STRIDE

Strategies To incRease confidence, InDependence and Energy

Cognitive behavioural therapy-based intervention to reduce fear of falling in older patients attending a community falls service: Therapy development and randomised controlled trial.

Part 2 A pragmatic patient randomised controlled trial

ISRCTN Number: ISRCTN78396615

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Protocol version 5.0

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Sponsored by: Newcastle upon Tyne Hospitals NHS Trust (R&D reference: 5977)

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2. Protocol signature page

2.1 Protocol authorisation signatories

Signature ..... **Date .....**
Dr Steve W Parry, Chief Investigator

Signature ..... **Date .....**
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Dr Peter McMeekin, Economist

Signature ..... **Date .....**
Dr Tracy Finch, Senior Lecturer

Signature ..... **Date .....**
Mr Chris Speed, Senior Trial Manager

2.2 Principal Investigator signature

I confirm that I have read and understood protocol version 5.0 dated 06 March 2014. I agree to comply with the study protocol, the principles of GCP, research governance and appropriate reporting requirements.

Signature …… Date ……

Print Name ……

Site Name/I.D……

3. Contents Page

4. Glossary of Abbreviations

Abbreviation	Definition
AE	Adverse Event
CBT	Cognitive Behavioural Therapy
CBTI	Cognitive Behavioural Therapy Intervention
CCF	Central Commissioning Facility
CE	Cost Effectiveness
CEACs	Cost Effectiveness/ Utility Acceptability Curves
CI	Chief Investigator
CRF	Case Report Form
CU	Cost Utility
DMEC	Data Monitoring & Ethics Committee
EQ-5D (5L)	EuroQoL 5D questionnaire (5 level)
ESDS	Economic and Social Data Service
FES	Falls Efficacy Scale
FES-I	Falls Efficacy Scale – International version
FoF	Fear of Falling
GCP	Good Clinical Practice
HADS	Hospital Anxiety & Depression Scale
HCA	Health Care Assistant
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
ISRCTN	International Standard Randomised Controlled Trial Number
LSNS-6	Lubben Social Network Scale
MMSE	Mini-Mental State Examination

MRC	Medical Research Council
NCTU	Newcastle Clinical Trials Unit
NHS	National Health Service
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
NRES	National Research Ethics Service
PGI	Patient Generated Index
PI	Principal Investigator
QALY	Quality Adjusted Life Year
QoL	Quality of Life
R&D	Research and Development
REC	Research Ethics Committee
RUF	Resource Utilisation Form
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SPPB	Short Physical Performance Battery
SF-36	Short Form 36
TMG	Trial Management Group
TMF	Trial Master File
TMT	Trial Management Team
TSC	Trial Steering Committee
WHOQoL-OLD	World Health Organisation Quality of Life measure for older people

5. Responsibilities

Sponsor: Newcastle upon Tyne Hospitals NHS Foundation Trust will act as the sponsor for this study.

Funder: National Institute for Health Research (NIHR) Health Technology Assessment programme is funding this study.

Trial Management:

A Trial Management Group (TMG) comprising, at a minimum, the Chief Investigator, together with the Trial Management Team (TMT, comprising Senior Trial Manager & Trial Manager), the trial statistician, qualitative researchers, CBT specialists, data manager & project secretary will be responsible for overseeing the progress of the study. The day-to-day management of the research will be co-ordinated by Dr Steve Parry (Chief Investigator).

Principal Investigator: This is a multi-centre study and the Principal Investigator will have overall responsibility for the conduct of the study at site.

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
1. Study preparation	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Secure and administer funding for the Study.	Sponsor	Chief Investigator
	c) Secure and contract for the supply of resources including medicinal products/devices/CRO services.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
2. Applications and Registration	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	
	b) Prepare Participant information sheet and consent form and other relevant documents to the Sponsor prior to ethics submission.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Prepare and submit ethics application.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Register the Study with an appropriate protocol registration scheme.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Obtain NHS permission.	Sponsor	Principal Investigator /

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
3. Protocol Amendments	a) Prepare and submit proposed substantial amendments of the Protocol to the, relevant ethics committee and NHS Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
4. Study Conduct	a) Ensure that legislation in relation to research is followed within the Site	Sponsor	Principal Investigator
	b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required.	Sponsor	Principal Investigator
	c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that no Participant is recruited to the Study until satisfied that all relevant permissions and approvals have been obtained.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and Clause 2 of this Agreement	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor	Chief Investigator / Newcastle Clinical Trials
	g) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.	Sponsor	Chief Investigator
	h) Maintain and archive Study documentation at the Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.	Sponsor	Principal Investigator

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
	j) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework.	Chief Investigator	Principal Investigator
	k) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	l) Report suspected research misconduct.	Sponsor	Principal Investigator
	m) Notify the relevant ethics committee of the end of the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	n) Notify the relevant ethics committee if the Study is terminated early.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
5. Adverse events	a) Maintain detailed records of all adverse events as specified in the Protocol.	Sponsor	Chief Investigator / Principal Investigator
	b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with Trust policy.	Sponsor	Chief Investigator / Principal Investigator / Newcastle Clinical Trials Unit
	c) Promptly inform ethics committees and investigators of any urgent safety measures taken to protect Participants in the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that annual safety reports and end of Study reports are generated and submitted to the relevant ethics committee within the required timeframes.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
6. Data Management	a) Design of case report forms and database.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure appropriate analysis of data.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit/Trial statistician
7. Publication	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
8. Archiving	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for a minimum of five (5) years	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
9. Clinical Trials	a) Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP).	Sponsor	Chief Investigator / Principal Investigator /Newcastle Clinical Trials Unit
	b) Ensure that all Serious Adverse Events (SAE), other than those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards the requirement for expedited reporting to the relevant ethics committee.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

6. Protocol Summary

Short title:	STRIDE – Strategies To incRease confidence, InDependence and Energy
Protocol version:	Version 5.0
Protocol date:	19 February 2014
Chief Investigator:	Dr Steve W Parry
Sponsor:	Newcastle upon Tyne Hospitals NHS Foundation Trust
Funder:	NIHR Health Technology Assessment (ref 09/07/04)
Study design:	Parallel-group patient randomised controlled trial of a novel cognitive behavioural therapy-based intervention (CBTI) plus usual multidisciplinary care versus usual multidisciplinary care alone in patients with significant fear of falling attending a community falls service.
Primary objective:	To determine the effectiveness of a new cognitive behavioural therapy-based intervention plus usual care versus usual care alone (the control condition) in reducing fear of falling.
Secondary objectives:	• To measure the impact of the intervention versus control on fall and injury rates in the trial participants and its impact on functional abilities. • To measure the effectiveness of the intervention versus control on anxiety, quality of life, social isolation and social participation. • To measure the costs and outcomes of the intervention in this setting. • Investigate the acceptability of the intervention for patients, family members and professionals • To further investigate the professional and organizational factors that promote or inhibit the implementation and integration of the intervention.
Number of study sites:	5 (Two NHS Trusts)
Study population/size:	412 older adults (aged 60 years and over) with significant fear of falling (FES-I score > 23), attending a multidisciplinary community falls service.
Study duration:	32 months

7. Background

Falls are common, frequently devastating events in older people, with between 30% and 62% of older individuals falling per year.[1,2] Falls are responsible for considerable morbidity and mortality, with around 10% of falls resulting in fractures.[1] The health economic costs of falls are considerable; the cost of falls to the UK economy is estimated at £981 million,[3] with more recent data showing that 0.07-0.20 of the gross domestic product and 0.85-1.5% of total healthcare expenditure in western economies was accounted for by falls and their consequences.[4] Adverse consequences of falls are by no means limited to physical injury and escalating levels of dependence. Many older individuals, both fallers and non-fallers, suffer from a variety of adverse psychosocial difficulties related to falling[5-15] including fear, anxiety, loss of confidence, and impaired self-efficacy (the self-perception of ability to perform within a particular domain of activities)[9,12] resulting in activity avoidance, social isolation and increasing frailty.[5-15] The umbrella term for these problems is "fear of falling", a common and disabling problem in older individuals, found in between 3% and 85% of community dwelling elders who fall, and up to 50% of those who have never fallen.[7-9,15]

The optimal management strategy for fear of falling and its adverse physical and psychosocial sequelae is poorly understood. Much previous research has focussed on physical treatments including home and community based exercise interventions, Tai Chi and multifactorial interventions aimed at reducing fall rates, with fear of falling reported as a secondary outcome in the majority of these studies.[7] A recent systematic review found 12 high quality randomised controlled trials reporting effects on fear of falling in such studies, but only one primarily aimed at reducing fear of falling.[16] The interventions were conducted across a variety of settings, but home-based exercise, community Tai Chi and home-based multifactorial interventions all improved fear of falling,[7] though a recent geriatric outpatient based multifactorial intervention study found no such benefit.[17]

