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# Evaluation of Individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling: A Pilot Study AND

Clinical Research Portfolio

# **VOLUME I**

(Volume II bound separately)

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July 2013

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Submitted in part fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology



Name DANIELLE GRAHAM

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# **VOLUME I: TABLE OF CONTENTS**

	<b>Page</b>
<b>Chapter 1: Systematic Review</b> The Feasibility and Efficacy of Cognitive Behaviour Therapy for Fear of Falling: A Systematic Review	5
Chapter 2: Major Research Project Evaluation of Individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling: A Pilot Study	44
Chapter 3: Advanced Clinical Practice I: Reflective Critical Account (abstract only) Communicating a Psychological Approach to Other Disciplines: A Support or Stressor?	77
Chapter 4: Advanced Clinical Practice II: Reflective Critical Account (abstract only) Developing the Application of Psychological Skills in Multi-Disciplinary Teams: Is there a Middle Ground between Diagnosis and Formulation?	79
Systematic Review Appendices 1.1. Instructions for Authors for Submission to International Psychogeriatrics 1.2. Quality Rating Scale 1.3. Table Outlining the Key Methodological Limitations of Included Studies	81 90 93
Major Research Project Appendices  2.1. Instructions for Authors for Submission to The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences.	95
<ul><li>2.2. NHS Ethical Approval letter</li><li>2.3. NHS Research &amp; Development Management Approval letter</li><li>2.4. Participant Information Sheet</li></ul>	101 104 106
<ul><li>2.5. Participant Consent Form</li><li>2.6. GP Information Sheet</li><li>2.7. Intervention Protocol</li></ul>	109 110 112
2.8. Major Research Project Proposal	115

## **Chapter 1: Systematic Review**

# The Feasibility and Efficacy of Cognitive Behaviour Therapy for Fear of Falling: A Systematic Review

## Danielle Graham\*

Prepared in accordance with guidelines for submission to *International Psychogeriatrics* (Appendix 1.1)

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#### **ABSTRACT**

**Background:** Fear of falling is a debilitating condition that is prevalent amongst older adults and is associated with activity restriction and loss of confidence to avoid future falls. Cognitive behavioural interventions may be effective in treating fear of falling and there is an emerging evidence base. This study systematically reviews evidence regarding the efficacy and feasibility of Cognitive Behavioural Therapy (CBT) for fear of falling.

<u>Method:</u> Eight databases were searched and reference lists of obtained articles were hand searched. Two prominent authors in the field were contacted to source further papers. Nine studies were identified and rated according to a modified version of the Clinical Trials Assessment Measure (CTAM) (Tarrier & Wykes, 2004) and effect sizes were calculated.

<u>Results:</u> Two of the nine studies were rated as high quality and two as moderate. Six studies demonstrated beneficial effects of intervention post treatment and at follow-up. Hence, there is preliminary evidence for the efficacy of CBT for fear of falling, however, there is insufficient information to draw firm conclusions regarding the practical use of this approach. Key limitations in published studies are: failure to employ adequate comparison groups; failure to use recognised theoretical models to guide the CBT intervention; high attrition rates; failure to report the training of CBT therapists; and failure to report intervention fidelity.

<u>Conclusion:</u> There is preliminary evidence to recommend group delivered CBT for use with fear of falling in older adults with less severe physical impairments. Future research should focus on improving methodological quality.

#### Key Words:

Older Adults, Cognitive Behaviour Therapy, Fear of Falling

#### **INTRODUCTION**

A third of community dwelling older adults have one or more falls each year (Friedman et al., 2002) and 50% of these develop a 'fear of falling' (Tinetti et al., 1988). This condition is not specific to those who have fallen and is found in non-fallers (Friedman et al., 2002). There is no agreed definition of fear of falling (FoF), but some consensus that it entails a loss of confidence in the ability to avoid future falls (Tinetti et al., 1990), and avoidance of activity that is disproportionate to injuries sustained from a fall (Tinetti & Powell, 1993).

FoF is recognised to be debilitating and is associated with institutionalisation, increased risk of future falls (Cumming et al., 2000), and poorer rehabilitation outcomes (Oude Voshaar et al., 2006). Furthermore, it is associated with reduced overall activity (Tinnetti & Powell, 1993), reduction in social activities (Lachman et al., 1998), loss of independence (Howland et al., 1993), impaired quality of life (Cumming et al., 2000), and damage to personal identity (Scheffer et al., 2008). Several studies report associations between FoF and general anxiety and depression (van Haastregt et al., 2008) and suggest that general anxiety or depression could worsen FoF because of loss of confidence in physical abilities or, that FoF may result in anxiety and depression due to activity avoidance, fewer opportunities for positive reinforcement, and an increased expectancy for negative events.

#### Measurement of FoF

Zijlstra et al. (2007) recommend the Falls Efficacy Scale International (FES-I) (Yardley et al., 2005) to measure FoF. The Activities, Balance and Confidence Scale (ABC) (Powell and Myers, 1995) and the Survey of Activities and Fear of Falling in the Elderly (SAFFE) (Lachman et al., 1998) are also validated measures of FoF (Scheffer et al., 2008). There is

limited evidence for the reliability and validity of single item measures of FoF which often include one question such as 'are you fearful of falling?' (Scheffer at al., 2008).

#### Interventions for FoF

In a review of FoF interventions, Zijlstra et al. (2007) highlighted that multi-factor interventions (including components such as falls risk education, community and home risk factors, and safety plans), home and community based exercise, and Tai Chi were beneficial in reducing FoF. However, the majority of the 19 trials in their review were not primarily aimed at reducing FoF and instead focused on falls incidence and risk. Furthermore, very few studies included information regarding the process of the intervention and it was unclear whether interventions followed a specific protocol.

Due to the psychological correlates of FoF, Letgers (2002) suggests that cognitive and behavioural changes must occur for interventions to be optimal. Cognitive Behaviour Therapy (CBT) is an effective intervention for depression (Laidlaw, 2001) and anxiety (Thorpe et al., 2009) late in life and there is emerging evidence for the efficacy of group based CBT for FoF (Van Haastregt et al., 2007).

#### Aims

This systematic review investigates the efficacy of CBT for FoF. There are no previous systematic reviews of this subject. Included are studies that incorporate cognitive behavioural interventions in a wider multi-factor intervention. The review also considers the feasibility of CBT for FoF by examining subject retention, the use of reliable and valid outcome measures, and adherence to intervention protocol.

#### Research Questions

- 1. Is CBT a beneficial intervention for FoF?
- 2. Is CBT a feasible intervention for FoF?

#### **METHODS**

Search Strategy

An electronic search of the following databases was conducted: PsycArticles, PsycInfo,

CINAHL, Science Direct, ERIC, EMBASE, Health and Psychosocial Instruments, and

Medline. Searches were limited to papers published in English.

The following search terms were used:

Intervention\* OR Cognitive Behav\* Therapy OR Psychological Intervention\*OR

Psychological Therapy

AND

Fear\* of Falling OR Ptophobia OR Post Fall Syndrome

(\*denotes the truncation command where the search will identify all words beginning with that term).

Articles identified by the search strategy were screened using the following criteria:

Inclusion criteria

- Published in a peer reviewed journal
- Studies an older adult population (age 65 and above)
- Involves an intervention for FoF in older adults that is stated to be cognitive behavioural
- Examines the efficacy of the cognitive behavioural intervention on FoF

# **Exclusion Criteria**

- Review articles
- Books and book chapters
- Commentaries
- Case studies/reports
- Does not examine the efficacy of the cognitive behavioural intervention on FoF

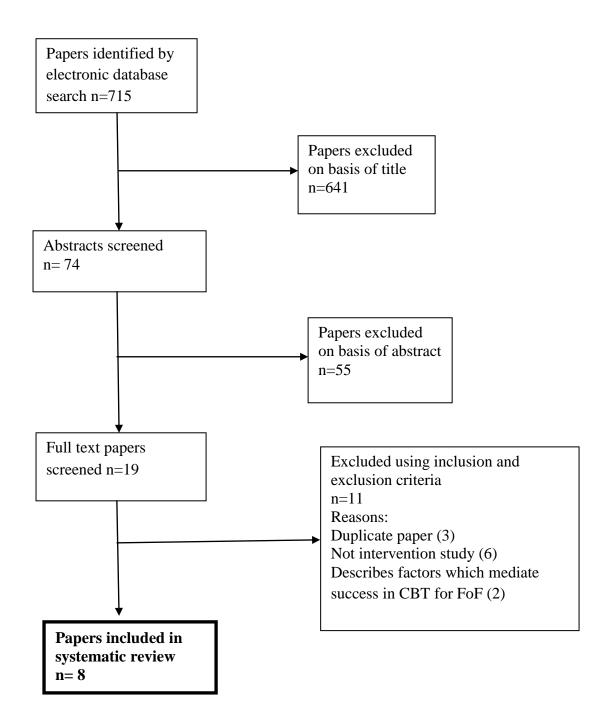


FIGURE 1: FLOW DIAGRAM INDICATING ELECTRONIC SEARCH PROCESS

Eight papers met the inclusion and exclusion criteria and were included in the review (see Figure 1).

Reference lists of the eight included papers yielded no additional articles. Two prominent authors in the field, Dr Tennstedt and Dr Zijlstra, were contacted to source additional papers.

This yielded one additional article that was not publicly available at the time of the electronic search. This resulted in an overall total of nine papers.

#### Quality Rating Criteria

All included studies were rated for quality using a modified version of The Clinical Trials Assessment Measure (CTAM) (Tarrier & Wykes, 2004). This is an assessment tool which can be used to estimate the quality of clinical trials. It has adequate internal consistency and excellent external validity (Wykes et al., 2007). Endorsing an item affords a score of 1, 3, 4, 5, 6, or 10. The CTAM was modified for this review by including items specific to the measurement of FoF and the feasibility and efficacy of the CBT intervention. The modified-CTAM consisted of 26 items covering six areas of trial design. Items added for this review were weighted according to their relevance to the research questions where 1 = low importance, 3 = medium importance, and 5 = high importance. The maximum score was 145. Scores were converted into percentages, with 49% or below considered 'low quality'; 50 – 74% 'moderate quality'; and 75 -100% 'high quality'. These ratings were used to provide the author with an overall indicator for the level of confidence in which a particular study's findings could be taken.

To assess inter-rater reliability an independent reviewer rated all nine papers. Overall agreement was high (99.2%). Any discrepancies between reviewers were resolved through discussion.

#### **RESULTS**

Two papers were rated as 'high quality', two papers as 'moderate quality', and five papers as 'low quality' (see Table 1).

TABLE 1: DESCRIPTION AND QUALITY RATINGS OF INCLUDED STUDIES

Study	Quality rating	Description of intervention	Sample characteristics	FoF outcome measure	Other outcome measures	Conclusions	Effect sizes
Papers rated as							
Tennstedt et al. (1998)	77.93%	Randomised Controlled Trial (RCT). Control group: 'social contact' (2 hour session including group discussion). Intervention: group delivered, 2 sessions a week for 4 weeks. Techniques: strength training exercises; cognitive restructuring; goal setting; increasing activity levels; and assertiveness training.	Control n = 218, intervention n = 216, male = 45 female = 389. Groups homogenous on baseline characteristics (age, gender, marital status, ethnic background, education level) and baseline scores on outcome measures.	FES FCS FMS	Falls Incidence: self-report.  Functional ability: SIP Intended activity Scale (developed by authors).	Intent to treat analysis: intervention group demonstrated increased levels of intended activity and less health related dysfunction post treatment. No significant change in FES scores between groups.  Analysis of participants attending >5 sessions: intervention group had increased falls efficacy and perceived ability to manage falls post treatment; not maintained at 6-month but significant at 12-month follow up.	Compliant with intervention (attending > 5 sessions) Intervention vs. Control group: FES 6 week d = 0.20 6 month = not presented 12 month d = 0.12  FMS 6 week follow up d=0.51 6 month follow up d = 0.39 12 month follow up d = 0.36
Zijlstra et al. (2009)	76.55%	RCT. Control group: treatment as usual. Intervention: group delivered, 8 weekly 2-hour sessions and a booster session 6	Control group n = 260, intervention group n= 280, female = 388, male = 152.	FES FCS	Activity levels: Frenchay Activities Index.  Perceived consequences of	Intervention group experienced significantly greater improvements in FoF, concerns about falling, activity, and attitudes	Between subjects FES: 2 month d = 0.27 8 month d= 0.41 14 month d= (not presented)

T		,		T	
	months later.	Groups	falling: 2, 6 item	about the consequences	FCS:
	Techniques: low	homogenous on	subscales from	of falling. Effects	2 month d=(not
	intensity physical	baseline	Yardley & Smith	maintained at 8-month	presented)
	exercises; cognitive	characteristics	(2002).	follow up. The	8 month d= 0.25
	restructuring; goal	(age, sex, living		intervention group	14 month d= 0.32
	setting; and	status,	Falls incidence:	showed greater	
	behavioural	cognitive	unclear how this	improvements in FoF	Within subjects
	activation.	status, health	was recorded.	and control over falling	<b>Intervention Group</b>
		status, falls		at 14-month follow up.	FES:
		incidence)		Per protocol analysis	Pre vs. Post d= 0.31
		,		(intervention group):	Pre vs. 8 month
				increased perceived	d = 0.35
				control over falling,	Pre vs. 14 month
				reduced avoidance of	d= 0.21
				activity, and concerns	FCS:
				about falling and	Pre vs. Post
				increased daily activity	$\mathbf{d} = -0.30$
				at 14 month follow up.	Pre vs. 8 month
				at I i monus rosso w up.	d= -0.28
					Pre vs. 14 month
					d= -0.30
					u- 0.50
					Control Group
					FES:
					Pre vs. Post d = 0.23
					Pre vs. 8 month
					d= 0.07
					Pre vs. 14 month
					d = 0.14
					G = 0.14 FCS
					Pre vs Post d = -0.27
					Pre vs Post a = -0.27 Pre vs. 8 month
					d = -0.16
					Pre vs. 14 month
					$\mathbf{d} = \mathbf{-0.12}$

Papers rated as							
Huang et al. (2011)	73.1%	RCT (3 groups): 1. Control group: treatment as usual. 2.CBT: group delivered; 8 weekly sessions of 60-90 minutes. Techniques: cognitive restructuring; falls management strategies; and problem solving. 3. CBT + Tai Chi: group delivered, received the CBT intervention outlined above and attended Tai Chi lessons 5 times a week for 8 weeks.	Control n = 60, CBT n = 62, CBT + Tai Chi n= 56, female = 109, male= 69. Groups similar on baseline characteristics (age, gender, education level, marital status, living status, health status, falls incidence) and baseline scores on outcome measures.	FES GFFM	Falls Incidence: Falls Record Checklist (Huang & Acton, 2004).  Mobility: Tinetti Scale (Tinetti, 1986).  Social Support: WHOQOL-BREF Inventory of Social Support Behaviours (Barrera et al., 1981).	FoF significantly decreased at 5-month follow up in the CBT and the CBT + Tai Chi groups compared to the control group. There was no difference in falls incidence between groups. The mobility of participants in the CBT + Tai Chi group was higher at 5-month follow up compared to the CBT group. The CBT + Tai Chi group reported significantly higher levels of social support following the intervention compared to CBT and control groups.  WHOQOL scores significantly higher in the CBT + Tai Chi group than in the CBT group or the control group.	FES Within groups Control Pre vs. Post d=0.09 Pre vs. 5month follow up d=0.11 CBT Pre vs. Post d= -0.07 Pre vs. 5month d= -0.12 CBT + Tai Chi Pre vs. Post d=-0.15 Pre vs. 5month d= -0. 34  Between groups CBT vs. Control Post treatment d= -0.07 5month d= -0.14 CBT vs. CBT + Tai Chi Post treatment d= -0.41 5month d= -0.60 CBT + Tai Chi vs. Control Post treatment d= -0.45 5month d= -0.69  GFFM Within groups

Clemson et al.	68.28%	PCT Control groups	Control no 152	MFES	Falls incidence:	Intervention group	Control Pre vs. Post d= -0.02 Pre vs. 5month d= -0.28 CBT Pre vs. Post d=0.31 Pre vs. 5month d=0.29 CBT + Tai Chi Pre vs. Post d= 0.37 Pre vs. 5month d= 0.63  Between groups CBT vs. Control Post treatment d= 0.54 5month d=0.79 CBT vs. CBT + Tai Chi Post treatment d=-0.02 5month d= 0.21 CBT + Tai Chi vs. Control Post treatment d= 0.59 5month d=1.09
(2004)	08.28%	RCT. Control group: up to two social visits. Intervention group: 7 weekly sessions and a	Control n= 153, intervention n= 157, male = 80 female = 230. Groups similar	MES MES	self-report.  Perception of health: SF-36.	Intervention group reduced falls incidence compared to the control group. No significant difference was found	It was not possible to calculate effect sizes as only mean change scores were presented.

		booster session at 3 months. Described as 'cognitive behavioural learning'. Group delivered.  Techniques: physical exercises; assessing and managing home hazards; community safety advice; information regarding health	on most baseline characteristics (gender, falls incidence, incidence of stroke, incidence of arthritis, use of psychotropic medication). Control group had higher		Physical activity: PASE.  Mobility and balance: The Get up and Go Test (Mathias et al., 1986). Romberg test of balance.  Anxiety: The	after the intervention in falls self-efficacy.	
		issues; and mobility exercises.	incidence of hip fracture.		Worry Scale (Wisocki, 1988).		
Papers rated as	low qualit		macture.	<u> </u>	(11 ISOCKI, 1 700).		
Healy et al. (2008)	39.3%	Single group pre-post design. Intervention: group delivered, 8, 2-hour sessions over 4 weeks. Techniques: behavioural activation; cognitive restructuring; goal setting; modifying home risk factors; and strength and balance exercises.	N=335, female = 289, male = 46.	FES FCS FMS	Falls Incidence: self-report.  Readiness for exercise: PACE.	There was a significant increase in falls efficacy, perception of control over falling, and perceptions of ability to manage falls post treatment and at 6 and 12 month follow-up, increased exercise and significant decrease in falls incidence at 6 and 12 month follow up.	It was not possible to calculate effect sizes as only mean scores were presented.
Reinsch et al. (1992)	29.65 %	RCT (4 groups) 1. Exercise: stand ups and sit-ups. 2. Cognitive behavioural intervention: group delivered.	N= 230, female = 185, male = 45. Groups similar on baseline characteristics (age, gender,	Single item measure – rated on a 5 point scale.	Falls incidence: self-report.  Perceived health: single item measure.	Falls incidence and levels of FoF did not differ significantly after intervention between groups.	Within subjects Exercise intervention d=-0.11 Cognitive behavioural: d=-0.25 Exercise + Cognitive

		Techniques: a 'health and safety' curriculum to prevent falls; relaxation training; and 'videogame playing', delivered once a week for 1 year.  3. Exercise & cognitive behavioural intervention: group delivered 3 days a week for 1 year.  4. Discussion control group.	falls incidence)		Level of injury associated with falls: self-report scale (Greenspan et al., 1985).  Muscle strength and balance: 10 stands test (Cuska & McCarthy, 1985).  One leg balance test (Bohannon et al., 1984).		behavioural d=0 Discussion: d=-0.36  Between subjects Exercise vs. Cognitive behavioural d=-0.12 Cognitive behavioural vs. Exercise + cognitive behavioural d=0.23 Cognitive behavioural vs. Discussion d=-0.9 Exercise + cognitive behavioural vs. Discussion
							Discussion d= -0.28
Manckoundia et al. (2007)	27.59%	Single group pre-post design. Intervention group delivered once a week for six weeks. Techniques: physiotherapy; participants detailing their falls history to their group; and behavioural desensitization.	N= 28, female = 25, male =3.	M-FES	Functional independence: FIM. Mobility: Tinetti Scale (Tinetti, 1986), Dual task test (developed by the authors of the paper).  Depression: BDI	Significant improvement post treatment for FoF, mobility, and falls incidence. FoF effect was maintained at 6 and 9 month follow up.	Pre vs. Post: d= -0.43 Pre vs. 6 month d=-0.83 Pre vs. 9 month d=-0.73

Zijlstra et al. (2012)	27.59%	Single group pre-post design. Intervention: group delivered; 8 sessions of 2 hours and one 'booster session 2 months after the intervention. Techniques: education; cognitive restructuring; goal setting; assertiveness; increasing realistic activities; and recognizing fall hazards.	N=125, female = 87, male = 38.	FES-I (short)	II.  Anxiety: Covi Scale (Lipman & Covi, 1976).  Falls Incidence: self-report.  HADS  Loneliness: single question developed by authors.  Daily Activity: Frenchay Activities Index (Holbrook & Skillbeck, 1983).	Significantly reduced concerns about falls, activity avoidance, and anxiety and depression post treatment and at 4 months follow up. Process evaluation: facilitators and two thirds of the participants reported the intervention to be beneficial directly after the intervention.	Baseline vs. post: d= 0.18 Baseline vs. 4 month d=0.18
Mansdorf et al. (2009)	18.62%	Single group pre-post design. Internet-based approach aimed at reducing falls incidence. Weekly sessions of 35-45 minutes for 12 weeks. Techniques: problem solving; behavioural rehearsal; modelling; self-instructional	N= 26, female =16, male =10.	FES-I (short)	Falls incidence: documented by staff. Perceived risk of falls: rated by staff on a likert scale. Perceived staff burden: rated by staff on a likert scale. Attitude towards	Falls incidence reduced overall.  8/17 who completed the FES-I reported increased concern about falling.  6/17 reported reduced concern about falling.  3/17 subjects showed	It was not possible to calculate effect sizes as only mean scores were presented.

training; 'trial and error' learning;	treatment : AFRIS.	no change.	
cognitive			
restructuring; and			
'repeated practice'.			

