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A pilot feasibility study of a randomized controlled trial of goal setting using the Values in Action Inventory of Strengths following brain injury

AND

Clinical Research Portfolio

Jessica Wainman-Lefley, M.A (Hons) Psychology, PhD

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

Institute of Health and Wellbeing
College of Medicine, Veterinary and Life Sciences
University of Glasgow

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Jessica Wainman-Lefley

Chapter 1 Systematic review

Chapter 1: SYSTEMATIC REVIEW

A systematic review of studies evaluating goal-setting methods in rehabilitation settings

Jessica Wainman-Lefley[1]*

[1] Mental Health and Wellbeing, Institute of Health and Wellbeing, University of Glasgow

***Correspondence Address:**

Mental Health and Wellbeing
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
G12 0XH
E-mail: jessica.wainman-lefley@ggc.scot.nhs.uk

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Abstract

Background

Goal-setting is considered a key component of rehabilitation. Despite this, there is sparse agreement regarding the best procedures for goal-setting, nor how to measure its effects.

Aims

To evaluate the effectiveness of goal-setting interventions in rehabilitation settings, and investigate the methodological quality of the evidence, the varying methods for setting goals, and how effectiveness is measured.

Method

Four databases were systematically searched. Interventions that compared a goal-setting intervention with a control intervention, and measured rehabilitation outcomes, were included. Eleven papers were identified. The Physiotherapy Evidence Database-PsycBITE Scale for randomised and non-randomised controlled trials (Maher et al., 2003) was used to rate the methodological quality of papers.

Results

The eleven papers varied in country, sample size, and study setting; with a mix of neurological, non-neurological physical, and psychiatric rehabilitation. Four studies met criteria for low risk of bias. There was inconsistency in the methods of the goal-setting intervention, including any pre or post goal-setting strategies to increase engagement. There was also variability in the control intervention, and rehabilitation outcomes measured, making the synthesis of this evidence challenging. Nonetheless, there was moderate evidence for benefits of increased involvement to self-efficacy and goal attainment, specifically in non-neurological physical rehabilitation. Overall, there was limited evidence that goal-setting interventions improve other rehabilitation outcomes, particularly in neurorehabilitation settings.

Conclusions

Results demonstrate limited evidence for the effectiveness of specific goal-setting interventions in rehabilitation settings. The evidence is restricted by varying approaches to goal-setting interventions, and study limitations in the existing literature, which future research can amend.

Keywords: rehabilitation, goal-setting, goal planning, engagement, function

Word count: 248

Introduction

The focus of rehabilitation is to support people to learn strategies to overcome or manage physical, cognitive, and emotional difficulties arising from health conditions, to enable them to accomplish life goals and engage in personally meaningful activities. Policy makers are encouraging healthcare towards a more person-centred approach, including involving patients in decisions about their treatment (Coulter and Collins, 2011, Smith, 2010). An opportunity to involve patients in decision-making in rehabilitation is during the process of setting goals. Goal-setting is the selection of, and agreement on, an objective, which the client and rehabilitation team will work collaboratively towards over a specified timeline (ISW, 2012). It is widely acknowledged as an integral part of rehabilitation (Wade, 2009), and Evans (2012) argued that goal-setting is a form of clinical intervention in the rehabilitation process. Goal-setting is used to increase patients' sense of autonomy, satisfaction, and motivation to engage in rehabilitation programmes, and has been shown to have positive impacts on patients' health and wellbeing (Rosewilliam et al., 2011). It can also assist in task performance and teamwork (Levack et al., 2006a). Despite this, there remains a lack of agreement about what strategies would constitute 'gold standard' goal-setting procedures.

Previous systematic reviews of this area are now dated, and have been limited by the quality of papers published at the time (Levack et al., 2006b), in their lack of evaluation of the varying levels of participant involvement in goal-setting and their effects on rehabilitation outcomes (Levack et al., 2015), or have evaluated only a specific goal-setting method (Rose et al., 2017). There remains a need for an up-to-date review of all goal-setting methods in the rehabilitation literature, focusing on studies that have used a randomised or non-randomised controlled trial (RCT) design to evaluate more rigorously the effectiveness of goal-setting interventions.

Present review

The present review aimed to identify and synthesise studies that have evaluated the impact of goal-setting on rehabilitation outcomes.

Objectives

To evaluate:

1. The effectiveness of goal-setting interventions in rehabilitation settings.

2. The methodological quality of available evidence on this topic.

3. How the included studies tried to improve goal-setting in rehabilitation settings.

4. How the included studies measured effectiveness of the goal-setting intervention.

Methods

Eligibility criteria

Participants/ setting

Studies were limited to rehabilitation settings, regardless of diagnosis. The definition of rehabilitation used was the World Health Organization (2011): "a set of measures that assist individuals, who experience or are likely to experience disability, to achieve and maintain optimum functioning in interaction with their environments". Searches for studies in a rehabilitation setting included physical, cognitive, and emotional needs, and participants were of all ages.

Intervention

Studies that evaluated the effects of goal-setting interventions were included. The method of the goal-setting interventions could take any form. Studies were only included if rehabilitation interventions following goal-setting were comparable between groups.

Comparators

The review included studies that investigated rehabilitation outcomes with a goal-setting intervention compared to a control goal-setting intervention, usually 'goal-setting as usual'.

Outcome

Only studies that reported quantitative outcome measures, which reflect rehabilitation outcomes were included. Studies that only reported qualitative outcomes were excluded.

Study Design

Included study designs were RCTs and non-randomised controlled trials (non-RCT). Studies were excluded if they were not published in English, as were reviews, dissertations, conference abstracts, and book chapters.

Search strategy

The following electronic databases were searched from inception until 2nd February 2019: CINAHL, Medline (Ovid), Embase (Ovid), and psycINFO via the University of Glasgow library online services (http://eleanor.lib.gla.ac.uk/search~S0/y). The search strategy used for all databases is available in appendix 1.2.

After the initial search, duplicate articles were deleted using EndNote software (http://endnote.com/). The references of these articles were hand searched for any additional articles. Of the remaining articles, titles were screened to exclude irrelevant papers, followed by abstracts, and finally full texts (figure 1). Attempts were made to contact study authors for clarification of study methods as required. A second independent person rated the selection of studies at full-text for inclusion, in order to assess inter-rater reliability.

Rating of Methodological Quality

The methodological quality rating tool used was the Physiotherapy Evidence Database-PsycBITE (PEDro-P: appendix 1.3) Scale for RCTs and non-RCTs (Maher et al., 2003, Murray et al., 2013, Tate et al., 2004). It consists of 11 items; criterion 1 related to external validity and does not count toward the final quality rating. Criteria 2-9 assess internal validity and criteria 10-11 assess the interpretability of the findings. An information sheet with details about each criterion (appendix 1.3) accompanies the scale. The binary (yes = 1, no = 0) answers to criteria 2-11 are summed to give a quality score from 1 to 10, where increasing scores reflect higher quality. Studies are in the high quality, low risk of bias range for scoring 6 or more out of 10, and in the poor quality, high risk of bias range for scoring 5 or less (Maher, 2000).

The author and a second rater rated 50% of the papers to establish inter-rater reliability of the quality scores. There was 97% agreement across all the checklist items in the methodological quality rating tools, indicating adequate reliability. Differences in opinion were resolved through discussion.

The findings of a paper were judged as positive if the intervention arm demonstrated statistically significant benefits to rehabilitation outcomes from the control arm, neutral if there were no significant differences between groups, and negative if the control arm reported significant benefits compared to the intervention arm. Evidence was deemed strong when multiple high quality and low risk of bias papers produced generally consistent findings. Moderate evidence was demonstrated when generally consistent findings occurred in multiple low quality or one high quality paper and one or more low quality papers. Evidence was judged as being limited if it was only demonstrated in one paper, or if findings from multiple papers were inconsistent (Guzmán et al., 2001).

Results

Study selection

Figure 1 is the flowchart showing details of the search process and results.

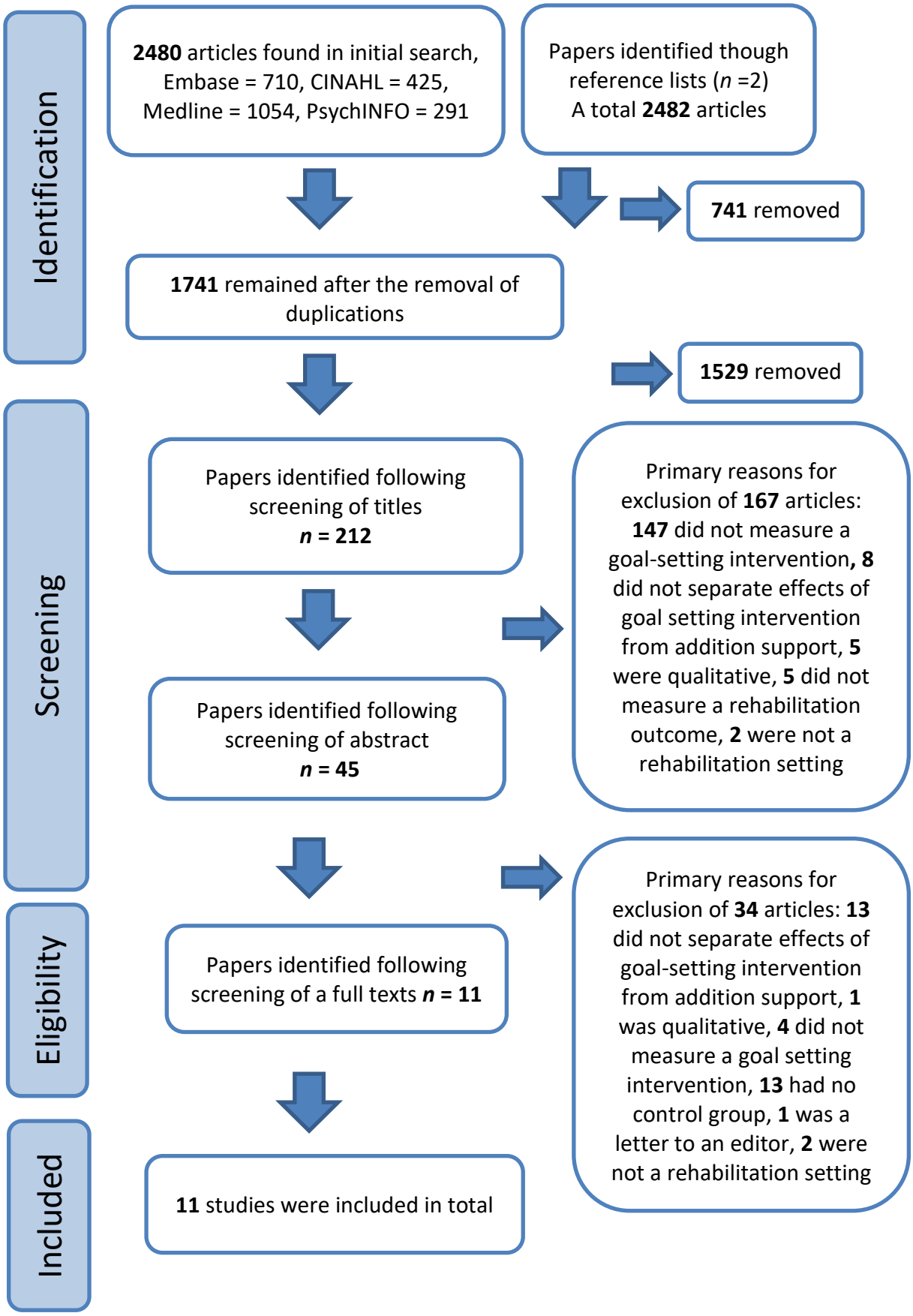

Figure 1: Flowchart of the study selection process and results for inclusion in the systematic review

Study characteristics

Eleven papers were identified; a detailed description of the included papers is given in appendix 1.4. Four studies were conducted in the UK (Coppack et al., 2012, Dalton et al., 2012, Evans and Hardy, 2002, Holliday et al., 2007), one in New Zealand (Taylor et al., 2012), one in Hong Kong (Cheng, 2018), three in Sweden (Arnetz et al., 2004, Vroland-Nordstrand et al., 2016, Wressle et al., 2002), one in Japan (Ogawa et al., 2016), and one in the USA (Willer and Miller, 1976).

Four studies took place in a non-neurological physical rehabilitation setting (36%), four in a neurological setting (36%), two in a mix of neurological and physical settings (19%), and one in a psychiatric setting (9%). Overall, the studies examined 859 participants; 98% were adults, and 2% children.

Quality of the evidence

Table 1 displays the results of the methodological quality scores. Four studies scored in the high quality, and seven in the poor quality range. One paper lacked the additional measure of external validity (Willer and Miller, 1976). Only one study (Evans and Hardy, 2002) scored a point for blinding the therapists who were conducting the intervention. By contrast, the most common (91%) criteria fulfilled was reporting between intervention group statistical comparisons for at least one key outcome. One paper did not fulfil this criteria, however as a feasibility study, it is not appropriate for such a design to perform this analysis (Taylor et al., 2012).

Table 1: Methodological quality scores in descending order using the PEDro-P rating scale

	1 external validity	2	3	4	5	6	7	8	9	10	11	Total of 2-11 (%)
Coppack *et al.* (2012)	✓	✓	✓		✓		✓	✓	✓	✓	✓	**80**
Vroland-Nordstand *et al.* (2016)	✓	✓	✓	✓			✓	✓	✓	✓	✓	**80**
Evans and Hardy (2002)	✓	✓	✓	✓	✓	✓	✓			✓	✓	**80**
Arnetz *et al.* (2004)	✓	✓	✓	✓				✓	✓	✓	✓	**70**
Ogawa *et al.* (2016)	✓			✓				✓	✓	✓	✓	**50**
Dalton *et al.* (2012)	✓			✓	✓			✓	✓	✓		**50**
Willer & Miller (1976)		✓						✓	✓	✓		**40**
Holliday *et al.* (2007)	✓			✓					✓	✓		**30**
Cheng *et al.* (2018)	✓			✓					✓	✓		**30**
Taylor *et al.* (2012)	✓						✓	✓			✓	**30**
Wressle *et al.* (2002)	✓								✓	✓		**20**
% of total	**91**	**45**	**36**	**64**	**25**	**9**	**36**	**64**	**82**	**91**	**55**	

SCORE OF EXTERNAL VALIDITY: 1 = eligibility criteria SCORES OF INTERNAL VALIDITY: 2 = random allocation, 3 = concealed allocation, 4 = comparable baseline characteristics between groups, 5 = subjects blinded, 6 = therapists blinded, 7 = assessors blinded, 8 = an outcome measured for at least 85% of allocated subjects, 9 = all subjects with outcome measure data received allocated condition, otherwise data analysed by 'intention to treat', SCORES OF INTERPRETABILITY OF THE FINDINGS: 10 = between group analysis reported, 11 = point measure and measures of variability reported for key outcomes.

The effectiveness of goal-setting interventions

Table 2 displays the findings of each paper; goal-setting intervention effects on rehabilitation outcomes varied, including within papers. Two papers reported significant benefits to all rehabilitation outcomes measured (Arnetz et al., 2004, Evans and Hardy, 2002), two reported no benefits of the intervention (Dalton et al., 2012, Vroland-Nordstrand et al., 2016), and seven reported a mixture of benefits and no benefits. Within the high quality papers, results varied from finding benefits (Arnetz et al., 2004, Evans and Hardy, 2002), no benefits (Vroland-Nordstrand et al., 2016), to mixed results (Coppack et al., 2012). No studies reported significant benefits to the control group compared to the experimental group. Heterogeneity of effectiveness did not clearly relate to study quality/risk of bias.

Study design

Sample sizes ranged from 32 to 201. One study was reported as being a pilot feasibility study (Taylor et al., 2012), and was therefore not designed to detect statistically significant differences between groups. The study designs of the papers included 45% randomised controlled trials (RCT) 55% non-RCT (appendix 1.4). Study design did not appear to explain the variability in findings amongst papers.

Setting

A paper reporting benefits to all rehabilitation outcomes measured from the goal-setting intervention was set in non-neurological physical rehabilitation units (Arnetz et al., 2004), and the two papers reporting a lack of benefits were set in neurological rehabilitation units (Vroland-Nordstrand et al., 2016, Dalton et al., 2012). The remaining papers that found a mix of benefits and no benefits were in the following settings: non-neurological physical rehabilitation (Cheng, 2018, Coppack et al., 2012, Evans and Hardy, 2002), neurological rehabilitation (Holliday et al., 2007), psychiatric rehabilitation (Willer and Miller, 1976), and a mix of neurological and physical rehabilitation (Wressle et al., 2002, Ogawa et al., 2016).

Table 2: Findings of the included papers

Author	Measure used	Exp group	Control group	Outcome
Arnetz *et al.* (2004)	1. Goal achievement 2. Patients' subjective rating of the quality of care.	*N* = 39 N = 77 not specified by group	*N* = 38	1. The experimental group were more likely to achieve success for balance, strength, and range of motion than controls. 2. The experimental group gave higher ratings for the quality of their physical therapist and the physical therapy.
Cheng *et al.* (2018)	1. Goal achievement. 2. Perceived functional disability. 3. Perceived functional health status. 4. Perceived self-efficacy in self-managing chronic illness. 5. Patient satisfaction in goal setting.	*N* = 35	*N* = 25	1. The experimental group achieved a higher percentage of their goals. 2. No significant difference between groups. 3. No significant difference between groups. 4. No significant difference between groups. 5. No significant difference between groups.
Coppack *et al*. (2012)	1. Adherence to rehabilitation. 2. Self-efficacy. 3. Treatment efficacy. 4. Treatment outcome: the modified Biering-Sorensen test.	*N* = 16	*N* = 16	1. No significant difference between groups. 2. Self-efficacy was significantly higher in the experimental group. 3. No significant difference between groups. 4. No significant difference between groups.
Dalton *et al.* (2012)	1. Numbers of goals set. 2. Number of goals achieved. 3. Barthel Index. 4. Functional Independence Measure.	*N* = 54	*N* = 51	1. The experimental group set significantly more goals. 2. No significant difference between groups. 3. No significant difference between groups. 4. No significant difference between groups.
Evans and Hardy (2002)	1. Treatment adherence. 2. Self-efficacy. 3. Athletes' emotional responses to injury.	*N* = 13	*N* = 13	1. The intervention resulted in a significant increase in self-report treatment adherence, but not psychotherapist's estimate of adherence. 2. The intervention resulted in higher levels of self-efficacy. 3. *No group comparison reported for this outcome.*
Holliday *et al.* (2007)	1. Patients' perceptions of the relevance of goal set. 2. Patients' perceptions of their participation in the process. 3. Types of goals set. 4. Outcome of goals. 5. Duration of stay. 6. Satisfaction with goal setting. 7. Functional Independence Measure. 8. London Handicap Scale. 9. General Health Questionnaire- 28.	*N*= 101	*N* = 100	1. Experimental group perceived goals to be more relevant. 2. Experimental group reported greater autonomy. 3. Experimental group set more participation goals. 4. No significant difference between groups 5. No difference between groups. 6. Experimental group reported greater satisfaction. 7. No significant difference between groups. 8. No significant difference between groups. 9. No significant difference between groups.
Ogawa *et al.* (2016)	1. Hospital Anxiety and Depression scale. 2. General Health Questionnaire -28. 3. Pittsburgh Rehabilitation Participation scale. 4. Functional Independence Measure.	*N* = 22	*N* = 22	1. Anxiety was significantly lower in the experimental group. 2. No significant difference between groups 3. Treatment engagement was significantly higher in the experimental group. 4. No significant difference between groups.

