behaviour and functional disability (Fenton et al., 2017).

One study objectively measured sedentary behaviour and PA using the Sensewear Armband (Khoja et al. (2016). They reported that people with RA spent 9.8 hours/day sedentary. A significant inverse association between very light, light and moderate PA and CVD risk in people with RA was identified. A higher time spent being sedentary was significantly associated with higher BMI, higher diastolic and systolic blood pressure, impaired insulin sensitivity, and lower HDL levels (P< 0.05). PA was not associated with LDL and triglycerides. Also, a higher functional disability (HAQ) and disease activity scores (DAS28) were associated with time spent being sedentary.

However, there were inconsistences between both Khoja et al. (2016) and Fenton et al. (2017) in their definition of sedentary behaviour and light PA. Khoja et al. (2016) defined sedentary behaviour and LPA as activities requiring <1 MET, and 1 – 2.9 METS, respectively. Fenton et al.'s study defined sedentary behaviour as ≤1.5 MET. Thus Khoja et al.'s (2016) method might lead to an underestimation of sedentary time and an overestimation of LPA. However, it seems that people with RA spend more time being sedentary than the healthy population.

2.8.4 The consequences of interrupting sitting time

A study carried out by Healy et al. (2008) recruited 168 people with diabetes and identified that interrupting the time spent sitting reduced the waist circumference (P = 0.026), BMI (P = 0.026), triglycerides (P = 0.029), and glucose (P = 0.025). Reducing and breaking up the time of adults sedentary behaviour plays an important role in lowering postprandial glucose, triglyceride and insulin level also it is beneficial to BMI, waist circumference among overweight and obese adults (Dunstan et al., 2012, Owen et al., 2010). A RCT with cross over design on previously sedentary adults by Mutrie et al. (2012) found that the reducing sitting time improved quality of life.

Seventeen prospective experimental studies that examined the effectiveness of breaking up prolonged sitting time on CV risk factors were reviewed, along with the effect of replacing sitting with light intensity PA and standing (Benatti and Ried-Larsen, 2015). It was found that breaking up sitting time had beneficial effects on cardio metabolic risk factors. The intensity and frequency of PA should be considered, particularly in people who have a sedentary lifestyle (Benatti and Ried-Larsen, 2015). However, no study has examined the effectiveness of breaking up sedentary time in people with RA.

There is evidence that people with RA have an inactive lifestyle, which may be related to a number of reasons, including joint pain and stiffness, psychological disturbances or even fear of aggravating their disease. This inactive lifestyle could contribute to their CV risk profile. Therefore, the aim of this study was to increase (physical activity) step count, reduce sedentary behaviour in order to reduce the risk of CVD and improve the health outcomes in terms of disease activity, functional capacity, quality of life, and self-efficacy for PA. The following chapter describes the details of the current intervention (WARA), the theories underpinning the intervention and some explanation of the mechanism of action.

3 Walk for Rheumatoid Arthritis (WARA) intervention

This chapter begins by defining complex interventions, lifestyle, an unhealthy lifestyle and health risks. Then, it reviews the theoretical underpinning of the behavioural changes upon which the WARA intervention was grounded, and the behavioural change techniques that were used in the WARA intervention. It presents the evidence of the effectiveness of the behavioural changes with regard to targeting physical activity behaviour. The chapter also considers the duration and mode of delivery of interventions in relation to physical activity in RA. Finally, the development and content of the Walk for Rheumatoid Arthritis (WARA) intervention are described, along with the rationale for the content of the booklet that was given to the participants.

3.1 Definition of interventions and complex interventions

An intervention is defined as a set of actions with a coherent objective, which is intended to produce identifiable outcomes (Olander et al., 2013). A complex intervention is an intervention that consists of a number of interacting components with several outcome measures (Campbell et al., 2000, Craig et al., 2008). Programmes that focus on health promotion and disease prevention are complex interventions due to the complexity of health risk behaviours and also because they require several actions, in order to promote health behaviours or healthy lifestyles (Craig et al., 2008).

3.2 Unhealthy lifestyles and health risks

Lifestyle can be defined as the personal habits or the ways of living of individuals on a day to day basis. It takes into account physical, psychological, social or environmental factors, and is influenced by culture, family or social class (Ezzati et al., 2002, Trovato, 2012). Unhealthy lifestyles can predispose people to chronic conditions such as cardiovascular disease (CVD). There are many risk factors associated with CVD that can be treated or changed – these are called modifiable risk factors, (see section2.2.1). Physical inactivity, sedentary behaviour, and diets rich in saturated fats, are examples of modifiable risk factors which need addressed to promote a healthy lifestyle thus minimising, or

preventing, chronic conditions such as CVD. Lifestyle interventions address modifiable risk factors by tackling the behaviours requiring change, such as physical inactivity, within specific populations (Michie et al., 2012).

The Medical Research Council's evaluation guidance states that the key elements of evaluating complex interventions and understanding how the intervention works are: identifying the appropriate theory; assessing feasibility and piloting the interventions; assessing the effectiveness of the interventions; and understanding the change process (Medical Research Council, 2006). These elements were considered when designing the WARA intervention. The following sections discuss the role of the theory underpinning behaviour change and behavioural change techniques (BCTs), and the BCTs that were chosen in the WARA intervention. Based on the evidence of BCTs that are effective in increasing PA behaviour, increased self-efficacy for PA and their role in changing PA behaviour and improving the outcomes, seven BCTs were used in the WARA intervention. These are further discussed in the following sections.

3.3 Theoretical underpinning of behaviour change

A number of theories have been identified in attempting to explain behavioural change, with each theory being focused, to a greater or lesser extent, on social factors (Bandura, 1977, Morris et al., 2012). Underpinning theories focus on individual choice and behaviour at different points of an individual’s life, or on the relationships between behaviour, individuals, society, and physical environments (Morris et al., 2012, Riemsma et al., 2004).

Social Cognitive Theory (SCT) was developed by Bandura (1986) and is relevant for designing health education and health behaviour programmes (John et al., 2011a). SCT is a behavioural health theory that explains behaviour in a triadic and reciprocal model, where the environment, an individual, and behaviour interact to determine motivation and behaviour, Figure 3-1 (John et al., 2011a, Glanz et al., 2002). The interaction is complicated, and all of these dimensions are important for behaviour change (Bandura, 2001, Glanz et al., 2002). However, SCT has been criticised as it does not provide a full explanation of how the environment, behaviour and cognition interact, and there are many

hypotheses regarding this interaction (Munro et al., 2007, Plotnikoff et al., 2013).

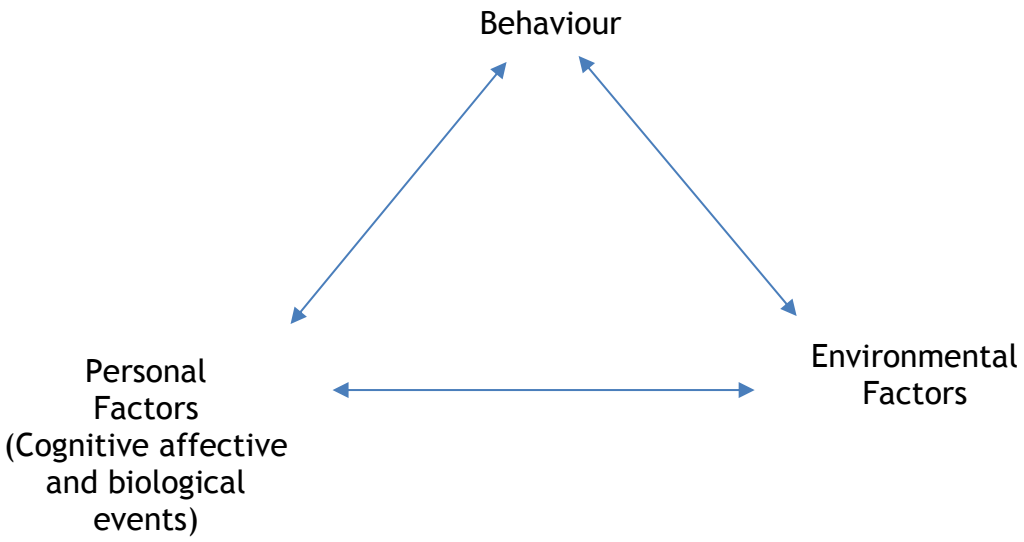

Figure 3-1 Overview of social cognitive theory
Adapted from (Pajares, 2002)

Increasing the knowledge and awareness of the participants in research studies, for example providing information to promote PA and a healthy diet, has been identified as influencing changes in behaviour as increasing knowledge has a significant influence on human actions and motivation (Romeike et al., 2016). Patient education is defined as "any set of planned educational activities designed to improve patient's health behaviours and/or health status" (John et al., 2011b, Riemsma et al., 2004). Education sessions and the associated material allow participants to access information on e.g. PA and to interact with other study participants (Artinian et al., 2010, Glanz and Bishop, 2010). However, van Achterberg et al. (2011) stated that knowledge and simply providing materials were insufficient to promote healthy behaviours in patients; professionals should consider alternative comprehensive strategies by combining knowledge, awareness and facilitation techniques.

A systematic review and meta-analysis by Young et al. (2014) concluded that SCT is a useful framework to explain PA behaviour. Another systematic review and meta-analysis by Plotnikoff et al. (2013) stated that few studies utilise SCT to explain objective PA behaviour, therefore more theoretically based studies are needed. Riemsma et al. (2004) and John et al. (2011a) concluded that any

successful programmes for people with RA, with the aim of changing unhealthy lifestyles and reducing the risk of CVD, should be based on social cognitive theory. This is expected to enhance the results because it targets knowledge, self-efficacy and behaviour (John et al., 2011a).

SCT assumes self-efficacy to be the core element of behaviour change (John et al., 2011a). Self-efficacy is defined as people's beliefs in their ability to perform a specific task within a given context (Bandura, 2004, Ng and Lucianetti, 2016). Self-efficacy is related to SCT in that people with high self-efficacy will face up to failures or setbacks. They are more likely to set challenging goals for themselves and even if they face barriers or relapse they will not give up (Bandura, 1977, Munro et al., 2007, Plotnikoff et al., 2013). Increasing participants' confidence in their ability to achieve their PA goal was found to be associated with motivating them towards the PA goal, overcoming perceived external barriers and improving outcome expectations (John et al., 2011a). Self-efficacy is related to people's experiences, either positive or negative, in terms of a particular task, and to other people's performance on a particular task (Bandura, 1977). Self-efficacy can be built by setting small specific goals which together relate to larger goals (Bandura, 1977, Munro et al., 2007, Plotnikoff et al., 2013).

The SCT theory also explains how people react according to their beliefs and according to the outcomes of their actions (Michie et al., 2008). For example, individual self-beliefs regarding exercise include people's beliefs about the outcomes of being physically active, and that enables them to undertake PA or exercise (Ezzati et al., 2002). Participants' beliefs, impulses and habits result from associative learning and the psychological state of the individual leads to a certain behaviour. The fact that an individual believes in the importance of PA does not necessarily mean that this individual will be physically active (Bandura, 1977).

To successfully increase PA, several elements have to be considered, such as the practice of a specific behaviour, the role of cognition in motivation and the impact of the situations an individual is faced with (Flynn et al., 2009, Larkin et al., 2015a). The motivation of the individual to engage in PA and the strength of their belief in the health benefits to be gained from PA may be significant

factors in increasing self-efficacy (Crain et al., 2010). Additionally, increasing people's knowledge regarding how PA influences their health is a fundamental factor that can motivate them and help to improve self-efficacy for PA (Larkin et al., 2016b). The intervention should aim to improve participants' knowledge, increase their self-efficacy for PA, and improve their behavioural and clinical outcomes. In particular, lifestyle education programmes such as those aimed at increasing PA behaviour for people with RA should be provided during the early stage of the disease to maximise the potential for appropriate behaviours to be implemented and maintained (Riemsma et al., 2004). However, there is a lack of evidence regarding the role of self-efficacy in determining levels of PA in people with RA (Bauman et al., 2012, Neuberger et al., 2007). The WARA intervention was designed to increase awareness and knowledge regarding the benefits of PA, and to enhance participants' self-efficacy for PA based on SCT in people with RA within 5 years of diagnosis.

SCT has a number of aspects that should be considered when designing an effective intervention, for example the perception of the environment, a healthy lifestyle and the external factors surrounding the individual, such as social support. Also, the behavioural capability of the individual should be considered in terms of their knowledge and skill to perform a given behaviour, such as regulating their goals. Observing other people's actions and the outcomes of other people's behaviour during the intervention also plays an important role in motivating people towards their goal. It is important to not only promote the behaviour but also to minimize relapse and help participants to overcome barriers. People can be trained on how to solve the problems that they may face during and after the programme.

Furthermore, to improve the outcomes, people should understand the benefits of adhering to the programme; self-initiated rewards and incentives are important to motivate them to progress further towards their goal. These factors can help people to increase their confidence to perform a behaviour and should be included in an effective intervention (Bandura, 2001, Glanz et al., 2002).

Taking into account the aforementioned aspects of SCT concepts, the WARA intervention was designed. The WARA intervention was grounded in the constructs of social cognitive theory (SCT) through the education of the

participants regarding their condition (RA) and it focuses on PA, heart disease in RA and the benefits of being physically active. It also included a session on healthy diet. Table 3-1 shows the process of the application of SCT concepts in the WARA intervention.

Table 3-1 Overview of the application of social cognitive theory of the WARA intervention

Social Cognitive Theory Construct	Process of the application
Self-efficacy	Verbal encouragement from physiotherapist during sessions or follow-up phone call
Observational learning	Interactive discussions of participant's experience of RA and PA, practice of strength training at group sessions
Social support	Group sessions promoting physical activity, and also participants encouraged to seek support from other people (partner, family or friends)
Self-control	Weekly goal setting, self-monitoring via pedometer and PA diary, problem solving of their PA barriers
Behavioural capability	Knowledge and skill to perform PA through planning of weekly goal and how to overcome PA barriers, either in education session activities or during discussion with physiotherapist in monthly phone call
Outcomes expectation	Raise awareness and knowledge regarding RA, CVD and PA. The benefits of being physically active (joints, health in general and mood)
Individual motivation	Verbal encouragement during phone calls with physiotherapist and from other participants in the sessions

Recent evidence has demonstrated that interventions that include BCTs (goal setting, feedback on outcomes of behaviour, action planning, problem solving and social support) are more effective in enhancing self-efficacy for PA and promoting PA behaviour (Olander et al., 2013). In addition, John et al. (2011a) concluded that participants should be trained in BCTs such as goal setting and the self-monitoring of behaviours to improve the outcomes of the intervention. The following sections discuss the BCTs that were chosen and used in the WARA intervention based on the evidence of their effectiveness in increasing PA behaviour.

3.4 Behavioural change techniques

A behaviour change technique (BCT) is defined as a technique in which there is a consistent set of activities organised to modify a particular behaviour (Cane et al., 2012, Michie et al., 2011b). A number of BCTs have been reported to promote positive lifestyle change, therefore in this study the most effective BCTs used in RCTs promoting PA were chosen. A review of 25 RCTs found that the most effective BCTs that influence PA in short-term interventions among inactive adults were feedback, behaviour practice and graded goals (Howlett et al., 2015). In addition, the intervention would be effective in the long term if it also included action planning, instructions on how to perform the behaviour and self-reward (Howlett et al., 2015). In another systematic review, action planning and providing instruction were found to be related to increasing self-efficacy and PA in healthy adults (Williams and French, 2011). Engagement with social support, goal-setting and self-monitoring and targeting healthy lifestyles, such as promoting PA and a healthy diet, increased the effectiveness of interventions designed to promote changes in diet and/or physical activity (Greaves et al., 2011).

Behavioural change interventions utilising goal setting, self-monitoring, and feedback on behaviours may increase self-efficacy for PA among people with RA (Smarr et al., 1997). Furthermore, a review concluded that self-monitoring and goal setting were the most employed technique in studies promoting PA in people with RA (Larkin et al., 2015b). Thus, goal setting, self-monitoring, feedback, action planning and social support are the BCTs that were mostly used, and they seem to be effective in promoting PA. The following sections discuss the BCTs used in the WARA intervention.

3.4.1 Goal setting

Goal setting is a motivational technique that involves setting a specific goal to enhance the performance of an individual (Lunenburg, 2011, McCarthy et al., 2010) by making the individual focus their attention on their task and on developing new learning strategies (McCarthy et al., 2010).

Setting SMART goals (specific, measurable, achievable, realistic and time-bound) is the most effective tool to achieve the objective (Lunenburg, 2011, McCarthy et al., 2010). When setting a SMART goal the following should be considered: what the individual wants to achieve, and how they will achieve it; a plan of the steps to achieve the goal; a breakdown of the goal into smaller targets; a written document that helps the person feel that the goal is tangible and that it is necessary to commit to reaching within a specific time period (Lunenburg, 2011, McCarthy et al., 2010).

To increase the effectiveness of PA programmes in RA, the goal needs to be realistic (Withall et al., 2016). Setting appropriate goals and achieving those goals plays an important role in enhancing self-efficacy, which impacts on PA behaviour (Lunenburg, 2011). An increase in self-efficacy for PA is observed if it is specified how the goals are to be achieved (Olander et al., 2013). This increases the belief in personal capabilities and efficacy, and leads to higher motivation and less stress (Michie et al., 2011b, Williams and French, 2011).

3.4.2 Self-monitoring of behaviour

Self-monitoring involves the individual recording their own specific behaviour (Cane et al., 2012). Interventions that encourage participants to self-monitor their behaviours are more likely to achieve behaviour change (Michie et al., 2011b, Williams and French, 2011). The use of a physical activity diary plays an important role in self-monitoring which then influences adherence (Conn et al., 2011, Dalle Grave et al., 2011).

3.4.3 Feedback on outcomes on behaviour

Feedback on outcomes of behaviour increases decision-making by increasing participants' understanding of the details of the target that has to be achieved, and can also improve the outcome. For example, unhealthy behaviour (physical inactivity) can lead to consequences in the future, therefore, decision-making is driven by long-term consequences rather than immediate outcomes (Brown, 2006, Ivers et al., 2012). It can motivate participants to continue certain behaviours they have acquired or it may provide them with a direction for

adjusting their behaviour in order to achieve a targeted goal (Artinian et al., 2010).

3.4.4 Action planning

Action plans describe what, where and how a goal will be achieved (Michie et al., 2011a). It has been found BCTs such as action planning are associated with a significant increase in self-efficacy for PA in obese adults (Olander et al., 2013) and play an important role in the improvement of individual self-efficacy and PA (Williams and French, 2011).The first step of an action plan is to identify a SMART goal or set of SMART goals to achieve (Lunenburg, 2011, McCarthy et al., 2010). The behaviour goal should be reviewed regularly and according to the situation, further plans made for progression toward the SMART goal (National Institute for Health and Care Excellence, 2013, Niedermann et al., 2004). To apply action planning, it is important to provide instruction to the participants during the education sessions, to encourage them to plan how they will reach their step goal and to help individuals to achieve their behavioural goal (Niedermann et al., 2004, Riemsma et al., 2003).

3.4.5 Problem solving

Problem solving is a process with a sequence of activities that includes problem identification, generation of alternatives and selection of solutions (Ashford et al., 2010). Problem-solving affected by attitudes and beliefs, and the problem-solving process includes how the individual attempts to handle the situation (Niedermann et al., 2004). For example, it is important to identify the barriers or obstacles to PA, such as poor weather, that might interfere with the implementation of walking plans. Barriers should be overcome by finding a solution that successfully copes with such problems, such as walking in a shopping centre in poor weather instead of at a park (Centers for Disease Control and Prevention., 2011).

3.4.6 Relapse Prevention

Relapse prevention aims to teach individuals how to anticipate and cope with a relapse (Hendershot et al., 2011). Relapse related to PA is defined as a return to physical inactivity (Williams and French, 2011). In relapse prevention training in

one study, the participants were taught about relapse and were able to practise skills to identify and cope with high-risk situations that might lead to relapse, such as the weather or personal problems (Hagobian and Phelan, 2013). To prevent relapse, programmes should increase the knowledge of patients regarding the benefits of PA, identifying motivational barriers that people could face, and enhancing their ability to plan strategies to overcome or avoid risky situations (Hagobian and Phelan, 2013). In addition, an effective strategy in preventing relapse involves supporting individuals by follow-up texts, emails, or telephone calls by the health provider (Wu et al., 2016, Burke et al., 2005).

3.4.7 Social support

Social support can increase PA behaviour (Olander et al., 2013). Social support could be provided by friends, relatives, colleagues or a group that share the same interests. People who receive more social support tend to have high levels of self-efficacy (Kim et al., 2008). A number of intervention studies revealed that social support helps to encourage, motivate and increase self-efficacy (Riemsma et al., 2003, van Achterberg et al., 2011). Providing an education programme in groups is a form of social support and may play a role in improving individual self-efficacy (Somers et al., 2012). Friendly contact between participants or with their other forms of social support can provide spiritual or material assistance to individuals when they are facing some difficulties in their PA task. Social support helps individuals to cope with stress, enhances their self-confidence and improves their self-efficacy (Miller and Dimatteo, 2013, Wang et al., 2015).

To implement the lifestyle intervention programme, the acceptability and adherence of participants to the programme is an important issue (Blekken et al., 2015). To achieve successful programme implementation, the mode of delivery, and the duration of the programme should be considered (Carroll et al., 2007). The following section discussed the relevant literature concerning the mode of delivery and duration of PA programmes, specifically in relation to RA.

3.5 Duration and mode of delivery of physical activity programmes for people with rheumatoid arthritis

3.5.1 Programme duration

The effectiveness of interventions vary considerably among studies, and is related to the purpose and the duration of the intervention. Different studies use different intervention durations: short-term (brief intervention), medium- and long-term intervention (extended intervention). Brief interventions may range from single education sessions to three sessions lasting up to 30 minutes (McQueen et al., 2011). An extended intervention consist of multiple education session(s) (National Institute for Health and Care Excellence, 2014).

Education programmes designed to increase the knowledge of RA patients' can be delivered as several sessions on consecutive days (Abourazzak et al., 2009), weekly sessions over several weeks such as 5 weekly sessions (Riemsma et al., 2003) or 6 weekly sessions (Lovisi Neto et al., 2009). It has been found that a short-term group education session in RA is unlikely to maintain its effect over the long term (Riemsma et al., 2004). Although long-term interventions that last more than six weeks are more successful, they carry an inherent risk of attrition (Riemsma et al., 2004). The arthritis self-management programmes were shown to have a small but significant effect on increasing PA among osteoarthritis patients when the programmes were offered for less than 12 months. The effect of the intervention was reduced when the programme exceeded 12 months.

A review of 11 randomised controlled trials of patient education in RA identified varied educational interventions that have been implemented. Although none of the short-term interventions showed a significant change in health status, improvements in the knowledge and compliance in short and long term of patient's education were generally observed. However, only two studies of long term interventions showed improvement in health status. A future strategy to maintain short-term improvement over long intervals of time is recommended (Niedermann et al., 2004).

3.5.2 Mode of delivery of physical activity programmes in rheumatoid arthritis

To change an inactive lifestyle to an active lifestyle, it is important to motivate and encourage people. Behavioural interventions may be delivered in different ways, through computer-mediated programmes and computer-based formats (Dunn et al., 1998, Portnoy et al., 2008), by SMS text messaging (Muller et al., 2016, Shaw and Bosworth, 2012), face-to-face in small groups (Conn et al., 2011, Noordman et al., 2012, Riemsma et al., 2004) or individual face-to-face (Noordman et al., 2012).

In order to encourage people to become habitually physically active over the long term, support should be offered at regular intervals (National Institute for Health and Care Excellence, 2014). Interventions delivered by face-to-face methods (mentored meetings, led walks, or educational sessions) significantly increase the levels of self-reported walking (Ogilvie et al., 2007).

Interventions based on education sessions are the most popular strategy used in arthritis self-management programmes (Warsi et al., 2003). Benefiting from the social support of a peer group, participants have an increased desire to succeed due to a sense of commitment to the group. There is also increased adherence of participants to the programme and the number of withdrawals is reduced (Appel et al., 2003, Artinian et al., 2010, Wadden et al., 2005).

In addition, incorporating telephone, text or email support from the group or the facilitator encourages participants to engage in the programme (Kozica et al., 2015). Frequent contact with participants can provide many advantages, such as the establishment of trust between the participants and the provider (Appel et al., 2003, Artinian et al., 2010, Wadden et al., 2005).

A systematic review was undertaken of 11 studies comparing PA interventions with a placebo, or no interventions in community-dwelling adults with symptomatic knee or hip osteoarthritis (2741 participants, mean age 62.2 years) (Williamson et al., 2015). Randomised controlled trials published between 1997 and 2013 were considered in the review. The programmes were delivered face-to-face and involved supervised exercise with the majority of the trials

incorporated an arthritis self-management programme, targeting self-efficacy and coping skills of the patients. No specific effective mode of delivery was noted possibly due to the small number of RCTs included in this review (Williamson et al., 2015).

A Cochrane systematic review by Riemsma et al. (2004) aimed to determine the effectiveness of patient education on health status in RA. This review compared the results of various kinds of studies including those which provided information only (9 studies; 687 patients), counselling (5 studies; 430 patients) and behavioural intervention versus control groups (24 studies; 2,493 patients). It concluded that any successful education programmes for people with RA, needs to be designed in the format of group education, as this improves participants' compliance and adherence to programmes and enhances motivation for behaviour change. Although this review is more than 10 years old, the more recent review of John et al. (2011a) supports these findings concluding that participants should be trained in BCTs such as goal setting and the self-monitoring of behaviours. The intervention should aim to improve participants' knowledge, increase their self-efficacy for PA, and improve their behavioural and clinical outcomes.

3.6 Ongoing support (booster sessions)

Booster sessions, are defined as additional sessions after the main sessions have ended, in order to reinforce any progress that had been made since the preliminary sessions have been conducted (Stuart-Shor et al., 2012). Booster sessions help people to maintain recently adapted behaviour such as increased PA levels acquired following the programme sessions that may help to avoid a relapse (Goyder et al., 2014). The evidence suggests that several group-based sessions with follow-up (booster) sessions are more effective than a single session (Evans, 2011).

A study conducted by Abbott et al. (2015) aimed to investigate whether booster sessions of exercise therapy over a year could improve outcomes by comparing a programme consisting of exercise therapy with booster sessions to one without booster sessions. The intervention consisted of aerobic, strengthening, stretching exercise and neuromuscular control exercises. All

participants were provided twelve 45-minute sessions of exercise therapy, supervised and progressed by a physical therapist. Booster sessions were defined as sessions of supervised therapy provided at intervals of time after the consecutive sessions, with intervening periods of no supervised therapy. The participants received 8 consecutive sessions in the initial 9 weeks with 4 booster sessions (2 booster sessions at 5 months, 1 booster session at 8 months, and 1 booster session at 11 months). It was reported that a 3-month interval between the booster sessions was selected due to the fact that the benefits from the exercise programmes may decline within this period. The results showed a significant improvement in the physical function of participants who received exercise therapy with booster sessions, compared to participants who received exercise therapy alone. However, although they were successful in improving physical function no theory or BCTs was described.

An RCT was carried out on people with osteoarthritis. The participants were randomly allocated to a group that received 12 weeks of physiotherapist-supervised exercise with two booster sessions (230 minutes) over 24 weeks, or to a group that received 12 weeks of physiotherapist-supervised exercise with no booster sessions (control). All of the participants were asked to perform their home exercises 4 times/week. No significance difference was found between groups in terms of pain. It was concluded that two booster sessions did not influence the outcomes or programme adherence (Bennell et al., 2014). The low number of booster sessions over 24 weeks, and also the fact that the programme did not explicitly incorporate BCTS and was not constructed on the behaviour theory could explain the reason for the failure.

An assessor blinded RCT targeted PA in people with osteoarthritis was undertaken where participants were randomised into an intervention group that received 18 sessions of behavioural activity over 12 weeks and then 7 booster sessions over a year, and a control group that received 18 sessions of usual care over 12 weeks without booster sessions (Pisters et al., 2010). There was a significant difference between groups. The behavioural activity group had higher adherence to the programme and met more of the recommendations of PA than the usual care group (Pisters et al., 2010).

3.7 Summary

The evidence suggests that the effectiveness of programmes aimed at increasing PA is increased if they are delivered in face-to-face sessions, with booster sessions in small groups, and with theory based interventions combined with behavioural change techniques.

The Walk for Rheumatoid Arthritis (WARA) intervention is a lifestyle intervention that has been designed to target PA behaviours. It aims to increase PA and encourage a healthy diet, to improve health outcomes and reduce CVD risk in people who have been diagnosed with RA within the last five years. The WARA intervention was designed with group education sessions and provides participants with written information in the form of a WARA booklet.

3.8 Description of the WARA intervention

The WARA intervention consisted of a physical activity component and an educational component. The PA component focused on a pedometer supported walking programme and strength exercises based on the UK physical activity guidelines (2011). The educational component consisted of six weekly sessions in small groups of up to six people and two booster sessions (at three and six months); the following sections explain the intervention structure and the contents of the WARA intervention.

3.8.1 Structure of the WARA Intervention

During the first six weeks' participants attended a one-hour session. During this education session, a number of topics were considered, and were discussed interactively with the participants, Table 3-3.

After the six weeks of education sessions, the physiotherapist contacted the participants at the end of weeks 7, 9 and 11 (i.e. when their step target increased by 1000 steps or changed from three to five days) to the end of the intervention (6 months). Contact was made either by phone or email according to individual preference and the physiotherapist discussed the participant's step counts for the past month and their step goals for the following month, also any PA barriers they faced and how they planned to overcome them. Participants

were told to make contact with the physiotherapist if they had any further questions or problems.

The WARA intervention also involved two group booster sessions, after 3 and 6 months. The aim of the booster sessions was to encourage participants' maintenance of, and motivation towards, their PA by providing support to the participants, to evaluate their own barriers to PA and to encourage them to continue to use their pedometers and to record their steps in their PA diary. The participants were encouraged to plan how to deal with anticipated obstacles.

3.8.2 Content of the WARA intervention

The programme consisted of two components; a physical activity component and an educational component. The PA component focused on walking and strength exercises based on the UK physical activity guidelines. The WARA programme was based on SCT and BCTs.

1 Physical Activity Component

A pedometer (DIGI WALKER SW-200, Japan) was given to each individual in the intervention group at the first education session. Participants were instructed to wear the pedometer on the waist band above the hip during all waking hours and daily PA. The only exceptions were when they were immersed in water (bathing or swimming) or in bed at night. They were also instructed to reset the pedometer to zero at the beginning of each day and remove it at the end of the day. They were given a physical activity diary in which they were asked to record: the time the pedometer was attached, removed and total number of steps displayed on the pedometer at the end of each day. Weekly PA diaries were given to participants during the six-month intervention period.

Baseline PA (defined as the average number of steps taken per day) was assessed during the first week using the pedometer. The participants were asked to wear the pedometer in week 1 while performing their normal PA, record the results in their PA diary, and bring the diary with them to the week 2 session. The mean daily step count of participants in week 1 was calculated by the physiotherapist, this figure represented the participant’s baseline PA. The participants were asked to add 1000 steps to their baseline value and this would be their step goal

for three days/week for the next two weeks, then 5 days/week for two weeks, see Table 3-2.

Table 3-2 Weekly walking goal of intervention group

Week of programme	Steps count goal
Week 2- week 3	Extra 1000 steps above baseline value on 3 days /week
Week 4- week 5	Extra 1000 steps above baseline value on 5 days /week
Week 6-week 7	Extra 2000 steps above baseline value on 3 days/week
Week 8-week 9	Extra 2000 steps above baseline value on 5 days/week
Week 10-week 11	Extra 3000 steps above baseline value on 3 days/week
Week 12-week 26	Extra 3000 steps above baseline values on 5 days/week

Modified from Fitzsimons et al. (2012)

The aim of the WARA programme was for the participants to increase their average daily step count 3000 above their baseline value on at least 5 days of the week by 6 months and to maintain this for a further 6 months. The evidence suggests that the using pedometers, which provide feedback to users and assist in self-monitoring of PA behaviour, is one of the most effective approaches used to increase PA. It typically facilitates an increase in daily step count of 2000-3000 steps/day over 12- 24 months (Harris et al., 2013, Tudor-Locke and Bassett, 2004). An adult walking at a moderate pace takes approximately 100 steps/minute (1000 steps in10 minutes).

The walking programme was adapted from Baker et al. (2008a) where it was used successfully to increase walking and reduce sedentary behaviour in a community population in Scotland, aged 25–61 years (Baker et al., 2008b). Adding incremental targets to the average step count for people who are physically inactive may make it optimally challenging for them to increase their step count (Tudor-Locke et al., 2011a). However, in Baker et al. (2008a) the population was healthy and the goal of the walking programme was an increase of 1500 steps, maintained for 2 consecutive weeks. With the WARA intervention, the population had RA, therefore the goal of the walking programme was modified to an increase of 1000 steps maintained for 2 weeks.

Participants who achieved 3000 steps above their baseline after the initial 6 weeks were asked to maintain that daily step count. Participants who did not reach this target were encouraged to continue to try to increase their step count, unless they had health problems that prevented them from so doing, such as joint pain, dyspnoea or tiredness.

During the fourth education session, i.e. one month after beginning the programme, participants were asked to add strengthening exercises to their programme. This involved strengthening exercises for the major muscles of the lower limb, trunk and upper limb at home twice a week, with 8-12 repetitions of each exercise in accordance with the UK physical activity guidelines (2011). Participants were encouraged to keep a record of their strengthening exercises in the PA diary, recording time, duration and any barriers to performing the exercise and how these were overcome.

2 Education Component

Participants attended six weekly sessions in small groups of up to six people; the content of the sessions was based on social cognitive theory and the behaviour change techniques in order to allow participants to challenge their way of thinking, and change negative coping skills, cognition and emotions (John et al., 2013). The sessions were interactive, took place at the participants' local hospital and each session lasted approximately one hour. The sessions were facilitated by a physiotherapist who offered advice and assisted the participants to overcome their PA barriers, create action plans, self-monitor using a pedometer and programme PA diary and problem solve, see Table 3-3.

Participants received education material in the form of a booklet that contained information describing the importance of both walking and a healthy diet for health benefits and the reduction of CVD risk and other co-morbidities of RA. The education material also discussed the importance of reducing sedentary behaviour and explained the strengthening exercise. In order to assess participant's knowledge, it also included quizzes about RA, with some closed questions requiring e.g. Yes, or No answers (Is pain a symptom of Rheumatoid Arthritis?); or they could tick more than one choice, for example 'From this list What other organs could be involved in Rheumatoid Arthritis? or open questions

such as ‘What are the benefits of physical activity in general and in relation to Rheumatoid Arthritis?’ The written material was presented in large text Times New Roman font, size 14 (Appendix 14). The facilitators’ manual was developed which helped maintain the consistency of delivery of the programme between groups.

Table 3-3 Content of WARA education sessions and behaviour change techniques

Label	Content	BCT	Process
First education session	CVD, RA, Risk of CVD in RA, the importance of PA, the importance of reducing sedentary behaviour, instruction and practice on how to use pedometer.	Self- monitoring of behaviour	Pedometers and PA diaries were given to each individual. They were instructed on how to use them.
Second education session	Exercise and PA and barriers to PA, discussion on the importance of social support.	Goal setting	The participants set a step goal and planned how to achieve it. Each participant wrote their goal for the next week, using the SMART framework (specific, measurable and achievable, realistic and time limited).
		Feedback on behaviour	Review of activity diaries and immediate feedback from the pedometer raises the participants' awareness regarding the current walking behavior.
		Problem solving	The participants discussed their problems and how to overcome them. That was done both individually and group.
		Social support	Providing the education programme in groups was a form of social support. The participants were encouraged to walk together at times if appropriate. Participants were asked to identify who might provide social support and how that would be provided.
Third education session	How to reduce the risk factors of heart disease in RA via healthy lifestyle.	Goal setting Feedback on behaviour	The participants were motivated to set a new goal. Review of PA diaries.

		Action planning Relapse prevention	Instructions were provided during the education session which encouraged participants to plan how they would reach their step goal (SMART goal). In addition, the physiotherapist encouraged the participants to plan their goal for the next few weeks and to write their own plans individually in the workbook– where, when, and who they would walk with. They also recorded any problems that they faced, how they overcome them and how they knew they had achieved their goal. Participants were taught about relapse and the skills needed to identify and cope with high-risk situations that might lead to relapse to sedentary or physical inactivity. The participants were encouraged to generate or suggest strategies to help overcome any problems to prevent or minimize the relapse.
Fourth education session	Relevance and importance of strength training and opportunity to practice exercises.	Goal setting Feedback on behaviour Action planning	The participants were motivated to set a new goal. Review of PA diaries. Participants planned their goal for the next week. A goal in relation to PA strength training was added.
Fifth education session	Healthy diet, how to reduce the risk of heart disease through dietary change.	Goal setting Feedback on behaviour Action planning	The participants were motivated to set a new goal. Review of PA diaries. Participants planned their PA goal for the next week.
Sixth education	Social support, maintaining change and review/revision of	Goal setting Feedback on	The participants were motivated to set a new goal. Review of PA diaries.

session	the importance of reducing sedentary behaviour. Discussion around the implementation of the walking programme for the next 6 weeks.	behaviour Relapse prevention Social support Action planning	 Participants were taught about relapse and the skills needed to identify and cope with high-risk situations that might lead to relapse to sedentary or physical inactivity. The participants were encouraged to generate or suggest strategies to help overcome any problems to prevent or minimize the relapse. Participants were asked to identify who might provide social support and how that would be provided. Participants planned their goals for the next 6 weeks and to write their own plans individually.
First booster session	Review the progress made over the previous six weeks. Discuss any barriers, and tips to avoid too much sitting, encouragement, motivation of the participants to continue in this programme.	Feedback on behaviour Problem solving Relapse prevention	Review of PA diaries. Discuss how participants overcome their PA barriers they have faced. Participants were asked to plan strategies to avoid relapse individually.
Second booster session	Review the progress made over the previous three months, barriers to PA and how to maintain their PA.	Feedback on behaviour Problem solving Relapse prevention	Review of PA diaries. Discuss how participants overcame any PA barriers they may have faced. Group discussion how to maintain their PA.

4 Literature Pertaining to the Methodology

This chapter reviews the outcome measures used in this study and provides justification for the quantitative and qualitative methods used. It also presents evidence of the reliability and validity of the outcome measures chosen.

4.1 Mixed methodology

Quantitative and qualitative research methods have their strengths and weaknesses and they can be extremely effective when used in combination (Curry et al., 2009, Bryman, 2006, Harwell, 2011). Quantitative methods are commonly used to measure the impact of disease activity and clinical interventions, using a number of approaches such as instrumental tools and laboratory tests (Curry et al., 2009). The findings of phenomena studied by way of quantitative methods can be generalised and the time taken over data analysis can be reduced by using statistical software; however, general findings achieved in this manner may not be applicable to specific situations, individuals or contexts (Kruger, 2003). The quantitative method is based on numerical data and it has the benefit of allowing a comparison between variables, facilitating the comparison of results over time, allowing an understanding of relationships between variables and establishing cause and effect (Curry et al., 2009, Harwell, 2011).

Qualitative research is an in-depth approach that allows an understanding of the area under investigation (Bryman, 2006, Harwell, 2011). There are many methods by which to collect qualitative data such as interviews, focus groups and the observation of events or people in order to discern behaviour and their interaction within natural settings (Curry et al., 2009). The interview approach used in qualitative research can be directed by the researcher in the case of semi-structured interviews or focus group (Harwell, 2011). However, it is dependent on the researcher's skills and can potentially be influenced by the researcher's prejudices, interpretations and descriptions (Curry et al., 2009, Kruger, 2003).

In this study, a mixed methodology was chosen in order to strengthen the study and to comprehensively answer the research questions. The outcome

measurements at baseline, three, and six months generated quantitative data. Qualitative data was obtained by way of semi-structured telephone interviews at six months (the end of the intervention) in order to explore participants' views.

4.2 Basic concepts of clinical measurements

Clinical measurements are used to monitor changes in disease activity and responses to pharmacological and non-pharmacological interventions (Combe et al., 2017). The psychometric properties of outcome measures; reliability, validity and accuracy are important for both research and clinical practice (Wade D T, 2004, Roach, 2006, Streiner, 2015). Understanding the psychometric properties of the outcome measures is important in order to select the best measures for a particular purpose (McGoey et al., 2010, Roach, 2006). Outcome measures are important in terms of decision making in relation to healthcare provision for patients (Curry et al., 2009). In addition, outcome measures help to evaluate the patient's response to a particular intervention (Boers et al., 2014).

4.2.1 Reliability

Reliability is an indicator of the accuracy of a measurement over time and under similar conditions (Streiner, 2015, Roach, 2006). There are several types of reliability. The first type is test–retest reliability where measurements are collected on more than one occasion, with the assumption that no real change will have occurred between sessions (Streiner, 2015, Roach, 2006). Another type of reliability, known as internal consistency, is a measure of the extent to which all items in an outcome measure address the same underlying concept (McGoey et al., 2010, Streiner, 2015).

Participating raters should be adequately trained to administer and score measures; otherwise, measurement errors may occur, which will adversely affect reliability (Streiner, 2015, McGoey et al., 2010, Fitzpatrick et al., 1998).There are two types of rater reliability: intra-rater reliability indicates how consistently a rater administers and scores an outcome measure, while inter-rater reliability indicates how well two or more raters agree on the way in which they administer and score an outcome measure (Streiner, 2015). An

outcome measure can be considered reliable only for a particular purpose with a particular type of subject (McGoey et al., 2010).

4.2.2 Validity

Validity is an indicator of whether an outcome measure is appropriate for the proposed purpose (Roach, 2006, McGoey et al., 2010, Fitzpatrick et al., 1998). It expresses the ability of a test to measure what it is supposed to measure (McGoey et al., 2010, Streiner, 2015). There are many types of validity, including concurrent validity, which can be determined by administering two tests simultaneously (the results of which should be consistent) and construct validity, which reflects the ability of a test to measure the underlying concept of interest to the clinician or researcher (Streiner, 2015). A number of strategies are employed to examine the construct validity of an outcome measure, including applying the test to groups of subjects who are known to differ on the construct of interest; the test scores of the groups will differ if the test actually measures what it is supposed to measure (McGoey et al., 2010, Roach, 2006).

4.2.3 Floor and ceiling effects

Related to the validity measurement is the influence of floor and ceiling effects. A floor effect is present where participants cannot achieve the minimum score of a measurement (Wang et al., 2009, Lim et al., 2015). Floor effects may occur when participants find the task too difficult so no improvements occur (McBee, 2010, Windle et al., 2011). In order to overcome this problem, a pilot study can help to identify if there are any floor effects (Wang et al., 2009). A ceiling effect occurs when participants achieve the highest score on a measurement; this may happen if a test is relatively easy, allowing high-scoring participants to answer every item correctly and reach the highest possible score (Lim et al., 2015, McBee, 2010). Ceiling effects can lead to unrealistic and biased results in data analysis and parameter estimation (Lim et al., 2015, Wang et al., 2009).

Both described situations are considered problematic and will lead to an inaccurate representation of the outcome measure results. In this situation, so as to compensate for any floor and ceiling effects, the use of secondary outcome measures is recommended (Fries et al., 2014, Wang et al., 2009). In order to

avoid floor and ceiling effects in this study, a pilot of the intervention and outcome measures was undertaken and, in addition, primary and secondary outcome measures were employed.

4.3 Study outcome measures

The primary outcome measures in the current study were objective and subjective measures of PA, while secondary outcomes were related to RA and its consequences: disease activity, quality of life, functional capacity, cardiovascular risk factors, dietary assessment, PA self-efficacy and co-morbidity.

A large number of outcome variables have been used in recent decades to evaluate RA disease activity in clinical trials, and Core Outcome Measures in Effectiveness Trials (COMET) have been developed in order to improve the outcome measurements for many rheumatologic conditions such as RA, ankylosing arthritis and osteoarthritis (Boers et al., 2014). COMET classifies the core areas of health conditions into death, life impact, resource use, pathophysiology of the area of manifestation and contextual factors that are not the primary objects of the research, but may influence the results or interpretations (Boers et al., 2014, Prinsen et al., 2016). The outcome measures of the current study were included in the Core Outcome Set (COS), “A COS is defined as an agreed minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population” (Prinsen et al., 2014).

Efforts have been made to standardise the assessment of RA in order to allow study results to be interchangeable, for the purpose of both comparing study results and allowing meta-analyses to be carried out. The quantitative data of this study were generated by the way that both assessors rated the outcome measures, and self-administered questionnaires.

4.3.1 Physical activity assessment

Several methods can be used to assess PA including objective and subjective methods. PA can be objectively measured using such as activPAL™, or Actigraph

or using more simple devices such as pedometers (Broderick et al., 2014, Vanhees et al., 2005). Subjective methods include questionnaires such as international physical activity questionnaires (IPAQ) and PA diaries (Vanhees et al., 2005). Measures of PA gathered using objective methods are more accurate and less open to bias in comparison with subjective methods (Reilly et al., 2008). Objective methods can provide data on the degree of PA and sedentary behaviour, and also allow an examination of the dose response of PA and health outcomes (Reilly et al., 2008, Vanhees et al., 2005). Therefore, it has been recommended that clinical trial studies assessing interventions related to changes in PA should use objective methods in order to confirm and quantify the magnitude of any changes (Reilly et al., 2008).

Despite the advantages offered by objective methods of assessing PA and sedentary behaviour, they have several limitations: it is difficult to quantify non-walking activities such as swimming and cycling; the participants have to remember to wear the device for several days; there is a lack of context of the activities; and they are more expensive than subjective methods (Bassett, 2003, Hoos et al., 2012). A number of studies recommend that both objective and subjective methods should be utilised in order to assess actual and contextual PA (Andre et al., 2006, Bassett Jr, 2000). In this study, activPAL™ inclinometers were selected to measure objective PA and the International Physical Activity Questionnaire short form (IPAQ) (Oyeyemi et al., 2011) was used to assess subjective PA.

1 activPAL™ monitor

The activPAL™ is a commonly used PA monitor (PAL Technologies Ltd, Glasgow, Scotland), it is a small, single unit device (Vanhees et al., 2005). The activPAL™ contains a uni-axial accelerometer that responds to gravitational acceleration as well as acceleration resulting from segmental movement (Edwardson et al., 2016). From the inclination of the thigh, posture can be classified as sitting/lying, standing or walking. In addition, lower limb movement can provide information relating to step number and cadence (Ryan et al., 2006). The device has a substantial processing capacity and memory, allowing activity and posture to be recorded continuously for periods of up to ten days (Vanhees et al., 2005). To assess habitual PA with intra-class correlation coefficient (ICC) of 0.80, 3–4

day of monitoring is required, and to estimate patterns of inactivity and to achieve reliability (ICC) of 0.90 for all the activity indices seven days of monitoring are required (Harrington et al., 2011, Trost et al., 2005).

Although the reliability and validity of the activPAL™ have been ascertained in assessing objective PA in both healthy and chronic cases, only one study has assessed its validity in people with RA (Larkin et al., 2016c). This study included 24 patients with a confirmed diagnosis of RA; the participants wore one activPAL™ on each thigh under video recording and direct observation for criterion measures. The testing procedure consisted of tasks of activities of daily living (ADLs) such as reading newspapers, gardening or cleaning and components included sitting, standing, lying and walking on a treadmill; the duration of each activity (two, three, four or five minutes) was randomly chosen.

The activPAL™ was accurate in its measurement of sitting time, walking and standing/light activity of the 20 RA patients included in the final analysis. However, underestimations of step counts of 26% were noted (Larkin et al., 2016c). The sample size was small, the duration of data collection during walking periods was short and the gait speed of the participants was not reported. The validation of daily physical activities in a laboratory environment was also a limitation of Larkin et al.'s study. In addition, the participants of the Larkin study affected the movement patterns. Just under half of the participants were either overweight or obese, and the majority of the participants had an inactive lifestyle, potentially leading to inaccurate measurements.

Ryan et al. (2006) determined that the activPAL™ monitor is a reliable and valid method for measuring walking speeds between 0.90m.s $^{-1}$ and 1.56m.s $^{-1}$ among the general population. A study conducted by Dowd et al. (2012) using the activPAL™ and Actigraph accelerometer to compare posture with sedentary behaviour in adolescent females aged 15-18 years revealed that activPAL™ and Actigraph have a high concurrent validity of ($r = 0.96$, $P<0.01$). The study concluded that activPAL™ is a valid tool for the measurement of PA and sedentary behaviours in female populations.

It has been reported that activPAL™ is more accurate in measuring sedentary behaviour more than Actigraph and a study concluded that activPAL™ should be

considered for studies that aimed to examined sedentary behaviour(Steeves et al., 2015).

Dahlgren et al. (2010) assessed the test and retest reliability of the activPAL™ in healthy individuals over a one week period and reported the activPAL™ to be a reliable method for assessing PA. High levels of correlation were reported between treadmill walking at 4.5 km/h on the flat and with a very high incline (ICC, 0.94 and 0.95 respectively), high incline treadmill walking at 3.2 km/h (ICC, 0.88), jogging at 8.0 km/h and stair walking (ICC 0.81 and 0.70), whereas a moderate correlation was identified between self-paced ground walking and cycling at 75 rpm (ICC, 0.69 and 0.55 respectively).

Convenience samples of healthy individuals were included in the study conducted by Busse et al. (2009) in which the step count data from StepWatch Activity Monitors (SAMs), activPAL™ data and self-reported PA levels were analysed and compared. The intra-class correlation coefficient was used to determine reliability. The study revealed that activPAL™ provides accurate and reliable data related to actual PA.