Bold typeface indicates effect sizes that were calculated by the first author of this review.

Abbreviations:

AFRIS = Attitude to Falls Related Intervention Scale (Prevention of Falls Network Europe, 2006)

BDI II = Beck Depression Inventory (II) (Steer et al., 2000)

FCS = Falls Control Scale (Tennstedt et al., 1998) FES = Falls Efficacy Scale (Tinetti et al., 1990)

FES-I (short) = Falls Efficacy Scale International, short form (Kempen et al., 2008)

FIM = Functional Independence Measure (Linacre et al., 1994) FMS = Falls Management Scale (Tinetti, Richman & Powell, 1990)

GFFM = Geriatric Fear of Falling Measure (Huang, 2006)

HADS = Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983)

MES = Mobility Efficacy Scale (Lusardi & Smith, 1997) M-FES = Modified Falls Efficacy Scale (Hill et al., 1996)

PACE = Physician-Based Assessment and Counselling on Exercise (Cardiovascular Health Branch Centres for Disease Control,

1992)

PASE = Physical Activity Scale for the Elderly (Washburn et al., 1993)

SF-36 = Short Form of the Medical Outcome Study (Ware et al., 1994)

SIP = Abbreviated Sickness Impact Profile (Bergner et al., 1981)

WHOQOL-BREF = World Health Organisation Quality of Life Measure: Brief Form (Taiwan version) (Yao et al., 2002)

Table 2 in the appendix describes the key methodological limitations of each of the included studies.

Papers Rated as 'High Quality'

Tennstedt et al. (1998): 77.93%

This study investigates the effects of a multi-component cognitive behavioural intervention on FoF and related activity restriction. The sample was recruited through housing organisations and responded to posted notices of the programme, or were referred by staff. Those who responded to notices may represent a particularly motivated sample compared to the general population. To be included, participants had to endorse concern about falling and a related activity restriction. The study was adequately powered. Participants were randomised to intervention group; this was achieved using the senior housing site as the unit of randomisation with sites being pair-matched. The intervention is well described and was led by 'trained facilitators'. No information is provided about their level of training. A treatment protocol was utilised and members of the research team assessed fidelity through session logs kept by the facilitators and session observations. The control group received a 'social contact' intervention aiming to account for non-specific treatment effects, however this did not equate to the level of input received by the intervention group. Outcome assessments were administered by telephone by interviewers blinded to group allocation; no information about the method of rater blinding is provided. Cronbach's alpha scores are presented for all outcome measures indicating a good level of validity. The study incorporates two long-term follow-ups. Attrition in the intervention group was high with only 63.9% of participants attending five or more sessions. Comparisons between completers and dropouts highlighted that drop outs had greater avoidance, higher Sickness Impact Profile scores, and

increased physical limitations, indicating higher levels of FoF and activity restriction than completers. This study overall has a robust design however results are limited by the high level of attrition.

Zijlstra et al. (2009): 76.55%

This study investigates the effects of a cognitive behavioural group intervention on FoF and activity avoidance. Out of 7,431 individuals who received posted questionnaires inviting them into the study, 1,358 were deemed eligible according to the inclusion criteria (participants reporting FoF and activity avoidance). Of these, 818 declined participation. Those who declined were older, less educated, and in poorer health. The sample size is appropriate and was determined using a power calculation. Participants were randomised to treatment groups using computer generated block randomisation that was carried out independently from the research team. The active intervention is well described. Trained nurses facilitated the groups and a treatment protocol was used. The level of training in CBT received by the nurses is not reported and nor is adherence to the protocol. Independent assessors blinded to group allocation administered outcome measures. Methods of rater blinding are not described. No information is provided about the level of care received by the control group. Two idiosyncratic measures were used to assess FoF alongside standardised measures and reliability and validity of these measures is not reported. The study incorporates two long-term follow-up time points. There was a high rate of attrition in the intervention group: 57.9% of participants attended five or more sessions and 30% were lost to follow-up. There were no significant differences in demographic variables between dropouts and completers however, health difficulties were cited as the most common reason for dropout. Despite this, this study can be considered to have a robust design and the results are encouraging.

Papers Rated as 'Moderate Quality'

Huang et al. (2011): 73.1%

This paper investigates the effects of CBT coupled with Tai Chi on FoF, mobility, quality of life, and levels of social support compared with CBT alone and treatment as usual. The sample included participants randomly selected from a geographical area to receive a study invitation that was followed up with a telephone conversation. Inclusion criteria were that the participant was over 60 years old, 'mentally intact', and residing in the community. Of the 660 individuals invited to the study, 43.97% did not respond and 16.1% refused participation indicating that the included sample may not be representative of the general population. A sample size estimation was calculated and the study was adequately powered. Not all included participants were concerned about falling (44/62 participants in the CBT group, 37/60 participants in the control group, and 43/56 participants in the CBT plus Tai Chi group). Participants were randomly assigned to intervention group by the first author of the paper using a computer developed randomisation table. The authors refer to the CBT evidence base and model yet the techniques employed are only briefly described. The intervention was delivered by a nurse trained in the intervention although their level of training in CBT is not reported. No information is provided about whether a treatment protocol was used. A research assistant blinded to group allocation administered outcome measures, the method of rater blinding is not described. Cronbach's alpha scores are presented for all outcome measures. A strength of this study is that attrition rates were low (3.2% in the CBT group, 9.7% in the CBT plus Tai Chi group). There is no information provided about the level of care received by the control group and the level of contact was significantly higher in the CBT plus Tai Chi group, which could have affected the study's results. Furthermore, as there was no Tai Chi only group it is impossible to determine the efficacy of CBT alone.

Clemson et al. (2004): 68.28%

This paper investigates the efficacy of 'cognitive behavioural learning' on falls incidence, with FoF a secondary outcome measure. The sample was recruited though posted leaflets, presentations at community organisations, advertisements in local media, and health professional referrals. Several of these methods include volunteer participants which, as mentioned previously, may not be representative of the general population. Inclusion criteria included those who had fallen in the last year or felt at risk of falling. A sample size estimation was calculated and the study was adequately powered. The control and intervention groups were homogenous in the majority of baseline characteristics however, the control group had sustained a higher number of hip fractures. This may represent a more severely affected group however; data was adjusted for this statistically with no differences reported. Participants were randomised to treatment group using a method of stratification. The control intervention included up to two social visits from an occupational therapy student. The active intervention is described in detail in the appendix of the paper yet no reference is made to previous literature regarding cognitive behavioural interventions. Despite the intervention claiming to enhance 'cognitive behavioural' learning there were no cognitive components to the intervention. There is no information provided about whether a treatment protocol was used. The intervention was provided by an occupational therapist with 12 years' experience and other facilitators who were trained by the first author of the paper; no information is provided about their level of training in CBT. A research assistant blinded to group allocation carried out the outcome assessments. The subject retention for the intervention was high (93.6%) and an intent to treat analysis was used, however no information is provided about the characteristics of dropouts.

Papers Rated as 'Low Quality'

Healy et al. (2008): 39.3%

This paper investigates whether the cognitive behavioural intervention employed by Tennstedt et al. (1998) can translate to a community delivered model. Participants responded to advertisements in newspapers or attended community presentations. Participants who then declined intervention used more assistive devices indicating that they may have had increased mobility difficulties. The techniques used in the intervention were outlined briefly in the paper and group leaders were volunteers who received two days of training in the intervention. No information is provided about their formal training in CBT. A treatment manual was used and group leaders were mentored by one of the research team and observed during a session to ensure fidelity. All outcome measures included in this trial were standardised and Cronbach's alpha scores are provided for each measure. No information is provided about who administered the outcome measures. The study includes two long-term follow up points. Attrition rates were high: 89% of the sample attended five or more sessions; 73% completed the post treatment outcome measures; 68% completed the six-month outcome measures; and 58% completed the twelve-month outcome measures. The majority of people who completed the follow-up measures had attended five or more sessions, indicating that these may be highly engaged in the programme compared to non-responders. A possible reason for the low response rate to follow up may be that participants were posted the questionnaires and were required to post them back once completed; this may have been difficult for the less mobile participants. No significant differences in demographic variables were found between the responders and non-responders however, those who failed to complete the intervention were found to have higher levels of restricted activity. This study demonstrates that the intervention is feasible in a community setting however, the absence of a control limits the validity of the study's findings.

Reinsch et al. (1992): 29.65%

This study aimed to reduce falls incidence; FoF was included as a secondary outcome measure. Participants were 'invited' to participate in the study and did not have to have fallen or be fearful of falling to be included. A sample size estimation was conducted and the study was adequately powered. Treatment centres were included as the unit of randomisation however, the method of randomisation used is not described. The study fails to use a recognised cognitive behavioural intervention and no reference is made in the paper to theoretical intervention models or to previous literature. There is no information provided about who delivered the intervention or whether a treatment protocol was used. Overall attrition from the study was 20%, however, in the cognitive behavioural intervention this was 27%. This is despite the use of adherence improving strategies including participants being provided with a wristwatch and \$5 a month. Dropouts from the study did not differ from completers with regard to age or level of injury however, a higher proportion of the dropouts were fallers indicating that these may represent more severe cases. The majority of the outcome assessments employed in this study were idiosyncratic and a single item measure was used to assess FoF. No information is provided about who carried out the outcome assessments or whether any statistical tests were used to analyse scores for the FoF measure as only mean scores are presented. Furthermore, analysis conducted was not intention to treat which, considering the relatively high attrition rate of the sample, limits the validity of the study's findings. The non-significant results may be due to participants having relatively low levels of FoF at the start of the intervention.

Manckoundia et al. (2007): 27.59%

This study investigates the efficacy of the intervention on motor abilities and concerns about falling in elderly fallers. This study included participants from a day hospital who had a

history of falls in the previous six months and had developed 'psychomotor disadaptation syndrome' (characterised by disequilibrium whilst standing and sitting, gait modifications, reduced confidence, functional limitations, increased dependence, risk of institutionalism, and social withdrawal). The sample size is relatively small (28 participants). The intervention was multi-component, however no cognitive techniques were employed and no reference was made to the cognitive behavioural model or previous literature. There is no information provided about whether a treatment protocol was used. It is unclear who delivered the intervention; the research team consisted of a geriatrician, physiotherapist, and psychologist, and no information is provided about their training in CBT. The majority of the outcome measures utilised were standardised however, no information is provided about who administered them. This study includes one long-term follow up point. Intent to treat analysis was not performed despite 14.2% of participants failing to complete the intervention. No significant differences were found in the characteristics of dropouts and completers.

#### Zijlstra et al. (2012): 27.59%

This study aims to evaluate the effectiveness of CBT for FoF when delivered in the community. Participants were responders to leaflets about the study who reported concerns about falling and subsequently avoided activity. The use of volunteers again limits the generalisability of the sample. The sample size is appropriate. The intervention is well described, was facilitated by trained nurses, and utilised a manual, however there is no information about whether adherence to treatment protocol was assessed. No information is provided about the level of therapists' training in CBT. The majority of the outcome measures used were standardised however, no information is provided about who administered them. There is no detail provided about subject retention for the intervention and no information is provided about whether an intention to treat analysis was used.

Mansdorf et al. (2009): 18.62%

This internet-based approach aimed to reduce falls incidence and improve falls efficacy. Participants were recruited from a nursing home and were those who were considered by staff to be at falls risk and for which previous interventions had been unsuccessful. It is thus possible that the sample consisted of a particularly treatment resistant group. A sample size estimation was not calculated and the sample size is relatively low, indicating that this study may not be adequately powered. The intervention was delivered by psychologists. It is stated that the psychologists received training in the computer programme, completed 'mock runs' of the intervention, and were observed during a session by a member of the research team. However, no information is provided about their level of training in CBT. There is no information provided about whether a treatment protocol was used. Measures used include idiosyncratic assessment tools developed by the authors, limiting the reliability and validity of the study's conclusions. No information is provided about who administered the outcome measures. The study fails to provide information regarding subject retention and methods of analysis are not clearly described; only mean scores and percentage difference figures are presented. The study only presents partial results as not all participants completed the FES-I. In addition, the internet-based approach used in this study limits the generalisability of the findings as it will only be suitable for older adults who are computer literate.

#### **DISCUSSION**

*Is CBT a Beneficial Intervention for FoF?* 

Six out of the nine studies demonstrate benefits of an intervention for FoF, with maintenance of effects at follow-up. Three of the above studies were rated as 'low quality', which reduces the confidence in these findings. Furthermore, one of these studies included an intervention described as 'cognitive behavioural' that failed to use a recognised model or accepted

cognitive behavioural techniques. This poses difficulties for assessing efficacy and presents a clinical governance issue.

The use of adequately trained therapists is a further issue; five studies provided some information on the training of therapists in the intervention and two further studies provided information on their therapists' vocational training. Only one study provided information on the length of training (two days) in the intervention received by therapists and none provided information on therapists' training in CBT. As CBT is recognised as a specialist psychological intervention, practitioners are expected to undertake a diploma or masters level qualification prior to practicing ('The Matrix', Scottish Government, 2011). Tarrier & Wykes (2004) highlight that evaluation of emerging psychological interventions should involve experienced therapists. It is therefore not possible to be confident that the interventions included in this review were delivered by therapists who were adequately trained in CBT. This raises a question about the validity of the interventions as CBT.

With regard to study design, the use of adequate comparison groups is important when assessing the efficacy of emerging interventions. Only five out of the nine included studies used a control group. The contact time for the control groups was not detailed or was not comparable to the intervention group, thus failing to control for non-specific treatment effects that may affect treatment outcomes. However, all of these five studies randomised participants to intervention group, strengthening their results. The majority (8/9) of the papers used a standardised measure to assess FoF however, only four used outcome assessors who were blind to treatment allocation indicating a potential source of bias. Although the majority (7/9) of these studies had relatively large sample sizes, most (6/9) used volunteer participants who are likely to be highly motivated to engage. This limits the generalisability

of the samples to older adults who often under-report anxiety and are often less help seeking than younger adults (Broomfield & Birch, 2009). Furthermore, none of these studies used individually delivered interventions (8 were group delivered; one was delivered via the internet) despite evidence suggesting that individually delivered CBT is superior to group delivered CBT for older adults in terms of treatment outcomes (Engels & Verney, 1997).

The effect sizes for included studies were small to moderate, except for the follow up data of Manckoundia et al. and the between group comparisons on the Geriatric Fear of Falling Measure (GFFM) of Huang et al. which demonstrate large effect sizes. These studies were of low and moderate quality respectively, and neither of the studies which were rated as high quality (Tennstedt et al. 1998; Zijlstra et al. 2009) found large effect sizes. This may suggest that there is a relationship between effect sizes and the methodological quality of studies where poorly designed studies are more likely to find large effects due to issues such as non-randomisation, biased data collection techniques and the use of non-standardised measures. Therefore, there is only preliminary evidence that CBT for FoF is efficacious and further research from well designed studies is required.

#### *Is CBT a Feasible Intervention for FoF?*

Zijlstra et al. (2012) demonstrated that the majority of participants reported beneficial effects of FoF treatment and generally viewed the intervention and the facilitators favourably. However, of the six studies reporting beneficial effects of their intervention, attrition rates exceeded 15% in three of these studies. This might suggest that CBT is not an acceptable intervention for all older adults affected by FoF. As treatment dropouts from these studies tended to have more physical limitations and higher levels of restricted activity, it may be particularly less acceptable for the more severely debilitated individuals. This finding has

been discussed in the wider literature for CBT for older people. For example, in a metaanalysis of the efficacy of CBT for late life depression, Pinquart et al. (2007) found weaker intervention effects for physically ill or cognitive impaired older adults.

It would be expected that engagement would influence acceptability and due to the high attrition rates in the Zijlstra et al. (2012) study it may be that the participants who completed their process evaluation were particularly well engaged with the intervention. Furthermore, Tennstedt et al. (1998) only found significant effects for their intervention for FoF when they limited analysis to those attending five or more sessions, indicating that CBT for FoF may not be effective as a brief intervention. It may be sensible to conclude that CBT is an acceptable intervention for some older adults (likely to be those with less health and mobility problems) but not all.

It is important to consider whether interventions used in research studies can be delivered in real world settings. However, only 4/9 studies in this review used a treatment protocol and only two studies assessed adherence to protocol. No study provided information about the number of protocol deviations, and it is not possible to draw firm conclusions regarding the feasibility of delivering CBT for FoF.