	5. Patient Participation scale in goal setting.			5. No significant difference between groups.
Taylor *et al*. (2012)	1. Quality of life at 12 weeks using the Schedule for Individualised Quality of Life. 2. Functional Independence Measure. 3. Short Form 36. 4. Satisfaction with Rehabilitation. 5. Duration of stay.	*N* = 21	*N* = 17	This paper did not plan to, or conduct between group analyses, due to the pilot and feasibility design of the study. Nonetheless, the confidence intervals reported in the results show no indication of an effect of the goal setting intervention, with this sample size.
Vroland-Nordstand *et al.* (2016)	1. Programme adherence. 2. Goal attainment. 3. Types of goals set.	*N* = 17	*N* = 15	1. No significant difference between groups. 2. No significant difference between groups. 3. The parents mainly identified goals around activities of daily living (ADL), whereas the children's goals were more varied and concerned ADL, leisure, and schoolwork.
Willer & Miller (1976)	1. Client and therapist rating of goal attainment. 2. Satisfaction with rehabilitation. 3. Perceived functional ability. 4. Duration of stay.	*N* = 15	C1 *N* = 21, C2 *N* = 23, C3 *N* =13	1. The experimental group led to higher goal attainment scores for both client and therapist. 2. The experimental group showed higher ratings of satisfaction. 3. No significant difference between groups 4. No significant difference between groups.
Wressle *et al*. (2002)	1. Satisfaction with rehabilitation. 2. Memory for goals. 3. The Klein-Bell Activities of Daily Living Scale. 4. The Clinical Outcome Variables Scale.	*N* = 88	*N* = 30	1. No significant difference between groups. 2. The experimental group had a better memory for goals. 3. The experimental group had higher improvement on the Klein-Bell Activities of Daily Living Scale. 4. No significant difference between groups.

Red = no statistically significant difference between groups, green = experimental group showed a statistically significant benefit, white = not a rehabilitation outcome

Measure of effectiveness of the goal-setting interventions

Table 3 displays the outcome measures used in the included papers. This review is interested in rehabilitation outcomes, however it was noted that nine studies (82%) measured further process outcomes of rehabilitation (range = zero to four, median = one; table 3). Rehabilitation outcome measures were diverse in type and number; ranging from one to five (median = three).

One of the most common outcome measures was goal attainment (*n* = 6). One high quality paper demonstrated significant benefits to goal attainment following a goal-setting intervention in an adult population (Arnetz et al., 2004), whereas Vroland-Nordstrand et al. (2016) found no benefits in a child population. The low quality papers all used adult populations, with some finding evidence for benefits to goal attainment (Cheng, 2018, Willer and Miller, 1976), and others showing a lack of evidence (Dalton et al., 2012, Holliday et al., 2007). Interestingly, all the papers that found no benefits to goal attainment were set in neurological rehabilitation, whereas the benefits were identified in non-neurological physical and psychiatric rehabilitation.

Six papers measured physical functioning, yet specific measures within this outcome varied amongst studies. The only paper to find benefits was a low quality paper that found the experimental group had higher improvement scores on the Klein-Bell Activities of Daily Living Scale (Wressle et al., 2002). The lack of repeated use of this measure limits comparison, and thus provides limited evidence for the link between goal-setting interventions and improved physical functioning.

A variety of psychosocial outcomes was used. Where significant results were reported, there was moderate evidence for improvements to self-efficacy in non-neurological physical rehabilitation settings (Evans and Hardy, 2002, Coppack et al., 2012). Arnetz et al. (2004) found significantly higher subjective rating of the quality of treatment, however this was the only paper to measure this. There was no evidence for benefits to perceived functioning or treatment efficacy, and little evidence of benefits to emotional functioning; only one low quality paper reported reduced anxiety (Ogawa et al., 2016). Similarly, there was weak evidence that goal-setting interventions increased participants' satisfaction with rehabilitation or the goal-setting process, with papers reporting contradictory findings. Taylor et al. (2012) was the only paper to measure quality of life, with no evidence of effects from a goal-setting intervention, however no strong conclusions can be drawn from this feasibility paper.

Goal-setting interventions

Compared with the control goal-setting, the intervention group in every paper had additional actions, at different steps of the goal-setting procedure, which increased participants' involvement (table 4).

Preparation for goal-setting

Whether the goal-setting intervention included any preparation varied (table 4). Two studies did not include any preparation, with one still finding improvements to ratings of self-efficacy, (Evans and Hardy, 2002) and the other finding mixed results (Willer and Miller, 1976). Of the remaining papers, the number of preparations for goal-setting ranged from one to three. There was contradictory evidence that the most common preparation (participants define their current problems or level of functioning) improved rehabilitation outcomes; including amongst the high quality papers alone (Arnetz et al., 2004, Coppack et al., 2012, Vroland-Nordstrand et al., 2016).

Arnetz et al. (2004) also used a structured goals checklist to focus participants to goals for treatment, and had the health professional complete the same goal checklist with their summary of goals. This combination may have contributed to the experimental group achieving significantly more goals and reporting a higher rating of quality of care. Coppack et al. (2012) also asked participants to define their strengths and prioritise areas of work, and found improvements to ratings of self-efficacy. However, they found no effect for treatment efficacy or outcomes. In Vroland-Nordstrand et al. (2016) the only preparation was to ask participants to define their level of functioning from picture cards (Perceived Efficacy and Goal-Setting System), and found no benefit to goal attainment. Evidence from the low quality studies differed in using the following pre goal-setting preparations: participants defining areas of goal priorities, their strengths, having the goal process described in advance, predicting outcome at discharge, and identifying goals from a structured tool (e.g a Goal Register).

Table 3: Characteristics of outcomes measured in included papers

Papers	Outcome measures: Rehabilitation outcomes: Goal attainment	P subjective rating of quality of treatment	Perceived functioning	Physical functioning	Emotional functioning	Satisfaction	Self-efficacy	Treatment efficacy	Quality of life	Total per paper	Process outcomes: Number of goals	Adherence with treatment	P Participation in GS	Relevance of goals	Types of goals set	Duration of stay	Memory for goal	Total per paper	Total number of outcomes per paper
1. Arnetz *et al.* (2004)	X	X								**2**								**0**	**2**
2. Cheng *et al.* (2018)	X		x[1, 2, 3]			X[16]				**5**								**0**	**5**
3. Coppack *et al.* (2012)				X[11]			X	X		**3**		X						**1**	**4**
4. Dalton *et al.* (2012)	X			X[6, 7]						**3**	X							**1**	**4**
5. Evans and Hardy (2002)					X[13]		X			**2**		X						**1**	**3**
6. Holliday *et al.* (2007)	X			X[6, 8]	X[14]	X[16]				**5**			X	X	X	X		**4**	**9**
7. Ogawa *et al.* (2016)				X[6]	X[12, 14]					**3**		X	X					**2**	**5**
8. Taylor *et al.* (2012)			X[4]	x[6]		x[15]			X	**4**						x		**1**	**5**
9. Vroland-Nordstand *et al.* (2016)	X									**1**		x			x			**2**	**3**
10. Willer & Miller (1976)	X		X[1]			X[15]				**3**						X		**1**	**4**
11. Wressle *et al.* (2002)				X[9, 10]		X[15]				**3**							X	**1**	**4**
Frequency	**6**	**1**	**3**	**6**	**3**	**5**	**2**	**1**	**1**		**1**	**4**	**2**	**1**	**2**	**3**	**1**		

Note: P = patient, X = primary outcome, x = secondary outcome (if specified), [1] perceived functional ability, [2] perceived functional health status, [3] perceived self-efficacy in self-managing illness, [4] The 36-Item Short Form Survey, [6]The Functional Independence Measure, [7] The Barthel Index, [8] The London Handicap Scale, [9] The Klein-Bell Activities of Daily Living Scale, [10] The Clinical Outcome Variables Scale, [11] The modified Biering-Sorensen test, [12] The Hospital Anxiety and Depression Scale, [13] Athletes' emotional responses to injury, [14] The General Health Questionnaire-28, [15] Satisfaction with rehabilitation, [16] Satisfaction with goal setting process

This contradictory evidence indicates that the research lacks strong evidence that using methods to prepare participants for goal-setting led to benefits in rehabilitation outcomes.

Goal-setting intervention

The number of strategies for goal selection ranged from one to three (table 4). The most common method was to have a collaborative goal-setting discussion between the participant and a health professional (64%), increasing participants' involvement in the goal-setting process.

Evaluating evidence from the high quality papers, two studies adopted the collaborative discussion. Arnetz et al. (2004) found the experimental group achieved significantly more goals and higher ratings of quality of care, and Evans and Hardy (2002) found higher rates of self-efficacy. The other two high quality papers did not use a collaborative discussion approach, and found mixed effects on rehabilitation outcomes using a goal scaling calculation (Coppack et al., 2012), or no benefits using a picture book to select goals (Vroland-Nordstrand et al., 2016). This pattern shows more person-centred goal planning may lead to benefits to rehabilitation outcomes. There was some evidence from the low risk papers that this method lead to improvements in some rehabilitation outcomes; whereas others demonstrated no benefits (Dalton et al., 2012, Taylor et al., 2012).

Further to Vroland-Nordstrand et al. (2016), Dalton et al. (2012) also found no benefits to rehabilitation outcomes resulting from the use of strategies to focus goal selection. However Cheng (2018) had their participants select goals from a Goal Register, and Wressle et al. (2002) used the Canadian Occupational Performance Measures to enable participants to select goals around self-care, productivity and leisure areas, and both found benefits. These strategies appear to help focus the participant's goal selection to a rehabilitation context relevant goal, whilst empowering participants to choose their goals. Alas, the contradictory evidence indicates limited evidence for its use in enabling participates to select their own goals.

Similar to Coppack et al. (2012), two low quality papers found mixed support for the use of setting goals by linking them to predicted outcomes. Ogawa et al. (2016) found when participants' goals were set by therapists linking them to participants' prioritised results on a Life Goals questionnaire, treatment outcomes improved. Whilst Cheng (2018) found higher rates of goal achievement when participants selected goals from a Goal Register, which were then constructed into goal statements, specifying expected outcome levels for a particular health problem. These strategies appear to incorporate the values and

priorities of the participant into the goal choice, whilst in Cheng (2018), combining them with expected outcome to constrain them to realistic outcomes. Nevertheless, these studies also found no benefits to other rehabilitation outcomes measured.

There is limited evidence for the use of strategies that lead to goal-setting being engaging, personal, collaborative, and somewhat structured to assist participants to select their own goal. Direct comparison is difficult owing to variations in outcome measures, and goal-setting conditions.

Strategies to increase engagement in goal pursuit

Use of strategies to increase engagement in goal pursuit (the act of striving towards a desired end state) was limited to five papers (table 4). Coppack et al. (2012) ranked the importance of goals after they were set, and also compared them to an expected performance profile, demonstrating benefits to self-efficacy. Arnetz et al. (2004) also ranked goals and found positive effects to rehabilitation outcomes. Of the low quality papers, Cheng (2018) asked participants to sign a goal agreement, and found higher goal achievement, and Dalton et al. (2012) had a family member or a health professional present at the collaborative goal-setting discussion, but found no benefits to goal achievement, or physical functioning. Ogawa et al. (2016) also asked participants to rank the importance of goals and found mixed results. It would seem from the contrasting results of papers that there is limited evidence that strategies to increase engagement in goal pursuit lead to improved rehabilitation outcomes.

Post goal-setting strategies to improve outcomes

Eight papers included post goal-setting strategies to improve outcomes through maintenance of focus on goals, ranging from one to three strategies (appendix 1.5). Interestingly, a high quality paper reporting no benefits to all outcomes measured did not use such strategies (Vroland-Nordstrand et al., 2016). Other low quality papers that also did not include these strategies found mixed results (Willer and Miller, 1976, Wressle et al., 2002). Of the remaining high quality papers that did use these strategies, Arnetz et al. (2004) documented goals for participants, and set a time frame for achievement. Two others found mixed results when documenting goals (Evans and Hardy, 2002, Cheng, 2018). The most common strategy was to review the goals and/ or repeat the goal-setting (n = 4). These papers found mixed results regardless of quality. The remaining strategies were only evidenced once, and lead to mixed benefits to rehabilitation outcomes (table 2). There appears to be limited evidence for using strategies post goal-setting to improve outcomes, yet this comparison is limited by varying outcome measures and methods.

Table 4: Characteristics of the goal-setting interventions in the experimental groups of the included papers

Papers	Goal-setting intervention characteristics															
	Preparation for goal setting								Goal selection			Strategies to increase engagement in goal pursuit				
	P define current problems/ level of functioning	P define goals using structured format	HP gives their opinion	G-S process described to P	Strengths of P identified	Predict outcome at discharge	Identify Life Goals	P prioritise areas of work/ goal	Collaborative discussion to set goal between P and HP	Strategies for P to select goals	By linking to benefit of goal completion	Sign goal agreement	Performance profile	Rank importance of goals	Family/ carer/ HP present	Total
1. Arnetz *et al.* (2004)	X	X	X						X					X		**5**
2. Cheng *et al.* (2018)		X		X		X				X[4]	X[8]	X				**6**
3. Coppack *et al.* (2012)	X				X			X			X[9]		X	X		**6**
4. Dalton *et al.* (2012)	X					X			X	X[5]					X	**5**
5. Evans and Hardy (2002)									X[3]							**1**
6. Holliday *et al.* (2007)				X				X[1]	X							**3**
7. Ogawa *et al.* (2016)							X	X			X[10]			X		**4**
8. Taylor *et al.* (2012)	X	X							X	X[6]						**4**
9. Vroland-Nordstand *et al.* (2016)	X									X[7]						**2**
10. Willer & Miller (1976)									X							**1**
11. Wressle *et al.* (2002)	X	X							X	X[6]						**4**
Frequency	**6**	**4**	**1**	**2**	**1**	**2**	**1**	**3**	**7**	**5**	**3**	**1**	**1**	**3**	**1**	

Note: G-S = goal-setting, P = participant, [1] Using a workbook, [2] What participant desired and health professional thought realistic, [3] Negotiated between participant and health professional, [4] Goal menu, [5] 21 impairment, activity and participation functional goal domains, also Speech & Language support available, [6] Canadian Occupational Performance Measure, [7] The Perceived Efficacy and Goal-Setting System pictures of daily tasks, [8] Link goal to health, [9] Link goals to priorities and current health, [10] health professional set goals based of participant's Life goal questionnaire results. Full description of characteristics in appendix 1.5.

Control group intervention

Overall, the control group of every paper involved participants less in goal-setting; table 5 shows further descriptions.

Table 5: Characteristics of control interventions*

	Goals set by others and P made aware of goal	Goals set by others but P not aware of goal	Goals set by team and verbally agreed with P	Non-structured G-S	Non-structured G-S and verbally agreed with P	No goal	Total no. of control interventions*
1. Arnetz *et al.* (2004)					X		**1**
2. Cheng *et al.* (2018)	X[1]						**1**
3. Coppack *et al.* (2012)				X			**1**
4. Dalton *et al.* (2012)			X				**1**
5. Evans and Hardy (2002)	X[1]						**1**
6. Holliday *et al.* (2007)			X				**1**
7. Ogawa *et al.* (2016)				X		X	**2**
8. Taylor *et al.* (2012)				X			**1**
9. Vroland-Nordstand *et al.* (2016)	X[2]						**1**
10. Willer & Miller (1976)	X[1]	X				X	**3**
11. Wressle *et al.* (2002)	X[1]						**1**
Frequency	**5**	**1**	**2**	**3**	**1**	**2**	

Note: P = participant, G-S = goal-setting [1] by health professionals, [2] by parents of the participant, * total number of control interventions for which effects of intervention could be compared. If this was not possible, this review excluded the comparison of some control interventions (see table 9, appendix 1.4 for details)

There were no similarities in characteristics in control interventions in the high quality papers that found benefits to all rehabilitation outcomes measured (Arnetz et al., 2004, Evans and Hardy, 2002). In addition to Evans and Hardy (2002), three low quality papers had their control group goals set by a health professional and found a mix of benefits and no benefits to their experimental goal-setting intervention (Cheng, 2018, Wressle et al., 2002, Willer and Miller, 1976). One high quality paper that did not find any benefits to rehabilitation outcomes had the goals of their control intervention set by the parents of the child participants (Vroland-Nordstrand et al., 2016). This was the only study to have control intervention goals set by family members, and it might be that goals decided by parents are likely to be similar to those important to the children due to shared interests and time spent together. This may be a strength of this design, because it is more likely to control for the main intervention factor of interest, the effect of participant' autonomy and involvement in goal-setting.

There was little overlap in the remaining papers in the specific designs of the control goal-setting intervention, other than generally less involved than the intervention group. Despite this, where similar procedures were used, results of studies varied. Consequently,

there is little evidence that differences in study findings are explained alone by increased levels of participation in goal-setting in the intervention group.

Discussion

The aims of this review were to identify and describe the goal-setting interventions used in rehabilitation settings, and to examine the effectiveness of goal-setting interventions, taking into account the methodological quality of the evidence. Eleven articles contributed to the findings.

There was some overlap in rehabilitation outcomes measured, with moderate evidence of benefits from goal-setting interventions to self-efficacy and goal attainment. Interestingly, these outcome measures are used across different rehabilitation settings, therefore it is likely that this conclusion can be drawn because of repeated findings in the literature. This highlights a limitation of the remaining literature, in the variability of the rehabilitation outcomes measured, which inhibit cross-study comparison, and inevitably, the development of an evidence base of the effectiveness of goal-setting interventions. No evidence of benefits to physical or emotional functioning were found.

Studies set in non-neurological physical and psychiatric rehabilitation showed more benefits of goal-setting interventions than neurological rehabilitation. This might be explained by the heterogeneous sequelae for neurological rehabilitation patients (Wilson et al., 2009), which may make goal-setting and rehabilitation generally more complex than other settings. More research into goal-setting interventions is required in this specific population.

The goal-setting interventions all included some level of increased participation and engagement; however, they varied vastly in method. Overall, moderate to weak evidence exists that prior knowledge of the goal-setting process, asking participants to define their current functioning or problem, and asking them to prioritise goals positively effects rehabilitation outcomes. There was weak to moderate evidence that a collaborative approach during goal-setting that was more person-centred to participants' values and priorities helped increase participants' rating of quality of care and satisfaction. This review also found moderate evidence that documenting goals for participants and setting a time frame for goal achievement after setting goals led to some benefits in rehabilitation outcomes, however the general practice of using post goal-setting strategies to improve outcomes was poorly reported. Further, there was variation in the conditions of the comparison group, which inevitably made it impossible to unpick the

varying effects of the additional levels of participation in the intervention in the experimental groups.

Generally, evaluation of the evidence from this literature is restricted by the variation in design, settings, methods, and outcome measures. Future studies can assist this by replicating and therefore strengthening the current evidence base in terms of goal-setting procedures (e.g. person-centred, knowledge, increased participation, documenting goals, time frames), control intervention procedures, considering a high quality study design, and by using outcome measures that are applicable across all rehabilitation setting (e.g. goal attainment).

Overall completeness and applicability of the evidence

This review did not restrict papers by country, and included participants of any age undergoing rehabilitation for a wide range of health conditions. The search strategy was restricted by study design to enable closer comparison of study findings. Single case studies exist that may contribute to the evidence base of effectiveness of goal-setting interventions. This review did not find high quality evidence; thus, the depth of the analysis was limited, and the review questions may only be partially answered.