While such physical interventions may be of benefit in selected populations, the profile of the disorder and its psychosocial complications suggest that well designed psychological interventions may help ameliorate fear of falling more definitively. Several studies have examined an explicitly cognitive behavioural therapeutic approach in fear of falling in community-dwelling elders, or used cognitive behavioural therapy techniques as part of a wider intervention strategy. Tennstedt et al's Matter of Balance study assessed the ability of an 8-session, 4 week group cognitive behavioural approach with exercise instruction to improve fear of falling and related activity restriction.[18] A total of 434 patients were randomised to intervention and control groups, with significant differences seen in fear of falling as measured by the Falls Efficacy Scale (FES)[12] and activity during follow-up. The magnitude of improvement in FES scores attenuated over time, prompting the authors to suggest a booster session should be used in future studies and in clinical practice.[18] Clemson et al similarly used what they described as a "small-group learning environment" (though in practice, some of the methods used included cognitive behavioural techniques) of 12 individuals per group for 2 hours per session over 7 weeks to improve self-efficacy and reduce falls.[19] The intervention incorporated a variety of learning strategies to facilitate behaviour change, including education regarding exercises to decrease the risk of falls , medication and home environmental review and medication management.[19] There was a 31% reduction in falls (relative risk 0.69, 95% CI 0.50-0.96, p= 0.025) in the intervention group, though interestingly there was no corresponding change in FES scores.[19] More recently, Zijlstra and colleagues conducted a randomised controlled trial of a multicomponent cognitive behavioural group intervention in older community-dwelling elders.[20] Five hundred and forty participants were drawn from a random sample of 7431 individuals sent questionnaires who reported "at least some fear of falling", though the method of assessment was not specified. Following randomisation, the intervention group underwent a structured 2 hour group cognitive behavioural therapy intervention based on the investigators' previous work once weekly for 8 weeks, with booster sessions 6 months following the last session.

The beginning of the trial predates widespread use of the FES-International version [FES-I][21] (later advocated by the same group as the most appropriate measure for such studies[7]), instead using a single item question on fear of falling as well as an unspecified scale, likely to be the original FES from the description and reference supplied.[20] Other outcomes included perceived control over falling and daily activity as well as falls. There were no measures of physical function despite the prior evidence base suggesting improvement in fear of falling with the exercise-related measures as described above. All outcomes showed significant differences between control and intervention groups at 2 and 8 months follow-up, with between group differences persisting at 14 months in fear of falling and perceived control over falling but not in the other outcome measures. There was a 30% attrition rate in the intervention group and 19.6% attrition rate in the control group.[20] The study intervention was carefully developed and grounded in cognitive behavioural theory, but is hampered considerably by the lack of clarity on sample size calculation and outcome measures and the absence of generic quality of life measures and measures of physical functioning. Importantly there is also no health economic analysis[20] to guide commissioners and providers of health care, crucial in this context because of the size of the clinical problem.

Fear of falling is thus a common, disabling and debilitating condition in older adults but the current understanding of its management is limited. There is a small evidence base to support the use of some physical therapies to improve the syndrome, and promising early data from a few studies supporting the use of psychological therapies, in particular cognitive behavioural therapy. The cognitive behavioural quintet [22] of a situation or practical problem (falls, declining mobility, and social isolation), altered thinking and emotion, altered physical symptoms with behavioural change and activity reduction and avoidance is paradigmatic for fear of falling, and offers the hope of a viable therapeutic option. Previous studies are hampered by the factors already described, while the issue of the economic viability of such a treatment has yet to be explored. There is a need for many more trained cognitive behavioural therapists than are currently available; the development of a cognitive therapeutic package for the management of fear of falling that can be delivered routinely by non-specialist staff such as healthcare assistants is vital if this common and debilitating condition is to be tackled effectively. Cognitive behavioural therapy can be delivered by suitably trained non-psychotherapist staff,[23,24] but to our knowledge, this approach has not been attempted with health care assistants in this context previously. In addition, only group interventions have been studied so far, with therapy delivered on a one-to-one basis yet to be tested in a fear of falling cognitive behavioural intervention study.

Understanding the dynamics of developing, delivering and trialling a novel intervention as a *process* is useful because it will contribute to understanding the professional and organisational factors that promote or inhibit adherence to treatment protocols and intervention delivery; and how practical and methodological problems are defined, understood and resolved by the project team in the course of the study. The need for understanding the dynamics of complex interventions,[25] and undertaking process evaluation is now well understood.[26] Such work is important to underpin the transportability, workability, and integration of interventions into routine clinical practice. In the case of this study, our aim is to collect longitudinal ethnographic data that will help us to understand the social *processes* and *relationships* that lead the intervention and future trial to take a particular shape and direction. In earlier studies of trials and other interventions, May and Finch developed a robust explanatory model of normalization processes [27] that defines psychological and sociological mechanisms of behaviour and action that have been empirically demonstrated to be important in the implementation of complex interventions, and that have been revealed by evaluation in randomized controlled clinical trials. This approach is vital for the understanding and more widespread adoption of such an intervention.

We plan to conduct a randomised controlled study of this intervention and training plus usual multidisciplinary care versus usual multidisciplinary care alone.

8. Objectives

To conduct a pragmatic patient randomised controlled study of the new cognitive behavioural therapy-based intervention plus usual care versus usual care alone (the control condition) in community-dwelling older people attending a community falls service with excessive or undue fear of falling, to determine:

- The effectiveness of such an intervention in reducing fear of falling.
- The impact of the intervention versus control on fall and injury rates in the trial participants and its impact on functional abilities.
- The effectiveness of the intervention versus control on anxiety, quality of life, social isolation and social participation.
- The costs and outcomes of the intervention in this setting.
- The acceptability of the intervention for patients, family members and professionals.
- The professional and organizational factors that promote or inhibit the implementation and integration of the intervention.

9. Study Design

This is a multi-centre, parallel-group patient randomised controlled trial of the novel cognitive behavioural therapy-based intervention (CBTI) plus usual multidisciplinary care versus usual multidisciplinary care alone in patients with significant fear of falling attending a multi-disciplinary community falls service.

The study will recruit 412 older adults (aged 60 years and over) with significant fear of falling who will participate for 12 months.

9.1 Primary outcome measure

The primary outcome is change in Fear of Falling (FoF) as measured by the Falls Efficacy Scale International version (FES-I) at 12 months. This measures confidence in performing a range of activities of daily living, without falling.

9.2 Secondary outcome measures

- Falls: number of patients falling; number of falls, time to first fall; and fractures and significant soft tissue injuries.
- Hospital Anxiety & Depression Score (HADS). A 14 item questionnaire designed to detect the presence and severity of anxiety and depression.
- World Health Organisation's broad measure of quality of life, with specific questions for older people (EUROHIS-QOL-8 & WHOQOL-OLD).
- A patient generated index (PGI) of aspects of life affected by a fear of falling.
- EuroQol-5 Dimensions Scale (EQ-5D). A generic quality of life measure, which also enable cost utility analysis.
- Short Form 36 (SF-36). A 36 item questionnaire which measures functional health and wellbeing.
- The De Jong-Gierveld Loneliness Scale (11 item). An 11 item scale to measure loneliness, including emotional and social loneliness.
- The Lubben Social Network Scale – 6 (LSNS-6). A six-item scale to assess social isolation in older adults.
- Social Participation Questionnaire. A questionnaire to record the total number of times in which the subject participated in 10 activity categories during the previous two weeks.
- Numeric rating scale for fear of falling when walking. A 0 – 10 scale to measure the participants fear when walking.
- Short Physical Performance Battery (SPPB). An objective assessment tool for evaluating lower limb functioning in older persons.
- Functional reach. An indicator of confidence in balance and increased risk of having a fall.
- Isometric handgrip strength. A measurement of muscle strength.
- The cost effectiveness and cost per quality adjusted life year of the intervention.

Process Evaluation Ethnographic sub study:
Additionally we will undertake a qualitative evaluation involving key service/training personnel and a purposive sample of patients and family members.

9.3 Definition of end of study

The end of study will be the last participant's final study contact, at 12 months follow up.

9.4 Health Economic Evaluation

The purpose of the health economics sub study is to estimate both the cost effectiveness (CE) and cost utility (CU) [28] of the intervention arm of the trial in comparison with the usual treatment.

The perspective of the study will be that of the NHS, however data will also be gathered about the resource implications to the patients and their families using a questionnaire at six and twelve months collecting information about resource utilisation over the previous six months. Appropriate unit costs will be attached to the NHS resources used by each trial participant. Similarly, the costs of the intervention (from which any cost savings are deducted) will be estimated by calculating the average cost to the NHS of providing the intervention to one patient.

Marginal CE, cost per unit reduction in FES-I, will be estimated by comparing the change in FoF as measured by the FES-I at 12 months in the intervention arm with that of the control arm and by measuring the cost of the intervention and any changes in resource utilisation between the two arms.