In another study, no significant difference was evident between the results achieved using activPAL™ and Actigraph and in video recorded step rates of 62 female participants who walked from 3.2 km h^{-1} (slow speed) and 7.0 km h^{-1} (fast speed) on the treadmill. However, at the slowest speed both devices under estimated the number of steps taken ($P < 0.05$) (Harrington et al., 2011). Kanoun (2009) reported that the activPAL™ is a valid tool in assessing walking steps at 0.67, 0.90 and 1.33m.s^{-1} and recommended further study to investigate the validation of activPAL™ in the elderly with a slower walking speed of 0.45m.s^{-1}.

Pedometers are reliable tools for the measurement of steps during walking and running (Broderick et al., 2014, Vanhees et al., 2005). They can record movement in the vertical direction and are very useful for measuring total daily steps; as such, they are a useful tool in providing real time feedback to people to promote PA. However, pedometers are unreliable in recording sedentary behaviour, intensity of activity and kilocalories (Broderick et al., 2014, Vanhees et al., 2005). Overall, based on the evidence, activPAL™ is reliable and valid tool

using to assess PA and sedentary behaviour therefore in this study, PA and sedentary time were assessed using an activPAL™ activity monitor.

2 International Physical Activity Questionnaire (IPAQ)

Several methods have been used to subjectively assess PA, such as PA diaries (Bratteby et al., 1997, Sylvia et al., 2014), Global Physical Activity Questionnaire (GPAQ) (Hoos et al., 2012) and the International Physical Activity Questionnaire (IPAQ) (either short or long form) (Oyeyemi et al., 2011).

Diaries are inexpensive and can provide details regarding daily PA. However, this method of data recording can lead to an under- or over-estimation of PA (Bratteby et al., 1997, Sylvia et al., 2014). The Global Physical Activity Questionnaire (GPAQ) was developed by the World Health Organisation (WHO) in 2002 for PA surveillance as part of the WHO stepwise approach to the risk of chronic disease (Hoos et al., 2012). The GPAQ includes 16 questions to assess PA in various domains of work, transport and leisure time (Singh and Purohit, 2012). It was used in a study assessing PA in nine countries. Although a moderate to strong relationship was demonstrated between the IPAQ (described below) and the GPAQ (in the range 0.45 to 0.65), validation of GPAQ was found to be poor (Bull et al., 2009).

The International Physical Activity Questionnaire (IPAQ) is available in both a long form (which consists of 31 items) and a short form (9 items) (Oyeyemi et al., 2011). It is a self-report questionnaire containing items related to leisure time PA, domestic and gardening activities, work-related PA and transport-related PA carried out over the previous seven days (Appendix 6). Results from the IPAQ categorise individuals into three levels of PA: inactive, minimally active and Health Enhancing PA (HEPA) (a more active category). Inactive is the lowest level of PA, those individuals who not meet criteria for categories of minimal and HEPA. Minimally active is categorised as three or more days of vigorous PA for at least 20 minutes per day, five or more days of moderate intensity activity or walking for at least 30 minutes per day, or five or more days of any combination of moderate intensity or vigorous intensity walking. Meanwhile, HEPA relates to vigorous intensity PA on at least three days, or seven days or

more of any combination of moderate intensity or vigorous intensity walking (Guidelines for data processing and analysis of IPAQ, 2004).

The short form IPAQ is a reliable and valid self-administrated questionnaire. A greater number of validation studies have been undertaken in relation to the short form IPAQ than any other PA questionnaire (Bull et al., 2009, Craig et al., 2003).The reliability and validity of the IPAQ short and long forms have been examined in 12 countries (including the UK) and the method has been found to moderately agree with objective methods (accelerometer) (Craig et al., 2003).

A study undertaken by Tierney et al. (2015) examined the validity of the short form IPAQ (IPAQ SF) in comparison with the Sense Wear Armband (SWA) in terms of energy expenditure from PA in 22 patients with RA. There was a non-significant correlation between SWA and IPAQ SF (r=0.407, P=0.60). In addition, the SWA estimated energy expenditure more accurately than the IPAQ short form by 41%. The authors concluded therefore that the IPAQ SF is of limited use as an absolute method of estimating energy expenditure during PA in those with RA.

The IPAQ short form has high test-retest reliability for active and sitting hours per day. Intra-class correlations range from 0.30 for moderate PA hours to 0.80 for sitting hours (Kurtze et al., 2008). The IPAQ short form also exhibits a moderate and significant correlation with $VO2_{max}$ ($r = 0.41$, $P \leq 0.01$) (Kurtze et al., 2008). Craig et al. (2003) reported that the IPAQ instruments have acceptable and reasonable reliability and validity when assessing PA of adults from 18 to 65 years in both developed and developing countries. Furthermore, Craig et al. (2003) concluded that there is no difference between the reliability and validity of the short and long form IPAQ.

Based on the evidence of the reliability and validity of self-administered questionnaires (IPAQ), and in an effort to avoid burdening participants, the short form was selected in this study. In this study, a subjective measure of PA (IPAQ) was used to assess any changes in the manner of PA that were not measured by objective measures (activPAL™). Using both subjective and objective measures of PA allowed an assessment of the actual activity and the context of this activity.

4.3.2 Rheumatoid arthritis assessment

1 Disease activity

RA disease activity is a reversible aspect of the disease and is affected by multiple factors. The unpredictable course of RA and the varied clinical presentations of the disease can confound the process of measuring disease activity. Therefore, monitoring of disease activity requires a composite evaluation of a variety of clinical parameters. Several methods have been identified to provide physicians and patients with simple and comprehensible instruments to measure disease activity, such as the Disease Activity Score (DAS), DAS 28, the Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI).

The Disease Activity Score (DAS) is an important tool used to discriminate between active disease and disease that is in remission; it helps also in the evaluation of treatment outcomes and facilitates clinical decisions (Anderson et al., 2012). The DAS or DAS28 involves assessing the number of swollen and tender joints and the ESR measure. The DAS measures 44 joints and DAS28 assesses 28 joints. The DAS is scored between 0 and 10 (Smolen et al., 2003) where disease activity is categorised into: high: >5.1, moderate: >3.2 to 5.1, low: 2.6 to ≤ 3.2, and remission <2.6 (Fransen and van Riel, 2009). The remission category of the DAS28 has been criticised as it does not take into account good radiographic outcomes (Wechalekar et al., 2012). Provider (physician) global assessments are not included in DAS28 and it requires a more complex calculation (Anderson et al., 2012).

The SDAI score is the sum of the following: joint tenderness and swelling, a patient global score, which is a visual analogue scale (VAS) 0-10 cm, a provider global score, which is physician global assessment of disease activity (VAS) 0-10 cm and C-reactive protein mg/dl (Appendix 7). An SDAI value of 3.4-11.0 is low disease activity, moderate is >11-26, high activity values range from 26.1 to 86 and the remission value is 0.0-0.3 (Smolen et al., 2003).

CDAI is a patient and provider composite tool that comprises provider assessments - 28 swollen joint counts, and 28 tender joint counts. However, it

does not provide detailed joint counts reliably and it does not include laboratory acute-phase reactants (Anderson et al., 2012).

The DAS, DAS28, SDAI and CDAI are all valid and potentially useful tools for evaluating disease activity with intra-class correlation coefficients ranging from 0.85 to 0.89 (Gaujoux-Viala et al., 2012). However, the DAS28 is less effective in defining remission than SDAI (Gaujoux-Viala et al., 2012, Gilek-Seibert et al., 2013). Balsa et al. (2010) assessed 97 RA patients considered as being in remission using the DAS 28 and the SDAI. They found a moderate correlation between the DAS28 and SDAI ($r = 0.45$, $P < 0.001$) however the SDAI was superior to the DAS 28 in determining remission.

The SDAI is a valid and reliable tool for the assessment of RA (Balsa et al., 2010, Fleischmann et al., 2015), the treatment response and also for evaluating RA disease activity in routine clinical practice (Anderson et al., 2012, Smolen et al., 2003). It has been stated that the SDAI is the most sensitive and specific for prediction of clinical decisions to change DMARD and the remission score of SDAI is one of the recommended definitions of RA remission by the ACR and EULAR 2011 to be used in RA clinical trials (Anderson et al., 2012). Therefore, the SDAI has been selected for use in this study.

2 Rheumatoid Arthritis Quality of Life (RAQoL)

Quality of life has become an important concept within health outcome appraisal, in general as well as with chronic disease. It is an indicator of burden of disease, in terms of both physical and mental health, and provides insight into the outcome of a treatment programme (Burckhardt and Anderson, 2003, Salaffi et al., 2009). A number of scales have been used to assess quality of life in RA, including the Health-Related Quality of Life (HRQoL), the Quality of Life Scale (QOLS) and the Rheumatoid Arthritis Quality of Life (RAQoL).

The HRQoL measures overall quality of life in terms of the effects of health on different domains of life, such as physical, social, psychological/emotional and cognitive functioning (Centers for Disease Control and prevention, 2016b). The QOLS is a reliable and valid instrument that can be used in assessing quality of

life across different patient groups and cultures (Burckhardt and Anderson, 2003). However, both tools are generic rather than disease specific.

The RAQoL is a disease-specific, self-report questionnaire originally developed in the UK and the Netherlands. It consists of 30 items, with a yes/no (1/0) response format (Whalley et al., 1997) (Appendix 8). Whalley et al. (1997) interviewed 50 RA patients (25 in the UK and 25 in the Netherlands) regarding their quality of life in relation to RA. The study concluded that RA affects people in many aspects of their life: social, mental, physical and emotional. A qualitative approach was used in order to develop a tool that was suitable for use in clinical trials as well as in the monitoring of patients in routine clinics. Based on the interviews, appropriate items for inclusion in the RAQoL were derived, and thus a tool specific for use with RA patients was designed. One negative aspect is that the disease-specific nature of the tool does not facilitate its results being compared to other diseases. The RAQoL has been found to be a reliable and valid instrument with which to measure quality of life among RA patients, with very good test and retest reliability (Spearman's correlation > 0.90). It has also been demonstrated to correlate with the Disease Activity Score (DAS) (r 0.41-0.82), and Health Assessment Questionnaire (HAQ) (r 0.73-0.86) (Maska et al., 2011a). As the RAQoL is a valid instrument for assessing quality of life in people with RA (Linde et al., 2008, Maska et al., 2011a, Tijhuis et al., 2001), it was chosen for measuring quality of life in the current study.

4.3.3 Assessment of functional capacity

Rheumatoid arthritis is a chronic disease that affects patients' daily activity performance and may cause varying degrees of disability. There are no specific guidelines on assessing functional capacity in RA sufferers (Santana et al., 2014). However, various instruments have been used such as the Modified Stanford Health Assessment Questionnaires (MHAQ), Arthritis Impact Measurement scales (Aims), the six-minute walk test (6MWT), the hand grip test (dynamometer), and the sit and reach, sit back and stand up tests (Santana et al., 2014). In this study, the modified HAQ (Appendix 9), 6MWT and hand grip tests were selected to assess functional capacity, based on evidence of their reliability and validity in assessments of people with RA and also as they are simple clinical assessments, well tolerated by patients.

1 Modified Stanford Health Assessment Questionnaire (MHAQ)

The HAQ is used to measure the capacity of participants to perform activities in their daily lives (Oliveira et al., 2015). This is a self-report questionnaire that quantifies the degree of disability in carrying out certain functional activity: dressing, grooming, rising, eating, walking, hygiene, degree of reach, strength of grip and other common daily activities. The HAQ has been identified as a reliable and valid instrument that can be used to assess functional capacity in various chronic conditions (Uhlig et al., 2006, Linde et al., 2008, Bruce and Fries, 2003). There are two versions of the HAQ: full and modified. The full HAQ was adopted by the Arthritis, Rheumatism, and Aging Medical Information System (ARAMIS) in 1980 for evaluating the clinical status and health outcomes in observational as well as in clinical trials. The modified HAQ is mainly used to assess disability and has been employed in the assessment of a variety of diseases such as osteoarthritis, juvenile rheumatoid arthritis, fibromyalgia, psoriatic arthritis and systemic sclerosis (Bruce and Fries, 2003).

Although there are a number of instruments used in assessing the functional capacity of people with RA, the HAQ is considered the most familiar tool (Scott et al., 2000). In addition, the HAQ is a useful tool in evaluating functional capacity across all levels of RA severity (Marra et al., 2004). A study undertaken by Uhlig et al. (2006) examined both the HAQ and the modified HAQ (MHAQ) in 182 RA patients and demonstrated strong significant correlations between adjusted/unadjusted HAQ and MHAQ scores of 0.85/0.88 ($P<0.01$).

The HAQ has also been found to correlate with the RAQoL (r 0.73-0.86) and the test–retest reliability for the MHAQ is shown to be strong (0.65-0.91, $P<0.01$) (Maska et al., 2011a). As the HAQ and MHAQ remain the gold standard for measuring the functional capacity of people with RA (Maska et al., 2011a) the MHAQ was selected for use in this study.

2 Six-minute walk test (6MWT)

There are several walking tests, such as the two minute walk test, the 12-minute walk test and the self-paced walk, but the 6-minute walk test (6MWT) is the most commonly used test in research and clinical investigation, as it is a simple

test, and is well tolerated (Zielinska et al., 2013). The 6MWT was undertaken according to the American Thoracic Society (ATS) guidelines (2002) for assessing exercise tolerance in people with chronic respiratory disease and heart failure. The test has been used to assess functional capacity in a range of diseases such as stroke, fibromyalgia and heart failure (Pollentier et al., 2010) and also in healthy individuals (Zielinska et al., 2013). Enright (2003) reported that the 6MWT distance was lower for old people, the obese and people with arthritis or any other musculoskeletal diseases than for healthy individuals.

A study conducted by Pankoff et al. (2000) used the 6MWT as a tool to assess cardio-respiratory fitness in people with fibromyalgia, where the results demonstrated a significant correlation between the 6MWT and $VO2_{max}$ ($P<0.001$). In a later study, a positive correlation was found between the 6MWT and $VO2_{max}$ after knee arthroplasty ($r = 0.71$) (Bennell et al., 2011). However, the use of the 6MWT has some contraindications in particular conditions, such as unstable heart disease, high blood pressure (>180 mmHg), diastolic BP (>100 mmHg) and tachycardia (Zielinska et al., 2013). However, a number of studies examined the validity and reliability of 6MWT in fibromyalgia (Pankoff et al., 2000), scleroderma and knee arthroplasty (Bennell et al., 2011) a lack of in RA.

3 Hand grip strength

Hand grip strength can be used as a measure of estimated general muscle strength (Wind et al., 2010). Hand dynamometers are widely used in measuring hand grip strength, and are considered gold standard tools (Roberts et al., 2011). The reliability and validity of the hand grip test using a hydraulic hand dynamometer has been addressed in connection with several conditions, such as cervical radiculopathy (CR) (Savva et al., 2014) and RA (Shiratori et al., 2014), as well as in healthy individuals (Massy-Westropp et al., 2011). Hand grip tests administered on patients with cervical radiculopathy gave an interclass correlation coefficient of (0.97); this is evidence of high test-retest reliability and supports their applicability as indicators of muscle strength in those patients (Savva et al., 2014).

In addition, Boon et al. (2010) stated that the hydraulic dynamometer and biometrics electronic dynamometer have excellent concurrent validity in both

the right hand (0.98) and left (0.98), and are valid tools in the measurement of grip strength in healthy individuals. A small change in hand grip strength magnitude may be significant and may reflect clinical changes in people with RA, and therefore it is recommended to evaluate hand grip strength using a tool that is sensitive to detecting the degree of change in people with RA (Kennedy et al., 2010, Shipham and Pitout, 2003).

A literature review evaluating the hand grip strength test in people with RA reported that 47.5% of studies assessed hand grip strength using a hydraulic dynamometer and considered it to be a gold standard tool in terms of the provision of quantitative information regarding the physical capacity of people with RA. Therefore, a hand grip test using a hydraulic dynamometer was chosen in this study.

4.4 Cardiovascular (CV) risk factors

4.4.1 Blood samples and ASSIGN score

Several studies have assessed the risk of CVD in healthy individuals as well as in RA patients, where biochemical variables such as C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), plasma glucose, total cholesterol, low-density lipoprotein (LDL), high density lipoprotein (HDL) and triglycerides have been assessed. The biochemical variables used in the assessment of risk of CVD in people with RA, such as the testing of lipids (e.g. total and HDL cholesterol and triglycerides), glucose, insulin, HbAlc, and inflammatory biomarkers (CRP) were based on the Scottish Intercollegiate Guidelines Network, 2008 (SIGN).

Myasoedova et al. (2011) studied 651 people with RA and reported ESR to be an important biochemical variable in measuring inflammation related to the risk of CVD in people with RA (Hazard Ratio (HR) =1.2 per 10mm/h increase, CI 1.1-1.3 95%). In addition, LDL level is associated with risk of CVD. Lipid levels have been found to be paradoxically associated with CVD risk among people with RA, where an increased risk of CVD has been noted with total cholesterol (TCH) < 4mmol/l (95% CI 1.5-7.2), whereas CVD risk has not been found to be increased with TCH ≥4 mmol/l (Myasoedova et al. (2011).

To estimate the risk of developing CVD over a ten-year period, cardiovascular risk can be assessed with SIGN (Scottish Intercollegiate Guidelines Network) (ASSIGN score) Version 1.5.1 (http://assign-score.com). The ASSIGN score is a cardiovascular risk score developed by Dundee University, Scotland in 2006, which includes social deprivation and family history of CVD, features that are not included in certain other scores such as the Framingham risk score. The Framingham risk score calculates the risk of CVD based on a United States cohort. It includes age, sex, smoking, blood pressure, diabetes and lipids but does not include the social status items featured in the ASSIGN score (Tunstall-Pedoe, 2011). There is a lack of literature regarding the use of ASSIGN scores in RA and further studies are required.

4.4.2 Anthropometric variables

Adipose tissue is a metabolically active tissue that has the ability to synthesise and secrete hormones; this in turn has an effect on metabolism, immune function and vascular homeostasis (Coelho et al., 2013). Adipose tissue is strongly associated with insulin resistance and CVD in the general population (Arbel et al., 2012) as well as in RA patients (Soeiro Ade et al., 2012). Body composition has been used as an important indicator of health outcomes, including CVD risk (Kremers et al., 2008). Anthropometric measures are employed to assess body mass index (BMI) and abdominal obesity [waist circumference (WC), waist to hip ratio (WHR) and waist to height ratio (WHtR)]. Studies have revealed a strong association between anthropometric measures (BMI, WHR, WHtR) and major metabolic CVD risks such as hypertension, hyperlipidemia and abnormal glucose tolerance (Ashwell et al., 2012, Paniagua et al., 2008).

1 Body Mass Index (BMI)

Body mass index (BMI) is a measure of total body fat and is an important tool in assessing the risk of CVD (Summers et al., 2008, Paniagua et al., 2008). The use of BMI alongside other anthropometric measures of abdominal obesity can be applied to enhance the identification of risk of CVD and other metabolic disorders, however BMI does not reflect fat distribution (visceral fat) (Zhu et al., 2004). BMI is calculated as weight (kg)/ height (m)^2. Based on information

taken from the World Health Organization (World Health Organization, 2011), BMI is categorised into <18.5 kg/m^2 (underweight), 18.5 to 24.9 (normal weight) and 25 to 29.9 (overweight), with values above 30 being considered obese.

2 Waist-to-Hip Ratio (WHR)

WHR is an important tool for assessing CVD risk. It has been reported that WHR is a superior clinical measure of obesity for predicting all cases of CVD and CVD mortality (Welborn and Dhaliwal, 2007). In addition, WHR appeared to be a more appropriate measure of obesity than WC and BMI in high functioning older men and women. WHR was found to be positively associated with all causes of mortality (Srikanthan et al., 2009).

3 Waist-to-Height Ratio (WHtR)

Statistical evidence from studies conducted on over 300,000 adults from several ethnic groups shows the superiority of WHtR over WC and BMI for detecting cardiometabolic risk factors in both sexes because it measures central obesity, a better discriminator of CVD risk (Ashwell et al., 2012). WHtR helps differentiate between individuals with excess adipose tissue from high muscle mass, in addition, the distribution of body fat can be recognised (Ashwell et al., 2012, Lee et al., 2008). A meta-analysis conducted by Lee et al. (2008), which analysed data from 88,000 individuals, reported that WHtR was more accurate than BMI in discriminating those people with CVD risk factors such as hypertension, dyslipidaemia and diabetes from both sexes. There was a lack of studies examining WHR and WHtR in relation to RA.

4.5 Dietary assessment–Dietary Instrument for Nutrition Education (DINE)

There are a number of dietary assessments such as the Short Form Food Frequency Questionnaire (SFFQ), the long form Food Frequency Questionnaire (FFQ), the Five-A-day Community Evaluation Tool (FACET) and the Dietary Instrument for Nutrition Education (DINE). The SFFQ test is used to assess the quality of overall diet which includes examining the intake of a number of different foods such as fruit and vegetables (Shim et al., 2014). The reliability and validity of the SFFQ has not been examined extensively. The FFQ, which is a

long questionnaire consisting of 217 items, takes a long time to complete and is therefore inconvenient to the participants (Shim et al., 2014).

The FACET, which was designed to examine the effectiveness of a pilot initiative to enhance the consumption of fruit and vegetables in deprived areas, focuses on the intake of fruits and vegetables (Ashfield-Watt et al., 2007). The DINE tool was chosen for this study (Appendix 11). It was developed in 1994 and is a simple self-administered inexpensive tool designed for dietary assessment within primary care health promotion programmes (Little et al., 1999, Roe et al., 1994) and it has also been implemented in a health survey conducted in England. The DINE consists of questions regarding food and drink consumed over the previous seven days, and scores are obtained for fatty foods, sugary foods, and fruit and vegetable intake.

It is a valid method of dietary assessments that can be used effectively within the general population (Hardcastle et al., 2013, Roe et al., 1994). One of the advantages of the DINE questionnaire is that 70% of its questions concern fat and fibre, which are typical within the UK diet (Hardcastle et al., 2013). There are significant correlations between the DINE tool and estimated food diaries; total fat ($r = 0.51$), polyunsaturated: saturated fat ratio ($r= 0.43$) and fibre ($r = 0.46$) (Hardcastle et al., 2013, Roe et al., 1994). The DINE has been successfully implemented in a number of studies to investigate inflammatory polyarthritis and also in the field of the secondary prevention of coronary heart disease (Byrne et al., 2005, Pattison et al., 2004). However, no study has examined the reliability and validity of DINE among people with RA, but the same is true for the other methods of dietary assessment.

4.6 Self-efficacy for physical activity

Self-efficacy is related to people's beliefs regarding their ability to perform exercise regularly (Neupert et al., 2009). Increasing levels of self-efficacy can play a role in the likelihood of an individual with RA achieving PA goals (Knittle et al., 2011). A number of methods have been used to assess an individual's self-efficacy in terms of regulating exercise, such as the general self-efficacy scale (GSE). The GSE is valid for the assessment of PA self-efficacy, and can be used with patients with chronic pain or in rehabilitation programmes.

The self-efficacy to regulate exercise is a straightforward, reliable and valid questionnaire that can be used within clinical settings (Bandura, 2006). Scores range from 0-100, with high scores (90-100) indicating a high certainty of undertaking exercise and low scores (0) indicating that the individual cannot participate in the exercise (Appendix 10). Its reliability is shown to be (0.92 Cronbach's alpha) and its validity of self-efficacy correlation with minutes of exercise per week is shown to be ($r = 0.41$, $P < 0.0001$) (Davis et al., 2007). A significant correlation has been demonstrated between self-efficacy for PA and the generalised self-efficacy scale (Spearman $r = 0.316$; $P < 0.05$) (Kroll et al., 2007). The self-efficacy to regulate exercise has been used in this study as it is a reliable instrument with high internal consistency (alpha= 0.92 and r ranged from 0.38 to 0.76) (Resnick and Jenkins, 2000).

4.7 Qualitative study

A number of methods are used to collect qualitative data in research, such as focus groups and interviews, either face-to-face or via the telephone (Gill et al., 2008). A focus group is a group discussion on a particular topic organised for research purposes (Gill et al., 2008). A focus group aims to identify the thoughts, perceptions and suggestions of a selected group of people regarding a specific topic under examination (Larkin et al., 2016b). This discussion is guided, monitored and recorded by a researcher (Gill et al., 2008). However, great care needs to be taken in order to obtain the best quality discussion. This depends on the researcher's skills and the group interaction, which is considered the key to a successful focus group. In addition, the transcription of focus groups is more complex and time consuming than in one-to-one interviews (Gill et al., 2008).

The interview is one of the most frequently used methods of collecting qualitative data. Although face-to-face interviews can collect good-quality data with visual aids and the detection of body language, they have a number of disadvantages such as being more time consuming, delivering a biased response, and safety concerns for the researcher and participants (Szolnoki and Hoffmann, 2013).

Semi-structured telephone interviews can be useful to collect quantitative and qualitative data (Burnard, 1994). Telephone interviewing may provide an

opportunity to obtain data from participant or groups who are otherwise difficult to access in person (Oltmann, 2016). Also, a telephone interview is preferred for the discussion of sensitive topics such as those that are emotionally painful. Telephone interviewing is a cost-effective method of data collection (Novick, 2008).

It was concluded that in general, telephone interviewing was an acceptable and valuable method of data collection and that it can also yield good-quality data with a good response rate (Sturges and Hanrahan, 2004). Therefore, semi-structured telephone interviews were chosen to be used in this study.

5 Materials and Method

This chapter will describe the study design, ethical approval, study setting, patient recruitment and selection and method of allocating participants to intervention or control groups. It also presents a description of the sample and sample size, data management, quantitative and qualitative data collection processes and methods of analysis of the outcome measures.

5.1 Study design

A single blind, randomised controlled trial was used to investigate the effectiveness of a six-month, community-based, pedometer-supported, walking programme, along with an education component, incorporating behavioural change techniques (BCTs), on step count and sedentary time, disease activity, functional capacity and cardiovascular risk of people within the first five years of being diagnosed with RA.

The trial protocol was registered on Clinical Trials.gov (http://www. Clinical Trials.gov; Identifier NCT02467205). The assessments were taken by the chief investigator (AE) who was blind to the group allocation and the study intervention was delivered by a physiotherapist with expertise in this field. The primary outcome measures were objectively measured changes in daily step count and sedentary time from baseline to 6 months (end of the intervention) with data obtained using an activPAL™ activity monitor. In addition, data was collected on subjectively measured PA and sitting time with a self-reported questionnaire (IPAQ). All measures were collected at baseline, 3 and 6 months (end of the intervention) and 12 months. The secondary outcome measures were related to disease activity, functional ability, cardiovascular risk factors, dietary assessment and physical activity for self-efficacy. In addition, interviews were conducted with 10 participants from the intervention group at six months in order to explore participant views regarding the WARA intervention.

5.2 Hypothesis

The null hypothesis was that there was no significant difference between the control and intervention group in primary outcome measure (PA and sedentary time) over the study period (6 months).

The alternative hypothesis was that there was a significant difference between the intervention and the control group in primary outcome measure over the study period (6 months).

5.3 Ethical approval

Ethical approval for the study was obtained from the West of Scotland Research Ethics committee (14/WS/0131) (Appendix 2) in July 2014 and all procedures were carried out in accordance with the Declaration of Helsinki. Participants were identified by a study number, and remained anonymous throughout the study. All participants provided written informed consent (Appendix 4) which included permission to access their medical records and were free to withdraw from the study at any time. Serious adverse events (SAE) are defined as any events or adverse reactions that result in death or are life threatening. They require hospitalisation or a prolongation of an existing inpatient's hospital stay, or result in significant disability or incapacity (Good clinical practice, 2014). The safety of the participants was addressed at several stages in this intervention. Strength exercises and walking are considered a popular and ideal mode of physical activity; exercise is not only important for promoting and maintaining health in the general population, but it also poses little risk of injury for sufferers of RA (Baxter et al., 2016). However, a serious adverse event that happened in this study was reported to the West Scotland Research Ethics Committee (further discussed in section 6.1).

5.4 Study setting

The participants were recruited from rheumatology outpatient clinics at Gartnavel General Hospital, Glasgow Royal Infirmary Hospital and Stobhill Hospital, Glasgow, UK. Physiological assessment and completion of questionnaires took place in a room at the participant's local hospital.

5.5 Patient recruitment and selection

Participants were eligible to participate in the trial if they were aged 18 years or over, had a confirmed diagnosis of RA according to the American College of Rheumatology (ACR)/ European League Against Rheumatism criteria (EULAR) 2010 (Aletaha et al., 2010), were within five years of diagnosis and willing and able to give written informed consent. Participants were excluded from the study if they suffered from severe hypertension, joint replacement in the previous 6 months, unstable cardiac conditions or other serious pathology such as uncontrolled diabetes which would affect their ability to take part in physical activity. Those who were pregnant, unable to understand written and spoken English or had cognitive impairment as determined by the clinical judgment of the researcher were excluded.

Recruitment to this trial took place from November 2014 to August 2015. Patients were informed of the study at their routine clinical appointments and given study information sheets (Appendix 3). If the patient was willing to take part in the study, they contacted the chief investigator by phone and a suitable date/time for baseline assessment was arranged and confirmed by letter. Participants were recruited in blocks of 12 participants in order to randomise them into intervention and control group (six participants in each group). On the initial assessment day, the participant had the opportunity to ask further questions before signing a consent form for the study.

5.6 Method of allocating participants to intervention and control groups

All participants who agreed to take part in the study consented to being randomised to either the intervention group or control group. For the randomisation process the physiotherapist generated a list of random numbers using an Excel spreadsheet where odd numbers represented the intervention group and even numbers the control group. Then each number and the group which it represented were put into sealed envelopes, in the order they were listed on the spreadsheet and the physiotherapist gave the participants these envelopes consecutively. Randomisation was performed with 1:1 allocation for each of the two groups. The participants were not blind to the group allocation.

The flow of participants through the recruitment process and randomisation is presented in Figure 6-1.

5.7 Sample and sample size

Physical activity defined as the mean number of steps per day, was one of the primary outcome measures. The sample size for this study was calculated using data from the study by Mutrie et al. (2012) in which 41 healthy adults aged ≥65 years were included in a 12 week crossover, two arm (intervention/control), randomised control trial; both groups were followed up at 12 and 24 weeks. The participants in the intervention group received two 30-minute PA consultations, as well as a pedometer and a walking programme. An activPAL™ monitor was used to assess participants' step counts. The mean (SD) of the step count at baseline for the intervention group was 7469 (2312) and for the control group was 7351 (2360). At week 12, the mean (SD) step count of the intervention group was 9351(2017) and of the control group was 7138 (2169). At week 24, the mean (SD) step count of the intervention group was 9161 steps (2631) and of the control group was 9100 steps (3175).

The interest of the current study is the difference in step count between the baseline and primary end points (six months – i.e. the end of the intervention). In order to achieve a 2000 step difference between the two groups, with a two-sided 5% significance level and a power of 90%, a sample size of 34 participants per group was required. Sedentary time is defined as time spent sitting or lying (including sleeping time).

5.8 Piloting the intervention

Testing of the pedometers was carried out in the School of Nursing and Health Care at the University of Glasgow to ensure the validity and reliability of the pedometers. Each pedometer was individually tested at the first education sessions by the participants with help of the physiotherapist, by ensuring that a test of 100 walked steps provided an error of <5%, as suggested by the Japanese Industrial Standard of 3% by Hatano (1997, cited in Baker et al. (2008a).

The intervention included 6 weekly small group sessions and 2 booster sessions (at 3 and 6 months). The specific topics covered are outlined in Table 3-3.The intervention (education sessions and outcome measures) was piloted with the first group. Feedback from the participants and the physiotherapist who delivered the programme suggested a number of small changes were required; included promoting greater group interaction by the use of flip charts in the education sessions on RA and the benefit of reducing sedentary behaviour. Also, quizzes were employed on the subjects of 'What is RA?', 'The risk of CVD in RA' and 'diet', to help participants to self-assess their knowledge and in order to optimise the learning outcomes. Also, some participants reported the exercises were too easy, therefore some exercises using Theraband were added to education session 4.

5.9 Data management

All of the participants' data (physiological and subjective data) were stored on a password protected computer server in the School of Nursing and Healthcare at the University of Glasgow. The names of the participants and their contact information were held separately in a securely locked room. They were checked by the chief investigator.

5.10 The use of mixed methodology

The use of mixed methodology can strengthen a study (Bryman, 2006, Harwell, 2011). A mixed methodology approach was used to overcome the disadvantage of single methodology studies. For instance quantitative methodology may focus on numerical data and therefore lacks the ability to understand the context of participant's behaviour however qualitative methodology may be seen as being subjective and lacking reliability and validity, (Creswell, 2014) (further discussed in section 4.1). Quantitative data were collected at baseline, 3, and 6 months (the end of the intervention) and 12 months (end of the study). The qualitative data were collected from telephone interviews of a sample of 10 participants in the intervention group at 6 months.

5.10.1 Quantitative data collection tools and processes

The chief investigator recruited participants from each hospital in blocks of 12 participants in order to randomise them into intervention and control group (six participants in each group). After participants gave their verbal consent to participate, a date and time was arranged for baseline assessment. If a participant had a 'flare' of their arthritis when the assessment was due the assessment was postponed until the flare reduced; up to 2 weeks after the original assessment date.

During the baseline assessment, the chief investigator confirmed that the participants had read and understood the participant information sheet and also asked if they had any questions regarding the study before signing the consent form. Then, the participants were asked to complete the study questionnaires which included demographic, family history and medical history, current treatment, smoking, alcohol consumption and work status (data collection sheet in Appendix 5). Physical activity was assessed objectively with an activPAL™, (PAL Technologies, Glasgow, Scotland) which participants wore for seven days continuously to quantify daily PA step counts and time spent sitting/lying. The activPAL™ provides valid and reliable data related to physical activity (Dahlgren et al., 2010, Ryan et al., 2006), (further discussed in section 4.3.1).

The monitor was attached to the skin of participants at the midpoint of the anterior aspect of the right thigh, using Tegaderm (3M™). Self-reported PA was assessed with the International Physical Activity Questionnaire (IPAQ) (Appendix 6) (Bull et al., 2009, Craig et al., 2003), (further discussed in section 4.3.1). Continuous scores were calculated based on the IPAQ guidelines; the total minutes of walking, moderate and vigorous intensity PA per week was calculated by multiplying the minutes of PA activity per day by the number of days per week the activity was reported. The Metabolic Equivalent of Task (MET) scores of 3.3, 4.0 and 8.0 for walking, moderate and vigorous intensity activity were assigned as per the IPAQ scoring protocol.

Walking MET-minutes/week = 3.3 walking minutes/ day for the days per week on which walking was reported.

Moderate MET-minutes/week = 4.0 moderate intensity minutes/day for the days per week on which moderate intensity activity was reported.

Vigorous MET- minutes per week = 8.0 vigorous intensity minutes/ day for the days per week on which vigorous intensity activity was reported.

Total physical activity MET-minutes/week = Walking + Moderate + Vigorous MET minutes/week scores.

The self-efficacy for PA was assessed with the Self-Efficacy to Regulate Exercise (SERE) questionnaire (Appendix 10). The participants completed the SERE; scores can range from 0-100, with 90-100 indicating 'high certainty can perform the exercise' and zero indicating 'cannot do' (Davis et al., 2007, Kroll et al., 2007). Other assessments were the Rheumatoid Arthritis Quality of Life (RAQoL) for quality of life (Appendix 8). RAQoL scores range from 0 to 30 with higher scores reflecting a poorer quality of life (Linde et al., 2008, Maska et al., 2011a). The Modified Stanford Health Assessment Questionnaire (HAQ) assessed functional capacity (Appendix 9) and scores range from 0-3, with higher scores indicating more disability (Bruce and Fries, 2003, Linde et al., 2008, Uhlig et al., 2006). The Modified Dietary Instrument for Nutrition Education (DINE) (Appendix 11) scores were obtained for fatty foods, sugary foods, and fruit and vegetable intake (Little et al., 1999). If the participants had any questions regarding the questionnaires, the chief investigator clarified them at the time. Further details regarding the questionnaires used in this study were discussed in chapter 4.

After the participants completed the questionnaires, their blood pressure was measured with the participants in a sitting position. Blood pressure were taken from the right arm and a mean of the three readings recorded. Height was measured to the nearest 0.5cm using a stadiometer (Seca 217 stadiometer, Ltd., Liverpool, UK), with the subject barefoot and standing erect. Weight in kg was measured using a portable electronic scale (Seca model 770, Ltd., Birmingham, UK) with the subject wearing light clothing and without shoes.

The waist circumference was measured midway between the upper margin of the iliac crest and lower rib margin of the last palpable rib with the participant standing erect and with their clothing raised, and was measured with an

inelastic tape measure. Hip circumference was measured round the widest part of the buttocks (World Health Organization, 2011).

To assess clinical disease activity the Simplified Disease Activity Index (SDAI) was used (Appendix 7) (www.rheumatology.org). The SDAI score consists of four components; joint tenderness and swelling based on a 28-joint assessment, patient global score is a visual analogue scale (VAS) 0-10cm, provider global score is physician global assessment of disease activity (MDGA VAS 0-10cm (0-10) and C-reactive protein mg/dl. An SDAI value of 3.4-11.0 is low disease activity, moderate (>11-26), high activity values range from 26.1 to 86 and the remission value is 0.0-0.3 (Fleischmann et al., 2015).

The chief investigator was trained by the rheumatologist at GGH on how to perform the SDAI. The chief investigator was trained on how to assess tender and swelling joint counts based on 28 joint assessments. This involved assessing 10 proximal interphalangeal joints of the fingers, 10 metacarpophalangeal joints, the wrists, elbows, shoulders and knees. The swollen joint count reflects the amount of inflamed synovial tissue. Joint swelling is defined as soft tissue swelling of the joint which is detectable along the joint margins and characterised by fluctuation (Scott and Scott, 2014). The tender joint count is associated more with the level of pain. Joint tenderness is defined as pain at rest that is induced by pressure during the examination of the joints (Scott and Scott, 2014).

A handgrip dynamometer (Hydraulic Hand Dynamometer, Model 5030J1, Ltd, Nottinghamshire, UK) was used for measuring handgrip strength. The hand grip test was done with the participant in a sitting position with shoulders adducted and neutrally rotated, elbow flexed at 90°, forearm in neutral and wrist between 0 and 30° of extension. The test was repeated 3 times with the dominant hand. The participant was instructed to apply as much grip pressure as possible on the dynamometer and the maximum reading was taken.

The participant then completed the 6-minute walk test, where they were asked to walk for a period of six minutes, at their own pace, along a straight, 30 m hallway. Participants were asked to cover as much ground as possible in six minutes and allowed to stop if required; the reason and time of any stops were

recorded. The distance walked in metres at the end of the six minutes was recorded (Alameri et al., 2007).

The Charlson Comorbidity index (Appendix12) was used as a prognostic measure of illness burden, the data were collected by the chief investigator from the participants' medical records. The score was reached by adding the comorbidity score to the age score (Pedersen et al., 2006).

For estimating the risk of developing cardiovascular disease over 10 years the ASSIGN score (Scottish Intercollegiate Guidelines Network, version 1.5.1) was used (ASSIGN score, 2008) (http://assign-score.com). The ASSIGN score includes age, sex, place of residence (Scottish postcode), family history of CHD/stroke, diabetes mellitus, tobacco smoking (cigarettes, pipe tobacco or cigars), systolic blood pressure reading, blood total cholesterol and HDL-cholesterol (SIGN guideline 97(2007) version 1.5.1).

The ASSIGN score is between 1 and 99. The higher the score, the higher the risk of developing cardiovascular disease. Participants with a high score (20 or more) are considered to have a high chance of CVD or stroke compared to those who have a score below 20 (Hippisley-Cox et al., 2007, Woodward et al., 2007). The variables are filled out on a web form and a score of 20 or more is considered a high risk of CVD, where advice and treatment is required (http://www.assign-score.com/estimate-the-risk/calculation-format/).

To assess the level of PA, participants wore an activPAL™ activity monitor (PAL Technologies, Glasgow, Scotland) for seven days continuously (24 hours a day) to quantify daily PA step counts and time spent sitting/lying. The monitor was attached by the chief investigator to the skin of participants on the midpoint of the anterior aspect of the right thigh, using Tegaderm (3M™). Waterproof wrapping of the monitors allowed wearing during showering. The participants were asked to perform their normal daily activities and to remove the device only when they wanted to take a bath or swim. Participants were asked to return the monitor to the chief investigator at the end of the seven-day period in the stamped addressed envelope provided. Validity and reliability of the activPAL™ in assessing PA has been discussed in (section 4.3.1).

Finally, the chief investigator took blood samples from participants. The blood samples were collected from the antecubital vein into EDTA 9 mls (purple top tubes in UK), Fluoride Oxalate 2 mls (grey top tube in UK) and Serum separator 7 mls (orange top tubes in UK). Blood samples were processed according to the flow diagram in Figure 5-1. The following outlines the blood collection procedure based on standard operating procedure (SOP) of the WARA study, transportation of biological samples for processing and sample storage (Elliott and Peakman, 2008, Somoza and Tora, 2009).

A disposable tray for the blood sample was set out with the following: labelled blood sample bottles, alcohol wipe, gauze swab, plaster, vacutainer holder, butterfly needle and tourniquet. All equipment was collected together and expiry dates checked.

The chief investigator explained the procedure to the participant, checked if the patient was taking any anticoagulant medications and ensured the participant was sitting/lying comfortably with their arm supported. Before starting the procedure hand hygiene was performed based on WHO guidelines (World Health Organization, 2010), and gloves were worn. The needle was attached to the vacutainer holder, and a tourniquet was applied to the patient's upper arm. Venous blood flow was suppressed to ensure a pulse was palpable distal to the tourniquet. The limb was placed below the level of the heart, and participants were asked to open and close their fist. Palpation was used to find a suitable vein.

The participant's arm was cleaned with alcohol wipes and allowed to dry before a needle was inserted. After the entry site was cleaned, it remained untouched to preserve the sterile conditions. The non-dominant hand of the chief investigator was used to stabilise the vein by applying traction to the side or below the insertion site. A needle was inserted into a vein with the bevel up, to ensure the smooth puncture of the vein. The vacutainer bottles were attached to the holder and blood was collected in the tubes. All vacutainer tubes were labelled with details of the participants' unique study identification and the date. The tourniquet was slackened once a good blood flow was achieved and at least10 seconds were allowed for a complete blood draw into each tube. It was ensured that blood had stopped flowing into the tube before it was removed.

Once a full sample had been collected, the tourniquet was removed and the puncture site covered with a gauze swab. The needle was removed from the arm and pressure was applied to the area. The participant was instructed to keep their arm straight and press firmly on the area for several minutes.

All vacutainer bottles were inverted gently eight times, to ensure thorough mixing of the blood. Used needles and the vacutainer holder was placed in the sharps bin. The swab was disposed of in a clinical waste bag. The patient's arm was checked to ensure that the puncture site had stopped bleeding before a small sterile self-adhesive plaster was applied, after first verifying that the participant was not allergic to plasters.

All blood samples were stored and transferred to the sample processing area at 4°C, in a cool bag with an ice pack. The aim was to get the samples processed (as per blood processing and storage standard operating procedure) and stored in the -80°C freezer within 24 hours of sample collection (ideally within 12 hours). Whole blood, plasma and serum aliquots were pre-labelled before specimens were added. The Specimen ID label was applied and the tube stored horizontally. The edges of the label were checked to ensure that the label was firmly affixed.

For processing the 9 ml EDTA tube (purple top), a new transfer pipette was used to dispense 2 x 1 ml whole blood into pre-labelled storage tubes. The remaining blood in the EDTA tube was centrifuged at 4000 RPM at 4°C for 15 minutes. A new transfer pipette was used to dispense 5 x 0.5 ml EDTA plasma into pre-labelled storage. Serum tube 7 ml (red top) was allowed to clot for at least 30 minutes after sample collection. The serum tube was centrifuged at 4000 RPM at 4°C for 15 minutes. A new transfer pipette was used to dispense 5 x 0.5 ml serum into pre-labelled storage.

The fluoride oxalate tube 2 ml (grey top) was centrifuged at 4000 RPM at 4°C for 15 minutes. The blood glucose was measured immediately using YSI 2300 STAT plus Glucose & Lactate Analyzer. A new transfer pipette was used to dispense 1-2 x 0.5 ml fluoride oxalate plasma into pre-labelled storage tubes.

All 14 barcoded aliquots were stored at -70 or -80˚C in bar-coded boxes in the West Medical Building of the University of Glasgow. The boxes were placed in an alarmed freezer, allowing samples to be promptly removed and placed into a spare freezer in the event of a freezer breakdown.

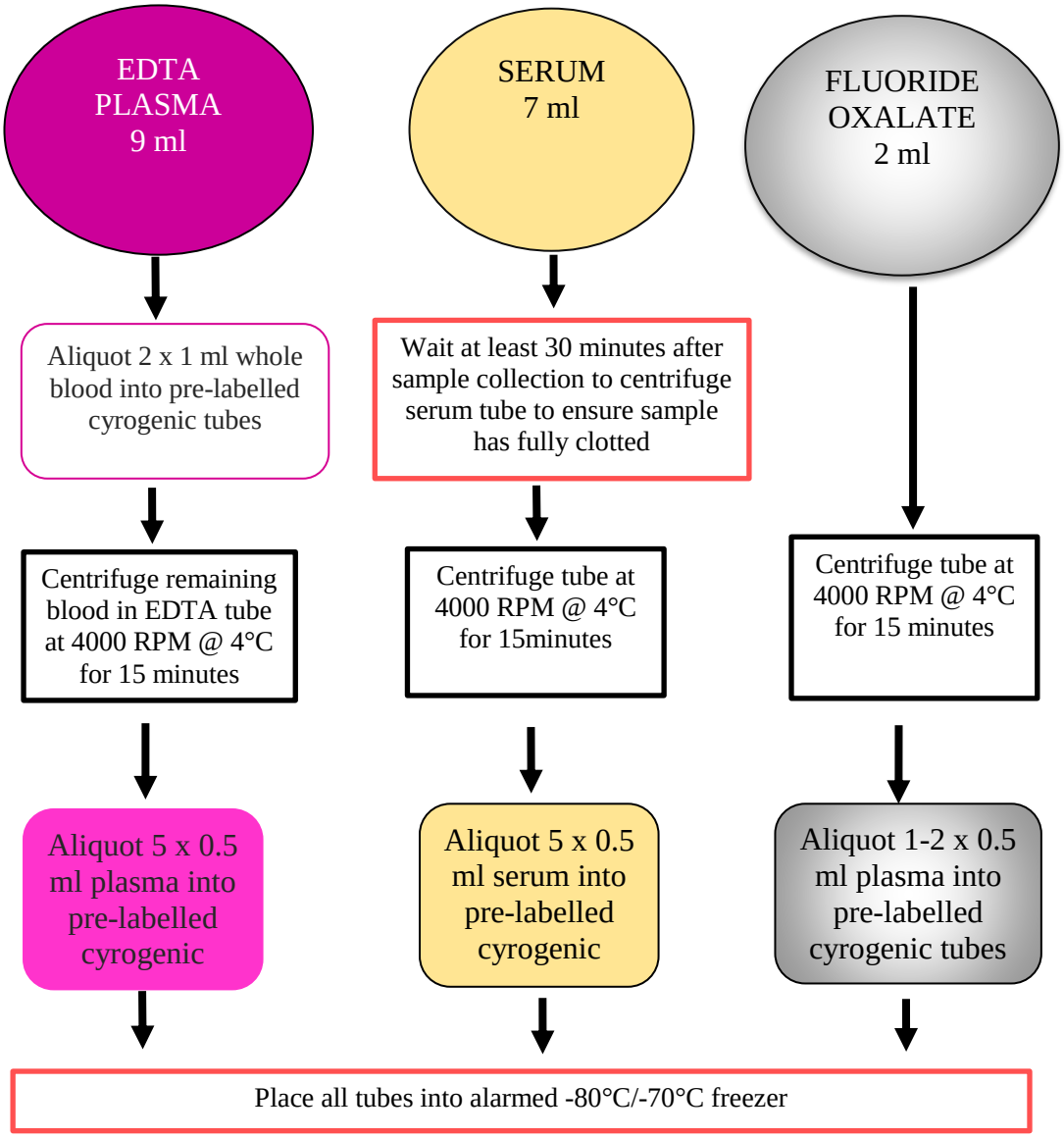

Figure 5-1 Processing of study bloods for storage

5.10.2 Walking programme for the intervention group

The aim of the walking programme was for the participants to increase their average daily step count by 3000 steps above their baseline value on at least 5 days of the week by 6 months and to maintain this up to 12 months. The UK physical activity guidelines (2011) recommended 150 minutes/week in 10-minute bouts, which can also be achieved with 30 minutes 5 days/week.

The walking programme of this study was adapted from (Baker et al., 2008a) where it was used successfully to increase walking and reduce sedentary behaviour in a Scottish community sample. The evidence showed that adding a fixed increment to the average step count for people who are physically inactive may make it challenging for them to increase their step count. It may also help participants to reinforce their increased levels of walking, or participants may try to create strategies in order to successfully accumulate the additional steps (Baker et al., 2008a). However, in Baker et al. (2008a) the population was healthy and the goal of the walking programme was 1500 steps increase, maintained for 2 consecutive weeks. With the WARA intervention, the population had RA, therefore the goal of the walking programme was modified to 1000 steps increase maintained for 2 weeks.

5.10.3 Intervention and control group

Participants in the intervention group attended six weekly sessions in small groups of up to six people; the sessions were interactive and each session lasted approximately one hour. Thereafter the physiotherapist contacted the participants at the end of weeks 7, 9 and 11 (i.e. when their step target increased by 1000 steps or changed from three to five days) to the end of the intervention (6 months) to discuss their step counts for the past month, their step goals for the following month, any barriers to PA they faced and how they planned to overcome them. Participants also received two booster sessions, 3 and 6 months after starting the programme. The content of all education sessions and BCTs presented in Table 3-3.