Quality of the evidence

The risk of bias ratings demonstrate diversity across the included papers. Whilst blinded RCTs may be the gold standard, it remains a challenge to conduct this design in a rehabilitation setting. For example, in-house staff are typically involved in goal-setting and long-term rehabilitation work with patients, and so it is difficult to blind the therapists to group allocation. Yet one study was able to do this (Evans and Hardy, 2002), so although challenging, with enough planning and funding, it is possible. The sample sizes were also generally quite small, and future trials should plan to maximise recruitment and retention of participants.

Potential biases in this review

The PEDro-P scale has limitations, for example it has been shown to have poor agreement with other quality scales such as the Cochrane Risk of Bias criteria (Armijo-Olivo et al., 2015). Despite this, it was appropriate for the study designs included. Nonetheless, the nature of the rehabilitation setting meant that some papers lost points for quality that were unavoidable. These papers may still make important contributions to the evidence base. As only one reviewer selected papers for inclusion at title and abstract level, there

is a possibility of eligible studies having been missed. Lastly, the current review focussed on quantitative measures of rehabilitation outcome, and between group comparison studies. A broader scope of papers that include qualitative outcomes may lead to different results to those found here. A strength of the papers included was the high number of reported 'non-significant' results, which reduces the risk of publication bias in this field.

Conclusions

Despite how common the practice of goal-setting in rehabilitation is, this review found few consistencies in methods for increasing patient involvement and engagement before, during, and after goal-setting, with varied outcome measures. Some weak to moderate evidence of benefits (goal attainment and self-efficacy) were found for the effectiveness of goal-setting interventions in non-neurological physical rehabilitation settings. It is uncertain which specific goal-setting interventions improve rehabilitation outcomes for people receiving rehabilitation. The analysis of methodological quality of available evidence revealed limited quality evidence in this field, yet even the evidence from the best quality papers was contradictory. Future studies could improve this by replicating methods and outcome measures.

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Chapter 2 Major Research Project

A pilot feasibility study of a randomized controlled trial of goal setting using the Values in Action Inventory of Strengths following brain injury

Jessica Wainman-Lefley[1*]

[1] **Mental Health and Wellbeing, Institute of Health and Wellbeing, College of Medicine, Veterinary and Life Sciences**

***Correspondence address:**

Mental Health and Wellbeing
Administration building
Gartnavel Royal Hospital
1055 Great western Road
Glasgow
G12 0XH
E-mail: jessica.wainman-lefley@ggc.scot.nhs.uk

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Plain English Summary

Title

Exploring the feasibility of using the Values in Action Inventory of Strengths in the process of goal-setting in an acquired brain injury community rehabilitation setting

Background

There exists no gold standard procedure for setting goals for rehabilitation after brain injury (BI). A person-centred approach to goal-setting is important to motivate and empower clients (Dalton et al., 2012). There is potential to use methods from positive psychology (PP) (the study of positive individual traits, and subjective experience, and how these factors lead to improved quality of life) in BI rehabilitation. The Values in Action Inventory of Strengths (VIA-IS), is a validated tool designed to identify individual's positive traits (Peterson and Seligman, 2004), and may be helpful in assisting goal-setting after BI.

Aims and Questions

To examine the feasibility and acceptability of using the VIA-IS in the goal-setting process for BI rehabilitation, within a randomised controlled trial (RCT) context.

The research questions include:

1. What number of potential participants identified fulfils eligibility criteria?

2. What proportion of potential participants agree to take part?

3. What number of participants can be followed-up at two weeks via telephone call?

4. Is it acceptable to use the VIA-IS during the goal-setting process in a community treatment setting for brain injury?

5. What is the measurement variance for the key outcome measure of memory for goals?

6. Does using the VIA-IS in the goal-setting process cause there to be differences in the categories of goals set compared with the typical method of setting goals?

7. Is it feasible for the assessor to be blind to condition?

What the Study Involved: The study recruited two groups of BI participants from the Community Treatment Centre for Brain Injury (CTCBI). Participants in the VIA-IS group completed the VIA-IS and had the option to use the results to help set goals for rehabilitation. The control group set their goals for rehabilitation as usual, then completed the VIA-IS. Outcomes included the feasibility and acceptability of the VIA-IS and its use in goal-setting based on feedback from BI and CTCBI clinician participants, and whether it affected types of goal set. Memory for goals was measured approximately two weeks after goal-setting, and these data were used to calculate a sample size for a full-scale trial.

Results: We recruited twenty-two BI participants; nine completed the VIA-IS condition and two dropped out, ten completed the control group condition, and one has not yet completed the study. Participants largely found the VIA-IS to be acceptable to complete, providing mixed feedback ranging from positive (it was interesting and enjoyable), to criticisms of the online nature and Americanised language. Participants who did use the VIA-IS to select goals for rehabilitation reported it was helpful, and CTCBI clinicians gave feedback about how it helped to build rapport. There were no obvious large differences in goal category between the groups. Based on the variability of scores for memory of goals, a sample size of 66 was calculated for a full-scale future trial.

Conclusion: Although recruitment was slow, we obtained enough information about the recruitment strategy, and helpful feedback about the study, which will contribute to designs of RCT's in this field. A future RCT in this field might want to identify specific participants who may benefit from additional engagement during the goal-setting stage of rehabilitation.

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Word count: 535

Abstract

Background: There exists no gold standard procedure for goal-setting for rehabilitation after brain injury (BI). A person-centred approach is important to motivate and empower clients (Dalton et al., 2012). Assisting clients to identify personal values and drawing on these when setting goals may increase the personal relevance of rehabilitation goals.

Objective: To determine feasibility and acceptability of using the Values in Action Inventory of Strengths (VIA-IS) during the rehabilitation goal-setting process, and whether this was feasible in the context of a randomised controlled trial (RCT).

Method: In a single-blind feasibility pilot RCT design, BI participants were recruited from a community BI rehabilitation centre and randomised into goal-setting using the VIA-IS, and goal-setting as usual. Outcomes included the feasibility and acceptability of completing the VIA-IS, and its use in setting goals in a BI rehabilitation context, and whether it affected types of goals set, categorised using the International Classification of Functioning (ICF), Disability, and Health activities and participation categories (WHO, 2001). Memory for goals approximately two weeks after goal-setting was measured, and a sample size calculated for a future full-scale trial.

Results: Twenty-two BI participants were recruited, and randomised to the VIA-IS (*n* = 11) and control group (*n* = 10). Two dropped out of the VIA-IS condition prior to completion, and the group allocation of one is unknown due to non-completion of the study, leaving a total *n* = 19. The majority (89%) of participants rated the VIA-IS as acceptable; both groups described the goal-setting process as 'easy'. Feedback ranged from positive (enjoyment, rapport building), to negative (repetitive, too long). Two thirds of the VIA-IS group used their VIA-IS results to set goals and described it as helpful. There were no major differences in ICF categories between groups. Based on the data from this study, a sample size of 66 was calculated for a full-scale trial.

Conclusions: A full-scale trial with multi-centre design appears warranted though may be more clinically beneficial if limited to BI clients who are more difficult to engage.

Keywords: brain injury, goal-setting, goal planning, rehabilitation, positive psychology

Word count: 327

Introduction

People who experience brain injury (BI) can experience a plethora of physical, cognitive, and emotional sequelae, including impaired language, memory, motivation, concentration, planning, and changes in mood and personality (Wilson et al., 2009). The focus of neuropsychological rehabilitation is to support clients to learn strategies to overcome or manage these difficulties and to engage in personally meaningful activities.

Goal-setting is a core component of rehabilitation following BI (Playford et al., 2009). Evans (2012) argued it is an opportunity for clinical intervention in the rehabilitation process. In particular, if clients are actively involved in the goal-setting process, they rate their experience of rehabilitation more positively, and the nature of the goals set as more personally relevant. Currently, there is no defined form that goal-setting should take to be most helpful to BI clients. However, evidence has shown that personal relevance is important, having a motivating and empowering effect on engaging clients in rehabilitation; goals perceived as meaningful increase clients' perception of wellbeing, and improve goal achievement (Malec, 1999, Cheng, 2018, Holliday et al., 2007). Further, survivors of BI often have difficulty in formulating relevant goals for rehabilitation (Sherer et al., 1998), which may be due to impairments in cognitive functioning after BI. There is a need for research to identify effective ways to set goals in neurorehabilitation.

Positive psychology (PP) is the scientific study of positive individual traits, subjective experience, and institutions, and how these factors lead to improved quality of life (Seligman and Csikszentmihalyi, 2014). Evans (2011) emphasised the overlapping focus of PP with neuropsychological rehabilitation following TBI, and the relevance and potential application of PP techniques within this setting. Since then, evidence has shown constructs of PP (resilience, character strengths, and positive mood states) are related to rehabilitation-related variables (perceptions of functional ability, and expectations of treatment); further highlighting the potential application of PP constructs to neurorehabilitation (Bertisch et al., 2014).

The Values in Action Inventory of Strengths (VIA-IS) is a central tool of PP, and is a reliable measure designed to identify individuals' profile of Character Strengths (Peterson and Seligman, 2004). Character Strengths are positive human traits considered to transcend cultures, and research has shown the identification and development of Character Strengths can lead to improvements in enjoyment and engagement of activities (Seligman et al., 2009). It is argued that there are 24 Character Strengths that fall within six value categories: Wisdom (curiosity, creativity), Courage (bravery, honesty), Humanity (love, kindness), Temperance (forgiveness, humility), Justice (leadership, teamwork), and

Transcendence (gratitude, hope). The VIA-IS is not presently utilised during goal-setting in rehabilitation services after BI, however we speculate that if goals are closely linked to personal values, they may be considered more personally meaningful and as a result, better remembered. This in turn may increase engagement with the rehabilitation process.

Given that the VIA-IS is not routinely used in community BI rehabilitation services to aid goal-setting, it is necessary to investigate whether it is feasible and acceptable to use the VIA-IS as part of the rehabilitation goal-setting process linking goals to personal values. To justify administering the VIA-IS, it would need to be demonstrated that it is beneficial over and above usual goal-setting procedures. Therefore, the present study will examine whether it is feasible to evaluate the use of the VIA-IS in the context of a randomised controlled trial (RCT) in which use of the VIA-IS in goal-setting is compared with usual goal-setting practice.

Current study

The purpose of this study was to investigate whether using the VIA-IS aids the experience of goal-setting for BI participants and staff members who facilitate these sessions, and whether it affects the types of goals set and memory for goals two weeks later, above and beyond the current practice. We aimed to measure variance for the key outcome measure (memory for goals), so that we could calculate a sample size for future trial.

Aims and hypotheses

The primary aim of this study was to examine the feasibility and acceptability of using the VIA-IS in the goal-setting process for BI rehabilitation, within an RCT context.

The research questions were:

1. What number of potential participants identified fulfils eligibility criteria?

2. What proportion of potential participants consent to participate?

3. What number of participants can be followed-up at two weeks via telephone call?

4. Is it feasible and acceptable to use the VIA-IS during the goal-setting process in a community treatment setting for brain injury?

i) What proportion of participants complete the VIA-IS?

ii) What feedback do participants provide regarding their experience of completing and using the VIA-IS to set goals?

iii) What feedback do CTCBI clinicians provide regarding their experience of including the VIA-IS in the goal-setting process?

5. What is the measurement variance for the key outcome measure of memory for goals?

6. Does using the VIA-IS in the goal-setting process cause there to be differences in the categories of goals set compared with the typical method of goal-setting?

7. Is it feasible for the assessor to be blind to condition?

Method

Design

The study was a single-blind feasibility pilot RCT.

Ethics

Ethical approval was provided by West of Scotland Research Ethics Committee 4 on 03/12/18 (18/WS/0197; appendix 2.2). NHS Greater Glasgow and Clyde Research and Development board approval was received on 03/12/18 (GN18MH486; appendix 2.3).

Participants

Participants with a brain injury (BI) were recruited from the Community Treatment Centre for Brain Injury (CTCBI); a community-based service for adults aged 16 and over, who have experienced a BI (e.g. traumatic, subarachnoid haemorrhage, anoxic/hypoxic brain damage, encephalitis/meningitis). The CTCBI is an interdisciplinary team that provides client-centred interventions to reduce disability associated with BI, and to assist clients to become independent. Clients are provided with a meeting for setting goals for rehabilitation, followed by a programme that focuses on engagement in meaningful and productive activities. The present study is a feasibility study of a new approach to goal-setting and therefore it is not powered to detect differences in outcome measures. The CTCBI typically assesses approximately twenty new BI clients a month. We estimated that

approximately half of this population would be eligible and consent to take part, and so we expected to recruit roughly eight participants a month. We estimated from this that two groups of twenty-four participants would be recruited over six-months.

CTCBI clinicians who facilitated the goal-setting sessions provided feedback about the session, thus were also recruited as participants. The term 'CTCBI clinicians' refers to a core team of one Speech and Language Therapist, two Clinical Psychologists, and three Occupational Therapists who conduct the assessments and goal-setting at the CTCBI.

Inclusion and Exclusion Criteria

Inclusion criteria comprised clients with a previous BI, referred to the CTCBI, and were due to set goals as part of their engagement with the service. Exclusion criteria were clients under the age of 18, those lacking the capacity to consent, and whose language ability (judged subjectively by CTCBI clinicians) would affect their ability to understand the VIA-IS questionnaire.

For CTCBI clinician participants, inclusion criterion was any CTCBI staff who assess new referrals to the service and facilitate goal-setting sessions as part of their job role.

Recruitment Procedures

CTCBI clinician participants

Potential CTCBI clinician participants were identified by a list of staff members, held by the site manager. The site manager checked inclusion criteria, and offered a participant information sheet to appropriate clinicians (appendix 2.4). CTCBI clinicians contacted the research team if they had any questions or wanted to participate, and they were then recruited via written consent (appendix 2.5).

Brain injury participants

Eligible BI clients were identified and invited to participate by CTCBI clinicians. Those interested were offered a participant information sheet (appendix 2.6) at their first assessment, and permission was sought for the research team to contact them. After a week, potential participants received a phone call from the researcher, to answer any questions about the study and to seek verbal consent to take part. The researcher informed the CTCBI clinicians of agreeable potential participants, and they were consented into the study by a CTCBI clinician at their next appointment (appendix 2.7).

A record was kept of the number of potential participants identified, approached, and consented.

Measures

Outcome measures for brain injury participants:

1) Data concerning participants' demographic characteristics were collected including age, gender, and postcodes to determine socioeconomic deprivation. Postcodes were transformed into Scottish Index for Multiple Deprivation (SIMD) 2016 quintiles, ranging from 1 (most deprived) to 5 (most affluent). Brain injury characteristics were collected from participants' self-reports, including; cause of injury and severity of injury (lowest Glasgow Coma Scale score, length of any loss of consciousness and of post-traumatic amnesia where known). Permission to access participants' medical records was sought during the consent process to check these details. This information was gathered via a proforma (appendix 2.8).

1) BI participants completed the VIA-IS 120 for adults (appendix 2.9 for sample). It is a validated measure designed to identify individuals' 24 Character Strengths profile (Peterson and Seligman, 2004). Participants completed the VIA-IS online using laptops. The number of participants who completed and reasons and number who did not complete the VIA-IS was recorded.

2) Participants' and CTCBI clinicians' feedback about the goal-setting session was obtained via a questionnaire at the end of the session (appendix 2.10; 2.11; 2.12).

3) Memory for goals two weeks after they were set was measured as an indicator of how personal they were to participants (Culley and Evans, 2010). Participants received a phone call from the researcher two weeks after setting goals, who prompted them to recall their goals. The variance from these scores was used to calculate a sample size needed to power a full-scale trial of a similar nature.

4) For exploratory analysis, goals were categorised using the International Classification of Functioning, Disability, and Health (ICF) to see if the nature of the goal areas set was different between groups. ICF is the WHO framework for measuring health and health related domains (WHO, 2001). Goals were categorised using the ICF 2017 activities and participation categories (ICF codes d410–d6401) (Turner-Stokes, 2009, Choi et al., 2017). The categories include: 1) learning and applying knowledge, 2) general tasks and demands, 3)

communication, 4) mobility, 5) self-care, 6) domestic life, 7) interpersonal interactions and relationships, 8) major life areas, 9) community, and social and civic life. Following categorisation, any differences between groups was explored descriptively.

Research Procedures

At their second appointment at the CTCBI, willing BI participants were consented to the study and randomised into a goal-setting as usual group, or a goal-setting plus VIA-IS group, using a computer-generated block randomisation sequence. Only a CTCBI administrator who allocated participants to groups knew the sequence; the researcher was blind to it.

VIA-IS group goal-setting procedures

Participants in the goal-setting plus VIA-IS group were asked to complete an online version of the VIA-IS on a laptop at the beginning of the goal-setting session. Participants were told to "not overthink answers to the questionnaire, to answer as honestly as possible" and were reminded that their answers were private. The CTCBI clinician who was present for the goal-setting session sat separately whilst participants completed the VIA-IS. Clinicians were instructed not to assist participants in answering the questions. When completed, participants' top five Character Strengths were generated, and flashcards with further information about them were provided (appendix 2.13).

The CTCBI clinician and participant set goals for rehabilitation using the guidance from the PoPsTaR manual (Cullen et al., 2018) (appendix 2.14). Briefly, this involved giving examples of how Character Strength could be put into action, then participants were asked to think of examples where their Character Strengths might be seen in action in various areas of their life using a diagram of life areas (appendix 2.15). Participants then set goals and were invited to use the Character Strengths that they identified to help them, or they were free to select goals they had identified as important to them prior to recruitment. It was made clear that goals did not need to be linked to Character Strengths if this process was not helpful for producing meaningful goals. CTCBI staff were provided with training to discuss these procedures in order to manualise and standarise the process of goal-setting in the VIA-IS group.

Control group goal-setting procedures

Participants in the goal-setting as usual group set their goals for rehabilitation at the beginning of the session, using the typical method. CTCBI clinicians' reports show that this can vary; sometimes clients know their goals in advance, while others require some assistance from the clinicians to think of goals. Therefore, the 'goal-setting as usual' group was not standardised, however in doing this, it was representative of current practice. After the goal-setting as usual group set their goals for rehabilitation, they completed the VIA-IS. The purpose of this was to investigate whether clients' goals are consistent with their Character Strengths despite not knowing them.

Procedures after goal-setting

At the end of the goal-setting sessions, CTCBI clinicians and all BI participants completed a feedback form evaluating their experience of goal-setting and of completing the VIA-IS for BI participants only (appendix 2.10; 2.11; 2.12).

Replicating methods used in a study investigating memory of goals set for rehabilitation following BI (Hart et al., 2002, Culley and Evans, 2010), participants were telephoned two weeks after their goal-setting sessions and asked if they could recall their goals. Participants were informed that they would receive a telephone call, but not that this was the purpose of it to avoid effects of effort to remember goals. Information was gathered about any further contact with participants between the goal-setting session and the follow-up telephone call, as this may affect memory for goals. After each call, the researcher guessed the allocation of each participant to determine the success of blinding.

Goals set were categorised into the ICF 2017 activities and participation categories (Oliveira et al., 2017, Rice et al., 2017). Information was also collected around participants not completing the VIA-IS or withdrawing from the study, to evaluate acceptability. Retention of participants to follow-up was noted to evaluate feasibility.

Data Analysis

Rates of recruitment, follow-up, declining to participate, and attrition during the study were reported using a CONSORT 2010 flow chart. The feedback from CTCBI clinicians and BI participants was summarised and differences in the average Likert scale responses compared visually. Types of goals set were described using the ICF classifications, they were then summed within categories and differences between groups were explored descriptively.