Marginal CU, cost per quality adjusted life year (QALY), will be estimated in by comparing changes in health related quality of life at six and twelve months in each arm of the study. HRQoL will be measured using EQ-5D [29] and SF-36 [30]. The instruments differ in their responsiveness to changes in HRQoL and the number of dimensions of HRQoL they encompass. Previous research[31] has shown a significant correlation between EQ-5D scores and a fear of falling, however little information exists about its responsiveness to changes in a fear of falling. SF-36 has the ability to provide more detailed information about changes in HRQoL.

Uncertainty around estimates of CE and CU will be explored using cost effectiveness/utility acceptability curves (CEACs) which express uncertainly of outcome as a function of willingness to pay for a unit of outcome.

Previous studies have demonstrated the link between a fear of falling and a reduction in HRQoL[32]. However no information exists about if and how utility values could be associated with the FES-I (or FES) allowing direct estimation HRQoL. The final component of the Health Economics component will examine the suitability of the FES-I for this purpose. Some of this analysis will be informed by data gathered outside of the study, however participants will be asked to generate an index (PGI)[33] of the most important effects a fear of falling has on their life at the outset of the study and at six and twelve months. This index will facilitate the interpretation of utility values gathered with EQ-5D and SF-36.

9.5 Process Evaluation Ethnographic Sub study

The aim of the process evaluation ethnographic sub study is to identify, describe and explain the professional and organisational factors that promote or inhibit the implementation and integration of the CBTI. The sub study was initiated in part 1 (REC reference 11/NE/0090).

Data collection will involve a variety of ethnographic methods, including semi-structured interviews, observations, audio/video recordings of intervention delivery and supervision and documentary analysis.

Participants in the process evaluation will include:

- members of the trial team (n = 10-15, each interviewed 2-3 times during the study),
- professionals involved in the delivery of the intervention (n = 15, interviewed at multiple points during the study)
- patients participating in the trial (n=20, each interviewed up to 3 times during the study) and family members (n = 5–10 each interviewed up to 3 times during the study).

Members of the trial team

Throughout the study we will track the activities of key study personnel and their interactions with each other as the trial develops. We will examine the implementation of the intervention by a rolling programme of interviews with members of the trial team (maximum n= 10-15), along with observations of team and other relevant meetings (n=9 approx.), that focus on the development, delivery and take-up of the intervention.

Professionals

We will interview all professionals involved in delivering the intervention and those who work in the falls clinics and are involved in identifying and recruiting patients to the study (n=15 approx.)
Professionals involved in delivering the intervention will be interviewed at multiple time points across the duration of the study to explore how the evaluation and interpretations of the intervention change over time. To avoid over-burdening individual respondents some interviews may be conducted by telephone if appropriate. We will also observe the initial and any follow up training sessions provided to professionals providing the cognitive behavioural therapy sessions. To capture additional training and development needs and to gain insight into the fidelity of the intervention we will audio and/or video record routine supervision sessions and the CBT sessions with patients (with their consent). These data would typically be collected in routine practice.

Professionals working in the falls clinics will be interviewed two or three times during the trial. The initial interview will focus on views of the intervention we have developed, a second interview will explore experiences of identifying and recruiting patients to take part in the study and examine whether their views of the intervention have changed over time. Professionals may also be invited to take part in a final interview or discussion with the researcher to review their experiences of the study and provide respondent validation of the emerging analyses. In addition up to ten routine clinics will be observed to gain a better understanding of the ways in which recruitment to the intervention is embedded into routine practice.

Patients and family members

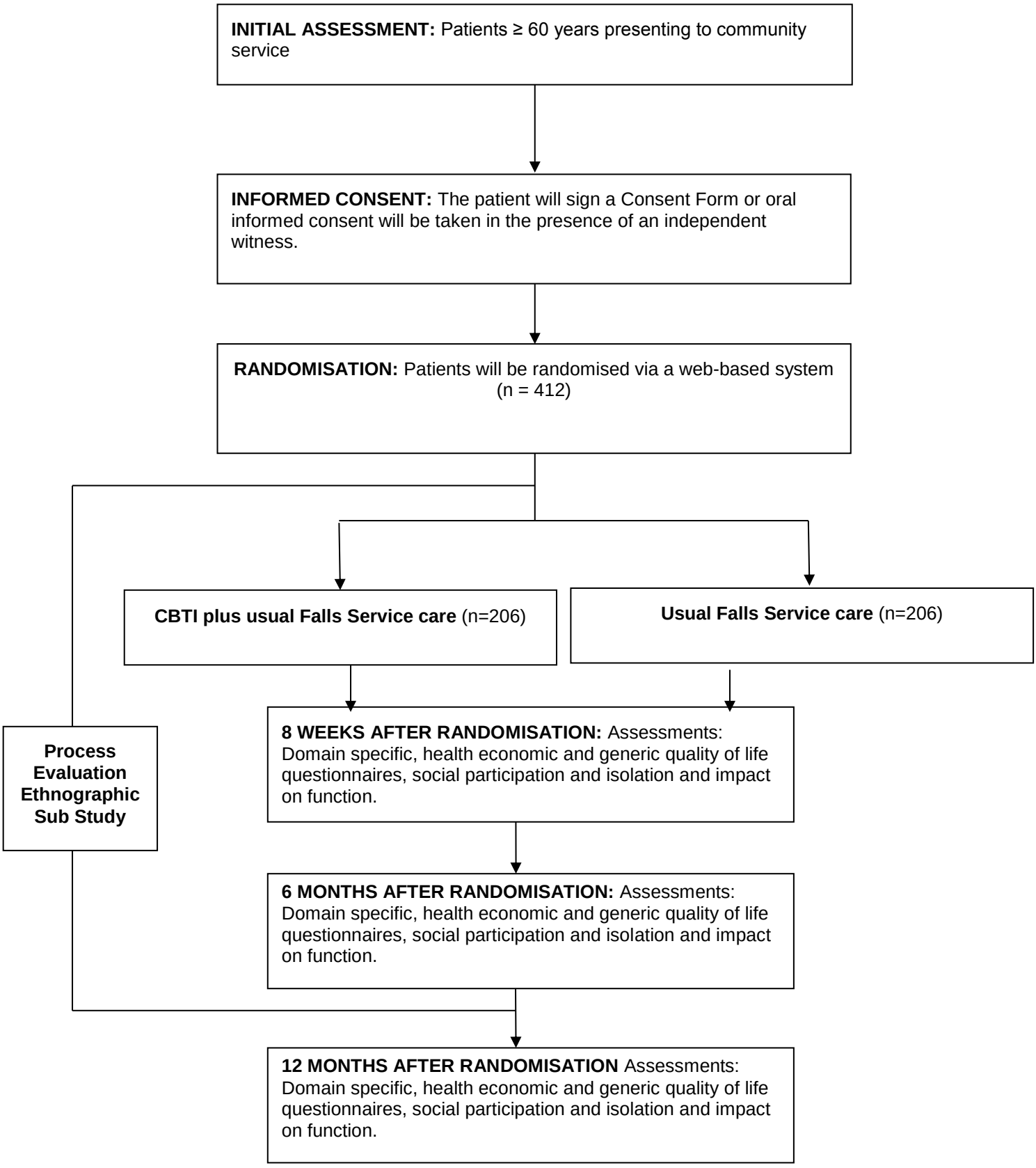
We will interview a purposive sample of patients (n=24) focusing on their experiences of the intervention and factors affecting normalisation from their perspective. We will also approach a small sample of family members of participating patients (n = 6 -12) to explore their views of the intervention. Each participant will be interviewed up to three times at key points in the trial. The timing of interviews will vary for individual participants, but typically will include three of the following key points: part way through the cognitive behavioural therapy sessions; on completion of the initial eight cognitive behavioural therapy sessions; in the period between the end of the sessions and the provision of the 'booster' session at six

months; shortly after the 'booster' session; and during the last three months of the trial. We have elected to limit participation to a maximum of three interviews in order to avoid excessive respondent burden. We anticipate that initial interviews will take around 45 minutes but that the later follow-up interviews may only take around 30 minutes. To reduce the burden of research, interviews with participating patients and family members will not exceed 45 minutes duration without their express permission.

In all cases, interviews and observations will be undertaken only when informed consent has been obtained from participating members of the trial team, health professionals and patients and family members. All interviews will take place at a time and location of the interviewee's choosing. Meetings and interviews will be audio recorded using digital voice recorders. These audio recordings will be transcribed, checked, and edited to ensure participants' anonymity (with particular attention to removing identifying data from professionals' transcripts). Transcripts will be stored in password protected computer systems, and non-anonymised voice recordings or transcripts will be handled only by members of the research team and transcribers who have signed appropriate confidentiality agreements. A purposive sample of recordings of cognitive behavioural therapy and supervision sessions will be listened to and summarised in field notes. Selected sections may be transcribed in full for more detailed analysis and to illustrate key points. Data from observation of routine clinics will be recorded in anonymised field notes for inclusion in the analysis.

We will use Normalization Process Theory as a conceptual framework from which to develop a structured qualitative analysis of the transcript data-set using the Framework method pioneered by Ritchie and Spencer.[34] This analysis will lead to a robust conceptual model of the factors that have affected the course of the intervention. This model will be of value to other clinicians and researchers wishing to deploy the intervention.