For the purposes of the current study participants randomly allocated to the control group received one education session regarding the importance of exercise and healthy diet, were given written education material and encouraged to read it (Appendix 15). The session took place at the participant's local hospital and lasted approximately one hour. On completion of the study participants in the control group were given a pedometer and PA diaries and advised on how to use them. The study programme for intervention group shown in Table 5-1 and the control group in Table 5-2 .

Table 5-1 Study programme for intervention group

Visit	Label	Programme Content	Duration
Visit (1)	Baseline Assessment	Study explanation and consent. Activity monitor attached to the participant's thigh to wear for 7 consecutive days. Baseline assessment complete questionnaires face to face and measured blood pressure, anthropometric measurements,6-minute walk, and blood samples was collected.	One hour
Visit (2) 7-10 days later	First education session	Interactive discussion on CVD, Rheumatoid arthritis, Risk of CVD in Rheumatoid Arthritis, the importance of physical activity, Goal setting, instruction and practice on how to use pedometer. Each participant will be given a pedometer to take away with them, as well as a physical activity diary, instructions on how to use it.	One and half hour
Visit (3) week 3	Second education session	Group discussion regarding exercise and physical activity and self-monitoring of behaviour, barriers to physical activity (Problem solving), advice, discussion on the importance of social support.	One hour
Visit (4) week 4	Third education session	Relapse prevention, Control over CVD via lifestyle behaviour.	One hour
Visit (5) week 5	Fourth education session	Relevance and importance of strength training and opportunity to practice exercises.	One hour
Visit (6) week 6	Fifth education session	Interactive discussion regarding healthy diet, strategies to enhance perceived control.	One hour
Visit (7) week 7	Sixth education session	Motivation, Social facilitation, Action planning for the next 6 weeks.	One hour
Visit (8) week 13	First post intervention assessment	Attach activity monitor to participant's thigh; Complete questionnaires face to face. Measured blood	One hour

		pressure, anthropometric measurements,6-minute walk, and blood samples was collected.	
Visit (9) week 14	First booster education session	Discuss any barriers, encouragement and motivation of the participants to continue in this programme.	One hour
Visit (10) week 26	Second post intervention assessment	Attach activity monitor to participant's thigh, complete questionnaires face to face and measured blood pressure, anthropometric measurements,6-minute walk, and blood samples was collected.	One hour
Visit (11) week 27	Qualitative Interview	Participant's views on the programme.	30 minutes
Visit (12) week 28	Second booster education session	Discuss any barriers, encouragement and motivation of the participants to continue in this programme.	One hour
Visit (13) week52	Last visit, final assessment (end of the study)	Attach activity monitor to participant's thigh, complete questionnaires face to face and measured blood pressure, anthropometric measurements,6-minute walk, and blood samples was collected.	One hour

Table 5-2 Study programme for control group

Visit	Label	Programme	Duration
Visit (1)	Baseline Assessment	Study explanation and consent. Activity monitor attached to the participant's thigh to wear for 7 consecutive days. Baseline assessment: (blood sample, anthropometric measurement). Complete questionnaires face to face.	One hour
Visit (2)7-10 days later	Education session	Single education session will include topic regarding importance of physical activity and healthy diet.	One hour

Visit (3) week 13	First assessment post intervention	Attach activity monitor to participant's thigh, collect questionnaires posted one week before the appointment. If participants have not completed the questionnaire; will be done face to face. 6-minute walk, blood sample and anthropometric measurement.	One hour
Visit (4) week 26	Second assessment post intervention	Attach activity monitor to participant's thigh, collect questionnaires posted one week before the appointment. If participants have not completed the questionnaire; will be done face to face, 6-minute walk, blood sample and anthropometric measurement.	One hour
Visit (5) week 52	Third and final Assessment (end of the study)	Attach activity monitor to participant's thigh, collect questionnaires posted one week before the appointment. If participants have not completed the questionnaire; will be done face to face.6-minute walk, blood sample and anthropometric measurement.	One hour

5.10.4 Qualitative data collection

To explore participant's views regarding the effectiveness of the intervention a purposive sample of ten participants from the study was asked to take part in a semi-structured 30-minute telephone interview. This included both males and females, participants from the three recruiting hospitals, those who did and did not increase their PA, and those whose step counts declined. Telephone interviews were chosen as they are less time consuming, less expensive and less burdensome for participants. A topic guide was developed which contained main and prompt questions regarding the education sessions, questions regarding the programme (walking and strength exercise) and questions to determine the participant's overall views of the intervention. The interview schedule can be found in (Appendix 13).

The interview questions were piloted on PhD students at the Nursing and Healthcare School in order to determine the most logical order of the questions,

and to identify wording issues that need to be addressed for clarity. After participants gave their additional verbal consent to participate in interviews and a time was arranged for the physiotherapist to phone the participant. Telephone interviews were audio recorded, and transcribed. The telephone interview was done following the six months' assessment and was carried out by the physiotherapist.

5.11 Data Analysis of the outcome measures

5.11.1 Quantitative data analysis

Data were analysed using IBM SPSS Version-21 and Microsoft Excel. The normality assumption was assessed using the Shapiro-Wilk test. Descriptive statistics were calculated, and independent sample t-test and chi-square were used as appropriate to compare baseline values between groups. To assess the effect of the intervention on outcome measures, mixed Generalised Linear Models (GLM) were used incorporating restricted maximum likelihood (REML) to estimate missing values. The group x time interaction was used to assess the effect of the intervention on outcomes relative to the control, and the statistical significance was defined as $P<0.05$.

Post-hoc analyses from the GLM-REML were used as appropriate, and the statistical significance was defined as $P<0.05$. Multiple comparisons between groups were carried out using the t-test. The Bonferroni correction was applied to control for type I error from multiple comparisons and the statistical significance was defined as $P<0.025$.

The relationship between change in PA and sedentary behaviour and other outcomes was analysed using Pearson's correlations where statistical significance was defined as $P<0.05$.

The effect of the intervention was noted in terms of average changes of the outcomes in both groups. The difference between both groups (intervention and control) from the baseline to the end of the intervention (6 months) is considered the main comparison. The primary outcome measure was based on data from the activPAL™ in terms of step count and time spent being sedentary

(including sleeping time). The average daily steps count and time spent sedentary (including sleeping time) were recorded over one week with activPAL™ for each participant, and the total average daily steps and time sedentary (including sleeping time) of both the intervention and control group were calculated at each assessment time point (baseline, 3 and 6 months and 12 months).

5.11.2 Qualitative data analysis

Qualitative data from the telephone interviews were analysed thematically. The process of thematic analysis includes identification, analysing and reporting the pattern (themes) within the data (Braun and Clarke, 2008). The interviews were audio-recorded, transcribed and coded independently by the chief investigator and the transcripts from the interviews were analysed thematically using the framework approach and NVivo 11 software for the coding and organization of data (Jane.Ritchie and Lewis, 2003).

Inductive approaches were used where the researcher identified themes in the interview transcripts and attempted to verify, confirm and qualify them by searching through the data and repeating the process to identify further themes and subthemes. In the first stage the researcher read and re-read the transcripts and coded them. Then heading of thematic was chosen from grouped data in order to provide clarification of each theme. The coding, themes and sub-themes were reviewed by supervisor (CG), and the interpretation and analysis were discussed and agreed (further discussed in section 7.2).

6 Quantitative Findings

This chapter presents the study sample characterises and results of the analysis of quantitative data of primary and secondary measures outcome measures. It also includes a summary of the findings.

6.1 Study sample

Three hundred and twenty people with RA were asked to participate in the study between November 2014 and August 2015. Seventy-six individuals (63 women and 13 men), aged 56 (± 15) years, met the inclusion criteria and provided informed consent. After baseline assessment, the participants were randomised into intervention and control groups. The intervention group attended six, weekly sessions and two booster sessions in small groups of up to six participants. The control group had single education session in small groups of up to six participants.

The primary end point of the study was 6 months. As shown in the CONSORT diagram, Figure 6-1, 37 (94.9%) people from the intervention group and 22 (59.4%) people from the control group completed the trial. Due to the time limits of the study, only 22 participants were followed up at 12 months. While data were available for all 11 participants in the intervention group at 12 months, 4 of the 11 participants in the control group were lost to follow-up.

Three serious adverse events were reported in the intervention group, although they were not related to the study (Hodgkin lymphoma, nasopharyngeal carcinoma and oesophageal carcinoma). There were no SAEs in the control group.

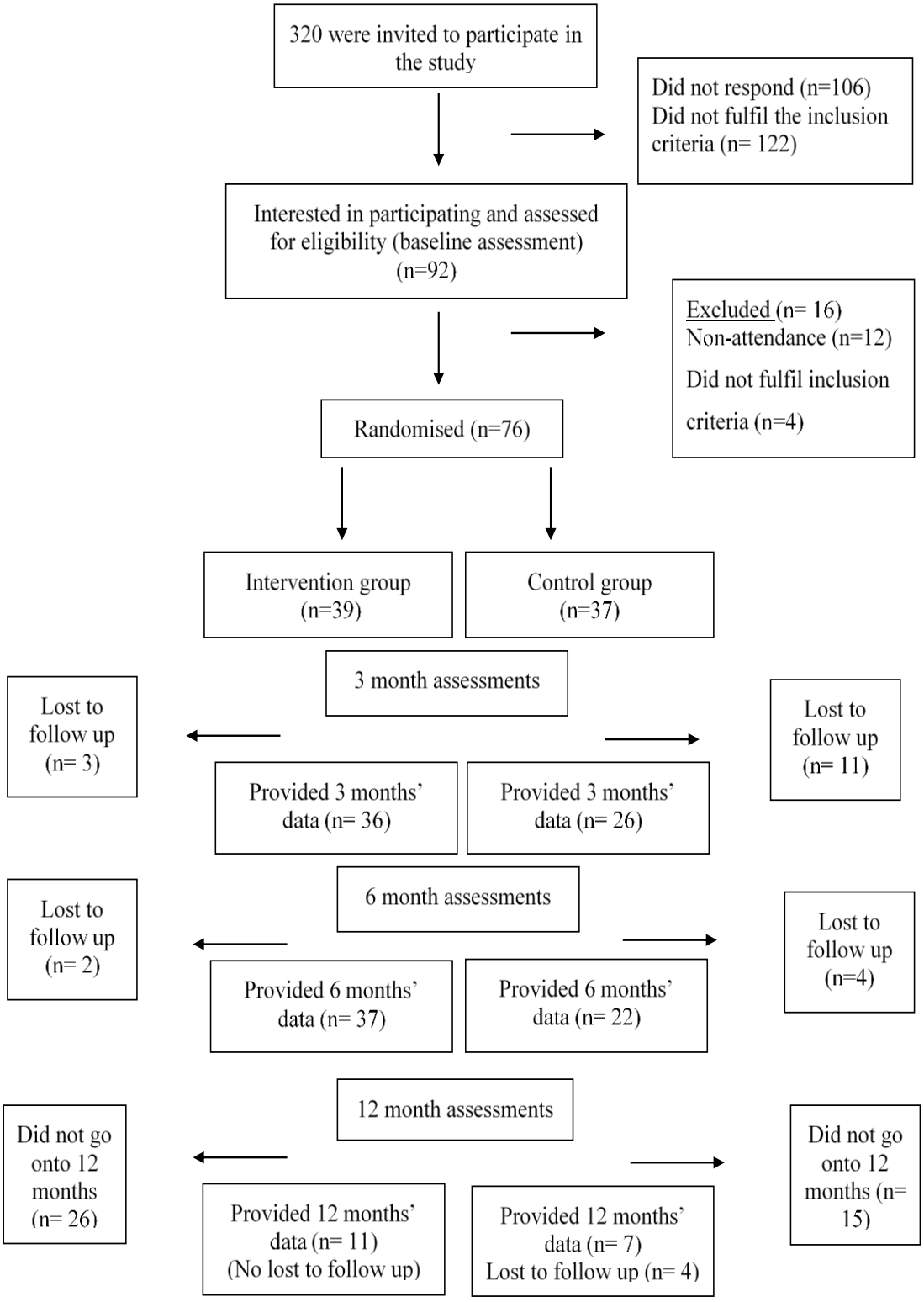

Figure 6-1 CONSORT diagram for flow of participants through the trial

6.2 Demographic characteristics of study sample

After the baseline assessments, the participants were randomised into intervention or control groups. The intervention group contained 39 participants, (29 females and 10 males) and the control group contained 37 participants (34 females and 3 males). There was no significant difference between the intervention and control groups for any of the variables recorded at baseline. The characteristics of the participants in both groups are shown in Table 6-1 and Table 6-2.

Table 6-1 Descriptive characteristics of the study sample (n=76)

Variable	Intervention (n=39)	Control(n=37)	P-value
Age(years)* mean(SD)	58.2 (13.5)	54.5 (15.8)	0.29
Gender**, n (%)	10M (25.6) 29F (74.4)	3M (8.1) 34F (91.1)	0.06
Level of education ** n (%) Elementary, and high school, Post-secondary education	17 (43.6) 22 (56.4)	19 (51.4) 18 (48.6)	0.65
Marital status**, n (%) Married Other (single, separated, divorced or widowed)	20 (51.3) 19 (48.7)	19 (51.4) 18 (48.6)	0.59
Height (m)*, mean(SD)	1.7 (0.1)	1.6 (0.1)	0.08
Weight (kg)*, mean(SD)	78.1 (16.4)	71.2 (16.6)	0.07
BMI(kg/m^2)*, mean(SD)	28.1 (5.4)	26.7 (5.9)	0.27
Waist circumference (cm)*, mean(SD)	86.8 (12.2)	81.3 (12.9)	0.06
WHR*, mean(SD)	0.86 (0.1)	0.83 (0.1)	0.08
WHtR*, mean(SD)	0.52 (0.7)	0.49 (0.8)	0.19
Hip circumference (cm)*, mean(SD)	100.7 (11.4)	98.2 (11.6)	0.33
Tobacco use**, n (%) Yes No and previous	10 (25.6) 29 (74.4)	9 (24.3) 28 (75.7)	0.58
Alcohol use**, n (%) Yes No	26 (66.7) 13 (33.3)	20 (54.1) 17 (45.9)	0.26
Disease duration (months)*, mean(SD)	23.6 (18.9)	19.7 (13.9)	0.30
Medications, n (%) ** DMARDs Prednisolone Cholesterol lowering medication,	39 (100.0) 0 (0.0) 3 (7.7)	36 (97.3) 1 (2.7) 2 (5.4)	0.89 0.69
PA activPAL™ Step count (steps/day)*, mean(SD)	7251 (2345.2)	7219 (1938.8)	0.95
PA activPAL™ Time being sedentary (hrs/day)*, mean(SD)	18.0 (1.9)	18.5 (1.4)	0.20
IPAQ Total MET-min/week*, mean(SD)	2965.0 (2501.4)	2799.9 (2877.4)	0.79
IPAQ Time spent sitting* Weekday (hrs), mean(SD)	5.3 (1.9)	4.7 (2.5)	0.29
IPAQ Time spent sitting weekend (hrs), mean(SD)*	5.1 (2.1)	4.6 (2.5)	0.42

The data were analysed using Independent sample t test*, chi square test or Fisher exact test**, Statistical significance was accepted at $P < 0.05$. SD= Standard Deviation, n= number, m= meter, kg= kilogram, cm= centimeter, min= minutes, hrs= hours, WHR=Waist to Hip Ratio, WHtR= Waist to Height Ratio, DMARDs= Disease-Modifying AntiRheumatic Drugs, IPAQ= International Physical Activity Questionnaire, MET= Metabolic Equivalent of Task.

Table 6-2 Descriptive characteristics of rheumatoid arthritis features at baseline (n=76)

RA features variable	Intervention (n=39)	Control (n=37)	P-value
Functional capacity			
HAQ, mean(SD)	1.1 (0.8)	1.2 (0.8)	0.72
Hand grip (kg), mean(SD)	23.2 (11.2)	19.9 (11.3)	0.13
RA outcome			
RAQoL, mean(SD)	10.3 (7.9)	13.3 (9.7)	0.13
SDAI, mean(SD)	13.5 (19.7)	13.2 (12.5)	0.94
Self-efficacy for PA, mean(SD)	42.9 (23.6)	37.7 (26.6)	0.37
Blood pressure, mmHg mean(SD)			
Systolic	124.0 (14.5)	125.0 (17.5)	0.82
Diastolic	77.0 (6.9)	75.0 (8.8)	0.38
Blood analysis, mean (SD)			
Blood glucose (mmol/L),	6.2 (2.4)	5.7 (1.4)	0.23
GGT (U/L)	26.9 (17.8)	32.1 (29.9)	0.36
Insulin (µIU/mL)	15.2 (13.0)	16.4 (14.7)	0.69
CRP (mg/L)	8.5 (19.4)	5.6 (7.6)	0.40
ALT (U/L)	24.1 (12.1)	27.6 (15.3)	0.27
AST (U/L)	21.5 (6.2)	23.4 (7.8)	0.24
HDL (mmol/L)	1.5 (0.5)	1.4 (0.4)	0.19
Trig (mmo/L)	1.4 (0.5)	1.6 (0.8)	0.14
Cholesterol (mmo/L)	5.3 (1.1)	5.4 (1.2)	0.63
HbA1c (%)	5.4 (1.1)	5.2 (0.9)	0.50
ASSIGN score, mean(SD)	19.4 (16.3)	19.6 (15.0)	0.95
DINE, mean(SD)			
Fatty food	17.6 (6.7)	17.6 (5.4)	0.99
Sugary	5.3 (2.0)	5.8 (2.4)	0.27
Fruits and vegetables	3.2 (2.0)	2.6 (2.0)	0.18

The data were analysed using Independent sample t test*. Statistical significance was accepted at $P < 0.05$. SD= Standard Deviation, n= number, mmol/L = millimole per litre, mmHG= millimeter of mercury, mg = milligram , U/L = Units/Litre , µIU/mL=micro litre unite per millimole, HAQ= Health Assessment Questionnaire, RAQOL= Rheumatoid Arthritis Quality of Life, SDAI= Simple Disease Activity Index, ASSIGN score =Assessing cardiovascular risk using SIGN (Scottish Intercollegiate Guidelines Network), DINE= Dietary Instrument for Nutrition Education. CRP= C-Reactive Protein, GGT= Gamma-Glutamyl Transpeptidase , ALT= Alanine aminoTransferase ,AST= Aspartate aminoTransferase , HDL= High Density Lipoprotein, Trig= Triglyceride, Chol= Cholesterol, HBA1c=Glycated Haemoglobin.

There was no significant difference in the demographic characteristics of the people in the intervention group who were lost to follow up at 6 months (n=2) and those who completed the 6-month assessment (n=37), however, although presented the number lost to follow up was very small for meaningful analysis. Also, there was no significant difference between control group who were lost to follow up (n=15) and those who completed the 6-month assessment (n = 22). However, there was a significant difference in the overall group who assessments at 6 months (n=59) and those who were lost to follow up (n=17) in terms of age (P=0.017) and gender (P=0.033). Overall, the people who were lost to follow up were younger and more likely to be female, Table 6-3.

Table 6-3 Descriptive characteristics at baseline of the sample who did and did not attend 6 month follow up in the both groups

Variable	Intervention (completed study) n=37	Intervention (lost to follow up) n=2	P-value	Control (completed study) n=22	Control (lost to follow up) n=15	P-value	Overall (completed study) n=59	Overall (lost to follow up) n=17	P-value
Age (years)* mean(SD)	57.9 (13.2)	64.0 (24.0)	0.540	56.0 (15.5)	50.4 (17.7)	0.330	58.2 (13.3)	48.4 (18.2)	0.017*
Gender, ** Female, n (%)	27 (73.0)	2 (100.0)	1.000	19 (86.4)	15 (100.0)	0.261	46 (78.0)	17 (100.0)	0.033*
Disease duration*, mean (SD)	22.6 (18.9)	42.0 (8.5)	0.162	19.9 (14.1)	19.3(14.1)	0.904	21.6 (17.2)	22.0 (15.3)	0.933
Marital status**, n (%) Married Other (single, separated ,divorced or widowed)	 19 (51.4) 18 (48.6)	 1 (50.0) 1 (50.0)	0.657	 11 (50.0) 11 (50.0)	 8 (53.3) 7 (46.7)	0.842	 30 (50.8) 29 (49.2)	 9 (52.9) 8 (47.1)	0.879
Level of education**, n (%) Elementary and high school,	 17 (45.9) 20 (54.1)	 1 (50.0) 1 (50.0)	0.254	 14 (63.6) 8 (36.4)	 5 (33.3) 10 (66.7)	0.070	 31 (52.5) 28 (47.5)	 5 (29.4) 12 (70.6)	0.092

Post-secondary education									
Tobacco use **, n (%) Yes No and previous	 9 (24.3) 28 (75.7)	 1 (50.0) 1 (50.0)	 0.452	 6 (27.3) 16 (72.7)	 3 (20.0) 12 (80.0)	 0.711	 15 (25.4) 44 (74.6)	 4 (23.5) 13 (76.5)	 1.000
Alcohol use **, n (%) Yes No	 25 (67.6) 12 (34.4)	 1 (50.0) 1 (50.0)	 1.000	 14 (63.6) 8 (36.4)	 6 (40.0) 9 (60.0)	 0.157	 39 (66.1) 20 (33.9)	 7 (41.2) 10 (58.8)	 0.064
DMARD**, n (%)	37 (100.0)	2 (100.0)	0.751	21 (95.5)	15 (100.0)	0.842	58 (98.3)	17 (100.0)	0.645
BMI (kg/m^2) *, mean (SD)	28.2 (5.4)	27.8 (5.3)	0.926	26.5 (5.3)	26.9 (6.8)	0.842	27.8 (5.3)	27.0 (6.5)	0.647
PA activPAL ™ Step count (steps/day), mean (SD)	7195 (2392.5)	8295 (784.2)	0.530	7754 (1777.0)	6436 (1956.0)	0.06	7369 (2182.3)	6772 (1990.9)	0.315
PA activPAL™ Time being sedentary (hrs/day) mean (SD)	18.0 (1.9)	17.7 (0.6)	0.801	18.4 (1.3)	18.7 (1.6)	0.53	18.1(1.7)	18.8 (1.4)	0.092

The data were analysed using Independent sample t test* or chi square or Fisher exact test**, Statistical significance was accepted at $P < 0.05$, n=number, SD=Stander Deviation, hrs=hours, PA= Physical Activity, BMI= Body Mass Index, DMARDs= Disease-Modifying AntiRheumatic Drugs.

6.3 Attendance at education sessions

The physiotherapist who carried out the education sessions provided attendance records for both groups. Twenty-six (66.7%) participants in the intervention group attended all 8 education sessions (6 sessions and 2 booster sessions) and 28 (71.8%) attended 6 sessions. The control group had a single education session in small groups of up to six people; 21 (56.8%) of the participants in the control group attended this session. There was no significant association between attendance of education sessions and step count in the intervention group at 3 and 6 months respectively (r= 0.27, P=0.11 and r=0.14, P= 0.41) or sedentary time (r= - 0.07, P=0.72 and r=0.09, P= 0.63). Although attendance was high overall, the highest attendance was recorded at the first two education sessions, then it declined but stayed above 70% throughout, see Figure 6-2.

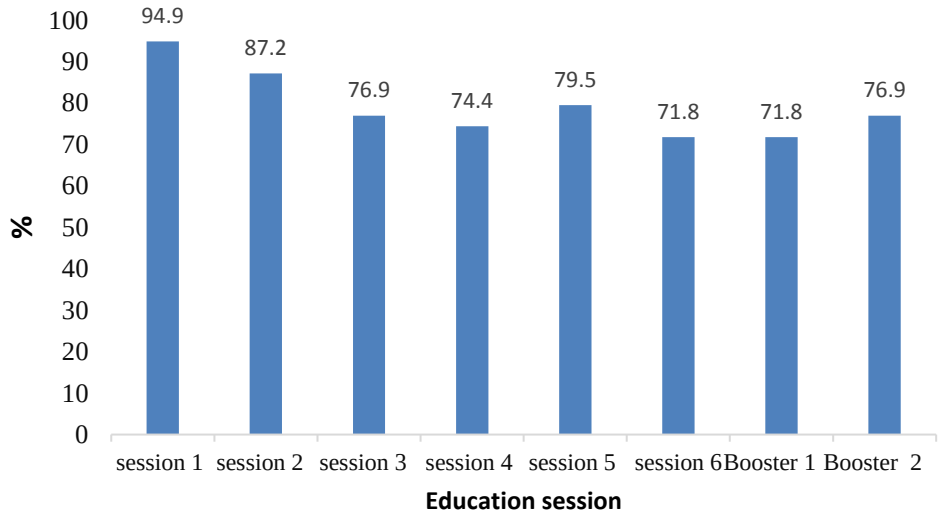

Figure 6-2 Attendance of intervention group in each session (n=39)

6.4 Physical activity and sedentary behaviour results at baseline, 3 and 6 months

The step count and time spent being sedentary (including sleeping time) was measured using objective monitoring (activPAL™) at 3, 6 and 12 months. At baseline 44 (57.9%) participants had a data for 7 consecutive days, 12 (15.8%) participants for 6 days, 9 (11.8%) participants for 5 days, 4 (5.3%) participants for 4 days and 7 (9.2%) participants had 3 days of data for analysis. At 3 months 28 (45.2%) participants had data from 7 consecutive days, 19 (30.6%) participants

for 6 days, 5 (8.1%) participants for 5 days, 3 (4.8%) participants for 4 days and 7 (11.3%) participants had 3 days of data for analysis. At 6 months 28 (47.4%) participants had data for 7 consecutive days, 15 (25.4%) participants for 6 days, 9 (15.3%) participants for 5 days, 4 (6.8%) participants for 4 days and 3 (5.1%) participants had 3 days of collected data. At 12 months 13 (72.2%) participants had data from 7 consecutive days, and 5 (27.8%) participants had data for 5 days. Participants who had activPAl ™ data for 3 days or more were analysed.

Table 6-4 displays the objective measure of PA (average step count/day, sedentary time/hrs) and subjective data of IPAQ total MET min/week and time spent sitting at weekday and weekend/hrs) for both groups at baseline, 3 months and 6 months. The step count increased over time in the intervention group, but decreased in the control group. A significant interaction was identified between the groups (intervention and control) in step count, ($P < 0.001$). Post hoc analysis demonstrated a significant increase in the average step count from baseline to 3 months, and from baseline to 6 months ($P < 0.001$). The participants' step count continued to be high between 3 and 6 months ($P=1.000$). However, in the control group the step count reduced between baseline and 3 months ($P=0.024$) and baseline 6 months ($P=0.039$), see Table 6-4. Also, there was significant differences between groups (intervention and control), step count at 3 months (mean difference 3413 steps/day, 95% CI: 1835-4990) ($P<0.001$) and at 6 months (mean difference 3599 steps/day, 95% CI: 2135-5062) ($P<0.001$).

There was a significant interaction effect in the IPAQ total MET ($P=0.006$). The IPAQ total MET-min/week increased in the intervention group at 3 months then declined at 6 months, but was still higher than the baseline. Total MET-min/week increased in the intervention group between the baseline and 3 months ($P= 0.005$), and it then reduced between 3 months and 6 months ($P= 0.037$). In the control group however, non-significant change were noted, between baseline and 3 months ($P= 0.622$), and between 3 months and 6 months, ($P=1.000$), see Table 6-4 and Table 6-5.

There was a non-significant interaction effect between the groups (intervention and control) in objective sedentary time (including sleeping time) ($P=0.190$).

However, a significant interaction effect between the groups (intervention and control) was noted in the self-reported weekday (P= 0.014) and weekend sitting time (P= 0.046). There was a significant difference within the groups (intervention and control) in the weekday and weekend self-reported sitting time. The weekday and weekend sitting time reduced in the intervention group, between baseline and 3 months, (P=0.036) and between baseline and 6 months, (P=0.016). The weekend sitting time reduced between baseline and 3 months, (P= 0.057) and between baseline and 6 months, (P= 0.003). However, in the control group it increased, between baseline and 3 months, (P= 0.391), and between baseline and 6 months, (P=0.493), Table 6-4.

There was a significant difference between groups in the self-reported weekday sitting time at 6 months – it reduced in the intervention group and increased in the control group (P = 0.009), Table 6-5. No significant changes between both groups in weekend sitting time were noted at 3 months (P = 0.047) or at 6 months (P = 0.034).

Table 6-4 Findings from primary outcome measures at baseline, 3 and 6 months within groups changes

Variables	Intervention (n=39)			Control (n=37)			Significance	Post hoc Analysis P value (Within group changes)					
	B	3 m	6 m	B	3 m	6 m	Interaction effect P value	B v 3 m (InG)	B v 3 m (CG)	B v 6 m (InG)	B v 6m (CG)	3 m v 6m (InG)	3 m v 6m (CG)
PA activPAL™ Step count (step/day)	7251 (345)	9820 (504)	9802 (447)	7219 (355)	6182 (574)	5933 (550)	< 0.001*	< 0.001*	0.024*	< 0.001*	0.039*	1.000	1.000
PA activPAL™ Sedentary time(hrs/day)	18.0 (0.27)	17.6 (0.3)	17.2 (0.3)	18.5 (0.2)	18.3 (0.37)	18.7 (0.41)	0.190						
IPAQ Total, MET min/week	2965 (431)	4239 (468)	3080 (416)	2799 (448)	2147 (526)	2080 (513)	0.006*	0.005*	0.622	1.000	0.698	0.037*	1.000
IPAQ Time spent sitting (hrs)Weekday	5.3 (0.36)	5.4 (0.3)	4.2 (0.3)	4.7 (0.3)	5.0 (0.38)	5.6 (0.46)	0.014*	0.036*	0.555	0.016*	1.000	1.000	1.000
IPAQ Time spent sitting (hrs)Weekend	5.1 (0.37)	4.1 (0.3)	3.9 (0.4)	4.6 (0.3)	4.8 (0.38)	5.1 (0.50)	0.046*	0.057	0.391	0.003*	0.493	1.000	1.000

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at P < 0.05. The data are mean ±SE, SE =Standard Error, IPAQ=International Physical Activity Questionnaire, hrs=hours, n= number, B= Baseline, m= months, MET= Metabolic Equivalent of Task, min= minutes.

Table 6-5 Findings from primary outcome measures at baseline, 3 and 6 months between groups (intervention and control)

Variables	Intervention			Control			P Value IG v CG B	P Value I G v CG 3 months	P value I G v CG 6 months	Between- group differences (Intervention- Control)	
	B (n=39)	3 months (n=36)	6 months (n=37)	B (n=37)	3 months (n=26)	6 months (n=22)				3 months	6 months
PA activPAL™ Step count (step/day)	7251 (345)	9855 (788)	9820 (499)	7219 (355)	6442 (739)	6221 (466)	0.4745	< 0.001*	< 0.001*	3413 (1835-4990	3599 (2135-5062)
IPAQ-Total MET(min/ week)	2965 (400)	4269 (506)	3055 (408)	2799 (479)	2311 (471)	2500 (408)	0.431	0.002*	0.021	1957 (520-3394)	555 (-824-1934)
IPAQ Time spent sitting (hrs) Weekday	5.3 (0.31)	4.4 (0.32)	4.2 (0.33)	4.7 (0.41)	5.1 (0.41)	5.7 (0.53)	0.143	0.094	0.009*	-0.69 (-1.73-0.34)	-1.56 (-2.75 to-0.36)
IPAQ Time spent sitting (hrs) Weekend	5.3 (0.36)	4.1 (0.31)	3.9 (0.33)	4.6 (0.38)	4.9 (0.42)	5.1 (0.63)	0.211	0.047	0.034	-0.87 (-1.91-1.55)	-1.22 (-2.52-0.09)

The data were analysed using Independent sample t test, statistical significance was accepted at adjusted P < 0.025. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, min =minutes, hrs= hours, PA= Physical Activity, MET= Metabolic Equivalent of Task, IPAQ= International Physical Activity Questionnaire

Multiple comparison t test illustrated a significant difference in step count between both groups at 3 and 6 months. The step count of the intervention group significantly increased; however the step count in the control group significantly decreased at 3 and 6 months, see Figure 6-3.

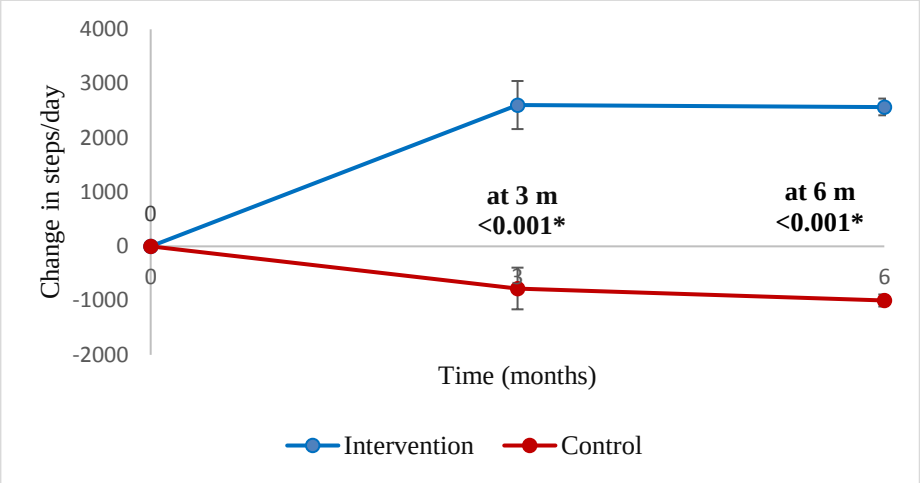

Figure 6-3 Changes in objective physical activity (step count/days) between the intervention group and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

The intervention group showed a reduction in objective sedentary time (including sleeping time) whereas the control group showed a slight increase in time spent sedentary. However, this was not significant, therefore post-hoc analysis was not undertaken, Figure 6-4. However, sedentary times were not powered to detect a difference so this finding is not unexpected.

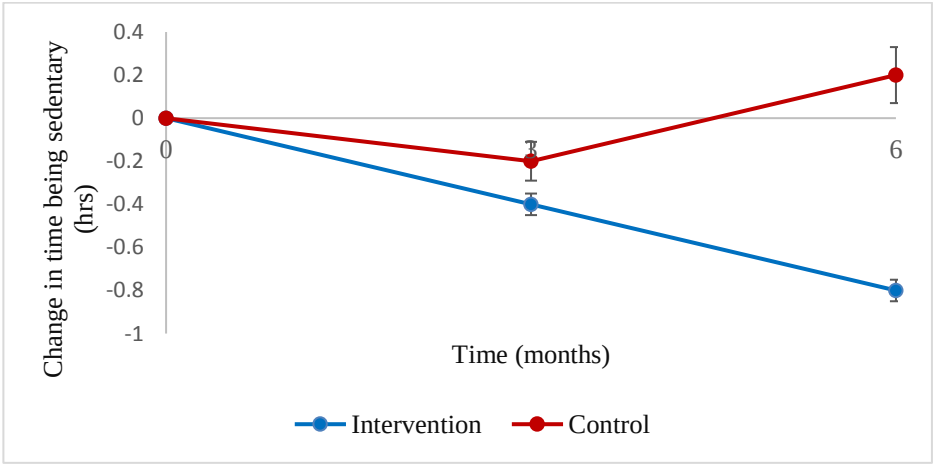

Figure 6-4 Change in objective time being sedentary (hrs) for intervention group (n=39) and control group (n=37) at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
(However, the changes is not significant therefore post hoc analysis did not apply)

There was a non-significant decline in self-reported weekday sitting time in the intervention group, whilst it increased in the control group at 3 months. There was a significant decline in self-reported weekday sitting time in the intervention group at 6 months, however in the control group it had further increased at 6 months, see Figure 6-5.

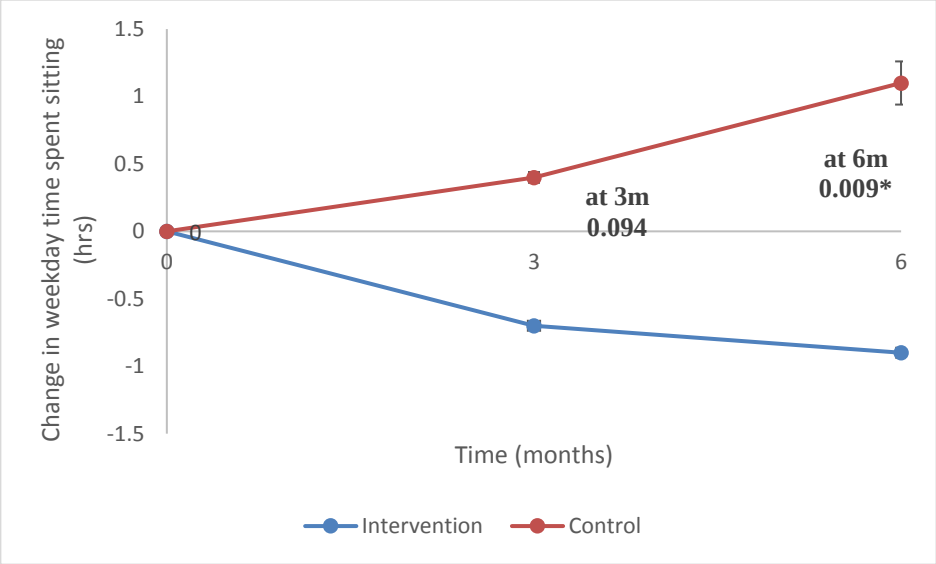

Figure 6-5 Changes in self-reported weekday time spent sitting (hrs) between the intervention and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P< 0.025

There were no significant changes in weekend sitting time between the groups at 3 and 6 months. Although there was a decline in weekend sitting time at 3 and 6 months in the intervention group and a slight increase in the control group, these were non-significant, see Figure 6-6.

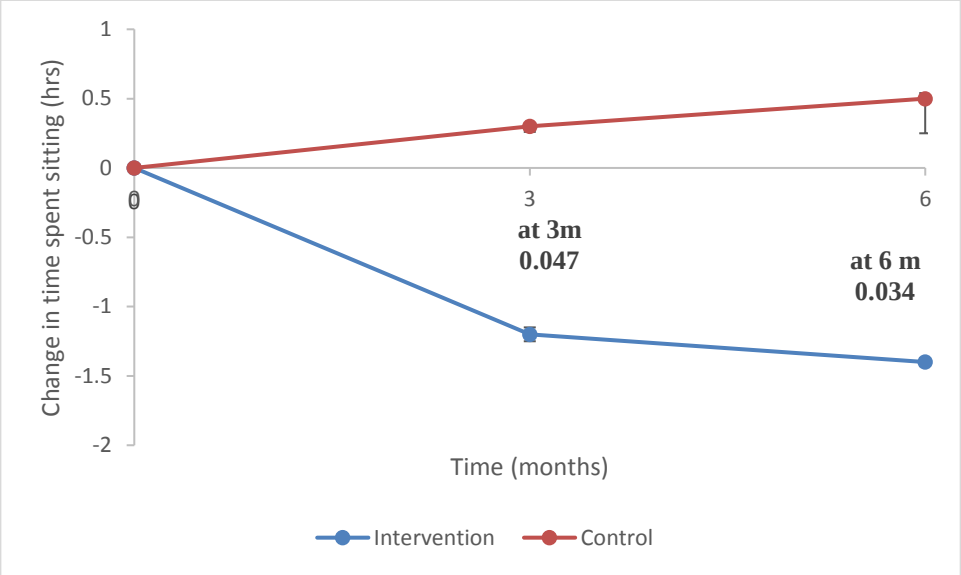

Figure 6-6 Changes in self-reported weekend time spent sitting (hrs) between the intervention and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

There was a significant difference in terms of marital status between the people whose step count increased over 6 months and the people whose step count reduced or continued the same as the baseline over the 6-month period, (P = 0.031), see Table 6-6.

Table 6-6 Demographic characteristics of people who their step count increased over study time period and those who their step count continues same or reduce in the intervention group

Variables	Step count increased over study period (n=25)	Step count reduced or same over study period(n=11)	P value
Age (yrs)*,mean(SD)	60.4 (10.4)	52.9 (18.8)	0.139
Gender**, n (%)	8M (32.0) 17F (68.0)	2M (18,2) 9F (81.8)	0.688
Disease duration (months)*,mean(SD)	26 (20.7)	12.7 (7.3)	0.058
Level of education**, n (%), Elementary and high school, Post-secondary education	13 (52.0) 12 (48.0)	4 (36.4) 7 (63.6)	0.481
Marital status**, n (%) Married Other (single, separated, divorced or widowed)	10 (40.0) 15 (60.0)	9 (81.8) 2 (18.2)	0.031*
Tobacco use **, n (%) Yes No & previous	6 (24.0) 19 (76.0)	3 (27.3) 8 (72.7)	1.000
Alcohol use **, n (%) Yes No	17 (68.0) 8 (32.0)	7 (63.6) 4 (36.4)	1.000
BMI (kg/m^2) *, mean (SD)	27.9 (4.5)	29.2 (6.6)	0.508
SDAI, mean(SD)	14.1 (23.9)	13.2 (11.7)	0.901

The data were analysed using Independent sample t test*, chi square test or Fisher exact test**, Statistical significance was accepted at $P < 0.05$. SD= Standard Deviation, n= number, m= meter, kg= kilogram, yrs= years.

6.5 Rheumatoid arthritis outcome results at baseline, 3 and 6 months

Table 6-7 displays a mixed- model analysis of SDAI, RAQoL and Charlson co-morbidity index at study time points. There were no significant changes in either group over time in the SDAI and RAQoL. There was no significant interaction effect noted in SDAI, RAQoL or Charlson co-morbidity index.

Table 6-7 Rheumatoid arthritis outcome results at baseline, 3 and 6 months

Variables	Intervention (n=39)			Control (n=37)			Significance
	B	3 m	6 m	B	3 m	6 m	Interaction effect
SDAI	13.4 (2.7)	10.9 (2.6)	7.3 (1.4)	13.2 (2.7)	13.0 (3.0)	13.4 (1.8)	0.179
RAQoL	10.3 (1.4)	7.9 (1.4)	7.5 (1.4)	13.3 (1.4)	11.2 (1.6)	12.3 (1.6)	0.085
Charlson co-morbidity index	3.6 (0.3)	3.6 (0.3)	3.6 (0.3)	3.3 (0.3)	3.4 (0.3)	3.4 (0.3)	0.274

The data were analysed using GLM REML = Generalized Linear Model, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error, SDAI=Simple Disease Activity Index, RAQoL=Rheumatoid Arthritis Quality of Life, n= number, B= Baseline, m= months.

6.6 Disease activity - Simple Disease Activity Index score (SDAI) at baseline, 3 and 6 months

The percentage of participants who had remission scores increased between the baseline and 6 months in the intervention group and decreased in the control group, however these changes were not statistically significant as shown in Table 6-8.

Table 6-8 The percentage of participants in each SDAI category at baseline, 3 and 6 months

SDAI Score Interpretation	Intervention n (%)			Control n (%)			P B	P 3m	P 6m
	B (n=39)	3 m (n=36)	6 m (n=37)	B (n=37)	3m (n=26)	6m (n=22)	0.521	0.322	0.102
Remission (0-3.3)	5 (12.8)	9 (25.0)	12 (32.4)	4 (10.8)	2 (7.7)	2 (9.1)			
Low activity (3.4-11)	20 (51.3)	17 (47.2)	18 (48.7)	18 (48.7)	14 (53.8)	11 (50.0)			
Moderate activity (33.1-26)	13 (33.3)	8 (22.2)	6 (16.2)	11 (29.7)	8 (30.8)	6 (27.3)			
High activity (26.1-86)	1 (2.6)	2 (5.6)	1 (2.7)	4 (10.8)	2 (7.7)	3 (13.6)			

The data were analysed using Likelihood ratio, statistical significance was accepted at $P < 0.05$, SDAI= Simple Disease Activity Index, n=number, B= Baseline, m=months.

6.7 Physical activity self- efficacy at baseline, 3 and 6 months

There was a significant difference between the groups (intervention and control) in overall PA self-efficacy. There was a significant interaction effect in PA self-efficacy. A significant difference within the groups (intervention and control) was noted. PA self-efficacy increased in the intervention group but decreased in the control group. In the intervention group PA self-efficacy increased from baseline to 3 months, (P= 0.002) and between baseline and 6 months, (P= 0.002). However, it reduced in the control group over the study time points (6 months), see Table 6-9. A multiple comparison t test illustrated a significant difference between the intervention and control groups in PA self-efficacy at 3 and 6 months, see Table 6-10.

6.8 Dietary Instrument for Nutrition Education (DINE) at baseline, 3 and 6 months

In terms of the DINE there were non-significant interaction effects between the intervention and control groups in the consumption of fatty foods, sugary foods or fruits and vegetables, as shown in Table 6-9. Although there was a slight increase in the consumption of fruits and vegetable and a decline in sugary and fatty foods in the intervention group, these were not significance. Diet was not powered to detect a difference so this finding is not unexpected.

Table 6-9 Physical activity self-efficacy and DINE outcome results at baseline, 3 and 6 within groups changes

Variables	Intervention (n=39)			Control (n=37)			Significance	Post hoc Analysis P Value (Within group changes)					
	B	3 m	6 m	B	3 m	6 m	Interaction effect	B v 3 m (InG)	B v 3 m (CG)	B v 6 m (InG)	B v 6 m (CG)	3 m v 6m (InG)	3 m v 6m (CG)
PA Self-efficacy	43.0 (4.0)	58.0 (4.3)	57.0 (3.9)	38.0 (4.1)	35.0 (4.9)	33.5 (4.7)	0.008*	0.002*	1.000	0.002*	1.000	1.000	1.000
DINE Fatty food	17.6 (0.9)	17.3 (0.9)	17.1 (0.8)	17.6 (1.0)	19.2 (1.0)	17.0 (1.0)	0.239						
DINE Sugary food	5.3 (0.4)	4.9 (0.4)	4.6 (0.3)	5.8 (0.4)	5.3 (0.4)	5.2 (0.3)	0.838						
DINE Fruits and vegetables	3.2 (0.3)	3.7 (0.3)	3.9 (0.3)	2.6 (0.3)	2.9 (0.3)	2.7 (0.3)	0.583						

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error, DINE= Dietary Instrument for Nutrition Education, n= number, B=Baseline, m= months, InG= Intervention Group, CG= Control Group.

Table 6-10 Physical activity self-efficacy outcome results at baseline, 3 and 6 months between groups (intervention and control)

Variables	Intervention			Control			P Value IG v CG B	P Value I G v CG 3 months	P value I G v CG 6 months	Between- group differences (Intervention- Control)	
	B (n=39)	3 months (n=36)	6 months (n=37)	B (n=37)	3 months (n=26)	6 months (n=22)				3 months	6 months
PA self-efficacy	43.0 (4.0)	58.9 (3.8)	57.3 (3.9)	38.0 (4.1)	36.2 (5.9)	36.1 (5.6)	0.183	< 0.001*	0.001*	22.7(9.3-36.1)	21.2(7.8-34.5)

The data were analysed using Independent Sample t test, statistical significance was accepted at adjusted P < 0.025. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, n= number, PA=Physical Activity. Between groups difference (intervention and control) with 95% confidence interval.

Multiple comparison t test illustrated a significant difference in PA self-efficacy between the groups over 6 months. There was a significant increase in PA self-efficacy in the intervention group at 3 months and this remained high at 6 months. In the control group there was decline at 3 months and 6 months, see Figure 6-7.

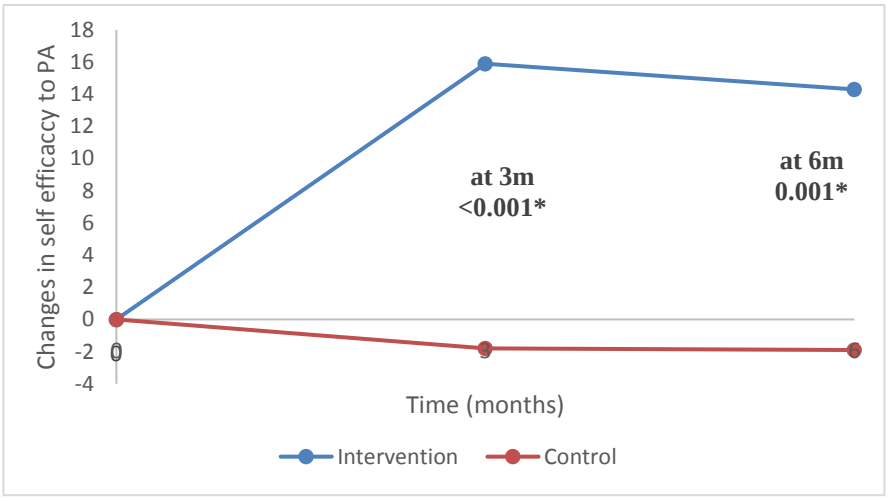

Figure 6-7 Changes in self-efficacy for physical activity score between the intervention and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P< 0.025

6.9 Functional capacity (6MWT, HAQ and hand grip strength) at baseline, 3 and 6 months

The distance walked in six minutes (6MWT) improved in the intervention group but reduced in the control group between baseline and 6 months. There was a significant interaction effect between groups in 6MWT (P < 0.001) – an increase was observed in 6 MWT in the intervention group between baseline and 3 months, (P=0.021); between baseline and 6 months (P < 0.001); and between 3 months and 6 months, (P=0.001).

A significant decline in the 6MWT in the control group was observed between baseline and 3 months (P=0.039) and between baseline and 6 months (P=0.003). There was no difference however between 3 months and 6 months, (P=0.189), see Table 6-11. Multiple comparison t test illustrated a significant difference in the 6MWT between the groups at 3 and 6 months, see Table 6-12.