Participants' free recall of goals was scored with the criteria used by Culley and Evans (2010) and Hart et al (2002, p563), whereby participants were awarded points based on accuracy of recall. Three points were given if the response mirrored the original goal statement in terms of ideas and accuracy of content; two points if the participant recalled the general theme of the goal but was unable to provide further specific details, or their answer showed evidence of intrusions or distortions, and one point if the participant demonstrated a basic awareness of the goal but demonstrated significant distortions in content or was lacking in specific details. Zero points were given if participants provided a "don't know" response, had no recall, or their recall did not reflect goals in any way. Two independent researchers scored answers, and an interrater reliability analysis using the Kappa statistic was performed to determine consistency among raters. These scores were summed and averaged across all goals set. Variance in participants' free recall of goals in both conditions was calculated, to inform a sample size calculation for a future trial.

Results

Characteristics of the sample

CTCBI clinicians

Six CTCBI clinicians were recruited: two Clinical Psychologists, one Speech and Language Therapist, and three Occupational Therapists.

Brain injury participants

Recruitment of BI participants occurred over an almost 7-month period (figure 2), between 4th December 2018 and 30th June 2019. A break in recruitment occurred for one week between 24th December 2018 and 3rd January 2019 due to staff holidays, and 2 weeks between 27th February and 13th March 2019 due to a temporary closure of the CTCBI, which was moving location.

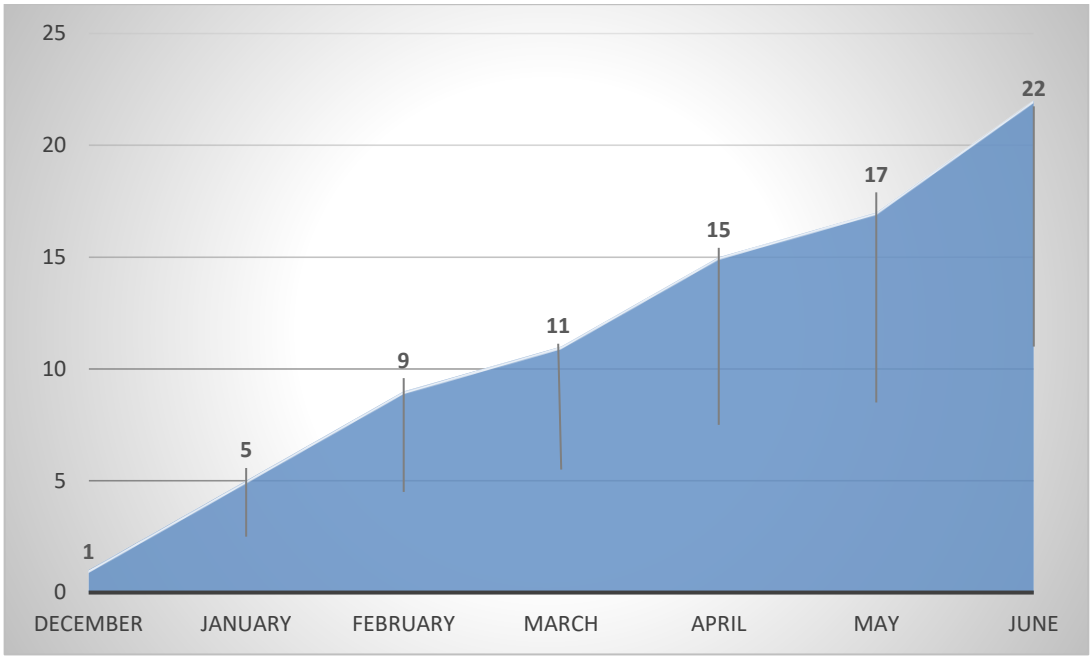

Figure 2: A stacked chart displaying recruitment figures of brain injury participants

Potential participants were identified from people referred to the CTCBI for initial assessment. A total of 86 potential patients were identified, of whom *n* = 38 (44%) were eligible, *n* = 16 (19%) declined to participate, leaving *n* = 22 (26%) who enrolled in the study, with one (1%) participants' group allocation and results not yet known as they have not completed the study. Figure 3 displays the CONSORT flow diagram of recruitment and follow-up of BI participants. This shows that *n* = 22 were recruited and *n* = 19 (86%) completed the study procedures. Two (9%) participants did not complete the VIA-IS; for one person, the online questionnaire did not work correctly, and the participant became frustrated, and the other said it was boring, though the staff member sensed low motivation from the onset. Both ceased participation and were in the VIA-IS group. All of the 19 participants who completed the study procedures were followed up for the two-week telephone call, 14 (74%) were phoned exactly on the 2-week follow-up deadline, the remaining ranged from 1- 12 days overdue (median = 2, IQR: 1.5, 9.5).

CONSORT 2010 Flow Diagram

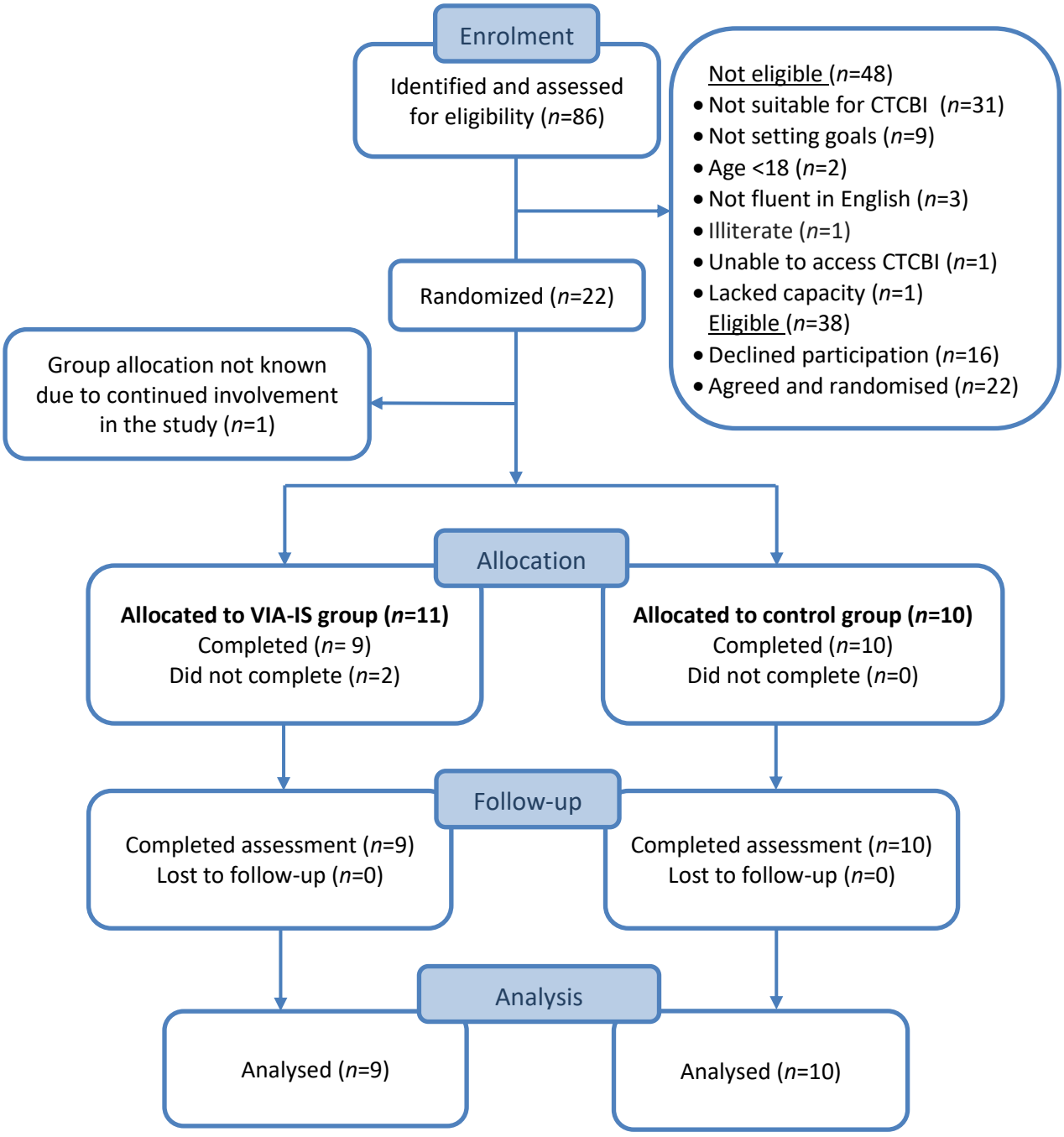

Figure 3: Consort 2010 flow diagram of brain injury participant' recruitment and dropout

Table 6: Demographic and clinical characteristic of the brain injury sample

			Overall	Intervention	Control
Age (years)		*n* (missing)	19	9	10
		Median (25th, 75th percentile)	53 (49, 55)	50 (48, 57)	54 (49, 55)
Gender		*n* (missing)	19	9	10
		Female *n* %	10 (53)	8 (89)	2 (20)
SIMD 2016 quintile		*n* (missing)	19	9	10
		Median (25th, 75th percentile)	2 (1, 5)	3 (1, 5)	1 (1, 3)
Characteristics of the head injury					
Cause of injury *n*	Secondary hypoxia	(*n*, %)	2 (11)	1 (11)	1 (10)
	Assault	(*n*, %)	4 (21)	1 (11)	3 (30)
	Aneurysm	(*n*, %)	6 (32)	5 (56)	1 (10)
	Fall	(*n*, %)	4 (21)	2 (22)	2 (20)
	Brain surgery	(*n*, %)	2 (11)	0 (0)	2 (20)
	Unknown	(*n*, %)	1 (5)	0 (0)	1 (10)
Lowest Glasgow Coma Scale score		*n* (missing)	13 (6)	6 (3)	7 (3)
		Median (25th, 75th percentile)	8 (8, 14)	8 (5, 13)	12 (8, 15)
Lost consciousness		Yes *n* (%)	13 (68)	6 (67)	7 (70)
		Length known *n* (missing)	8 (5)	2 (4)	6 (1)
Length		Median (IQR) minutes	31.5 (2.5, 600)	361 (2, *)	31.5 (3, 900)
Post-traumatic amnesia		Yes *n* (%)	16 (84)	8 (89)	8 (80)
		Length known *n* (missing)	17 (2)	8 (1)	9 (1)
Length		Median (IQR) hours	60 (10.5, 354)	54 (23.3, 375)	60 (1.6, 396)

* **= data not available**

Demographic and clinical characteristics of the intervention and control group are shown in table 6. There was no difference between groups in age (p = 0.911) or SIMD quintiles (p = 0.440). There were more women in the intervention group, and more men in the control group (p <0.01, ϕ = 0.69). The most common cause of injury in the intervention group was aneurysm, whereas the control group demonstrated more variation in cause of injury. The intervention group had more severe brain injuries in terms of lower average Glasgow Coma Scale scores. The length of post-traumatic amnesia was similar in both groups indicating comparable severity of brain injuries by this classification.

Acceptability and feedback of the use of the VIA-IS in goal-setting

Appendix 2.15 and 2.16 show the full feedback about completing the VIA-IS and setting goals from the nineteen BI participants in both groups and CTCBI clinicians, and the descriptions of the Likert scales.

Of the nineteen participants who completed the study procedures, seventeen (89%) participants said the VIA-IS was acceptable to complete. Within this group, participants' gave mixed feedback. Some gave positive feedback, such as "*I enjoyed the process and reflecting on my strengths*", and "*it was interesting*", whilst others gave critical

feedback, "It was repetitive", "*It was confusing at points*", and "*the language was Americanised and some parts did not feel relevant to my culture"*. CTCBI clinicians also gave some positive feedback, "*It was good for building rapport, and learning about the client. It created a level of engagement that I would not have gotten otherwise. It helped the client to articulate why the goal was important to them",* and *"It was a useful tool to get the client to think about different goals in relation to different areas of her life"*. Whereas for other participants, CTCBI clinicians commented*, "The client found the wording confusing and the computer mouse difficult to operate"* and *"They required support using the computer. He struggled to read the screen and became frustrated with how long it took to complete"*.

There were two participants (11%) who completed the VIA-IS and said it was not acceptable. One said, "*It made me think about how different I am after my injury",* and the other said, *"Some items of the questionnaire were poor and harder to answer"*. A CTCBI clinician commented that one of these participants "*required support using the computer, and found some of the language hard to understand. She was thinking about herself before the injury, and was worried about failing the questionnaire"*.

Participants in the VIA-IS group rated their goals as slightly more related to their Character Strengths (median = 4, IQR: 1.5, 5) than control participants (median = 3.5, IQR: 2.5, 4.3). Participants rating of how easy it was to set goals in the VIA-IS group (median = 4 ("*easy*"), IQR: 3.4, 4.5) was similar to the control group (median = 4, IQR: 2.8, 4). CTCBI clinicians rated the goal-setting session as slightly easier in the control group (median = 4.5, IQR: 4, 5) than the VIA-IS group (median = 4, IQR: 2.5, 4).

Of the nine participants in the VIA-IS group who completed the study, a third used the VIA-IS results to set goals, a third used them a little, and a third did not. Of the 67% of these participants who did use the VIA-IS results to some extent, median rating score for how helpful it was to set goals was 4 ("*helpful*": IQR: 3, 4). CTCBI clinicians gave a median rating of 3 ("*neither helpful nor unhelpful*": IQR: 2, 3).

Categories of goals

Table 7 displays the frequency of goals set organised by ICF 2017 activities and participation categories. Participants in the control group set marginally more goals overall and showed a higher frequency of goals in the following groups: learning and applying knowledge, community, and social and civic life, and domestic life. Participants in the VIA-IS group set more goals in the mobility, major life areas and interpersonal interactions and relationships categories. The largest differences were still minor, with

the VIA-IS groups setting slightly more major life area and interpersonal interactions and relationships goals, and the control group setting slightly more goals in the learning and applying knowledge, and community and social and civic life categories.

Table 7: Brain injury participants' goals organised into ICF 2017 activities and participation categories

	VIA-IS group (*n*=9) frequency	Control group (*n*=10) frequency
1 Learning and applying knowledge	4	6
2 General tasks and demands	1	1
3 Communication	0	0
4 Mobility	1	0
5 Self-care	4	4
6 Domestic life	0	2
7 Interpersonal interactions and relationships	4	2
8 Major life areas	3	1
9 Community, and social and civic life	1	3
Total	**18**	**19**

Success of blinding

All follow-up phone calls were conducted by a blinded assessor who guessed allocation at the end of the study. On 2 occasions (11%) the assessor was unblinded; both participants were in the VIA-IS group. Of the remaining participants, 53% of group allocation was guessed correctly; 43% (*n* = 3) of intervention participants and 60% (*n* = 6) of control participants.

Memory for goals

Accuracy of memory for goals was rated by two independent researchers, and the interrater reliability for the raters was found to be Kappa = 0.79 (p <0.0001), 95% CI (0.643, 0.932), indicating moderate to strong levels of agreement (McHugh, 2012). Table 8 summarises participants' average memory for goals per participant.

Table 8: Median score for memory for goals at follow-up

	VIA-IS group (*n*=9)	Control group (*n*=10)
Median (IQR)	0.5 (0.0, 2.5)	1.5 (0.0, 1.6)

Participants' frequency of contact with the CTCBI service in-between goal-setting and follow up phone call was monitored to observe whether this might explain major differences in memory for goal. Control participants had more contact overall (median = 1, IQR: 0, 1) than the VIA-IS group (median = 0, IQR: 0, 1).

Sample size calculation for full-scale trial

Memory for goals would be the primary outcome of interest in a future full-scale trial. The standard deviation of the mean memory score of all participants in this pilot trial was 1.05. Following discussion in the research team, it was concluded that a one point difference between groups would constitute a clinically important difference in recollection of goals, as this would represent a category change on the rating scale used (e.g. going from no recall of the goal to at least some recollection, or from having a general idea of the goal to a detailed recollection of the goal). A one-point difference, with an SD of 1.05 reflects an effect size of 0.95. With two-tailed alpha of 0.05, power at 0.80, a sample size of n = 19 per group would be required to detect a significant difference between groups. However, to take a more cautious approach we would recruit 30 per group, which would provide power of 0.95, to detect a between-groups effect size of 0.95. Assuming 90% retention, n = 33 per group would be required to be randomised (total n = 66). Based on numbers recruited compared to numbers eligible this would mean that 114 eligible participants would likely needed to be approached. Furthermore, given numbers eligible as a proportion of total referrals to the centre, this would mean that a total of 259 referrals to the centre would be required to be considered for eligibility.

Discussion

The primary aim of this study was to examine the feasibility and acceptability of using the VIA-IS in the goal-setting process for BI rehabilitation, within an RCT context. Recruitment to this pilot trial was challenging, however we recruited a small sample, which was representative of patients with BI attending community rehabilitation in Glasgow. We gained an understanding of realistic recruitment figures, as well as reasons for ineligibility of potential participants. Due to the slow recruitment rates at this one CTCBI site, it might be helpful to run a future RCT at multiple sites.

The dropout rate was low compared to the accepted rate of 20% for RCTs (Furlan et al., 2009), and the 100% follow-up of all participants who completed the study procedures is higher than an average of 6% loss to follow-up found across trials (Akl et al., 2012). There was slight variation in follow-up time; yet this is unsurprising in this clinical population where disability and disruption to lifestyle following injury is common (Thornhill et al., 2000). Sample attrition was different in the two arms, with the two withdrawals coming from the intervention arm. However, the stage at which they withdrew does not indicate it was related to the procedures of using the VIA-IS to set goals. BI participants said they withdrew because they found completing the VIA-IS challenging. Other feedback by BI participants about the acceptability of the VIA-IS was mixed, with some finding it interesting and enjoyable, whereas others criticised the length, and repetitive nature.

From the CTCBI clinicians' point of view, some noted that a few participants requiring support navigating the computerised questionnaire. Whereas for other BI participants, the clinicians commented that the VIA-IS was helpful for building rapport and engagement with clients and it assisted the process of thinking of a wider variety of goals. CTCBI clinicians rated goal-setting as slightly easier in the control group, however this might be related to familiarity with these procedures. BI participants in both groups rated the goal-setting procedures as 'easy'. Overall, it can be concluded that completing the VIA-IS appears mostly acceptable, however it may not be suitable for or well received by all patients, particularly if the person struggles with using computers or has difficulty concentrating. A limitation of the VIA-IS is that the language is Americanised, and may not be understood as easily by other cultures, which was fed back by one participant in the study. It would be helpful to validate a British English version of this tool for use in the UK. The team behind the VIA-IS have recently created a shorter online version of the tool, which may improve its usability and acceptability.

This pilot study gained valuable feedback from the intervention group, using the VIA-IS to set goals. Two-thirds of these participants used the results of the VIA-IS in some form to set their goals, giving positive feedback such as finding it interesting and enjoying the process, and staff reported other benefits to the process of rehabilitation (rapport building). For those who did not use the VIA-IS, CTCBI clinicians commented that these participants knew what goals they wanted to set prior to the goal-setting session. There appears to be a place for VIA-IS in rapport building and engagement in rehabilitation, particularly for those who do not know what goals to set for rehabilitation, which should be investigated in future trials.

There were a few minor differences in ICF 2017 activities and participation categories of the goals, therefore using the VIA-IS to set goals did not appear to significantly alter the

types of goals set. With the exception of two cases where the researcher was unblinded to group allocation, group allocation guessing was kept to almost chance level, indicating it is feasible to blind the researcher to the conditions in an RCT of this nature. The number of participants recruited was smaller than originally planned but were sufficient to be able to estimate the key statistical parameters needed to plan an RCT. An adequately powered RCT to detect a clinically meaningful different score in memory for goals following a goal-setting intervention will need to be 66, which is practical.