Figure 1 – Trial Flow Chart



10. Participants

Participants will be patients aged 60 years and over, of both sexes attending community falls services with excessive or undue fear of falling as assessed by an FES-I score of > 23.

10.1 Inclusion criteria

- Patient has provided written informed consent for participation in the study prior to any study specific procedures
- FES-I score of > 23
- Age ≥ 60 years

10.2 Exclusion criteria

- Patients with cognitive impairment (mini-mental state examination MMSE < 24)
- Life expectancy < 1 year or unlikely for any other reason to be unable to complete one year follow-up duration
- Patients requiring psychosocial interventions unrelated to fear of falling
- Current involvement in other investigational studies or trials, or involvement within 30 days prior to study entry
- Patients who have taken part in part 1 of the study

10.3 Process Evaluation Ethnographic Sub study Participation

All members of the trial team will be eligible for participation but a purposive sample of individuals will be selected for interview on the basis of their role within the study and expertise.

The professional sample for the ethnographic sub study will comprise members of staff within the falls service and those involved in the delivery of the psychological intervention. In view of the small numbers of professionals involved, all will be invited to undertake interviews for the ethnographic sub study.

For the ethnographic sub study, patients (n=24 approx.) will be purposively sampled (to ensure balance of different gender and degree of fear of falling) and invited to participate in the ethnographic sub study following recruitment procedures as outlined below (Section 11.4). Patients themselves are the focus of this part of the sub study, however, we recognise that informal carers are likely to offer important insights concerning the questions of interest and thus a supplementary sample of family members (n= 6 -12 approx.) associated with patients included in the study, will be approached after patient interviews have been conducted, where the patient's agreement has been obtained. For the ethnographic sub study, patients meeting the above criteria will be eligible for selection into the sub study. For this part of the study, neither participants who are hearing impaired but sign, nor non-English speaking participants will be excluded, providing appropriate interpreters can be arranged to assist the conduct of the semi-structured interviews.

11. Screening, Recruitment and Consent

11.1 Identification and screening of participants

- Potential participants will be identified retrospectively and prospectively through a community falls service with a fear of falling as identified by an FES-I score of greater than 23 by the staff at the falls service. Where the FES-I is not carried out routinely consent will be taken prior to administering this measure.
- At the majority of sites all screening assessments are part of routine clinical practice.
- Part 1 participants who have expressed an interest in the CBTI intervention will be offered the opportunity to receive the CBTI intervention.

11.2 Recruitment procedures

CBTI intervention for Part 1 participants

Part 1 participants will be offered the opportunity to receive the intervention (but not the baseline and follow up assessments). Part 1 participants who have expressed an interest in the intervention will be sent an invitation letter by the researcher who conducted the initial interview in part 1 of the study, participant information sheet and asked to return an expression of interest form if they are interested. Patients who return an expression of interest form will be contacted by telephone by the researcher who conducted the initial interview (either VD or CB) to discuss participation further, answer any questions and arrange a time to meet to take formal written informed consent. The patient details will then be passed on to the health care assistant who will arrange a time to meet with the patient and start the CBTI.

To maximise the potential to learn from their experiences, patients will be invited to participate in up to three interviews about their experiences of the CBTI. We will also invite a small number of family members to take part in an interview to share their views about the CBTI. We will ask patients to pass on a participant information sheet, expression of interest form and pre-paid envelope to an appropriate family member. Family members who return an expression of interest form will be contacted by telephone by Claire Bamford (who will also conduct the interview) to discuss participation further, answer any questions and arrange a time to meet to take formal written informed consent and conduct the interview.

Prospective Recruitment of participants to the RCT

North Tyneside Falls Prevention Service

With the routine appointment letter inviting patients to attend the Falls Service an invitation letter and summary participant information leaflet with details of the STRIDE study will be enclosed.
The research team member (STRIDE Therapist or CLRN Research Nurse) will be present in the waiting area at the Falls Service to discuss the STRIDE study with patients waiting for their appointment and those who have attended their appointment.
It will be explained to the patient that they may not be eligible for the study and eligibility will be confirmed by the clinic staff following the patient's appointment. If the patient expresses an interest in participating in the study a detailed participant information sheet will be provided and the patient can take this home to read over.
If the patient is interested in taking part he/she completes the expression of interest form; this form will be forwarded directly to the research team at Newcastle University. Patients will be

advised that one of the Research Assistants/ Associates/ Interviewers will contact them within approximately one week to discuss participation and arrange a convenient time to meet to take consent and complete the baseline assessments.

If the patient is unsure about completing the expression of interest form at this stage then they will be offered an expression of interest form and pre-paid envelope to take away and complete at a later date if they wish to participate, after discussing with friends and family.

If the patient does not return the expression of interest form to the STRIDE office within one week of their clinic appointment a member of the clinical team will contact the patient by telephone to ensure they have no further questions and to ask if they would like to participate. If the patient expresses an interest in taking part, the member of clinic staff will complete consent to release contact details form which will be passed onto the research team. One of the Research Assistants will then contact the patient by telephone to discuss the study further and answer any questions. Arrangements will then be made to meet those patients who are willing to proceed in a place of their choice to take formal consent and administer the baseline measures.

Galleries Day Unit, Washington – City Hospitals Sunderland NHS Foundation Trust

An invitation letter and summary participant information leaflet with details of the STRIDE study will be enclosed with the routine appointment letter inviting patients to attend the Falls Service.
A research team member will be present in the waiting area to discuss the STRIDE study with patients waiting for their appointment and those who have attended their appointment. It will be explained to the patient that they may not be eligible for the study and eligibility will be confirmed by the clinic staff following the patient's appointment. If the patient expresses an interest in participating in the study a detailed participant information sheet will be provided and the patient can take this home to read over.
If the patient is interested in taking part he/she completes the expression of interest form; this form will be forwarded directly to the research team at Newcastle University. Patients will be advised that one of the Research Assistants/ Associates/Interviewers will contact them within approximately one week to discuss participation and arrange a convenient time to meet to take consent and complete the baseline assessments.

If the patient is unsure about completing the expression of interest form at this stage then they will be offered an expression of interest form and pre-paid envelope to take away and complete at a later date if they wish to participate, after discussing with friends and family.

If the patient does not return the expression of interest form to the STRIDE office within two weeks of their clinic appointment a member of the clinical team will contact the patient by telephone to ensure they have no further questions and to ask if they would like to participate. If the patient expresses an interest in taking part, the member of clinic staff will complete consent to release contact details form which will be passed onto the research team. One of the Research Assistants/ Associates/Interviewers will then contact the patient by telephone to discuss the study further and answer any questions. Arrangements will then be made to meet those patients who are willing to proceed in a place of their choice to take formal consent and administer the baseline measures.

Falls and Syncope Service & Newcastle Day Hospitals (Melville & Belsay) Newcastle upon Tyne Hospitals NHS Foundation Trust

Potentially eligible patients will be invited to participate by staff members (nursing and/or medical) and the study explained to them.

If the patient expresses an interest in participating in the study a detailed participant information sheet will be provided and the patient can take this home to read over.
If the patient is interested in taking part he/she completes the expression of interest form; this form will be forwarded directly to the research team at Newcastle University. Patients will be advised that one of the Research Assistants/ Associates/Interviewers will contact them within approximately one week to discuss participation and arrange a convenient time to meet to check eligibility (including completion of the FES-I (following consent)), take consent and complete the baseline assessments.

If the patient is unsure about completing the expression of interest form at this stage then they will be offered an expression of interest form and pre-paid envelope to take away and complete at a later date if they wish to participate, after discussing with friends and family.

If the patient does not return the expression of interest form to the STRIDE office within two weeks of their clinic appointment a member of the clinical team will contact the patient by telephone to ensure they have no further questions and to ask if they would like to participate. If the patient expresses an interest in taking part, the member of clinic staff will complete consent to release contact details form which will be passed onto the research team. One of the Research Assistants/ Associates/Interviewers will then contact the patient by telephone to discuss the study further and answer any questions. Arrangements will then be made to meet those patients who are willing to proceed in a place of their choice to check eligibility, take formal consent and administer the baseline measures.

Retrospective Recruitment of participants to the RCT

Eligible patients who have attended the Galleries Day Unit clinic in the last three months will be identified by a member of clinic staff. Patients are asked at the clinic to give consent for their details to be used for research, and only those who have given this permission will be included. Identified patients will be sent an invitation letter, detailed participant information sheet, expression of interest form and a prepaid envelope. A member of clinic staff will telephone those patients who have not returned the expression of interest form after one week to check that they have received the letter and explore their views on participation. If the patient expresses an interest in taking part, the member of clinic staff will complete consent to release contact details form which will be passed onto the research team. One of the Research Assistants/ Associates/Interviewers will then contact the patient by telephone to discuss the study further and answer any questions. Arrangements will then be made to meet those patients who are willing to proceed in a place of their choice to take formal consent and administer the baseline measures.