#### Suggestions for Future Research

The evidence base for effective treatments for FoF is small. Cognitive behavioural techniques are highlighted in the literature as being important, yet few good quality studies exist. Future studies need to: (i) employ adequate comparison groups to control for non-specific treatment effects, (ii) ensure that cognitive behavioural interventions have a sound theoretical basis and use therapists who are adequately trained in CBT, (iii) use treatment protocols and report

protocol deviations to further assess feasibility, (iv) report attrition rates with suggestions about maximising retention, (v) consider individually delivered approaches which may be more acceptable to older adults.

Strengths and Limitations of this Review

This study is the first to systematically review the evidence base for FoF. It used a recognised quality assessment tool in order to identify methodological weaknesses present in the available literature. The search strategy only included studies in English although no studies in other languages were found. The criteria used for methodological evaluation are open to subjective interpretation and there is a possibility of biased results, despite the use of an independent rater.

#### Conclusion

Unhelpful behaviours and cognitions are likely to maintain FoF, and hence CBT has been suggested as an appropriate intervention. The evidence base for the efficacy and feasibility of CBT for FoF is small but positive. Preliminary evidence allows CBT to be recommended for older adults with FoF who do not have severe physical impairments. Methodological weaknesses in the literature prevent firmer conclusions and it is imperative that further research is conducted in this important area.

#### Conflict of interest:

None

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# **Chapter 2: Major Research Project**

# Evaluation of Individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling: A Pilot Study

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### LAY SUMMARY

### Background

It has been found that approximately 30% of over 65s living in the community will fall each year and of these, 50% develop a 'fear of falling'. Fear of falling involves loss of confidence in the ability to avoid future falls and the avoidance of daily activities because of fear of falling again. This has a significant impact on daily life and can result in: anxiety; depression; reduced independence; isolation; reduced quality of life; and loss of confidence.

### Aims

Due to the impact of fear of falling, researchers have been looking at psychological treatments which may help to improve the condition. Cognitive Behaviour Therapy (CBT) is a widely used treatment for anxiety and depression. It helps people to think and behave in ways that are more helpful. Previous research has found that group delivered CBT for fear of falling was beneficial. However, some people may prefer individual therapy to group therapy. The current research investigates whether individual CBT is a useful treatment for fear of falling.

### Methods

This research involved 18 people; 6 received CBT and their standard physiotherapy and 12 received standard physiotherapy. All participants completed questionnaires at the beginning and end of the study to measure fear of falling, anxiety, and overall quality of life. The participants' scores at the start of the study were compared with their scores at the end to investigate whether there had been any change.

# Results

Those treated with CBT showed greater reductions in fear of falling than those who received physiotherapy alone. There was no change in scores on the anxiety or quality of life questionnaires.

# Conclusion and Practical Applications

Individually delivered CBT is an effective treatment for older people who are fearful of falling and future studies should aim to replicate these results. It is hoped that the results of this study will help to improve services for those who fear falling, by demonstrating that CBT can be helpful.

**ABSTRACT** 

Objective: It has been found that 50% of older adults who fall will develop fear of falling.

Group delivered Cognitive Behaviour Therapy (CBT) has been found to be effective in

reducing fear of falling however, research has found that individually delivered CBT may be

more effective and acceptable than group delivered CBT. This research is a preliminary study

evaluating the effectiveness of an individually delivered CBT intervention for fear of falling

in older adults compared to a control group receiving physiotherapy. The study also reports

data on indicators of the acceptability and feasibility of CBT in this sample.

Method: Eighteen participants were recruited from the NHS Greater Glasgow and Clyde

Falls Prevention Service and were allocated to either the CBT or control group according to

the treatment site that they attended for the Falls Prevention Service. Measures of fear of

falling, anxiety, and quality of life were compared within subjects and between groups at pre

and post treatment.

Results: On the measure of fear of falling, significant within subject differences for those

who received the CBT and between subject differences compared to a group receiving

standard physiotherapy were found. No differences were found within subjects or between

groups on measures of anxiety or quality or life. The intervention was found to be acceptable

to older adults and practical in terms of delivery.

Discussion: Individually delivered CBT is an effective and feasible intervention for older

adults who are fearful of falling and is more effective than standard physiotherapy. Future

studies should aim to investigate if this beneficial effect is replicable.

Key terms: Cognitive Behaviour Therapy, Older People, Fear of Falling

### INTRODUCTION

Approximately 30% of over 65s living in the community will fall each year (Tinetti et al.,1994). Falls can lead to fractures, long hospital admissions, physical discomfort, injury, and social and psychological consequences. It has been found that 50% of those who have fallen in the last year develop fear of falling (Tinetti et al., 1988). Fear of falling has also been found in non-fallers (Friedman et al., 2002) and serious injury is not necessary for the development of fear of falling (Tinetti et al., 1988). Fear of falling is conceptualised as low perceived self-efficacy at avoiding falls during non-hazardous daily activities (Tinetti et al., 1990) and restriction of activities that is out of proportion to injuries sustained from a fall (Tinetti & Powell, 1993). Van Haastregt et al. (2008) found that individuals who avoid activity because of fear of falling showed elevated levels of anxiety and depression. Fear of falling has also been associated with: reduced independence and ability to perform activities of daily living (Tinetti et al., 1994); reduced involvement in social activities and isolation (Howland et al., 1993); impaired quality of life (Cumming et al., 2000); loss of confidence (Zijlstra et al., 2007); increased institutionalisation (Cumming et al., 2000); poorer rehabilitation outcomes (Oude Voshaar et al., 2006); and increased risk of future falls (McKee et al., 2002; Cumming et al., 2000) through deconditioning and muscle weakness (Hindmarsch & Estes, 1989) and poor posture (Maki et al., 1991). In summary, fear of falling is a specific concern for older adults, it is prevalent, and has a substantial impact on the individual's daily life. Thus, there is a need for a specific intervention to tackle this problem.

There have been a number of multi-factor interventions designed to reduce falls risk however, it has been argued that these interventions are not sufficient to reduce fear of falling (Letgers, 2002). Fear of falling is thought to involve unhelpful cognitions, reduced confidence, and activity avoidance, thus it has been proposed that an intervention for fear of falling must promote cognitive and behavioural changes in order to be successful (Letgers, 2002). An

emerging area of research has begun to investigate the effects of Cognitive Behavioural Therapy (CBT) for fear of falling. Tennstedt et al. (1998) and Zijlstra et al. (2009) conducted group cognitive behavioural interventions designed to reduce fear of falling, and utilised techniques such as: cognitive restructuring; education regarding falls prevention and the benefits of exercise; management of the physiological symptoms of fear of falling; goal setting; and behavioural experiments. Both studies reported beneficial effects of their interventions on fear of falling, however effect sizes were small to moderate. There have been no studies to date examining individually delivered CBT for fear of falling, despite research evidence suggesting that individually delivered CBT is superior to group delivered CBT in terms of treatment outcomes. Sharp et al. (2004) compared individual and group delivered CBT for panic disorder and agoraphobia in the general adult population, and found that the individual CBT treatment group showed the largest proportion of patients achieving clinically significant change at the end of treatment. They also found that the group intervention demonstrated the highest dropout rate (47%) and when given a choice at the end of the study, the majority (95%) of waiting list patients chose to receive the individual treatment, indicating that individually delivered treatment may be preferable for patients. In addition, in a review of the literature for psychological therapy for late life depression, Engels & Verney (1997) concluded that individually delivered interventions were more beneficial than group interventions for older adults. Furthermore, it is recognised that older adults under report anxiety disorders and this may be due to the stigma associated with such disorders (Broomfield and Birch, 2009). It has thus been suggested that individually delivered interventions may help alleviate this anxiety in some individuals (Barrowclough et al., 2001).

### Aims

This is a preliminary study that evaluates the effectiveness of an individually delivered CBT intervention for fear of falling in older adults compared to a control group receiving

physiotherapy. It aims to investigate whether individual CBT for fear of falling reduces fear of falling, improves anxiety, and improves quality of life. The study also reports data on indicators of the acceptability and feasibility of CBT in this sample, including dropout rates, the number of sessions of CBT attended, and therapist adherence to the treatment protocol.

# Hypotheses

- Those treated with CBT will show reductions in scores on the Beck Anxiety
   Inventory (BAI: Beck et al., 1998) and Falls Efficacy Scale International (FES-I:
   Yardley et al., 2005) and will show improvements in scores on the World Health
   Organisation (WHO) Quality of Life Measure for Older People (WHOQOL-OLD:
   Power et al., 2005).
- Those treated with CBT will show greater reductions in scores on the BAI and FES-I, and greater improvements in scores on the WHOQOL-OLD, than a physiotherapy control group.

# **METHODS**

# Design

This is a between groups intervention trial comparing individually delivered CBT plus standard physiotherapy with physiotherapy only.

### Ethical Approval

Ethical approval was granted from the West of Scotland Ethics Committee on the 2<sup>nd</sup> October 2012 and was supported by the local NHS Research and Development Department.

### **Participants**

This study comprised 18 participants over the age of 65 who were referred to NHS Greater Glasgow and Clyde Community Falls Prevention Service. This is a pilot study, however a preliminary power calculation was conducted to inform future studies of required sample size. It was inappropriate to base the power calculation on the aforementioned trials of group delivered CBT, as the current research was not comparable as it utilises different measures and employs a different treatment modality. The BAI was selected as the most appropriate measure on which to base a sample size calculation due to its high internal validity, factorial validity, and discriminant validity within the older adult population (Kabacoff et al., 1997), and its demonstrated power to detect effects in clinical research. The power calculation was based on a within subjects comparison which relates to this study's first hypothesis. Thorpe et al. (2009) conducted a meta-analysis comparing different behavioural treatments for late life anxiety. They calculated that the mean within subjects effect size (Hedges g) for CBT trials for late life anxiety was 0.86 (0.63 -1.08). The majority of these studies utilised the BAI; using this effect size, power of 0.8, and a significance level of 0.05 (G Power version 3.1) the required sample size was 10 (8-18) for the intervention group.

### Recruitment

Participants were recruited from two day hospital sites within NHS Greater Glasgow and Clyde Falls Prevention Service. Participants were recruited between October 2012 and February 2013 and were allocated to treatment group according to which site they attended for the Falls Prevention Service. It was therefore impossible for the researcher to be blind to group allocation. The CBT intervention group consisted of participants from the New Victoria Day Hospital, and the physiotherapy control group consisted of participants from the Southern General Day Hospital. Participants reporting anxiety around fear of falling were referred to the study by physiotherapists within the treatment sites. Physiotherapists described

the study to participants and participants were then provided with further information about the study by a member of the research team, screened for inclusion, and provided written consent for their participation.

Inclusion criteria were; individuals over the age of 65 who had experienced a fall in the last year, and experienced fear of falling as assessed by the FES-I (score of 30 and above). There is currently no accepted cut-off score in the literature on the FES-I. A cut-off was determined through consultation with clinicians experienced in this area (Conaghan, personal communication). A score of 30 or above was selected as this would demonstrate that the individual had a significant level of concern about falling whilst engaging in a number of routine daily activities (e.g. cleaning the house, dressing and undressing, preparing simple meals). Exclusion criteria were; individuals who lacked capacity to consent to participation, those with significant cognitive impairment (as defined by a MMSE score of less than 24: Schultz-Larsen, Lomholt & Kreiner, 2007)), the presence of a major health or physical condition that would preclude participation in the intervention, or non-English-speaking individuals.

# Research Procedures

The physiotherapy control group comprised twelve participants who received the standard physiotherapy input offered by the Falls Prevention Service on an individual or group basis according to level of need. Sessions were provided by trained physiotherapists at the Southern General Day Hospital and typically included strategies to prevent falls, such as mobility exercises, ensuring the home environment is safe, and strategies the individual can use to minimise difficulties if they do fall. The physiotherapy input was not manualised, and the number of sessions each individual received varied according to individual need. The average number of sessions received was calculated for comparison with the CBT group.

Participants from the physiotherapy control group met with the first author of this paper on two occasions (pre-treatment and post treatment) to complete outcome measures for the study.

The intervention group comprised six participants who received individual CBT delivered by a Consultant Clinical Psychologist and a Trainee Clinical Psychologist at the New Victoria Day Hospital. The therapists were trained in CBT to doctorate and masters level respectively. Each session lasted one hour and the median number of sessions received was five (range 4-9). A CBT intervention protocol was developed for the purpose of this research and specific techniques utilised included: relaxation; cognitive restructuring; and graded exposure to feared and avoided situations (see appendix for full intervention protocol). Adherence to the intervention protocol was assessed by the use of session logs, where the therapists detailed the techniques used in each session. The session logs were then assessed for major protocol deviations by the first author of this paper. Outcome measures were administered at baseline and post treatment by a different psychologist to the psychologist who provided the intervention to minimise researcher bias. These participants continued to receive physiotherapy input as standard from the Falls Prevention Service (as detailed above), with the number of physiotherapy sessions received recorded for comparison with the control group.

On entry to the study, Tinetti Mobility Scale (Tinetti, 1986) scores (administered by the participant's physiotherapist) were collected for each participant to assess whether the intervention and control group were homogenous in terms of physical impairment at baseline.

It was intended that all participants would complete outcome measures at one follow-up point (one month after the end of intervention). Unfortunately, recruitment was slower than anticipated and it is not possible to report follow-up data at this time. Follow-up is continuing and will be reported in a later publication.

### Measures

Outcome measures were the Falls Efficacy Scale International (FES-I), the Beck Anxiety Inventory (BAI), and the World Health Organisation Quality of Life Measure for Older People (WHOQOL-OLD). The Mini Mental State Examination (MMSE) and the Tinetti Mobility Scale were used as initial screening measures.

### Outcome measures:

FES-I: The Falls Efficacy Scale International (FES-I) (Yardley et al., 2005) is a short tool that measures the level of concern about falling during social and physical activities inside and outside the home. It is a self-report measure and an individual's level of concern is measured on a four point likert scale (1=not at all concerned to 4=very concerned). Higher scores indicate higher levels of fear of falling. The FES-I is an expansion of the original Falls Efficacy Scale (Tinetti et al., 1990). The initial validation (Yardley et al., 2005) found the FES-I to have good internal and test-retest reliability and it is said to be 'the best validated and most widely used instrument for this purpose,' (Yardley et al., pp. 618).

BAI: The BAI (Beck et al., 1988) is a 21 item self-report questionnaire measuring commonly experienced symptoms of clinical anxiety. Each item is rated on a 4-point scale with higher scores indicating higher levels of anxiety. Suggested diagnostic cut-offs are: 0-7 minimal anxiety; 8-15 mild anxiety; 16-25 moderate anxiety; 26-36 severe anxiety. The utility of the BAI in an older adult population has been examined. Kabacoff et al. (1997) found the BAI to have high internal reliability, good factorial validity, and good discriminant validity in an older adult psychiatric outpatient population.

WHOQOL-OLD (Power et al., 2005): The WHOQOL-OLD is a module developed further to the original WHO Quality of Life measure (WHOQOL: World Health Organisation, 2004) and contains items relating to issues which are pertinent to older people. The questionnaire consists of six domains: sensory abilities; autonomy; past, present and future abilities; social participation; death and dying; and intimacy. It is a self-report measure and each item is rated on a 5-point scale with higher scores indicating a higher quality of life. The WHOQOL-OLD manual provides reference data based on a sample of 5566 older adults which provides an overall mean raw score of 87.57. The measure was found to have good factorial validity (Power and Schmidt, 2006) and good internal consistency and test-retest reliability (Peel et al., 2007).

### Screening measures:

MMSE: The MMSE (Folstein et al., 1975) consists of eleven questions and is designed to be used as a screening tool to assess cognitive impairment and cognitive change over time. It is a clinician administered test. It includes orientation to time and place; registration and recall of three words; attention and calculation; language; and visual construction. The MMSE has a maximum score of 30 and a score of 23 or less is the generally accepted cut-off for indicating the presence of cognitive impairment (Schultz-Larsen, Lomholt and Kreiner, 2007) The MMSE has been found to have good inter-rater reliability and good convergent validity (Cockrel & Folstein, 2002).

Tinetti Mobility Scale: The Tinetti Mobility Scale (Tinetti, 1986) is a widely utilised measure of mobility. It has two subscales (gait and balance) which can be combined to provide an overall mobility score. The total score is out of a possible 28 points, and low scores (<14) are associated with recurrent falls (Tinetti, 1986). The measure has been found to have good inter-rater reliability (Tinetti, 1986) and high internal consistency (Huang et al., 2011).

### Data Analysis

Statistical analysis was performed using SPSS version 19, and all analysis was performed according to intention to treat. The method used for handling missing data in the intent to treat analysis was last- observation-carried-forward. This is a widely used measure in clinical trial research and it is straightforward to compute. Other methods of intent to treat were considered such as those which employ mixed models, however these methods have been suggested to be only suitable for large sample sizes (Hamer & Simpson, 2009). The data was tested for normality and when satisfied, within group analysis was conducted using t-tests to compare the data from outcome measures between baseline and post treatment in line with the study's first hypothesis. ANCOVA was used for all outcome variables with group entered as a factor, post treatment scores entered as the dependent variable, and pre-treatment scores entered as a covariate, to compare post treatment scores between groups. It is understood that ANCOVA can be conducted using either post treatment scores or change scores (post-pre) as the dependent variable. However, it has been highlighted in the literature that change scores may be less reliable than post treatment scores (e.g. Cronbach & Furby, 1970) thus the latter was used in this instance. Effect sizes were calculated using Cohen's d where 0.20 is considered small, 0.50 medium, and 0.80 large. The decision to utilise the above statistical tests was made after consultation with a statistician.

### **RESULTS**

Figure 1 demonstrates participant flow through the study.

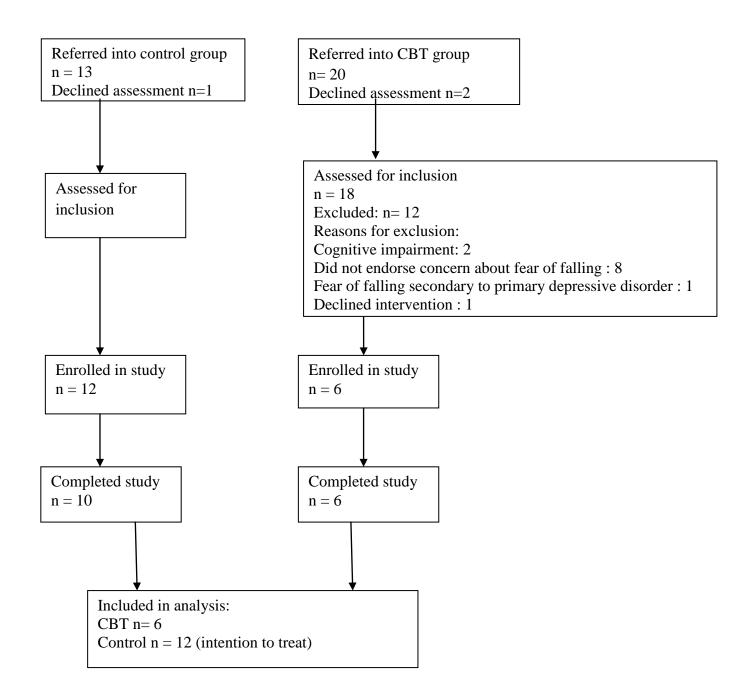


FIGURE 1: PARTICIPANT FLOW THROUGH THE TRIAL

Data was assessed for normality using Kolmogorov-Smirnov tests. For the CBT group, data for the FES-I (D(6) = 0.163 p>0.05), BAI (D(6)=0.255 p>0.05), and the WHOQOL-OLD (D(6) = 0.224 p>0.05) were normally distributed. For the control group, the data for the FES-I (D(12)=0.182 p>0.05), BAI (D(12) = 0.164 p>0.05), and WHOQOL-OLD (D(12) = 0.142 p>0.05) were normally distributed indicating that parametric tests could be used.