Strengths and limitations

Although we facilitated training in an attempt to standardise the process of goal-setting in the VIA group, with six different members of staff delivering the intervention there may have been some inconsistency across practice. This study also did not measure cognitive impairments, which may have affected participants' recall of goals at the two-week follow-up. A strength of this study was the blinding of participants to the between group nature of the study, and therefore their own group allocation. This encourages unbiased feedback by the BI participants. Conversely, a further limitation was the lack of blinding of CTCBI staff, therefore their knowledge of study group and hypothesis of the study may bias their subjective feedback. A future trial would benefit from blinding therapist to prevent any bias in feedback. Nevertheless, research has established that this is challenging in a rehabilitation setting (Wade et al., 2010).

Conclusion

Although the sample size was small, it was adequate for obtaining information about the recruitment strategy, and helpful feedback from those who did and did not complete the study, which will contribute to future designs of RCT's in this field. A full-scale RCT using the VIA-IS to set goals for community rehabilitation following BI appears to be feasible, however clinical benefit may be limited to specific BI clients who are computer literate, more difficult to engage, and do not know what goals they want to set for rehabilitation. A multi-centre design to achieve sufficient sample sizes to detect the effects of the intervention will aid the recruitment of this specific, yet sometimes challenging to engage client group.

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Appendix

Appendix 1.1: Author guidelines for submission to Clinical Rehabilitation

1. What do we publish?

1.1 Aims & Scope

Before submitting your manuscript to Clinical Rehabilitation, please ensure you have read the Aims & Scope.

1.2 Article Types

The journal publishes original papers, systematic reviews, Rehabilitation in Practice articles correspondence relating to published papers and short reports. Other article types should be discussed with the editor before submission.

For queries regarding the suitability of your submission please contact clinical.rehabilitation@sagepub.co.uk

1.2.1 Summary of manuscript structure:

- A title page with names and contact details for all authors;
- A **structured** abstract of **no more than 250 words** (the website checks this);
- The text (usually Introduction, Methods, Results, Discussion);
- Clinical Messages (2-4 bullet points, 50 words or less);
- Acknowledgements, author contributions, competing interests and funding support;
- References (Vancouver style);
- Tables, each starting on a new page;
- Figures, each starting on a new page;
- Appendix (if any).

Please note that short reports follow a different format:

- The main text of a short report will usually be between **1000 and 1500 words** in length.
- A short report should have sufficient key references to cover all important points, but no more and usually there will be a **maximum of 15 references**.
- Tables and figures can be very efficient and effective ways of presenting data. A short report will usually have **no more than three tables and figures** (in total) and most will be restricted to two.

Further information on short reports can be found here.

1.3 Writing your paper

The SAGE Author Gateway has some general advice and on how to get published, plus links to further resources.

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When writing up your paper, think about how you can make it discoverable. The title, keywords and abstract are key to ensuring readers find your article through search engines such as Google. For information and guidance on how best to title your article, write your abstract and select your keywords, have a look at this page on the Gateway: How to Help Readers Find Your Article Online.

2. Editorial policies

2.1 Peer review policy

The journal's policy is to obtain at least two independent reviews of each article. It operates a single-blind reviewing policy in which the reviewer's name is always concealed from the submitting author. Referees will be encouraged to provide substantive, constructive reviews that provide suggestions for improving the work and distinguish between mandatory and non-mandatory recommendations.

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- Drafted the article or revised it critically for important intellectual content,
- Approved the version to be published,
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

Any acknowledgements should appear first at the end of your article prior to your Declaration of Conflicting Interests (if applicable), any notes and your References

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It is the policy of Clinical Rehabilitation to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a 'Declaration of Conflicting Interests' statement is included at the end of your manuscript, after any acknowledgements and prior to the references, under a heading 'Conflict of Interest Statement'. If no conflict exists, please state that 'The Author(s) declare(s) that there is no conflict of interest'. For guidance on conflict of interest statements, please see the ICMJE recommendations here.

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Any commercial or financial involvements that might represent an appearance of a conflict of interest need to be additionally disclosed in the covering letter accompanying your article to assist the Editor in evaluating whether sufficient disclosure has been made within the Conflict of Interest statement provided in the article.

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Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, and all papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you have provided the full name and institution of the review committee, in addition to the approval number.

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Information on informed consent to report individual cases or case series should be included in the manuscript text. A statement is required regarding whether written informed consent for patient information and images to be published was provided by the patient(s) or a legally authorized representative.

Please also refer to the ICMJE Recommendations for the Protection of Research Participants

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The relevant EQUATOR Network reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed CONSORT flow chart as a cited figure and the completed CONSORT checklist should be uploaded with your submission as a supplementary file. Systematic reviews and meta-analyses should include the completed PRISMA flow chart as a cited figure and the completed PRISMA checklist should be uploaded with your submission as a supplementary file. The EQUATOR wizard can help you identify the appropriate guideline. Clinical Rehabilitation expects all clinical trials to be registered with a recognised registry, and the name of the registry and the registration number to be given in the paper, usually in the first paragraph in the methods section.

Other resources can be found at NLM's Research Reporting Guidelines and Initiatives

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3. Publishing Policies

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6. On acceptance and publication

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7. Further information

7.1 Important 'Instructions to Authors' – from the Editor

Further specific advice on editorial aspects of the journal and of writing for the journal are also available.

Click here for further information and advice on submitting to Clinical Rehabilitation.

Clinical Rehabilitation Editor: Derick Wade clinical.rehabilitation@sagepub.co.uk
Instructions to Authors Revision: Oct 6th 2010

Reviews

The journal gives high priority to two types of review (see below), but does not generally publish 'simple' reviews. The reviews preferred are:

- **Systematic reviews** of published evidence, including Cochrane reviews. These may be longer than the stated preferred word count.
- **'Position' reviews** that draw upon published information in a systematic way but use it to develop and support a personal hypothesis or point of view. The position, or view being advocated should be challenging in some way; we are looking for something to challenge the routine and orthodox.

Papers espousing a specific point of view (position reviews) should have a summary that makes explicit the diversity of opinion that exists and the opinion of the authors, and it should also explain how the authors have collated their evidence in support of their point of view. The main article should then expand on the logical arguments and evidence base.

It is not possible to dictate or suggest a specific layout or structure for a position review. However the article will be judged against criteria such as:

- Clarity of writing and lay-out (use tables and figures if necessary)
- Logical coherence, and use of evidence
- How reasonable and sensible it is; dangerous or irrational ideas are unlikely to be published!

Appendix 1.2: Search strategy for systematic review

Search strategy of databases:

Goals[†]/ OR goal setting OR goal-setting OR goal planning

AND

Rehabilitation[†] OR rehabilitat*

AND

Client satisfaction OR patient satisfaction OR patient participation[†] OR patient particip* OR client particip* OR engage* OR programme adherence OR goal achiev* OR goal attain* OR treatment outcome[†] OR outcome

AND

Limit search findings to English Language and humans

[†] For the search of Embase and Medline, these terms were mapped to medical subject headings, helping to find relevant official medical subject headings for the terms.

Appendix 1.3: PEDro-P quality rating scale

PEDro-P Scale

Rating Scale for Randomised and Non-Randomised Controlled Trials

For each item, please justify scoring (for both "yes" and "no" responses), by at least mentioning page and paragraph numbers in the field underneath the tick boxes.

	Rater 1:		Rater 2:		Consensus	
	yes	no	yes	no	yes	no
1. Eligibility criteria were specified	☐ specify page & paragraph	☐	☐ specify page & paragraph	☐	☐ specify page & paragraph	☐
2. Subjects were randomly allocated to interventions (in a crossover study, subjects were randomly allocated an order in which treatments were received)	☐	☐	☐	☐	☐	☐
3. Allocation was concealed	☐	☐	☐	☐	☐	☐
4. the intervention groups were similar at baseline regarding the most important prognostic indicators	☐	☐	☐	☐	☐	☐
5. There was blinding of all subjects	☐	☐	☐	☐	☐	☐
6. There was blinding of all therapists who administered the therapy	☐	☐	☐	☐	☐	☐
7. There was blinding of all assessors who measured at least one key outcome	☐	☐	☐	☐	☐	☐
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	☐	☐	☐	☐	☐	☐
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	☐	☐	☐	☐	☐	☐
10. The results of between- intervention group statistical comparisons are reported for at least one key outcome	☐	☐	☐	☐	☐	☐
11. The study provides both point measures and measures of variability for at least one key outcome	☐	☐	☐	☐	☐	☐

The PEDro-P Scale

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

Appendix 1.4: Table of characteristics of studies included in the systematic review

Characteristics of included articles

Author (year), country	Setting	Study population (number)	Design	Goal-setting intervention	Control intervention	Target outcome
1. Arnetz *et al.* (2004) Sweden	Physical rehabilitation: A rehabilitation unit of the department of rheumatology	Rheumatology patients (77)	Randomised control trial with two arms.	Patients and physical therapist complete separate "goal checklist", defining pain levels and specific goals for treatment, for physical ability, and for functional ability. Then they both participated in a "goals forum" where checklist were compared and goals agreed upon. Goals were written down, ranked and a timeframe of achievement was set (N = 39).	The patient describes and explains both situation and symptoms. The extent to which the patient is then involved in treatment decisions is very much dependent upon the individual physical therapist and/or the individual patient. Therapist and patient may discuss goals for treatment, which are often in the form of a verbal agreement (N = 38).	1. Goal achievement 2. Participant's subjective rating of the quality of care.
2. Cheng *et al.* (2018) Hong Kong	Physical rehabilitation: Community Nursing Service	Patients receiving Nursing care with a diagnosis of a chronic illness (60)	A quasi-experimental design with repeated measures.	Mutual Goal-Setting is a structured and collaborative goal practice involving the community nurses and patients in planning care through using a goal menu. The process involves 1) Explaining the process of mutual goal setting; 2) Identifying the goal of care from the goal menu in collaboration with patient; 3) Identifying the current health situation with reference to the goal statements; 4) Engaging the patient to discuss the expected level of outcome; 5) Sign a goal-setting record to actualize the agreement of care; 6) Review the progress of goal achievement during follow-up visits (N = 35).	Patients received usual care only, health advice and nursing care from the community nurses. The community nurses set the goals of care but did not necessarily involve patients in making decisions. (N = 25).	1. Goal achievement at T1, T2, and T3. 2. Perceived functional disability 3. Perceived functional health status 4. Perceived self-efficacy in self-managing chronic illness. 5. Patient satisfaction in goal-setting.

3. Coppack *et al*. (2012) Surrey, England, United Kingdom	Physical rehabilitation: A residential rehabilitation centre for military personnel.	Military personnel volunteers with a diagnosis of non-specific low back pain (48).	A mixed-model 2 (time) × 3 (group) randomised controlled trial.	The subject was asked 'What are your priorities and goals for the three-week rehabilitation programme?' Subjects were assisted to generate several priority goals. They were asked to rate the perceived importance of each goal on a 10-point scale. Subjects then rated their current 'state' against an ideal of 10 for each goal. Using these scores, a calculation was completed to establish each subject's treatment priorities. This personal goal profile formed a basis for goal setting and the subject's exercise rehabilitation. Follow-up meetings were held on days 6 and 11, and included a repeat administration of the procedures, adding any new goals (N = 16).	1. Therapist-led exercise therapy group including non-structured informal goal-setting, coaching and correct exercise technique (C1, N = 16)[†] 2. Non-therapist-led exercise therapy group (C2, N = 16).* * C2 excluded from this SR analysis as the effects of therapist/ social support on target goal could not be separated. [†] Research group contacted for this description of the control intervention.	1. Adherence to rehabilitation 2. Self-efficacy 3. Treatment efficacy 4. Treatment outcome (the modified Biering-Sorensen test).
4. Dalton *et al*., (2012) London, England, United Kingdom	A tertiary neurological rehabilitation unit.	Younger adults with a single incident neurological events other than spinal injury; 90% had an acquired brain injury (105).	Retrospective related samples design (before and after new goal-setting intervention).	Patients and family or carers being present throughout the goal-setting process, in goal-setting meetings with the treating team (nursing staff, therapists and medical staff). For patients with severe communication or cognitive impairments, strategies were put in place to enhance communication and their ability to participate, and if event they were unable to participate they were represented by their family or carer in the process (N = 54).	Goals were pre-set by the therapy and nursing teams using the information from assessments, and then discussed and agreed with each patient during a goal-setting meeting lasting 20–30 minutes (N = 51).	1. Numbers of goals set 2. Number of goals achieved 3. Barthel Index 4. Functional Independence Measure.
5. Evans and Hardy (2002) Wales, United Kingdom	Physical rehabilitation: an athlete's rehabilitation unit	Injured athletes (39).	A three group randomised controlled trial.	Participants met with a sport psychologist every 7 to 10 days, for 5 weeks. The session involved collaborative goal-setting between physiotherapist and participant, specific to each individual's particular needs. Goals were recorded, and participants completed a self-monitor daily diary of rehabilitation progress. At each subsequent meeting, the extent the goals had been achieved was reviewed and	1. Physiotherapist mandated goals, including meeting with a sport psychologist every 7-10 days for 5 weeks to act as a source of social support. They completed a daily diary of rehabilitation progress (N =13). 2. Physiotherapist mandated goals with no social support. Participants received a telephone call every 10 days to encourage	1. Treatment adherence 2. Self-efficacy 3. Athletes' emotional responses to injury.

				recorded, which informed further goal setting (N = 13).	adherence to the study and they kept a record in a training log (N = 13).* *C2 omitted from this review, as effects of self-monitoring goal progress or social interaction with sport psychologist on outcome could not be separated.	
6. Holliday *et al.* (2007) London, England, United Kingdom	An inpatient neurological rehabilitation unit	Neurological patients (201)	AB optimised balance block design with each block lasting 3 months, over an 18-month period.	A ‘‘goal setting workbook’’ completed by the patient. It asked patients to prioritise activity and participation domains, and to identify specific tasks within those domains that they wished to work on. The final section involved determining what individuals wanted to achieve within the time frame of the rehabilitation admission. Patients then attended a goal-setting meeting with therapists allowing a formal opportunity for both to discuss the projected outcome and the reasons for this. Patients could then set realistic goals (N = 101).	Long-term, short-term goals were set for patients by staff at a multi-disciplinary team (MDT) meeting based on an MDT assessment. These were put in writing and given to the patient who was asked if they were happy with them (N = 100). *Research group contacted for this description of the control intervention.	1. Patients’ perceptions of the relevance of goal set 2. Patients’ perceptions of their participation in the process 3. Types of goals set 4. Outcome of goals 5. Reasons for non-compliance 6. Duration of stay 7. Satisfaction with goal setting 8. Functional Independence Measure 9. London Handicap Scale. 10. General Health Questionnaire-28.
7. Ogawa *et al.* (2016) Japan	Physical and neurological rehabilitation ward.	Patients with disabling diseases: 50% orthopaedic diseases, 40% neurological diseases, and 10% have disuse syndrome (66).	A quasi-randomised, non-blinded, controlled trial with three arms.	A goal-setting intervention group with the life goal concept. In which patient’s life goals were assessed using the Rivermead Life Goal Questionnaire. The patient rates the importance of their life goals on a scale and then they select the three high priority areas. Rehabilitation goals were then set by therapists with reference to the patients’ life goals (N = 22).	1. A standard rehabilitation group with no goal-setting intervention (N = 22) 2. A goal-setting intervention group without the life goal concept (N = 22).	1. Hospital Anxiety and Depression scale 2. General Health Questionnaire-28 3. Pittsburgh Rehabilitation Participation scale (engagement) 4. Functional Independence Measure

						5. Patient Participation scale in goal-setting.
8. Taylor *et al.* (2012) New Zealand	Inpatient neurological rehabilitation unit.	Stroke patients (41).	A cluster randomised controlled trial.	Patient-centred and structured goal elicitation using the Canadian Occupational Performance Measure (N = 21).	Goal-setting as usual, a process that is not typically structured or organized to the same degree as the COPM and was often framed in terms of discipline- specific goals by individual therapists (N = 17).	1. Quality of life at 12 weeks using the Schedule for Individualised Quality of Life 2. Functional Independence Measure 3. Short Form 36 4. Satisfaction with Rehabilitation 5. Duration of stay.
9. Vroland - Nordstand *et al.* (2016) Sweden	Neurological rehabilitation: paediatric rehabilitation.	Children admitted to paediatric rehabilitation centres (32).	Randomised control trial with two arms.	Children self-identified goals using the Swedish version of the Perceived Efficacy and Goal-Setting System (N = 17).	Goals identified by their parents by use of the Canadian Occupational Performance Measure (N = 15).	1. Programme adherence 2. Goal attainment 3. Types of goals set
10. Willer & Miller (1976) United States of America	Psychiatric rehabilitation.	Admissions to a unit in a psychiatric hospital (72).	4 groups randomly assigned.	Actively involved in setting the goals (N = 15).	1. Not actively involved in setting the goals, but had been informed (N = 21) 2. No knowledge of the goals that were set (N = 23) 3. No goals set during hospital stay (N = 13).	1. Client and therapist rating of goal attainment 2. Satisfaction with rehabilitation 3. Perceived functional ability 4. Duration of stay.
11. Wressle *et al.* (2002) Sweden	Physical and neurological rehabilitation ward	Patients receiving hospital rehabilitation and/or home rehabilitation: geriatric orthopaedic, or stroke patients (118).	Two groups, two hospitals assigned to either experimental group or control group.	The Canadian Model of Occupational Performance presents a structure for formulating treatment goals identified by the client, in cooperation with the occupational therapist through a semi-structured interview (N = 88).	Non-structured, non-client-centred goal setting. Patients may have been present during the goal-setting conversation, but generally, they were not asked what was important to them. Commonly, therapists set goals based on functional deficits and diagnoses (N = 30)* *Research group contacted for this description of the control intervention	1. Satisfactions with rehabilitation 2. Memory for goals 3. The Klein-Bell Activities of Daily Living Scale, 4. The Clinical Outcome Variables Scale.

Appendix 1.5: further description of variables in table 4

Description of variables in table 4

Variable	Description
P define current problems/ level of functioning	Participants asked to self-report their own subjective current problems, and/or level of functioning.
P define goals using structured format	A specific structured format for defining goals was used.
HP gives their opinion	The health professional gives their opinion on.
G-S process described to P	The process and details about the goal-setting intervention were explained to participants prior to the intervention.
Strengths of P identified	As a part of thinking of their global current performance, participants were asked to think about their strengths.
Predict outcome at discharge	The goal setting meeting ended with a long-term outcome prediction at discharge from rehabilitation, agreed with participant.
Identify Life Goals	Life goals are defined as "the desired states that people seek to obtain, maintain or avoid." They are identified using the Rivermead Life Goal Questionnaire.
P prioritise areas of work/ goal	Participants were asked to give their opinion of their areas of rehabilitation work/ goal they prioritise as important to them.
Collaborative discussion to set goal between P and HP	The goal-setting process involved a discussion between participants and health care professionals that was deemed to be collaborative in focus and contribution
Strategies for P to select goals	A specific structured tool was used to aid participants selecting their own goals, such as a goal menu: a list of care goals commonly encountered in home care.
By linking to benefit of goal completion	The benefit of goal completion was discussed to assist participants in identifying goal
Sign goal agreement	A 'goal agreement contract' was signed by participants.
Performance profile	A technique to improve the rehabilitation process including the following steps: participant identifying constructs (priorities and goals) they considered priorities for successful rehabilitation. Participants are then asked to rate their perceived importance of each on a 10-point scale. Participants then rate their current 'state' against an ideal of 10 for each goal. A calculation is completed using these scores to establish each participant's treatment priorities.
Rank importance of goals	Participant ranked goals from most important to least important.
Family/ carer/ HP present	A family member, carer, and/or health professional was present during the goal setting session.