There were no significant changes in the Health Assessment Questionnaire (HAQ) in either group. Hand grip strength reduced in the control group and slightly improved at 6 months in the intervention group, although this was not significant. There was no interaction effect in either group, see Table 6-11.

Table 6-11 Functional capacity outcome results at baseline, 3 and 6 months within groups changes

Variables	Intervention (n=39)			Control (n=37)			Significance	Post hoc Analysis P Value (Within group changes)					
	B	3 m	6 m	B	3 m	6 m	Interaction effect	B v 3 m (InG)	B v 3 m (CG)	B v 6 m (InG)	B v 6 m (CG)	3 v 6 m (InG)	3 v 6 m (CG)
6MWT (m)	361 (19.7)	389 (19.4)	417 (18.9)	341 (20.2)	311 (20.6)	295 (20.7)	< 0.001*	0.021*	0.039*	<0.001*	0.003*	0.001*	0.189
HAQ	1.1 (0.1)	0.7 (0.1)	0.7 (0.2)	1.1 (0.1)	1.0 (0.1)	1.2 (0.2)	0.074						
Hand grip strength (kg)	23.2 (1.8)	22.1 (1.7)	24.2 (1.7)	19.8 (1.8)	19.3 (1.9)	19.6 (1.9)	0.182						

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error, InG= Intervention Group, CG= Control Group, B= Baseline, m=months, kg= kilogram,6MWT= Six Minutes' Walk Test, HAQ= Health Assessment Questionnaire.

Table 6-12 Six minutes' walk outcome results at baseline, 3 and 6 months between groups (intervention and control)

Variable	Intervention			Control			P Value IG v CG B	P Value I G v CG 3 months	P value I G v CG 6 months	Between- group differences (Intervention-Control)	
	B (n=39)	3 months (n=36)	6 months (n=37)	B (n=37)	3 months (n=26)	6 months (n=22)				3 months	6 months
6MWT (m)	361 (19.7)	397 (17.2)	421 (18.6)	341 (20.2)	323 (27.3)	311 (24.7)	0.240	0.009*	< 0.001*	74.1 (12.6-135.6)	109.2 (47.6 - 170.8)

The data were analysed using Independent Sample t test, statistical significance was accepted at adjusted $p < 0.025$. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, n= number, 6MWT= Six Minutes' Walk Test. Between groups difference (intervention and control) with 95% confidence interval.

In the 6MWT there was a significant difference between the intervention and control groups over 6 months. There was a significant increase in the 6MWT in the intervention group at 3 months with 95% CI; 74.1 (12.6-135.6) and at 6 months 109.2 (47.6 -170.8). However, in the control group there was a significant decline at 3 months, and it continued to decline at 6 months, see Figure 6-8.

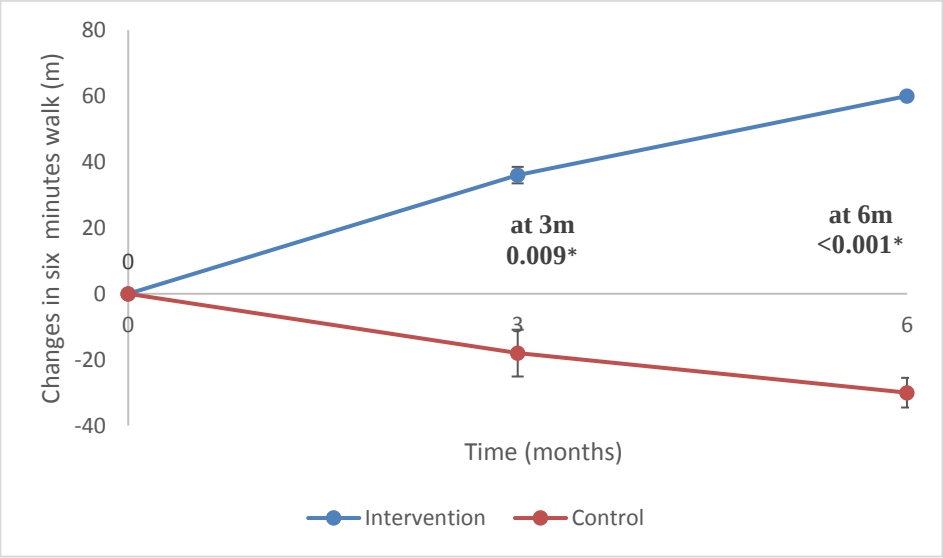

Figure 6-8 Changes in 6MWT (m) between the intervention group and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

6.10 Cardiovascular risk at baseline, 3 and 6 months

Systolic blood pressure fell in the intervention group but increased in the control group over 6 months; with a significant interaction effect between groups (P=0.002). There was a significant difference within group changes. A significant reduction was seen in systolic blood pressure in the intervention group between baseline and 6 months, (P= 0.013), however in the control group there was a non-significant increase between baseline and 6 months, (P=0.120),Table 6-13. There were no significant differences in diastolic blood pressure in either group, Table 6-13. Multiple comparison t test illustrated a significant difference between the intervention and control groups in SBP at 6 months, 95% CI; - 13.9(-21.9 to -5.8), see Table 6-14.

The 10 Year CVD score (ASSIGN score) reduced in the intervention group however increased in the control group, in the intervention group ASSIGN score declined

from the baseline score 19.4 to 17.1 at 6 months (P <0.001). The ASSIGN score increased in the control group from score 19.6 at baseline to 21.5 at 6 months, (P=0.016), Table 6-13. Also, Multiple comparison t test illustrated a significant difference between the intervention and control groups in the ASSIGN score at 6 months (P<0.001) and 95% CI; -7.8 (-8.4 – to -6.5), see Table 6-14.

Table 6-13 Cardiovascular risk outcome results at baseline, 3 and 6 months within groups changes

Variables	Intervention (n=39)			Control (n=37)			Significance	Post hoc Analysis P Value (Within group changes)					
	B	3 m	6 m	B	3 m	6 m	Interaction effect	B v 3 m (InG)	B v 3 m (CG)	B v 6 m (InG)	B v 6 m (CG)	3 m v 6m (InG)	3 m v 6m (CG)
Systolic blood pressure (mmHg)	124.0 (2.6)	120.7 (3.2)	116.8 (2.4)	125.0 (2.6)	124.0 (3.5)	129.0 (2.9)	0.002*	0.572	1.000	0.013*	0.120	0.437	0.089
Diastolic blood pressure (mmHg)	77.0 (1.3)	78.4 (1.8)	75.4 (1.4)	75.3 (1.3)	76.3 (2.0)	78.6 (1.7)	0.063						
ASSIGN score	19.4 (2.5)	18.6 (2.5)	17.1 (2.5)	19.6 (2.6)	20.5 (2.7)	21.5 (2.7)	<0.001*	0.527	0.736	<0.001*	0.016*	0.027*	0.179

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error, InG= Intervention Group, CG= Control Group, B= Baseline, m= months, mmHG = millimeter of mercury, ASSIGN score =Assessing cardiovascular risk using SIGN (Scottish Intercollegiate Guidelines Network).

Table 6-14 Findings from secondary outcome measures at baseline, 3 and 6 months between groups (Intervention and Control)

Variables	Intervention			Control			P Value IG v CG B	P Value I G v CG 3 months	P value I G v CG 6 months	Between- group differences (Intervention- Control)	
	B (n=39)	3 months (n=36)	6 months (n=37)	B (n=37)	3 months (n=26)	6 months (n=22)				3 months	6 months
SBP (mmHG)	124.0 (2.6)	121.6 (3.4)	116.9 (2.4)	125.0 (2.6)	123.5 (3.5)	130.7 (3.2)	0.410	0.359	< 0.001*	- 1.8 (-11.9-8.2)	-13.9 (- 21.9 -5.8)
ASSIGN score	19.4 (2.5)	18.2 (2.4)	16.1 (2.3)	19.6 (2.6)	21.8 (3.4)	24.0 (3.9)	0.473	0.382	<0.001*	- 3. 6 (-11.7- 4. 6)	-7. 8 (-8.4 -6.5)

The data were analysed using Independent Sample t test, statistical significance was accepted at adjusted P < 0.025. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, n= number. SBP= Systolic Blood Pressure, ASSIGN score =Assessing cardiovascular risk using SIGN (Scottish Intercollegiate Guidelines Network). Between groups difference (intervention and control) with 95% confidence interval.

In both groups SBP declined at 3 months however this was not significant. A significant difference between the intervention and control group was noted at 6 months, SBP declined in the intervention group and increased in the control group, Figure 6-9.

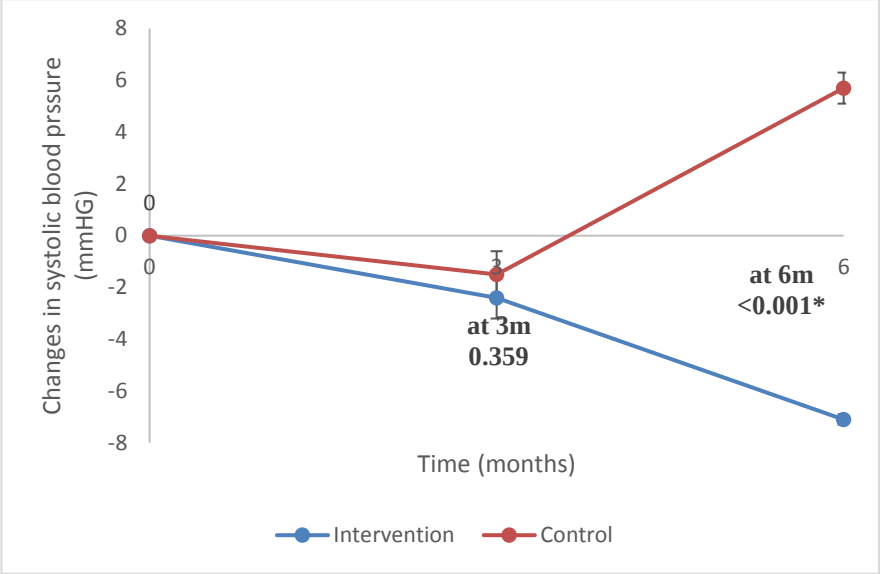

Figure 6-9 Changes in systolic blood pressure (mmHG) between the intervention group and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

There was a significant difference in the ASSIGN scores between the groups at 6 months. A significant decline in the ASSIGN score was observed in the intervention group at 6 months, however in the control group it increased over time, Table 6-10.

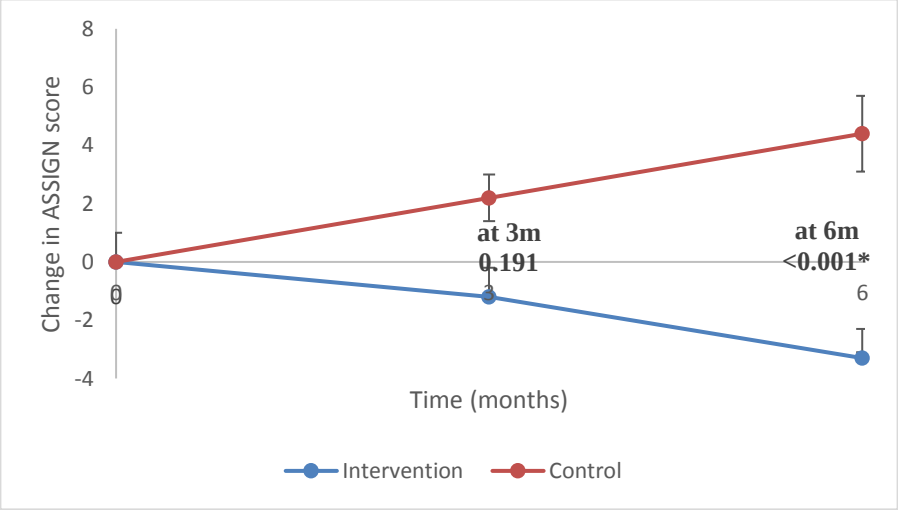

Figure 6-10 Changes in ASSIGN score between the intervention and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

6.11 Blood analysis results at baseline, 3 and 6 months

There were non-significant changes in blood results in both groups. Some variables increased from baseline to 6 months, such as insulin in the intervention group and triglyceride in the control group. Other variables were found to decrease in the intervention group, such as CRP, GGT and cholesterol and HDL in the control group, however there were no statistically significant changes. There was no significant interaction effect noted in terms of the results for insulin, CRP, glucose, GGT, ALT, AST, triglyceride, cholesterol, HDL or HBA1c, see Table 6-15.

Table 6-15 Blood results full analysis at baseline, 3 and 6 months

Intervention				Control			Significance P Value
Variables	B	3 m	6 m	B	3 m	6 m	Interaction effect
Insulin (µIU/mL)	15.2 (2.2)	26.6 (7.0)	27.9 (7.5)	16.4 (2.2)	19.0 (8.2)	20.7 (8.9)	0.704
CRP (mg/L)	8.5 (2.4)	5.6 (1.2)	5.8 (1.1)	5.6 (2.4)	4.0 (1.4)	4.1 (1.4)	0.936
Glucose (mmol/L)	6.2 (0.3)	5.5 (0.4)	5.6 (0.3)	5.7 (0.3)	6.2 (0.5)	6.0 (0.4)	0.131
GGT (U/L)	26.9 (3.9)	23.4 (3.3)	24.5 (10.9)	32.1 (4.0)	31.7 (3.7)	48.0 (13.6)	0.532
ALT (U/L)	24.1 (2.2)	24.6 (2.2)	24.4 (2.3)	27.6 (2.3)	25.0 (2.5)	23.5 (2.7)	0.332
AST (U/L)	21.5 (1.1)	20.3 (0.8)	20.8 (1.0)	23.4 (1.1)	21.4 (0.9)	21.1 (1.2)	0.602
HDL (mmol/L)	1.5 (0.1)	1.4 (0.1)	1.4 (0.1)	1.4 (0.1)	1.3 (0.1)	1.2 (0.1)	0.485
Trig (mmol/L)	1.4 (0.1)	1.3 (0.1)	1.3 (0.1)	1.6 (0.1)	1.8 (0.2)	1.8 (0.2)	0.375
Chol (mmol/L)	5.3 (0.2)	4.7 (0.2)	4.6 (0.1)	5.3 (0.2)	5.2 (0.2)	5.1 (0.2)	0.139
HbA1c (%)	5.4 (0.2)	5.2 (0.1)	5.2 (0.2)	5.3 (0.2)	5.2 (0.1)	5.3 (0.2)	0.761

The data were analysed using GLM REML= Generalized linear model, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error. B= Baseline, m= months, CRP= C - Reactive Protein, GGT=Gamma-Glutamyl Transpeptidas, ALT= Alanine aminoTransferase Alanine, AST= Aspartate aminoTransferase, HDL= High Density Lipoprotein, Trig= Triglyceride, Chol= Cholesterol, HBA1c=Glycated Haemoglobin.

6.12 Anthropometric measures at baseline, 3 and 6 months

There was a decline in BMI in the control group but not in the intervention group. There was an interaction effect between groups in terms of BMI, (P=0.044), Table 6-16. Although post hoc tests showed no significant difference over the 6 months, a significant difference between the intervention and control groups in BMI at 3 months was noted with multiple comparison t test, Table 6-17. There were no interaction effects in terms of weight, waist or hip circumference, WHR, and WHtR in either group, Table 6-16.

Table 6-16 Anthropometric full analysis at baseline,3 and 6 months within groups changes

Variables	Intervention (n=39)			Control (n=37)			Significance	Post hoc Analysis P Value (Within group changes)					
	B	3 m	6 m	B	3 m	6 m	Interaction effect	B v 3 m (IG)	B v 3 m (CG)	B v 6 m (IG)	B v 6 m (CG)	3 m v 6m (IG)	3 m v 6m (CG)
Weight (kg)	78.1 (2.6)	78.9 (2.6)	78.5 (2.5)	71.2 (2.7)	70.6 (2.6)	70.4 (2.6)	0.080						
WC (cm)	86.8 (2.0)	86.9 (2.0)	87.6 (2.0)	81.3 (2.1)	80.5 (2.1)	80.2 (2.1)	0.122						
HC (cm)	100.7 (1.8)	100.5 (1.8)	100.6 (1.8)	98.2 (1.9)	97.1 (1.9)	96.3 (1.9)	0.307						
WHR	0.86 (0.01)	0.86 (0.01)	0.87 (0.01)	0.82 (0.01)	0.83 (0.01)	0.83 (0.01)	0.897						
WHtR	0.52 (1.2)	0.52 (1.2)	0.52 (1.2)	0.50 (1.2)	0.49 (1.2)	0.49 (1.3)	0.085						
BMI (kg/m^2)	28.1 (0.9)	28.5 (0.9)	28.3 (0.9)	26.7 (0.9)	26.4 (0.9)	26.3 (0.9)	0.044*	0.082	0.596	1.000	0.342	0.316	1.000

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at $P < 0.05$. B= Baseline, m= months. The data are mean ±SE, SE =Standard Error, WC= Waist circumference, HC=Hip circumference, WHR= Waist-to-Hip Ratio, WHtR= Waist-to-Height Ratio, BMI= Body Mass Index, kg= kilogram, cm= centimeter. IG= Intervention Group, CG= Control Group.

Table 6-17 Results of BMI at baseline, 3 and 6 months between groups (intervention and control)

Variable	Intervention			Control			P Value IG v CG B	P Value I G v CG 3 months	P value I G v CG 6 months	Between- group differences (Intervention-Control)	
	B (n=39)	3 months (n=36)	6 months (n=37)	B (n=37)	3 months (n=26)	6 months (n=22)				3 months	6 months
BMI(kg/m^2)	28.1 (0.9)	28.7 (0.9)	28.3 (0.9)	26.7 (0.9)	26.0 (0.9)	26.1 (1.0)	0.134	0.022*	0.054	2.7 (0.07-5.3)	2.2 (- 0.5-5.0)

The data were analysed using Independent Sample t test, statistical significance was accepted at adjusted P < 0.025. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, n= number, BMI=Body Mass Index. Between groups difference changes with 95% confidence interval.

There were significant differences in BMI between the groups at 3 months. BMI was reduced in the control group, whereas it increased in the intervention group. However, there was no significant difference between the intervention and control groups at 6 months, see Figure 6-11.

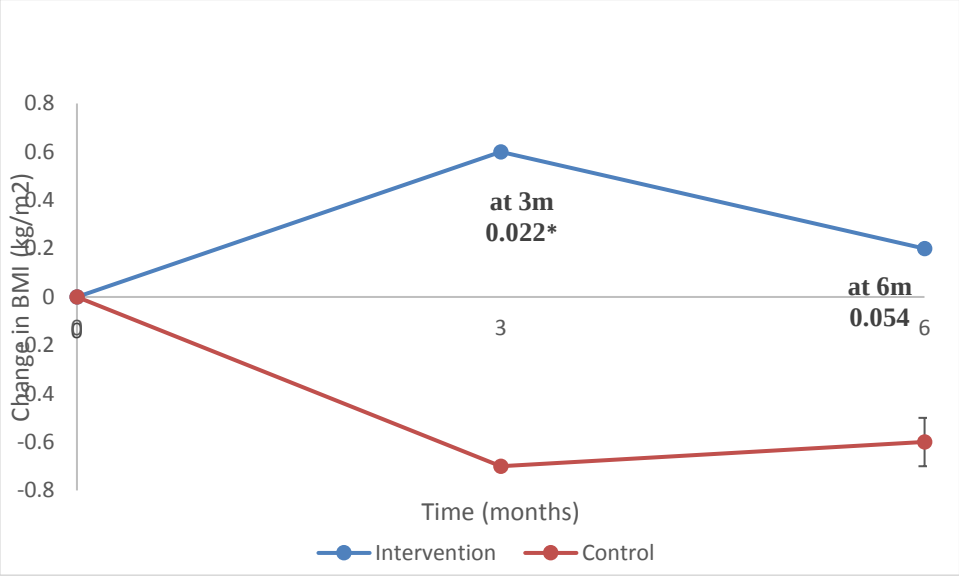

Figure 6-11 Changes in BMI score between the intervention and control group at 3 and 6 months, error bars represent (mean ±SEM) at 3 & 6 months.
Statistical significance was accepted at adjusted P < 0.025

6.13 Relationships between step count and secondary outcome measures in both groups

In the intervention group, a higher step count was inversely associated with functional capacity (HAQ) at baseline in the intervention group, (P= 0.04), but not at 3 or 6 months. A higher step count was associated with higher 6MWT in the intervention group at baseline (P= 0.03) and 3 months (P=0.01), Table 6-18. A higher step count was inversely correlated with triglyceride at 3 months (P=0.04); in the intervention group, Table 6-18. In addition, a non-significant correlation was identified between step count and blood glucose, cholesterol, HDL, insulin and ALT at baseline, 3 and 6 months in either group.

A higher step count was associated with better PA self-efficacy at baseline (P=0.01), and 3 months, (P=0.04) in the intervention group. SDAI was associated with higher step count (P= 0.03) in the intervention group, Table 6-18. No significant relationships were found between step count and other variables in either group.

Table 6-18 Relationships between step count and secondary outcome measures in both groups at baseline, 3 and 6 months

Variables	Intervention			Control		
	B (n=39)	3 m (n=36)	6 m (n=37)	B (n=37)	3 m (n=26)	6 m (n=22)
HAQ r p value	- 0.33 0.04*	- 0.23 0.19	- 0.12 0.47	0.31 0.06	- 0.14 0.48	0.17 0.43
6MWT r p value	0.18 0.23	0.49 0.03*	0.43 0.01*	0.37 0.02*	0.22 0.28	0.22 0.33
PA Self-efficacy r p value	0.41 0.01*	0.35 0.04*	0.15 0.39	0.15 0.36	0.01 0.99	- 0.11 0.64
SDAI r P value	0.04 0.83	- 0.36 0.03*	- 0.04 0.82	- 0.19 0.26	0.06 0.75	0.54 0.12
Triglyceride r p value	0.29 0.06	- 0.35 0.04*	- 0.08 0.65	0.07 0.69	- 0.02 0.92	0.33 0.12
Hand grip strength r p value	0.042 0.799	0.072 0.675	0.059 0.732	0.292 0.080	0.132 0.521	0.080 0.722
WC r p value	-0.268 0.098	-0.081 0.645	-0.215 0.208	-0.083 0.625	-0.139 0.499	0.036 0.875
HC r p value	-0.083 0.615	-0.146 0.404	0.108 0.530	-0.035 0.839	-0.030 0.884	-0.029 0.898
BMI r p value	0.243 0.135	-0.189 0.278	-0.116 0.502	-0.125 0.460	-0.330 0.099	0.071 0.755
WHtR r p value	-0.241 0.140	-0.190 0.267	-0.159 0.355	-0.155 0.361	-0.182 0.375	-0.012 0.959
SBP r p value	-0.220 0.179	-0.059 0.734	-0.238 0.103	-0.147 0.385	-0.068 0.743	0.028 0.900
GGT r p value	-0.210 0.200	-0.141 0.420	-0.123 0.481	-0.138 0.415	0.031 0.882	-0.101 0.655

The data were analysed using Pearson's correlations, Statistical significance was accepted at p <0.05. n=number, B= Baseline, m= months, HAQ= Health Assessment Questionnaire, 6MWT= 6 Minutes' Walk Test, SDAI=Simple Disease Activity Index, SBP= Systolic Blood Pressure, GGT= Gamma-Glutamyl Transpeptidase , WC= Waist Circumference, HC=Hip Circumference, WHtR = Waist-to-Height Ratio.

6.14 Relationships between time sedentary and secondary outcome measures in both groups

A greater time spent being sedentary was associated with an increase in systolic blood pressure, WC, HC, BMI, WHtR, triglyceride and GGT in the intervention group at 3 months, (P < 0.05), Table 6-19. A higher time spent being sedentary was also associated with lower functional capacity (HAQ) at 6 months in the control group (P=0.04). In addition, greater sedentary time was correlated with an increase in triglyceride level at 3 months in the control group, (P=0.03) and SDAI at 3 months in intervention group (P=0.02). Lower objective measured

sedentary time (including sleeping time) was significantly associated with improved hand grip strength (P= 0.03) and PA self-efficacy, (P=0.02), among the control group at 6 months, Table 6-19.

Table 6-19 Relationships between time being sedentary and secondary outcome measures in both groups at baseline, 3 and 6 months

Variable	Intervention			Control		
	B (n=39)	3 m (n=36)	6 m (n=37)	B (n=37)	3 m (n=26)	6 m (n=22)
HAQ r p value	0.22 0.18	0.07 0.71	0.04 0.82	0.02 0.93	0.17 0.41	0.43 0.04*
6MWT r p value	-0.28 0.07	-0.16 0.35	-0.14 0.41	0.066 0.699	-0.100 0.627	-0.271 0.222
Hand grip strength r p value	- 0.34 0.03*	0.05 0.79	- 0.15 0.39	0.11 0.51	0.18 0.38	- 0.45 0.03*
PA self-efficacy r p value	- 0.21 0.21	- 0.13 0.46	0.08 0.62	- 0.28 0.09	0.08 0.69	- 0.49 0.02*
SDAI r P value	0.033 0.844	0.391 0.021*	-0.109 0.539	-0.175 0.300	-0.260 0.200	-0.139 0.549
SBP r p value	0.17 0.32	0.36 0.03*	0.02 0.89	0.03 0.87	0.04 0.85	- 0.13 0.57
WC r p value	0.10 0.55	0.41 0.02*	- 0.10 0.55	- 0.14 0.41	0.31 0.12	0.30 0.09
HC r p value	0.16 0.34	0.37 0.03*	0.09 0.59	0.06 0.71	0.05 0.79	- 0.25 0.26
BMI r p value	0.16 0.32	0.39 0.02*	0.02 0.91	- 0.04 0.80	0.26 0.20	- 0.39 0.07
WHtR r p value	0.02 0.90	0.35 0.04*	- 0.08 0.62	- 0.18 0.29	0.28 0.16	- 0.38 0.08
GGT r p value	0.14 0.41	0.38 0.03*	- 0.17 0.33	- 0.25 0.14	- 0.26 0.22	- 0.08 0.74
Triglyceride r p value	0.20 0.92	0.43 0.01*	0.15 0.38	- 0.29 0.07	0.42 0.03*	0.31 0.15

The data were analysed using Pearson's correlations, Statistical significance was accepted at p <0.05. n=number, B=Baseline, m= months, WC= Waist Circumference, HC= Hip Circumference, BMI= Body Mass Index, SBP= Systolic Blood Pressure, WHtR= Weight Height Ratio, GGT= Gamma-Glutamyl Transpeptidase.

6.15 Physical activity outcome results at 12 months (end of study)

Twelve-month data was available for only 18 participants due to the limited time of the study; intervention (n=11) and control (n=7). The step count of the intervention group continued at a high level at 12 months follow up, however it had reduced in the control. As displayed in Table 6-20, there was a significant interaction effect in step count in the 12 month data ($P < 0.001$). However, the step count of the control group reduced at 3 and 6 months and then returned back to the baseline level at 12 months, see Table 6-20.

Also, a multiple comparison t test illustrated a significant difference between the intervention and control groups in the step count at both at 3 and 6 months. The step count increased in the intervention group over 6 months, and it was maintained at high levels at 12 months, very small numbers at 12 months although at a non-significant level. However, the step count regressed in the control group over 6 months, Table 6-21.

There was no significant interaction effect between the intervention and control groups in terms of sedentary time, total MET-min/week, weekday and weekend sitting time of the IPAQ at 12 months, Table 6-20.

Table 6-20 Physical activity outcome results at baseline, 3, 6 and 12 months within groups changes

Variables	Intervention (n=11)				Control (n=11)				Sig	Post hoc Analysis P Value(Within group changes)					
	B	3 m	6 m	12 m	B	3 m	6 m	12m	Interaction effect	B v 6m (InG)	B v 6m (CG)	B v 12m (InG)	B v 12m (CG)	6m v 12m (InG)	6m v 12m (InG)
PA activPAL™ Step count (step/day)	8402 (806)	12133 (957)	11314 (845)	10268 (1138)	7780 (806)	6867 (990)	6868 (1014)	7797 (1442)	0.007*	0.075	1.000	0.829	1.000	1.000	1.000
PA activPAL™ Sedentary time (hrs/day)	17.2 (0.49)	16.4 (0.68)	17.2 (0.59)	16.8 (0.52)	18.0 (0.49)	17.6 (0.71)	17.8 (0.64)	18.4 (0.66)	0.590						
IPAQ Total MET-min/week	4057 (1198)	7746 (1889)	6139 (1391)	4041 (685)	4963 (1256)	5103 (1981)	4920 (1601)	2180 (841)	0.175						
IPAQ time spent sitting (hrs) Weekday	4.7 (0.54)	4.2 (0.48)	4.1 (0.63)	4.3 (0.68)	4.8 (0.54)	5.0 (0.50)	5.8 (0.74)	5.0 (0.83)	0.516						
IPAQ time spent sitting (hrs) Weekend	4.7 (0.63)	3.5 (0.52)	3.7 (0.65)	3.5 (0.60)	4.8 (0.63)	5.0 (0.53)	5.7 (0.76)	5.1 (0.72)	0.220						

The data were analysed using GLM REML = Generalized Linear Model, Post hoc analysis within GLM REML output, statistical significance was accepted at $P < 0.05$. The data are mean ±SE, SE =Standard Error, IPAQ=International Physical Activity Questionnaire, hrs=hours, n= number, B= Baseline, m= months, Sig =Significant.

Table 6-21 Physical activity outcome measures at baseline, 3, 6 and 12 months between groups (intervention and control)

Variable	Intervention				Control				P V IG v CG B	P V I G v CG 3 m	P V I G v CG 6 m	P V I G v CG 12 m	Between-group differences (Intervention-Control)	
	B (n=11)	3 m (n=11)	6 m (n=11)	12 m (11)	B (n=11)	3 m (n=10)	6 m (n=7)	12 m (n=7)					6 m	12 m
PA activPAL™ Step count (step/day)	8402 (925)	12133 (1043)	11314 (787)	10269 (949)	7779 (667)	6084 (910)	6943 (1168)	7871 (4877)	0.295	<0.001*	0.002*	0.117	4370 (1499-7241)	2396 (-1728-6522)

The data were analysed using Independent Sample t test, statistical significance was accepted at adjusted P < 0.025. The data are mean ± SE, SE= Stander Error, B= Baseline, IG= Intervention Group, CG= Control Group, PA= Physical Activity, n= number, m= months.

6.16 Summary of the results

The quantitative study found that participation in the WARA intervention positively influenced the primary outcome measure (step count/day), with the average step count increasing over the 6 months by around 35% in the intervention group, whereas it reduced in the control group. However, the co-primary outcome measure (sedentary behaviour) was not achieved. Participants' self-efficacy for PA was also improved. The participants in the intervention group had improved functional capacity in terms of the 6MWT, cardiovascular profile and 10-year risk of CVD.

Higher PA and a lower time being inactive were associated with a higher self-efficacy for PA, functional capacity, and hand grip strength, and a lower body mass index, waist circumference, hip circumference and blood triglyceride.

7 Facilitators and Barriers of the WARA Intervention – Participants' Experiences: A qualitative Study

This chapter will present the views and experiences of the participants in the WARA intervention. Qualitative methods were chosen to obtain a participant-centred perspective in relation to: positive and negative aspects of the intervention; experiences of PA facilitators and barriers that were faced during the intervention; and perceptions of the role of intervention components in supporting and encouraging PA. A semi-structured topic guide (Appendix 13) was developed. Telephone interviews were undertaken after the intervention (at 6 months), and these were then analysed using a general inductive method.

7.1 Rationale for using qualitative methods

Using a mixed methodology is important as it facilitates a deeper explanation of findings revealed by quantitative research. Utilising qualitative data, the views and opinions of the participants can be obtained in a way that quantitative methods are unable to achieve (Michie et al., 2008). Qualitative data that is based on human experience is powerful and sometimes more compelling than quantitative data (Anderson, 2010), a view that is further discussed in (section 4.1,4.7).

The evidence suggests that PA facilitators and barriers should be considered in intervention studies to help health providers plan interventions that will safely and successfully improve or maintain PA levels (Flynn et al., 2009, Larkin et al., 2016a). In addition, evidence-based behavioural change techniques for the identification of barriers and problem solving were specifically used to help participants overcome their personal PA barriers.

A number of methods are used in qualitative study. The most common methods of qualitative data collection used in research are focus group and interviews, with the latter being either face-to-face or over the telephone. The results obtained through these two qualitative methods depend mainly on the subject being investigated. In-depth interviews are an effective qualitative method for getting people to talk about their views of the research topic and also to express

their personal feelings, opinions, and experiences (van Achterberg et al., 2011). However, sometimes sensitive topics are easier to discuss on the telephone than in face-to-face interviews, and they may lead to more honest answers. In addition, telephone interviews save resources (time and money) (Bauman et al., 2012).

Participants in the WARA intervention had a number of commitments, such as attending eight education sessions plus being assessed at the baseline and at follow-up, in addition to their routine check-up with the GP and rheumatologist; therefore, telephone semi-structured interviews were chosen to reduce the burden on the participants. This also enabled the researcher to discuss the participants' views regarding the WARA intervention openly; it might have been difficult in a face-to-face interview to discuss negative aspects of the WARA intervention or the reasons behind not changing or even reducing their PA.

The WARA intervention and its outcomes were the main focus of the interviews – they allowed the researcher to understand why some participants in the WARA intervention increased their PA and for others their PA reduced or stayed much the same over the study time period. Of 37 participants who completed the intervention, a sample of 10 participants was invited to take part in a semi-structured telephone interview at 6 months (after the end of the intervention). The sample included 7 females and 3 males with a mean age 59.6 (± 13.0) years.

Two participants from each group were invited to take part in the interviews, however in groups 5 & 6 only one participant did so; the reason for this was that it was difficult to secure an appointment with the participants as they had commitments or were on holiday. Participants whose step count either increased or decreased by 10% or more compared with their baseline over the 6 months and participants whose step count did not change (within 10%) of their baseline value were invited to take part. Table 7-1 illustrates the characteristics of the participants who were interviewed. The mean time of the interviews was around 22 minutes (15-30 minutes). All of the participants consented at baseline to take part in an interview at the end of the intervention, and additional audio-recorded verbal consent was taken from selected participants at the beginning of the telephone interview.

Table 7-1 Participants characteristics who taken part in a telephone interview at end of the intervention

Participants number	Gender	Age (years)	Step count mean (steps/day) Baseline	Step count mean (steps/day) 6 months	Difference of step count from Baseline to 6 months (%)	Physical activity category
PN 5 (IG1)	M	74	14,444	14,362	- 0.6	Not changed
PN 11(IG1)	F	64	6661	10,019	+ 50.4	Increased
PN 16(IG2)	F	32	7636	8439	+ 10.5	Increased
PN 21(IG2)	F	51	5855	14,802	+ 152.8	Increased
PN 23(IG3)	F	67	7030	7178	+ 2.1	Not changed
PN 24(IG3)	F	74	5979	5571	- 6.8	Not changed
PN 40(IG4)	F	50	9050	8908	- 1.6	Not changed
PN 47(IG4)	F	65	5904	14,093	+ 138.7	Increased
PN 50(IG5)	M	66	7250	9677	+ 33.5	Increased
PN 71(IG6)	M	53	7340	5023	- 31.6	Reduced

PN= Participant Number, IG= Intervention Group.

As the chief investigator was blinded to group allocation, the physiotherapist who facilitated the WARA carried out all of the telephone interviews, which were conducted from a private office at the School of Nursing and Health Care, University of Glasgow. The interview time was arranged by the physiotherapist based on a suitable time for the participants. At the beginning of the interviews, the participants were informed that their participation was voluntary and that the interview could be stopped at any time. All interviews were audio-recorded and transcribed by chief investigator with participant consent.

7.2 Analysis of interviews

There are a number of approaches to qualitative data analysis such as the inductive and deductive approaches. The former uses data to generate ideas (hypothesis generating), while the latter starts with the idea and then uses the data to confirm this idea (hypothesis testing) (Gale et al., 2013, Thorne, 2000). In this study, the data were analysed using a general inductive approach similar to that described by Thomas (2006) as described below.

The chief investigator listened to the recordings of the telephone interviews, and read the transcripts several times with the transcribed notes in order to improve the reliability of coding and the identified themes. The data was coded independently by the chief investigator and supervisor (CG) to identify the initial topic areas. Then the chief investigator and supervisor (CG) met to discuss the coding. If new codes emerged, the coding frame was changed and the transcripts were reread according to the new structure. Themes were discussed, refined and agreed with the supervisor (CG), leading to the presented themes and sub-themes.

7.3 Overview of thematic analysis

Analysis revealed three broad themes that were subsequently coded to sub-themes, see Figure 7-1. Illustrative quotes are used to report the findings, and individual participant numbers, age and gender are provided in parenthesis.

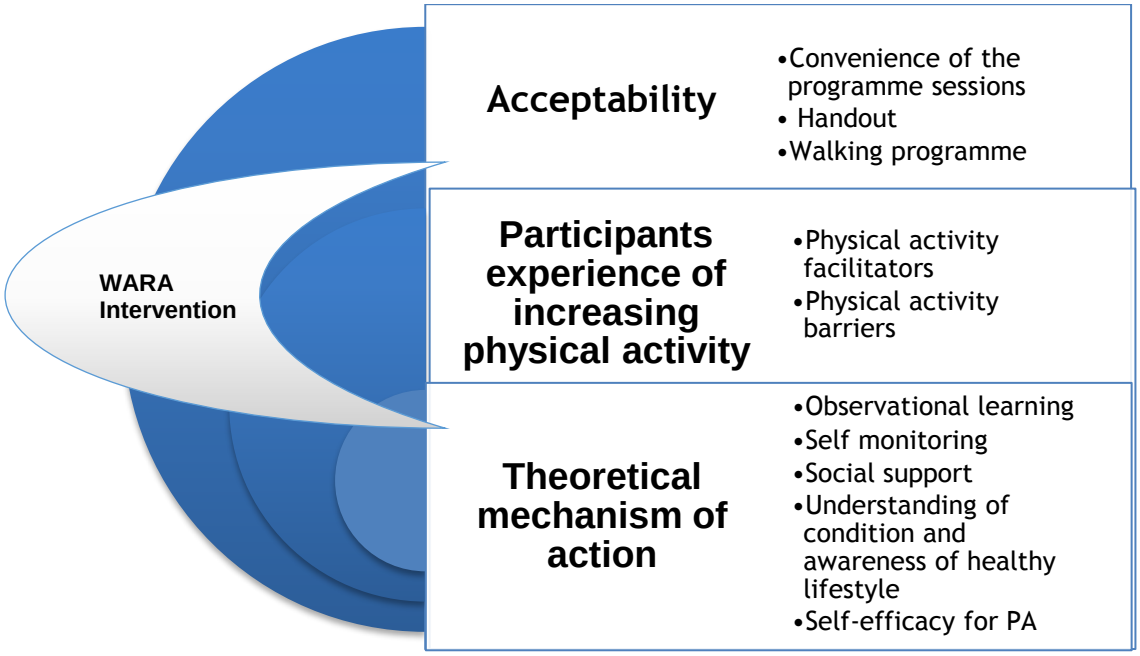

Figure 7-1 Themes and sub-themes on physical activity in WARA intervention

Three broad themes were identified, which were: acceptability of the WARA intervention, participant's experience of increasing PA and the theoretical mechanism of action. Although there was variation in the PA outcomes amongst the participants who were interviewed, the thematic analysis revealed that many participants shared the same views regarding the WARA intervention. This is potentially important to determine the key factors of the WARA intervention that might help future research in designing an intervention for people with RA. Physical activity was explored throughout the entire interview as the participants talked about what was important to them and how the WARA intervention had influenced their PA. However, the clearest information about what influenced them and the reasons why some participants reduced or did not change their PA was brought out in the answers to the following two questions: "What are the positive aspects of the WARA intervention that make you physically active?" and "What are the reasons for it not influencing you to change your physical activity?".

The three themes emerged from a number of different sub-themes. Overall the acceptability of the WARA intervention emerged as a bridge that allowed some participants to adhere to the programme regardless of whether their PA changed or not.

7.3.1 Acceptability

The interviewees found the WARA intervention to be acceptable in terms of convenience of the sessions, the handout and walking programme. The following sections present each sub-theme of acceptability with illustrative quotes.

1 Convenience of the sessions

a Group size

The WARA intervention recruited participants aged 18 years and above who had been diagnosed with RA within the last 5 years. The group size was about 6 people per group, which helped them to enjoy the programme. Almost all of the participants found the group size acceptable. For example, one-woman participant highlighted the benefits of being in a small group, as she said that a small group can facilitate engagement in the sessions in terms of practising the exercises, entering into discussions and asking questions. She mentioned that a small group was likely to be more beneficial than a large group.

> "Small group was fine because you were able to show us the exercises and explain things clearly and we were able to ask questions and you were able to answer specific questions. Small group people became friendly. I think in a big group it would have been less effective" (PN40, 50yrs, F, IG4).

The participants liked the group sessions and found them helpful. This was the case regardless of whether the participants increased, reduced or did not change their PA. For example, one old man whose PA level did not change over 6 months said:

> "Group sessions are more encouraging, better than being on your own. It [group] was motivating" (PN5, 74yrs, M, IG1).

b Sessions content

The WARA intervention consisted of eight education sessions. The content of the sessions was related to PA, RA and heart disease. The majority of the participants spoke favourably about the education sessions; they acknowledged that many of them had learned new things. They highlighting topics that the participants were not aware of, and this encouraged the participants to be

physically active. One-woman participant whose PA increased over 6 months attended all of the education sessions and found that the sessions were good, with all the relevant topics of a healthy lifestyle being covered with the right level of content. She said:

> "I think the sessions covered everything – what you are eating, drinking, walking, it was quite comprehensive just made us all think about everything that we're doing on a daily basis so I think that was good" (PN47, 65yrs, F, IG4).

c Sessions venue

The education sessions were held at the hospital. With regard to the venue, almost all participants acknowledged that they had no problem accessing the venue where the education sessions took place. The majority of the participants considered that the hospital was a good place to have the group sessions as they were used to going there. For example, one man said:

> "…used to go to hospital, it suited me perfectly, I live nearly to the hospital it was easy to access …" (PN50, 66yrs, M, IG5).

However, one woman said that she would prefer the sessions to be held outside the hospital setting in a leisure centre (gym). Going to the gym emerged as an important external barrier to people with RA.

> "I think maybe taking a session in the gym might be useful to show the kinds of exercise and to get the people going to the gym and they understand what they should be trying to do within the gym" (PN40, 50yrs, F, IG4).

Although the participants would have liked the sessions to be held at a leisure centre, this participant still performed the strengthening exercise regularly. However, if the WARA intervention took place at a gym it would be more exciting and encouraging, and also help people to go to the gym in the long term.

It seems that people with RA had a limitation with regards to going to the gym as they had no idea what they could do there – therefore offering the sessions at the gym would have been a good opportunity, as it would have helped people to realise what they could do safely in the gym. This might have helped them to go

to gym regularly even after the intervention and adhere to the exercise goals. This highlighted a barrier that could be considered in future interventions, and also regarding the services provided at the gym, it would be helpful if there were a specialised trainer to teach those with RA to allow them to feel safe and understood.

d Sessions time

The education sessions were normally attended, mostly between 4 and 5pm, as some participants were employed; others had to take care of children and others had to pick up their grandchildren from school. These factors were considered when arranging the time of the education sessions.

The participants were satisfied and generally found the time to be suitable. However, one participant said that she would have preferred a different time, such as the morning. The time of the sessions was difficult for her as she had a commitment with her grandson to take care of him after school as his parents were working. She attended four education sessions out of eight.

> "I would have preferred probably to be morning sessions, I have to pick up my grandson from school and he stays with me until his parents finish their work" (PN24, 74yrs, F, IG3).

This participant was 74 years old and retired - this might another reason why she preferred the sessions to be in the morning. This discussion provided an insight into the external barriers that may have prevented this participant from attending all the education sessions.

e Booster sessions

The WARA intervention involves two group booster sessions, after 3 and 6 months. Their aim was to encourage participants' maintenance of and motivation for PA by providing support, evaluating their own barriers to PA and how to overcome them. They also encouraged them to continue to use their pedometers and to record their steps in their PA diary. The participants talked about the booster sessions and how they helped them to progress towards their PA goal since the start of the WARA intervention.

There was positive feedback regarding the booster sessions. Quantitative data showed 71.8 % attended the first booster session and 76.9% attended the second booster session. It seems that the booster sessions influenced the participants to keep physically active. For example, a woman whose PA increased over the 6-month period commented on the benefits of the booster sessions that made her keep on the programme. She said:

> "The booster sessions made you think about the content again, it made you motivated towards the goal you were trying to achieve and helped to come back again" (PN16, 32yrs, F, IG2).

This was also the view of the participants whose PA did not change – they also found that the booster sessions helped them to keep motivated. This highlighted an important factor that the RA participants did not think only about the PA, but that meeting people with a similar condition acted as a motivator for them. The participant stated for example:

> ''I think it probably did help to keep you motivated because you knew that you were going to meet again" (PN40, 50 yrs, F, IG4).

2 Handout

A WARA booklet given to the participants contained information describing the importance of both walking and a healthy diet for health benefits and the reduction of CVD risk and other co-morbidities of RA. The handout also described the importance of the strengthening exercise, and reducing sedentary time. There was a general agreement amongst all participants in the intervention group that the booklet was helpful for them as a reference point for the instructions on exercise. The following two participants spoke about the handout given in the WARA intervention; they found it useful although the two participants were in different age groups and also their PA levels differed over 6-month period. For example, one woman liked the handout and she commented on how she used the handout. She spoke about the handout facilitating the performance of the strengthening exercise, by looked at the instructions. This participant's hand strength increased over 6 months.

> "It [handout] was useful to have to refer to, especially with exercise. If I forget I can go back and look to the strength exercise. The

> exercises I found were kind of the best things in WARA intervention because I still have it [handout]" (PN24, 74yrs, F, IG3).

However, this participant's PA level did not change over 6 months. She only attended 4 education sessions, but she enjoyed the strengthening exercise and really performed it. This was confirmed by the quantitative data as this participant increased her grip strength over 6 months.

A young woman whose PA level increased by 10.5% over 6 months used the handout. She found that the handout was informative and it also reaffirmed her knowledge. She stated:

> "I looked through them [handout] a couple of times. They were helpful, they confirmed things that you knew. It was very useful. It was good" (PN16, 32yrs, F, IG2).

It emerged that providing the participants with a handout may play a role in facilitating the intervention; the handout seems to help participants to perform the strengthening exercise and also think about the content of the sessions.

3 Walking programme

There was a general agreement that the WARA intervention was well-constructed, even among participants whose PA did not change at 6 months. For example, one woman found that the WARA intervention walking programme was good, but because of various issues she encountered (for example, she has to pick up her grandson from school and he stays with her until his parents finish their work, see section 7.3.1, 1d) this affected her regular attendance of the education sessions. She attended only four education sessions, and she was unable to increase her PA.

> "The walking programme is excellent and I think it's up to the individual" (PN24, 74yrs, F, IG3).

There were some participants who directly expressed that the walking programme had such a positive effect on them and that they had improved their health, which kept them walking. One man who was able to increase his step count over the study period, talked about being out walking improving his health. However, he spoke about his experience in the past before joining the

programme and at that time, pain, stiffness and his feeling of inability to walk were enough to stop him going outside. The WARA programme seemed to be able to change his attitude and experience.

> "The walking programme is excellent, I did increase my walking and I continue to walk, I have been quite enjoying it. Walking has helped me, I feel much better and I try to do a walk every day. Before I joined the programme I would be going out but I was getting frustrated because of pain and stiffness so difficult, I am afraid" (PN50, 66yrs, m, IG5).

Although many reflected on the WARA intervention as an excellent intervention and one that motivated them to keep walking and increase their physical activity, two participants regretted the lack of group walking in the WARA intervention, which they thought would be a good motivator to walk more. For example, one woman said:

> "… group walking is a good idea; a group walk is an incentive to go out but it never happened in the WARA programme. I would have liked it more if in the WARA programme there was group walking at least once" (PN11, 64yrs, F, IG1)."

Another woman highlighted the benefits of walking with a group; it seems that people liked to engage with each other. She said:

> "Walking with other people encourages you when you have got other company or if somebody is taking you on the kind of route so you can try and you do not have to be in the flat all the time" (PN47, 65yrs, F, IG4).

Although these participants talked about the lack of a walking group in the WARA intervention, both were able to increase their PA above their baseline over 6 months. Thus, the lack of group walking did not affect their physical activity progress.

However, including group walking for people with RA in the intervention would need to take into account people's physical abilities and safety. Also, it would have been difficult to include in the WARA intervention because the participants started the programme at different times of year with different weather. Some groups started their intervention programme in winter, others in spring, summer or autumn.

7.3.2 Participants' experience of increasing physical activity

1 Physical activity facilitators

This discussion provided an insight into the facilitators of the WARA intervention that helped to make the WARA intervention successful by increasing participants' PA. Almost all of the participants whose PA level increased over 6 months found that social support was a key factor in helping them to adhere to the programme and increase their PA.

They were a key part of the WARA intervention as they allowed the participants to share their experiences and to receive practical advice from each other on overcoming barriers, progressing towards their PA goals or handling setbacks. The findings suggest that the group-based nature of the programme supported the participants' adherence to the programme. For example, one woman whose PA increased 152.8% over 6 months commented on the benefits of sharing experiences with other people with a similar condition. She said:

> "It was quite interesting to know how other people were getting on, I liked the group sessions because you got to hear other people's perspectives and any problems." (PN21, 50yrs, F, IG2).

Another old woman whose PA level increased over 6 months found that meeting with other people with a similar condition helped her to engage in PA. She stated:

> "...group meetings were very good, helping me to get started with the physical activities, just discussing things with other people it was quite good, you were getting feedback from other people with rheumatoid arthritis" (PN11, 64yrs, F, IG1).