A screening log will be kept at each site to document details of subjects invited to participate in the study. For subjects who decline participation, this will document any reasons available for non-participation. The log will also ensure potential participants are only approached once.

11.3 Consent procedures

Informed consent discussions will be undertaken by Researchers and Research Assistants/ Interviewers (as per delegation log) involved in the study, with opportunity for participants to ask any questions. Following receipt of information about the study, participants will be given reasonable time (minimum of 24 hours) to decide whether or not they would like to participate. Those wishing to take part will provide written informed consent by signing and

dating the study consent form, which will be witnessed and dated by a member of the research team with documented, delegated responsibility to do so. Written informed consent should always be obtained prior to randomisation and prior to study specific procedures/investigations.

The original signed consent form will be retained in the Investigator Site File, with a copy in the clinical notes and a copy provided to the participant. The participant will specifically consent to their GP being informed of their participation in the study.

The right to refuse to participate without giving reasons must be respected.

Interpreters will be arranged for all visits of patients who require them either for verbal translation or for deaf subjects wishing to take part in the study, via local NHS arrangements. Qualified interpreters will be used to explain the consent form and information sheet, and great priority will be placed on finding the most direct communication.

11.4 Process Evaluation Ethnographic Sub study recruitment

All members of the trial team are aware that the study involves a process evaluation. All members will be given the relevant Participant Information Sheet at the outset of the trial and asked to provide consent for recording meetings. Formal consent will be sought separately for participation in interviews.
Professionals involved in delivering the intervention will be given the relevant Participant Information Sheet and will provide written informed consent by signing and dating the study consent form, which will be witnessed and dated by a member of the research team responsible for the process evaluation. Members of staff within the falls service will be given a Participant Information Sheet and asked to provide written informed consent prior to interview. All potential participants will be given time to read and consider the study information, before a second contact is made by the sub study research team to ascertain willingness to participate in the interviews as professionals.

During the consent process for the trial, patients will be made aware that they may be invited to participate in an interview to explore their views and experience of the cognitive behavioural therapy intervention when they are recruited to the study. The trial participation consent form will include a box for the patient to initial if they are willing to be contacted about participating in the qualitative sub study. From those who give consent to be contacted for the sub study, we will purposively sample patients based on their baseline assessments and level of engagement in the CBTI (as evaluated by the health care assistants delivering the intervention). Patients who consented to be contacted for interview will be approached initially by telephone by the member of the research team who conducted their baseline assessment. This will ensure that the first contact is with a known individual. The member of the research team will confirm whether the patient is still willing to be invited to take part in an interview and, if so, they will pass the patient's contact details onto the researchers responsible for the ethnographic sub study. These researchers will then send potential participants a further Participant Information Sheet with more details about the interview. They will then telephone the patient within a week of receipt of the letter to discuss participation further, answer any questions, and, where appropriate, arrange an interview. Participating patients will be asked to pass study information on to their carer/supporting family member. This will include the relevant Participant Information Sheet and an expression of interest form to return to the research team if they are willing to be considered for participation in the study. Those who return the expression of interest form will be consented using the same process as indicated for patient participants in the ethnographic sub study. We anticipate that some family members may be present during the interview with patients; if so, we will liaise directly with them and invite them to consider participating in an interview. The relevant Participant Information Sheet will be left with the carer/ supporting

family member and a follow up telephone call will be made within one week to check whether the carer/ supporting family member is willing to participate.

A simplified procedure will be used for follow-up interviews with all participants. On completion of each interview the participant will be asked whether they would be willing to participate in a follow-up interview. Only those agreeing at this point will subsequently be approached regarding a further interview. Participants approached for a follow-up interview will be reminded about the purpose of the interview and given a copy of the information sheet. Formal written consent will not be sought for follow-up interviews; instead, participants will be asked to confirm their willingness to participate verbally once the electronic recording has started.

12. Study Intervention

We will conduct a multicentre, parallel group patient randomised controlled trial comparing two treatments for fear of falling. Patients will be randomised in a 1:1 ratio, with stratification by, centre, gender, severity of numeric rating scale for pain when walking and referral to strength and balance training classes to one of the following two groups:

Group 1 (control group) will receive usual care. This consists of detailed falls-oriented physiotherapy assessment, beat-to-beat lying and standing blood pressure measurement, electrocardiography, Mini Mental State Examination (MMSE)[35], bone health assessment using the $FRAX_{TM}$ tool[36] 15-item Geriatric Depression Scale[37], FES-I [20] and visual acuity assessment. [1] A comprehensive medical review by a consultant geriatrician with falls expertise, utilising the information gained from the other parts of the evaluation, rounds off the assessment. Patients are then referred back to their general practitioner for medication or other review, to secondary care, day hospital, community physiotherapy and occupational therapy as appropriate, for bone densitometry and/or to targeted strength and balance training classes run in conjunction with the voluntary sector (Age UK) in North Tyneside, via Healthworks in the Newcastle services or through on-going training at the Galleries Service.

Group 2 (intervention group) will receive usual care as detailed for Group 1 plus cognitive behavioural therapy intervention (CBTI) delivered by trained Health Care Assistants (HCAs) at participant's homes, the Falls Service or community centres or facilities (e.g. Age UK offices in North Shields), Newcastle University or the Royal Victoria Infirmary, Newcastle as per patient choice.
HCAs will be trained in basic CBT assessment, formulation and treatment skills. Assessment and formulation skills will allow them to identify, with the patient, the unique set of beliefs, behaviours, emotions and physical factors that are maintaining the fear of falling. Treatment sessions will focus on targeting these beliefs and behaviours CBTI sessions will last approximately 45 minutes with 15 minutes preparation time and will be based on an individualised formulation that identifies and targets the beliefs and behaviours maintaining fear of falling for that individual. Treatment will be once per week for eight weeks, with a single reinforcement CBTI session six months after the last CBTI session. The CBTI was developed by our team in part 1 of this research (REC reference 11/NE/0090).

13. Randomisation

A blocked allocation (permuted random blocks of variable length, block size will not be disclosed to the investigators) will be used to allocate patients in a 1:1 ratio to intervention and control groups. Randomisation will be stratified by centre, gender, numeric rating scale for pain when walking and whether the patient has been referred for strength and balance training.

Randomisation will be administered centrally via Newcastle Clinical Trials Unit (NCTU) internet accessed secure web based system. The CI, or individual with delegate authority, will access the web-based system. Patient screening ID, initials and stratifying variables will be entered into the web-based system, which will return the allocation status. Participants will be informed of their allocated treatment group following randomisation.

Participants will be randomised to either:

Group 1 (control group) who will receive usual care.

Group 2 (intervention group) who will receive usual care plus CBTI delivered by trained Health Care Assistants (HCAs).

Contact details for Randomisation:

Web address: https://apps.ncl.ac.uk/random/

14. Study Data

14.1 Assessments / Data Collection

The data collected at each time-point is summarised in table 1. All outcomes will be assessed and recorded by research assistants/interviewers (unless specified otherwise) at baseline, 8 weeks, 6 months and 12 months. The assessments will be at participant's homes, the Falls Service or community centres or facilities (e.g. Age UK offices in North Shields), Newcastle University or the Royal Victoria Infirmary, Newcastle as per patient choice.

As per recent consensus guidelines,[38] falls will be defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level'. Participants and family members will be given verbal and written instructions to 'record *each day* in monthly-returned postage paid falls diaries any fall including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?'. Falls diaries[39,40] will be returned by postage paid envelopes to the Project Secretary. Telephone prompts carried out by a Research Assistant will be used to ensure contemporaneous reporting.

The HADS, EUROHIS-QOL-8, WHO-QOL-OLD, EQ-5D, SF-36 and Lubben Social Network Scale (LSNS) will be sent to patients for self-completion at the appropriate time-points.
If participants do not return the self-completion questionnaire within 2 weeks of the Research Assistant visit; a member of the team will contact the participant by telephone and remind them to return the self-completion questionnaire if they have completed it or if they are unable to self-complete the questionnaire the data will be captured via the telephone.
If the participant has misplaced the questionnaire a covering letter, replacement self-completion questionnaire and freepost return envelope will be posted.

If the participant wishes to complete the questionnaire via the telephone the questions will be asked in the following order to obtain the key measures in the event the participant does not wish to complete the full questionnaire;

1. EQ-5D
2. SF36
3. WHO-QoL-OLD
4. EuroHIS-QoL-8
5. Lubben Social Network Scale (LSNS)

The Hospital Anxiety & Depression Score (HADS)[41,42] is designed to detect the presence and severity of anxiety and depression. The World Health Organisation's (EUROHIS-QOL-8 & WHOQOL-OLD)[43] is a broad measure of quality of life, with specific questions for older people. The EuroQol-5 Dimensions Scale (EQ-5D)[44,45,46] is a generic quality of life measure, which also enables cost utility analysis. The Short Form 36 (SF-36) is a 36 item questionnaire which measures functional health and wellbeing [33, 47.] The Falls Efficacy Scale – International (FES-I), measures confidence in performing a range of activities of daily living without falling.