### Baseline Data

Table I shows the baseline demographic characteristics for all participants included in the study. For the CBT group, data for the MMSE (D(6) = 0.211 p>0.05), Tinetti Mobility Scale (D(6) = 0.172 p>0.05), and participant's age (D(6)=0.313 p>0.05) were normally distributed. For the control group, the data for the MMSE (D(12) =0.180 p>0.05), Tinetti Mobility Scale (D(12)=0.165 p>0.05), and participant's age (D(12)=0.165 p>0.05) were normally distributed. No significant differences in baseline demographics between groups for age (t (16) = -0.578 p >0.05) and Tinetti Mobility Scale Scores (t(16) = 0.084 p >0.05) were observed. MMSE scores were lower in the CBT group (t (16) = 2.22 p < 0.05).

TABLE I: BASELINE DEMOGRAPHICS OF PARTICIPANTS; PERCENTAGE OR MEAN (± SD)

Demographic	Control Group	Intervention Group	
Information			
Gender (% Female)	100%	66.67 %	
Age (Years)	78.00 (6.38)	80.25 (8.26)	
Tinetti Mobility Scores	16.83 (3.24)	16.67 (5.24)	
MMSE scores	28.33 (1.44)	27.00 (1.83)	

T-tests revealed no significant differences between groups pre-treatment for fear of falling (t(16) = 0.492 p > 0.05) or anxiety (t(16) = -0.037 p > 0.05). However, a significant difference was found between groups pre-treatment for quality of life scores (t(16) = 2.376 p < 0.05) where, on average, the CBT group had lower quality of life scores at baseline (M=71.00) compared to the control group (M=82.25).

# Amount of Physiotherapy Input

The mean number of physiotherapy sessions received by the CBT group was 6.83 and by the control group was 5.75. This data was normally distributed for the CBT group (D(6) = 0.299 p>0.05) but not for the control group (D(12) = 0.275 p<0.05). A Mann-Whitney test revealed that differences between groups were not significant (U= 26.50, Z= -0.901, p>0.05).

### Subject Retention

Overall, subject retention for the study was high. Two participants dropped out of the control group and no participants dropped out of the intervention group.

# Fear of Falling Outcomes

The mean FES-I score for the CBT intervention group was 44.00 (SD = 5.29) pre-treatment and 30.17 (SD= 3.97) post treatment. The mean FES-I score for the control group was 45.75 (SD= 7.80) pre-treatment and 47.25 (SD=7.44) post treatment (see figure 2).

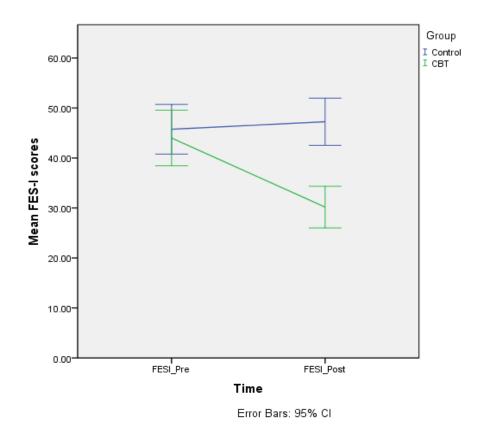


FIGURE 2: MEAN FES-I SCORES PRE AND POST TREATMENT

A paired t-test revealed that the CBT group had reduced fear of falling post treatment (M = 30.17, SE= 1.62) compared to pre-treatment (M = 44.00, SE=2.16) (t(5) = 6.57 p<0.05). The effect size for this difference is large (d = 2.96).

ANCOVA demonstrated that the covariate, pre-treatment FES-I scores, was significantly related to the post treatment scores (F(1, 15) =17.123, p<0.05). There was also a significant difference in post treatment FES-I scores between the CBT and control group after controlling for baseline FES-I scores (F(1, 15) = 46.61, p<0.05). The adjusted mean scores highlight that the CBT group (M = 30.95, SE = 1.90) experienced significantly less fear of falling at post treatment than the control group (M= 46.86, SE=1.34).

Anxiety Outcomes

The mean BAI score for the CBT group was 26.00 (SD = 13.11) pre-treatment and 21.00 (SD= 9.79) post treatment. The mean BAI score for the control group was 25.75 (SD=13.60) pre-treatment and 24.08 (SD= 9.11) post-treatment (see figure 3).

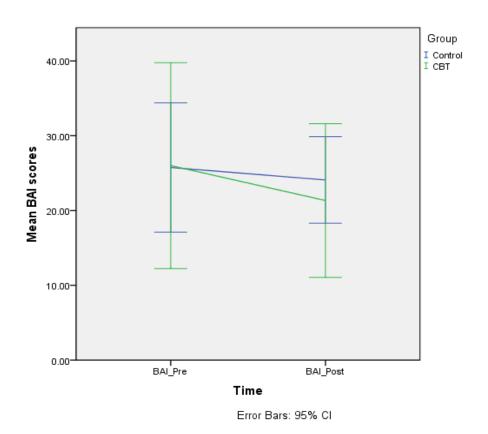


FIGURE 3: MEAN BAI SCORES PRE AND POST TREATMENT

A dependent t-test revealed that for the CBT group, the BAI scores post treatment (M = 21.00, SE= 3.997) did not significantly differ from scores pre-treatment (M = 26.00 SE=5.35) (t(5) = 2.150 p>0.05). The effect size for this difference is small to moderate (d=0.43).

ANCOVA demonstrated that the covariate, pre-treatment BAI scores, was significantly related to the post treatment scores (F(1, 15) = 31.798, p<0.05). There was no significant difference in post treatment BAI scores between the CBT and control group after controlling for the pre-treatment scores (F(1,15) = 1.125, p>0.05).

# Quality of Life Outcomes

The mean WHOQOL-OLD score for the CBT group was 71.00 (SD= 7.04) pre-treatment and 75.00 (SD= 12.85) post treatment. The mean WHOQOL-OLD score for the control group was 82.25 (SD=10.38) pre-treatment and 80.41 (SD=11.48) post treatment (see figure 4).

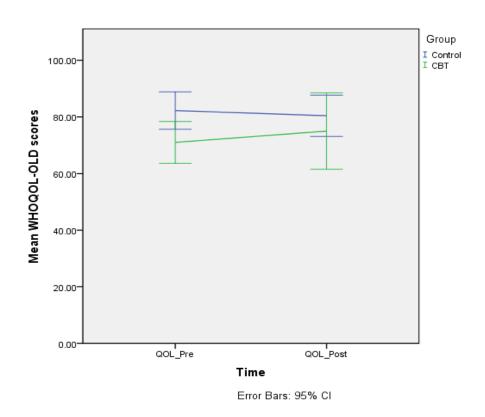


FIGURE 4: MEAN WHOQOL-OLD SCORES PRE AND POST TREATMENT

A dependent t-test revealed that for the CBT group, WHOQOL-OLD scores post treatment (M = 75.00, SE = 5.25), did not significantly differ from pre-treatment scores (M = 71.00, SE = 2.88) (t(5) = -0.907 p>0.05). The effect size difference is small to moderate (d=0.39)

ANCOVA demonstrated that the covariate, pre treatment WHOQOL-OLD scores, was significantly related to the post treatment WHOQOL-OLD scores (F(1, 15) = 32.085,

p<0.05). There was no significant difference in post treatment WHOQOL-OLD scores between the CBT and control group after controlling for pre-treatment scores (F(1,15) = 2.415, p>0.05).

Table II summarises the results of the between group comparisons.

TABLE II: SUMMARY RESULTS OF BETWEEN GROUP COMPARISONS

	CBT	Control	<b>Between Group</b>	Effect Sizes
	Mean (SD)	Mean (SD)	Comparison	(Cohen's d)
Outcome	Post-treatment	Post- treatment		
Measure				
FES-I	30.17 (3.97)	47.25 (7.44)	F= 46.614	2.84
			P= 0.000	
BAI	21.00 (9.79)	24.08 (9.11)	F= 1.125	0.33
			P= 0.306	
WHOQOL-	75.00 (12.85)	80.41 (11.48)	F= 2.415	0.44
OLD			P= 0.141	

Acceptability and Feasibility of the CBT Intervention

All participants in the CBT group completed the intervention. Of all appointments offered, 21.7% were not attended. The median number of non-attendances per participant was 1.50 (range 0-3). This suggests that the intervention was acceptable to participants. All participants and therapists reported a beneficial effect of the intervention on fear of falling

and activity levels. In addition, there were no protocol deviations indicating that the intervention can be feasibly delivered.

### DISCUSSION

This study demonstrates that individual CBT plus physiotherapy is an effective intervention for reducing fear of falling compared with physiotherapy alone in older adults. Individually delivered CBT for fear of falling was an acceptable method of intervention for older adults as all CBT participants completed the intervention. CBT was practical in terms of delivery as the intervention protocol was adhered to and there were no known protocol deviations. The average number of CBT sessions required was five (range 4-9), indicating that individual CBT for fear of falling is effective as a brief intervention.

There were no group effects on measures of anxiety or quality of life. As fear of falling is considered to impair quality of life (Cumming et al., 2000) and provoke anxiety (van Haastregt et al., 2008) this may seem surprising. This finding may have occurred for a number of reasons. It is possible that the non-significant results for the BAI and WHOQOL-OLD are a result of the study being underpowered on these measures. A post hoc power calculation revealed that the achieved power for the BAI and WHOQOL-OLD was 0.19 and 0.36 respectively. Therefore the power to detect an effect on these measures was low which limits confidence in these findings. This should be considered in future studies which should aim to include larger sample sizes in order to improve power. In order to measure anxiety in this population alternative measures may be also more appropriate. It is recognised that general anxiety often presents differently in older adults, with a higher incidence of somatic symptoms often reported (Bryant et al., 2008). It might therefore have been helpful to utilise a measure of anxiety that is tailored to the older adult population. However, the BAI does include a number of somatic symptoms associated with anxiety and has been found to be

reliable and valid for use in the older adult population (Kabacoff et al., 1997). Alternatively, it may simply be that the group effects on the BAI and WHOQOL-OLD would not be apparent until follow-up, allowing the participant opportunity to experience a sustained benefit of the CBT. It is also possible that the observed result relates more to the condition of fear of falling. Due to the particular experience of falling, and the resulting pattern of unhelpful cognitions and behaviours that appear to maintain fear of falling, it is possible that fear of falling is a distinct clinical condition which is not necessarily related to general anxiety or overall quality of life. This has been suggested in the literature; for example Bhala et al., (1982), coined the term 'ptophobia' to describe fear of falling, and stated that fear of falling is a distinct psychological problem which is not related to agoraphobia. Therefore, it may be that increased anxiety and impaired quality of life do not always occur co-morbidly with fear of falling. In addition, the CBT intervention delivered in this research specifically targets fear of falling, therefore it may not impact on general symptoms of anxiety or quality of life. The CBT sample in this study had lower WHOQOL-OLD scores than were expected from normative data, which could be due to other issues unrelated to fear of falling, such as loneliness or financial worries, which are likely to have remained unaffected by the CBT for fear of falling intervention.

These results strengthen those of Zijlstra et al. (2009) and Tennstedt et al. (1998) who also found beneficial effects of CBT for fear of falling. However, Tennstedt et al. only found improved fear of falling in participants attending five sessions or more. Although the average number of sessions attended in the present study was five, there were beneficial effects for two participants who only attended four CBT sessions, which indicates that fewer sessions were required for beneficial effects in the present study. In contrast to Tennstedt et al., Zijlstra et al. found beneficial effects of their intervention for their intention to treat analysis, with additional effects found for treatment completers. However, both of these studies had

high rates of attrition and effect sizes were small to moderate, despite both studies having large sample sizes (Zijlstra et al. n=540, Tennstedt et al. n=434). In these two studies, interventions were group delivered and it may be reasonable to suggest that, as all participants in the present study completed the intervention and effect sizes were large, individually delivered CBT for fear of falling is potentially more acceptable and more efficacious than group delivered CBT for this population. This is consistent with the findings of Engels & Verney (1997) on CBT for older adults.

### Strengths and Limitations of this Study

This is the first study to investigate the effects of individually delivered CBT for fear of falling. A particular strength is that it demonstrates that large effects on levels of fear of falling can be found with a brief intervention. A further strength is the high subject retention rate in the intervention group, in contrast to previous studies in this field which report high rates of attrition. In addition, an intervention protocol developed for this study, which was specific to fear of falling, has been demonstrated to be acceptable to older adults, and can be feasibly delivered. In a review of the literature for CBT for late life depression, Laidlaw (2001) highlights that data from clinical trial research is often not applicable to real world settings as clinical trials are often conducted in research settings and include a sample which differs somewhat from the patients you would expect to see in a clinical setting. In contrast to this, the present research was delivered in a clinical setting and included patients who were referred as part of their routine care. Therefore, the results of the present study can be considered relevant and meaningful to clinicians working in this area.

There are a number of limitations to the present study. Primarily, the recruited sample size was slightly smaller than intended and the study was underpowered for the measures of anxiety and quality of life. The difficulty with recruitment was due to slower rates of referral

to the clinical team than anticipated. In addition, all participants recruited into the CBT group were female. This limits the generalisability of the results to females. However, higher proportions of females are common in this population; several studies have demonstrated that females are more likely to be fearful of falling than males, for example, in a large scale fear of falling prevalence study, Kempen et al. (2009) reported that 72% of their sample were women.

Participants in this study were not randomised to treatment group and the groups were recruited from different sites. This may have resulted in potential sources of bias and the inclusion of potential confounding variables which could have affected the results.

This study was able to report on intervention fidelity assessed through session logs kept by therapists. It is possible that therapists may have chosen to omit protocol deviations from the session logs, however as there were only two therapists delivering the intervention (one of whom was the primary researcher) this is unlikely. Despite this, it may have been preferable to utilise a more robust method of assessing intervention fidelity such as recording of sessions.

Another potential limitation is that although the study included a control group, the amount of input, with respect to overall number of contacts, was not equitable between groups. The CBT group received a higher number of overall contacts than the physiotherapy control group. There is therefore a possibility that non-specific effects of the CBT intervention, such as increased time spent with a professional and the development of a supportive and trusting relationship with a professional, may have contributed to the beneficial effects of the CBT intervention. However, all of the included participants reported cognitive and behavioural changes, such as a reduced frequency of unhelpful cognitions regarding falling and reduced

avoidance of feared situations. Therefore, it would be reasonable to conclude that the cognitive restructuring and graded exposure techniques employed in the intervention had a considerable effect on the results.

### Suggestions for Future Research

Future, larger scale studies are required to investigate if the beneficial effect found in this study is replicable. These studies should include adequate comparison groups which account for non-specific treatment effects, and intervention protocols which are assessed for fidelity in order to provide further data regarding the acceptability of this intervention. Future studies should also administer repeated measures at appropriate follow up points in order to assess whether treatment gains can be maintained. In addition, robust behavioural measures of outcome (i.e. those which reliably assess the impact of the intervention on the person's behaviour and daily functioning) should be developed in order to strengthen the results of future studies.

All participants in the present study had experienced a fall, however it is highlighted in the literature that fear of falling can occur in non-fallers (Friedman et al. 2002). In the present study, all of the participants in the CBT group completed the intervention, which is in contrast to the previously mentioned trials of CBT for fear of falling which suffered high rates of attrition. Of interest, both Zijlstra et al. (2009) and Tennstedt et al. (1998) had a significant percentage of non-fallers in their intervention groups (43.9% and 65.6% respectively) and, as they suffered a high rate of attrition, it may be that the mechanism of fear acquisition in those with fear of falling (i.e. whether the fear of falling developed because of having a fall or because of another reason) has an impact on response to treatment completion. Future research should aim to investigate the mechanisms which are implicated

in the development of fear of falling in fallers and non-fallers and should further investigate

the impacts of these mechanisms on response to treatment and subject retention.

Conclusions

Individually delivered CBT is an effective and feasible intervention for older adults who are

fearful of falling and is more effective that standard physiotherapy.

Word Count: 6001

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Submitted in part fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

# **Abstract**

Introduction: This account focuses on a particular experience of communicating a psychological approach to a staff team regarding a case of distressed behaviour in dementia. It is highlighted in Scotland's National Dementia Strategy (Scottish Government 2010) that staff working with dementia must be supported to develop an understanding of the causes underlying behaviours, and appropriate skills to manage behaviours. In addition, a key proficiency for practitioner psychologists outlined by the Health and Care Professions Council (2010) is that psychologists use formulations to assist multi-professional communication, understanding of clients, and intervention planning. Despite this, there are often barriers to working in this way.

Reflection: I use Gibbs (1988) model to structure my reflections on the experience. I discuss the feelings and thoughts that were evoked from the experience, how I evaluated and made sense of the experience, and how I used my reflections to inform my future practice. I also consider the implications that these issues have for the profession of Clinical Psychology as a whole

Reflective Review: From my reflections, I considered that the staff team I was working with were experiencing significant stress which is likely to have impacted on their capacity to manage the distressed behaviour and to engage in a psychological approach. This prompted me to reflect on the wider literature regarding staff stress, staff attitudes, and group processes and I discuss how my reflections on these areas influenced my understanding of the experience and my future practice. I also discuss the experience in the context of the Dementia Strategy. I finally review my development in the competency of consultancy throughout training.

Conclusion: This experience has allowed me to consider some of the challenges of the consultancy model however, through wider reflection, it has highlighted to me the crucial role that clinical psychologists have in promoting a psychological formulation and intervention approach for patients with distressed behaviour.

# Chapter 4: Advanced Clinical Practice 2, Reflective Critical Account

Developing the Application of Psychological Skills in Multi-Disciplinary Teams: Is there a Middle Ground between Diagnosis and Formulation?

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Submitted in part fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

# **Abstract**

Introduction: This account focuses on an experience of working with a staff team to develop a formulation of a service user. It is highlighted by the Department of Health (1999) that developing a shared formulation within a team can help the team to work together, improve communication, and achieve shared goals. In addition, the British Psychological Society advocates that team formulation has a number of benefits such as: it promotes a consistent team approach to intervention; challenges negative perceptions of service users; increases empathy for service users; and allows the team to support each other with complex cases.

Reflection: In order to structure my reflections I use Gibbs' (1988) model. I discuss my emotional reactions to the experience, how I evaluated and made sense of these reactions, and how my reflections allowed me to consider ways to improve my clinical practice. I also consider the implications of the issues raised by my reflections for the profession of Clinical Psychology as a whole.