Another factor that emerged as a facilitator of the WARA intervention and helping participants to increase their PA was the participants' increased ability to perform PA (self-efficacy for PA). There is a further discussion of self-efficacy for PA in section **Error! Reference source not found.** and also a discussion of social support in (section 7.3.3).

2 Physical activity barriers

This sub-theme captured the participants' barriers regarding the PA barriers they faced when taking part in the WARA intervention. Although the majority of the participants believed that they had received many benefits from walking, they faced some difficulties during the intervention such as the weather, working, health problems and a lack of motivation.

a Weather

The weather especially was experienced as a barrier, preventing a few participants from engaging in daily activities. For example, a 66-year-old male participant commented on the weather as the main barrier for him to walking. However, his PA increased by 33.5% over 6 months so it seems that even with bad weather he could manage and overcome his barrier – maybe his improvement would have been higher if the weather had been better. He said:

> "Because of the bad weather I am doing a wee bit less walking. Gradually I will build up my physical activities with the weather improving. I am waiting for the good weather to come back" (PN50, 66yrs, M, IG5).

Another woman identified the weather as a barrier to doing PA outside, however the shopping centre was a facilitator for her to continue her walking and she overcame her PA barrier and her PA increased over 6 months. She said:

> "If it's bucketing with rain it's easier to go to the shopping centre. Scottish weather is pretty harsh but still I walk at the shopping centre, I walk up and down" (PN47, 65yrs, F, IG4).

b Work commitments

A few participants described that when the goal increased and they had to walk 5 days a week, it was difficult due to work commitments. For example, a woman participant was working full time, and her work was at a reception, so it entailed a lot of time sitting down. She said that because of work commitments she tried to be physically active at the weekend. Although she spoke about her barriers to PA, this participant's PA increased by 152%, so it appeared that she overcame her barrier and she did a lot of walking at weekends. She said:

> "In the last stage when I had to do it every day because there are couple of days I am working, it was not quite easy. I tend to do the walking more at the weekend. Because of my work commitments I cannot do much walking on normal days I tried to walk more at weekends" (PN21, 51yrs, F, IG2).

c Health problems

Two participants in the WARA intervention said that symptoms such as back pain and fatigue limited their daily PA levels. However, these are the commonly experienced symptoms of people with RA. For example, one old male participant had back pain, and he felt low because of his back problem, and it made it difficult for him to walk and also he only attended 3 education sessions out of 8. His PA level reduced by 31.6% over the 6-month period. This barrier emerged as an important PA barrier as the participant could not overcome it and it had a negative effect on his PA. This discussion revealed an important barrier that should be considered in future research; some exercises could be added that would help to overcome this barrier.

> "It was a bit disappointing later on when I had problem in my back and I could not do it [walking]" (PN71, 53yrs, M, IG6).

d Lack of motivation

Self-motivation is what influences the individual to initiate or undertake the task that needs to be done. A lack of self-motivation also emerged as a barrier to carrying out daily physical activity. A few participants commented on the lack of self-motivation; one woman said that her barrier to PA was mainly a lack of motivation. However, this participant attended only 4 education sessions and her PA did not change over the 6-month period.

> "I am probably not pushing myself enough to go out…" (PN24, 74yrs, F, IG3).

7.3.3 Theoretical mechanisms of action

The theoretical mechanisms of action were identified as the participants talked about what was important to them and how the WARA intervention helped them to modify their PA lifestyle, and the benefits to their health that they gained from being physically active, see Figure 7-2.

1 Observational learning- physical activity group

The majority of participants reported that observing other participants' progress towards achieving the PA goal and sharing their experiences regarding PA motivated them and increased their likelihood of adhering to the WARA intervention. For example, one younger woman who was able to increase her PA over 6 months spoke about her experience with the WARA intervention. She felt low when she started the WARA intervention as she was unable to progress towards her goal because of her symptoms. She found the programme intense and described how observing other participants who were older than her progressing towards their PA goal motivated her to walk, she said:

> "At the beginning I struggled at first to try to do all the steps, I struggled to do exercise some days. It was negative for me and I was getting frustrated because of pain and stiffness. I felt like I have done enough and I cannot do more. I was looking at the other people who were older than me and were managing to do it; I was thinking how can they do it and I cannot? I think we're good sharing the experience. It was an encouragement" (PN16, 32yrs, F, IG2).

2 Self-monitoring

a Pedometer

The majority of participants also talked about the use of the pedometer and the PA dairy as key parts of their success in reaching their goal. The pedometer (DIGI WALKER SW-200, Japan) used in this programme was a research-quality device that had been validated at the Nursing and Health Care School before being given to participants. Two PhD students had worn the pedometer while walking for a couple of days and compared their counting of steps manually with steps recorded on the pedometer by ensuring that a test of 100 walked steps provided an error of <5%, as suggested by the Japanese Industrial Standard of 3% by Hatano (1997, cited in Baker et al., 2008b).

The majority of participants found that the pedometer encouraged and motivated them to walk more. It helped them to know what distance they had covered, and which days they were inactive. For instance, one old woman was able to increase her PA over 6 months. She used the pedometer at the beginning

of the WARA intervention, and she talked about her positive experience with the use of the pedometer – it motivated her to buy a Fit Bit. She said:

> "It [pedometer] was wonderful at the beginning. I bought a Fit Bit after the sessions finished. I would never have done it by myself, only because of being in the programme. I check every day and I check my progress. I am actually addicted to my steps" (PN47, 65yrs, F, IG4).

However, not all of the participants agreed about the positive effects from the use of the pedometer, as a few participants had a negative experience. For example, one woman found that the pedometer was stressful, and it make her nervous and she kept checking it all the time. She said:

> "When I stopped it, I did feel a bit of freedom. I lost it at the airport and I remember the effort at the airport to check all sort of things and I said after about an hour I am free. I did develop a nervous habit of checking it all the time, to see if it has not fallen off, it was a stressful experience, I was worrying about losing the pedometer" (PN11, 64yrs, F, IG1).

Although the participant talked about her negative experience with the pedometer, her PA increased by 50% over 6 months.

Two participants found other technology such as a Fit Bit and an iPhone more accurate than the pedometer. They claimed that the pedometer was inaccurate in counting the steps and also that it did not record steps done at a slow speed.

> "I did not think the pedometer was accurate, I needed to take my iPhone out with me and the iPhone was always more than the pedometer and actually that's why I bought a Fit Bit. I thought a Fit Bit watch would more accurately count the steps" (PN71, 53yrs, M, IG6).

The other participant claimed that the pedometer did not record slow speed or incidentally movement such as cooking and she found the iPhone better than the pedometer in terms of accuracy. She stated:

> "I think the pedometer does not always record small movements. The iPhone seems to give more steps than the pedometer – when you are cooking or walking gently I am not convinced that the pedometer actually records" (PN 23, 67yrs, F, IG3).

b Physical activity diary

The other important self-monitoring tool was the PA diary. PA diaries were given to the participants each session, including booster sessions, to ensure that the diaries covered the whole trial period. The participants were asked to record their step count. The majority of the participants were positive about the PA diaries and described how they encouraged them to keep up their walking, for example a woman participant said:

> "I did keep my diary. Made you think about your steps because you had to write it down daily, it made you work harder, I was very aware of my steps. It is absolutely wonderful when I look back at those days and now" (PN21, 50yrs, F, IG2).

This participant's PA level increased 152.8% over 6 months; it appeared that the use of the PA diaries was one of the key factors that increased participants' PA.

However, one participant disagreed with the positive comments on the use of the PA diaries in the WARA intervention. He found that the PA diaries were boring as he had to record his steps every day. He stated:

> "It [diary] was a chore; it's too much you have to remember it and to write every day I did use it at the beginning" (PN5, 74yrs, M, IG1).

However, this participant had not really used it, just at the beginning of the programme. He commented on the use of pedometer, and he talked about the benefit of the pedometer as it made him think about the distance he was walking. However, this participant was unable to increase his PA. He said:

> "I use it [pedometer], I am aware of the distance; you get to the stage when you know roughly how many steps you have taken in certain directions. If I'm walking to town I know that would be five or six thousands steps. It is very good, it makes me walk" (PN5, 74yrs, M, IG1).

It seems that he used the pedometer at the start of the WARA intervention then replaced it with the distance walked, which was roughly measured. This might explain the reason why his PA did not improve, as he focused on the distance without recording the steps.

The qualitative thematic analysis of the interviews showed that some participants whose PA level did not change or reduce did not follow the recommendations of the WARA intervention, such as using the pedometer, PA diaries, or both. For example, in the previously mentioned example of the old man who did not change his PA levels, it was noted that he only used the pedometer at the beginning of the WARA intervention. He then replaced this by walking and estimating the distance. Also, he did not use the PA diaries therefore his PA did not change.

Additionally, there was a participant whose PA level did not change over 6 months, and she only attended 4 education sessions because of her social commitments. It was also noted that she lacked the motivation to walk and also she claimed that the pedometer was not accurate and therefore it seems she did not use it. Another participant whose PA reduced over 6 months attended only 3 education sessions and also he claimed that the pedometer did not count the steps accurately. However, it seems he did not follow the recommendations of the WARA intervention, and in addition this participant noted that he had back pain as a PA barrier.

3 Social support

The education sessions in the WARA intervention contained some interactive discussion activities. There was a general agreement about the benefits of conducting the sessions in groups. The participants found the groups to be a good opportunity to meet other people with a similar condition. They were able to interact with others with similar experiences of RA, to build friendships and share information. At times this motivated them to keep attending the sessions.

The participants liked the group discussion; people with RA may feel isolated because of their condition. Feelings of isolation were evident throughout the interviews. There was also insight into the physical difficulties experienced when they could not join social activities or join friends because of the condition, and it also affected their daily lives. Their condition also restricted them from going to some places such as going to the gym, as discussed in (section;7.3.1, 1c). They felt isolated from the community, and this feeling might have led to loneliness and they felt they lacked a useful role in society, which may

contribute to psychological problems such as depression. For example, one young woman participant commented on the benefits of having group discussions, she said:

> ''It was very helpful, you get to hear what other people are doing and how they sort of managing to keep mobile. You get told you have arthritis and this is the tablets go take them and that is all. Attending the sessions gave us awareness about what you are doing every day" (PN16, 32yrs, F, IG2).

The same participant talked about her experience with arthritis and how it affected her life - she said:

> ''…Group sessions are a chance to meet others with arthritis, sharing experience, not everyone understands my condition, I have difficulties to have normal life some days I have pain I cannot work, go out, I cannot enjoy life'' (PN16, 32yrs, F, IG2).

Another woman attended all the education sessions however she works, as discussed in the PA barriers section. Despite her barriers to PA and her commitments she was able to increase her PA over 6 months and adhere to the programme. She commented throughout the interview that the WARA intervention was a good opportunity to meet people with RA, she said:

> This is a good chance to share experience with other rheumatoid arthritis people, not everyone in the community has arthritis" (PN21, 50yrs, F, IG2).

The group sessions helped reduce the feelings of social isolation they normally experienced. An-old man said that RA is not well understood in the general population and once you are diagnosed with this disease your daily life will change and other people will not understand. He talked about a negative experience with his friends.

> "The group sessions were good because rheumatoid arthritis people are very isolated, if you get an illness like this because other people don't understand it, they know about arthritis but the other type like osteoarthritis, your perception, daily life is changed completely because you have got this. I lost a friend or two because of this. So it's good to meet other people who know the disease" (PN5, 74yrs, M, IG1).

4 Understanding of condition and awareness of benefits of healthy lifestyle in terms of physical activity in relation to rheumatoid arthritis

Additionally, attending the education sessions of the WARA intervention helped the participants to understand their condition, and to raise their knowledge and awareness regarding a healthy lifestyle. For example, one participant whose PA did not change over the study period, and who attended all the education sessions, commented that the education sessions content had positively encouraged him and raised his knowledge and awareness of his condition. He stated:

> "It [session's content] was good to learn things I was not aware of; I did find it useful. It covered everything to make me more active. I think it was very well covered, refreshed my memory, made me knowledgeable, aware of the condition and encouraging" (PN5, 74yrs, M, IG1).

The majority of the participants found that the topics covered the basics as they provided them with information about RA, PA, heart disease and PA in RA and also a healthy diet. They stated for example:

> "The sessions were varied. The information about heart risk was new to me. It also gives us information about what we have to eat as you know the Scottish diet is terrible. I did stop a few things and I stopped sugar and bread. I became even more careful about my diet and I made it much healthier" (PN50, 66yrs, M, IG5).

Some participants appreciated that the sessions were giving them information about a healthy diet that could help them to control their co-morbidities with RA, such as diabetes. They therefore considered that the sessions offered new knowledge for them. The participants talked about a lack of information regarding their condition and also health issues in general. They were within five years of being diagnosed with RA, had been prescribed medication and no further explanations had been given in terms of, for example, the associated co-morbidity.

> "The sessions gave me the information that I was not aware of, it made me think more of what's happening and what I could do to help myself. It was helpful and I should be more careful about my diet, it helps my diabetic diet" (PN40, 50yrs, F, IG4).

The sessions also helped the participants to become more aware of the importance of being physically active.

It emerged from the interviews that the participants held false beliefs about walking in RA, as they believed once you were diagnosed with RA it was better to sit.

> "I thought walking worsened my arthritis. Now, I am very much aware of spending too much time sitting down and more aware of going for a walk" (PN 47, 65yrs, F, IG4).

Some of the participants were also unsure about the safety of strengthening exercises in RA. It seems that this uncertainty made them physically inactive. The education sessions and the handout highlighted an important issue related to the safety of strengthening exercise in RA. One stated for example:

> "Strengthening exercise, that is really good idea, I was not sure about strengthening exercise, whether it is safe or not in RA, was good to do or not, and now I know it is good to do strengthening exercise" (PN21, 50yrs, F, IG2).

5 The benefits of being more physically active

The participants who successfully increased their step count and maintained a high step count over 6 months stated that with the walking programme they felt much healthier, had less joint pain and their mood improved. In addition, no adverse effects from walking were reported. This was true even for those who previously believed that walking was not good for their condition.

> "Walking helped me and I try to walk every day, it helps to lift your mood. It might be nice if group walks were included in the programme. I don't have any problems with walking. My joints are better, but it could be that they have just got the balance right with my medication, I just feel better" (PN50, 66yrs, M, IG5).

Participants described their enjoyment and the benefits of being more physically active during the WARA intervention. For instance, one woman was able to reach her weekly walking goal, and talked about the benefits of being physically active. She spoke about the importance of being able to walk even short distances outside and how that helped her to overcome the pain she had.

> "I reached my weekly walking goal. I feel quite good; I did feel better. I am in a good mood. I think if you go even for short walk outside I think it seems you able to forget your pain and you feel better" (PN47, 65yrs, F, IG4).

The same participant found that in addition to the exercise, the healthy diet helped her in terms of losing weight and improving joint pain, which made her feel healthier. She stated that:

> "I lost two stone with healthy food and the exercise and I found losing weight helped my joints. Now if I do not walk enough my legs start crawling. It was very positive, I feel much healthier than I have for years, my pain is much less. I feel better; I feel a difference" (PN47, 65yrs, F, IG4).

These participants were their PA increased over 6 months therefore they enjoyed the benefits of being more physically active.

In addition, some participants reported positive benefits from the strengthening exercises within the programme. For example, a young woman stated:

> "I look at my strength exercise and use my Theraband. I was watching TV it is easy to do it, I did find a bit of improvement" (PN16, 32yrs, F, IG2).

Although many participants found that the strengthening exercises helped them, an equal number found that it made their pain worse.

> "I did strength exercise at the beginning, I have not done any of the strength exercise now, I think because I feel sore after the exercise" (PN47, 65yrs, F, IG4).

This finding may explain the lack of improvement in hand grip strength in both groups in the study.

6 Self-efficacy

Self-efficacy has been demonstrated to influence health behaviours. Self-efficacy is an important mediator of PA's effects on health outcomes (McAuley et al., 2011). The participants stated that their ability to perform PA improved after the programme. Observing others perform the task and sharing the

experience may explain the increased self-efficacy for PA in the participants. They stated for example:

> "I have much more energy. I am doing much more than the programme; I reach my target every single day. I need steps, I need to walk. It has been wonderful to join the programme, my life is changing, I feel confident. It's very easy to sit down when you are sore whereas you do walking the more you do the more you can do and you start to feel more confident about going out and doing things and it just make such a difference" (PN47, 65yrs, F, IG4).

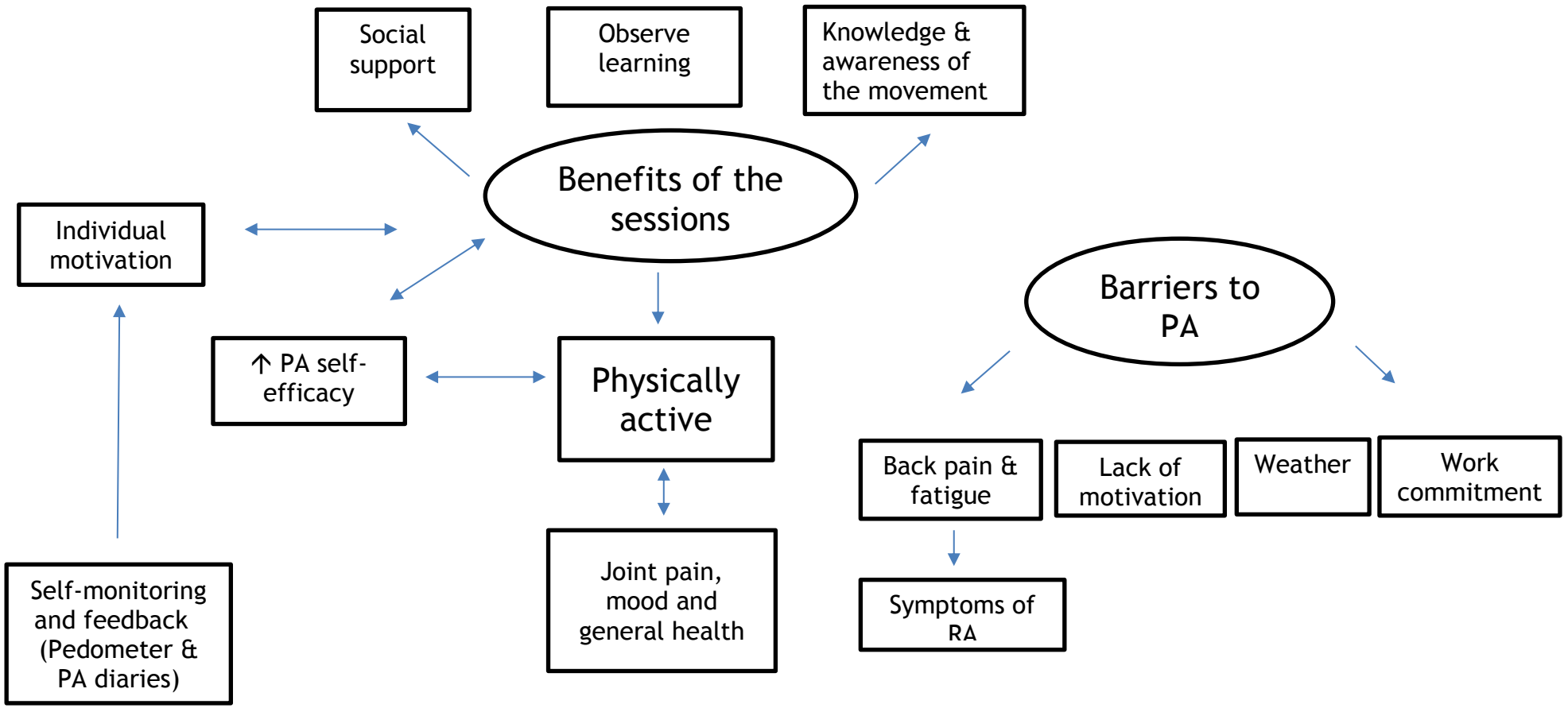

Figure 7-2 The theoretical mechanisms of action in WARA intervention

7.4 Summary of qualitative findings

The participants found that the WARA programme was enjoyable and helpful in terms of raising their knowledge regarding their condition and their awareness of the importance of being physically active. They also learned that walking did not worsen their condition. The participants found that group-based education sessions, observed learning and self-monitoring (pedometer, PA diaries) improved their confidence and were the keys to reaching their goals. In addition, many stated that walking helped them in terms of feeling healthier, reducing joint pain and improving mood. However, not all of the participants agreed on that.

In fact, not all of the participants adhered to the WARA intervention – for example, some participants did not perform the strengthening exercises and a few of the participants, who suffered from fatigue and tiredness, did not have the motivation to walk; they felt much more comfortable with sitting. Also, a few of the participants did not use the PA diaries so they may not have realised how much they had walked; others claimed that the pedometer was inaccurate when recording the step count. These factors may explain why not all of the participants increased their step count, improved their strength or enjoyed the health benefits of being physically active.

7.5 Integration of both qualitative and quantitative findings

The quantitative study found that participation in the WARA intervention positively influenced the primary outcome (average step count/day), with the average step count increasing over 6 months by around 35% in the intervention group. Similarly, participants' interviews showed that those participants whose PA increased over 6 months talked about being out walking and their PA improved after engaging in the WARA intervention. They stated that group-based education sessions were one of the key factors that motivated them to increase their PA and adhere to the programme. In addition, attending the education sessions helped them to understand their condition, as it highlighted the importance of being physically active in people with RA and also corrected their incorrect beliefs regarding walking and strengthening exercise and how these

would affect their condition. They also commented on the pedometer, PA diaries and walking programme as motivators that helped them to progress towards their PA goal. Despite some of them facing some PA barriers during the programme, they were able to overcome them and increased their PA.

However, the participants whose PA reduced or did not change over 6 months did not follow the recommendations of the WARA intervention as they either did not use the pedometer or PA diaries and also did not attend the education sessions regularly.

Thus, adherence to the WARA intervention and following the recommendations had a strong influence on PA and increased the participants' confidence in performing PA. Subsequently they enjoyed the benefits of being physically active, as was evident in the interviews. For example, one participant whose PA increased by 138.7% over 6 months felt less joint pain, and much healthier. This participant attended all the education sessions and she really used the pedometer, and bought a Fitbit. Another participant who adhered to the programme and the recommendations was able to increase his PA by 33.5% over 6 months and he found that his mood improved and he had less joint pain.

Thus, based on the findings of both studies (quantitative and qualitative), it seems that there was an interactive theoretical mechanisms of action. Increasing the participants' awareness and the knowledge of their condition, and increasing their PA self-efficacy by using motivation methods such as group education sessions, self-monitoring and feedback tools (pedometer and PA diary), may lead to increased adherence to the programme, increased PA and improved health outcomes.

8 Discussion

This chapter discusses the results from the quantitative data (primary and secondary outcome measures) and the findings of the qualitative study. It then considers these results in relation to previous literature. It discusses the findings in order to provide a comprehensive understanding of the motivators and key factors of the success of the participants' engagement in PA and also the barriers that the participants faced during the intervention. The strengths and limitations of the study are also presented.

A six-month, community-based, pedometer-supported walking programme, with an education programme incorporating behavioural change techniques (Walk for RA – WARA) resulted in an increased step count over 6 months (primary outcome measure). There were also changes in some secondary outcome measures such as 6MWT, self-efficacy for PA, systolic blood pressure and 10-year CVD risk.

8.1 General findings

The six-month WARA intervention had a statistically significant effect on the primary outcome measure of physical activity. For the secondary outcome measures, the results indicated a statistically significant improvement in the functional capacity of the intervention group in terms of the 6MWT; however, there were no significant differences in HAQ or the hand grip test. Although there were no significant differences between the groups in SDAI, a greater proportion of those in the intervention group went into remission (as defined by a score 0-3.3). Also, a significant improvement was noted in self-efficacy for PA, systolic blood pressure and the ASSIGN score (10-year CVD risk) due to the intervention. There was no evidence that the WARA intervention had any statistically significant effect on RAQoL, DINE score or co-morbidity over 6 months.

Thus, the null hypothesis for the outcome measures was rejected and the alternative hypothesis was accepted – i.e. there was a significant difference between the intervention group and the control group in primary outcome measures over the time period of the study (6 months) (further discussed in section 5.2). Generally, the intervention group improved in most of the outcome

measures, however of note the control group deteriorated compared to the baseline for measures of functional capacity (6MWT), systolic blood pressure and the 10-year risk of CVD. The following sections will discuss the results for each outcome measure.

8.2 Discussion of primary outcome measures

8.2.1 Physical activity levels (over 6 months)

The key finding from this study is the improved PA levels in the intervention group in terms of step count/day as measured objectively by the activPAL™ while the control group displayed a decrease in steps per day at all study time points compared to the baseline.

In the present study, the mean step count of the intervention group increased by 2569 steps per day, 35% above the baseline, over the 6-month period. This result is in line with the previous RCTs of Beghianimoghaddam et al. (2016), Baker et al. (2008a) and Stovitz et al. (2005), which also used pedometers to provide feedback but to healthy people in terms of their daily step count. These studies reported increased step counts in the intervention group over the study period (over 6 months) by around 40% (Baghianimoghaddam et al., 2016, Baker et al., 2008a, Stovitz et al., 2005). The increase in PA in the study by Baghianimoghaddam et al., carried out on Tabriz University employees, reported a significant improvement in step count in the intervention group from baseline (4715 ± 1751) to the end of the study (16 weeks) (8279 ± 2759 steps/day) by around 75.6% (Baghianimoghaddam et al., 2016).

Additionally, a cross-over study by Baker et al. (2008a) found that a 12-week pedometer-supported walking programme with PA consultations promoted walking in healthy individuals. They reported a significant increase in step count (activPAL™) from baseline (6802 ± 3212 steps/day) to week 12 (9977 ± 4669 steps/day) ($P < 0.001$) (46.7%) for the participants on the programme; however, no change was observed in the control group. The step counts of the intervention group were maintained in the follow-up period, between 12 and 24 weeks of the programme.

The pedometer and consultation evaluation (PACE-UP) study also found a significant increase in PA in the intervention group (Harris et al., 2017). There was significant difference in the change in step counts from baseline to 3 months between the intervention group and the control group. It also identified an increase in exercise self-efficacy in both the intervention groups (pedometer intervention or nurse-supported pedometer intervention). However, the increase was greater for those in the nurse-supported pedometer group (face-to-face). The study concluded that the pedometer-based walking intervention was effective in increasing PA among physically inactive people aged 45 to 75 years old. A pedometer intervention, with minimal support, provided in primary care may address the challenge of public health physical inactivity (Harris et al., 2017).

Hurkmans et al. (2010) reported that a pedometer is an important tool for health initiatives (Hurkmans et al., 2010). However, this is not consistent with a systematic review of PA interventions that used accelerometers or pedometers in people with chronic musculoskeletal pain, which found no significant difference between the intervention and control groups in objectively measured PA (Oliveira et al., 2016). This was true in the short-term (≤3 months), intermediate (>3 months and <12 months), and long-term (≥12 months) trials. There was notable heterogeneity in the studies reviewed with regard to data-processing techniques as well as reported outcomes. There was also a risk of bias, as most of the trials failed to blind the assessors and a high dropout rate was noted in the studies (Oliveira et al., 2016).

The current study supports the evidence from a systematic review by Bravata et al. (2007), who demonstrated that the use of a pedometer can increase PA levels by 27% and daily step count by 2000-3000 steps/day. The feedback from the pedometer in terms of step count encourages and motivates changes in behaviour as it raises awareness of the current level of walking, which may help to promote increasing levels of physical activity (Baker et al., 2008a, Mansi et al., 2013, Pal et al., 2009).

However, few pedometer-based PA intervention studies in RA could be found within the literature. One, a pedometer-based PA intervention in people with RA, by Katz et al. (2015) (further details discussed in section 2.6) showed a

positive change in step count from the baseline to 21 weeks (2132 ± 2698 steps/day, 92% ± 125%) in the intervention group, who used a pedometer and PA diary. When a step target was included in addition to the pedometer and diary, the step counts increased (by 1299 ± 2389 steps/day, 188% ± 506 %) (P=0.02). In the control group, the step count also increased but by a much smaller amount (-327 ± 2429 steps/day, 3% ± 56%) (P=0.53) (Katz et al., 2015).

The result suggests that prescribing pedometers, with or without a specific step target, to people with RA can be effective in promoting PA (Katz et al., 2015). This finding is in agreement with that of the current study where those who used a pedometer and PA diary, attended the education sessions and followed the recommendation of the WARA intervention increased their step count by up to 152%. Thus, the result may be related to the adherence of the participants to the programme.

In the present study, the step count increased in the intervention group, comparable to that observed in pedometer-based PA interventions in other populations, indicating that this type of intervention is effective for people with RA. In addition, the participants' views, explored during the telephone interviews, helped explain the improvement in step count. The participants who successfully increased their step count identified the pedometer, PA diary, a challenging goal, the group sessions, booster sessions and handout as keys to their success. The majority of the participants specifically identified the pedometer as being key to their success, as it encouraged them to work towards their walking goal and because the feedback it provided allowed self-monitoring of their PA. Thus, pedometers may be an important tool in influencing PA in people with RA.

The present study supports previous literature in the fact that the use of a PA diary may play a role in increasing participants' adherence to a PA programme, in self-monitoring behaviour (Conn et al., 2011, Dalle Grave et al., 2011) and progressing more effectively towards their PA goal (Bravata et al., 2007). Similarly, participants in the current study said that the pedometer and PA diaries were good tools for feedback, encouraging them to achieve their PA goal.

The findings of the interviews in this study suggest that group-based education enhanced the participants' adherence to the programme. This finding is supported by Withall et al. (2016), who conducted focus groups with people with RA: 15 females and 4 males with a mean age of 59.9 ± 10.3 years and a mean disease duration of 44 ± 34 months. They identified that group-based education as part of a PA programme supported by health care workers positively influenced the recruitment and adherence to the programme as it facilitated social support from other members of the group and provided a source of motivation. Furthermore, a focus group conducted by Crowley and Kennedy (2009) involving 12 people with RA found that the factors that enhanced adherence to exercise include disease activity (remission), environmental (social support) and personal factors (individual motivation). Specifically having less pain and having good social support played a role in motivating the individual. This agreed with the findings of this study where the participants commented that the group-based programme and a good motivation within the WARA intervention helped the participants' adherence to the sessions.

In the present study, one of the main targets of the intervention was to increase self-efficacy for PA and to encourage social support through group education sessions. However, there was a significant difference between the marital status of the participants in the intervention group and the change in step count. Single, separated, divorced or widow participants increased their step count more than those who were married. Although there is a lack of literature in this area, it may be that those who were single, separated, divorced or widowed had more free time to perform PA than those who were married and further study is recommended. The interviews also highlighted the important issue of people with RA feeling isolated due to their condition. There was also insight into the physical difficulties experienced when they could not join social activities or meet up with friends because of their condition. Their RA therefore affected their daily lives; they felt isolated and away from the community as there was a lack of people who understood their condition. Social support can be provided by friends, relatives, colleagues or a group that shares the same interests (Kim et al., 2008).

In the interviews, the participants expressed the view that they enjoyed the group-based programme, as they found it a good opportunity to meet other people with a similar condition. They were able to interact with others with similar experiences of RA, to build friendships and share information. They mentioned that the group-based nature of the programme was one of the key factors of their success in increasing PA levels and also it motivated them in issues related to the condition such as joint pain. People who receive more social support tend to have higher levels of self-efficacy (Kim et al., 2008). Providing an education programme in groups is a form of social support and may play a role in improving individual PA self-efficacy (Somers et al., 2012), as well as helping individuals to cope with stress and enhancing their self-confidence (Miller and Dimatteo, 2013, Wang et al., 2015). Furthermore, interventions delivered by face-to-face methods (mentored meetings, led walks, or educational sessions) significantly increase the levels of self-reported walking (Ogilvie et al., 2007). Thus, face-to-face groups with the associated social support were motivating factors that helped participants to succeed with the WARA intervention.

A systematic review and meta-analysis carried out by Warsi et al. (2003) identified that education programmes increase the awareness of patients and are highly effective for managing arthritis. Also, Withall et al. (2016) reported that people with early RA requested group education with information regarding RA, along with discussions and sharing thoughts with other people with RA. Consistent with the findings of this study, the participants found that the education sessions with WARA helped them to understand their condition, and to raise their knowledge and awareness regarding a healthy lifestyle.

In the current study, the participants were also given a handout during the education sessions. They found the handout a useful reference, particularly for the strengthening exercises. The findings of the present study are consistent with the evidence of Glanz and Bishop (2010), Artinian et al. (2010), who stated that education sessions and associated material allow participants to access information on PA and to interact with other study participants through interactive discussions. Similarly the focus groups by Crowley and Kennedy (2009) found that people with RA liked to receive exercise instructions.

The interviews in this study suggest that the booster sessions reinforced the progress that had been made since the start of the WARA programme, and motivated the participants to keep walking. This finding is consistent with the evidence that booster sessions help people to maintain recently adapted behaviour acquired during interventions (Goyder et al., 2014). Furthermore, there was a significant improvement in the physical function of the participants who received exercise therapy with booster sessions, compared to the participants who received exercise therapy alone (Abbott et al., 2015), (further details discussed in section 3.6).

In order to increase the adherence of participants to the programme, the venue and time of the sessions should be considered (Alvarado et al., 2015). In the current study, the participants found the hospital a suitable place to hold the education sessions. The focus group by Crowley and Kennedy also revealed that people with RA preferred the sessions to take place on 'common ground' (defined as a comfortable place that is available to people with good transportation and facilities) (Crowley and Kennedy, 2009). People with RA are used to going to the hospital and may find it a comfortable and familiar setting as they know the place and the staff, and have experience of the services offered.

The aforementioned influential factors such as self-monitoring, group sessions, social support, use of handouts and a familiar location may explain the success of the WARA intervention in promoting PA among participants in the intervention group.

In the interviews of the present study, the participants stated that the duration of the intervention was suitable for them, that the number of the sessions was adequate and that they covered the content well. A study by Withall et al. (2016) involved a PA programme in people with RA, which consisted of 5 education sessions over 12 weeks (4 group sessions and 1individual session with guided exercise). The findings of the focus group of Withall et al. (2016) suggested that the participants would have preferred a less intense programme with less contact and more flexibility. However, an RCT carried out by Mayoux-Benhamou et al. (2008) identified that a 12-month study consisting of home-

based exercise with guidelines for leisure PA was suitable for people with RA (further details discussed in section 2.5.3).

Although programmes that last more than six weeks are more successful, they carry an inherent risk of attrition in people with RA (Riemsma et al., 2004). In the present study however, with 6 weekly education sessions with two booster sessions at 3 and 6 months, the loss to follow-up was higher in the control group (40%) compared to the intervention group (5%).

In the current study, as well as an increase in objectively measured PA, the total metabolic equivalent task (MET)/minutes, measured by the IPAQ, increased in the intervention group between baseline and 3 months, but declined between 3 and 6 months. In the control group it declined between baseline, and 3 and 6 months. Also, there was a significant difference between the groups at 3 months. This finding is contrary to the results of a pedometer-based workplace intervention of 154 women employees (Baghianimoghaddam et al. 2016) which found a significant increase in self-reported PA at the end of the study (16 weeks) in the intervention group but not in the control group. However, in the current study, the finding of the IPAQ does not reflect the finding of activPAL™, where the step count increased over the study period. The IPAQ is a self-reported measure of PA, and participants may have underestimated (Ahn et al., 2015) or overestimated (Quick et al., 2016) their levels of PA. Self-report questionnaires do not provide accurate estimates of the absolute amount of PA due to, for example, the accuracy of recall of PA and social desirability bias (under or over-reporting good behaviour) (Boon et al., 2010, Sallis and Saelens, 2000). Participants in the current study commented that their PA had reduced at the 6-month assessment period; however, their objective step count showed an increase. This may explain the lower IPAQ scores at 6 months.

Alternatively, the discrepancy between the objective and subjective measures of PA could be explained by the fact that the activPAL™ measured all PA and the IPAQ only measured activity in bouts of 10 minutes and longer (Baker et al., 2008a, Wolin et al., 2008). However, Larkin et al. (2016c) reported that activPAL™ underestimated step counts by 26% in people with RA, but there were some limitations in Larkin et al.'s study such as the fact that the validation of daily physical activities was carried out in a laboratory setting. In addition, the

participants of Larkin et al.'s study affected movement patterns, (further discussed in section 4.3.1).

The reason why some participants increased their step count and others did not in the present study may be explained by several factors. For example, group-based education and social support helped the participants to increase their steps; however, a lack of individual motivation was one of the barriers that led to a reduced step count. As this study was based on social cognitive theory, it seems that self-efficacy plays an important role in increasing participants' PA. It assumes that self-efficacy is an important factor of behaviour, and associates self-efficacy with many other components such as goals, outcome expectations and individuals' motivation and behaviour (John et al., 2011a, Glanz et al., 2002).

The finding of the current study was consistent with that of a study conducted by Anderson-Bill et al. (2011) which involved 703 adults aged between 40 and 92 years old. The participants received a pedometer, and a PA diary. Participants also used a step counter to verify the recordings in the PA diary. The change in mean daily step count between the baseline and 16 months, the end of the study, was calculated using a pedometer. Also, PA-related social cognitive theory components (social support, self-efficacy, outcome expectations and self-regulation) were assessed. It was reported that increasing self-efficacy is an effective way of increasing PA. Indeed, the results of the present study showed that a higher step count was associated with higher self-efficacy in the intervention group, which fits with social cognitive theory.

The findings of the interviews in this study suggest that work commitments, individual motivation, weather, fatigue and back pain were the main barriers to PA. A previous review of barriers to PA in people with RA also identified that pain and fatigue were barriers to PA and additionally the fear that PA would aggravate their condition (van Zanten et al., 2015). Focus groups, carried out by Withall et al. (2016), also found that people with RA have a fear that exercise may worsen their condition. Although the participants of the current study did not mention a lack of knowledge regarding exercise and safety as barriers, they stated that the study increased their knowledge and awareness regarding PA,

and that it corrected misconceptions and also the fear they had regarding exercise and RA.

The focus groups conducted by Crowley and Kennedy (2009) similarly identified pain and fatigue as barriers to exercise but also identified fear of falling and the psychological effects of RA as other barriers to PA. Participants in the present study believed that once you were diagnosed with RA it was better to sit than to be physically active. They were also unsure about the safety of strengthening exercise for people with RA.

In the present study, no injuries were reported related to walking or strengthening exercises. This finding is consistent with the studies of Hurkmans et al. (2010) Stavropoulos-Kalinoglou et al. (2013), van den Berg et al. (2006) and Breedland et al. (2011) where no injuries were reported related to PA or exercises. Thus, it seems that walking is a good form of PA for those with RA (Baxter et al., 2016) and that fear of injury should not be a barrier for undertaking PA.

Additionally, a systematic review of chronic conditions such as osteoarthritis, RA and lower back pain found that pain, low PA self-efficacy, individual motivation and poor social support were the main barriers to participating in PA (Jack et al., 2010). The findings of this review are consistent with the current study in terms of individual motivation and low back pain. It seems that the low back pain affected the motivation of the individual to be physically active.

In summary, it seems that fatigue and pain, and symptoms related to disease activity, are commonly reported barriers to PA in people with RA. A further barrier is related to the misbelief that walking and strengthening exercises will worsen their condition. In addition, a lack of individual motivation was identified in the current study and in that of Jack et al. as a barrier to PA. It is important to identify PA barriers so that they main be considered when designing future lifestyle interventions for people with RA.

8.2.2 Sedentary time (over 6 months)

The UK physical activity guidelines (2011) not only recommend an increase in PA, but also emphasise that adults should reduce the time spent being sedentary. This is important as sedentary time is a risk factor for CVD independent of the level of PA.

In the present study, despite no significant interaction effect, objective sedentary time (including sleeping time) reduced between the baseline and 6 months by around 40 minutes/day in the intervention group, compared with the control group who increased their sedentary time (including sleeping time) by 20 minutes/day. In terms of clinically significant differences half of the baseline standard deviation could be clinically significant for sedentary behaviour(Norman et al., 2003). In the present study, half of baseline standard deviation of sedentary behaviour was 50 minutes/day however, the sedentary behaviour only reduced by an average of 40 minutes/day in the intervention group and increased 20 minutes/day among the control group over the 6 months Thus, overall no clinical significant differences were noted in sedentary behaviour in both groups. However,14 (37%) participants in the intervention group had a clinically significant reduction in sedentary time were there sedentary time reduced more than 50 minutes/day over the 6 months.

Similarly, in the current study, self-reported weekday and weekend sitting hours decreased in the intervention group, but increased in the control group. However, the discrepancy between the objective and subjective measures of sedentary behaviour in the current study could be partially explained by the fact that the activPAL™ measured all sedentary behaviour (sitting/lying) over 24 hours, (in this study the sleeping time was included in the sedentary behaviour) and the IPAQ only measured the time spent sitting.

The self-reported findings of the current study are consistent with a physical activity consultation and 12-week pedometer-based walking programme among a healthy population carried out by Baker et al. (2008a). They found a significant reduction in time spent sitting during weekdays (P = 0.003), weekends (P = 0.001) and in total (P = 0.001). However, Baker et al. investigated a healthy population and the present study investigated those with RA.

Furthermore, a systematic review and meta-analysis of Martin et al. (2015) found a reduction of 22 min/day in sedentary time in favour of the intervention group (95% CI −35 to −9 min/day, n=5868) in 34 studies out of 51, where sedentary behaviour was measured objectively or self-reported. Lifestyle interventions reduced SB by 24 min/day (95% CI −41 to −8 min/day, n=3981, moderate quality) and the interventions that focused only on sedentary behaviour reduced SB by 42 min/day (95% CI −79 to −5 min/day, n=62, low quality). However, there was no evidence of an effect of PA and combined PA/SB interventions on sedentary behaviour. Martin et al. (2015) highlighted that if the primary aim of a study is to change sedentary behaviour, then the intervention should focus on that, rather than increasing physical activity. The result of Martin et al. may help to understand to some extent the lack of change in objectively measured sedentary behaviour, as the focus of the present intervention was on increasing physical activity. However, self-reported measures showed reduced weekday and weekend sitting time.

An RCT with a cross-over design was carried out by Mutrie et al. (2012). The participants were previously sedentary adults and the intervention group received two 30-minute individual PA consultations delivered by a trained practice nurse, a booklet with information about the walking programme and a pedometer. The programme also included a walking group twice weekly for 12 weeks. The intervention led to an improvement in the participants' quality of life and a reduction in their sedentary time. Studies generally seem to show a reduction in sedentary time following a PA intervention.

Walking groups, like that in the study above, play an important role in motivation and also in increasing adherence to a PA programme (Helmink et al., 2010). The current study did not include a walking group, which a few participants raised as a deficit in the WARA intervention. The participants commented, in telephone interviews, that they thought group walking would be a valuable addition and would provide an incentive to encourage walking.

8.2.3 Physical activity and sedentary time 6 months after the intervention (12 month)

In the present study, only a small number of participants were followed up 6 months after the intervention. The result showed that the step count of the intervention group was slightly reduced compared to 6 months, but it remained at a higher level than the baseline. However, the step count of the control group returned back to baseline levels at 12 months. In this study, there was no significant difference between the intervention and control groups in terms of weekday and weekend sitting hours at 12 months (P = 0.441 & 0.172 respectively). Due to the time limits of the study, only 22 participants were followed up at 12 months, but data were available for only 18 participants thus the 12-month results might not accurately reflect the participants' level of PA as the sample size was small.

The overall findings suggest that an intervention based on pedometers, grounded in behaviour theory and incorporating behaviour change techniques (particularly self-monitoring, feedback and social support) can promote PA and to a lesser extent reduce sedentary behaviour, in people with RA who are within the first five years of diagnosis. This effect was seen for 6 months and, where data were available, the step count at 6 months' follow-up remained higher than the baseline. The following sections discuss the results of the secondary outcome measures.

8.3 Discussion of the secondary outcome measures (at 6 months)

8.3.1 Self-efficacy for physical activity

The concept of self-efficacy, in relation to PA, concerns the level to which an individual has belief in their capabilities to perform exercise and to be physically active (Williams and French, 2011). The findings showed that the WARA intervention lead to a significant improvement in the self-efficacy for PA in the intervention group at 6 months. It increased from baseline to 3 months and baseline to 6 months; self-efficacy for PA reduced in the control group over the study time points. In addition, high self-efficacy for PA was associated with a

higher step count and lower sedentary time ($P < 0.05$) at 3 months in the intervention group and at 6 months in the control group.

Similarly to a systematic review of lifestyle and physical activity interventions that aimed to increase physical activity and self-efficacy in healthy adults, a change in self-efficacy has been found to correlate with a change in PA ($r = 0.690$, $P < 0.001$) (Williams and French, 2011).

The results of this trial are in agreement with an RCT of a 6-week walking intervention, where the participants in the intervention group received a pedometer and instructions on a walking route to be completed 3-4 times per week (Baxter et al., 2016). The walking route was designed so that the RA participants could choose a walk of an appropriate length for them. The trial, which involved 33 RA patients and 22 control individuals, reported that the intervention group experienced greater improvement in their self-efficacy for PA and wellbeing, and less pain, compared with the control group (Baxter et al., 2016). Although the trial was successful in increasing self-efficacy for PA in the target population, no theoretical underpinnings of the intervention were reported, which makes it difficult to explain the mechanism of its success (further details discussed in section 2.5.3). Increasing self-efficacy for PA can play a role in the likelihood of an individual with RA achieving their PA goals, which is important in improving outcomes (Knittle et al., 2011).

In contrast a study conducted by Larkin et al. (2016b) examined self-reported PA levels and self-efficacy in 102 people with inflammatory arthritis with a mean age of 59.6 ± 13.2 years. Self-efficacy for PA was measured using the Rheumatoid Arthritis Self-Efficacy questionnaire. No significant relationship was noted between self-efficacy for PA and reported PA levels in the study population, while beliefs about PA correlated with self-reported PA. However, PA was measured subjectively and also a non-specific measurement of self-efficacy, which measured general self-efficacy for RA as opposed to PA-specific self-efficacy, was used, which may have led to an underestimation of the participants' confidence in their ability to engage in PA.

A study by Neuberger et al. (2007) investigated the effects of 12 weeks of aerobic exercise for 1 hour 3 times/week in 220 adults with RA aged between 40

and 70. They were randomised into class exercise, home exercise following a exercise video, or a control group. The exercises consisted of a warm-up, low-impact aerobics, strengthening, and cool-down exercises. The outcome measures were assessed at baseline, 6 weeks and 12 weeks (end of the study). It was reported that self-efficacy for PA measured with the exercise self-efficacy scale influenced exercise participation in people with RA. Despite the positive outcome of the study, convenience sampling was used and therefore the sample may be biased towards more highly motivated participants. Also, the control group was in remission and fewer were treated with Disease-Modifying Antirheumatic Drugs (DMARDs) than in the intervention group (Neuberger et al., 2007).

In the qualitative interviews of the present study, the participants stated that after participating in the WARA intervention they were more confident in walking, whereas they had not been confident before the programme. The success of the WARA intervention may be explained by the fact that it was based on social cognitive theory, as the participants' views showed that observing others perform the PA task and sharing the experience helped the participants to increase their ability to perform PA.

8.3.2 Rheumatoid arthritis assessment

1 Disease activity

The simple disease activity index (SDAI) has been validated for use in clinical trials and practice, and the ACR/EULAR recommend using the remission criteria of SDAI in clinical trials (Felson et al., 2011). In the current study, there was no significant interaction effect between the two groups over time in the SDAI. The percentage of people in remission as determined by the SDAI remission score increased from 12.8% at baseline to 32.4% at 6 months in the intervention group. No real changes were noted in the control group. The MCID for RA disease activity have not been well-defined in real-world clinical settings, especially for patients early on in RA, who are experiencing low/moderate disease activity (Curtis et al., 2015).

Higher disease activity (SDAI) was associated with both lower step count (P = 0.03) and higher sedentary time (P = 0.02), at 3 months in the intervention group.

The findings of this study are in contrast with a study conducted by Prioreschi et al. (2013) who reported no correlation between SDAI and PA (P = 0.976). However, in the present study the population consisted of people with RA within the first five years of diagnosis and the participants in the Prioreschi study had a disease duration from 1.8 years to 14.6 years. However, there is a lack of RCTs examining the effectiveness of PA on disease activity (SDAI) in people with RA and further work in this area is required.

The most appropriate PA for RA is aerobic exercise such as walking. It can enhance cartilage integrity and joint lubrication, and increase the range of motion and flexibility, increase the muscle mass and physical function of people suffering from RA without damaging the joints of exacerbating the disease (Cooney et al., 2011, Pal et al., 2009). The combination of increased PA and effective medication may help to inhibit disease progression, improving quality of life and health outcomes (Metsios et al., 2011).

In the telephone interviews the participants stated that after engaging in the WARA intervention, those who increased their PA, felt much healthier and had less joint pain.

The effect of regular aerobic PA on CRP is not yet fully understood, although regular PA is associated with a reduction in CRP levels in healthy men (Albert et al., 2004) as well as in people with RA (Metsios et al., 2009, Metsios et al., 2008). SDAI is based on CRP, and in the current study CRP showed no significant interaction between groups, which explains the SDAI results. However, the exact mechanisms to explain the link between increased PA and reduced disease activity are not clear. Exercise-induced immune changes have been identified, in particular muscle contractions that regulate the expression of specific cytokines such as in interleukin (IL) 6-8, IL10, and IL15, and TNF-alpha; thus the effect may be due to the anti-inflammatory effects of exercise (Brandt and Pedersen, 2010). Exercise has several other benefits, including improving blood and synovial fluid circulation in joints in the general population. However, the dose

response of PA in people with RA is not yet fully known (Cooney et al., 2011) and further study is recommended in this area.