Appendix 1.6: Characteristics of post goal-setting strategies to improve outcomes in the included papers

	Goal-setting intervention characteristics									
	Post goal-setting strategies									
	Goals recorded	Time frame set	Review/ Repeat goal setting	Action plan for P	Action plan for staff	Continued self-monitoring	Weekly feedback from HP	Links between rehab goals and life goals explained	Staff informed of goals	Total
1. Arnetz *et al.* (2004)	X	X								**2**
2. Cheng *et al.* (2018)	X		X							**2**
3. Coppack *et al.* (2012)			X							**1**
4. Dalton *et al.* (2012)				X	X					**2**
5. Evans and Hardy (2002)	X		X			X				**3**
6. Holliday *et al.* (2007)			X							**1**
7. Ogawa *et al.* (2016)							X	X		**2**
8. Taylor *et al.* (2012)									X	**1**
9. Vroland-Nordstand *et al.* (2016)										**0**
10. Willer & Miller (1976)										**0**
11. Wressle *et al.* (2002)										**0**
Frequency	**3**	**1**	**4**	**1**	**1**	**1**	**1**	**1**	**1**	

Full description below

Description of variables in table above

Variable	Description
Goals recorded	Goals were written down somewhere for participants to access
Time frame set	A period of time to achieve goals was agreed
Review/ Repeat goal-setting	Goals set were reviewed and goal-setting intervention was repeated at set time points
Action plan for P	An action plan to achieve goal was given to participants
Action plan for staff	An action plan for participants to achieve goal was given to staff
Continued self-monitoring	Participants offered to self-monitored progression towards goals using a daily diary.
HP feedback goal attainment weekly	Weekly feedback from health professional to participant about their progress and performance
Links between rehab goals and life goals explained	The coherence between the rehabilitation goals and the patient's life goals was explained to the Life Goal group
Staff informed of goals	Staff members were informed of goals set by participants

Appendix 2.1: Author guidelines for submission to Neuropsychological Rehabilitation

Instructions for authors

Thank you for choosing to submit your paper to us. These instructions will ensure we have everything required so your paper can move through peer review, production and publication smoothly. Please take the time to read and follow them as closely as possible, as doing so will ensure your paper matches the journal's requirements. For general guidance on the publication process at Taylor & Francis please visit our Author Services website.

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- Open Access
- My Authored Works
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About the Journal

Neuropsychological Rehabilitation is an international, peer-reviewed journal publishing high-quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy.

Please note that this journal only publishes manuscripts in English.

Neuropsychological Rehabilitation accepts the following types of article: original articles, scholarly reviews, book reviews.

Neuropsychological Rehabilitation is an international, peer-reviewed journal, publishing high-quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy. Please note that this journal only publishes manuscripts in English. This journal accepts the following article types: original (regular) articles, scholarly reviews, and book reviews.

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2. Should contain an unstructured abstract of 200 words.
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4. Between 5 and 5 **keywords**. Read making your article more discoverable, including information on choosing a title and search engine optimization.
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This work was supported by the [Funding Agency] under Grant [number xxxx].

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All authors are required to follow the ICMJE requirements on privacy and informed consent from patients and study participants. Please confirm that any patient, service user, or participant (or that person's parent or legal guardian) in any research, experiment, or clinical trial described in your paper has given written consent to the inclusion of material pertaining to themselves, that they acknowledge that they cannot be identified via the paper; and that you have fully anonymized them. Where someone is deceased, please ensure you have written consent from the family or estate. Authors may use this Patient Consent Form, which should be completed, saved, and sent to the journal if requested.

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Updated 8-02-2019

Appendix 2.2: Ethical approval

West of Scotland Research Ethics Committee 4 approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Jonathan Evans
Professor of Applied Neuropsychology
University of Glasgow
Admin Building, Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

West of Scotland REC 4
Research Ethics
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ
(Formerly Yorkhill Childrens Hospital)

Date 3 December 2018
Direct line 0141 232 1808
E-mail WoSREC4@ggc.scot.nhs.uk

Dear Professor Evans

Study title:	**Exploring the use of the Values in Action Inventory of Strengths in the process of goal setting in an acquired brain injury community rehabilitation setting: a feasibility trial**
REC reference:	**18/WS/0197**
Protocol number:	**N/A**
IRAS project ID:	**244241**

Thank you for your submission of 20 November 2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

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

Registration of Clinical Trials

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

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS sites

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter for REC]	1	14 September 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical trials insurance]		06 August 2018
Interview schedules or topic guides for participants [Guidelines for linking Character strengths to goals for rehabilitation]	1	14 May 2018
Interview schedules or topic guides for participants [VIA Assessments Guidelines for CTCBI staff to read]	1	14 May 2018
Interview schedules or topic guides for participants [Further Description of Character Strengths for ABI participants]	1	14 May 2018
IRAS Application Form [IRAS_Form_17092018]		17 September 2018
Non-validated questionnaire [CTCBI clinician participant questionnaire]	1	02 September 2018
Non-validated questionnaire [Acquired brain injury participant questionnaire]	1	02 September 2018
Non-validated questionnaire [Participant feedback forms]	2	28 August 2018
Other [Answers to queries]		19 September 2018
Other [Brain injury participant Consent form]	1.3	16 November 2018
Other [CTCBI clinician Consent form]	1.2	16 November 2018
Other [Brain injury participant information sheet]	1.3	14 November 2018
Other [CTCBI clinciian participant information sheet]	1.2	14 November 2018
Research protocol or project proposal [Research Protocol]	4.1	02 September 2018
Summary CV for Chief Investigator (CI) [CV for Prof Jonathan Evans]		06 August 2018
Summary CV for student [CV Jessica Wainman-Lefley]	1	28 May 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Diagram of study procedures]	1.2	02 September 2018
Validated questionnaire [Sample of Values in action questionnaire, the adult survey version]		31 December 2016

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

18/WS/0197	**Please quote this number on all correspondence**

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

Yours sincerely

On behalf of
Dr Ken James
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Miss Emma-Jane Gault
Mr Paul Dearie, NHS Greater Glasgow and Clyde
nhsg.NRSPCC@nhs.net

West of Scotland REC 4

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Michael Fail	Consultant Geriatrician	Yes	Chair of sub-committee
Dr Christine Milligan	Retired - Pharmaceutical Industry	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rozanne Suarez	REC Manager

Appendix 2.3: Board approval

NHS Greater Glasgow and Clyde Research and Development approval

Senior Research Administrator: Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.Mckenna@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

03/12/2018

Dr Jessica Wainman-Lefley
NHS Greater Glasgow & Clyde
Mental Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

NHS GG&C Board Approval

Dear Dr Jessica Wainman-Lefley,

Study Title:	Exploring the use of the Values in Action Inventory of Strengths in the process of goal setting in an acquired brain injury community rehabilitation setting: a feasibility trial
Principal Investigator:	Dr Jessica Wainman-Lefley
GG&C HB site	Community Treatment Centre for Brain Injury
Sponsor	NHS Greater Glasgow and Clyde
R&D reference:	GN18MH486
REC reference:	18/WS/0197
Protocol no: (including version and date)	V4.1 dated 02.09.18

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form

c. Any amendments – Substantial or Non Substantial
d. Notification of Trial/study end including final recruitment figures
e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

Appendix 2.4: CTCBI Clinician Participant Information Sheet

CTCBI CLINICIAN PARTICIPANT INFORMATION SHEET

Project Title: Setting goals for rehabilitation after brain injury

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being carried out and what is involved. If you would like more information or if anything is not clear, please ask.

What is the purpose of the study?
An important part of the rehabilitation programme at the Community Treatment Centre for Brain Injury (CTCBI) is the process of setting goals with clients. This study is investigating the process of setting goals at the CTCBI, and whether linking client's Character Strengths to their goals affects three things: 1) goals set, 2) client's memory for goals, and 3) clients and staff members experience of setting goals. This study is also contributing towards an educational programme, the Doctorate in Clinical Psychology for the trainee Dr Jessica Wainman-Lefley.

Why have I been chosen?
You work at the Community Treatment Centre for Brain Injury (CTCBI), and part of your job is the initial assessment of, and goal setting for rehabilitation with, brain injury clients who are referred to your service.

Do I have to take part in the study?
No. It is up to you to decide whether you want to join the study. The study will be described and you will have time to go through this information sheet. If you are interested in taking part, a member of the research team will call you to answer any questions you might have about the study. If you agree to take part, you will be asked to sign a consent form. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?
You will be asked to sign a form to say you are happy to take part in the study. As previously discussed and agreed, you will be involved in the identification of participants and the running of the goal setting sessions with clients as part of your typical first assessments of clients. Following this part of the study, you will be asked to fill in a feedback form about each goal setting session. This form should take approximately 5 minutes to complete, at the end of every appointment. There will be no risk to you when taking part in these research procedures. On your consent form, you will be offered the option of receiving a brief summary of the findings at the end of the study.

Will my taking part in the study be kept confidential?
The personal information (your job title, and the length of time you have worked with brain injured clients) collected in the study will be known only to the researcher Dr Jessica Wainman-Lefley, and her supervisor Professor Jonathan Evans. Your data will

be stored in a secure way to ensure your confidentiality. Any paper records will be stored in locked, secure filing cabinets at the University of Glasgow. Data that is stored electronically is also stored securely on password protected computers at the University of Glasgow. Findings from the study may be published in academic journals but only group information is reported so individuals cannot be identified. Data will be stored for up to 10 years and after that all paper records will be securely destroyed. Fully anonymised electronic data may be used in future research. Your study data may be examined by authorised individuals from the study sponsor, NHS Greater Glasgow and Clyde, and/or the regulatory authorities to ensure the study has been conducted to the proper standards. If you withdraw from the study, we will keep the information about you that we have already obtained. You can find out more about how we use your information my contacting Professor Jonathan Evans on 0141 211 0694.

Who is organising and paying for the research?
The research is being conducted as part of the Doctorate in Clinical Psychology at The University of Glasgow. If you have any questions about the study, please contact the researcher Dr Jessica Wainman-Lefley on 07546 509 008.

Who do I contact if I have a complaint about the study?
If you are unhappy about any aspect of the study, please first contact Dr Jessica Wainman-Lefley on 07546 509 008 or Professor Jonathan Evans on 0141 211 0694. If you have a complaint, please contact the NHS Greater Glasgow & Clyde Complaints Department on 0141 201 4500.

Who do I contact for independent information about the study?
If you want to talk about the research with someone who is not part of the research team you can contact Dr Breda Cullen, Lecturer in Mental Health, on 0141 211 0694.

Appendix 2.5: CTCBI Clinician Participant Consent Form

Professor J Evans
Mental Health & Wellbeing
Gartnavel Royal Hospital
0141-211-0694

Participant Identification Number:.....

CTCBI Clinician Participant Consent Form

Title of Project: Setting goals for rehabilitation after brain injury

Name of Researcher: Dr Jessica Wainman-Lefley

		Please Initial Box
1.	I confirm that I have read and understand the information sheet dated 14/11/2018 (Version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	☐
3.	I understand that data collected during the study, may be looked at by individuals from University of Glasgow, from regulatory authorities or from the NHS Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	☐
4.	I understand that personal information will be stored securely for 10 years and then destroyed, and that anonymous electronic data may be used for other research but it will not be possible to identify me from that data.	☐
5.	I agree to take part in the above study.	☐
6.	When the study has finished, I would like to receive a brief summary of the findings in the post (If yes, please provide your address overleaf).	☐

Name of Staff Participant	Date	Signature
Name of person taking consent	Date	Signature

Version 1.2: 16/11/2018

My address for the purpose of receiving a summary of the study findings at the end of the study:

Name:.....

Address:.....

.....

.....

Postcode: .....

Appendix 2.6: Brain Injury Participant Information Sheet

ACQUIRED BRAIN INJURY PARTICIPANT INFORMATION SHEET

Project title: Setting goals for rehabilitation after brain injury

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being carried out and what is involved. Please take time to read this information carefully and discuss it with friends or relatives if you wish. If you would like more information or if anything is not clear, please ask.

What is the purpose of the study?
An important part of your rehabilitation programme is the process of talking with the team members about what you want to achieve during your rehabilitation programme. With the Community Treatment Centre for Brain Injury (CTCBI) team you will set rehabilitation goals. Your goals describe what you hope to achieve while you are working with the CTCBI team. This study is investigating how the team can help you to identify the goals that are most important to you. This study is also contributing towards an educational programme, the Doctorate in Clinical Psychology for the trainee Dr Jessica Wainman-Lefley.

Why have I been chosen?
You have been referred to the Community Treatment Centre for Brain Injury following a brain injury, and are over 18 years old.

Do I have to take part in the study?
No. It is up to you to decide whether you want to join the study. The study will be described and you will have time to go through this information sheet. If you are interested in taking part, a member of the research team will call you to answer any questions you might have about the study. If you agree to take part, you will be asked to sign a consent form on your next visit to the centre. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive in any way.

What will happen to me if I take part?
The study will take place when you attend the centre to discuss your rehabilitation goals. You will be asked to sign a form to say you are happy to take part in the study. We will also ask for your permission to access your medical records just for information about the injury to your brain. During a visit to the rehabilitation centre you will set your rehabilitation goals with a CTCBI team member. You will also complete a questionnaire on a computer that asks you about the important things in your life. About two weeks after your visit to the centre to set goals, one of the

research team members will call. The call will probably only last about five minutes and will involve a few questions about your rehabilitation programme. There will be no risk to you when taking part in these research procedures. On your consent form, you will be offered the option of receiving a brief summary of the findings at the end of the study.

Will my taking part in the study be kept confidential?

The personal information (postcode, address, phone number) collected in the study will be known only to the researcher Dr Jessica Wainman-Lefley, her supervisor Professor Jonathan Evans, and your CTCBI rehabilitation team. Your data will be stored in a secure way to ensure your confidentiality. Any paper records will be stored in locked, secure filing cabinets at the University of Glasgow. Data that is stored electronically is also stored securely on password protected computers at the University of Glasgow. Findings from the study may be published in academic journals but only group information is reported so individuals cannot be identified. Data will be stored for up to 10 years and after that all paper records will be securely destroyed. Fully anonymised electronic data may be used in future research. Your study data may be examined by authorised individuals from the study sponsor, NHS Greater Glasgow and Clyde, and/or the regulatory authorities to ensure the study has been conducted to the proper standards. If you withdraw from the study, we will keep the information about you that we have already obtained. You can find out more about how we use your information my contacting Professor Jonathan Evans on 0141 211 0694.

Who is organising and paying for the research?

The research is being conducted as part of the Doctorate in Clinical Psychology at The University of Glasgow. If you have any questions about the study, please contact the researcher, Dr Jessica Wainman-Lefley on 07546 509 008.

Who do I contact if I have a complaint about the study?

If you are unhappy about any aspect of the study, please first contact Dr Jessica Wainman-Lefley on 07546 509 008 or Professor Jonathan Evans on 0141 211 0694. If you have a complaint, please contact the NHS Greater Glasgow & Clyde Complaints Department on 0141 201 4500.

Who do I contact for independent information about the study?

If you want to talk about the research with someone who is not part of the research team you can contact Dr Breda Cullen, Lecturer in Mental Health, on 0141 211 0694.

Appendix 2.7: Brain Injury Participant Consent Form

Professor J Evans
Mental Health & Wellbeing
Gartnavel Royal Hospital
0141-211-0694

Participant Identification Number:.....

Brain Injury Participant Consent Form

Title of Project: Setting goals for rehabilitation after brain injury

Name of Researcher: Dr Jessica Wainman-Lefley

Please Initial Box

1. I confirm that I have read and understand the information sheet dated 14/11/2018 (Version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights, or care being affected. ☐
3. I understand that data collected during the study, may be looked at by individuals from University of Glasgow, from regulatory authorities or from the NHS Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. ☐
4. I understand that personal information will be stored securely for 10 years and then destroyed, and that anonymous electronic data may be used for other research but it will not be possible to identify me from that data. ☐
5. I agree that the research team can access my medical records. ☐
6. I agree to take part in the above study. ☐
7. When the study has finished, I would like to receive a brief summary of the findings in the post (If yes, please provide your address when asked to). ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Version 1.3: 16/11/2018

My address for the purpose of receiving a summary of the study findings at the end of the study:

Name:.....

Address:.....

.....

.....

Postcode: .....

Appendix 2.8: Brain Injury Participant Proforma

Participant information

Participant Identification Number:…….. Date ……

Age:

Gender:

Postcode:

Cause of Injury:

Lowest Glasgow Coma Scale Score recorded:

/ 15

Length of post traumatic amnesia (specify if minutes, hours, days, or weeks):

If the person lost consciousness:

Length of loss of consciousness (specify if minutes, hours, days, or weeks):

Version 1: 20/12/2018

Appendix 2.9: VIA-IS questionnaire sample

	Very Much Like Me	Like Me	Neutral	Unlike Me	Very Much Unlike Me
Being able to come up with new and different ideas is one of my strong points.	○	○	○	○	○
I have taken frequent stands in the face of strong opposition.	○	○	○	○	○
I never quit a task before it is done.	○	○	○	○	○
I always keep my promises.	○	○	○	○	○
I have no trouble eating healthy foods.	○	○	○	○	○
I always look on the bright side.	○	○	○	○	○
I like to think about what life means.	○	○	○	○	○
I know how to handle myself in different social situations.	○	○	○	○	○
I always finish what I start.	○	○	○	○	○
	Very Much Like Me	**Like Me**	**Neutral**	**Unlike Me**	**Very Much Unlike Me**
I really enjoy doing small favors for friends.	○	○	○	○	○
There are people in my life who care as much about my feelings and well-being as they do about their own.	○	○	○	○	○
As a leader, I treat everyone equally well regardless of his or her experience.	○	○	○	○	○
Even when candy or cookies are under my nose, I never overeat.	○	○	○	○	○
I practice my religion.	○	○	○	○	○
I rarely hold a grudge.	○	○	○	○	○
I am always busy with something interesting.	○	○	○	○	○
I am thrilled when I learn something new.	○	○	○	○	○
I like to think of new ways to do things.	○	○	○	○	○

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Appendix 2.10: CTCBI Clinician Feedback Form

CTCBI staff feedback form

Title of Project: Setting goals for rehabilitation after brain injury

Staff ID:..... **Date:**.....

☐ Did the participant complete the VIA-IS?

Yes ☐ No ☐

☐ If the participant completed the VIA-IS, how do you think they found it?

Very hard	slightly hard	neither	easy	very easy
1	2	3	4	5

☐ How easy was it to identify goals?

Very hard	slightly hard	neither	easy	very easy
1	2	3	4	5

☐ Do you think the VIA-IS helped to process of identifying goals? (only for the VIA-IS group)

Not at all	not really	neither	helpful	very helpful
1	2	3	4	5

☐ Is there anything that would be helpful to do differently next time?

.....
.....
.....
.....

Appendix 2.11: Brain Injury Participant Feedback Form (VIA-IS group)

Acquired Brain injury participant feedback form

Title of Project: Setting goals for rehabilitation after brain injury

Participant ID:..... **Date:**.....

- How did you find filling in the VIA-IS?

  Acceptable □ Not acceptable □

- Comments

  .....
  .....
  .....
  .....

- Do you think your goals are related to one of your Character Strengths?

Really not related	slightly unrelated	neither	related	really related
1	2	3	4	5

- How easy was it to identify goals?

Very hard	slightly hard	neither	easy	very easy
1	2	3	4	5

- Did you use your Character Strengths to help you set goals?

  Yes □ No □ A little □

- If you did, were they helpful for setting goals?