The Lubben Social Network Scale – 6 (LSNS-6)[48] is a questionnaire which is designed to gauge social isolation in older adults by measuring perceived social support from family and friends. It consists of 10 items which are used to measure size, closeness and frequency of contacts of a respondent's social network.

Prior to randomisation the Research Assistant will administer the numeric rating scale for pain when walking which will be completed by the patient. The scale involves asking the

participants to rate their pain when walking by selecting a number on a scale from 0-10 (11 point scale) by circling the number which best describes the level of pain they experience.[49]

At each of the protocol visits the Research Assistant will administer the, FES-I, numeric rating scale for fear of falling when walking, the De Jong-Gierveld Loneliness Scale and the Social Participation Questionnaire.

The numeric rating scale for fear of falling when walking involves asking the participants to rate their fear when walking by selecting a number on a scale from 0-10 (11 point scale) by circling the number which best describes the level of fear they experience.

The De Jong-Gierveld Loneliness Scale [50] (11 item) is a well validated and reliable 11 item scale which measures loneliness, including two subscales measuring emotional loneliness and social loneliness.

The Social Participation Questionnaire consists of 10 items derived from a measure of social functioning by House (1982)[51,52]. Participants are asked to report on their participation in 10 activities in the past two weeks. A summary score of social participation is calculated as the total number of times in which the participant participated in any of the 10 activity categories during the two week period in question. This method has been used in previous studies, looking at falls and social isolation and recovery of social function after hip fracture.

Short physical performance battery (SPPB) [53,54,55] is a well validated set of lower limb performance tests (measures walking speed over middle 8 feet of 12 foot course at participant's own 'usual speed', a series of chair stands to assess muscle power, plus a test of balance). Performed by one trained person, the SPPB takes 10-15 minutes to complete, with a composite score being derived by summing the category scores for each of the three tests. The SPPB will be completed at each study visit by the Research Assistants.

Functional reach and handgrip strength will be measured at each of the protocol visits by the Research Assistants. Functional reach is a good indicator of confidence in balance and increased risk of having a fall [56], while the measurement of maximum isometric handgrip strength (using a dynamometer) has functional relevance for supporting weight (e.g. holding on to a stair rail [57]. It has been included in numerous surveys, and is predictive of both disability and mortality. Functional reach and handgrip strength will be measured three times at each protocol visit and the mean value calculated from the three values.

If the Research Assistant is unable to arrange one of the follow-up visits in person and the participant is willing the FES-I, numeric rating scale for concern about falling, social participation questionnaire, De Jong-Gierveld Loneliness Scale and Resource Utilisation form will be obtained via telephone.

14.2 Data Handling and Record Keeping

Data will be handled, computerised and stored in accordance with the Data Protection Act 1998. No participant identifiable data will leave the study site.

The quality and retention of study data will be the responsibility of the CI (Dr Steve Parry). All study data will be retained in accordance with the latest Directive on GCP (2005/28/EC) and local policy**.**

Questionnaires and falls diaries will be returned to the Project Secretary as above and will be checked and logged.

Interviews conducted as part of the ethnographic sub study will be electronically recorded, transcribed, checked and anonymised. Audio recordings and transcripts will be stored on a secure, password protected network. Field notes of meetings, observation and reflective

notes made after interviews will all be anonymised and stored on a secure, password protected network.

Table 1 Data collection at each time-point

	Visit 1 Initial Screening	Visit 2 Baseline Visit Confirmation of Eligibility and Randomisation			Visit 3 End of CBTI intervention 8 weeks (visit window +/- 1 week)	Visit 4 6 months post randomisation (visit window +/- 2 – 4 weeks)	Visit 5 12 months post randomisation (visit window +/- 2 - 4 weeks)
		0	0a	0b			
Study Discussed/ PIS given	X						
Informed consent		X					
Randomisation (post eligibility checked and baseline tests)				X			
Numeric Rating Scale for pain when walking			X				
Numeric Rating Scale for fear of falling when walking			X		X	X	X
Hospital Anxiety and Depression Score (HADS)			X		X	X	X
Mini-mental state examination (MMSE)	X		X				X
Falls Efficacy Scale (FES-I)	X		X		X	X	X
Resource Utilisation From (RUF)						X	X
EUROHIS-QOL-8 & WHO-QoL-OLD			X		X	X	X
EQ-5D			X		X	X	X
SF-36			X		X	X	X
De Jong-Gierveld Loneliness Scale 11 item			X		X	X	X
Lubben Social Network Scale- 6 (LSNS-6)			X		X	X	X
Social Participation Questionnaire			X		X	X	X
Short Physical Performance Battery (SPPB)			X		X	X	X
Functional Reach			X		X	X	X
Handgrip strength			X		X	X	X
Adverse Events					X	X	X
Falls diaries				X			

14.3 Process Evaluation Ethnographic sub study data collection

The process evaluation interviews will focus on perceptions of key factors that might impede or facilitate the proposed intervention being effective and workable in practice. For the research to be conducted with patients and family members, to reduce the burden of research, interviews will not exceed 45 minutes duration without their express permission. For both patients and professionals, interviews will take place at a time and location of the interviewee's choosing.

For both patients and professionals, the respective interview schedules will draw on Normalization Process Theory (NPT)[27] as a conceptual framework to guide data collection. NPT specifies four key areas of 'work' that are important for new interventions to have the potential to be taken up and normalised in routine practice: Coherence (ways in which the intervention 'makes sense' and has clear purpose and objective); Cognitive Participation (willingness and ability to commit time and energy needed to make it work); Collective Action (the resources, arrangements, skills etc. required to make the intervention work); and Reflexive Monitoring (formal and informal mechanisms for appraising the process and outcomes of the intervention). The interview schedules are loosely structured around NPT, however the underlying theoretical constructs are not explicit within in the areas of questioning indicated on the topic guides, to ensure that appropriate and understandable language is used to facilitate the interview process. This loose structuring with respect to the NPT means that the interviewees will have the opportunity to respond openly about factors that they themselves see as important to making the developing intervention effective and useful that may extend beyond the focus of NPT.
Observational data will be collected by observing and taking field notes during team and other relevant meetings (n=5-10 approx.), that focus on the development, delivery and take-up of the intervention by participating health professionals and service users. Where meetings or other activities are to be audio recorded, participants will be informed at the beginning of the event and asked to provide verbal consent (recordings will not be made unless all participants consent to this).
Meetings and interviews will be audio recorded using digital voice recorders. Audio recordings will be transcribed, checked, and edited to ensure participants' anonymity (with particular attention to removing identifying data from professionals' transcripts).

All data (interview and observations) will be analysed thematically. As data will be collected using NPT as a guiding framework, qualitative analysis of the data will be undertaken using a grounded theory approach, employing the constant-comparison technique.[58] This process allows for the meaning of the data – and themes represented within it – to emerge freely without the constraints that might be imposed on the data if coding themes to a pre-specified coding frame. This analysis will lead to a robust conceptual model of the factors that are likely to affect the intervention's development, for the approach ensures that (i) there is a strong theoretical basis underlying the collection of data to ensure that appropriate and important areas of questioning are included, but (ii) there is scope for the emergence of important insights from the data that may not be adequately specified or emphasised with the frame of the NPT. This model will be of value to other clinicians and researchers wishing to use the intervention since it will provide a guide to implementation, embedding, and integration in everyday clinical practice.

15. Statistical Considerations

15.1 Statistical Analysis

The primary analysis will be based on fear of falling (FES-I) assessed at baseline and 12 months. The change in fear of falling will be analysed using analysis of covariance. The dependent variable will be the FES-I score at 12 months; baseline FES-I will be included as a covariate. Estimates of the effectiveness of the intervention will be adjusted for stratification variables (study centre as a random effect, gender, pain score and referral to strength and balance training classes as fixed effects. Potential differences between therapists (HCAs delivering CBTI) will be investigated by fitting an additional random effect. Secondary outcomes will be assessed using similar methods.

Effect of missing data

This is a comparatively frail population and we can expect some drop out during the study. It is likely that those participants who are lost to follow up during the trial may also be people with a tendency to experience poorer quality of life (in terms of fear of falling) than those who remain in the study. In this situation the data cannot be considered to be missing at random. On the contrary the event of a patient failing to complete the study may be informative. It is necessary to take into account any difference in dropout rates and the non-randomness of the drop out when comparing quality of life between the two treatment groups. This will be done by jointly modelling —survival in the study and the repeated measures of functional status simultaneously using software that has been developed as part of an MRC funded programme of work (Grant G0400615; Statistical methodology for longitudinal studies in clinical research; Williamson PR, Diggle PJ and Henderson R). Time to drop-out will be analysed using a Cox proportion hazards model incorporating random effects. Fear of falling will be modelled using mixed models appropriate for repeated measures. A key feature of each of these models is that within each of them it is possible to fit a latent variable that can be conceptualised as the patient‘s propensity to experience poor outcomes (both their likelihood to drop out of the study and their likelihood to have poorer quality of life [i.e. greater fear of falling scores]). It is the inclusion of this latent variable that allows us to adjust our estimates of the treatment effect to allow for the different rates of drop out in each group. Both models are estimated simultaneously; parameter estimates are based on maximising the joint likelihood over both the survival and repeated measures data.