2 Rheumatoid arthritis quality of life (RAQoL)

Quality of life is an important concept within health outcome appraisals, in general as well as in chronic disease. It is an indicator of the burden of the disease, in terms of both physical and mental health, and provides insight into the outcome of a treatment programme (Burckhardt and Anderson, 2003, Salaffi et al., 2009). People with RA have a low level of PA, and this has a high negative impact on quality of life (Arne et al., 2009). In the present study, there was no interaction effect between groups in terms of RAQoL; however, there was a non-significant improvement in both groups. Based on MICD, the fact that the ability to detect improvement in RAQoL in clinical setting if the RAQoL score reduced by an average of – 0.67 to – 0.51 over 6 months (Maska et al., 2011b). In the present study, the RAQoL score reduced by an average of 2.8 in the intervention group and by 1 among the control group over the 6 months. Thus, based on MICD, there was an overall clinical significant difference in RAQoL in the both groups, the results suggest a strong trend towards an improved quality of life in the clinical setting among the intervention group.

Plasqui (2008) stated that aerobic or strengthening exercises have a positive effect on RA disease progress, range of motion, quality of life and functional capacity. In a number of studies quality of life was measured with the EuroQol five-dimension questionnaire (EQ-5D). EQ-5D consists of the dimension's mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, which differs from the RA specific tool used in this study and may explain the different results of this study from previous studies.

In other chronic disease such as diabetes, quality of life of people is increased if they achieve their PA goal (Arne et al., 2009) and this may also be true of people with RA. However, this effect of PA, and more specifically walking, on quality of life in people with RA has not yet been established and further work in this area is required.

In contrast to the present study, Hurkmans et al. (2010) reported improved quality of life of people with RA, measured by RAQoL at 24 months following one-year internet-based PA intervention. This may be explained by the fact that the people who were motivated and physically active completed the 24 months, as it was reported that 26.7% were lost to follow-up. On the other hand, it may be related to other factors such as disease activity controlled by treatment or pain and fatigue; further study is needed.

Although there was no statistically significant difference in RAQoL in the present study, the results suggest a strong trend towards an improved quality of life and possibly a larger sample is needed. Also, there may be other factors such as fatigue and pain that are related to quality of life, but that were not considered in this study.

8.3.3 Functional capacity

Functional capacity in this trial was assessed with the six-minute walk test (6MWT), hand grip strength and the Health Assessment Questionnaire (HAQ). In the current study, the distance walked in six minutes increased in the intervention group but fell in the control group. In the intervention group, a higher step count at 6 months was significantly associated with an improvement in 6MWT.

The finding of the current study is consistent with that of Neuberger et al. (2007), which involved 220 adults with RA. The exercise programme consisted of 12 weeks of warm-up, low-impact aerobics, and strengthening and cool-down exercises for 1 hour 3 times/week. The time to walk 50 feet was used to assess functional capacity. A significant interaction effect was reported between the intervention and the control group in walk time ($P \leq 0.005$) in favour of the intervention group. However, walking 50 feet might be insufficient to identify any improvement in functional performance in people with RA. The current study used 6MWT, which is more reliable for assessing and evaluating functional capacity (Du et al., 2009).

In the current study, 6MWt showed a significant improvement from the baseline to six months (361m at baseline to 417m at six months) for an average of 36.3-

74.9m. However, based on MCID, even the smallest difference in score for some measurements may be beneficial to the patient (Cook, 2008). It has been reported that clinically meaningful change in 6MWT is approximately 15-30 meters (Shoemaker et al., 2013). Therefore, even though there wasn't a statistically significant increase in the 6MWT there may have been a clinically significant change.

In terms of grip strength the finding of the current study contrasts with the study by Neuberger et al. (2007) (described above), which identified a significant interaction effect between the intervention and control group ($P \leq 0.005$) in favour of the intervention group. The intervention in the study by Neurberger et al. included strengthening exercises with elastic exercise bands and for one group it was supervised. However, in the current study the strength exercise was included in just one of the education sessions and the handout instructions may have been insufficient to motivate participants to perform the exercise at home. Also, a number of participants in the interviews said that the strengthening exercise made them sore, therefore they stopped doing it.

The WARA study findings were also consistent with a prospective study carried out by Hakkinen et al. (2001) where 70 participants with RA were randomly assigned to either the control group or to a dynamic strength-training group, who had to perform 8–12 repetitions per set of exercises twice a week, giving an exercise duration of 45 minutes. The training programme included exercises for the upper and lower extremities, with elastic bands for resistance, and exercises for the abdominal and back muscle exercises, using dumbbells.

In addition, the patients were encouraged to perform PA including walking, cycling, skiing, and swimming 2–3 times/week for 30–45 minutes. The participants completed training diaries, which were emailed to the researcher every second month. They were assessed at 6-month intervals for 2 years. Functional capacity was assessed with muscle strength tests (isometric grip strength, trunk flexor, and knee extensor measured with a dynamometer), walking speed (maximum walking speed in meters/second over a distance of 30 meters) and HAQ. The greatest increase in muscle strength was noted in the strength-training group, where it increased by 19–59% over 24 months. The corresponding change in the control group was 1–31%. HAQ and walking speed

also showed significant improvements in the strength-training group. The study concluded that combined endurance PA with regular strength training can improve the functional capacity of people with RA (Hakkinen et al., 2001).

The target population was those with RA within 2 years of diagnosis, and all of the participants were treated with medication to achieve disease remission. The primary outcome measure was the improvement in muscle strength. Furthermore, the intervention was intensive and lasted for two years – so the improvement in the functional capacity of RA was unsurprising. Such an increase in strength is unlikely in the current study, where the main focus was on promoting PA.

In contrast to the current study, an RCT carried out by Stavropoulos-Kalinoglou et al. (2013) on aerobic and high intensity resistance exercise in people with RA reported that there was a significant difference between the intervention and control groups in HAQ (P = 0.003). The improvement may be due to the intensity of the intervention.

A study carried out by Khoja et al. (2016) reported that light, very light, and moderate intensity PA was significantly associated with lower functional disability in people with RA. Although in the present study PA intensity was not measured, higher physical activity (steps/day) was associated with higher functional capacity at baseline in the intervention group (P= 0.04). Also, higher functional disability was associated with higher objectively measured sedentary time at 6 months in the control group.

Joints are susceptible to insufficient or excessive activities, leading to joint degeneration; lack of exercise is known to induce joint contracture, leading to impaired functional capacity in osteoarthritis (Ozkan et al., 2007). People with RA who develop functional limitations secondary to immobility early in the disease course are at risk of becoming disabled (Cooney et al., 2011). A few studies were able to improve functional capacity (HAQ). They were studies where the examined cohort was in the early stage of RA and had low disease activity (Hakkinen et al., 2001) or convenience sampling was used (Stavropoulos-Kalinoglou et al., 2013) or the programme was supervised with intensive

intervention and the participants were young, aged between 18 and 53 years old (Orlova et al., 2015).

Previous literature suggests that exercise, whether aerobic or strengthening, has a positive effect on RA functional capacity (Plasqui, 2008). The findings of a review of RCTs by Metsios et al. (2009) demonstrated that PA plays an important role in improving functional capacity in people with RA and the results of the current study add to that evidence. The present study adds to that literature by using the 6MWT, which does not seem to have been used before.

The interviewed participants said that after participating in the WARA intervention they could do more walking and they felt much healthier. The improvements in walking discussed at interview would explain the improved distance walked in the 6MWT.

The lack of improvement in hand grip was perhaps expected. Although the strength training was a component of this study, there was no supervised resistance training programme. In addition, the qualitative findings added context to these results whereby although a few participants found that the strengthening exercise helped them and they enjoyed performing the exercises, the majority of the participants mentioned that they did not do the strengthening exercise very often. Also, some participants experienced an increase in pain after the strengthening exercises.

The findings of this study indicate that the WARA intervention improved 6MWT but not the HAQ or hand grip strength. This may be expected as, despite the strengthening component of the intervention, the strengthening programme was not intensive and was unsupervised. It was also not the main focus of the study.

8.3.4 Cardiovascular risk factors

1 Blood results

There were no interaction effects between the two groups in blood lipids in this study (HDL, TG, cholesterol level CRP, glucose, GGT, insulin, ALT and AST). However, there was a significant association between objectively measured time spent being sedentary (including sleeping time) and TG, with a higher sedentary

time (including sleeping time) being associated with a higher level of TG at 3 months in both the intervention and control group. Also, there was a significant inverse relationship between sedentary time (including sleeping time) and GGT ($P < 0.05$). Hamilton et al. (2007) showed that increased time being sedentary leads to suppression of the lipoprotein lipase activity of skeletal muscle (LPL) due to a loss of local contractile stimulation. LPL is the enzyme that is engaged in the uptake of free fatty acids and triglyceride and high density lipoprotein (HDL) in skeletal muscle (Hamilton et al., 2007).

Thus, the increase in sedentary time may lead to a reduction in the uptake of triglyceride and HDL, which consequently increases levels of free fatty acids and triglycerides in the blood stream and reduces the protective effect of HDL against cardiac events, which may increase the risk of developing CVD. The relationship between sedentary time and cardiometabolic biomarkers, independent of PA, has been established (Qi et al., 2015). This emphasises the importance of reducing sedentary behaviour for the prevention of CVD, even in those who meet PA recommendations (Qi et al., 2015).

The findings of this study contrast with an RCT conducted by Murphy et al. (2002), who utilised an RCT cross-over design with previously sedentary adults. The intervention comprised 6-week of brisk walking with short and long bouts. The results showed a reduction in triglyceride level and triglyceride level/ total cholesterol level, and increased HDL in the intervention group ($P < 0.05$). In addition, a study by Khoja et al. (2016) reported that very light, light and moderate intensity PA was significantly associated with improved insulin sensitivity and HDL as well lower functional disability, SBP, DBP, and BMI in people with RA.

The evidence suggests that that there is a dose-response association between exercise duration and health outcomes such as lipid profile (Dalleck et al., 2009) and that higher intensity PA favourably affects the lipid profile (Cornelissen et al., 2009). The UK physical activity guidelines (2011) recommended a healthy lifestyle including moderate intensity/vigorous PA.

A significant dose-response association between blood glucose and high intensity PA ($P = 0.04$) in an adult population was reported by Teh et al. (2015). Also a

large cohort study carried out in the United States on more than 70,000 healthy women aged 40-65 years reported that brisk walking and vigorous exercise were associated with a 25% reduction in diabetes incidence (Hu et al., 1999). In other studies in adults with diabetes, by Loprinzi and Cardinal (2013) and Healy et al. (2015) a significant association was found between light intensity PA, low inflammatory markers and blood glucose. In the present study PA intensity may not have been high enough to change lipid profiles and blood glucose.

2 Blood pressure and 10- year CVD risk

In the present study, there was a significant improvement in CV profile in terms of systolic blood pressure (SBP), which declined by a mean of 7.2 mmHg in the intervention group and increased in the control group by 4 mmHg at 6 months. A significant interaction effect was seen between groups in the ASSIGN score ($P < 0.001$). A decline in the ASSIGN scores was noted within and between the intervention and the control group. In the intervention group the ASSIGN score significantly reduced between baseline and 6 months ($P < 0.001$).

A reduction in SBP and DBP was observed following a PA programme with healthy individuals at 12 weeks and 12 months (Hunt et al., 2014). Moreau et al. (2001) demonstrated that SBP reduced by 11 mmHg and body mass reduced by 1.3 kg over the 24 weeks of a walking programme in postmenopausal women.

This study's findings are also in line with those by Metsios et al. (2009), which demonstrated a reduced risk of developing CVD and an improved functional capacity in RA patients who were physically active. A significant difference was detected among groups (physical active and inactive group) in systolic blood pressure ($P = 0.006$), cholesterol ($P < 0.001$), low-density lipoprotein ($P = 0.01$). Although the findings of both studies are consistent, the Metsios study calculated the 10-year probability of a CVD event using the Framingham risk score. In the current study the CVD risk was measured using the ASSIGN score. The ASSIGN score was developed in Scotland and it includes social deprivation and family history of CVD, features that are not included in the Framingham risk score.

Stavropoulos-Kalinoglou et al. (2012) reported that CVD was reduced ($P= 0.012$) in RA patients who participated in a 6-month programme of high intensity

resistance exercises. The 10-year CVD event probability was assessed with the Heart Score programme of the European Society of Cardiology. Although the current study and the study by Stavropoulos-Kalinoglou et al. reduced the 10-year CVD risk, the current study was a less intensive programme than Stavropoulos-Kalinoglou study and thus the WARA intervention may be more appropriate and more acceptable to people with RA.

The finding of the current study is in line with a meta-analysis of prospective cohort studies on healthy individuals conducted by Li and Siegrist (2012) where the lipid profile, blood pressure, adiposity variables, endothelial function and coagulation factors were all evaluated following the PA intervention. There was a reported reduction in risk of CVD by 20-30% among women and men who engaged in high levels of leisure time PA, while moderate leisure time PA decreased the risk of CVD by 10-20%. However, the study did not distinguish between CHD and stroke and the overall relative risk of CVD was calculated.

Studies reveal that sedentary behaviour is significantly associated with increased risk of CVD (Chomistek et al., 2013, Dunstan et al., 2010), (further discussed in section 2.8.3). In addition, Kaplan (2010), van Halm et al. (2009), Liao and Solomon (2013) reported that a low level of PA is associated with increased risk of CVD. On the other hand, Chiuve et al. (2011) and Greenland et al. (2010) stated that regular PA is associated with a low risk of sudden cardiac death. Consistent with the evidence, the current study found that spending more time sedentary was associated with high SBP at 3 months in the intervention group and high triglyceride at 3 months in both the intervention and control groups.

Hypertension contributes to the increased risk of CVD in the general population as well as in those with RA (Liao and Solomon, 2013). Hypertension can lead to an increased workload on the heart (increased vascular resistance) that could increase/accelerate the atherosclerotic changes; it can also induce left ventricular hypertrophy, congestive heart failure and cerebrovascular accidents (Evaristi et al., 2016). There is evidence that people with RA are more likely to have hypertension than non-RA individuals (Siebert et al., 2016). In the current study, 16 participants (21.0%) had a history of hypertension. Lifestyle modifications have an important role to play in preventing hypertension,

reducing BP and lowering the risk of hypertension complications (Gupta and Guptha, 2010).

Exercise has several physiological effects that affect the cardiovascular system through autonomic and hemodynamic adaptations (Whyte and Laughlin, 2010). Cardiac debt, the extra oxygen required after exercise for the oxidative energy process in order to convert the lactic acid to glucose and to decompose adenosine triphosphate and creatinine phosphates to their original state, increases in line with rises in SBP (Whyte and Laughlin, 2010).

Peripheral resistance to blood flow is reduced by the vasodilatation within the skeletal muscle; this is compensated for by the induced vasoconstriction occurring in non-exercised tissues. Physical exercise causes a reduction in the peripheral vascular resistance due to an accumulation of muscular metabolites (potassium, lactate and adenosine) (Whyte and Laughlin, 2010).

SBP increases in line with exercise intensity; however, DBP changes little during sub-maximal exercise, irrespective of intensity (Council et al., 2013). Blood pressure changes vary with the type of exercise. Aerobic exercise increases the heart rate and increases the pressure with which blood is pumped, thus raising the SBP. This is the preferred exercise for the heart. However, during strength/resistance training, peripheral vascular resistance increases due to sustained static muscle contractions, which lead to restricted blood flow through arterial and venous blood vessels. This can lead to an increase in SBP and DBP (Council et al., 2013). As this study involved a walking programme, the aerobic nature of the exercise many explain why SBP but not DBP declined.

During the recovery period post-exercise, SBP decreases below the pre-exercise levels for up to 12 hours and the DBP can also remain low for hours afterwards. This may have an important application in promoting a healthy lifestyle as exercising regularly can reduce BP on a daily basis (Council et al., 2013).

Education of participants regarding the condition seems to play a role in reducing the consequences of the disease (Glanz et al., 2002). In the present study during the interviews participants in the intervention group stated that the education sessions raised their awareness and knowledge of CVD and RA. It also

made them aware of the importance of people with RA being physically active to reduce the CVD risk and to improve functional capacity and reduce disability, which they said was new knowledge for them.

This finding is consistent with a study conducted by Bartels et al. (2013), who interviewed 10 people with RA aged from 23 -81 years, in order to evaluate CVD preventive care. Almost all of the participants were unaware of the increased risk of CVD in RA. In addition, the majority of the participants who were interviewed reported receiving no consistent CVD preventive care. The study recommended that rheumatologists should consider interventions in order to overcome the CVD preventive care gap in clinics. The increased awareness regarding the co-morbidities associated with RA, particularly CVD, might help to motivate people to increase their PA and subsequently reduce their blood pressure and CVD risk. Knowledge and awareness regarding CVD can influence a patient's choice with regard to adopting a healthy lifestyle, including PA (Koniak-Griffin and Brecht, 2015).

This study supports the evidence on the role of lifestyle interventions, including promoting PA in order to reduce SBP and 10-year CVD risk. The decline in the ASSIGN score is likely to be due to changes in SBP, cholesterol levels and HDL, but specifically SBP.

3 Anthropometric measurement

In the current study, although there was a significant interaction effect in BMI in favour of the control group, there was no significant difference within group changes. There was no significant interaction between groups in adiposity variables (WC, HC, and WHR). This is in contrast to the RCT of Murphy et al. (2002), which reported no significant changes in BMI following a 6-week programme of brisk walking in previously sedentary adults; however, WC and HC were reduced in the intervention and control groups ($P < 0.05$). This may be not the case with RA, as the evidence revealed that BMI has a paradoxical association with RA as low BMI (<20kg/m^2) is associated with increased CVD risk (Boyer et al., 2011, Zegkos et al., 2016). Furthermore, muscle loss due to systemic inflammation and reduced PA may contribute to low BMI (Stavropoulos-Kalinoglou et al., 2007).

In the present study, a higher time spent being sedentary (including sleeping time) was associated with higher WC, HC, BMI, and WHtR in the intervention group at 3 months but not the control group. This result is in line with a study by Wijndaele et al. (2014) that assessed 171 adults with a history of DM using an accelerometer to measure their PA, self-reporting television viewing time and an assessment of their cardiometabolic risk. The results showed that increased sedentary time is associated with clustered cardiometabolic risk (CCMR) which includes greater waist circumference, dyslipidaemia, hypertension and hyperglycaemia (CCMR: 0.08, 95% CI 0.01, 0.15). Thus, promoting walking and reducing time being sedentary can help to reduce anthropometric measurements and thus cardiometabolic risk.

The fact that the adiposity variables did not change in this study may be because the intervention did not target energy intake and energy expenditure (see section 8.3.5 below). It may be that an intervention of higher intensity alongside a dietary component is needed to improve the adiposity variables.

8.3.5 Dietary assessment

There were no interaction effects between the intervention and control groups in the scores of the DINE questionnaire in the current study in terms of the consumption of fatty and sugary food, and fruits and vegetables. The present finding contrasts with an RCT conducted by Hunt et al. (2014), which identified a significant difference between groups (intervention and control) in DINE score. However, the main aim of Hunt et al.'s study was to examine the effect of a healthy living programme on weight loss and the targeted population was football players, which could explain their success at changing their food intake. However, no previous studies in RA have used the DINE questionnaire, therefore it was difficult to fully explain the present findings.

In the current study, changing diet was not within the main objectives of this study; only one education session on diet was given to the intervention group and advice and material about diet was provided to the control group as well. Findings from the interviews suggested that participants found the topic of diet very useful, and the information provided increased their awareness of an appropriate diet. Some participants stated that they changed their dietary

habits after the session, however these individual changes were not sufficient to alter the DINE scores.

8.3.6 Charlson co-morbidity index

There was no significant difference across the period of the study in the Charlson co-morbidity in either group. In particular, there was no significant increase in co-morbidity over the 6-month intervention period. However, a previous study identified a significant increase in co-morbidity over a year in people with RA – more so than in people with other conditions such as osteoarthritis, and non-arthritis patients. Additionally, people with RA did not show improvements in survival (Charlson co-morbidity) similar to their non-RA peers and more attention should be paid to mortality in people with RA (Gabriel et al., 1999). However, Radner et al. (2010) reported that increased co-morbidity in RA patients is independent of disease activity and physical function.

8.4 Strengths of the study

The WARA intervention has many strengths; it was designed specifically for people with RA, and was a single blind, randomised controlled trial. It was grounded on the constructs of SCT and also the behavioural change techniques used integral to the intervention were well established. In addition, it compared the effectiveness of the programme with usual care in this patient group. The programme was piloted in the first group and subsequent changes were implemented according to the physiotherapist's and the participants' feedback. A mixed methodology was employed using both quantitative and qualitative components, in order to explore findings in more depth.

The primary outcome, PA at 6 months, was assessed with both objective and subjective measures. The secondary outcomes considered many aspects of RA (disease activity, functional capacity, quality of life, self-efficacy for PA, co-morbidity and CVD risk). More than two-thirds of participants in the intervention group increased their step count over 6 months, and 25/37 (67.6%) participants whose step count increase over the 6 months – 19/25 (76%) participants increased their step count by more than 2000 steps/day from baseline to the primary end point (6 months).

The programme also improved the participants' self-efficacy with regard to PA and health outcomes including functional capacity, SBP, and 10-year-risk of CVD.

Participant's views on the programme were sought and participants reported that the programme was good for them and, as they often felt very isolated, the programme gave them the chance to share their experience and gain new knowledge. They reported the education sessions improved their knowledge such as the higher risk of CVD and the detrimental effects of sedentary behaviour.

The programme was acceptable in terms of content, time, venue, group size, number of sessions, content, handout, method of delivery, use of the pedometer and physical activity diary. From the quantitative and qualitative findings, it seems that there was an interactive theoretical mechanism of action. Increasing the participants' awareness and knowledge of their condition, and increasing their PA self-efficacy by using motivation methods such as group education sessions, self-monitoring and feedback tools (pedometer and PA diary), enhanced their adherence to the WARA intervention. Subsequently, PA increased and improved health outcomes were observed.

8.5 Limitations of the study

The study has offered an evaluative perspective on an important condition, and was conducted in a people with first five years of diagnosed of RA. The study had a number of limitations, which need to be considered. As with other studies, a high number of participants were lost to follow-up in the control group. Seventeen (22.4%) participants were lost to follow-up in the study, two in the intervention group and fifteen in the control group. This differential loss to follow-up in the control group may be because they have no programme, thus no motivation to continue attending assessments. Telephone interviews with people who had been lost to follow-up would have helped to explore the reasons for this. The loss to follow-up figures are consistent with other studies such as the RCT of Neuberger et al. (2007), where around 28% were lost to follow-up at 12 weeks; however Knittle et al. (2015) lost only 14.1% participants to follow-up (18.4% in the intervention group and 10% in the control group).

In terms of generalisability, patients who participated in the exercise study displayed a relatively high baseline step count and had a disease duration of within 5 years so were not representative of the general rheumatology population. The step counts of those with a short disease duration, less than 12 months, did not change or reduce in comparison with participants whose disease duration was more than 12 months.

Flares or exacerbations of RA were not captured in the study. In addition, variables such as mood, pain, fatigue and sleep were not captured systematically in the study, although they are key components of RA, and may affect, or be affected by, exercise intervention.

Limited physical strengthening- resistance exercises were included in the present study as the focus was on increasing physical activity however the effect of strength training on RA cachexia should be explored in future studies.

Due to the large number of outcome measures and the focus on more clinically based measures the maximum volume of oxygen ($VO2_{max}$), as a measures of cardiovascular fitness was not included. However, it would have been interesting to explore any association between the change in physical activity and cardiovascular fitness.

The study consisted of two primary outcome measures: step count and sedentary behaviour, however the study sample size was based on only one primary outcome measure i.e. step count. The study was powered for 68 participants, although the aim was to recruit 90 participants, in order to allow for people dropping out/missing data. Due to the time constraints of the study, only 76 participants were recruited, which did, however, provide sufficient numbers.

In addition, including pilot data within the data set is a weakness in the experiment. It would have been better to undertake a separate pilot.

Due to a high number of ‘lost to follow up’ participants among the usual care (control group) the current study did not compare people who increased their physical activity or those who did not change or reduce PA among the usual care group.

Use of a cross-over design or incentives, such as a specific programme for the control group after finishing the intervention may have helped to counteract the high drop-out rate, particularly among the control group.

The current study did not evaluate the intensity of PA, therefore future studies should aim to identify the dose-response relationship between PA and clinical outcomes in those with RA.

Sedentary data included sleep, as it was not possible to separate this from other sedentary behaviour. Future studies should consider the addition of sleep diaries to better differentiate between night time sleep and day time sedentary behaviour. It is also possible that exercise could lead to a better/longer sleep but this needs to be explored in future study.

8.6 Discussion summary

Walking has been reported as being popular and convenient for all ages, it requires no specialist skills and carries little risk of injury in the general population (Kassavou et al., 2013, Ogilvie et al., 2007) and in people with RA (Baxter et al., 2016). In the present study there was no adverse effect or injury recorded related to walking. Participants in the WARA intervention stated that walking was good for their health and mood and that it did not worsen their condition or cause injuries as they had previously believed.

The positive outcomes that have emerged from this trial can guide others to promote walking in people with RA and encourage an approach that incorporates patient education. Although the results highlight the ef

fectiveness of walking for 6MWT, SBP, and CVD risk, further work to investigate the effect of walking on joint pain, fatigue and mood may be required.

A high number of people were lost to follow-up in the control group (n=15), the majority of which were female and of a younger age, so the losses may be explained by work commitments or child care commitments. Telephone interviews with people who had dropped out of the study would have helped to explore the reasons for this.

9 Summary, Conclusions and Recommendations of the Study

The following chapter offers a summary and considers the implications of this research for future work in this area. It offers recommendations that may help in clinical practice and finally it presents the conclusion of the study, highlighting the novelty of this research.

9.1 Summary of the study

Although there is evidence that PA has a beneficial effect on health and that interventions that include behavioural change techniques can promote PA in the general population, there is still a lack of evidence regarding whether behavioural change interventions can promote PA among people with RA. There is also insufficient evidence regarding the role of PA, particularly walking, on CVD in RA. This trial was designed to address some of these unanswered questions in RA.

The primary outcome of this study was assessed with an objective measure (activPAL™) and the subjective measure of PA. Thus, the findings are robust and directly relevant to people with RA. The 6-month WARA intervention was effective in that the intervention group increased their physical activity; it helped people with RA to overcome barriers to PA and it brought them benefits in a number of ways. The secondary outcome measures (functional capacity, RAQoL, disease activity, CV risk and 10-year-risk of CVD) were assessed with subjective and objective measures. The results demonstrated that the intervention had a statistically significant, positive effect on functional capacity (6MWT), CV risk profile and 10-year- risk of CVD.

There were no adverse effects or injuries related to the intervention. The results of this study indicate that this type of intervention is suitable and appropriate for people with RA within the first five years of their diagnosis. The results from the qualitative study supported some of these findings in that the participants felt an improvement in mobility, had less pain and felt healthier.

Also, the participants' interviews identified the fact that group-based education sessions and the use of a pedometer, PA diaries and a handout had a great influence on the participants' increased PA. The results also highlighted the importance of BCTs, such as using pedometers and PA diaries for self-monitoring, in promoting PA and the social benefits of group education sessions. Additionally, results underlined the fact that theoretical based intervention was essential in influencing lifestyle changes, such as PA and also explained the outcomes of the intervention.

9.2 Recommendations

Encouraging PA in people with RA may play a role in improving the functioning of individuals in terms of 6 minutes' walk and reducing the 10-year-risk of CVD.

9.2.1 Key recommendations for future research

Future intervention research should include telephone interviews with people who drop out of the study, in order to understand the reasons for this. Understanding these factors would help the design of future studies.

Future physical activity intervention trials should evaluate the intensity of physical activity for people with RA. This would help investigate the dose-response relationship between physical activity and clinical outcomes in those with RA.

Further studies are needed to replicate the results of this study, which may play a critical role in the management of long-term RA.

9.2.2 Key recommendations for clinical practice

People with RA wish to know about RA, physical activity in RA, and the consequence of sedentary behaviour, in order to improve their understanding of the condition and the benefits of PA. To that effect, a specific education programme for people diagnosed with RA should be offered to those with early RA. This could be provided as an interactive online patient education package.

Finally, the trial could be designed to be crossover design, which may make the study more acceptable to patients and reduce the dropout rate.

9.3 Conclusions

This study found that WARA, a community-based pedometer-supported walking programme, along with education sessions incorporating behavioural change techniques, is effective at promoting walking in these patients over 6 months in people within the first five years of being diagnosed with RA. The WARA intervention improved the participants' self-efficacy for PA and health outcomes in terms of functional capacity (6MWT), CV profile (systolic blood pressure) and the 10-year-risk of CVD. The WARA programme may be a useful adjunct to current clinical practice in rheumatology.

Appendices

Appendix 1 Preface

Relevant research concerning rheumatoid arthritis, physical activity and cardiovascular disease (CVD) risk was identified by searching the databases for primary research material before designing this trial. Databases were searched for publications from 1965 through to 2014, with key articles obtained primarily from PubMed, Medline, Google Scholar, Cochrane Library, Web Sciences and PsycINFO. Cross-sectional studies, case controls, cohort studies, literature reviews, systematic reviews, Meta-analyses and clinical trials were reviewed, all related to rheumatoid arthritis, physical activity/exercise, and CVD. The next step was a detailed examination of the papers in order to identify the limitations, gaps and inconsistencies in the body of knowledge in this area. This helped to determine the research objectives, hypotheses and theoretical frameworks of this study.

A summary of the reviewed studies is included in the following tables. In order to ensure that relevant studies were not missed, the search terms remained broad. These were "rheumatoid arthritis and "physical activity" or "physical inactivity" or "exercise" or "aerobic exercise" or "walking or sedentary behaviour" and "CVD" or "heart disease" anywhere in the title or abstract. Further reviews were carried out after designing this study, while analysing the present data and during the writing up stages (chapter 2). This was done in order to compare the results of this study with previous literature, to explain the results in depth, and to critically evaluate the study and existing knowledge. This strategy also helped the researcher to understand the limitations and the implications of the present findings for policy and practices.

Preface (Cross sectional studies)

Citation	Title	Method		Result and conclusion
		Study type	Study population and outcome measures	
(Castillo et al., 1965)B. Published in Ann. rheum. Dis. (1965), 24, 522.	Physical activity, cystic erosions, and Osteoporosis in rheumatoid arthritis.	Cross-sectional	153 RA patients review of medical record, each patient was graded for degree of PA.	There is a significant inverse relation between the grades of osteoporosis and PA.
(Eurenius and Stenstrom, 2005) Arthritis Care & Research Volume 53, Issue 1, pages 48-55, 15 February 2005	Physical activity, physical fitness, and general health perception among individuals with rheumatoid arthritis.	Cross-sectional	298 RA patients Data on self-reported PA, physical fitness, activity performance.	47% reported PA behaviours that did not comply with public health recommendations. Findings indicate that there is a case for recommendations on and support for healthy PA behaviours among people with RA.
(Henchoz et al., 2012) Rheumatology (Oxford). 2012 Aug; 51(8):1500-7.	Physical activity and energy expenditure in rheumatoid arthritis patients and matched controls.	Cross-sectional	110 RA patient 440 control Age- and sex-matched controls were included in this study. Energy expenditure was assessed using the validated PA frequency questionnaire. (DAS-28), functional status (HAQ), pain visual analogue scale (VAS) and fatigue VAS.	All DAS significantly poorer in sedentary compared with active patients. Daily energy expenditure is significantly lower in RA patients compared with matched controls. Disease activity and fatigue are important contributing factors, which is an important issues to be considered if PA among RA in health goal.
(Elkan et al., 2011) BMC Musculoskelet Disord. 2011 Jan 14;12:13.	Low level of physical activity in women with rheumatoid arthritis is associated with cardiovascular risk factors but not with body fat mass--a cross sectional study.	Cross-sectional	61 RA patients, 61out-ward RA women, (57.3-64.4) years, answered a self-administered questionnaire, to estimate total daily PA during the previous year. PA level was given as metabolic equivalents (MET) × h/day. Diet content was assessed by a food frequency questionnaire and body composition by whole-body dual-energy X-ray absorptiometry.	41% of the women had BMI > 25, 6% were centrally obese and 80% had FM% > 30%. The median (IQR) total PA was 40.0 (37.4-47.7).RA women with fairly low disease activity, good functional capacity had the same total PA level as healthy Swedish women in the same age. However, low total PA was associated with dyslipidaemia, insulin resistance, which is of interest in the context of increased frequency of CVD in RA.
(Piva et al., 2010), arthritis Care Res (Hoboken). 2010 Aug;62(8):1144-51.	Association of physical function and physical activity in women with rheumatoid arthritis	Cross-sectional	Women with RA (n = 47, mean +/- SD age 56.5 +/- 7.0 years). Social and biomedical characteristics explored included age, ethnicity, disease duration, marital and educational status, height, weight, co morbidity, and disease activity. HAQ).	HAQ score remained significantly associated with PA. The results indicate that measures of PA may represent different constructs and support the need to measure PA in rehabilitation research in RA.

(Demmelmaier et al., 2013) Arthritis Care Res (Hoboken). 2013 Jul;65(7):1166-76	Current and maintained health-enhancing physical activity in rheumatoid arthritis	Cross-sectional	5391 RA patients, self-reported PA Questionnaire, aerobic PA and muscle strength training.	The result indicate that a minority perform maintained PA, including both aerobic PA and muscle strength training.
(Henchoz et al., 2013) JRheumatol. 2013;42(2):136-45	Stages of change, barriers, benefits, and preferences for exercise in RA patients.	Cross-sectional	120 RA patients Administered a questionnaire to determine their exercise stage of change, their perceived benefits and barriers to exercise, and their preferences for various features of exercise.	Eighty-nine (74%) patients were finally included in the analyses. Their mean age was 58.4 years, mean RA duration 10.1 years. The participants preferred exercising alone (40%), at home (29%), at a moderate intensity (64%).Walking was by far the preferred type of exercise, in both the summer (86%) and the winter (51%).
(Munsterman et al., 2013) J Rehabil Med. 2013 Feb;45(2):164-9	Low aerobic capacity and physical activity not associated with fatigue in patients with rheumatoid arthritis.	Cross-sectional study	60 RA patients, (Multidimensional Assessment of Fatigue scale; MAF), disease activity (DAS 28), pain, physical and psychological status (Arthritis Impact Measurement Scales 2; AIMS 2), aerobic capacity and PA (Short Questionnaire to Assess Health-enhancing PA.	Participants age was 51.8 (SD 10.4) years and 73.3% were women. Duration of disease was 10.2 (SD 0-41) years and mean disease activity score was 3.4 (SD 1.4). Total amount of physical activity was 176.9 (10.6-1,492.3) MET hours/wee. However, no relationship was found between aerobic capacity and fatigue.
(Chang et al., 2009) Clin Rheumatol. 2009 Jun;28(6):685-91	The relationship between quality of life and aerobic fitness in patients with rheumatoid arthritis		66 RA patients (10 male, 56 female). Maximum graded exercise tolerance testing to determine their subsequent aerobic fitness.	Age-matched men and women, respectively. The female patients' BMI was significantly lower than that of the reference data. The results indicated that impaired aerobic fitness, combined with poor physical and psychological well-being in RA women.
(Tierney et al., 2013) Arthritis care & research. 65(6):888-95, 2013 Jun.	Study to determine the criterion validity of the SenseWear Armband as a measure of physical activity in people with RA		14 subject 8 men and 6 women were diagnosed RA. The SWA was compared to the criterion measures of the Oxygen.	The SWA can be considered a valid tool to estimate energy expenditure during ADL in the RA population; however, attention should be paid to its tendency to overestimate energy expenditure.
(Metsios et al., 2009). European journal of Rehabilitation and Exercise Physiology. 16 (2) (pp 188-194), 2009.	Association of physical inactivity with increased cardiovascular risk in patients with rheumatoid arthritis.		Levels of PA were assessed in 65 RA patients (43 females). Using the IPAQ, patients were allocated into three groups: active, moderately active and inactive. Anthropometric characteristics, RA activity/severity, multiple classical and novel CVD risk factors and 10-year CVD event probability were assessed and compared among the three groups	Physically inactive RA patients have significantly worse CVD risk profile compared with physically active patients. The possible beneficial impact of increased PA, including structured exercise, to the CVD risk of RA patients' needs to be accurately assessed in prospective studies.

Preface (Case Control study)

Citation	Title	Method		Result and conclusion
		Study design	Study population	
(Mancuso et al., 2007) Published in Arthritis Rheum. 2007 May 15;57(4):672-8. Pub Med	Comparison of energy expenditure from lifestyle physical activit ies between patients with rheumatoid arthritis and healthy controls.	Case control study	121 RA patients, 120 healthy control. completed the Paffenbarger PA and exercise index at time of enrolment from 1999 to 2000 and 1 year later to measure energy expenditure from walking, climbing stairs, and exercise/sports.	Mean age was 49 years, and 87% were women. The strongest predictor of more energy expenditure at 1 year for both groups. Most of the difference in energy expenditure between RA patients and healthy controls was due to less walking. Increasing walking should be a priority to improve cardiovascular risk in RA.
(Paul et al., 2014) Scand J Rheumatol.	Oxygen cost of walking, physical activity, and sedentary behaviours in rheumatoid arthritis		38(19 cases and 19 control), case and control matched for age, sex, and BMI. Demographic details and clinical characteristics of the RA population were recorded. Oxygen uptake per meter walked was measured in the laboratory using a portable gas analyser. Activity profiles including the number of steps per day, time spent sedentary.	People with RA took fewer steps, increased sedentary time and lower time walking at cadences with moderate to vigorous physical activity (MVPA) compared to controls. The changes inactivity/sedentary behaviours in people with RA and require further investigation.
(Metsios et al., 2013) Rheumatology (United Kingdom).	The effects of individualized aerobic and strength training on cardiovascular outcomes in patients with rheumatoid arthritis.		20 RA, 20 Control, Patients received a 6 month individualized aerobic and resistance interval exercise intervention three times per week. Another 20 patients matched for age, gender, BMI, and disease duration formed the control group which only received advice on the benefits of physical activity. VO2max, blood pressure, lipids, insulin resistance and body composition, disease activity (DAS28), health assessment questionnaire (HAQ), and C reactive protein (CRP) were taken at baseline, 3 and 6 months	The proposed combined aerobic and strength training intervention resulted in a significant improvement in VO2max and disease-related characteristics in RA patients. Significantly reduced individual CVD factors. Individualized exercise seems to be a promising intervention that may improve the increased prevalence of CVD risk factors and therefore reduce CVD mortality in RA.
(Durcan et al., 2012) Arthritis and Rheumatism.	The impact of targeted exercise intervention on health outcomes in rheumatoid arthritis.		Baseline assessments relating to cardiovascular risk factors, body composition, disability, sleep quality and PA were ascertained using standardized measures. Exercise was then prescribed in order to target individual functional limitations as identified by (HAQ).	Forty patients with RA (mean age 46 years) (SD8.0) and mean disease duration of 15.6 years (SD 10.9) were included. A 12 week targeted exercise program yielded significant improvements in strength, pain, joint stiffness, sleep, and fatigue and lipid profile, impacting on both

Preface (Cohort study)

Citation	Title	Method		Result and conclusion
		Study design	Study population	
(Solomon et al., 2003) Published in Circulation.2003;107:1303-1307 Published online February 17, 2003.	Cardiovascular Morbidity and Mortality in Women Diagnosed with Rheumatoid Arthritis.	A prospec tive cohort study	114 342 women. All self-reported cases of RA were confirmed by medical record review. Fatal and nonfatal myocardial infarctions and strokes were similarly confirmed.	527 incident cases of RA and 3622 myocardial infarctions and strokes were confirmed. Women who had RA for at least 10 years had a risk for myocardial infarction. Aggressive coronary heart disease prevention strategies should be tested for persons with RA.
(Tourinho et al., 2008) Rheumatology International August 2008, Volume 28, Issue 10, pp 1001-1007 Pub Med	Physical activity prevents bone loss in premenopausal women with rheumatoid arthritis.		71 RA cases, 29 healthy premenopausal women were followed for 2 years.	85% were Caucasian, aged 38 ± 6.6 years and with a duration of disease of 88 ± 50 months. Sedentary was a risk factor for osteopenia in RA. Moderate PA reduced the risk of osteopenia by 50%. Early preventive and therapeutic measures must be encouraged.
(Nordgren et al., 2012) BMC Public Health. 2012 Jun 1;12(1):397	Long-term health enhancing physical activity in RA.		450 patient's RA 2-year real-life intervention program including a minimum of twice-weekly circuit training, moderately intense PA the remaining days of the week and group meetings to support behaviours change every other week.	Increase muscle function and aerobic capacity, impact psychosocial factors and prevent future cardiovascular events.

Preface (Literature, Systematic review and Meta-analysis)

Citation	Title	Method			Result and conclusion
		Study design	Study population	Search strategy	
(Larkin and Kennedy, 2014) Published in J Phys Act Health. 2014 Aug 19. Midline	Correlates of Physical Activity in Adults With Rheumatoid Arthritis	Systematic Review	N= range from 52 to 6336 participants. Majority were female gender. Age 19-90 years.	Search of Medline, EMBASE, AMED, CINAHL plus, Pubmed, Web of Science and the Cochrane Library. It included 8 cross-sectional, 1 study observations and 1 randomized.	10 studies were met the inclusion criteria. PA positive associated with motivation, self-efficacy, health perception and previous PA levels. However, PA was associated inversely with fatigue. However, this systematic review included only 10 studies and majority is cross sectional design which cannot determine exact correlation between the causes and effect.
(Metsios et al., 2008) published in Rheumatology (Oxford). 2008 Mar;47(3):239-48. Epub 2007 Nov 28.	Rheumatoid arthritis, cardiovascular Disease and physical exercise	Systematic Review.	N= include case study from 1 RA to 139 participants	Six databases (Medline, Cochrane Library, CINAHL, Google Scholar, EMBASE and PEDor it included studies from1974 to December 2006. This review examined the role of exercise in improving disease related characteristic in patients with RA	40 studies were met the inclusion criteria. No studies were found examine the relationship between exercise interventions and CVD in RA. Low to high intensity exercise of various modes is effective in improving disease-related characteristics and functional ability in RA patients. This systematic review included RCTs and non RCTs, lack of evidence regarding RA and CVD, and also it included all type of exercise without focus on specific programme, from this review it difficult to identify specific regime that beneficial to people with RA
(Cramp et al., 2013b) Cochrane Database Syst Rev. 2013 Aug 23;8:CD008322.	Non-pharmacological interventions for fatigue in rheumatoid arthritis	Systemic Review	N= 2882 participants	Trials(CENTRAL)MEDLINE; EMBASE; AMED; CINAHL; PsycINFO; Social Science Citation Index; Web of Science. RCTs were included if they evaluated a non-pharmacological interventions in RA with self-reported fatigue as an outcome measure.	24 studies were met the inclusion criteria. This review included all non-pharmacological intervention which made it resulted in heterogamous between the interventions and is difficult to capture specific intervention can help to reduce fatigue in RA patients additionally there was no cut point between PA and psychological intervention which may lead to overlap of the results.

(Meune et al., 2010) Arch Cardiovasc Dis. 2010 Apr;103(4):253-61.	High risk of clinical cardiovascular events in rheumatoid arthritis: Levels of associations of myocardial infarction and stroke through a systematic review and meta-analysis	Systemic review and meta-analysis	N= 124,894 Age 50-55 years 46-100% female	A MEDLINE search from January 1960 to September 2009 and abstracts from international conferences from 2007 to 2009 were searched.	17 studies were met the inclusion criteria. 10 studies reported on standardized mortality ratio for fatal myocardial infarction. Nine studies reported on fatal stroke. The risks of myocardial infarction, stroke and mortality were increased with RA. The age of participant's ranges from 51 to 61.8 years and no specific conclusion regarding the age or traditional risk factors that could lead to increase the risk among RA was seen.
Liao KP, Solomon DH. Rheumatology (Oxford). 2013 Jan;52(1):45-52.	Traditional cardiov ascular risk factors, inflammation and cardiovascular risk in rheumatoid arthritis	Literature Review		Review previous studies regarding the relationship between RA and traditional risk of CVD	An increased CVD risk associated with RA compared with the general population. However, the risk partially appeared to be mediated by RA-specific factors, such as long-term inflammation, traditional CV comorbidities play an important role. It recommended further studies are needed in order to develop methods for accurate CV risk estimation in RA.
Gabriel SE, Crowson CS. Curr Opin Rheumatol. 2012 Mar;24(2):171-6.	Risk factors for cardiovascular disease in rheumat oid arthritis	Literature Review		Review the recent evidence on contribution of traditional and nontraditional factors of excess the CVD in RA	The traditional risk factors such as smoking are more pronounced on the development of CVD in RA are however; BMI seems to have paradoxical relationships. Inconsistent findings with dyslipidaemia were noted). CVD factors behave differently in RA. The need for RA-specific risk prediction tools. There was a significant association between excess risks of CVD in RA.
Turesson, et al. Current opinion in Rheumatology. March 2007-volume 19 -issue 2-p 190-196.	Cardiovascular risk factors, fitness and physical activity in rheumatic diseases.	Literature review		To highlights the factors associated with excess risk of CVD in RA. To identify the role of PA in preventing CVD risk in RA.	It found that inflammation and disabilities play an important role in increased risk of CVD in patients of RA. Increase risk of CVD in general population due to sedentary life style. It concluded that a successful treatment of RA, control of disease activity and high functional capacity may help in reducing the risk of CVD in RA.

Cramp F, et al Musculoskeletal Care. 2013 May 7.	Health Behaviour Change Interventions for the Promotion of Physical Activity in Rheumatoid Arthritis	Systematic review	Not mention	Three studies Four review	There was no comparison with usual care in studies included in this review therefore, the effectiveness whether HBC interventions can increase PA in the RA population cannot concluded and further research is required Further research in order to find the conclusive for clinical guidelines.
Tjerk Munsterman, et al. Published in BMC Musculoskelet Disord. 2012; 13: 202. Published online 2012 October 18.	Are persons with rheumatoid arthritis deconditioned? A review of physical activity and aerobic capacity	Systematic review	sample size varied from 8 to 35 participants	12 studies, Medline, Cinahl, Embase, Cochrane and PsycINFO up to 2010. Studies investigating PA, energy expenditure or aerobic capacity in patients with RA.	In one study the PA, energy expenditure in RA was significantly decreased. Patients with RA appear to have significantly decreased energy expenditure, very low aerobic capacity compared to normative values and spend less time in vigorous activities than controls
Tierney M, Fraser A, Kennedy N. J Phys Act Health. 2012 Sep;9(7):1036-48.	Physical activity in rheumatoid arthritis	Systematic review	Not mention	7 databases (Emabase, MEDLINE, AMED, Biomedical Reference Collection Expanded, CINAHL.	Sixteen studies meeting the criteria were deemed suitable for inclusion. The results of the included studies indicate that the level of physical activity may be lower among individuals with RA when compared with healthy controls or normative data. Further research on health benefits of PA in RA is indicated.
Plasqui G. Physiol Behav. 2008 May 23;94(2):270-5. Pub Med	The role of physical activity in rheumatoid arthritis.	Literature review			It has been identified that exercise improves muscle function without affecting disease activity. There was no evidence exercise, even high-intensity exercise, increases inflammation or joint damage, however care should be taken if have patients severe baseline damage. The effect of exercise on muscle mass or the ability to prevent or reverse cachexia are somewhat contradictory, it appeared that when exercise is adequate large, gains in muscle mass can be achieved
Baillet A, et al Rheumatology (Oxford). 2012 Mar;51(3):519-27.	Efficacy of resistance exercises	Systematic review	N= 547 patient	Pubmed, Embase and Cochrane databases through November 2009. RCTs	10 RCTs, including 547 patients included in this review. Resistance exercises significantly improved

	in rheumatoid arthritis			comparing resistance exercise. Outcomes studied HAQ, functional capacity assessed by walking speed, analogue scale (VAS), joint count, and grip strength.	isokinetic strength. Self-efficacy high with high intensity programme. Resistance exercise in RA is safe, and the improvement in most outcomes was statistically significant and possibly clinically relevant for RA disability.
Baillet A, et al. Arthritis Care Res (Hoboken). 2010 Jul;62(7):984-92	Efficacy of cardio-respiratory aerobic exercise in rheumatoid arthritis	Systematic review	N= 1040 patients	Medline, EM Base, and Cochrane databases up to July 2009 RCTs comparing aerobic exercises with non-aerobic interventions in RA patients were included. Outcomes studied were post intervention quality of life, function assessed by the HAQ, pain with VAS, joint count, DAS28.	14 RCTs, including 1040 patients, met the inclusion criteria. Exercise improved the post intervention quality of life, HAQ score, and pain VAS. Exercise in this RA population appeared safe, since global compliance, DAS28, and joint count were similar in both groups. In stable RA the cardio respiratory parameter seems to be safe and improves some of the most important outcome measures.
Cairns AP, McVeigh JG. Rheumatol Int. 2009 Dec;30(2):147-58	Effects of dynamic exercise in rheumatoid arthritis	Systematic review	Not mention	Searching Medline (1949-2007), Cinahl (1982-2007), Embase (1974-2007) and Cochrane library 12 RCTs included	12 studies were met the inclusion criteria. Early, stable, and active RA was included. An improvement in muscle strength, physical function and aerobic capacity with dynamic exercise were reported. CV outcomes were not reported in any study, and no data were presented to assess the effect of exercise on patients with CVD. Studies were suggested that patients with RA should be encouraged to undertake aerobic and/or strength training exercise.
George S Metsios et al. Open Cardiovasc Med J. 2010; 4: 89-96.	Vascular Function and Inflammation in Rheumatoid Arthritis: The Role of Physical Activity.	Literature review		A review studies related to inflammation and CVD Effects of exercise on CVD in RA.	The evidence of the beneficial effects of PA/exercise on inhibiting disease progression and improving disease outcomes were reported. There was associated between inflammations, vascular dysfunction and atherosclerosis in RA were reported.