Not at all	not really	neither	helpful	very helpful
1	2	3	4	5

Version 2 28.08.18

Appendix 2.12: Brain Injury Participant Feedback Form (Control group)

Acquired Brain injury participant feedback form

Title of Project: Setting goals for rehabilitation after brain injury

Participant ID:..... **Date:**.....

- How did you find filling in the VIA-IS?

  Acceptable ☐ Not acceptable ☐

- Comments

  .....
  .....
  .....
  .....

- Do you think your goals are related to one of your Character Strengths?

Really not related	slightly unrelated	neither	related	really related
1	2	3	4	5

- How easy was it to identify your goals?

Very hard	slightly hard	neither	easy	very easy
1	2	3	4	5

Appendix 2.13: Character Strengths full description

Further description of Character Strength, separated into flashcards

Character Strength	Exercise
Creativity Thinking of new ways to do things is a crucial part of who you are. *'Do things in a different way'*	You love to think of new ways to do things and are rarely content with doing anything conventionally if a better way is possible. You also apply your imagination in unique ways to solve everyday problems and to generate original ideas. You are a flexible person who can easily and often happily cope with changes and challenges.
Curiosity You like exploration and discovery. *'Ask questions. Lots of them'*	You find yourself interested in exploring new things. When things are not clear, you strive to explore them further. You are fascinated by new topics and constantly ask questions to discover more about them. You are able to focus on acquiring new information about a specific topic. Also, you are open to experiencing new and different things.
Judgement/ open-mindedness You think things through and examine them from all sides. *'Examine the details'*	You are very good at thinking things through and examining issues from all angles. In order to form an opinion or make decisions, you carefully weigh all the evidence. Thinking objectively and rationally is your asset. Your thinking is mostly realistic, flexible, and accurate. You don't jump to conclusions.
Love of learning You have a passion for mastering new skills, topics, and bodies of knowledge. *'Learn something from every situation'*	You love to learn new things. You make very good use of opportunities where you can gain knowledge about skills, concepts, ideas, and facts. You most likely enjoyed school and reading. When it comes to learning, you are persistent, even if you get frustrated or distracted, you refocus and don't give up until you have mastered the topic or skill.
Perspective People who know you consider you wise. *'Offer good advice'*	You are very good at putting things together to understand underlying meaning. You have a unique way of looking at a situation that makes sense to you and other people. You are good at recognizing an objective fact from a personal opinion. Due to these qualities, your friends think you are wise beyond your age, although you may not think of yourself as wise. You usually learn well from your mistakes. Your friends consult with you about important matters. You are the one who often brings people together, helping them to resolve conflicts in friendly ways.
Bravery	You do not give up easily in the face of hardship or a challenge; even when you are afraid, you overcome your fears to do what needs to be

You do not shrink from threat, challenge, difficulty, or pain. *'Face what you are afraid of'*	done. You are not afraid to speak up for what you think is right. You always are able to find courage to do the right thing.
Honesty **You live your life in a genuine and authentic way.** *'Tell people the truth, (almost) all the time'*	You almost always speak the truth. You are a genuine and authentic person who doesn't pretend to be someone you are not. You are also considered a trustworthy friend and take ownership of your actions.
Perseverance **You work hard to finish what you start.** *'Don't give up'*	You do not back away from difficult projects and assignments, and you finish them despite challenges and without much complaining. You almost always finish what you start and do not get distracted easily; even if you do, you are good at refocusing to complete the task. You are known as a hard-working person. You mostly do what you say you will, and sometimes even more, but rarely less.
Zest **You approach everything you do with excitement and energy.** *'When in doubt, take action!'*	You are an energetic, cheerful, and full-of-life person. You approach most things with excitement and enthusiasm. You do nothing half-heartedly. You wake up most mornings feeling energised and happy. The enthusiasm and passion you bring to activities often attract others to join you. When you experience something well done, you feel inspired and motivated.
Love **You value close relations with others.** *'Be a warm and strong listener'*	You are a very loving and caring person. Making and maintaining relationships comes naturally to you because you are genuinely interested in the wellbeing of your family and friends. You relate with you loved ones in many different ways but these ways show your love and care for them. You have a belief that your loved ones will be there for you, and you will be there for them, no matter what.
Social intelligence **You know how to fit in to different social situations.** *'Be friendly'*	You are well aware of your feelings and motives and of those around you. You are also very good at using this strength to put others at ease and fit in different social situations. You initiate conversations easily by finding common topics of interest. You show genuine interest in others and are very good at seeing different aspects of them- seeing each person as an individual.
Kindness **You are kind and generous to others.** *'Be helpful, err towards caring'*	You are a kind and generous person who loves doing favours and good deeds for others, even for those who you don't know well. You are never too busy to do a favour for a friend or family; in fact, you enjoy doing that. You are always more inclined to give than to receive. Your acts of kindness are in the best interest of other people, not to fulfil your own needs and wishes.
Fairness	You treat everyone fairly and stand up for others when they are bullied or ridiculed. You genuinely care about the welfare of others, even those you

One of your abiding principles is to treat all people fairly. *'Treat people the way you want to be treated'*	do not know personally. You do not make excuses to justify your mistakes and you do not let your feelings influence your decisions about other people. You give everyone a fair chance. With those who make the right decisions, you follow them as a role model.
Leadership **You excel at encouraging a group to get things done.** *'Organise activities for others'*	You excel at leadership tasks and activities. You are very good at organising group activities and seeing that they happen. You are the one others like to follow or often prefer that you take the lead. You also make everyone feel included. As a leader, whenever differences or conflicts occur, you are able to resolve these amicably and keep the harmony of the group intact. In fact, you are often able to bring the best out of every member.
Teamwork **You excel as a member of a group.** *'Work side-by-side with others'*	You are an excellent team player. In fact, you perform at your best when you are working with a group, rather than working alone. You work hard for the success and harmony of the group. You show respect to your group leaders, even if you disagree with some of their decisions.
Forgiveness **You forgive those who have done you wrong.** *'Let it go'*	You never hold grudges and are good at letting go of the wrong-doings of others. You forgive easily those who have offended or hurt you and once your forgive, you stay committed to it and rarely bring up the hurt again- because you don't believe in revenge and always give others a second chance.
Humility **You do not seek the spotlight and others recognize and value your modesty.** *'Place attention on others'*	You always let your accomplishments speak for themselves and do not seek the spotlight. You do not regard yourself as a special person, nor do you insist on being treated differently. You usually do not use status symbols (e.g., brand-name clothes or products) to impress others. Also, if you excel at something, you do not make others feel bad who may not be good at that. You are aware of your shortcomings and do not hesitate to admit them. Other recognize you as a humble or modest person.
Prudence **You are a careful person.** *'Think before you act'*	You are a careful person about your choices- I words or actions. You rarely yield to spontaneous escapades that you might later regret. You are refrain from making snap judgments. You are good at carefully evaluating risks and benefits of any decisions, and can anticipate potential problems and only then choose the best option.
Self-regulation **You are a disciplined person.** *'Manage your feelings'*	You are very good at managing your feelings and behaviours in both favourable and unfavourable situations. You are known as a disciplined person who follows most rules and routines (e.g. eating, sleeping, hobbies) without much complaining. Therefore, it is not very difficult for you to be patient and hold your wants, needs and impulses in check. Negative emotions of others do not easily overwhelm you and for the most

	part, you remain calm and do not panic easily. Despite challenges, you manage yourself well to achieve your desired goals.
Appreciation of beauty **You notice and appreciate beauty and excellence in all domains of life.** *'Find beauty in nature, art, ideas, and people'*	You are very good at perceiving and appreciating beauty and excellence in many areas of life, from nature to art to mathematics to science. Display of excellence inspires you. You love to incorporate things of beauty in your surroundings and feel at ease when you are amid art or watching a great performance.
Gratitude **You are aware of good things that happen and don't take them for granted.** *'Tell people "thank you" often'*	You never take things for granted and appreciate the good things in your life. When someone does a good thing for you, you don't just say "thank you", but also take time to express your heartfelt thanks through words and action. You recognize that it is important to sit down and regularly count your blessings. Therefore, you savour looking at the pictures and other memorabilia of the pleasant memories of the past. You share your joys and pleasant experiences with others with enthusiasm.
Hope **You expect the best in the future, and you work to achieve it.** *'Be positive, especially when others are not'*	Despite challenges and setbacks, you always remain hopeful that things will work out. You feel and believe that if you use all your resources and hard work, you wall achieve your goals. Therefore, a setback or a challenge does not dampen your spirits easily-because it doesn't affect every aspect of your life. This realistic perspective allows you to see the best, yet most realistic, aspects of a situation. You plan for the future with a good cheer and with sustained effort.
Humour **Bringing smiles to others people is important to you.** *'Laugh a lot, with others'*	It is very easy for you to find opportunities to laugh, be witty, playful and humorous in most situations. You are known for bringing smiles to other people and making them comfortable. You are also very good at seeing the lighter side of most situations, and therefore use humour to take the edge off a stressful situation. Your sense of humours bonds you with others.
Spirituality **Your beliefs shape your actions and are a source of comfort to you.** *'Look for what is sacred in this moment'*	Having a belief in God or in a higher power is very important to you. You like to participate in religious or spiritual activities at your will, not through coercion of others. You often look to God or a higher power for support and guidance. When you are in a tough situation, the first thing you do is to pray to God or a higher power for help.

Appendix 2.14: Instructions for setting goals using Character Strengths

Instructions given to CTCBI clinician and brain injury participant in the VIA-IS arm of the study for setting goals

Character Strengths in Action

Our Character Strengths influence all aspects of our lives in different ways. Now that you know what your Character Strengths are, you will start to see evidence for them in a range of different ways in your life, such as your strongest memories, your past achievements, your chosen pastimes and work, the kinds of people you enjoy being with, and your hopes for the future.

For example: -

- John uses his Character Strength of Humour to make his friends laugh; he is known as the joker of the group

- One of Anne's Character Strengths is Love of Learning: she is always planning the next evening class that she wants to take

- Mo uses his Character Strength of Gratitude to appreciate and reminisce about all the positive activities that he shares with his children.

Session Exercise

This diagram (over page) shows three main aspects of life, and how they overlap. Together with the CTCBI staff member, jot down some examples on the diagram of areas in your life where you might notice your own top 5 Character Strengths in action.

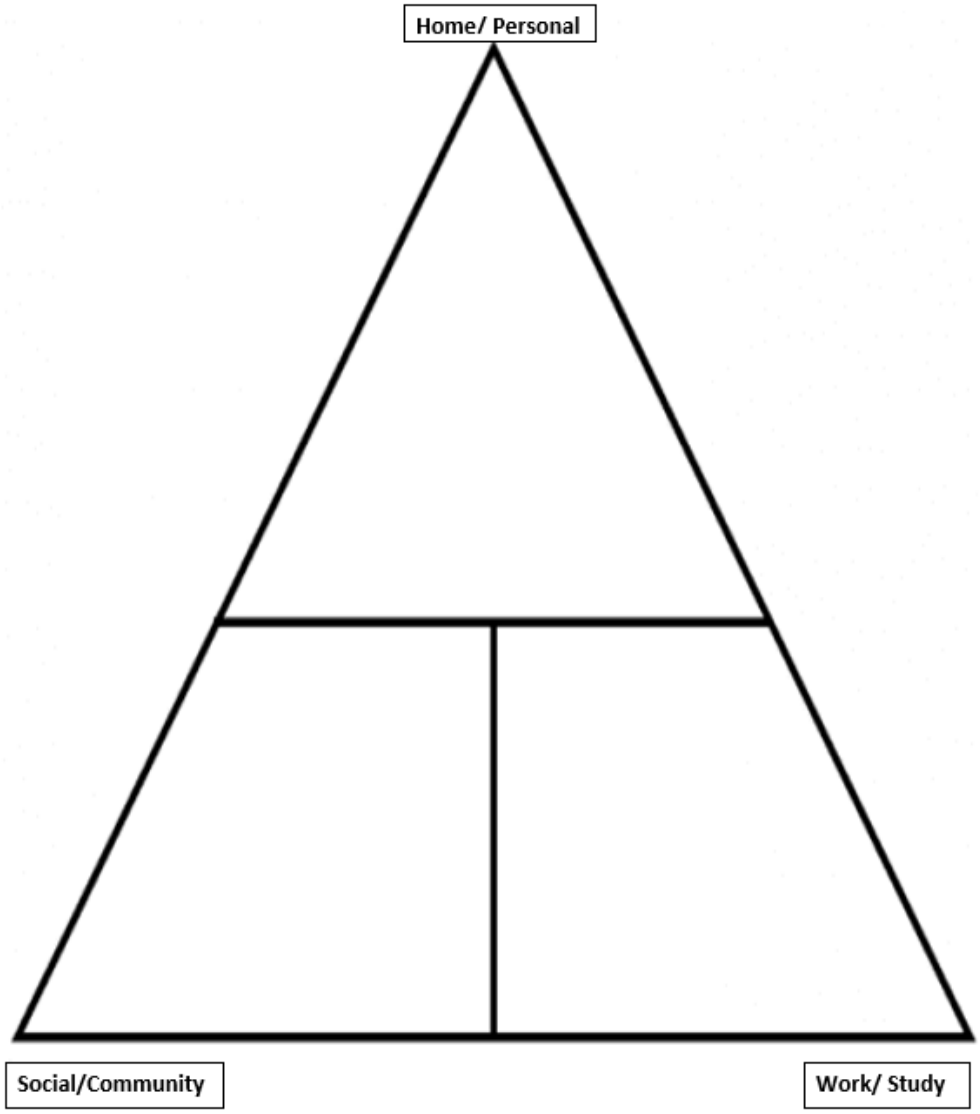
- Home/ personal:
- Work/ study:
- Social/ community:

Goal setting

Now can you think of goals you would like to work towards at the community treatment centre? These may be linked to what you might have learnt about yourself knowing your Character Strengths. It is OK if your goals are not linked to your Character Strengths. What would like to achieve in your work with the team at the community treatment centre?

Appendix 2.15: Diagram for setting goals using Character Strengths

Example of diagram to assist applying Character Strengths to setting goals in the VIA-IS group



Example of form that all participants used to note their goals for rehabilitation

GOALS FOR REHABILITATION:

……

……

……

……

……

……

……

……

Date:……

Appendix 2.16: Brain Injury Participant Feedback

Table 11: Brain injury participants responses about acceptability and ease of completing and using the VIA-IS

	Overall	Intervention	Control
Acceptable *n* (%) Comments:	17 (89)	8 (89) *It was straight forward* *It was easy to understand* *It was confusing at points* *I enjoyed the process and reflecting on my strengths* *The language of the VIA-IS was Americanised and did not feel relevant to my culture*	9 (90) *I was happy to help* *It was repetitive* (*n*=2) *It was confusing at points* *It was interesting* *There were too many questions about groups* *I enjoyed it: it made me look at myself and see some positives, and it showed me where I need to do some work. It also showed me how surgery has changed me for the better*
Not acceptable *n* (%) Comments:	2 (11)	1 (11) *It made me think about how different I am after my injury*	1 (10) *Some items of the questionnaire were poor and harder to answer*
Do you think your goals are related to one of your Character Strengths? Really not related (1) Slightly unrelated (2) Neither (3) Related (4) Really related (5) Median Likert rating (IQR)	*n*=19 (100%)	*n*=9 (100%) *n*= 2 (22%) *n*= 1 (12%) *n*= 0 *n*= 3 (33%) *n*= 3 (33%) 4 (1.5, 5)	*n*=10 (100%) *n*= 2 (20%) *n*= 0 *n*= 3 (30%) *n*= 3 (30%) *n*= 2 (20%) 3.5 (2.5, 4.3)
How easy was it to identify your goals? Very hard (1) Slightly hard (2) Neither (3) Easy (4) Very easy (5) Median Likert rating (IQR)	*n*=19 (100%)	*n*= 9 (100%) *n*= 0 *n*= 0 *n*= 2 (22%) *n*= 5 (56%) *n*= 2 (22%) 4 (3.4, 4.5)	*n*=10 (100%) *n*= 1 (10%) *n*= 1 (10%) *n*= 1 (10%) *n*= 6 (60%) *n*= 1 (10%) 4 (2.8, 4)
<u>VIA-IS group only</u> **Did you use your Character Strengths to help you set goals?** Yes (1)		*n*= 9 (100%)	

A little (2) No (3) Median Likert rating (IQR) **If you did, were they helpful for setting goals?** Not at all (1) Not really (2) Neither (3) Helpful (4) Very helpful (5) Median Likert rating (IQR)		*n*= 3 (33%) *n*= 3 (33%) *n*= 3 (33%) 2 (1, 3) *n*= 6 (67%) *n*= 0 *n*= 0 *n*= 1 (17%) *n*= 4 (66%) *n*= 1 (17%) 4 (3, 4)	

Appendix 2.17: CTCBI Clinician Feedback

Table 12: CTCBI clinician responses about acceptability and ease of completing and using the VIA-IS

	Overall (*n* = 19)	VIA-IS Group (*n* = 9)	Control Group (*n* = 10)
How do you think the participant found completing the VIA-IS?	*n*= 19 (100%)	*n*= 9 (100%)	*n*= 10 (100%)
Very hard (1)	*n*= 2 (11%)	*n*= 1 (11%)	*n*= 1 (10%)
Slightly hard (2)	*n*= 2 (11%)	*n*= 1 (11%)	*n*= 1 (10%)
Neither (3)	*n*= 2 (11%)	*n*= 1 (11%)	*n*= 1 (10%)
Easy (4)	*n*= 12 (62%)	*n*= 6 (67%)	*n*= 6 (60%)
Very easy (5)	*n*= 1 (5%)	*n*= 0	*n*= 1 (10%)
Median Likert rating (IQR)	4 (3, 4)	4 (2.5, 4)	4 (2.8, 4)
How easy was it to identify goals?		*n*= 9 (100%)	*n*= 10 (100%)
Very hard (1)		*n*= 1 (11%)	*n*= 0
Slightly hard (2)		*n*= 0	*n*= 0
Neither (3)		*n*= 0	*n*= 0
Easy (4)		*n*= 7 (78%)	*n*= 5 (55%)
Very easy (5)		*n*= 1 (11%)	*n*= 5 (55%)
Median Likert rating (IQR)		4 (4, 4)	4.5 (4, 5)
<u>VIA-IS group only:</u>		*n*= 9 (100%)	
Do you think the VIA-IS helped the process of identifying goals?			
Not at all (1)		*n*= 1 (11%)	
Not really (2)		*n*= 3 (33%)	
Neither (3)		*n*= 4 (45%)	
Helpful (4)		*n*= 0	
Very helpful (5)		*n*= 1 (11%)	
Median Likert rating (IQR)		3 (2, 3)	
Participants found it acceptable *n* (%)	17 (89)	8 (89)	9 (90)
Staff comments:		*The process felt like a positive experience with the participant* *The client found the wording confusing and the computer mouse difficult to operate. She thought some of the questions were irrelevant to her situation.* *It was good for building rapport, and learning about the client. It created a level of engagement that I would not have gotten otherwise.*	*Required support using the computer. He struggled to read the screen and became frustrated with how long it took to complete.* *The client needed correcting as they were missing out alternate questions because of the background*

		It helped the client to articulate why the goal was important to them. *It was a useful tool to get the client to think about different goals in relation to different areas of her life. She seemed to enjoy the process.* *The client knew what goal they wanted to set from the beginning (n=2)*	*colouring of the questionnaire.*
Participants found it not acceptable *n* (%) Staff comments:	2 (11)	1 (11) Participant found it difficult to fill in the VIA-IS, she required support using the computer, and found some of the language hard to understand. She was thinking about herself before the injury, and was worried about failing.	1 (10)

Appendix 2.18: Major Research Project Proposal

Title: Exploring the use of the Values in Action Inventory of Strengths in the process of goal setting in an acquired brain injury community rehabilitation setting: a feasibility trial.