Reflective Review: I consulted the wider literature to help me further understand my emotional reactions to the experience. This revealed some beliefs and values that I hold regarding the use of diagnoses and the unhelpful aspects of this approach which my experience had highlighted. However, I also considered some of the limitations to a formulation based approach and used this to consider ways to improve my future experiences of developing formulations with staff teams. I finally discuss my reflections on my development in the competency of training others throughout my time in the Clinical Psychology training programme.

Conclusion: This experience has allowed me to explore my own emotions, values, and beliefs which were evoked during a particular experience of working with a staff team to develop a formulation. Through my reflections, I am able to conclude that, although the use of diagnoses and the medical model still prevails, it is integral that Clinical Psychologists use training and methods such as team formulation to enhance understanding of the psychological approach amongst other professionals.

# **Appendix 1.1. Instructions for Authors for Submission to International Psychogeriatrics**

# CAMBRIDGE Instructions for Contributors

# International Psychogeriatrics

Please read these instructions carefully before submitting articles. Articles which are not prepared in accordance with these guidelines will be returned to authors unreviewed.

# Scope and contributions

International Psychogeriatrics is written by and for those doing clinical, teaching, and research work with elderly people. It is the official journal of the International Psychogeriatric Association (IPA) and is published by Cambridge University Press, Cambridge, UK. Although it is concerned primarily with psychogeriatrics, the journal welcomes contributions from all concerned with the field of mental health and aging. Original research papers are particularly sought.

Contributions include original research articles, reviews of the literature, "for debate" articles, case reports, letters to the editor, book reviews and editorials. Apart from editorials, "for debate" articles and book reviews, which are commissioned, contributions to International Psychogeriatrics are spontaneously written and submitted by authors. Papers are reviewed by at least two expert reviewers selected by the Editor-in Chief. At present about half of the papers submitted are accepted for publication in this journal which is published twelve times per annum. The journal's Science Citation Index Impact Factor (2011) is 2.24. Submission of a paper implies that it is neither under consideration for publication elsewhere, nor previously published in English. Manuscripts must be formatted double-spaced with ample margins on all sides and the pages should be numbered. Please leave a spare line between paragraphs to enable typesetters to identify paragraph breaks without ambiguity. International Psychogeriatrics uses the spelling of American English. Manuscripts written by those whose primary language is not English should be edited carefully for language prior to submission. International Psychogeriatrics has a Language Advisory Panel of English speakers willing to check manuscripts for style prior to submission. Details can be found at both the journal website (http://journals.cambridge.org/ipg) under the related links icon and the IPA website (http://www.ipa-online.org/).

# Submission of manuscripts

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To facilitate rapid reviewing, communications for peer review will be electronic and authors will need to supply a current e-mail address when registering to use the system.

When submitting your manuscript you will need to supply:

A cover letter, the manuscript with the text file in MS Word format, and all figures in TIFF or JPEG format. If the paper reports the results of a randomized controlled trial please ensure that it conforms to our requirements listed below under the heading 'Submission of randomized clinical trials' on page 2. If the research was paid for by a funding organization, the cover letter must contain the following three statements (this information does not have to be included in the manuscript itself but only in the cover letter). If the research was not paid for by a funding organization only the third statement is required:

- 1. That the authors have not entered into an agreement with the funding organization that has limited their ability to complete the research as planned and publish the results.
- 2. That the authors have had full control of all the primary data.

3. That the authors are willing to allow the journal to review their data if requested.

Submission of a manuscript will be taken to imply that all listed authors have seen the final version and approved it.

All papers will be assessed by two reviewers. If their opinions are too disparate to permit the Editor-in-Chief to make a decision on publication or the reviewers are unable to make clear recommendations, the paper will be assessed by a third reviewer. The Editor-in-Chief's decision to accept, reject or request revision of the paper for publication will be final. The abstract and author details will be seen by prospective reviewers of the manuscript. Authors can suggest the names and contact information of experts qualified to review the work, but the Editor-in-Chief is not obliged to follow these suggestions. Papers must bear the authors' names, titles (e.g., Dr, Professor, etc.), affiliation(s), and address(es). This information will be seen by reviewers. Reviewers' names will not be supplied to authors unless a reviewer asks to be so identified. Authors will be provided with a copyright transfer form to sign after acceptance of the manuscript, consenting to publication of the paper in *International Psychogeriatrics*.

The receipt of all submitted papers will be acknowledged. Authors who do not receive an acknowledgement of receipt of their paper within three weeks of submission should assume that their paper has not been received and should contact <a href="mailto:ipaj-ed@unimelb.edu.au">ipaj-ed@unimelb.edu.au</a>, Professor Nicola Lautenschlager. Normanby House, St George's Hospital, 283 Cotham Road, Kew, Victoria, 3101, Australia, Tel: +61 3 9816 0485, Fax: +61 3 9816 0477. Most authors can expect to receive an initial decision on the fate of their paper together with referees' reports within no more than 100 days of submission. Authors who have received no further communication 120 days after acknowledgment of receipt of their article should contact <a href="mailto:ipaj-ed@unimelb.edu.au">ipaj-ed@unimelb.edu.au</a>.

# Submission of papers reporting randomized controlled trials

In order to ensure the public availability of the results of randomized controlled trials, the International Committee of Medical Journal Editors has suggested that all such trials should be registered. In common with many leading medical journals *International Psychogeriatrics* has decided to follow this policy. Since 31 December 2006 we will not review any paper submitted to us reporting a randomized clinical trial unless the trial was registered in a public trial registry from the date it commenced recruitment or, if recruitment started before 30 November 2006, we require that the trial was registered no later than 30 November 2006. For further details on the reasons for this policy see the June 2006 editorial, Ames, D. (2006). Registration of Clinical Trials submitted for publication in *International Psychogeriatrics*. *International Psychogeriatrics*, 18, 191-193.

All manuscripts reporting randomized controlled trials should have the following sent with them or they will be returned to the authors.

- a. A check list and flow chart in accordance with the CONSORT guidelines which can be found at <a href="http://www.consort-statement.org">http://www.consort-statement.org</a>. Please send in the checklist as a supplementary file and include the flow chart as Figure 1 in the manuscript.
- b. The trial protocol is to be submitted as a supplementary file. This will not be published but it is needed to appraise and peer review the paper.
- c. The registration number of the trial and the name of the trial registry in which it was registered. Please add these to the last line of the paper's structured abstract. Trials that began enrolment of patients after 31 December 2006 must have been registered in a public trials registry at or before the onset of enrolment to be considered for publication in *International Psychogeriatrics*. Trials that began enrolment prior to 30 November 2006 must have been registered no later than that date. Our criteria for a suitable public trial registry are: free to access; searchable; identification of trials by unique number; free or minimal cost for registration; validation of registered information; inclusion of details to identify the trial and the investigator within the registered entry (including the status of the trial); research question; methodology; intervention; and funding and sponsorship disclosed.

# Organization and style of research articles

<u>Title page and corresponding author:</u> Each article must have a title page with the title of the article, a list of all authors and their titles, affiliations and addresses. Author qualifications should not be listed as these are not published in the journal. The title page should explicitly identify the author to whom correspondence about the study should be addressed and that author's email address, telephone number, fax number and postal address must be clearly stated.

<u>Abstract</u>: Abstracts should be brief, structured and should incorporate the 4 sub-headings: background, method(s), results and conclusion(s). Abstracts should communicate the primary findings and significance of the research. They should not exceed 250 words in length.

<u>Key words</u>: Under this heading and beneath the abstract, please list up to 8 words for the purpose of indexing.

Running title: This should contain no more than 50 characters including spaces.

<u>Introduction:</u> Briefly state the relevant background to the study to provide the necessary information and context to enable non-specialists to appreciate the objectives and significance of the paper. Most introductions to articles received for review are too long.

Methods: Materials and procedures should be described in sufficient detail to enable replication. Any statistical procedures used should be outlined and their use should be justified here. Results should not be included in the Method(s) section. If statistical procedures are used, they should be described here in adequate detail. Choice of statistical technique should be justified including some indication of the appropriateness of the data for the technique chosen. Adequacy of the sample size for the statistical technique(s) used must be addressed. If appropriate, a description of the statistical power of the study should be provided. If multiple univariate significant tests are used, probability values (p-values) should be adjusted for multiple comparisons, or alternatively a multivariate test should be considered.

Further advice about statistics and *International Psychogeriatrics* can be found in the following article: Chibnall, J. (2000) Some basic issues for clinicians concerning things statistical. *International Psychogeriatrics*, 12, 3-7. The following article may also be of assistance to intending contributors: Chibnall J.T. (2004). Statistical audit of original research articles in *International Psychogeriatrics* for the year 2003. *International Psychogeriatrics* 16, 389-396. Both of these are available at the *International Psychogeriatrics* website by following the link to <u>Statistical Advice for intending contributors</u>. This is also located under the related links icon at the journal homepage (<a href="http://journals.cambridge.org/ipg">http://journals.cambridge.org/ipg</a>).

Results: This section may contain subheadings. Authors should avoid mixing discussion with the results. Sample sizes should be delineated clearly for all analyses. Some indicator of variability or sampling error should be incorporated into the reporting of statistical results (e.g. standard deviation, standard error of the mean). Wherever possible an indicator of effect size (e.g. Cohens d,  $\eta^2$ , Cramers V, 95% confidence interval) should be reported in addition to p values. If multiple univariate statistical tests are used p values should be adjusted for multiple comparisons or alternatively a multivariate test should be used. Obtained statistical values for tests should be reported with degrees of freedom (e.g. t, F,  $\gamma^2$ ).

<u>Discussion</u>: Interpretation of the results with respect to the hypothesis(es) and their significance to the field should be discussed here. Results should be interpreted in the light of the size of the effect found and the power of the study to detect differences. Any methodological weaknesses of the study should be outlined, including limitations imposed by sample size. Careful consideration of the conclusion(s) for accuracy and alternative interpretation, and possible conflicts or resolution of conflicts in the field is encouraged. Limited speculation and directions for future research can be included

<u>Conflict of interest declaration:</u> This section must be completed. This should follow the discussion and precede the references. Where there is no conflict of interest perceived to be present the heading <u>Conflict of Interest</u> should be included with the single word "none" underneath it. For full details see below.

<u>Description of authors' roles:</u> This section must be completed if the paper has 2 or more authors. It should contain a very brief description of the contribution of each author to the research. Their roles in formulating the research question(s), designing the study, carrying it out, analysing the data and writing the article should be made plain. For example: H. Crun designed the study, supervised the data collection and wrote the paper. M. Bannister collected the data and assisted with writing the article. N. Seagoon was responsible for the statistical design of the study and for carrying out the statistical analysis.

<u>Acknowledgements:</u> Any acknowledgements other than conflict of interest declarations in regard to sponsorship should be listed briefly here.

<u>References:</u> No more than 30 articles that have been published or are in press should be cited. If authors believe that more than 30 references are essential this must be justified in the cover letter. Unpublished data, personal communications, and manuscripts submitted for publication should be cited in the text and the supporting material submitted with the manuscript. *International Psychogeriatrics* uses the Harvard referencing system. Within the text of each paper journal articles should be cited in the style (Smith and Jones, 1999). Where an article quoted in the body of the text has more than two authors the term "et al." should be employed, i.e., (Smith et al., 1999). Text citations of multiple articles should be separated by semicolons, i.e., (Smith and Jones, 1999; Smith et al., 1999). At the end of each paper, all cited references should be listed alphabetically in the style indicated below. If the Digital Object Identifier (doi) is known, it should be added to the reference.

For a journal article: **Smith**, **J.**, **Jones**, **W. I. and Doe**, **J. T.** (1996). Psychogeriatrics for pleasure and profit: an expanding field. *International Journal of Unreproducible Results*, 3, 240–242. doi:12.3456/S123456789.

For a book: Smith, J.A., Brown, P.Q., Jones, H.A. and Robinson, D.V. (2001). Acute Confusional States. New York: Cambridge University Press.

For a book chapter. **Park**, **K.**, **Tiger**, **B.** and **Runn**, **F.** (1999). Psychogeriatrics in context. In G.Verdi and A. Boito, (Eds.) *New Medical Specialties* (pp. 240–260) Cambridge: Cambridge University Press.

Where an article or book chapter has more than six authors only the first author's name should be given followed by the words "et al.".

For further examples of reference style see papers in recent issues of International Psychogeriatrics.

<u>Figures/Tables</u>: The manuscript should contain no more than five figures or tables. The copies submitted with the manuscript must be of sufficient quality to enable reviewers to evaluate the data. Ther journal has a small budget to permit some colour to be printed in come issues but authors wishing to publish figures requiring colour to communicate the data *may* be required to pay some or all the additional cost.

<u>Figure/Table legends:</u> Each caption should begin with a brief description of the conclusion or observation provided in the figure. These should be submitted as a separate section after the References.

<u>Supplementary material:</u> More detail about the submission of supplementary material is available below – see "Supplementary Material for online only publication" and "Instructions for contributors – Supplementary Material" in subsequent pages of this document.

<u>Word limits:</u> At present *International Psychogeriatrics* does not have a fixed word limit for articles, but because of limited space, short articles have a higher chance of acceptance than longer ones of an equivalent standard.

# Conflict of interest

Conflict of interest occurs when authors have interests that **might** influence their judgement inappropriately, regardless of whether that judgement is influenced inappropriately or not. *International Psychogeriatrics* aims to conform to the policies of the World Association of Medical Editors in regard to conflict of interest. For full details please see the website <a href="http://www.wame.org/wamestmt.htm#fundres">http://www.wame.org/wamestmt.htm#fundres</a>. To this end all authors must disclose potential conflicts of interest so that others may be aware of their possible effects. Specifically, under the heading conflict of interest, all articles must detail:

The source(s) of financial support for the research (if none, write "none").

A description of any sponsor's role(s) in the research (e.g., formulation of research question(s), choice of study design, data collection, data analysis and decision to publish).

Information about any financial relationship between any author and any organization with a vested interest in the conduct and reporting of the study. For example, in a study on the effects of a drug made by *Bigpharma* which directly competes with another drug made by *Megadrug* a declaration might say "Jane Smith has received research support and speaker's honoraria from *Bigpharma* and has received financial assistance from *Megadrug* to enable her attend conferences."

#### Reviews of the Literature

International Psychogeriatrics will publish at least 1 literature review in each issue. Authors intending to submit a literature review should check recent issues of International Psychogeriatrics to ensure that no review of the topic they propose to discuss has been published in the journal in recent times. Review articles may have up to 50 relevant references. Authors contemplating the submission of a literature review article are welcome to contact the editor to discuss the appropriateness of the topic prior to submission (<a href="mailto:ipaj-ed@unimelb.edu">ipaj-ed@unimelb.edu</a>). Literature reviews should have an abstract.

#### "For Debate" Articles

From time to time *International Psychogeriatrics* will publish "For debate" articles on topics of a controversial nature. "For debate" articles will be commissioned by the editor, but readers are welcome to suggest possible topics for debate by contacting the editor at <a href="mailto:ipaj-ed@unimelb.edu.au">ipaj-ed@unimelb.edu.au</a>. To view recently published debates see journal issues 19(6), 20(2), and 21(2).

#### Case Reports

Case reports will be accepted for review and considered for publication. They should be of 1200 words or less and should have no more than 10 references. An unstructured abstract of 100 words or less is required. When submitting case reports authors must enclose a letter of consent to publication from each of the patient(s) described or, if the patient(s) is/are deceased or not competent to consent the authors must indicate that they have obtained such consent from the patient's legal guardian(s). These letters will be kept confidential.

# Study protocol articles

Any author contemplating submission of a protocol only paper is advised to contact the editor of IPG via <a href="mailto:ipaj-ed@unimelb.edu.au">ipaj-ed@unimelb.edu.au</a> to discuss the paper's suitability for submission prior to submitting it.

# Qualitative research articles

Authors of qualitative research articles are advised to contact the editor of IPG via <a href="mailto:ipaj-ed@unimelb.edu.au">ipaj-ed@unimelb.edu.au</a> to discuss the paper's suitability for the journal before submitting online.

#### Letters to the Editor

Reader's letters will be considered for publication. Letters should be no longer than 1,000 words and should have no more than 5 references. No abstract is required. Usually tables will not be published in the Letters section of the journal, but may be accepted for online publication as supplementary material at the journal website.

#### Supplementary Material for online only publication

International Psychogeriatrics has the facility to publish unedited figures, tables, appendices and other material which is not suitable for inclusion in papers published in the paper copy of the

journal as supplementary online material attached to the electronic version of individual papers at <a href="http://journals.cambridge.org/ipg">http://journals.cambridge.org/ipg</a>. This renders such supplementary material accessible without clogging the journal with materials that will be of interest to only a small minority of readers. If submitting such supplementary material please follow the instructions below. If referring to supplementary material in a paper the following form of words should be used "see table \$1/figure \$1/appendix A1 published as supplementary material online attached to the electronic version of this paper at <a href="http://journals.cambridge.org/ipg">http://journals.cambridge.org/ipg</a>".

# Instructions for contributors – Supplementary Material

There will normally be one of the following reasons for you to be supplying supplementary material to accompany the online version of your article:

- You wish to link to additional information which due to its nature does not lend itself to print media (examples- full data sets, movie or sounds files etc...)
- The Editor of the Journal has requested that you extract certain information from the original article in order to allow for space constraints of the print version.
- You have requested additional material to be available to accompany an article that does not normally allow such material to be included (example – tables to accompany a correspondence article).
  - **N.B.** Please note that no copyediting or quality assurance measures will be undertaken on supplementary material (other than to ensure that the file is intact). The authors therefore warrant that the supplementary material that they submit is in a suitable format for publication in this manner. The material shall be published online in exactly the form that it is supplied.

#### Submission

Please follow the following instructions to supply supplementary material to accompany the online version of your article:

- 1. Each supplementary file must be supplied as a separate file. Do not supply this material as part of the file destined for publication in the print journal.
- 2. Each supplementary file must have a clear title (for example, Supplementary Figure 1).
- 3. Provide a text summary for each file of no more than 50 words. The summary should describe the contents of the file. Descriptions of individual figures or tables should be provided if these items are submitted as separate files. If a group of figures is submitted together in one file, the description should indicate how many figures are contained within the file and provide a general description of what the figures collectively show.
- The file type and file size in parentheses.
- Ensure that each piece of supplementary material is clearly referred to at least once in the print version of the paper at an appropriate point in the text, and is also listed at the end of the paper before the reference section.

#### Format and file size

- File sizes should be as small as possible in order to ensure that users can download them quickly.
- Images should be a maximum size of 640 x 480 pixels at a resolution of 72 pixels per inch.
- Authors should limit the number of files to under ten, with a total size not normally exceeding 3 MB. Sound/movie files may be up to 10 MB per file; colour PDFs/PowerPoint may be up to 5 MB per file; all other general file types may be up to 2 MB per file but most files should be much smaller.