					Future studies in RA to investigate the effects of exercise regimes on endothelial function and atherosclerosis both in RA.
Corrao S, Messina S, Pistone G, Calvo L, Scaglione R, Licata G. International Journal of Cardiology. 167(5):2031-8, 2013 Sep 1. Midline	Heart involvement in Rheumatoid Arthritis: Systematic review and meta-analysis	Systematic review and meta-analysis	Not mention	Case-control studies were identified by searching PubMed (1975-2010) and the Cochrane Central Register of Controlled Trials (CENTRAL) (1975-2010). Participants were adult patients with RA asymptomatic for CV.	10 relevant studies out of 2326. A significant associated of RA to pericardial effusion and valvular disease. The strength and the grade of both pericardial and cardiac valvular involvement underscore with echocardiographic in RA patients. Further research is required to understand the possible relationship of this findings and the increased CV mortality.
Amaya-Amaya J, et al. Immunologic Research. 56(2-3):267-86, 2013 Jul. MidLine.	Novel risk factors for cardiovascular disease in rheumatoid arthritis	Systematic review	N= 800 patients	Out of a total of 9.812 articles identified in PubMed and Scopus databases, 140 fulfilled the eligibility criteria and were included.	140 studies were met the inclusion criteria. There was, several factors and outcomes related to CVD were confirmed and identified. It has been categorized into genetics, RA-related, and others. It reported that traditional risk factors do not completely explain the high rates of CVD in patients with RA; therefore, the novel risk factors that is related to autoimmunity are now recognized as the main predicting the presence of CVD as strong as traditional risk factors.
Metsios GS et al. Open Cardiovascular Medicine Journal. 4:89-96, 2010	Vascular function and inflammation in rheumatoid arthritis: the role of physical activity	Literature review		The role of PA in RA	It identified that the associations between inflammation, endothelial dysfunction, and atherosclerosis.PA may play a role in blocking specific pathways in the inflammation, endothelial dysfunction - atherosclerosis network.
Puhl W. Gondolph-Zink B. Zeitschrift fur Rheumatologie. 51(6):305-8, 1992	Sports in advanced age in inflammatory rheumatic diseases	Literature review			The effect of PA on the course of RA has not yet been examined. The type and extent of PA should be studied with regard to the inflammatory changes of disease, and medical conditions.

Preface (Randomised Clinical Trial)

Citation	Title	Method		Result and conclusion
		Study type	Study population, intervention and the outcome	
(van den Berg et al., 2006) Published in Arthritis Care & Research Volume 55, Issue 6, pages 935-945, 15 December 2006	Using internet technology to deliver a home-based physical activity intervention for patients with rheumatoid arthritis.	RCT	160 RA patients Physically inactive patients with RA assigned to an Internet-based PA program with individual guidance. Outcome measures included quantity of PA (questionnaire and activity monitor)	There were no statistically significant differences regarding changes in PA as measured with an activity monitor, functional ability, quality of life, or disease activity.
(Metsios et al., 2013) Ann Rheum Dis. 2013 Jul 31. doi: 10.1136/annrheumdis-2013-203291.	Individualized exercise improves endothelial function in patients with rheumatoid arthritis.	RCT	40 RA patients, Age, gender-matched and BMI -matched patients were allocated to either an exercise group, 6 months tailored aerobic or resistance exercise intervention, the controls receiving only information about the benefits of exercise. Participants were assessed for endothelial function, maximal oxygen uptake, disease activity and severity (C-reactive protein (CRP), DAS 28 and HAQ.	Physical abilities significantly improve endothelial function in parallel with disease-related characteristics in RA patients. Further long-term study regarding the beneficial effects of such interventions at reducing cardiovascular risk in RA is required.
(.Zanten et al., 2013) Rheumatology (United Kingdom).	Endothelial function in patients with rheumatoid arthritis: The effects of exercise and anti-tnf treatment.		Twenty RA patients (14 female, age 55+/-10 years) underwent a 3 month individualized aerobic and resistance exercise intervention. Twenty-three patients (15 female, age 54+/-15 years) received anti-TNF treatment for 3 months. Measures of disease activity (DAS28 and CRP), functional ability (HAQ) and endothelial function (flow mediated dilatation and GTN-induced dilation) were taken	A significant interaction effect indicated a greater improvement in DAS28 and functional ability in response to anti-TNF treatment compared with exercise. Post hoc analyses revealed that endothelial function improved in patients in the exercise group, whereas no change was found in response to anti-TNF treatment. It suggests that successful anti-TNF treatment improves cardiovascular risk by reducing disease activity, whereas exercise-improves cardiovascular risk by enhancing the function of the vasculature. Increasing levels of PA may reduce the risk for CVD even further

Appendix 2- Ethical approval

WoSRES
West of Scotland Research Ethics Service

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Dear Dr Elramli

Study title: **Effectiveness of community based physical activity on step count and sedentary behaviour in patients with Rheumatoid arthritis within the first five years of diagnosis**
REC reference: **14/WS/0131**
IRAS project ID: **151340**

Thank you for your letter of 24 June 2014, received on 14 July 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 24 June 2014.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering letter on headed paper		24 June 2014
Participant consent form	3	24 June 2014
Participant information sheet (PIS)	3	24 June 2014
Validated questionnaire [Stanford HAQ 20 Item Disability Scale Modified to British English]		

Approved documents

The final list of approved documentation for the study is therefore as follows:

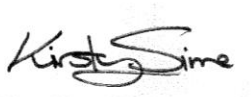
Document	*Version*	*Date*
Covering letter on headed paper		14 April 2014
Covering letter on headed paper		24 June 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		30 July 2013
GP/consultant information sheets or letters	2	16 June 2014

Document	*Version*	*Date*
Other [CV- Jason Gill]		08 May 2014
Other [CV - Aleksandra Dybus]		20 November 2012
Other [Telephone Survey Questions]		
Other [CV - Duncan Porter]		27 May 2013
Other [CV - Lorna Paul]		01 August 2012
Other [CV - Cindy Gray]		03 May 2014
Participant consent form	3	24 June 2014
Participant information sheet (PIS)	3	24 June 2014
REC Application Form	3.5	14 May 2014
Research protocol or project proposal	2	16 June 2014
Response to Request for Further Information		16 June 2014
Summary CV for Chief Investigator (CI)		02 May 2014
Questionnaire [International Physical Activity Questionnaire (IPAQ)]		
Questionnaire [Adapted DINE]		
Questionnaire [RAQoL]		
Questionnaire [Self efficacy to regulate exercise]		
Questionnaire [Simple Disease Activity Index (SDAI)]		
Questionnaire [Charlson Comorbidity Index]		13 June 2013
Questionnaire [Stanford HAQ 20 Item Disability Scale Modified to British English]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/WS/0131 **Please quote this number on all correspondence**

Yours sincerely



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Copy to: *Ms Emma Jane Gault*
Dr Maureen Travers, NHS Greater Glasgow and Clyde, R&D Management Office

Appendix 3- Participant's information sheet

NHS Greater Glasgow and Clyde

University of Glasgow

Participant Information Sheet

Effectiveness of community based physical activity on step count and sedentary behaviour in patients with Rheumatoid arthritis within the first five years of diagnosis

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important to 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 others if you wish. Do not hesitate to ask, if something is not clear, or if you would like more information.

It is important you are aware, that in consenting to take part you may be randomly allocated, either to the intervention group or the comparison group.

Thank you in advance for taking the time to read this, and deciding whether or not you wish to take part.

Part 1: Basic study information

The purpose of this study;

There is evidence that walking, taking more steps and spending less time being inactive can prevent many health problems and improve people's quality of life. From previous studies it was found that a pedometer, a small device which measures the number of steps people take when walking can encourage and motivate people to increase their physical activity, improve mobility, improve quality of life, and lower the risk of heart disease and other health problems. This is important, not only for people with Rheumatoid arthritis, but also for those without.

This study is to test whether a physical activity programme consisting of group education sessions on lifestyle and behaviour change, daily use of a pedometer and simple strengthening exercise can increase physical activity, improve strength, health and wellbeing, and reduce the risk of heart disease among those with rheumatoid arthritis within the first five years of diagnosis.

The study is being undertaken by staff in the Nursing & Health Care School University of Glasgow and as part of a PhD study.

Why have I been chosen?

You are able to participate in this study as you have rheumatoid arthritis and are suitable for inclusion, based on certain criteria required for this study.

Do I have to take part?

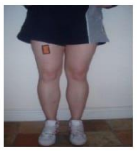
It is up to you to decide whether or not to take part in this study, as it is entirely voluntary. If you decide to take part, I will describe the study in greater detail during your initial appointment. I will also go through the information sheet with you; you can ask any questions you may have.

If you are willing to take part in the study; you can contact the main researcher using the contact details on page 7. You will be asked to sign a consent form to show that you agree to take part. Once included in the study, it is important to understand that the researcher can access your medical notes, with your consent.

If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

All participants will be assessed at the beginning of the study and again at 3, 6, and 12 months. The assessments will measure your step count, and time you have been inactive using an ActivPAL, which is a small device, attached to the thigh, and is worn for 7 consecutive days. While wearing the device you can go about your normal daily activities.



We will also be monitoring your rheumatoid arthritis and your risk of heart disease. This will involve a blood sample being taken at each of the four assessment sessions. The blood sample will be taken at your rheumatology clinic and stored at the University of Glasgow to be analysed at a later date. As samples will be analysed some time later you will not be notified of the results. You will continue to get your routine blood samples as part of your rheumatology clinic appointments. Also, height, weight, waist circumference, waist hip ratio and waist height ratio will be measured. Your functional ability will be assessed by taking part in a six minute walking test (6 MWT). You will be asked to walk for a period of six minutes, at your own pace, along a straight, 30 m hallway. You will be asked to cover as much ground as possible in six minutes, but will be allowed to stop if required. The distance in meters will be recorded at the end of the six minutes. The hand grip test will be done in a

sitting position, while you squeeze your hand around a measuring device three times as hard as you can.

In addition, we will ask you to fill out a number of questionnaires regarding your quality of life, diet and lifestyle. The assessment will be carried out in the Rheumatology clinics at your local hospital; Gartnavel General Hospital, Glasgow Royal Infirmary or Stobhill Hospital.

The aim of this study is to recruit 90 people with Rheumatoid Arthritis within the first five years of diagnosis. You will be involved for 12 months (6 month intervention and 6 month follow up) and is important to know that you may be allocated either to the intervention or the comparison group; comparison between two groups is necessary in order to discover if any benefits occur. Both groups will receive pedometers; however the intervention group will receive it at beginning of the study and comparison group at the end of the study.

Intervention Group

Participants in the intervention group will receive a six weekly, one hour group, education sessions and alccso 2 booster sessions, 3 months and 6 months later. The education sessions will be held at Gartnavel General Hospital, Glasgow Royal Infirmary and Stobhill Hospital. All participants will receive education material about physical activity and healthy diet. The education sessions will be carried out by a physiotherapist with expertise in this area. This group will also take part in a pedometer supported walking programme. A pedometer is a small device that can supply information about the number of steps, distance travelled and time spent on an activity. Participants will be asked to wear the pedometer every day on the waist band, above the hip during all waking hours and daily physical activity.

Participants in the intervention group will be required to use the pedometer for a 6 month period. At the first education session the participant will receive a pedometer along with information regarding how the pedometer should be used, how to wear it during all waking hours. Participants will be asked to record their daily steps in a diary. Participants allocated to the intervention group will also be asked to perform strengthening exercise for the major muscles of the lower limb, trunk and upper limb. Exercise will be performed at home twice a week with 8-12 repetitions of each exercise. The participants will be encouraged to keep a record in their diary of: time, duration, any barrier to performing the exercise and how it was overcome. Information regarding the strengthening exercises will be given during week 4 of the education session.

Participants in the intervention group will have 13 visits (4 visits for assessment, 8 education sessions and 1 for interview).

The physiotherapist will contact participants by phone, email or text each week for the first six weeks then monthly to the end of the intervention (6 month) to review their progress.

Comparison group

The comparison group, will receive a single, one hour, education session, and will be asked to continue their usual activity. The education session will take place at Gartnavel General Hospital, Glasgow Royal Infirmary or Stobhill Hospital. The participant will receive education material, which will consist of written information describing the importance of walking and the importance of a healthy diet for health benefits. Participants in the comparison group will have 5 visits (4 visits for assessments and one for education session). At the end of the study participants in the comparison group will be given a pedometer as thanks for participating in the study.

What do I have to do?

Participants in the intervention group will be required to use the pedometer for a 6 month period every day. Participants allocated to the intervention group will also be asked to perform strengthening exercise for the major muscles of the lower limb, trunk and upper limb. Exercise will be performed at home twice a week with 8-12 repetitions of each exercise. Participants in both the intervention group and the comparison group will be asked to attend 4 appointments at the hospital for assessment, which will each last about one hour. The details of the assessments are given on page 2. All participants will be asked to complete a series of questionnaires; they will gather information on quality of life, their diet and physical activity which will be sent to you by post. A sample of 10-12 participants from the study will be invited to attend an interview at 6 months, to help us gather your views on taking part. All interviews will be audio recorded and transcribed. Three months after the study is completed the audio recording will be destroyed, in accordance with the policy of the university.

If you are in the intervention group in addition you will be asked to attend 6, one hour, education sessions and two booster sessions, all of which will last approximately one hour. You will also be asked complete an activity diary, which will help us to follow your physical activity and make sure you have no problems while taking part. Also, if you decide to withdraw from the study you may be asked to take part in a telephone survey, to help us understand your reason for withdrawing from the research, and may help us to improve the future research.

What are the possible disadvantages and risks involved?

As this is mainly a walking programme there are few risks of associated. There is no evidence that exercise increases the symptoms of Rheumatoid Arthritis, and there are no side effects or any disadvantages expected from taking part in this study. However, as with all exercise and activity, participants taking part in the intervention group may notice some initial soreness. If

any adverse effects occur the participants contact the researcher, and any necessary further action will be taken.

What are the possible benefits of taking part?

We hope that the intervention will help you to lower the risk of heart disease and improve your quality of life. However, this cannot be guaranteed. The information we get from this study may help to improve future treatment for other people with Rheumatoid Arthritis.

What about expenses or payment involved with taking part in the study?

The pedometer will be given free of charge to both groups. We have been provided with funding, which means that we can offer you travel expenses for attending the education sessions and for your assessments.

What happens when the research study stops?

At the end of the study, participants in the intervention group should have gained more knowledge about rheumatoid arthritis, along with having improved their step count; an important activity for rheumatoid arthritis sufferers.

At the end of the research, people in the comparison group will be given a pedometer and advice on how to use it. Both groups can continue to monitor their physical activity using their pedometers.

Will my taking part in this study be kept confidential?

All information which is collected from you during the course of the research will be kept strictly confidential. Representatives of the study sponsor (NHS Greater Glasgow and Clyde) may look at your information to make sure that the study is being conducted correctly. With your consent we will inform your GP about your involvement in this study.

If the information in part 1 interests you, and you are considering taking part please read the additional part 2 information.

Part 2: Additional Information

What happens if new information becomes available?

Sometimes during the course of a research project, new information becomes available. Although, this is unlikely to happen during the study, the researcher would inform you and discuss whether you should stay in the study. If you decide to withdraw the researcher will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

What will happen if I don't want to continue in the study?

You can withdraw at any time, however I would encourage you to keep in contact with us and let us know your progress. The information collected from you will still be used.

What if there is a problem?

Should you have a concern about any aspect of the study you should contact the main researcher (see contact details below) in the first instance. She will do her best to answer any questions. If this does not resolve the issue, and you would like to formally complain you can do this through the NHS complaints procedure. Details can obtained from the Patients Relations and complaints office 01292 513620. Independent advice about the study can be obtained from Margaret Sneddon, Head of Nursing and Healthcare at the University of Glasgow, tel: 0141 330 2071.

What will happen to the results of the research study?

This study will be used as a project for a PhD at Glasgow University, and results of the study will be presented at national and international conferences and presentations in hospitals and universities. The result of the study may also be published in a medical journal. Should you wish to know the results of the study, I will send you a copy of the main findings once the research is complete.

Who is organising and funding the research?

The University of Glasgow is organising the research along with funding from the Libyan government. The funders will cover necessary expenses, such as pedometers, activity diary, non- routine laboratory tests and the participant's travel expenses.

Who have reviewed the study?

The study has been reviewed and pronounced favourable by the West of Scotland Research Ethics Committee, an independent group of people who aim to protect patient safety, rights, wellbeing and dignity and by the NHS Greater Glasgow and Clyde Research and Development department.

Contact for further information?

Should you wish to take part in this study or if you require any further information about this research study, have any concerns during the study please do not hesitate to contact the main researcher at the number below.

Amal Elramli
PhD student
Nursing &Health Care School
School of Medicine
University of Glasgow
59 Oakfield Avenue
Glasgow
G12 8LL
Email a.elramli.1@research.gla.ac.uk
Telephone number: 0141 330 5536
07834394857

Dr. Lorna Paul
Nursing &Health Care School
School of Medicine
University of Glasgow
59 Oakfield Avenue
Glasgow
G12 8LL
Email Lorna.Paul@glasgow.ac.uk
Telephone number 01413306876

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

Appendix 4- Study consent form

Patient Identification Number for this trial: ☐

Study Consent form

Title of project

Effectiveness of community based physical activity on step count and sedentary behaviour in patients with Rheumatoid arthritis within the first five years of diagnosis.

Name of researcher: Amal Elramli	**please initial box**
1-I confirm that I have read and understand the participant's information sheet dated 24 June 2014 (version 3) for the above study and have had the opportunity to ask questions.	☐
2-I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3-I understand that agreeing to take part in this study may also involve an interview lasting approximately 30 minutes which will be audio recorded and transcribed.	☐
4-I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	☐
5- I agree to my GP being informed of my participation in this study.	☐
6- I understand this study is being undertaken as research for a PhD student at University of Glasgow.	☐
7-I agree to take part in the above study.	☐

Name of Participant	Date	Signature
Researcher	Date	Signature

*1 copy for participant; 1 copy for researcher and 1 (original) to be kept in the medical notes.

Appendix 5-Data collection sheet

Patient Hospital Number ☐

Patient Identification Number for this trial: ☐

Date

_____

Age

Age Date of birth_____

Gender

Male ☐ Female ☐

Ethnicity

Scottish ☐ British ☐ Irish ☐ white ☐

other ☐ _____

Marital status

Single ☐ Married ☐ Separated ☐ Widow ☐ Divorced ☐

Address

Flat No_____Street _____

Postcode_____

Place of work_____

Phone number

Home_____ Mobile_____

Best time to call _____am/pm

Preferences contact

Phone ☐ Email ☐ Text ☐

Email address

_____

Employment

Student ☐ Employed ☐ Unemployed ☐ Retired ☐

Position_____

Full time ☐ Part time ☐

Level of education

No education ☐ Primary ☐ higher school ☐ college ☐ university ☐

GP Address

GP name_____ Phone_____

Disease duration

3

Weight/ kg		Height/cm	Waist circumference	Hip circumference
Reading				

BMI	Waist Hip ratio	Waist Height ratio

Hand grip strength circle the maximum	
First reading	
Second reading	
Third reading	

Six minute walk test (6MWT)	
Time	Result distance

activPAL™ monitor

Time spent sedentary	Time spent Lying	Time spent Walking	Total	

International Physical Activity Questionnaire (IPAQ)

Physical activity	
low	
Moderate	
High	

Rheumatoid Arthritis Quality of Life (RAQoL)

Overall score	

Stanford Health Assessment Questionnaire (HAQ)

The score ranges	
0	
1	
2	
3	

DINE

Score	Fatty	Sugary food	Fruit	Vegetable intake
Low				
Medium				
High				

Self-efficacy to Regulate Exercise

score ranges	

Simple Disease activity Index (SDAI)

Total score	range	value
Tender joint score	0-28	
Swollen joint score	0-28	
Patient global score	0-10	
Provider global score	0-10	
C-reactive protein (mg/dl)	0-10	
Add the above value (SDAI) score	0-86	

SDAI Score Interpretation	
0.0-3.3	Remission
3.4-11.0	Low Activity
11.1-26.0	Moderate Activity
26.1-86.0	High Activity

Charlson Comorbidity Index

Comorbidity score	
Age score	
Charlson score	

Result of Blood test

Lipid profile	Participants reading
TG	

5

HDL	
LDL	
Total cholesterol	

Blood test	Participants reading
Glucose	
Insulin	
HbAlc	
NMR	
CRP	

ASSIGN score

Total ASSIGN score	

Appendix 6-International physical activity questionnaire (IPAQ)

International Physical Activity Long Last 7 Days Self-Administered Format

Participant Identification Number for this trial_____

Date of assessment_____

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

Yes ☐

No ☐ **If No → Skip to part 2: Transportation**

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ **Days per week**

☐ No vigorous job- related physical activity **If No →** **Skip to question 4**

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ **Hours per day**
_____ **Minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

_____ **Days per week**

☐ No moderate job related physical activity **If No →** **Skip to question 6**

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **Hours per day**
_____ **Minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **Days per week**

☐ No job- related walking **If No** → **Skip to part 2: Transportation**

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **Hours per day**
_____ **Minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **Days per week**

☐ No traveling in a motor vehicle **If No** → **Skip to question 10**

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **Hours per day**
_____ **Minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **Days per week**

☐ No bicycling from place to place **If No** → **Skip to question 12**

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **Hours per day**
_____ **Minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → **Skip to part 3: Housework, House maintenance, and caring for family**

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **Hours per day**
_____ **Minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shovelling snow, or digging **in the garden or yard**?

_____ **Days per week**

☐ No vigorous activity in garden or yard **If No** → **Skip to question 16**

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **Hours per day**
_____ **Minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **Days per week**

☐ No moderate activity in garden or yard **If No** → **Skip to question 18**

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **Hours per day**
_____ **Minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did

you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **Days per week**

☐ No moderate activity inside home → **Skip to part 4: Recreation, sport and leisure- time physical activity**

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **Hours per day**
_____ **Minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **Days per week**

☐ No walking in leisure time **If No** → **Skip to question 22**

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **Hours per day**
_____ **Minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **Days per week**

☐ No vigorous activity in leisure time **If No** → **Skip to question 24**

23. How much time did you usually spend on one of those days doing vigorous physical activities in your leisure time?

_____ **Hours per day**

_____ **Minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **Days per week**

☐ No moderate activity in leisure time **If No** → **Skip to part 5: Time Spent Sitting**

25. How much time did you usually spend on one of those days doing moderate physical activities in your leisure time?

_____ **Hours per day**
_____ **Minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **Hours per day**
_____ **Minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ **Hours per day**
_____ **Minutes per day**

This is the end of the questionnaire, thank you for participating.

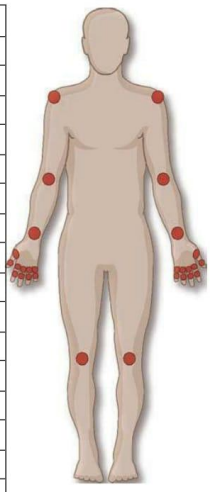
Appendix 7- Simple disease activity index (SDAI)

Simple Disease Activity Index (SDAI)

Participant Identification Number for this trial_____

Date of assessment_____

Joint	Left		Right	
	Tender	Swollen	Tender	Swollen
Shoulder				
Elbow				
Wrist				
MCP 1				
MCP 2				
MCP 3				
MCP 4				
MCP 5				
PIP 1				
PIP 2				
PIP 3				
PIP 4				
PIP 5				
Knee				
Total				



Patient Global Assessment of Disease Activity

Considering all the ways your arthritis affects you, rate how well you are doing on the following scale:

Well o o o o o o o o o o o o o o o o o o o o

o o Poor

Your Name_____ Date of Birth _____ today's Date _____

Provider Global Assessment of Disease Activity

Well o o o o o o o o o o o o o o o o o o o o

o o Poor

How to score the SDAI

Variable	Range	Value
Tender joint score		
Swollen joint score		
Patient global score		
Provider global score		
C-reactive protein (mg/dl)		
Add the above value to calculate the SDAI score		

SDAI Score Interpretation	
0.0-3.3	Remission
3.4-11.0	Low Activity
11.1-26.0	Moderate Activity
26.1-86.0	High Activity

Appendix 8- Rheumatoid arthritis quality of life (RAQoL)

Rheumatoid Arthritis Quality of life

Participant Identification Number for this trial_____
Date of assessment_____
It consists 30 items with a yes/no (1/0) response format. The overall score is the sum of individual item scores the score range from0-30 and the higher the score the poorer the quality of life.

Items	Yes	No
1-I have to go to bed earlier than I would like to		
2-I'm afraid of people touching me		
3-It's difficult to find comfortable shoes that I like		
4-I Avoid crowds because of my condition		
5-I have difficulty dressing		
6-I find it difficult to walk to the shops		
7-Jobs about the house take me a long time		
8-I sometimes have problems using the toilet		
9-I often get frustrated		
10-I have to keep stopping what I am doing to rest		
11-I have difficulty using a knife and fork		
12-I find it hard to concentrate		
13-Sometimes I just want to be left alone		
14- I find it difficult to walk very far		
15-I try to avoid shaking hands with people		
16-I often get depressed		
17-I'm unable to join in activities with my family or friends		
18-I have problems taking a bath/shower		
19-I sometimes have a good cry because of my condition		
20-My condition limits the places I can go		

21-I feel tired whatever I do		
22-I feel dependent on others		
23-My condition is always on my mind		
24-I often get angry with myself		
25-It's too much effort to go out and see people		
26-I sleep badly at night		
27-I find it difficult to take care of the people I am close to		
28-I feel that I'm unable to control my condition		
29-I avoid physical contact		
30-I'm limited in the clothes I can wear		

Appendix 9- Stanford health assessment questionnaire (HAQ)

Stanford Health Assessment Questionnaire

Participant Identification Number for this trial_____

Date of assessment_____

Please tick the one response which best describes your usual abilities over the past week.

Are you able to:	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING				
1. Dress yourself, including tying shoelaces and doing buttons?				
2. Shampoo your hair?				
ARISING				
3. Stand up from a straight chair?				
4. Get in and out of bed?				
EATING				
5. Cut your meat?				
6. Lift a full cup or glass to your mouth?				
7. Open a new milk carton?				
WALKING				
8. Walk outdoors on flat ground?				
9. Climb up to five steps?				

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

Devices used for dressing (button hook, zipper pull, etc.)	☐	Walker	☐
Special or built up chair	☐	Crutches	☐
Built up or special utensils	☐	Wheelchair	☐
Cane	☐		

Please tick any categories for which you usually NEED HELP FROM ANOTHER PERSON:

Dressing and grooming	☐	Eating	☐
Arising	☐	Walking	☐

Please tick the one best answer for your abilities over the past week.

Are you able to:	**Without ANY difficulty**	**With SOME difficulty**	**With MUCH difficulty**	**UNABLE to do**
HYGIENE				
10. Wash and dry your body?				
11. Are you able to take a bath?				
12. Get on and off the toilet?				
REACH				
13. Are you able to reach and get down a 5lb object (such as a bag of sugar) from above your head?				
14. Bend down to pick up clothing from the floor?				
GRIP				
15. Open car doors?				
16. Open previously opened jars?				
17. Turn tap on and off?				
ACTIVITIES				
18. Run errands and shop?				
19. Get in and out of a car?				
20. Do chores such as vacuuming or gardening?				

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

Raised toilet seat ☐	Long-handled appliances in bathroom ☐
Bath seat ☐	Long-handled appliances for reach ☐
Bath bar ☐	Jar opener (for jars previously opened) ☐

Please check any categories for which you usually NEED HELP FROM ANOTHER PERSON:

Hygiene ☐	Gripping and opening things ☐
Reach ☐	Errands and housework ☐

Appendix 10- Self efficacy to regulate exercise

Self –Efficacy to Regulate Exercise

Participant Identification Number for this trial_____

Date of assessment_____

A number of situations are described below that can make it hard to stick to an exercise routine. Please rate in each of the blank in the column how certain you are that you can get yourself to perform your exercise routine regularly (three or more times a week).

Rate your degree of confidence by recording a number from 0 to 100 using the scale given below

0	10	20	30	40	**50**	60	70	80	**90**	100
Cannot do at all					**Moderately can do**				**Highly certain can do**	

	Confidence (0-100)
When I am feeling tired	_____
When I am feeling under pressure from work	_____
During bad weather	_____
After recovering from an injury that caused me to stop exercising	_____
During or after experiencing personal problems	_____
When I am feeling depressed	_____
When I am feeling anxious	_____
After recovering from an illness that caused me to stop exercising	_____
When I feel physical comfort when I exercise after holiday	_____
When I have too much work to do at home	_____
When visitors are present	_____
When there are other interesting things to do	_____
If I do not reach my exercise goals	_____
Without support from my family or friends	_____
During holiday	_____
When I have other time commitments	_____
After experiencing family problems	_____

Appendix 11- Dietary instrument for nutrition education (DINE)

Dietary Instrument for Nutrition Education (DINE)

Participant Identification Number for this trial_____
Date of assessment_____

Looks at what you have EATEN and DRUNK over the LAST 7 DAYS. Please read each question carefully, ticking the appropriate box for each option.

1- About how many times OVER the LAST 7 DAYS did you eat breakfast?
Please tick One box

No times	1-2 times	3-5 times	6 or more times
☐1	☐2	☐3	☐4

2-	**About how many times OVER the LAST 7 DAYS did you eat / drink a serving of the following?**			
Please tick One box on EACH line	No times	1-2 times	3-5 times	6 or more times
Cheese (any except cottage cheese)	☐1	☐2	☐3	☐4
Beef burgers or sausages	☐1	☐2	☐3	☐4
Beef, pork or lamb	☐1	☐2	☐3	☐4
Fried food (fried fish, cooked breakfast)	☐1	☐2	☐3	☐4
Chips	☐1	☐2	☐3	☐4
Bacon, processed meat	☐1	☐2	☐3	☐4
Pies, quiches, pastries	☐1	☐2	☐3	☐4
Crisps	☐1	☐2	☐3	☐4
Fast foods (takeaway or sit in)	☐1	☐2	☐3	☐4
Nuts	☐1	☐2	☐3	☐4

3- Are you vegetarian?
Please tick One box

Yes ☐1

No ☐2

4-	**Thinking about the LAST 7 DAYS: about how many times a day did you eat the following:**			
Please tick One box on EACH line	Less than once a day	1-2 times a day	3-5 times a day	6 or more times a day
Fruit and vegetables (not potatoes)	☐1	☐2	☐3	☐4
Chocolate, sweets	☐1	☐2	☐3	☐4
Biscuits	☐1	☐2	☐3	☐4
Sugary drinks (fizzy drinks, diluting/ fruit juice)	☐1	☐2	☐3	☐4

5- Thinking about the LAST 7 DAYS: about how much milk did you use in a day, for drinking or in cereal, tea or coffee?

Please tick One box	Less than a quarter pint	About a quarter pint	About half a pint	1 pint or more
	☐1	☐2	☐3	☐4

6- What kind of milk do you usually use?

Please tick One box	Full cream (blue top)	Semi skimmed (green top)	Skimmed (red top)
	☐1	☐2	☐3

Appendix 12- Charlson comorbidity index

Charlson Comorbidity Index

Participant Identification Number for this trial_____
Date of assessment_____

1. Indication
    1. Assess whether a patient will live long enough to benefit from a specific screening measure or medical intervention
2. Scoring: Comorbidity Component (Apply 1 point to each unless otherwise noted)
    1. Myocardial Infarction
    2. Congestive Heart Failure
    3. Peripheral Vascular Disease
    4. Cerebrovascular Disease
    5. Dementia
    6. COPD
    7. Connective Tissue Disease
    8. Peptic Ulcer Disease
    9. Diabetes Mellitus (1 point uncomplicated, 2 points if end-organ damage)
    10. Moderate to Severe Chronic Kidney Disease (2 points)
    11. Hemiplegia (2 points)
    12. Leukaemia (2 points)
    13. Malignant Lymphoma (2 points)
    14. Solid Tumor (2 points, 6 points if metastatic)
    15. Liver Disease (1-point mild, 3 points if moderate to severe)
    16. AIDS (6 points)
3. Scoring: Age
    1. Age <40 years: 0 points
    2. Age 41-50 years: 1 points
    3. Age 51-60 years: 2 points
    4. Age 61-70 years: 3 points
    5. Age 71-80 years: 4 points
4. Interpretation
    1. Calculate Charlson Score or Index (i)
        1. Add Comorbidity score to age score
        2. Total denoted as 'i' below
    2. Calculate Charlson Probability (10-year mortality)
        1. Calculate Y = e^(i * 0.9)
        2. Calculate Z = 0.983^Y
        3. where Z is the 10-year survival

Appendix 13- Telephone interview questions

Telephone interview questions

Introduction

My name is Aleksandra and I was the physiotherapist who took the sessions for the walking study. I would like to conduct a telephone interview with you to get some feedback about the programme so that we can improve our studies in the future. Feel free to tell me your views about the programme. With your consent, I'm going to record our conservation in order to type it up later and so that I don't miss any important information. The recording will be used for the purpose of the study and no one will listen to it except the research team. You will not be identified from the recording and we will destroy the recording when we have typed it up. This interview will take no longer than 15 minutes.

Can you confirm that you are happy to take part in this telephone interview?

1-Views on the study

Could you tell me the positive/best things about the study?

Could you tell me the negative/worst things about the study?

a) Education sessions

What is your opinion about the education sessions?

Prompts:

What did you think about the content of the education sessions?

Was the number of sessions adequate?

Were the booster sessions necessary? If not why?

Did the time and location suit you?

How did you feel about group sessions?

What is your opinion on the handouts?

In your opinion, did you think the sessions included everything that was needed to improve your physical activity? If not why?

Were the sessions specific enough for those with rheumatoid arthritis?

Did you notice any benefits from attending the sessions?

In your opinion, how could we have improved the education sessions?

What did you think of the session about diet?

b) Walking programme

Did you note any changes in your physical activity?

How did you get on with the physical activity diary? Did you use it? If not why?

Were there any adverse effects on your health for example increasing joint pain, fatigue?

2

Prompts:

Did you reach your walking goals? If not why? Were there any problems that stopped you increasing your steps?

Did you use the pedometer? If not why? What did you think of the pedometer?

How did you feel following the walking programme? Can you explain your answer?

How did you get on with the programme? Would you want to continue with the walking programme in the future? Can you explain your answer?

Do you have any thoughts on how we could improve the walking programme?

c) Strengthening exercises

How did you find the strengthening exercises?

Did you perform the strengthening exercises twice each week? If not why?

How did you feel following the strengthening exercises?

2-General views

If you speak to other people with rheumatoid arthritis would you encourage them to participate in a programme such as this? Why?

Thank you so much for participating in this interview

Appendix 14- Education sessions for the intervention group 1-6 and booster sessions 1&2

WALK FOR RHEUMATOID ARTHRITIS
(WARA)
PARTICIPANTS BOOKLET

Walk for Rheumatoid Arthritis (WARA)

Welcome to the WARA programme!

- The intervention aims to increase the step count of people with rheumatoid arthritis within the first five years of diagnosis by 3000 steps above their baseline within 6 months.
- The intervention is a physical activity programme consisting of six group education sessions plus two booster sessions on lifestyle and behaviour change
- The programme utilises a pedometer and simple strengthening exercise to increase physical activity, improve strength, health and wellbeing, and reduce the risk of heart disease.

Session 1

Rheumatoid Arthritis, Heart Disease and Physical Activity

Contents

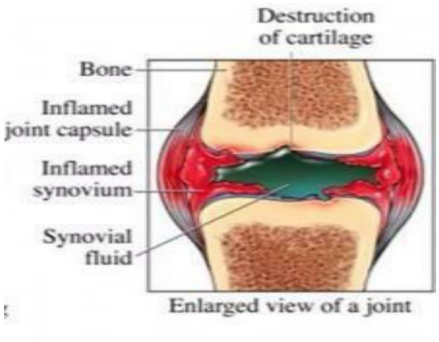
This first session will last one and a half hours. The topics to be discussed in this session are rheumatoid arthritis, heart disease, sedentary behaviour, physical activity, the use of the pedometer, counting steps, benefits of being active and cost of inactivity.

Rheumatoid Arthritis, Heart Disease and Physical Activity

Rheumatoid arthritis and heart disease

What is rheumatoid arthritis?

Rheumatoid arthritis mainly affects joints, causing inflammation, pain and swelling. It is the second most common arthritis in the UK after osteoarthritis. The disease usually starts in the wrists, hands or feet and can spread to other joints and other part of the body.



How does it affect me?

Rheumatoid arthritis affects everyone differently, there may be times when the disease is active and other times when it is inactive.

What are the symptoms of rheumatoid arthritis?

Joint pain and swelling

Stiffness

Fatigue

Depression

Anaemia: is a shortage of haemoglobin; haemoglobin is an oxygen carrying pigment in the blood. A lack of haemoglobin makes it more difficult for the blood to carry oxygen around the body.

Flu like symptoms, such as feeling generally ill, feeling hot, sweating.

Less common symptoms:

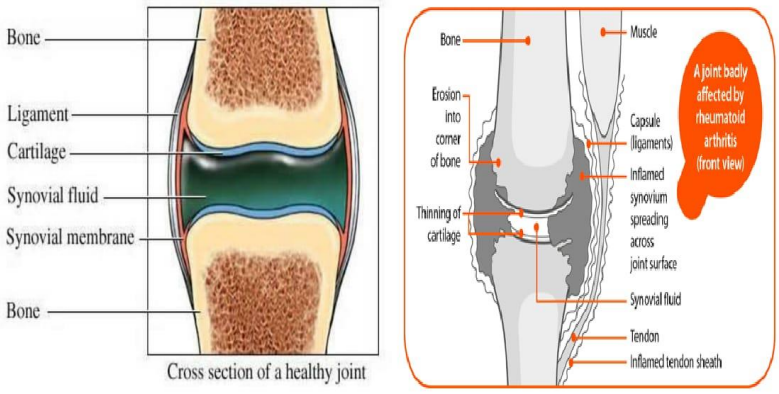
Inflammation of the eyes

Rheumatoid nodules

Inflammation of other parts of the body

How the normal joint work and what happens to joints affected by rheumatoid arthritis?

A joint is where two bones meet. Joints are designed to allow the bones to move in certain directions within certain limits. In rheumatoid arthritis inflammation takes place within the lining of the joint and the result is similar to inflammation that you may have seen if you have had an infected cut or wound; it goes red, it swells and it is painful. The redness is caused by the flow of blood increasing and, as a result, the inflamed joint may feel warmer than usual. The pain and swelling are due to extra fluid and inflammation of the joint.



What other organs could be involved in rheumatoid arthritis?

Rheumatoid arthritis may affect muscles, bones and other organs such as the heart, lung, kidney, spleen, and eyes.

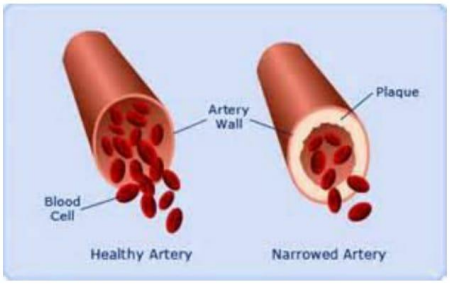
What is heart disease?

Heart disease refers to several different types of heart conditions. Coronary artery disease is a type of heart disease that occurs when a substance called plaque builds up in the arteries that supply blood to the heart.

Plaque is made up of cholesterol (fat) deposits, which can accumulate in the arteries.

Atherosclerosis is a condition that occurs when plaque builds up in the arteries, causing them to narrow. Atherosclerosis is commonly known as "narrowing of the arteries".

Cholesterol is a fat- like substance in the body, and high levels of cholesterol in the blood can lead to heart disease and stroke.



What is the risk of heart disease in rheumatoid arthritis?

There is evidence that rheumatoid arthritis is associated with an increased risk of heart disease compared with the general population. This risk may be as much as 50% higher.

How can you overcome these risks?

One of the things you can do to help overcome this risk is to be more physically active. You can do this by breaking up prolonged sitting, reducing your sedentary time and walking more.

1.3. Physical activity and its benefits

What is Physical activity?

Physical activity is any bodily movement produced by muscles that requires energy expenditure such as gardening, housework and shopping.

The UK physical activity guidelines state that

•Adults should aim to be active daily. Over a week, activity should add up to at least 150 minutes (2½ hours) of moderate intensity activity in bouts of 10 minutes or more. One way to approach this is to do 30 minutes on at least 5 days a week.

•Regular physical activity can help to reduce the risk of heart disease, premature death and chronic diseases such as coronary artery disease, high blood pressure and stroke.

•Thus being more physically active improves your chance of living longer and living healthier. Regular physical activity can improve your overall sense of wellbeing by improving fitness levels and self-esteem, reducing the effects of stress, and increasing energy.

Physical inactivity is associated with an increased risk of:

•Type 2 diabetes

•Heart disease

•Death from all causes

• Depression and poor mental wellbeing

• Being overweight or obese

How will being more physically active i.e. increasing the number of steps I take help me?

Rest will make an inflamed joint feel more comfortable but without movement joints will get stiffer and muscles become weaker. Physical activity is good for your heart and joints. So use your muscles and joints as much as you can without harming them. Physical activity will help your joints, muscles, and at the same time reduce the risk of heart disease. If a

particular activity causes one or more of your joints to become warm and swollen or if it causes severe pain stop and rest.

Increasing the number of steps can help people with rheumatoid arthritis to overcome restriction in their movement, reduce joint pain and improve quality of life.

1.4. Sedentary behaviour and health

Sedentary behaviour is defined as the amount of time spent sitting or lying down.

Common examples of sedentary behaviour include:

•Sitting while at work

•Watching television

•Using a computer or playing video games (this excludes 'active' gaming such as dance games)

•Reading

•Sitting socialising with friends or family

•Sitting in a car or other form of motorised transport

•Public health guidelines recommend that people of all ages should sit less. This can be achieved by getting up more often and moving around.

For example, increasing the number of steps you do each day, and decreasing sedentary time are two of the most important things you can do to help your mobility and to improve your heart.

•Get into a routine —Limit the time you spend watching TV or sitting in front of a computer during leisure time.

•Get active at home; break your activity into smaller bursts.

•Walk to a friend's house or shopping.

•Do indoor physical activity such as climbing stairs, and housework.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216370/dh_128210.pdf

file:///C:/Users/HP/Downloads/sedentary_evidence_briefing.pdf

Is physical activity safe for people with rheumatoid arthritis?

There is no evidence that physical activity increases the symptoms of rheumatoid arthritis, and there are no side effects or any disadvantages expected from taking part in this walking programme. However, as with all exercise and activity you may notice some initial discomfort.

Becoming more active can have some important health benefits. Take a step in the right direction.

http://www.patient.co.uk/health/rheumatoid-arthritis-leaflet

http://niams.nih.gov/Health_Info/Rheumatic_Disease/default.asp

1.5. Pedometer and instruction on how to use it

Pedometers record the number of steps you take and allow you to monitor and record your physical activity. Self-monitoring is one of the best, if not the very best, way of increasing your physical activity, and maintaining the increase over the long term.

What is a pedometer?

A pedometer is a simple device that provides information about the number of steps you take.

When and how to use the pedometer?

You will use a pedometer to record your steps. We will give you a pedometer which you should ideally wear at all times (except, of course, when you are in water bathing or swimming or in bed at night).

•Wear your pedometer on the waist band, above the hip.

•Reset the pedometer to zero at the beginning of each day and remove it at the end of the day.

•Record the time the pedometer was attached, removed and the total number of steps displayed on the pedometer at the end of each day in your physical activity diary.

Self-monitoring physical activity

Self-monitoring is the process of observing ones behaviour and evaluating it in relation to goals. Pedometers therefore play an important role in self-monitoring physical activity.

Self-monitoring

Thus self-monitoring allows you to work out what works and what doesn't work when you are making your physical activity plans each day/week and working towards your goals.

You are already self-monitoring if you are using your pedometer to count your steps, writing it in your physical activity diary and comparing it with your target for the week.

Rheumatoid Arthritis Quiz -Tick the answer the following questions (Yes or No):

Question 1 What are the symptoms of Rheumatoid Arthritis?

	Yes	No
Joint pain and swelling		
Stiffness		
Fatigue		
Vomiting		
Inflammation of the eyes		
Depression		
Sniffing		

Question 2 What other remedies beside drugs that can help in relieving the symptoms of Rheumatoid Arthritis

	Yes	No
Olive oil		
Positive attitude and thoughts		
Strength exercise		
Physical activity		

Question 3 What organs could be involved in Rheumatoid Arthritis?

	Yes	No
Lung		
Heart		
Blood vessels		
Spleen		
Kidney		
Eye		

Question 4 What is the risk of heart disease in people with Rheumatoid Arthritis?

	Yes	No
10%		
80%		
50%		
35%		

<u>Question 5</u> How can you overcome the risks of heart disease?

	Yes	No
Being more physically active		
Sitting more		
Walking more		
Breaking up prolonged sitting		
Watching TV		
Smoking		
Improve diet		

Activity for Week 1

How many steps do you take each day?

The first thing we need to know is how many steps you normally take each day.

•Take your pedometer with you and use it each day.

•Reset your pedometer to zero at the beginning of the day.

• At the end of each day record your total number of steps in your physical activity diary.

Here is your physical activity diary for week 1. Please complete it and bring it with you next week

Day	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**	**Monday**
Step counts						

Session 2

Physical Activity and the Barriers to Physical Activity

This session will discuss physical activity; physical activity barriers and suggestions to overcome them. This session lasts for one hour.

Physical Activity and the Barriers to Physical activity

2.1 Difference between physical activity and exercise

What is the difference between physical activity and exercise?

Physical activity is defined as any movement that involves contraction of your muscles. Any of the activities we do throughout the day that involve movement: housework, gardening, walking, climbing stairs are all examples of being physically active.

Exercise is a specific form of physical activity — planned, physical activity performed with the intention of acquiring fitness, for example swimming and yoga.

All forms of exercise contain physical activity but not all physical activity is exercise.

Physical activity or exercise can improve your health, reduce the risk of heart disease and reduce the risk of developing certain conditions including depression and anxiety. Physical activity can help you manage your weight and prevent osteoporosis.

Walking is a popular and an ideal way of being physically active for most people. Walking poses little risk of injury for people with Rheumatoid Arthritis, is inexpensive, does not need any particular skills, and you can do it anytime, anyplace and anywhere.

The benefits of walking

If you are regularly physically active (walking), you tend to:

•Reduce your risk of a heart attack

•Manage your weight better

•Have a lower blood cholesterol level

•Lower the risk of type 2 diabetes and some cancers

•Have lower blood pressure

•Have stronger bones, muscles and joints and lower the risk of osteoporosis

•Feel better – have more energy, happy and relaxed, and sleep well.

How can we increase our physical activity?

An increase in daily activity can come from small changes made throughout your day such as walking instead of using the car, getting off the bus a stop earlier and walking the rest of the way, or walking the children to school.

2.2. Physical activity barriers

What are physical activity barriers?

Physical activity barriers are barriers that prevent you from doing physical activity or exercises. They may include making excuses to avoid exercise, such as, a lack of time, fatigue and even the weather!

Common barriers to doing physical activity include:

•Do not have enough time to walk

•Weather – e.g. 'it's raining', 'it's too cold'

•Lack of self-motivation, can't be bothered, 'I don't feel like it'

•Do not find walking enjoyable

•Lack confidence to be physically active, 'I don't know how to be more active'

•Lack encouragement, support, or companionship from family and friends

•Do not have parks, pavements or safe and pleasant walking paths convenient to your home or workplace

•Lack of childcare

•You feel sick and cannot do any activity, 'I'm too tired, fatigued'.

• Joint pain, swelling.

How can we overcome these barriers?

Problem solving is a process that includes identifying the problem, generating a number of possible solutions, then selecting the most appropriate solution for you and finally evaluating if that solution works.

Here are some barriers and suggestions to overcome these barriers

a) Too tired

Everyone feels tired at times; it is a natural common barrier to physical activity.

Suggestions include:

•Try to incorporate small increases in physical activity into your daily life.

•Break your activity into smaller bursts; take the stairs instead of the lift.

•Walk to work, to a friend's house, shops.

•Get active at home, do indoor physical activity such as climbing stairs, gardening and housework.

•Brake up your sitting time e.g. every 20 minutes' walk around your house for 2 minutes.

•Exercise during your lunch break or build activity into your commute to work by walking part or all of the way.

b) Weather problem

It's too cold', 'it's raining'**.**

Suggestions include:

•Dress appropriately.

•Have a variety of indoor and outdoor activities to choose from so that weather can't interfere with your activity plans (indoor aerobic dance, indoor swimming, stair climbing, mall walking, bowling etc.).

•Take a walk through your local shopping centre such as Braehead or Silverburn.

c) Lack of Time

Suggestions include:

•Add physical activity to your daily routine. For example, walk to work or shopping, walk the dog, exercise while you watch TV, park farther away from your destination.

d) Lack of motivation

Suggestions include:

•Plan ahead. Make physical activity a regular part of your daily or weekly schedule and write it on your calendar.

•Make specific plans to exercise with other people. You are much likely to do it if you know someone else is depending on you for company.

• You can use your social support network to get you moving!

Lack of Social Support

Suggestions include:

•Explain your interest in physical activity to friends and family.

•Invite friends and family members to walk with you.

• Develop new friendships with physically active people e.g. by joining a local walking group

Arrange to go for walks with other members of the group.