15.2 Sample Size Calculation

Primary outcome is change in FoF (as measured by the FES-I) at 12 months. The estimated standard deviation is 12.5[21] the difference in group means that we wish to be able to detect is 4.0 (per clinical judgment in combination with observed effects in a range of studies)[19,59] corresponding to a standardized effect size of 0.32. Accordingly, the number required to provide full outcome data (80% power, 5% significance level) is 154 per group, or 308 in total. To allow for 25% dropouts, we will recruit 412 participants.

16. Compliance and Withdrawal

16.1 Assessment of compliance

Visit windows of +/- 1 week for visit 3 and +/- 4 weeks for visits 4 and 5 should ensure visit attendance or compliance; non-attendance for study visits will prompt follow-up by telephone.

16.2 Withdrawal of participants

Participants have the right to withdraw from the study at any time for any reason, and without giving a reason. The investigator also has the right to withdraw patients from the study intervention if s/he judges this to the in the patient's best interests. It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

There are two withdrawal options:

1. Withdrawing completely (i.e. withdrawal from both the study intervention and provision of follow-up data)
2. Withdrawing partially (i.e. withdrawal from study intervention but continuing to provide follow-up data by attending study visits and completing questionnaires).

Consent will be sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants will be asked if they would be happy for the reason for the decision to withdraw to be recorded.

17 Data monitoring, quality control and quality assurance

17.1 Discontinuation rules

The trial may be prematurely discontinued on the basis of new safety information, or for other reasons given by the Data Monitoring & Ethics Committee and/or Trial Steering Committee, Sponsor or Ethics Committee concerned.

17.2 Monitoring, quality control and assurance

The trial will be managed through Newcastle Clinical Trials Unit [central co-ordinating team]. The Trial Management Group (TMG) will include: the Chief Investigator, the TMT, the trial statistician, qualitative researchers, CBT specialists, data manager and project secretary.

The Principal Investigator will be responsible for the day-to-day study conduct at each site.

The Trial Manager will provide day-to-day support for the site and provide training through site initiation visits and routine monitoring visits.

Quality control will be maintained through adherence to SOPs, study protocol, the principles of GCP, research governance and clinical trial regulations.

An independent data monitoring and ethics committee (DMEC) (Prof Rose Anne Kenny, Professor of Geriatric Medicine, Prof Dawn Skelton, Professor in Ageing and Health, and Dr Steff Lewis, Deputy Director, Edinburgh MRC Clinical Trials Methodology Hub) will be convened to undertake independent review. The purpose of this committee will be to monitor efficacy and safety endpoints. The committee will meet at least 3 times, at the start, middle and completion of the study. At the first meeting, DMEC will agree on its charter of operation, and discuss and advise on the inclusion of an interim analysis and possible adoption of a formal stopping rule for efficacy or safety.

A Trial Steering Committee (TSC) will be established to provide overall supervision of the trial. The TSC will consist of Prof James Mason (Professor of Health Economics), Dr Cathy Bailey (Reader in Ageing and Health), Prof Mark Freeston (Professor of Clinical Psychology), Prof Craig Ramsay (Senior Statistician), Ms Angela Watt (lay member) , Dr Steve Parry (CI), Dr Nick Steen (Statistician), and the Trial Management Team. Observers from the HTA programme will be invited to all TSC meetings. The committee will meet every 6 months during recruitment, and annually thereafter for the duration of the trial.

Monitoring of study conduct and data collected will be performed by a combination of central review and site monitoring visits to ensure the study is conducted in accordance with GCP. Study site monitoring will be undertaken by Newcastle Clinical Trials Unit. The main areas of focus will include consent, serious adverse events and essential documents in study.

Site monitoring will include:

- All original consent forms will be reviewed as part of the study file. The presence of a copy in the patient hospital notes will be confirmed for 100% participants
- All original consent forms will be compared against the study participant identification list
- All reported serious adverse events will be verified against treatment notes/medical records (source data verification)
- The presence of essential documents in the investigator site file and study files will be checked

- Source data verification of eligibility data for 20% of participants entered in the study

Central monitoring will include:

- All applications for study authorisations and submissions of progress/safety reports will be reviewed for accuracy and completeness, prior to submission
- All documentation essential for study initiation will be reviewed prior to site authorisation

All monitoring findings will be reported and followed up with the appropriate persons in a timely manner.

The study may be subject to inspection and audit (as a matter of routine or 'for cause') by The Newcastle upon Tyne Hospitals NHS Foundation Trust under their remit as sponsor, and other regulatory bodies to ensure adherence to GCP. All participant information sheets will make explicit this level of access and participants will be required to confirm (on the consent form) their consent to this access. The investigator and institution will permit trial-related monitoring, audits, REC review and regulatory inspection(s), providing direct access to source data/documents.

18 Adverse Event reporting

18.1 Definitions

Adverse event (AE): Any untoward medical occurrence in a subject to whom a study intervention or procedure has been administered, including occurrences which are not necessarily caused by or related to that intervention. An AE, therefore, does not necessarily have a causal relationship with the treatment. In this context, "treatment" includes all interventions (including comparative agents) administered during the course of the study. Medical conditions/diseases present before starting study treatment are only considered adverse events if they worsen after starting study treatment.

Related AE: An AE that results from administration of any of the research study procedures. All AEs judged by either the reporting investigator or the sponsor as having reasonable causal relationship to a study procedure qualify as 'related adverse events'. The expression "reasonable causal relationship" means to convey in general that there is evidence or argument to suggest a causal relationship.

Causality:

The assignment of the causality should be made by the investigator responsible for the care of the participant using the definitions in the table below. All adverse events judged as having a reasonable suspected causal relationship to a study procedure (i.e. definitely, probably or possibly related) are considered to be related adverse events. In the case of discrepant views on causality between the investigator and others, all parties will discuss the case. In the event that no agreement is made, the main REC and other bodies will be informed of both points of view.

Relationship	Description
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

Unexpected Adverse Event: An adverse event that is not listed in the study protocol as an expected occurrence in the circumstances of this trial.

Serious Adverse Event (SAE): an untoward occurrence (whether expected or not) that:-

- Results in death
- Is life-threatening (refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- Requires hospitalisation, or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Is otherwise considered medically significant by the investigator

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important medical events that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

Severity (intensity) of Adverse Events and Adverse Reactions

Severity of all AEs will be graded on a three-point scale of intensity (mild, moderate, severe):

- Mild: Discomfort is noticed, but there is no disruption of normal daily activities.
- Moderate: Discomfort is sufficient to reduce or affect normal daily activities.
- Severe: Discomfort is incapacitating, with inability to work or to perform normal daily activities.

An AE may be severe but not serious

18.2 Expected adverse reactions:

The potential risks associated with the study are few. The main anticipated issue centres on the potential for patients to gain confidence and lose fear of falling in a way that is inconsistent with their improvement (or lack thereof) in physical function. In other words, patients who have hitherto considerably limited activity through fear of falling have the potential to increase activity levels through amelioration of the condition with the CBTI before any physical interventions have been able to take effect. In practice this is unlikely given the prolonged course of the CBTI. We believe the potential benefits to individuals and society in terms of increasing activity, avoidance of social isolation, enhancement of independence and avoidance of injuries and hospitalisations from examining the effectiveness of psychological interventions in people with fear of falling are, nevertheless, worth such risks.

18.3 Protocol Specifications

For purposes of this protocol:

- All adverse events will be elicited and recorded at all visits and categorised as to expectedness, relatedness and severity.
- All serious adverse events will be recorded throughout the duration of the trial.
- Serious adverse events exclude any pre-planned hospitalisations (e.g. elective surgery) not associated with clinical deterioration.
- Serious adverse events exclude routine treatment or monitoring of the studied indication (i.e. fear of falling), not associated with any deterioration in condition.
- Serious adverse events exclude elective or scheduled treatment for pre-existing conditions that did not worsen during the study.

18.4 Recording & Reporting Serious Adverse Events or Reactions:

All adverse events should be reported. Depending on the nature of the event, the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

Adverse Event (AEs): All non-serious adverse events during study participation will be reported on the study CRF and sent to NCTU within 2 weeks of the form being completed. Severity of AEs will be graded on a three-point scale (mild, moderate, severe). Relation (causality) and seriousness of the AE to the intervention should be assessed by the investigator at site in the first instance.

Serious Adverse Event (SAEs): All SAEs during study participation shall be reported to the Chief Investigator within 24 hours of the site learning of its occurrence. The initial report can be made by completing the serious adverse event CRF and faxing it to NCTU. In the case of incomplete information at the time of initial reporting, all appropriate information should be provided as follow-up as soon as this becomes available. Relationship of the SAE to study procedures should be assessed by the investigator, as should the expected or unexpected nature of the AE.