We accept files in any of the following formats (if in doubt please enquire first):

MS Word document (.doc), Adobe Acrobat (.pdf), Plain ASCII text (.txt), Rich Text Format (.rtf), WordPerfect document (.wpd), HTML document (.htm), MS Excel spreadsheet (.xls), GIF image (.gif), JPEG image (.jpg), TIFF image (.tif), MS PowerPoint slide (.ppt), QuickTime movie (.mov), Audio file (.wav), Audio file (.mp3), MPEG/MPG animation (.mpg)

If your file sizes exceed these limits or if you cannot submit in these formats, please seek advice from the editor handling your manuscript.

#### Supply of author-generated artwork

# Monochrome line subject illustrations supplied as hard copy only

These should have the author's name and figure number clearly marked on the back of each piece of artwork. The figures will be scanned at 1200 dpi and compressed using LZW. The scanning process can result in problems with some fine ornaments and with any grey tints used (e.g. tints can fill in; a Moiré interference pattern can be produced; or poor quality, patchy tints result). Illustrations of this kind may be acceptable in a desktop publishing format, but they do not proceed satisfactorily through the several stages before printing. Plain black/white is acceptable, but all other shades/tints should be replaced with distinct PostScript fills or custom fills.

# Monochrome line subject illustrations supplied in digital form

Macromedia Freehand, Adobe Illustrator and Adobe Photoshop are the preferred graphics packages. Before submitting your artwork, please do the following:

- Where possible, please supply illustrations as TIFF or EPS files (300 dpi). When submitting EPS files you must convert your text within the file to artwork/outlines. If your EPS file contains a scanned image, you must ensure that you supply a full EPS, i.e. binary data. Do not supply PostScript files. PostScript files cannot be included within our integrated page make-up system, or worked on in any way. For best results please save your files as TIFF or EPS files. If files cannot be supplied in this way other formats can be handled (although we do not guarantee to use them).
- · Draw or scan line artwork to finished size with appropriate line weights and typefaces.
- Indicate the file format (e.g. TIFF or EPS), the graphics software that you have used in originating the artwork files (e.g. Freehand 7.0, Illustrator 8.0, etc.) and the computer operating system used (e.g. Mac OS 8.6, Windows NT).
- Supply a laser print of all figures. List the name and version of the artwork package used and the names and libraries of fonts used in the artwork or EPS files.

#### Pattern fills and tints

Artwork packages do not always generate pattern fills for output on image/platesetters. Imagesetters will interpret them differently from your Mac or PC and the result often looks pixellated or blocked. Where possible, use PostScript fills, custom fills and conventional tints. PostScript fills frequently do not display well on screen but they do print out correctly. It is best to avoid the use of complex or very detailed tints, patterns and symbols. These seldom reproduce satisfactorily when reduced to fit the page and when used in a caption or legend may be completely illegible when represented on a screen (for example during page make-up, or on the Web) or when output on low-quality CUP artwork instructions.doc 2 laser printers. Supplying as TIFF or EPS files (see above) alleviates this problem.

# Please therefore:

- · Use only the tints, patterns and symbols shown here.
- Use conventional fills: solids, tints, lines or cross-hatching.
- Use a PostScript fill if possible.

- Do not use a screen value above 133 lpi. Generally, 100 lpi is better (even when scanned at high resolution finer tints do not reproduce satisfactorily when reduced).
- If possible, use just one kind of screen (line angle or dot shape) and one screen value throughout the document.
- Do not use pattern fills from a graphics program, as these are usually bitmap patterns, which do not output adequately to plate/image setters.
- Do not use colour tints, even if the figure is intended for monochrome printing; use black/white/greyscale.
- Do not use .hairline. line widths in graphics packages.

#### Monochrome halftone subjects

Figures composed of (hard copy) photographs should be unscreened glossy prints presented at publication scale; each component part should be named with a lower-case letter. Photographic artwork is numbered as part of the sequence of figures, not as separate plates.

If supplying these in digital form, your repro house should follow these instructions:

- Scanning: Scan at a resolution that is around twice the intended screen value; for example scan at 300 dpi for 133 or 150 screen.
- Dot range (halftones only): This is the term we use to describe the highlight/white area
  and shadow/black areas within a printed image. To prevent the heavy or dark areas of
  your halftones from filling in or the light areas being washed out we specify a dot range
  that allows for gains or losses during the process to lithographic printing. Pre-set the dot
  range at 1% highlight to 96% shadow where possible, we will check your files before
  outputting as a safeguard.
- Data files: Supply data as TIFF files; if you wish to compress them, use lossless compression software such as the LZW compression package.
- Laser proofs: Supply a good quality laser proof of all figures. List the name and version of
  the artwork package used and the names and libraries of fonts used in the artwork. If we
  are unable to use your electronic file, we can scan in the laser proof as an alternative until
  a revised file can be supplied.
- Line & tone combination: Files scanned as line & tone combination should be scanned at a higher resolution than a standard halftone to ensure better type/line quality, for example, 600 dpi.

# Colour halftone or line subjects

- Do not submit line subject drawings with coloured tints unless the figure is required as a colour plate; use only black/white/greyscale.
- If supplying colour subjects in digital form, submit as TIFF or EPS files and choose CMYK colour mode when saving your scans. If you supply files as RGB we need to convert them to the CMYK printing process before we can print, this usually results in a slight change of the colour values; therefore all colour correction must be carried out in CMYK mode on your machine.

#### Checklists

- Always supply a printed directory of file names, laser proofs of all the figures, and a list of fonts/typefaces used in labelling artwork.
- Transfer media
- You can supply artwork files in any of the following media:

#### Apple Mac/PC:

- disks at 3.5 inch
- 100/250 Mb Floppy ZIP drive
- CD-ROM

#### Virus check

Before dispatching your disks please run them through a virus checker program. If possible, also check Word and Excel files for viruses.

#### General notes

Following acceptance of a manuscript the contact author should receive proofs within 1-12 weeks. They also will be required to complete and forward a copyright form and authors' checklist both of which will be forwarded to the corresponding author by email when the article is accepted. There is an approximate 4-9 month delay from acceptance of an article to its publication in *International Psychogeriatrics*, but accepted articles will be e-published ahead of print as *First View* Articles within 6-10 weeks of acceptance provided authors return proofs promptly. E-publication generates a doi number and counts as full publication for citation purposes.

Editorials, "For Debate" articles and book reviews are commissioned by the editor.

Reviewers who reviewed papers in the previous calendar year will be acknowledged in the journal each year. *International Psychogeriatrics* no longer publishes an annual index as modern computerised search techniques have rendered annual hard copy indices obsolete.

Contributors should refer to recent issues of the journal for examples of formatting (abstracts, headings, references, tables, etc.).

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(Revised 5 Jun 2013)

# **Appendix 1.2: Quality Rating Scale**

# The Feasibility and Efficacy of Cognitive Behaviour Therapy for Fear of Falling: A Systematic Review

# **QUALITY RATING SCALE**

(Adapted from the Clinical Trials Assessment Measure, Tarrier & Wykes 2004)

Reviewer:
Title:
Authors:
Date:
Journal:
<ul> <li>Sample (maximum score = 15)</li> <li>1. Is the sample a convenience sample (score 2) or a geographic cohort (score 5) or highly selective sample (score 0) (Convenience sample: e.g. clinic attendees, referred patients. Geographic cohort: all patients eligible in a particular area)</li> </ul>
2. Is the sample size greater than 27 participants per group (score 5) or based on adequate and described power calculations (score 5) If no to both questions score 0.
3. Is data provided on the characteristics of refusers/ drop outs? Yes (score 5) No (score 0)
Total: /15
Control groups (maximum score = 26)  1. Is there a control group? (Yes – score 5)
<ol> <li>Is the control group TAU (score 6) and/or a control group that controls for non-specific effects o other established or credible treatment (score 10)</li> </ol>
3. Groups similar at pre-test (or adjustments made) (score 5)
Total: /26

# Allocation (maximum score = 16, if no control group – score 0 for section)

- 1. Is there true random allocation or minimisation allocation to treatment groups (if yes score 10)
- 2. Is the process of randomisation described (score 3)
- 3. Is the process of randomisation carried out independently from the trial research team (score 3)

Total: /16

# Outcome assessment (maximum score = 40)

- 1. Are the assessments carried out by independent assessors and not therapists (score 10)
- 2. List the main outcome measures below:

Are the above measures standardised assessments (score 6) or idiosyncratic assessments of symptoms (score 3)

Is the measure of fear of falling a valid and reliable measure? (Score 0 if not valid/reliable, score 3 if poor validity/reliability, score 5 if valid/reliable measure)

Was there a long term follow up measurement (> 6 months after end of intervention) of fear of falling conducted (if yes score 3)

- 3. Are assessments carried out blind (masked) to treatment group allocation (score 10)
- 4. Are the methods of rater blinding adequately described (score 3)
- 5. Is rater blinding verified (score 3)

Total: /40

# Analysis (maximum score = 19)

1. The analysis is appropriate to the design and type of outcome measure (score 5)

2.	The analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis ) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)		
3.	Was an effect size calculation completed (score 3)		
4.	Was there sufficient information provided for effect sizes to be completed (score 1)		
Tot	tal: /19		
	T for Fear of Falling intervention (maximum score = 29) Was the CBT treatment adequately described to allow replication? (score 3)		
2.	Was the CBT intervention evidence based (i.e. reference made to relevant literature, intervention consists of both cognitive and behavioural components (score 5)		
3.	Was a treatment protocol or manual used (score 5)		
4.	Was information provided on the training of therapists (score 3) were therapists adequately trained to deliver CBT (if yes score 5)		
5.	Was adherence to treatment protocol assessed (score 5)		
6.	Was subject retention for the CBT intervention 85% or higher (score 3)		
7.	Were recommendations provided for improving the intervention? (score 1)		
Tot	tal: /29		
Total Score for Paper: /145 Calculated as percentage: %			

# **Appendix 1.3 : Key Methodological Limitations of Included Studies**

# TABLE 2: KEY METHODOLOGICAL LIMITATIONS OF INCLUDED STUDIES

Study	Limitations			
Design				
Randomised Tennstedt et al. (1998): 77.93%				
Controlled	Use of some volunteer participants			
Trial	No information about method of rater blinding			
	No information about level of therapist training in CBT			
	Level of contact received by control group not equitable to that of the			
	treatment group			
	High rate of attrition in intervention group			
	Zijlstra et al. (2009): 76.55 %			
	Use of volunteer participants			
	No information about therapists' training in CBT			
	No information about whether intervention fidelity was assessed			
	No information about method of rater blinding			
	No information about level of care received by control group			
	High rate of attrition in intervention group			
	Huang et al. (2011): 73.1%			
	Use of volunteer participants			
	Not all of included sample fearful of falling			
	No information about randomisation method			
	Randomisation conducted by first author of paper			
	No information about whether treatment protocol/manual used			
	No information regarding length of therapists' training in CBT			
	No information about level of care received by control group			
	No information about method of rater blinding			
	Level of contact inequitable amongst intervention groups			
	Clemson et al. ( 2004): 68.28%			
	Use of volunteer participants			
	Level of contact time received by control group not equitable to that			
	of the intervention group			
	No information about therapists' training in CBT			
	No information about characteristics of dropouts			
	No information about whether treatment protocol/manual used			
	Fails to use a recognised, theoretically based intervention			
	Reinsch et al. (1992): 29.65 %			
	No information about reason for participants being invited in to the			
	study			
	Participants did not have to be fearful of falling			
	No information about process of randomisation			
	No information about whether a treatment protocol/manual was used			
	No information about who delivered the intervention			
	Single item measure used to assess fear of falling			
	No information about who administered the outcome measures			
	No statistical analysis reported			
	No intent to treat analysis			
	Fails to use a recognised, theoretically based intervention			

	High attrition rate		
Single group	Healy et al. (2008): 39.3%		
(Pre-Post)	Use of volunteer participants		
	No information about who administered outcome measures		
	No information about therapists' training in CBT		
	High attrition rate		
	Manckoundia et al. (2007): 27.59%		
	No information about whether a treatment protocol/manual was used		
	Unclear who delivered the intervention		
	No information about therapists' training in CBT		
	No information about who administered outcome measures		
	Intervention did not include any cognitive components		
	No intent to treat analysis		
	Zijlstra et al. (2012): 27.59%		
	Use of volunteer participants		
	No information about therapists' training		
	No information about who administered outcome measures		
	No information about characteristics of dropouts		
	No information about subject retention		
	No information about whether adherence to intervention protocol was		
	assessed.		
	No information about whether intent to treat analysis was used.		
	Mansdorf et al. (2009): 18.62 %		
	Small sample size		
	No information about therapists' training in CBT		
	No information about whether a treatment protocol/manual was used		
	No information about who administered the outcome assessments		
	Majority of measures used are idiosyncratic		
	No information about subject retention		
	No statistical analysis reported		
	Only presents partial results – not all participants completed the		
	FES-I.		

# Appendix 2.1: Instructions for Authors for Submission to The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences

# JOURNALS OF GERONTOLOGY SERIES B

#### March 2011: The journal has changed its citation format.

All articles accepted after March 1, 2011 will be cited using the following format:

The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences, vv, xxx-xxx.

(Note specifically, it starts with "The"; there is a comma and not hyphen before Series; there is no B on the volume number; and the letters have been removed from the page numbers.)

Please note that articles being cited prior to March 1, 2011 should be cited using the format in which they were originally published. Contact the journal inbox with any questions.

# Please note that the journal now encourages authors to complete their copyright license to publish forms online!

The Journal of Gerontology: Psychological Sciences (JG: PS) publishes articles on development in adulthood and old age that advance the psychological science of aging processes and outcomes. Articles in JG: PS have clear implications for theoretical or methodological innovation in the psychology of aging or contribute significantly to the empirical understanding of psychological processes and aging. Areas of interest include, but are not limited to, attitudes, clinical applications, cognition, education, emotion, health, human factors, interpersonal relations, neuropsychology, perception, personality, physiological psychology, social psychology, and sensation. Applied research with theoretical significance is welcome. Manuscripts reporting work that relates behavioral aging to neighboring disciplines are also appropriate. The Journal publishes three types of articles: (a) reports of original research, (b) brief reports of original research, and (c) New Directions in Aging Research—reviews of cutting-edge topics with theoretical or methodological implications. See word and page limitations below. All submissions are peer-reviewed, with final decisions made by the Editor.

# **SUBMISSION**

Please read these instructions carefully and follow them strictly to ensure that the review and publication of your paper is as efficient and quick as possible. The Editors reserve the right to return manuscripts that are not prepared in accordance with these instructions.

All material to be considered for publication in *The Journal of Gerontology: Psychological Sciences* should be submitted in electronic form via the journal's online submission system. Once you have prepared your manuscript according to the instructions below, instructions on how to submit your manuscript online can be found by clicking here.

#### **Ethics**

The Journal of Gerontology: Psychological Sciences expects that authors will observe high standards with respect to publication ethics. For example, the following practices are unacceptable: (a) falsification or fabrication of data; (b) plagiarism, including duplicate publication of the authors' own work, in whole or in part, without proper citation; (c) misappropriation of the work of others such as omission of qualified authors or of information regarding financial support. Allegations of unethical conduct will be discussed initially with the corresponding author. In the event of continued dispute the matter will be referred to the author's institution and funding agencies for investigation and adjudication.

Oxford Journals, publisher of *The Journal of Gerontology: Psychological Sciences*, is a member of the Committee on Publication Ethics (COPE), and the journal strives to adhere to the COPE code of conduct and guidelines. For further information, see <a href="http://www.publicationethics.org.uk">http://www.publicationethics.org.uk</a>.

# CORRESPONDENCE (EDITORIAL)

The Editorial Office can be contacted as follows:

Bob G. Knight, PhD, Editor, *Journal of Gerontology: Psychological Sciences*; Davis School of Gerontology, University of Southern California, Los Angeles, CA 90089. E-mail: jgps@usc.edu. If online submission is impossible, an alternative submission strategy can be arranged in advance with the editor.

#### **REVIEW OF MANUSCRIPTS**

Due to space restrictions and to the volume of high quality papers submitted, the Editors reserve the right to return immediately those papers that are unlikely to be competitive for space in the journal and/or those that do not conform to the general editorial philosophy and standards of *The Journal of Gerontology: Psychological Sciences.* 

# TYPES OF MANUSCRIPTS ACCEPTED FOR REVIEW

All articles should use 12 point, Times New Roman font. A word count should appear on the last page of the manuscript before the references.

NOTE: manuscripts that exceed the recommended word limit by more than several hundred words are returned to authors for revision before being entered into the system. Also, if those manuscripts are not in APA format, authors are asked to correct the format as they shorten the article.

- a. *Original Research Reports*. The text of manuscripts reporting empirical studies should not exceed 5,000 words; in unusual circumstances (multi-study reports, complex analyses), authors may submit up to 6,000 words of text. References, tables, figures, and illustrations should not exceed 10 pages.
- b. *Brief Reports*. The text of manuscripts should not exceed 2,000 words, and references, tables, figures, or illustrations should not exceed 3 pages.
- c. New Directions in Aging Research. The goal of these review articles is an integrative presentation of findings on a cutting-edge topic with attention to theoretical and methodological implications for future work on the selected topic. It is expected that these papers will include a novel integration and critical analysis of existing views in a specific area that has not been reviewed elsewhere, as well as proposed resolution(s) of controversial positions to advance the field. Methodological contributions should present innovative methods for the study of adult development and aging, which should be supported with examples based upon empirical data if possible. Page limits are the same as for empirical papers.

# **STYLE**

Manuscripts should be prepared according to the *Publication Manual of the American Psychological Association* (6th ed.), obtainable from APA, 750 First Street, N.E., Washington, DC 20002-4242, http://apastyle.apa.org/

#### MANUSCRIPT STRUCTURE

Please prepare your manuscript text using a word-processing package (save in .doc or .rtf format). Manuscripts should be double-spaced. Please number each page. We recommend that authors spell-check all files before submission.

Authors should submit a single file containing the complete manuscript (i.e., title page, abstract, text, figures and tables), as this makes the reviewing process easier for Editors and referees. Please include the tables and figures at the end of the manuscript, after references, and do not embed them within the text. This applies to the original version of the manuscript and any revised versions. Due to figure file sizes, you may have to submit separate files for figures. Please use short, simple filenames when saving all your documents, and avoid special characters, punctuation marks, symbols (such as &), and spaces. If you are a Macintosh user, you must also type the extension at the end of the file name you choose (.doc, .rtf, .jpg, .gif, .tif, .xls, .pdf, .eps, .ppt, .mov or .qt).

Other helpful hints are: (i) use the TAB key once for paragraph indents; (ii) where possible use Times New Roman for the text font and Symbol for any Greek and special characters; (iii) use the word processing formatting features to indicate **Bold**, *Italic*, Greek, Maths, Superscript and Subscript characters; (iv) please avoid using underline: for cases use italic; for emphasis use bold; (v) clearly

identify unusual symbols and Greek letters; (vi) differentiate between the letter O and zero, and the letters I and I and the number 1.

#### TITLE PAGE

The title should be short, specific, and informative. The first name, initial(s), and surname of each author should be followed by his or her department, institution, city with postcode, and country. The fax, telephone number, and Email address of the corresponding author should also be provided. It is editorial policy to list only one author for correspondence. Any changes of address may be given in footnotes. Any deletions or additions to the author list after acceptance of the paper must be submitted in writing, signed by all authors, to the appropriate editorial office. New sequence accession numbers (DDBJ/EMBL/GenBank) should be listed on the title page.