2.3. The importance of social support

Social networks are very important in motivation and encouragement of physical activity. They can help in increasing awareness of people about the importance of physical activity.

Social support is a determining factor in successfully overcoming life stress. An important psychological factor is helping to forget the negative aspects of your life, and thinking more positively about your life and preventing anxiety and depression from developing. Social support not only helps improve a person's well-being, it affects the immune system as well.

Social support could come from family, friends, and neighbours or new people who share the same goal, interests or activities.

For example:

You can arrange for the group to meet between sessions to go for a walk. Or arrange to walk with your friend or family. You may think, 'I can't be bothered going for a walk it's too cold,' but then a friend says 'come on, let's go'

20

Session activities

1. Game of Knowledge

Which is considered physical activity and exercise? Tick all that apply.

	Physical activity (PA)	**Exercise(E)**
Housework		
Gym		
Watching TV		
Cycling		
Sleeping		
Walking		
Reading		
Climbing stairs		
Yoga		
Gardening		
Swimming		

2. Goal setting

The goal for coming week is that on three days only you will take 1000 steps more than last week. For example, if you took an average of 3000 steps each day in Week 1 you will be asked to walk 4000 steps on three days each week. On the other days we want you to try and do at least the same number of steps you did at baseline (ie last week)

So what is your baseline number of steps

_____

So what is your target number of steps for this week

_____

•How are you actually going to do these extra steps on three days?

I will _____

_____

•Who will walk with you?

I will walk with_____

•What barriers might you face and how might you overcome them?

The barriers_____

_____

_____

_____

I will overcome these barriers by

_____

_____

_____

_____

3. Using your Physical Activity Diary

This week we want you to do a bit more with your physical activity diary.

Last week you recorded your steps each day. This week in addition to that we also want you to

Record/comment on the type of physical activity you did e.g. walking, swimming, gardening etc.

AND If you reached your new target that day or your baseline number of steps

Tips for filling Physical activity diary

•Fix this diary to something you see every day (e.g. the fridge/back of a door).

•If you have encountered any difficulties regarding your activity write them down, for example bad weather or sickness.

•Record any notes on how the activity felt, what you noticed and things you learned.

•Record any changes you'd like to make for the following week, if

• Tick whether you achieved the baseline target the target you achieved whether baseline or target achieved.

Physical Activity Diary week 2

Participant number_____

Week beginning___/___/20____

Step Target: _____ on _____days

Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	Total number of steps /day	Tick the Target achieved	Comments and Activities performed
Wednesday		1- Baseline ☐ 2-Target achieved ☐	
Thursday		1- Baseline ☐ 2-Target achieved ☐	
Friday		1-Baseline ☐ 2-Target achieved ☐	
Saturday		1-Baseline ☐ 2-Target achieved ☐	
Sunday		1-Baseline ☐ 2-Target achieved ☐	
Tuesday		1-Baseline ☐ 2-Target achieved ☐	

Session 3

Rheumatoid Arthritis & Heart Disease

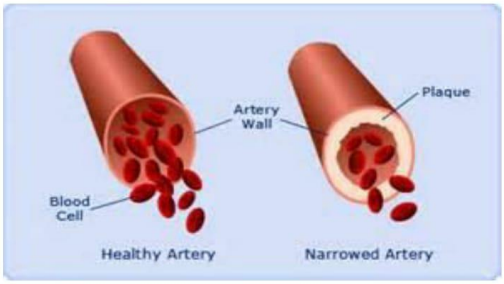
This session will revise the association between rheumatoid arthritis and heart disease and how to reduce the risk factors of heart disease. In this session will also discuss how to plan your physical activity.

Rheumatoid Arthritis and Heart Disease

Heart disease, risk factors and how to reduce risk factors

What is Heart disease?

Heart disease is a collection of conditions where the flow of blood is reduced to the heart muscle itself. The conditions include atherosclerosis, angina, and heart attack.



Why are people with rheumatoid arthritis at increased risk of heart disease?

Rheumatoid arthritis is associated with increased morbidity and mortality from heart disease such as myocardial infarction and ischemic heart disease. The risk of heart disease is 50% greater in people with rheumatoid arthritis than those without. The increased risk of heart disease among people with rheumatoid arthritis is not fully understood. However, inflammation of blood vessels might lead to atherosclerosis and heart disease in rheumatoid arthritis. What is clear however that is that those with rheumatoid arthritis who are physically active have a reduced risk of heart disease compared to those who are not so physically active.

What are the risk factors for heart disease?

1-Physical inactivity is related to the development of heart disease. It can impact on other risk factors including high blood pressure, high triglycerides (fat in the blood), diabetes and obesity.

2- Tobacco use increases the risk of heart disease and heart attack, and smoking also promotes atherosclerosis and increases the level of blood clotting factors.

3- Poor diet has been linked to heart disease, for example a diet high in saturated fat and cholesterol may lead to atherosclerosis which is commonly known as “narrowing of the arteries”.

4- Alcohol, excessive alcohol use leads to an increase in blood pressure, high triglycerides and increases the risk of heart disease.

What can you do to control your risk factors?

There are plenty of things you can do to manage your arthritis and at the same time control your risk of heart disease.

Let’s start taking a few actions which will help to control the risk factors you might you have. One step you can take is to adopt a heart healthy lifestyle.

Risk factors you can control

• Being more physically active -increasing your steps and decreasing the time sitting increases blood flow, lowers cholesterol, improves the heart muscle and lowers the risk of heart disease.

•Avoid fatty food to help lower blood cholesterol and triglyceride levels. A healthy diet includes a variety of vegetables and fruits, low fat or fat free dairy products can help lower blood cholesterol, may reduce the risk of coronary artery disease and lead to lower blood pressure.

•Try to stop smoking or even reduce the number of cigarettes you smoke, try to avoid second hand smoke may reduce the risk of coronary artery disease.

Planning and Goal Setting

Why is planning important?

•Planning is important to help you to achieve your objectives.

•Planning helps you to be prepared for difficulties you might face and to help create solutions for unexpected problems.

•Planning also helps to evaluate your progress.

The first step to planning is to clearly define your goals.

Why is goal setting important?

•Goal setting is a major component to long -term success. The steps you take to achieve your goal are like the road map that helps you get to your destination.

•The basic reason for goal setting is that you can't get where you are trying to go until you clearly define where you want to go and how you are going to get there. All parts of your life can be enhanced by setting goals and creating plans to achieve those goals.

•Goal setting helps you focus and allocate your time and resources efficiently, and is can keep you motivated when you feel like giving up.

•Goal setting allows you to measure progress and also help you believe in yourself.

•By setting goals you give yourself mental boundaries. When you have a certain end point in mind you stay focused towards the goal.

What is meant by a SMART goal?

S – Specific (precise, clear and simple)

M – Measurable (how will I know what I have achieved?)

A – Achievable (is it possible?)

R – Relevant-realistic (to provide the purpose, or reason)

T – Time framed (deadline and duration – how much time to spend doing it).

Plan for the week

For next week we want you to do the same again! Walk 1000 steps more than baseline on three days of the week.

What is your SMART goal for next week in relation to physical activity?

What is my SMART goal?	
My planning: • How I will do it?	
• When?	
•Where?	
•Who with?	
•What difficulties could I face?	
•How I will overcome them?	
How I will know I have achieved my goal?	

Physical Activity Diary week 3
Participant's number_____
Week beginning___/___/20____ Step Target: _____
on _____days
Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	Total number of steps /day	Tick the achieved	Comments and Activities performed
Wednesday		1- Baseline achieved ☐ 2-Target achieved ☐	
Thursday		1- Baseline achieved ☐ 2-Target achieved ☐	
Friday		1-Baseline achieved ☐ 2-Target achieved ☐	
Saturday		1-Baseline achieved ☐ 2-Target achieved ☐	
Sunday		1-Baseline achieved ☐ 2-Target achieved ☐	
Monday		1-Baseline achieved ☐ 2-Target achieved ☐	
Tuesday		1-Baseline achieved ☐ 2-Target achieved ☐	

Your Total steps _____

Session 4

Strength training

This session will discuss strength training and its importance in managing arthritis and will involve practicing some of the exercises.

Strength training

What is strength training and why is it important for people with Rheumatoid Arthritis?

Strength training is a type of physical exercise which uses resistance to induce muscular contraction, in order to build strength, endurance and the size of muscles.

Strength training also known as resistance training, weight training, or muscle-strengthening activity, is probably the most neglected component of fitness programmes but one of the most beneficial.

Studies have shown the benefits of strength training are:

•**Strengthen muscle**- strength training builds stronger muscles which can help to maintain/improve the ability to walk, rise from a chair and climb stairs.

Strength training can strengthen the muscles around your joints providing some extra support for your joints.

•**Strength bone -**strength training improves the structure of bone and helps fight osteoporosis.

•**Burns Calories-** strength training burns calories.

Many people with Rheumatoid Arthritis are wary of the idea of strength training or are afraid of injury

You might think strength training would make arthritis worse. But actually the correct strength training can help people with rheumatoid arthritis (RA) function better and reduce soreness, stiffness and pain.

This programme is designed according to the UK physical activity guidelines and Start Active, Stay Active (2011). Strength exercises for the major muscles of the legs, arms and trunk will be performed at home, twice a week, with each exercise repeated 8-12 times.

Flexibility training involves moving your joints through their full range of movement to reduce stiffness and improve flexibility. Flexible joints are less prone to injury.

Benefits of flexibility training:

Increased flexibility reduces the risk of muscle pulls and back pain.

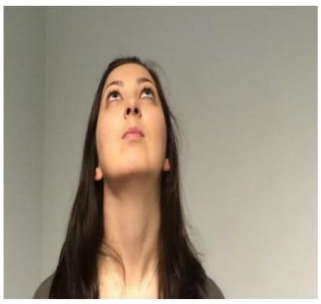
Strength Training Programme

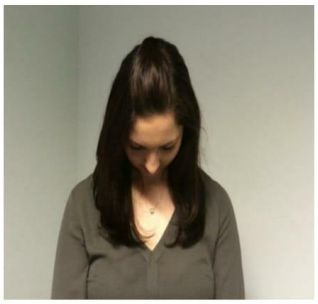
The programme consists of a warm up, strength exercises and a cool down. We will start with one or two strength exercises, depending on your RA symptoms, and these can be reviewed and progressed as appropriate.

Warm up and Flexibility exercises

•Standing or sitting relaxed, Repeat each of these 10 times.

1) Neck Stretches 1 - Tilt your head back, to look at the ceiling and then forward, to look at the floor.





Neck stretches 1

2) Neck Stretches 2 -Turn your head to the left, to look over your left shoulder then turn to look over your right shoulder.

Neck stretches 2

3) Neck Stretches 3 - Tilt your head toward the right shoulder, dropping your ear towards your right shoulder, then tilt to the left.

Neck stretches 3

4) Shoulder exercise - Shrug your shoulders up towards your ears. Drop them back down again. Roll your shoulders in a forward direction, then backwards. Repeat 10 times

Shoulder exercise

5) Shoulder elevation- Standing or sitting, put your hands on your shoulders. Stretch your arms up towards the ceiling then back to your shoulders, repeat 10 times.

Shoulder elevation

6) Breathing exercise/Core stability - Place one hand over your stomach. Inhale then exhale tightening your abdominal muscles while pressing your lower back against a chair. Hold for a count of five. Inhale relaxing your abdominal muscles.

Breathing exercise/Core stability

7) Leg exercises - In standing lift your feet one at a time off the floor (marching). Repeat 10 times with each leg.

Leg exercises

8) Hamstring/Calf Stretch **-** sit forward in a chair with your knees bent and feet flat on the floor. Extend your right leg in front of you; pull your toes towards the ceiling keeping your heel on the floor. Keep your hand placed gently on your left leg. Slowly lean forward at the hips, bending toward your right toes, trying to keep your back straight. Hold the stretch for a slow count of 20 to 30, breathing throughout. Release the stretch and repeat with your left leg.

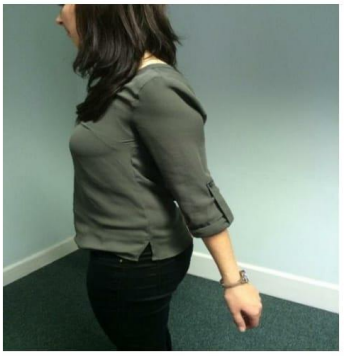
Hamstring/Calf Stretch

9) Quads (thigh) stretching- stand holding on to a secure object, or have one hand raised out to the side for balance. Raise one heel up toward your buttocks, and if possible grasp hold of your foot. Slowly pull your heel to your buttock while pushing your pelvis forward. Aim to keep both knees together, having a slight bend in the supporting leg.

Quads (thigh) stretching

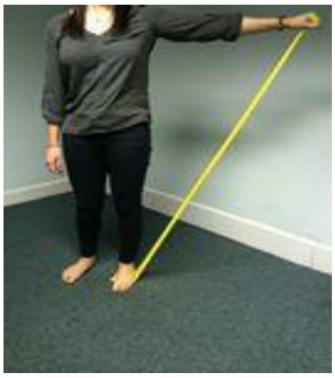
Strengthening exercise

1) Back Muscles **-** stand up straight bring your chest out, shoulders and arms back (Military style). Hold for five seconds, relax and repeat 10 times.



Back Muscles strengthening

2) Shoulder abduction- stand up straight, place one end of theraband under your foot and hold in one hand by your side. Keep your arm straight and raise it up out to the side to shoulder height. Hold for a few seconds slowly lowering your arm back down to your side. Repeat 10 times on each side.



Shoulder abduction

3) Bicep curls – stand up straight with the theraband under both feet and hold on to each end of the band. Bend your elbows, raising your hands up towards your shoulders. Keep your elbows close to your waist. Hold for a few seconds before straightening your arms, returning to your starting position. Repeat 10 times.

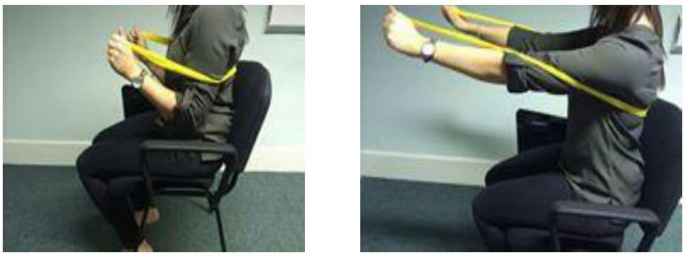
Alternatively rather than using the theraband do the exercise with bottles of water (as the triceps exercise below)

Bicep curls

4) Triceps - sit in a chair. Hold small weights or a bottle of water in each hand. Raise your arms above your head and bend your elbows. Straighten your arms, keeping your elbows close to the side of your head. Slowly lower the weight down by bending your elbows. Repeat 10 times.

Triceps extension

5) Chest press – sit up straight in the chair. Position the theraband around the back of your shoulders and hold the ends of the band securely in each hand. Straighten both arms out in front. Hold for a few seconds then slowly bend both elbows returning to your starting position. Repeat 10 times.



Chest press

6) Leg extension - sit in a chair. Straighten your knee, hold for a few seconds, then slowly lower it back down to the floor. If this is too easy, you can use theraband around your ankle and the leg of your chair. Repeat 10 times on both legs.

Leg extension

7) Standing knee flexion - stand near a table or chair, holding on if required. Stand on one leg and bend the other one to 90degrees, hold for 10 seconds and repeats 10 times each leg. If this is too easy use some ankle weights.

Standing knee flexion

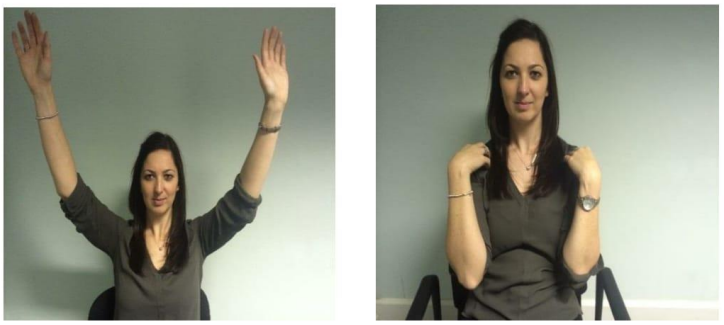
8) Calf raises **-** hold on to a table, stand up straight, rise up on to your toes and back down, repeat until your calf feels tired. When this gets too easy do the exercise standing on one leg at a time. It you want to make it harder still then wear a loaded backpack/rucksack.

Calf raises

Cool Down Exercise

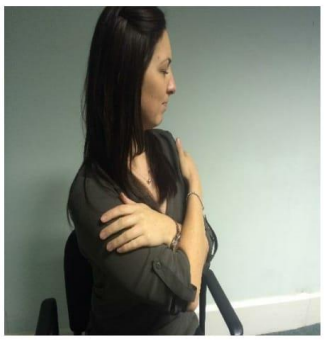
Once you have finished the strength exercises, you should gradually allow your heart rate and breathing to slow to a comfortable level. You should do these few stretches and/or some from the warm up exercises.

1) Arms stretch **-** Stretch your arms up towards the ceiling then back to your shoulders repeat 10 times.



Arms stretch

2) Body stretch **-** Stand or sit cross your hand over your chest, turn slowly to look over your right shoulder and hold this position for a count of 10, repeat to your left side.

Body stretch

You should repeat the hamstring and quads stretches see page (7).

Other exercises to try at home

1) Inner range quads **-** put a rolled up towel under the back of your knee, bring your knee to a straight position, hold for 5 seconds and repeat until your muscle feels tired. If that is too easy try adding a weight to your ankle.


Inner range quads

2) Bridging- begin this exercise lying on your back in the position demonstrated. Slowly lift your bottom pushing through your feet, until your knees, hips and shoulders are in a straight line. Tighten the back of your thigh (hamstrings) as you do this. Hold for 2 seconds then slowly lower your bottom back down. Repeat 10 times.

Bridging

Session activities

Plan for the week

Your target for Week 4 is to take 1000 steps more than week 1 on **5 days** of the week. For example if you took an average of 3000 steps each day in Week 1 you will be asked to walk 4000 steps on five days each week.

As well as the walking programme, start doing the strength training two times per week and record your strength training in your physical activity diary each time by ticking Yes or No.

What is your SMART goal for next week in relation to physical activity?

What is my SMART goal?	
My planning: • How I will do it?	
• When?	
•Where?	
•Who with?	
•What difficulties could I face?	
•How I will overcome them?	
How I will know I have achieved my goal?	

Physical activity diary week 4
Participant's number_____
Week beginning___/___/20____ Step Target: _____
on _____days
Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	**Total number of steps /day**	**Tick the achieved**	**Strength training**	**Comments and Activities performed**
Wednesday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Thursday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Friday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Saturday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Sunday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Monday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes No	
Tuesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes No	

Your Total steps _____

Session 5

Healthy Diet and Heart Disease in Rheumatoid Arthritis

This session will include the importance of a healthy diet, in general and in rheumatoid arthritis and how to reduce the risk of heart disease through dietary change.

Healthy Diet and Heart Disease in Rheumatoid Arthritis

Healthy Diet

What do you know about a healthy diet?

The crucial part of a healthy diet is that it should be balanced; high in fruits, vegetables and whole grain food, and low in saturated fats and processed and refined foods.

An immune supportive diet is a diet high in protein, antioxidants, essential fatty acids, and vitamins (A, B, E, C and K), and minerals. The information below is general information, if you have a particular dietary need for example Diabetic, Vegetarian or coeliac, you will also need to take that into consideration.

So what foods should you eat more of and which should you eat less of?

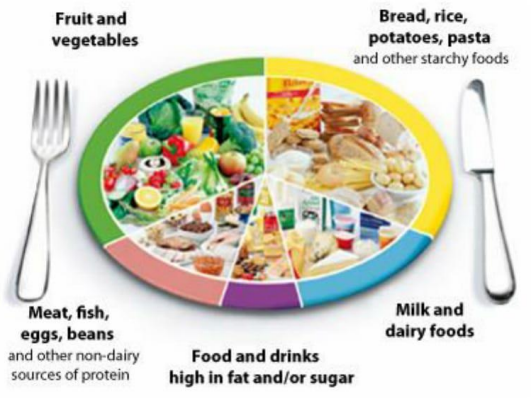
Eat More	**Eat Less**
Healthy fats: raw nuts, olive oil, fish oils, flax seeds, or avocados	Deep-fried foods; saturated fats e.g., dairy or red meat
Nutrients: fruits and vegetables fresh or frozen, prepared without butter	Pre-packed foods, especially those high in sodium
Fibre: cereals, breads, and pasta made from whole grains	White breads, refined pasta or rice
Omega 3 and protein: fish and shellfish, poultry	Red meat, bacon, sausage, fried chicken
Calcium and protein: egg whites, egg substitutes, skimmed or 1% milk, low-fat or non-fat cheese and yogurt	Egg yolks, whole or 2 percent milk, cheese or yogurt

What do you know about the Eatwell plate?

The Eatwell plate (shown below) highlights the different types of food that make up our diet, and shows the proportions of each we should eat to have a well-balanced and healthy diet.

The Eatwell plate is designed to make healthy eating easier by getting the correct amount of nutrients – protein, fat, carbohydrates, vitamins and minerals you need to maintain good health.

We take in too many calories from food and drink that are high in fat, sugar and salt. They provide very little of the essential vitamins and minerals your body needs. Limiting these is essential for healthy eating. Based on the Eatwell plate, try to eat: **Plenty of fruit and vegetables,** wholegrain varieties, lower-fat milk and dairy foods, **some meat, fish, eggs, beans and other non-dairy sources of protein and a small amount of foods and drinks that are high in fat or sugar.**



What is a good diet?

A good diet means eating the right quantities from the different food groups. There are five main food groups - carbohydrates, fruit and vegetables, protein, diary and fatty & sugar foods. These are all shown in the **Eatwell plate** above.

Whole grains

Whole grains are rich in fibre, minerals and vitamins. Whole grain products include breads, pastas and cereals. Whole grain wheat flour is usually slightly darker than refined flour.

Fruit and vegetables

Fruit and vegetables are rich in vital vitamins, minerals and fibre. These nutrients are important for your body to function well. Several studies have shown that a good intake of fruit and vegetables can offer protection from developing heart disease, diabetes and cancer.

Protein

We need protein for building and repairing of tissue in our body. Protein-rich food also includes essential minerals, such as iron, magnesium, zinc, as well as B vitamins. Meat, poultry, fish, eggs, beans, nuts are good sources of protein. The fat in meat should be trimmed, and any excess should be drained away after cooking. Skin should be removed from poultry.

Legumes are also a good source of protein. They are plants in the pea family that produce pods which slit open e.g. Soya beans, peas, nuts (peanuts).

Dairy

Dairy products such as milk, yoghurt and cheese, are a good source of calcium which is important for healthy bones and teeth. However, some have high fat content should be avoided where possible.

Fatty and sugary foods

Foods which are high in fat or sugar include chocolate, cakes, biscuits, jam, butter, margarine, mayonnaise, non-diet fizzy drinks.

There are two basic types of fat

1-Saturated fat- cream, margarine and fried foods are high in saturated fats. Consumption of saturated fat should be kept to a minimum, because excess consumption significantly increases the risk of developing diseases such as heart disease.

2-Unsaturated fat -vegetable oils and oily fish are rich in unsaturated fats. Omega-3 fatty acids, found in foods including walnuts and oily fish, have a protective effect on the heart. Eating unsaturated fats instead of saturated can help lower blood cholesterol, may reduce the risk of coronary artery disease, lower blood pressure levels and some types of cancer although should not eat too much.

So healthy eating involves:

•Plenty of bread, rice, potatoes, pasta and cereals – going for the wholegrain varieties whenever you can.

•Plenty of fruit and vegetables.

•Skimmed or semi-skimmed milk, low fat cheese and yoghurt.

•Red meat, poultry, eggs, beans and nuts should be limited.

•A very small amount of fats and oils.

•And a very small amount, of food and drinks high in fat, sugar and salt.

What are your barriers to healthy eating?

There are a number of barriers to healthy eating, for example, it is costly, you do not have enough time to prepare it, you do not like it, who does the cooking, access to food, convenience etc.

Some examples of ways to overcome these barriers

It costs too much to eat well.

Eating well does not have to cost more. Many pre-prepared foods are high in calories, fat, salt or sugar and cost more. Cutting back on pre-prepared meals and low nutrient snacks can save your pounds and can be good for your health and waistline.

Buy vegetables and fruit fresh when they are in season and freeze extras for later.

I don't have enough time to prepare healthy meals.

Getting healthy meals on the table in a hurry takes less time than you might think. It's all about being prepared.

Plan your meals and make a shopping list to ensure you have the ingredients in your kitchen to pull together meals quickly.
Ask your family to help get meals started.
Choose some healthy convenience products to help speed up preparation time. For example, frozen vegetables or bagged salad greens.
Skip the biscuits, baked goods, chips and other salty snack foods, soft drinks and other high calorie beverages. They cost a lot and are low in nutrients.

What is the importance of eating a healthy diet for Rheumatoid arthritis?

Nutrition is one of the many tools to help you live well and stay healthy. A healthy diet cannot cure rheumatoid arthritis, however, it can help you maintain health and reduce the risk of other conditions, such as heart disease. Even the smallest changes in your diet can translate into better nutritional status. The key to achieving and maintaining healthy weight is related to healthy life style healthy diet, balancing the number of calories you consuming and regular physical activity. Being overweight puts extra strain on your joints so keeping to a healthy weight is strongly recommended. The equivalent of four times the body weight goes through the joints.

Heart Disease and diet in Rheumatoid arthritis

As we have discussed, people with rheumatoid arthritis have double the risk of developing heart disease. Diet is a key factor in reducing the risk of heart disease. So for people with rheumatoid arthritis it is very important to try and eat a healthy diet as discussed above.

Session activities

Activity 1- What should we eat less of?

Tick the appropriate answers (*you can tick more than one answer*).

Fats:
O Raw nuts
O Fish oils
O Deep-fried foods
O Red meat
Nutrients:
O Frozen fruits & vegetables
O Pre-packed foods especially those high in Sodium
O Fresh fruits & vegetables
O Fresh cream
Fibre:
O Cereals
O White breads
O Refined rice
O Refined Pasta
Omega 3 and protein:
O Fried chicken
O Bacon
O Sausage
O Fish
Calcium and protein:
O Egg whites
O Skimmed or Semi- milk
O Full fat cheese and Yoghurt
O Egg yolks

Activity 2- Plan for the week

Your target for Weeks 5as in week 4 is to take 1000 steps more than week 1 on 5 days of the week.

In addition, you should continue with your strengthening programme.

What is your plan for next week?

_____

_____

____

What is your plan for strength training?

_____

_____

____

What are the problems you could face?

_____

_____

____

How will you overcome them?

_____

_____

____

Physical activity diary week 5

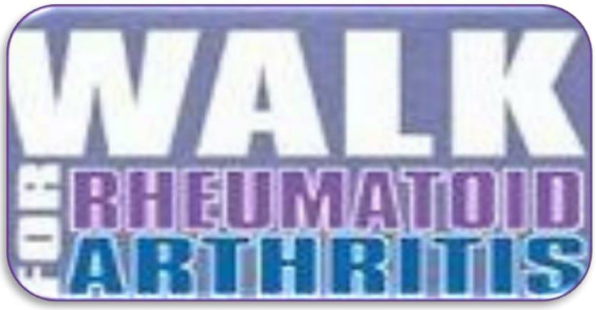
Participant's number_____

Week beginning___/___/20____ Step Target: _____ on _____days

Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	Total number of steps /day	Tick the achieved	Strength training	Comments and Activities performed
Wednesday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Thursday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Friday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Saturday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Sunday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Monday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Tuesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	

Your Total Steps _____



Session 6

Social Support, Maintaining Change and Sedentary Behaviour Revisited

This session, will discuss social support, maintaining change and will revisit sedentary behaviour and how to implement the walking programme for the next 6 weeks. It will last one hour.

Session 6

Social Support, Maintaining Change and Sedentary Behaviour Revisited

Social support is the idea that you will likely do better in achieving something with the encouragement and motivation from other people.

How can you feel socially supported within the programme?

Who do you have who can provide social support to help reach your physical activity targets going forward? It might be your husband, wife, son/daughter, workmate, friend, neighbour, dog! It might be one person or several people. Whoever they are they must be positive and supportive to you in this programme.

Social support takes many forms. It might be that someone come for a walk with you, or just give you a call every week or so to see how you are getting on.

Setbacks- triggers and how to avoid them

Becoming more physically active is one thing, maintaining the increase can be even harder. From time to time most people experience problems and sometimes these can lead to a setback, so that, for whatever reason, you don't achieve your step count target for a while.

Common triggers for setbacks:

•Becoming overly tired or unwell, stressful situation at home or work.

•Looking for an excuse to stop walking, such as, poor weather

•You are disappointed that you haven't been able to achieve your step count target.

•Thinking everything is okay with your rheumatoid arthritis and so not wanting to take part anymore.

•Feeling that the goals which have been set are unrealistic, or that they take time and effort to obtain and you are not willing to make the effort.

• You are on holiday and out of your normal routine.

What can you do to avoid a setback or to get back on track after a setback?

•The important thing is not to get disheartened; most people have setbacks along the way. Don't give up!

•Real change takes time.

•Try not to get downhearted- if you feel this way talk it over with someone close or Aleksandra she will be happy to help.

• Little by little, one step at a time; stay focused on your goals – not your emotions.

•To avoid your setback and to back on track make sure you

1- Are clear about what you want to achieve
2- Are clear about why you want to achieve it
3- Keep a record of your progress
4- Let people know how well you are doing
5- Set your SMART goals
6- Review your SMART goals regularly

When you experience a setback, you might experience feelings of failure, disappointment, and frustration.

The key to success is to not let these setbacks undermine your self-confidence. If you lapse back to an old behaviour, think about why it

happened. What triggered the relapse? What can you do to avoid these triggers in the future?

It is even more helpful to anticipate difficult situations that you might encounter, that might stop you being more active and to plan in advance how you would deal with them to avoid them triggering a setback if they do happen.

Sedentary behaviour

The health risks of sedentary behaviour are independent from those associated with physical activity i.e. no matter how active are you will still have an increased risk of ill health if you sit too much.

Too much sitting leads to

Increased risk of type 2 diabetes.

Increased risk of heart disease and other prevalent chronic health problems.

Stiffness of your joints and weakness of your muscles.

So try to reduce your sedentary time by reducing or breaking-up you're sitting time, for example getting up every 20 mins when you are watching TV.

The programme for next six weeks is detailed below

Your step count targets for next 6 weeks are

• Weeks 6and 7 - at this stage in the programme we will increase your step count target by1000 again but you only need to achieve this on 3 days per week. For example, if you took an average of 4000 steps each day in Week 2-5you, this would be 5000 steps on 3 days.

•Weeks 8 and 9 – we will ask you to take these additional 1000 steps on 5 days of the week. So in the example above that would be 5000 steps on 5 days each week.

• Weeks 10-11 weeks, at this point we will increase your step count target by 1000 again, but you only need to achieve this on 3 days per week. Again using the example this would be 6000 steps on 3 days.

•In 12-13 weeks we will ask you to take these additional steps on 5 days of the week. So in the example, that would be 6000 steps on 5 days each week.

For those of you who have reached your step count target we ask you to try and reach that target on five days of each week.

For next six weeks continue your walking goal as mentioned above, as well as your strength training two times per week.

Record your total number of steps in your physical activity diary at the end of each day, record your strength training in your physical activity diary each time.

The physiotherapist will contact with you at end of week 7, 9 and 11 i.e. when your step target is changing. She will contact you by phone, email or text according to your preference. The purpose of the contact is to discuss your programme, problems you have faced and plans for the next few weeks. If you have any questions or problems you can contact with physiotherapist outwith these times, she will be there to help and support.

In about six weeks' time the group will meet again for a 'booster session' to discuss progress. We will contact with you by phone to confirm the date and time of the session.

Also around that time you will be three months into the programme and you will receive an appointment to have the assessments you did at the beginning repeated. On the assessment day will be asked to fill out a number of questionnaires regarding quality of life, diet and lifestyle as you did before. The assessments will be carried out in the same place as your initial assessments. The researcher will send you a letter to confirm your appointment date and time.

Session activities

Activity 1-setbacks- triggers and how to avoid them

What are your own situations might lead to setback that prevents you from keeping active?

What can you do to avoid these triggers in the next 6 weeks?

Fill in the table below with your own situations could might to setback, and for each one, make a plan for coping with it.

Situations might lead to setback **If……**	How I will avoid or cope with them **Then….**
1_____ _____ _____ _____ _____ 2_____ _____ _____ _____ _____ 3_____ _____ _____ _____ _____	1_____ _____ _____ _____ _____ 2_____ _____ _____ _____ _____ 3_____ _____ _____ _____ _____

Activity 2- What is your plan for the next 6 weeks?

Discuss the following questions

How will you perform your plan?

_____

_____

_____

How will you overcome any barriers?

_____

_____

_____

What is your plan for social support?

_____

_____

_____

What is your SMART goal in relation to physical activity for the next 6 weeks?

_____

_____

_____

Physical activity diary week 6

Participant's number_____
Week beginning___/___/20____ Step Target: _____
on _____days
Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	Total number of steps /day	Tick the achieved	Strength training	Comments and Activities performed
Friday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Saturday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Sunday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Monday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Tuesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Wednesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Thursday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	

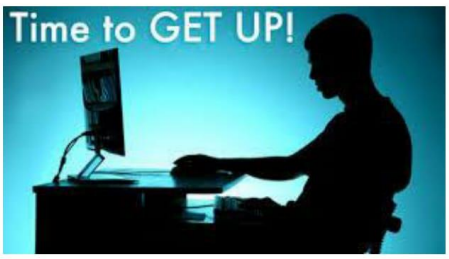
Your Total Steps _____

Staying Physically Active

Booster session 1

This session will discuss tips and advice on how to stay physically active and avoid too much sitting, how to implement the walking programme over the next three months. It will also revise strategies for avoiding setbacks and how to get back on track if this should happen. The session will last one hour.

Tips to avoid too much sitting



• Stand up while you are on the phone.

•Moving around or pacing while you work you will burn more calories than you may think.

•Walk after you eat lunch.

•Park your car farther away from your destination.

•Get vigorous about your daily cleaning and cooking.

•Work your calves when you brush your teeth!

•Stand up or do exercises while watching TV.

•Don't make things too convenient: Don't surround desk with everything you will need in easy grabbing distance. Place items further away so you will need to get out of your chair to get them.

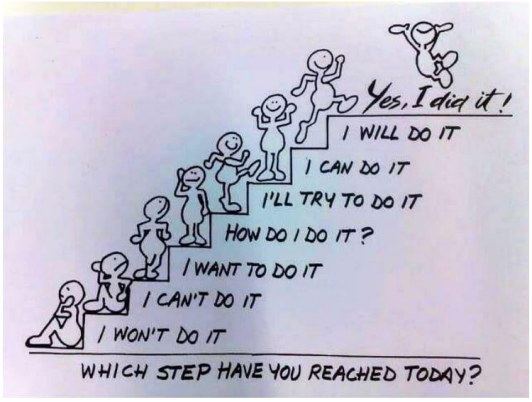
•Reduce your sedentary time by reducing or breaking-up your sitting time, for example getting up every 20 mins when you are watching TV.

•Practices strength training while you are sitting.

Remember

Any amount of physical activity a day is better than sitting. Don't think walking is a waste of time—it is never a waste of time.

Ways to motivate you to be physically active



• Stay positive - remind yourself of your past successes, and picture yourself being active for a lifetime.

• Physical activity can be a lot more fun when you do it with others. Take a walk with a colleague, your family, your dog, or a neighbour. Recruit a friend or family member to help meet your day challenge—the camaraderie and even a little competitiveness will keep you engaged and interested.

•Be prepared - today's high-tech, fast-paced lifestyle makes it easy to be inactive with conveniences such as remote controls, escalators, and elevators. Think of ways to add steps to your normal daily routine.

•Keep track and look back- keeping track of the physical activity you do each day. Look back to see how you've maintained or increased your activity each week.

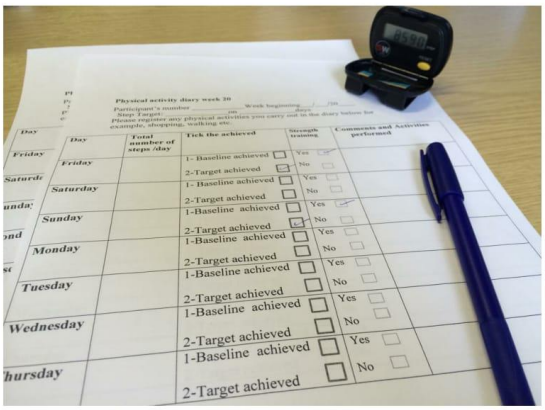
• Don't expect perfection - if you have a setback, learn from your experience and find ways to deal with similar situations in the future. Know that you can always get back on track. Keep things in perspective think of all the good things in your life, and try to maintain a positive attitude.

• Try setting reminders to be more active on your computer, watch, MP3 player, mobile phone you have with you that will prompt you to move. Also be sure to schedule the planned daily walk(s) into your calendar. Eventually it'll become natural and you can stop relying on reminders.

The programme for next 3 months is detailed below

For next three months those participants who have reached their step count target we ask them to continue that target on five days of each week. Those who haven't reached their target we will be increasing their step count. As well as walking, continue your strength training twice a week.

Maintain record your total number of steps in your physical activity diary at the end of each day, record your strength training in your physical activity diary each time you do as much as you can.



The physiotherapist will contact you monthly to discuss this programme and any problems you have faced as well as any plans for the next few weeks. If you have any questions or problems you can contact the physiotherapist outwith these times, she will be there to help and support.

In about 3 months' time the group will meet again for a final session. We will contact with you by phone to confirm the date and time of the session that has arranged.

Also around that time you will be six months into the programme and you will receive an appointment to have the assessments you did at the beginning repeated. On the assessment day will be asked to fill out a number of questionnaires regarding quality of life, diet and lifestyle as you did before. The assessments will be carried out in the same place as your initial assessments. The researcher will send you a letter to confirm your appointment date and time.

Session activity

Planning to avoid setbacks

Answer the following questions individually.

Describe your specific risk situations and how you could prevent this setback or reduce the impact of this setback on your physical activity programme for next 3 months?

Fill in the table below with your own situations might lead to setback, and for each one, make a plan for coping with it.

Situations might lead to a setback **If……**	How I will avoid or cope with them **Then….**
1_____ _____ _____ _____ _____ 2_____ _____ _____ _____ _____ 3_____ _____ _____ _____ _____	1_____ _____ _____ _____ _____ 2_____ _____ _____ _____ _____ 3_____ _____ _____ _____ _____

Physical activity diary week 13

Participant's number _____Week beginning___/___/20____
Step Target: _____on _____days
Please register any physical activities you carry out in the diary below for example, shopping, walking etc.

Day	Total number of steps /day	Tick the achieved	Strength training	Comments and Activities performed
Friday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Saturday		1- Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Sunday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Monday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Tuesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Wednesday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	
Thursday		1-Baseline achieved ☐ 2-Target achieved ☐	Yes ☐ No ☐	

Your Total Steps _____

Maintaining Physically Active

Booster session 2

This session will be the last session and the end of the programme. We will discuss the review of the previous three months and how you overcome any barriers you may have faced over the last three months. Also how will you maintain your physical activity? *The session will last one hour.*

Tips to be physically active

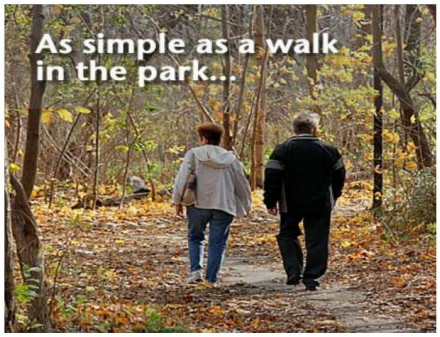
- Go out for a short walk before breakfast, after dinner or both! Start with 5-10 minutes and work up to 30 minutes.
- Walk to the shop instead of driving.
- Do strength training a few minutes while watching TV.
- Stand up while talking on the telephone.
- Walk the dog.
- Work in the garden or mow the grass.
- Park farther away at the shopping mall and walk the extra distance.
- Walk wherever and whenever you can.
- Take the stairs instead of the elevator, when possible.
- Carry your groceries home.
- Throw away video remote control. Instead of asking someone to bring a drink, get up off the couch and get it yourself.
- Setting your realistic goals, checking your progress.
- Rewarding yourself when you reach your goal.

- Try setting reminders to be more active on your computer, watch, mobile phone you have.
- Making a contract with a friend or family member also may help you keep your commitment.
- You're more likely to keep going if you choose activities you enjoy.
- If you can stick with physical activity for at least 6 months, it's a good sign that you're on your way to making physical activity a regular habit. Don't be afraid to try new things.

Although you won't be attending programme you should be trying to keep your increased physical activity going.

Although your body benefits as soon as you become more active, you may not see visible changes straight away. It can also take time for your body to adapt to the activity, so you should keep going and set goals that are right for you.

If you can stick with physical activity for at least 6 months, it's a good sign that you're on your way to making physical activity a regular habit.



Follow up assessment one year

You will receive an appointment to have the one year (final) assessment you did at the beginning repeated. On the assessment day will be asked to fill out number of questionnaires regarding quality of life, diet and lifestyle as you did before. The assessments will be carried out in the same place as your initial assessments. The researcher will send a letter to confirm your appointment date.

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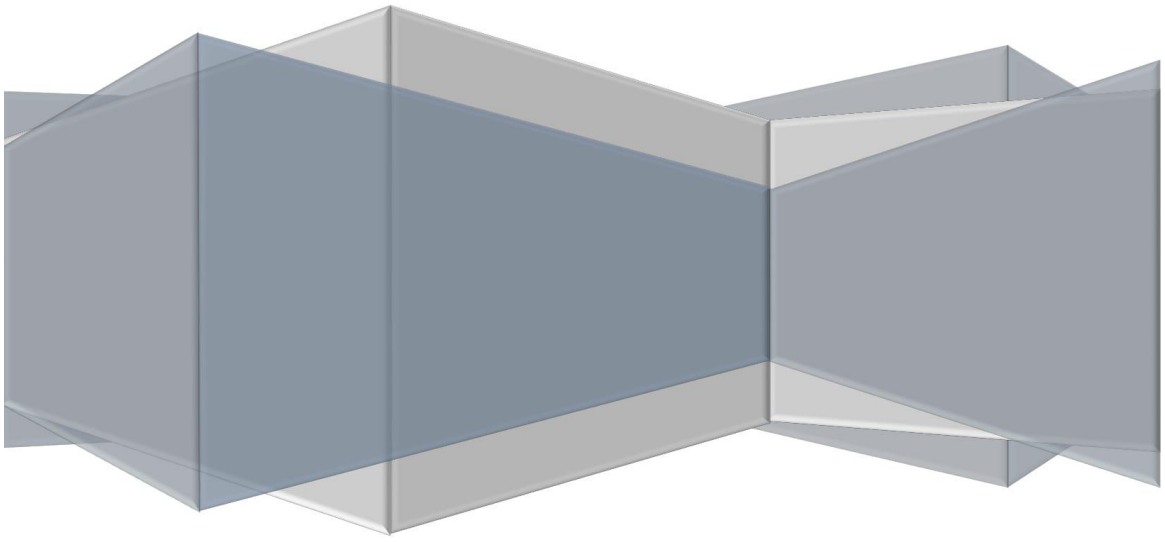
Thank you for participating in this programme

Appendix 15- Single education session for the control group

WALK FOR RHEUMATOID ARTHRITIS



This booklet provides information and answers your questions about:

1-Rheumatoid arthritis 2-Heart disease

3- Physical activity 4- Strength training

5-Healthy diet

1. Rheumatoid arthritis

What is rheumatoid arthritis?

Rheumatoid arthritis affects mainly affects joints, causing inflammation, pain and swelling. The disease usually starts in the wrists, hands or feet and can spread to other joints and other part of the body.

What are the symptoms of Rheumatoid Arthritis?

Common symptoms of Rheumatoid Arthritis include:

Joint pain and swelling

Stiffness

Fatigue

Depression

Anaemia: is a shortage of haemoglobin**;** haemoglobin is an oxygen carrying pigment in the blood. A lack of haemoglobin makes it more difficult for the blood to carry oxygen around the body.

Flu like symptoms, such as feeling generally ill, feeling hot, sweating.

Less common symptoms:

Inflammation of the eyes

Rheumatoid nodules

Inflammation of other parts of the body

How does it affect me?

Rheumatoid arthritis affects everyone differently, there may be times when the disease is active and other times when it is inactive.

What happens to joints affected by Rheumatoid Arthritis?

Inflammation takes place within the lining of the joint and the result is similar to inflammation that you may have seen if you have had an infected cut or wound; it goes red, it swells and it is painful. The redness is caused by the

flow of blood increasing and, as a result, the inflamed joint may feel warmer than usual. The pain and swelling are due to extra fluid and inflammation of the joint.

What other organs could be involved in rheumatoid arthritis?

Rheumatoid arthritis may affect muscles, bones and other organs such as the heart, lung and eyes.

2. What is heart disease?

Heart disease refers to several different types of heart conditions. Coronary artery disease is a type of heart disease that occurs when a substance called plaque builds up in the arteries that supply blood to the heart.

Plaque is made up of cholesterol (fat) deposits, which can accumulate in the arteries.

Atherosclerosis is a condition that occurs when too much plaque builds up in the arteries, causing them to narrow. Atherosclerosis is commonly known as "narrowing of the arteries".

Cholesterol is a fat- like substance in the body, and high levels of cholesterol in the blood can lead to heart disease and stroke.

What is the risk of heart disease in rheumatoid arthritis?

There is evidence that rheumatoid arthritis is associated with an increased risk of heart disease compared with the general population. This risk may be as much as 50% higher.

Risk factors for heart disease

1-Physical inactivity is related to development of heart disease. It can impact other risk factors including high blood pressure, high triglycerides (fat in the blood), diabetes and obesity.

2- Tobacco use increases the risk of heart disease and heart attack, and smoking also promotes atherosclerosis and increases the level of blood clotting factors.

3- Poor diet has been linked to heart disease, for example a diet high in saturated fat and cholesterol.

4- Alcohol, excessive alcohol use leads to an increase in blood pressure, high triglycerides and increases the risk of heart disease.

How can you overcome these risks?

One of the things you can do to help overcome this risk is to be more physically active. You can do this by breaking up prolonged sitting, reducing your sedentary time and walking more (taking extra steps).

3. Physical activity

The UK physical activity guidelines state that

•Adults should aim to be active daily. Over a week, activity should add up to at least 150 minutes (2½ hours) of moderate intensity activity in bouts of 10 minutes or more. One way to approach this is to do 30 minutes on at least 5 days a week.

•Regular physical activity can help to reduce the risk of heart disease, premature death and chronic diseases such as coronary artery disease, high blood pressure and stroke.

•Thus being more physically active improves your chance of living longer and living healthier. Regular physical activity can improve your overall sense of wellbeing by improving fitness levels and self-esteem, reducing the effects of stress, and increasing energy.

What is Physical activity?

Physical activity is any bodily movement produced by muscles that requires energy expenditure such as gardening, housework and shopping.

Is physical activity safe for people with Rheumatoid Arthritis?

There is no evidence that physical activity increases the symptoms of Rheumatoid Arthritis. If you're not active now, it can bring some health benefits. Take a step in the right direction.

Walking is considered a popular and an ideal mode of physical activity. Walking poses little risk of injury for sufferers of Rheumatoid Arthritis, is inexpensive, does not need any skills, you can perform it anytime, anyplace and anywhere.

4. Strength training

According to the UK physical activity guidelines and Start Active, Stay Active (2011). Strength exercises for the major muscles of the legs, arms and trunk will be performed at home, twice a week, with each exercise repeated 8-12 times.

Strength training is a type of physical exercise which uses resistance to induce muscular contraction, in order to build strength, endurance and the size of muscles.

Flexibility training involves moving your joints through their full range of movement to reduce stiffness and improve flexibility. Flexible joints are less prone to injury.

Many people with Rheumatoid Arthritis are wary of the idea of strength training or are afraid of injury

You might think strength training would make arthritis worse. But actually strength training can help people with rheumatoid arthritis (RA) function better and reduce soreness, stiffness and pain.

5. Healthy diet

Beside physical activity and strength training and flexibility, healthy diet is recommended to improve your health and reduce the risk of heart disease.

What do you know about the Eatwell plate?

The Eatwell plate (shown below) highlights the different types of food that make up our diet, and shows the proportions of each we should eat to have a well-balanced and healthy diet.

The Eatwell plate is designed to make healthy eating easier by getting the correct amount of nutrients – protein, fat, carbohydrates, vitamins and minerals you need to maintain good health.

We take in too many calories from food and drink that are high in fat, sugar and salt. They provide very little of the essential vitamins and minerals your body needs. Limiting these is essential for healthy eating. Based on the Eatwell plate, try to eat: Plenty of fruit and vegetables**,** wholegrain varieties,

lower-fat milk and dairy foods, some meat, fish, eggs, beans and other non-dairy sources of protein and a small amount of foods and drinks that are high in fat or sugar.

The Eatwell Plate

Healthy eating involves:

•Plenty of bread, rice, potatoes, pasta and cereals – going for the wholegrain varieties whenever you can.

•Plenty of fruit and vegetables.

•Some skimmed or1 %milk, low fat or non-fat cheese and yoghurt.

•Some meat, poultry, eggs, beans and nuts.

•A very small amount of fats and oils.

•And a very small amount, or even better none, of food and drinks high in fat, sugar and salt.

Helpful resources:

http://www.arthritisresearchuk.org/arthritis-information.aspx

Start active stay active (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216370/dh_128210.pdf).

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