Matriculation number:

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Abstract (226 words)

Background

There exists no gold standard procedure for goal setting for rehabilitation after acquired brain injury (ABI). Meaningful goals are important as they motivate clients to engage in rehabilitation programs. Assisting clients to identify personal values and drawing on these when setting goals may increase the personal relevance of rehabilitation program goals.

Aims

To investigate whether it is feasible and acceptable to use the Values In Action Inventory (VIA) as part of the rehabilitation goal setting process linking goals to personal values, and whether it is feasible to evaluate the use of the VIA in the context of a randomised controlled trial.

Methods

This feasibility and pilot study, with single blind design, will recruit participants with ABI from a community brain injury rehabilitation centre. Participants will be randomised into two groups; one will complete the Values in Action Inventory of Strengths (VIA-IS) and use their top five Character Strengths in considering goals for rehabilitation; the second group will set goals in the usual practice. Analysis will evaluate the feasibility and acceptability of using the VIA-IS for goal setting in an ABI rehabilitation context and whether it affects the types of goal set. Memory for goals approximately two weeks after goal setting will be measured.

Applications

This research has the potential to make ABI rehabilitation goal setting more personal, memorable, and satisfying, which in turn may increase engagement in rehabilitation programs.

Introduction

People who experience acquired brain injury (ABI), whether arising from cerebrovascular events, brain diseases, or head trauma, can experience a plethora of physical, cognitive, and emotional sequelae, including impaired language, memory, motivation, concentration, planning abilities, and changes in mood and personality (Wilson et al., 2009). The focus of neuropsychological rehabilitation is to support clients to learn strategies to overcome or manage these difficulties and to engage in personally meaningful activities.

Goal setting is a core component of rehabilitation following ABI (Playford et al., 2009). In a recent review, Evans (2012) argued that it is an opportunity for clinical intervention in the rehabilitation process. In particular, if clients are involved in the goal setting process, they rate their experience of rehabilitation more positively, and the nature of the goals set as more personally relevant. Currently, there is no defined form that goal setting should take in order to be most helpful to ABI clients. However, evidence has shown that personal relevance is important, having a motivating and empowering effect on engaging clients in the rehabilitation programme; goals perceived as meaningful increase clients' perception of wellbeing, and improve goal achievement (Dalton et al., 2012, Malec, 1999). Further, survivors of ABI often have difficulty in formulating relevant goals for rehabilitation (Sherer et al., 1998), which may be due to impairments in cognitive functioning after ABI. There is a need for research to identify what are the most effective ways to set goals in rehabilitation.

Positive psychology (PP) is the scientific study of positive individual traits, positive subjective experience, and positive institutions, and how these factors lead to improved quality of life (Seligman and Csikszentmihalyi, 2014). Evans (2011) emphasised the overlapping focus of PP with neuropsychological rehabilitation following TBI, and the relevance and potential application of PP techniques within this setting. Since then, evidence has shown constructs of PP (resilience, character strengths, and positive mood states) are related to rehabilitation-related variables (perceptions of functional ability, and expectations of treatment); further highlighting the potential application of PP constructs to rehabilitation following ABI (Bertisch et al., 2014).

The Values in Action Inventory of Strengths (VIA-IS), is a central tool of PP, and is a reliable measure designed to identify individuals' 24 Character Strengths profile (Peterson and Seligman, 2004). Character Strengths are positive human traits considered to transcend cultures, and research has shown the development of Character Strengths can

lead to improvements in enjoyment and engagement of activities (Seligman et al., 2009). The 24 Character Strengths fall within six value categories: Wisdom (e.g. curiosity, creativity), Courage (e.g. bravery, honesty), Humanity (e.g. love, kindness), Temperance (e.g. forgiveness, humility), Justice (e.g. leadership, teamwork), and Transcendence (e.g. gratitude, hope). The VIA-IS is not presently utilised during goal setting in rehabilitation services after ABI, however we speculate that if goals are closely linked to personal values, they may be considered more personally meaningful and as a result better remembered. This in turn may increase engagement with the rehabilitation process.

Given that the VIA-IS is not routinely used in community brain injury rehabilitation services to aid goal setting, it is necessary to investigate whether it is feasible and acceptable to use the VIA-IS as part of the rehabilitation goal setting process linking goals to personal values. In order to justify administering the VIA-IS, it would need to be demonstrated that it is beneficial over and above usual goal setting procedures. Therefore, the present study will examine whether it is feasible to evaluate the use of the VIA-IS in the context of a randomised controlled trial in which use of the VIA in goal setting is compared with usual goal setting practice.

Aims and hypotheses

The primary aim of this study is to examine the feasibility and acceptability of using the VIA-IS in the goal setting process for ABI rehabilitation, within a Randomised Control Trial (RCT) context. The research questions include:

1. What number of potential participants identified fulfils eligibility criteria?

2. What proportion of potential participants consent to participate?

3. What number of participants can be followed-up at two weeks via telephone call?

4. Is it feasible and acceptable to use the VIA-IS during the goal setting process in a community treatment setting for brain injury?

i. What proportion of participants complete the VIA-IS?

ii. What feedback do participants provide regarding their experience of completing and using the VIA-IS to set goals?

iii. What feedback do CTCBI clinicians provide regarding their experience of including the VIA-IS in the goal setting process?

5. What is the measurement variance for the key outcome measure of memory for goals, which would be used to calculate sample size for future trial?

6. Does using the VIA-IS in the goal setting process cause there to be differences in the categories of goals set compared with the typical method of setting goals?

7. Is it feasible for the assessor to be blind to condition?

Plan of Investigation

Participants

Participants will be recruited from the Community Treatment Centre for Brain Injury (CTCBI), which is a community based service for adults aged 16 and over, who have experienced a brain injury (including: traumatic brain injury, subarachnoid haemorrhage, anoxic/hypoxic brain damage, encephalitis /meningitis). The CTCBI is a multidisciplinary team that provides client-centred intervention to reduce disability associated with brain injury, and to assist clients to become independent in their home and community. Clients at the CTCBI are typically provided with a meeting for setting goals for rehabilitation, followed by a programme that focuses on clients engaging in meaningful and productive activities, in all aspects of their lives.

Inclusion and Exclusion Criteria

Inclusion criteria include clients who have had an ABI, and have been referred to the CTCBI. Exclusion criteria include clients that are lacking the capacity to consent to take part in the study, and whose language ability (judged subjectively by CTCBI clinicians) would impact on their ability to engage in the goal setting process including understanding the VIA-IS questions.

Recruitment Procedures

CTCBI clinicians will identify and recruit of participants to this study, in addition to combining the procedures of this pilot RCT into their current practice of facilitating goal setting with ABI clients. The term ‘CTCBI clinicians’ refers to a core team of one speech

and language therapist, and two occupational therapists who conduct the initial assessments and goal setting at the CTCBI.

Clients who are referred to the CTCBI will be invited to participate in the study. Potential participants will receive a Participant Information Sheet explaining that the study is investigating ways of helping to make decisions around goals for rehabilitation. Participants who consent to take part in the study will be randomised into a goal setting as usual group, and a goal setting plus VIA-IS group. The CTCBI clinicians will be asked to keep an excel sheet with a count of the number of potential participants approached, and for those who did not agree to participate, any reasons given. This information will be sent to the research student at the end of the study, and along with a count of participants who were able to be contacted at the two-week follow up, this information will be analysed in order to answer research questions pertaining to recruitment and retention figures.

Measures

Following recruitment and consent, data concerning participants' characteristics will be collected including age, gender, and postcode. Postcodes will be used to determine socioeconomic deprivation using the Scottish Index for Multiple Deprivation (SIMD) 2016. SIMD quintiles for the general population will be used to determine socioeconomic deprivation, ranging from 1 (most deprived) to 5 (most affluent). Type of injury and severity of injury (Glasgow Coma Scale score at hospital admission, or a retrospective calculation of Post Traumatic Amnesia where appropriate) will be collected from participants' self-reports and checked against their medical records held by the CTCBI team. Permission to access medical records will be sought in the consent process. This information will allow us to evaluate ABI clients' characteristics pertaining to consent and retention in a pilot RCT in a community rehabilitation setting. Participants will also be asked to provide a telephone number so the research student can contact them for follow-up in two weeks. The CTCBI clinicians will gather this information using a proforma created by the research student.

The procedures include participants completing the VIA-IS-120 for Adults. It is a validated measure designed to identify individuals' 24 character strengths profile (Peterson and Seligman, 2004). Participants will complete the VIA-IS online using laptops provided by the CTCBI. The top five character strengths for each participant will be shared with the participant and CTCBI clinician who is facilitating the goal setting session. These results will be used to set goals in the VIA-IS group. The goal setting as usual group will complete the VIA-IS at the end of the goal setting session, as it is important to evaluate whether

the goals they set are linked with their top five Character Strengths, regardless of their knowledge of them prior to goal setting. The number of participants completing the VIA-IS will be recorded.

Participants' and CTCBI clinicians' feedback about whether the VIA-IS results were used in the goal setting process and how useful the process was in identifying goals will be obtained via a questionnaire created by the research team (see Appendix A). Memory for goals two weeks after they were set will be used as an indicator of how personal they were to participants (Culley and Evans, 2010). Participants will receive a phone call by the researcher at two weeks, who will ask them to free recall their goals.

Exploratory analysis will categorise goals using the International Classification of Functioning, Disability, and Health (ICF) to see if the nature of the goal areas set is different between groups. ICF is the WHO framework for measuring health and health related domains (WHO, 2001). In this study, goals will be categorised by the research student using the ICF 2017 activities and participation categories, as has been shown in previous research (Oliveira et al., 2017, Rice et al., 2017). The categories include: learning and applying knowledge, general tasks and demands, communication, mobility, self-care, domestic life, interpersonal interactions and relationships, major life areas, community, and social and civic life. Following this, any differences in goal categories can be compared between the VIA-IS group and the goal setting as usual group.

Design

A feasibility pilot RCT study, with a single blind design.

Research Procedures

This research will take place as part of the typical assessment and goal setting sessions with ABI clients at the CTCBI. ABI clients will be invited to take part in the study by CTCBI clinicians, who will give them an information sheet at their first appointment, and given time to consider participating and to contact the research student to ask any questions about the study. Consenting participants will then be randomised to either goal setting with the VIA-IS, or goal setting as usual group, using a blocked randomisation process in order to have even numbers in each group. A blocked randomisation sequence will be created using an online randomisation programme with a block length of six (meaning that for every six participants there will be three in either group). The researchers will be blind to this sequence, which will be held by the CTCBI administrator who will inform of group membership ahead of the goal setting session.

Participants in the goal setting plus VIA-IS group will be asked to complete an online version of the VIA-IS on a laptop at the beginning of their goal setting session, which will automatically calculate their top five signature strengths. This should take approximately twenty minutes to complete. A prompt sheet will be provided clarifying any unclear wording, which will have been identified by piloting the VIA-IS at a brain injury group prior to study commencement. The CTCBI clinician who is facilitating the goal setting session will be in the room but sit separately to participants when completing the VIA-IS. Participants will be given the instructions to "not overthink their answers to the questionnaire, to answer as honestly as possible" and be reminded that the answers to the questions will not be seen by the CTCBI clinician. Participants will be told that they can ask the CTCBI clinicians for clarification if they do not understand a question, however the clinicians will be instructed not to assist participants in answering the questions. Any questions about the wording of the VIA-IS will be noted in the feedback from CTCBI clinicians at the end of the session and used to evaluate the feasibility and acceptability of using the VIA-IS in this setting.

After completing the VIA-IS, participants will receive further information about what their top five character strengths mean (See appendix D). The CTCBI clinicians and participant will set goals using the guidance from the PoPsTaRS manual (Cullen et al., 2018) (see Appendix B). Briefly, examples are given of how one may put their Character Strength into action, then participants are asked to think of examples of where their Character Strengths might be seen in action in various areas of their life. Participants will then be asked to set their goals, and will be invited to use the Character Strengths in action that they have just identified if they prefer, or any other goal that is important to them. It will be made clear to participants that goals do not need to be linked to Character Strengths if this process did not produce personal or meaningful goals. Training with opportunities to discuss these procedures will be provided to CTCBI clinicians in order to manualise and standarise the process of goal setting in the VIA-IS group.

Participants in the goal setting as usual group will set their goals for rehabilitation at the beginning of the session, using the typical method. Currently there are no standardised procedures for setting goals for community rehabilitation after brain injury, which is one reason why the feedback from this pilot may assist development of this practice. The CTCBI clinicians report that the process of setting goals can vary; sometimes clients know their goals before they attend their first appointment at the CTCBI, while others require some assistance from the clinicians to think of goals. Therefore, the 'goal setting as usual' group will not be standardised, however in doing this, it will be representative of current practice. The purpose of this study is to investigate whether using the VIA-IS aids the

experience of goal setting and memory for goals two weeks later above and beyond the current practice, for clinicians as well as for participants.

After the goal setting as usual group has set their goals for rehabilitation they will be asked to complete the VIA-IS. The purpose of this is to investigate whether clients' goals are consistent with their Character Strengths even if the process of setting goals has not been explicitly driven in relation to the Strengths. At the end of the goal setting session, CTCBI clinicians and participants in both groups will be asked to evaluate their experience of goal setting by completing a questionnaire which will take approximately five minutes, the answers to which will inform allow the evaluation of the acceptability and usefulness of both methods for settings goals (see Appendix A). The procedures for this study make take between 20-30 minutes to complete.

Replicating methods used in a study investigating memory of goals set for rehabilitation following brain injury by Hart et al (2002), the research student will phone the participants two weeks after their goal setting sessions and ask if they can recall their goals. Participants will not be forewarned that this is the purpose of the phone call to avoid effects of effort to remember goals. Participants' free recall will be scored with the criteria used by Culley and Evans (2010) and Hart et al (2002, p563), whereby participants were awarded points based on accuracy of recall. In these previous studies, three points were given if the response mirrored the original goal statement in terms of ideas and accuracy of content; two points if the participant recalled the general theme of the goal but was unable to provide further specific details, or their answer showed evidence of intrusions or distortions, and one point if the participant demonstrated a basic awareness of the goal but demonstrated significant distortions in content or was lacking in specific details. Zero points are given if participants provide a "Don't know" response or their recall did not reflect goals in any way. These scores will be summed and averaged across all goals set. Retention of participants to follow-up will be noted to evaluate the feasibility.

There is currently a 4-7 weeks gap between assessment and goal identifying session, and clients' next contact with the CTCBI, therefore it is unlikely there will be contact in this gap that may affect memory. CTCBI clinicians will be asked to provide information about any further contacts they have with participants in this time, and any differences between the two groups will be explored. If participants do not complete the VIA-IS, any reasons given for this will be analysed to evaluate acceptability. These participants will not be followed-up at two weeks, and their withdrawal from the study will be noted as due to failure in completing the required procedures.

Goals set will be categorised by the research student into the ICF 2017 activities and participation categories, as has been shown in previous research (Oliveira et al., 2017, Rice et al., 2017). They will use their judgment to assign each goal to an ICF classification, and log their responses on a SPSS spreadsheet. At the end of the study, the researcher will be asked to guess the allocation of each participant after the follow-up phone-call. Determining the success of blinding will inform plans for a future full-scale trial.

Data Analysis

The number of potential participants approached, recruited, followed-up and analysed will be reported using a CONSORT flow chart. This will allow investigation into rates of declining to participate and attrition during the study. Analysis of the Likert scale responses and summaries of qualitative feedback will provide valuable information about what specifically was acceptable or not acceptable regarding completing the VIA-IS, and whether it was helpful for setting goals for participants and CTCBI clinicians. Means and variance in participants' free recall of goals in both conditions will be calculated. Variance will inform a sample size calculation in a future trial. Types of goals set will be described and analysed by counting the frequency of the ICF classifications.

Justification of sample size

The present study is a feasibility study of a new approach to goal setting and therefore it is not powered to detect differences in outcome measures. A key aim will be to determine recruitment and retention rates over a recruitment period of six months. Currently, the CTCBI assess 20 new ABI clients a month. Following assessment of eligibility, and assuming that half of this population consent to take part, we expect to recruit approximately eight participants a month. We can estimate from this we will recruit two groups of twenty-eight participants over a seven-month recruitment process.

Settings and Equipment

The study will run at the Community Treatment Centre for Brain Injury (CTCBI). All CTCBI clinicians involved in goal setting with clients will be involved and will receive training in the administration of the VIA-IS, based on instructions on the VIA Institute of Character Website (see appendix C), and how to use information from this questionnaire in the goal setting process described in Appendix B and based on Cullen et al. (2018). They will use their on-site computers to allow participants to complete the VIA-IS and to get the results. Consent forms, Participant Information Sheets, and questionnaires to provide feedback

on the sessions will be provided by the research group. A phone will be required to make the follow-up phone calls to participants by the research team.

Health and Safety Issues

There are no research or participant health and safety concerns.

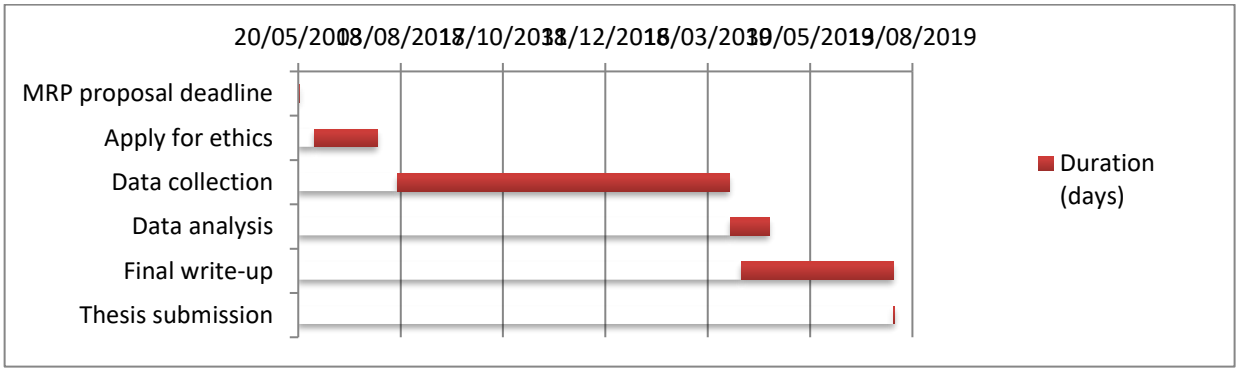
Ethical Issues

Ethical issues to consider include not reducing the quality of, or interfering with, the methods for goal setting already created by the CTCBI. Also, in order to use the online version of the VIA-IS, participants are asked to enter their age and gender. Advice from the University of Glasgow Data Protection and Freedom of Information Office confirms that this is acceptable within EU general data protection guidelines. Participants will be made aware prior to consent process that by completing the online VIA-IS, the VIA Institute on Character may use these non-identifiable answers for future archival studies and that this does not violate UK/EU data regulations. An ethics application will be submitted to NHS Greater Glasgow and Clyde (GG&C) ethics committee and research and development (R&D) office.

Financial Issues

There will be an approximate £17 cost towards printing the research materials such as PIS and consent forms.

Timeline



Practical Applications

If this project shows that rehabilitation goals set after ABI using the VIA-IS are more meaningful to participants, that they are more likely to remember these goals, and that it increased satisfaction in the process of setting goals for the clients and CTCBI clinician, there is the potential for further study of whether clients engage more in rehabilitation working towards these goals. This may increase the efficiency of community rehabilitation after ABI, improving outcomes for client.

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