A short running head not to exceed 50 letters and spaces should be placed at the top of the title page.

#### **ABSTRACT**

On the page immediately following the title page, include a structured abstract of not more than 200 words, double spaced. It should contain four sections: Objectives, Method, Results, and Discussion. Please provide 3 to 6 key terms.

#### **TEXT**

The text of research articles should be divided into major sections with the headings Introduction, Methods, Results, and Discussion. Articles may require subheadings within sections to clarify their content. The discussion section may include conclusions derived from the study and supported by the data. While full explication of a study is desirable, conciseness of expression is imperative. Sexist or ageist language should be avoided.

Nonstandard abbreviations should be defined at the first occurrence and introduced only when used multiple times. Authors should not use abbreviations in headings. Ensure that the use of abbreviations is clear and that each one is defined in the text at its first mention only.

#### **FUNDING**

Details of all funding sources for the work in question should be given in a separate section entitled 'Funding'. This should appear before the 'Acknowledgements' section.

The following rules should be followed:

- The sentence should begin: 'This work was supported by ...'
- The full official funding agency name should be given, i.e. 'the National Cancer Institute at
  the National Institutes of Health' or simply 'National Institutes of Health' not 'NCI' (one of
  the 27 subinstitutions) or 'NCI at NIH' (full RIN-approved list of UK funding agencies)
- Grant numbers should be complete and accurate and provided in parentheses as follows: '(grant number ABX CDXXXXXX)'
- Multiple grant numbers should be separated by a comma as follows: '(grant numbers ABX CDXXXXXX, EFX GHXXXXXX)'
- Agencies should be separated by a semi-colon (plus 'and' before the last funding agency)
- Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number 'to [author initials]'.

An example is given here: 'This work was supported by the National Institutes of Health (P50 CA098252 and CA118790 to R.B.S.R.); and the Alcohol & Education Research Council (HFY GR667789).'

#### **ACKNOWLEDGEMENTS**

Acknowledgements and details of non-financial support must be included at the end of the text before references and not in footnotes. Personal acknowledgements should precede those of institutions or agencies. Please note that acknowledgement of funding bodies and declarations regarding conflict of interest should be given in separate Funding and Conflict of Interest sections, respectively.

#### **REFERENCES**

In-text citations and references of journals, books, multi-author books and articles published online should conform to the 6th edition of the *Publication Manual of the American Psychological Association* (2009). References in the text are shown by citing in parentheses the author's surname and/or the year of publication [E.g., "A recent study (Jones, 2007) showed, or Jones (2007) has shown].

The reference list should be double spaced and arranged alphabetically by author's surname; do not number. The list includes only references cited in the text and should generally not exceed 50 entries for original research and theoretical/methodological articles, and 30 for brief reports. Do not include references to private communications. Please add Digital Object Identifiers (DOIs) to the reference section. One way to locate the DOIs is to use CrossRef.org. This is a free service by which one submits a formatted reference list and it returns the DOIs for the cited articles. After creating an account, go to Simple Text Query in the Technical Resources options.

# **FOOTNOTES**

Footnotes, indicated by superscript figures in the text, should be used rarely and only for essential explanatory notes. Footnotes should be numbered consecutively, should be kept as brief as possible, and should be placed on a separate page before the Tables. Authors are responsible for checking the accuracy of all footnotes and references.

#### **TABLES**

Tables should be typed with double spacing, but minimizing redundant space, and each should be placed on a separate page. Each Table should be numbered in sequence using Arabic numerals. Tables should also have a title above and an explanatory footnote below, if needed. Units in which results are expressed should be given in parentheses at the top of each column and not repeated in each line of the table. Ditto signs are not used. Avoid overcrowding the tables and the excessive use of words. The format of tables should be in keeping with APA style; in particular, vertical lines, colored text and shading should not be used. Please be certain that the data given in tables are correct.

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# **Appendix 2.2: NHS Ethical Approval Letter**



# **WoSRES**

#### West of Scotland Research Ethics Service

Professor Thomas McMillan Mental Health and Wellbeing First Floor, Admin Building, Gartnavel Royal Hospital 1055 Great Western Road, Glasgow, G12 0XH West of Scotland REC 1 Ground Floor, Tennent Building Western Infirmary 38 Church Street Glasgow G11 6NT

Date 2<sup>nd</sup> October 2012 Direct line 0141-211-6270 Fax 0141-211-1847

Dear Professor McMillan

Study title: Evaluation of individual Cognitive Behaviour Therapy for

Older People who are Fearful of Falling

REC reference: 12/WS/0209

Thank you for your letter of 14 September 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a sub-committee of the REC at a meeting held on 2<sup>nd</sup> October 2012. A list of the sub-committee members is attached.

# 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.

#### 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).

# Conditions of the favourable opinion

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

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

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

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

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

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

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

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).

# Approved documents

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

Document	Version	Date
Covering Letter		14 September 2012
GP/Consultant Information Sheets	two	14 September 2012
Investigator CV		13 August 2012
Other: Ms Danielle Graham CV		13 August 2012
Other: Dr Susan Conaghan CV		24 July 2012
Other: Instruction for administration and scoring of MMSE		
Other: Interpretation of the MMSE		
Other: The WHOQOL OLD- module -manual		
Other: WHOQOL-OLD manual	May 2006	
Participant Consent Form: tracked changes	four	14 September 2012
Participant Information Sheet: tracked changes	three	14 September 2012
Protocol	version 7	31 July 2012
Questionnaire: Falls efficacy scale - international (English)		
Questionnaire: Mini-mental state examination (MMSE)		
Questionnaire: BAI		
REC application		13 August 2012
Referees or other scientific critique report		25 July 2012
Response to Request for Further Information		14 September 2012

# Statement of compliance

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

# After ethical review

# Reporting requirements

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

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

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

#### Feedback

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

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

# 12/WS/0209

Please quote this number on all correspondence

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

Yours sincerely

For

Dr John Hunter

Chair

Email: sharon.jenner@ggc.scot.nhs.uk

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" [SL-AR2]

Copy to: Dr Erica Packard, NHS Greater Glasgow and Clyde, Research and

development management office

# Appendix 2.3: NHS Research and Development Management Approval Letter



Coordinator/Administrator: Dr Michael Barber/Mrs Elaine O'Neill Telephone Number: 0141 211 6208 E-Mail: michael.barber@ggc.scot.nhs.uk Website: www.nhsggc.org.uk/r&d R&D Management Office Western Infirmary Tennent Institute 1st Floor 38 Church Street Glasgow, G11 6NT,

17 October 2012

Dr Susan Conaghan Consultant Clinical Psychologist Mansionhouse Unit 100 Mansionhouse Road Glasgow G41 3DX

# NHS GG&C Board Approval

Dear Dr Conaghan,

Study Title: Evaluation of individual Cognitive Behaviour Therapy for Older People who are

Fearful of Falling

Principal Investigator: Dr Susan Conaghan

GG&C HB site Southern General Hospital & Victoria Infirmary

Sponsor NHS Greater Glasgow and Clyde

R&D reference: GN12CP371
REC reference: 12/WS/0209
Protocol no: V7; 31/07/2012

(including version and date)

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 (<a href="www.nhsggc.org.uk/content/default.asp?page=s1411">www.nhsggc.org.uk/content/default.asp?page=s1411</a>), evidence of such training to be filed in the site file.

# Delivering better health

www.nhsggc.org.uk



- 2. For all studies the following information is required during their lifespan.
  - a. Recruitment Numbers on a monthly 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

Dr Michael Barber Research Co-ordinator

Delivering better health

# **Appendix 2.4: Participant Information Sheet**





# Evaluation of individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling

#### Contact Details:

Danielle Graham
University of Glasgow
Mental Health and Wellbeing
Gartnavel Hospital
1055 Great Western Road
Glasgow
G12 0XH
d.graham.4@research.gla.ac.uk

Professor Thomas McMillan University of Glasgow Mental Health and Wellbeing Gartnavel Hospital 1055 Great Western Road Glasgow G12 0XH

Thomas.mcmillan@glasgow.ac.uk

You are being invited to take part in a research study. Before you decide whether or not you wish to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. Please ask the researcher if there is anything that is not clear or if you would like more information. You do not have to make an immediate decision.

#### **Background information**

Fear of falling involves the loss of one's confidence to avoid falls during every day activities and the avoidance of activities for fear of having another fall. This condition has a significant impact on one's daily life and can result in: anxiety; depression; reduced independence; isolation; reduced quality of life and loss of confidence. Due to the impact of fear of falling, researchers have been looking at psychological treatments which may help to improve the condition. Cognitive Behaviour Therapy (CBT) is a widely used treatment which aims to improve difficulties such as anxiety and depression by helping people to think and behave in ways that are more helpful. Previous research has found that group delivered CBT for fear of falling was helpful. However, it has also been found that some patients may prefer individual therapy to group therapy.

# What is the purpose of the study?

The purpose of this study is to investigate the effectiveness of individually delivered Cognitive Behaviour Therapy for older adults who experience fear of falling. This study will also be submitted as part of the main researcher's (Danielle Graham's) portfolio for examination by the University of Glasgow as part of the Doctorate in Clinical Psychology.

# Who is conducting the research?

This study is being carried out by Danielle Graham, Trainee Clinical Psychologist, Dr Susan Conaghan, Consultant Clinical Psychologist and is being supervised by Professor Tom McMillan from the University of Glasgow.

# Why have I been invited?

You have been invited to take part as you are over 65, have experienced a fall in the last year and your physiotherapist from the Falls Prevention Service identified that you experience fear of falling.

# What does taking part involve?

In order to carry out this study we need to have some people who get the treatment and some other people who do not get it. By being able to compare these results we are able to properly examine if the treatment is effective or not. Therefore if you decide to take part in the study you may not receive the CBT. Whether or not you receive the CBT depends on the location in which you attend the Falls Prevention Service. Each hospital is different and you will receive the standard care that is available at your local hospital. We will not be adding or taking away any treatments that are already available at your local hospital. If you attend the New Victoria Day Hospital you will be offered CBT whilst still receiving your physiotherapy from the falls prevention service as normal. If you attend the Southern General Hospital you will not be offered CBT as this is not a treatment that is currently offered here, but you will continue to receive your physiotherapy from the falls prevention service as normal.

Participants from the New Victoria Day Hospital: You will be required to attend the New Victoria Day Hospital for roughly seven to twelve hourly appointments of CBT. These will usually be held weekly and will be at a time that is convenient for you. Prior to commencing the CBT, your therapist will complete an assessment where you will have a chance to talk about your difficulties with fear of falling and will also fill in some questionnaires which measure your levels of fear of falling, anxiety and overall quality of life. After your sessions of CBT you will be required to fill in the same questionnaires that you filled in during the assessment session. We will then contact you one month later and ask you to again complete these questionnaires.

<u>Participants from the Southern General Hospital:</u> You will be required to attend the Southern General between October to December 2012 at a time that is convenient for you to complete three questionnaires which measure your levels of fear of falling, anxiety and overall quality of life. This will take roughly forty five minutes. You will be required to attend the Southern General between February 2013 and March to complete the same questionnaires that you filled in during your fist appointment. We will then contact you one month later and ask you to again complete these questionnaires.

# Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

# What happens to the information?

Your identity and personal information will be completely confidential. However, if a member of the research team becomes concerned that you or someone else may be at risk of coming to harm we are obliged to inform other professionals such as your GP to ensure that everyone remains safe.

The information obtained will be stored within a locked filing cabinet. The individuals who will have access to your personal information are Danielle Graham, Dr Susan Conaghan and Professor Tom McMillan (the research team).

Data collected will be anonymised and each participant will be assigned a numerical code. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people without your permission.

#### Will you contact my GP?

With your permission, we will send your GP a letter to let them know that you are taking part in the study. If you would like to see an example of the letter, please ask the researcher.

#### What are the possible effects on you?

It is possible that completing the questionnaires or taking part in CBT may generate some emotional reactions for you. Should you experience an unpleasant emotional reaction you will be offered the opportunity to discuss this with the researcher or a member of your clinical support staff.

#### What are the possible benefits of taking part?

By taking part in this research you will be providing information on the development of a psychological therapy that could potentially improve symptoms of fear of falling. You will be provided with an information sheet at the end of the study which will summarise our results

#### Who has reviewed the study?

This study has been reviewed by the West of Scotland Research Ethics Committee

#### If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull**, **Research Tutor**, **University of Glasgow**, **Mental Health and Wellbeing**, **email: sue.turnbull@glasgow.ac.uk**, **Tel no: 0141 211 3920**.

#### If you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint procedures are also available to you.

# **Appendix 2.5: Participant Consent Form**





# **Consent Form**

**Evaluation of Individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling** 

Contact details: Danielle Graham
University of Glasgow,
Mental Health and Wellbeing
1055 Great Western Road,
Glasgow, G12 0XH

Email: d.graham.4@research.gla.ac.uk

# Please write your initial in the box if you agree to each statement

I confirm that I have read and understand the information sheet for the above study.				
I confirm that the researcher has answered any queries to my satisfaction.				
I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.				
I understand that I can withdraw my data from the research database at any time.				
I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available  I understand that the research team and that authorised representatives of the sponsor, NHS Greater Glasgow and Clyde, will have access to my data.				
I consent to being a participant in the project.				
GP name and address:				
Name of participant:	Name of researcher:			
Signature :				
Date:	Date:			





# Evaluation of individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling

R.E: Patient Name:
D. O. B:/
Address:
Group Allocation :

The above patient has agreed to take part in a research study run jointly by NHS Greater Glasgow and Clyde and The University of Glasgow.

#### What is the purpose of the study?

The purpose of this study is to investigate the effectiveness of an individually delivered Cognitive Behaviour Therapy for older adults who experience fear of falling.

#### Who is conducting the research?

This study is being carried out by Danielle Graham, Trainee clinical Psychologist, Dr Susan Conaghan, Consultant Clinical Psychologist and is being supervised by Professor Tom McMillan from the University of Glasgow.

#### The Research procedures:

There are two groups involved in the study. One group of participants will receive CBT plus standard physiotherapy from the falls prevention service and the other group of participants will receive just standard physiotherapy from the falls prevention service. Whether or not the participant receives the CBT depends on the location in which they attend the Falls Prevention Service. Participants who attend the **New Victoria Day Hospital will** be offered CBT whilst still receiving physiotherapy from the falls prevention service as normal. Participants who attend the **Southern General Hospital will not** be offered CBT but will continue to receive physiotherapy from the falls prevention service as normal.

#### **Contact Details**

Danielle Graham
Trainee Clinical Psychologist
University of Glasgow
Mental Health and Wellbeing
1055 Great Western Road
Glasgow
G12 0XH
d.graham.4@research.gla.ac.uk

Professor Thomas McMillan University of Glasgow Mental Health and Wellbeing 1055 Great Western Road Glasgow G12 0XH Thomas.mcmillan@glasgow.ac.uk

Yours Sincerely,

Danielle Graham Trainee Clinical Psychologist

## **Appendix 2.7: Intervention Protocol**

#### INTERVENTION PROTOCOL

In addition to the following intervention phases, review sessions must be scheduled after every four intervention sessions. These should be used to review the patient's progress and engagement in therapy. In addition, any blocks or setbacks encountered in therapy should be reviewed and problem solved.

Phase One: Assessment

A clinical interview to be conducted with the patient which covers:

- The onset and course of the current difficulties. Attention to be given to the effects of fear of falling on the individual's functional independence/ lifestyle.
- Any precipitating events or vulnerability factors which may have contributed to the development of the problem.
- Maintenance factors: physiological arousal, negative thoughts, attribution errors, behavioural avoidance.
- Health: including any medical conditions and current medication.
- Social and interpersonal context: Including relationships with family, involvement in the community and living arrangements.
- Outcome measures to be administered.

Phase Two: Formulation

A cognitive behavioural formulation to be developed based on the above information including hypotheses regarding what factors resulted in the development and maintenance of the problem. The formulation should be shared with the patient and the patient should be encouraged to provide feedback on this. The patient should be educated in the CBT model focusing on the links between thoughts, feelings and behaviours. A copy of the formulation to be given to the patient.

Phase Three: Goal Setting

A maximum of three goals to be agreed with the patient. These should be specific and measurable. Using the formulation, the patient should be encouraged to identify the elements, which if improved, would lead to greatest benefit.

Phase Four: Anxiety Management

#### Should include:

- Information on the nature of anxiety including the 'fight or flight' response.
- Monitoring of symptoms by the individual through the use of diaries. Patient to be introduced to the Subjective Units of Distress (SUDS) (0-10) ratings and encouraged to use these to rate anxiety in diaries.
- Controlled breathing exercises. This should progress to progressive muscular relaxation exercise if the patient presents with a particularly high level of physiological arousal.
- These techniques should be supported by the use of homework exercises.

#### Phase Five: Constructing a hierarchy of feared situations

The patient should be supported to identify which situations they avoid because of their anxiety. They should then be supported to evaluate which situations are worse than others using the SUDS ratings. This should also include the identification of the individual's safety behaviours such as using a walking aid which they do not require or relying on the support of a relative, these should be incorporated into the hierarchy. The hierarchy should include a range of situations including those which provoke a relatively low level of anxiety (i.e. SUDS rating 3 or 4) and those that include a higher SUDS rating.

#### Phase Six: Cognitive Restructuring Techniques

Patients should be introduced to cognitive restructuring techniques in order to support them with exposure exercises. These should be selected according to the needs and abilities of the individual. These can include:

- Identifying thoughts using thought diaries.
- Thought challenging techniques including: examining the evidence for and against an unhelpful thought; considering what a friend or relative would say in response to the thought and identifying the presence of thinking errors. These should be used to aid the development of a more realistic, balanced thought.
- 'Coping cards' with more helpful and balanced thoughts which the individual can carry in their purse/wallet and can use throughout exposure exercises.
- Behavioural experiments where the individual can test out their unhelpful predictions in real life situations and use the data to develop more balanced and realistic thoughts.

#### Phase Seven: Graded Exposure Work

The patient should be supported to work through their hierarchy starting with the situation that has the lowest SUDS rating. Prior to each exposure exercise, discussions should cover a detailed description of what the patient needs to do (i.e. how long they should stay in the situation, how they will get there etc.) and problem solving of any possible challenges that the patient may encounter. The patient should also be provided with a record form where they can record their SUDS rating before, during and after each exposure task. The patient must be instructed not to move on to the next exercise until their SUDS rating on the current exercise has halved. Where possible, the patient should be encouraged to complete exposure exercises independently. If this is not possible, a family member or other trusted person can be recruited as a co-therapist. In this instance, the co-therapist must be educated as to the CBT model, the patient's goals and the rationale for the hierarchy. A set of ground rules should be drawn up with the patient and the co-therapist to ensure the co-therapist will be available, when agreed, to complete exposure exercises and also to ensure that the patient is supported to carry out the exercises as independently as possible. The patient should be supported in this phase until they agree that they have met their goals or feel able to continue working through their hierarchy independently.

#### Phase Eight: Discharge

This should be collaboratively agreed with the patient. The patient should be supported in the discharge with a review of their progress and the development of a relapse prevention plan. The relapse prevention plan should include:

- Early warning signs (physiological, behavioural, emotional, cognitive) that would indicate a worsening of the person's difficulties.
- What the patient should do should they notice early warning signs (e.g. use cognitive restructuring techniques or controlled breathing).
- High risk situations that may result in an increase in anxiety (e.g. bad weather).
- What the patient should do to prepare for high risk situations (e.g. use coping cards, behavioural experiments).

Outcome measures to be re-administered at the final session.

# Appendix 2.8: Major Research Project Proposal

# **Major Research Project Proposal**

Evaluation of individual Cognitive Behaviour Therapy for Older People who are Fearful of Falling

**Danielle Graham** – 1004601

Proposal Version 7.

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#### Abstract

#### Background

It has been found that 50% of older adults who fall will develop 'fear of falling'. Fear of falling is conceptualised as low perceived self-efficacy at avoiding falls during non-hazardous daily activities (Tinetti et al. 1990) and restriction of activities that is out of proportion to injuries sustained from a fall (Tinetti & Powell 1993). This is a debilitating condition, which has physical, social and psychological consequences. Group delivered Cognitive Behaviour Therapy (CBT) has been found to be effective in reducing fear of falling however, reported effect sizes are low to moderate. Research has found that individually delivered CBT may be more effective and acceptable than group delivered CBT.

#### Aims

This research aims to conduct a preliminary analysis to evaluate the effectiveness of an individual CBT intervention for fear of falling in older adults. The research aims to investigate whether individual CBT for fear of falling can be effective in reducing fear of falling and improving anxiety and quality of life.

## Methods

Outcome measures will include the BAI, WHOQOL and the FES-I. Results of these measures for the CBT intervention group at pre-treatment, post treatment and follow up will be compared with those of a physiotherapy control group using t tests and ANCOVA.

#### **Applications**

It is hoped that this study and further research emerging in the future will result in improved services for those who are fearful of falling and greater provision of psychological interventions for this client group.

#### Introduction

Approximately 30% of over 65s living in the community will fall each year (Tinetti et al. (1994). Falls can lead to fractures, long hospital admissions, physical discomfort, injury, and social and psychological consequences. It has been found that 50% of those who have fallen in the last year develop 'fear of falling' (Tinetti et al. 1988). Fear of falling has also been found in non-fallers (Friedman et al. 2002) and serious injury is not necessary for the development of fear of falling (Tinetti et al 1988). Fear of falling is conceptualised as low perceived self-efficacy at avoiding falls during non-hazardous daily activities (Tinetti et al. 1990) and restriction of activities that is out of proportion to injuries sustained from a fall (Tinetti & Powell 1993). Furthermore, Van Haastregt et al. (2008) found that individuals who avoid activity because of fear of falling showed elevated levels of anxiety and depression. Fear of falling has also been associated with: reduced independence and ability to perform activities of daily living (Tinetti et al. 1994); reduced involvement in social activities and isolation (Howland et al. 1993); impaired quality of life (Cumming et al. 2000); loss of confidence (Zijlstra et al. 2007); increased institutionalism (Cumming et al. 2000); poorer rehabilitation outcomes (Oude Voshaar et al. 2006); and increased risk of future falls (McKee et al. 2002, Cumming et al. 2000) through deconditioning and muscle weakness (Hindmarsch & Estes 1989) and poor posture (Maki et al. 1991). In summary, fear of falling is a specific concern for older adults, it is prevalent and has a substantial impact on the individual's daily life and thus there is a need for a specific intervention to tackle this problem. In addition, it is essential that interventions for fear of falling address psychological, physical and social factors.

There are currently two randomised controlled trials that have investigated the effects of group delivered psychological interventions aimed at reducing fear of falling in older adults.

Tennstedt et al. (1998) conducted a group cognitive behavioural intervention designed to

reduce fear of falling by increasing self-efficacy and sense of control over falling. The intervention comprised of eight two-hour sessions and included: cognitive restructuring; education regarding falls prevention and the benefits of exercise; management of the physiological symptoms of fear of falling; goal setting; and behavioural experiments. Results demonstrated that participants who attended five or more sessions of the intervention reported a significant increase in falls efficacy and perceived ability to manage falls compared to the control group. There were also slight improvements in mobility and social activity with no increase in falls. These effects were maintained at twelve-month follow up. However, the reported effect sizes for the increase in falls efficacy in the treatment completers were low (0.20 at six week follow up and 0.12 at twelve month follow up). In a further study, Zijlstra et al. (2009) compared cognitive behavioural treatment as a group-based intervention with treatment as usual. The CBT comprised of eight weekly sessions of two hours and included: cognitive restructuring; goal setting; changing the home environment to reduce falls risk; and increasing physical exercise to improve strength and balance. A booster session was included six months after the final session. Results demonstrated that the intervention resulted in improvements in fear of falling, individuals' sense of control over falling and activity levels. In addition, the number of recurrent fallers was significantly lower in the intervention group compared to the control group. Significant effects at follow up were maintained 12 months after the intervention. The reported effect sizes were again low to moderate in the intervention group (see Table 1).

Table 1: Effect Sizes Reported by Zijlstra et al. (2009)

Outcome Measure	Effect Size
Concerns about falling	
2 month follow up	0.27
8 month follow up	0.41
14 month follow up	-
Perceived control over falling	
2 month follow up	-
8 month follow up	0.25
14 month follow up	0.32
Daily activity	
2 month follow up	0.33
8 month follow up	0.33
14 month follow up	-
Loss of functional independence	
2 month follow up	0.41
8 month follow up	0.35
14 month follow up	-
Damage to identity	
2 month follow up	0.32
8 month follow up	0.25
14 month follow up	0.29

There have been no studies to date examining individually delivered CBT for fear of falling despite research evidence suggesting that individually delivered CBT is superior to group delivered CBT in terms of treatment outcomes. Sharp et al. (2004) compared individual and group delivered CBT for panic disorder and agoraphobia in the general adult population and found that the individual CBT treatment group showed the largest proportion of patients achieving clinically significant change at the end of treatment. They also found that the group intervention demonstrated the highest dropout rate (47%) and when given the choice, the majority (95%) of waiting list patients chose to receive the individual treatment at the end of the study indicating that individually delivered treatment may be preferable for patients. Furthermore, it is recognised that older adults under report anxiety disorders and that this may be due to the stigma associated with such disorders (Broomfield & Birch 2009). It has thus been suggested that individually delivered interventions may help alleviate this in some individuals (Barrowclough et al. 2001).

#### **Aims**

This research aims to conduct a preliminary study to evaluate the effectiveness of an individual CBT intervention for fear of falling in older adults. It will investigate whether individual CBT for fear of falling reduces fear of falling and improves anxiety and quality of life. Finally, the study will report data on indicators of the acceptability of CBT for this sample, including dropout rates, the number of sessions of CBT attended and therapist adherence to the treatment protocol.

#### **Hypotheses**

- 3. Those treated with the CBT intervention will show reductions in their scores on the Beck Anxiety Inventory (BAI: Beck et al. 1998) and Falls Efficacy Scale International (FES-I: Yardley et al. 2005) and will show improvements in their scores on the WHO Quality of Life measure (WHOQOL: World Health Organisation 2004))
- 4. Those treated with the CBT intervention will show greater reductions in their scores on the BAI and FES-I and will show greater improvements in their scores on the WHOQOL than a physiotherapy control group.

#### **Plan of Investigation**

#### **Participants**

This study will include thirty participants over the age of 65 who have been referred to the NHS Greater Glasgow and Clyde Community Falls Prevention Programme. This is a city wide physiotherapy led service thus the participants involved in this study are all attending the same service however are seen at different sites.

CBT Intervention Group: The intervention group will comprise fifteen participants attending the Falls Prevention Service at the New Victoria Day Hospital. In the Falls Prevention

Service, clients receive an initial assessment from a physiotherapist following which they are then triaged to the appropriate service which can include the psychology service. Falls patients who are referred to the psychology service are offered individual CBT as standard. Patients reporting anxiety around fear of falling and scoring higher than 30 on the FES-I will be referred to the psychology service. These patients will continue to receive physiotherapy input as standard from the Falls Prevention Service. The physiotherapists see clients on a one to one basis. Sessions typically include strategies to prevent falls, such as mobility exercises and ensuring the home environment is safe, and strategies the individual can use to minimise difficulties if they do fall. Following one to one sessions, the individual may progress on to community based exercise classes. The physiotherapy input is not manualised and the number of sessions of physiotherapy required will depend on individual need.

Physiotherapy Group: This group will comprise fifteen patients attending the Falls Prevention Service at the Southern General Day Hospital who have reported anxiety around fear of falling and scored higher than 30 on the FES-I. At this site, there is no psychology service available and these patients are managed by physiotherapists. This group will receive the standard falls prevention service physiotherapy as detailed above. The amount of physiotherapy received by each participant in both the intervention and the physiotherapy control group will be recorded by the physiotherapists and used in the study's descriptive analysis. It is not anticipated that the amount of physiotherapy received by each group will differ.

#### Inclusion and Exclusion Criteria

Inclusion criteria include individuals over the age of 65 who have experienced a fall in the last year and experience fear of falling as assessed by the FES-I (score of 30 and above). Exclusion criteria include individuals who lack capacity to consent to participation; patients

with significant cognitive impairment (as defined by a Mini Mental State Examination [MMSE] score of less than 24); the presence of a major heath or physical condition that would preclude participation in the intervention and non-English-speaking individuals.

#### Recruitment

Participants will be recruited from the NHS Greater Glasgow and Clyde Falls Prevention Service. The CBT intervention group will consist of participants referred to the psychology service in the New Victoria Day Hospital between September 2012 and February 2013. Currently the psychology service receives approximately five referrals per month for fear of falling. The physiotherapy control group will be recruited from the Falls Prevention Service at the Southern General Hospital. These participants will be referred to the study by physiotherapists working in the service.

#### Measures

Outcome measures are the Falls Efficacy Scale International (FES-I), the Beck Anxiety Inventory (BAI) and the World Health Organisation Quality of Life Measure (WHOQOL). The Mini Mental State Examination (MMSE) will be used as an initial screening measure.

#### Outcome measures

FES-I: The Falls Efficacy Scale-International (FES-I) (Yardley et al. 2005) is a short tool that measures the level of concern about falling during social and physical activities inside and outside the home. It is a self-report measure and an individual's level of concern is measured on a four point Likert scale (1=not at all concerned to 4=very concerned). The FES-I is an expansion of the original Falls Efficacy Scale (Tinetti et al. 1990). The initial validation (Yardley et al. 2005) found the FES-I to have good internal and test-retest reliability and it is said to be 'the best validated and most widely used instrument for this purpose,' (pp. 618).

BAI: The BAI (Beck et al. 1988) is a 21 item self-report questionnaire measuring commonly experienced symptoms of clinical anxiety. Each item is rated on a 4-point scale with higher scores indicating higher levels of anxiety. Suggested diagnostic cut offs are: 0-7 minimal anxiety; 8-15 mild anxiety; 16-25 moderate anxiety; 26-36 severe anxiety. The utility of the BAI in an older adult population has been examined. Kabacoff et al. (1997) found the BAI to have high internal reliability, good factorial validity and good discriminant validity in an older adult psychiatric outpatient population.

WHOQOL: It is recognised that difficulties such as fear of falling affect an individual's psychological, social and physical functioning and that quality of life measures may provide a general overview of an individual's wellbeing (Hwang et al. 2003). The WHOQOL (World Health Organisation 2004) is a widely validated measure and consists of four domains: Physical Capacity; Psychological wellbeing; Social relationships and Environment. It is a self-report measure and each item is rated on a 5-point scale with higher scores indicating a higher quality of life. The reliability and validity of the WHOQOL was tested on a sample of community dwelling older adults by Hwang et al. It was found that all domain scores demonstrated excellent discriminant validity, construct validity, and responsiveness. The measure was also found to have good internal consistency and good intra- and inter- observer test-retest reliability.

#### Screening measure

MMSE: The MMSE (Folstein et al. 1975) consists of eleven questions and is designed to be used as a screening tool to assess cognitive impairment and to assess cognitive change over time. It is a clinician administered test. It includes orientation to place; registration and recall of three words; attention and calculation; language; and visual construction. The MMSE has a maximum score of 30 and generally accepted cut off scores are as follows: 24-30 no

cognitive impairment; 18-23 mild cognitive impairment; 0-17 severe cognitive impairment (Tombaugh & McIntyre 1992). The MMSE has been found to have good test-retest reliability and internal reliability and good criterion validity and construct validity (Tombaugh & McIntyre 1992).

#### **Design**

This study is a between groups intervention trial comparing an individually delivered CBT intervention plus standard physiotherapy with a physiotherapy control group.

# Research procedures

Individuals referred to the study will be allocated to the physiotherapy control group or CBT intervention group based on the site that they attend. Thus those attending the falls prevention service at the Southern General Day Hospital will be allocated to the physiotherapy control group and those attending the falls prevention service at the New Victoria Day Hospital will be allocated to the CBT intervention group. It is therefore impossible for the researcher to be blind to group allocation. Outcome measures will be administered to all participants at baseline, following the final session of intervention and at one-month follow up. Data routinely collected by the Falls Prevention Service will also be gathered regarding independence, mobility, repeated falls, injuries and presentation to services. A Trainee Clinical Psychologist (the primary researcher) and a Consultant Clinical Psychologist will deliver the CBT intervention. A different psychologist to the psychologist that will provide the intervention will assess participants using the above measures at baseline, post-treatment and follow up to minimise researcher bias. To aid intervention fidelity an intervention protocol has been developed (see appendix). Therapists will also keep a written record of techniques covered at the end of each session. Assessment measures for the physiotherapy control group will be administered by the Trainee Clinical Psychologist.

#### Intervention Protocol (please see appendix for detailed description)

Participants in the CBT intervention group are expected to receive 7 - 12 sessions each of CBT (some participants may receive more or less than this depending on individual level of need over a period of six months) plus standard physiotherapy from the Falls Prevention Service. Sessions of CBT will last one hour and will be delivered on a one to one basis. The CBT techniques used will be: relaxation; cognitive restructuring and graded exposure to feared and avoided situations.

#### **Data Analysis**

Descriptive data will be presented for all variables of interest. All analysis will be performed according to intention to treat. Data will be assessed for normal distribution. Assuming the data is normally distributed, an initial within group analysis, relating to the study's first hypothesis, will be conducted comparing the data from outcome measures from baseline to post treatment using t-tests. Post treatment data will also be compared between the two groups with the baseline scores entered as covariates using ANCOVA. Statistical analysis will be carried out using SPSS version 18. Effect sizes will be calculated using Cohen's d where 0.2 is considered small, 0.50 medium and 0.80 large.

#### <u>Justification of Sample Size</u>

This research is a pilot study however, a preliminary power calculation was conducted with the aim of informing future studies of required sample size. It was inappropriate to base the power calculation on the aforementioned randomly controlled trials of group delivered CBT, as the current research was deemed not comparable to these studies as it will be using different measures and is employing a different treatment modality. The BAI was selected as the most appropriate measure on which to base a sample size calculation due to its high internal validity, factorial validity and discriminant validity within the older adult population

(Kabacoff et al. 1997) and its demonstrated power to detect effects in clinical research. The power calculation was based on a within subjects comparison which relates to this study's first hypothesis

Thorpe et al. (2009) conducted a meta-analysis comparing different behavioural treatments for late life anxiety. They calculated that the mean within subjects effect size (Hedges g) of CBT trials for late life anxiety was 0.86 (0.63 -1.08). The majority of these studies utilised the BAI This effect size, a required power of 0.8 and a significance level of 0.05 were entered into G Power version 3.1 to calculate the required sample size for this research. This gave a required sample size of 10 (8-18) for the intervention group. However, as the current research involves a different population (individuals who have fear of falling as opposed to those with general anxiety) it was decided that a larger sample size would be more appropriate. When considering the feasibility of the research in respect of the timescale involved, a sample size of 15 participants per group was considered desirable.

#### **Settings and Equipment**

The CBT intervention will be delivered in a private clinic room in the New Victoria Day Hospital. Equipment will include outcome measures, patient handouts, instructional diagrams, clinical notepaper and pens.

#### **Health and Safety Issues**

**Researcher Safety Issues:** Sessions will be conducted in an NHS base with other NHS staff members in adjacent rooms. Sessions will take place within normal working hours and will comply with standard organisational safety procedures

Participant Safety Issues: Confidentiality will be explained to participants at the outset and participants will be given the opportunity to ask questions. Should a participant present with active suicidal ideation and the psychologist assesses there to be an urgent risk the duty psychiatrist and/ or the participant's general practitioner will be consulted according to level of urgency. If a participant presents with a co-morbidity issue (e.g. depression) that can be seen in the service then this will be an additional target issue for intervention. Should a participant present with a co-morbidity that cannot be treated within the service they will then be referred on to the most appropriate service. If a patient becomes distressed when completing the assessment measures then they will be offered support by the assessor. Should they require further support after the assessment session, they will then be referred on to the most appropriate service.

#### **Ethical Issues**

Ethical approval from WOSRAD and R & D will be sought before data collection begins. It is intended that the IRAS and R &D submissions will be made in July 2012. Participation in the study will be voluntary and participants will be free to withdraw from the study at any time. Written information will be provided to every participant detailing the research and they will have the opportunity to ask questions. Informed consent will be sought from each participant. Should a patient referred to the study decline to participate they will be offered the usual treatment that is available at that site. In the case of patients referred to the psychology service this will be CBT. Data will be handled in accordance with the Data Protection Act and NHS policy.

#### Financial Issues (equipment, stationary costs etc.)

Equipment: Outcome measures (90 of each). The FES-I and WHO-QOL will be photocopied at an NHS base. The BAI will be purchased.

Stationary: Clinical notepaper, therapy materials etc. for the intervention will be provided by the NHS base.

Travel: Travel claims will be made by the researcher for journeys between the NHS base at the New Victoria Day Hospital and the Southern General Day Hospital for the purpose of attending meetings related to the research and collecting data.

# **Timetable**

April 2012: Submit proposal to University

May/June2012: Proposal assessed

July 2012: Apply for ethical approval

September 2012: Begin recruitment

February 2012: End recruitment

March 2013: Data analysis

April-June 2013: Write up research

July 2013: Submit final research paper to University

September 2013: VIVA Examination

#### **Practical Applications**

This study will be the first to examine the efficacy of individually delivered CBT for fear of falling in older adults. It is hoped that this study will inform clinicians working in the area and will inform those at a management level. In particular, it is hoped that this study and further research emerging in the future will result in improved services for those who are fearful of falling and greater provision of psychology services for this client group. It is also recognised that there is a consistently low referral rate for older adults presenting with

disorders such as anxiety and depression in the greater Glasgow and Clyde area (Cross, personal communication; Graham, unpublished audit) and it is hoped that this research will inform referrers as to the availability and efficacy of psychological interventions for the older adult population.

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