The main REC will be notified by the Trial Management Team (on behalf of the Sponsor) of all SAEs within 15 days of the CI becoming aware of the SAE (unless urgent safety measures are required, in which case initial notification by telephone will be made immediately the CI becomes aware of the AE, with notice in writing following within 3 days). SAEs will be reported using the NRES Report of Serious Events Form, version 3, April 2007, available from

http://www.nres.npsa.nhs.uk/applications/after-ethical-review/safetyreports/safety-reports-for-all-other-research/

The Chief Investigator will ensure the Newcastle upon Tyne Hospitals NHS Foundation Trust as Sponsor is notified of any SAEs in accordance with local trust policy.

Contact details for reporting Serious Adverse Events
Please send SAE form(s) to the Newcastle Clinical Trials Unit FAO Claire Macdonald
Fax 0191 208 8901
Email claire.macdonald@ncl.ac.uk
Tel: 0191 208 3825 (Mon to Fri 09.00 – 17.00)

19 Ethics & Regulatory Issues

The conduct of this study will be in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Favourable ethical opinion from an appropriate REC and R&D approval will be sought prior to commencement of the study. The NCTU as the study coordination centre will require a written copy of local approval documentation before initiating the site and accepting participants into the study.

Information sheets will be provided to all eligible subjects and written informed consent obtained prior to any study procedures. All participants will have the capacity to provide consent on their own behalf on entry to the study. For subjects who cannot initial, date and sign consent for themselves, an appropriate independent witness will witness their oral consent and will initial, date and sign the informed consent form on their behalf.

For participants who lose capacity during the course of the study participants will be withdrawn from the study and we will continue to use the data captured up until the point of loss capacity for analysis.

20 Confidentiality

Personal data will be regarded as strictly confidential. To preserve anonymity, any data leaving the site will identify participants by their initials and a unique study identification code only.

Questionnaires and diaries will be identified by the unique study identification code and initials. Only members of the research team will be able to link the unique study identification code to patient identifiable data needed for record linkage and participant contact.

The study will comply with the Data Protection Act, 1998. All study records and Investigator Site Files will be kept at site or at NCTU as appropriate in a locked filing cabinet with restricted access.

All study personnel will work to a written code of confidentiality.

21 Insurance and Finance

The Newcastle Hospitals NHS Foundation Trust has liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS Indemnity covers NHS staff and medical academic staff with honorary contracts conducting the trial for potential liability in respect of negligent harm arising from the conduct of the study. The Newcastle upon Tyne Hospitals NHS Foundation Trust is the study Sponsor and provides NHS indemnity in respect of potential liability and negligent harm arising from study management. Indemnity in respect of potential liability arising from negligent harm related to study design is provided by NHS schemes for those protocol authors who have their substantive contracts of employment with the NHS and by Newcastle University Insurance schemes for those protocol authors who have their substantive contract of employment with the University. This is a non-commercial study and there are no arrangements for non-negligent compensation. The National Institute for Health Research Health Technology Assessment Programme funds this study (HTA reference 09/70/04).

22 Study Report / Publications

The data will be the property of the Chief Investigator and Co-Investigators. Publication will be the responsibility of the Chief Investigator and published under the authorship agreed with the Co-Investigators.

It is planned to publish this study in peer review articles and to present data at national and international meetings. Results of the study will also be reported to the Sponsor and Funder, and will be available on their web site. All manuscripts, abstracts or other modes of presentation will be reviewed by the Trial Steering Committee and Funder prior to submission. Individuals will not be identified from any study report.

Participants will be informed about their treatment and their contribution to the study at the end of the study, including a lay summary of the results.

Publication of the results of the study will follow NIHR guidance on communicating research outcomes, which includes submitting an electronic copy of the proposed research output, as it will be issued, to the Programme Manager at the NIHR Central Commissioning Facility (NIHR CCF), at least 28 days before it is published. The 28-day rule also applies to news releases to be issued by The Newcastle upon Tyne Hospitals NHS Foundation Trust or Newcastle University. NIHR will also receive full citations of research outputs when these become available.

All research reports issued by individual researchers and/or research teams will:
- Credit the NIHR as a funding organisation
- Carry the NIHR disclaimer

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Appendices

Appendix A The World Medical Association Declaration of Helsinki (2008)

Appendix B Hospital Anxiety and Depression Scale (HADS)

Appendix C EUROHIS-QOL-8

Appendix D WHO-QoL OLD

Appendix E EQ-5D

Appendix F SF-36

Appendix G 11 item loneliness scale

Appendix H LSNS-6

Appendix I Social Participation Questions

Appendix J Short Physical Performance Battery

Appendix K Falls Efficacy Scale –International version

Appendix L Resource Utilisation Form

Appendix M Numeric rating scale for pain when walking

Appendix N Numeric rating scale for fear of falling when walking

Appendix A – The World Medical Association Declaration of Helsinki (2008)

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

B. PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of

participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

Appendix B

Hospital and Anxiety and Depression Scale

Hospital Anxiety and Depression Scale (HADS)

Patients are asked to choose one response from the four given for each interview. They should give an immediate response and be dissuaded from thinking too long about their answers. The questions relating to anxiety are marked "A", and to depression "D". The score for each answer is given in the right column. Instruct the patient to answer how it currently describes their feelings.

A	**I feel tense or 'wound up':**	
	Most of the time	3
	A lot of the time	2
	From time to time, occasionally	1
	Not at all	0

D	**I still enjoy the things I used to enjoy:**	
	Definitely as much	0
	Not quite so much	1
	Only a little	2
	Hardly at all	3

A	**I get a sort of frightened feeling as if something awful is about to happen:**	
	Very definitely and quite badly	3
	Yes, but not too badly	2
	A little, but it doesn't worry me	1
	Not at all	0

D	**I can laugh and see the funny side of things:**	
	As much as I always could	0
	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3

A	**Worrying thoughts go through my mind:**	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not too often	1
	Only occasionally	0

D	**I feel cheerful:**	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0

A	**I can sit at ease and feel relaxed:**	
	Definitely	0
	Usually	1
	Not often	2
	Not at all	3

D	**I feel as if I am slowed down:**	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0

D	**I get a sort of frightened feeling like 'butterflies' in the stomach:**	
	Not at all	0
	Occasionally	1
	Quite often	2
	Very often	3

D	**I have lost interest in my appearance:**	
	Defiantly	3
	I don't take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care as ever	0

A	**I feel restless as if I have to be on the move:**	
	Very much indeed	3
	Quite a lot	2
	Not very much	1
	Not at all	0

D	**I look forward with enjoyment to things:**	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3

D	**I get sudden feelings of panic:**	
	Very often indeed	3
	Quite often	2
	Not very often	1
	Hardly at all	0

D	**I can enjoy a good book or radio or TV program:**	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

	Scoring
	Add the As = Anxiety Add the Ds = Depression
	The norms below will give you an idea of the level of anxiety and depression.
	0 -7 = Normal
	8 – 10 = Borderline abnormal
	11 – 21 = Abnormal

Appendix C

EUROHIS-QOL-8

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.** For example, thinking about the last two weeks, a question might ask:

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks. Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
3	Do you have enough energy for everyday life?	1	2	3	4	5
4	Have you enough money to meet your needs?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
5	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
6	How satisfied are you with yourself?	1	2	3	4	5
7	How satisfied are you with your personal relationships?	1	2	3	4	5
8	How satisfied are you with the conditions of your living place?	1	2	3	4	5

Do you have any comments about the assessment?

.....

.....

THANK YOU FOR YOUR HELP

Appendix D

WHOQOL OLD

Instructions
This questionnaire asks for your thoughts and feelings about certain aspects of your quality of life and addresses issues that may be important to you as an older member of society.

Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks.

For example, thinking about the last two weeks, a question might ask:

How much do you worry about what the future might hold?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5

You should circle the number that best fits how much you have worried about the future
over the last two weeks. So you would circle the number 4 if you worried about your future "Very much", or circle number 1 if you have worried "Not at all" about your future. Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

Thank you for your help

The following questions ask about how much you have experienced certain things in the last two weeks, for example, freedom of choice and feelings of control in your life. If you have experienced these things an extreme amount circle the number next to "An extreme amount". If you have not experienced these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to indicate your answer lies somewhere between "Not at all" and "Extremely". Questions refer to the last two weeks.

1. (F25.1) To what extent do impairments to your senses (e.g. hearing, vision, taste, smell, touch) affect your daily life?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5

2. (F25.3) To what extent does loss of for example, hearing, vision, taste, smell or touch affect your ability to participate in activities?

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

3. (F26.1) How much freedom do you have to make your own decisions?

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

4. (F26.2) To what extent do you feel in control of your future?

Not at all	Slightly	Moderately	Very	Extremely
1	2	3	4	5

5. (F26.4) How much do you feel that the people around you are respectful of your freedom?

Not at all	Slightly	Moderately	Very	Extremely
1	2	3	4	5

6. (F29.2) How concerned are you about the way in which you will die?

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

7. (F29.3) How much are you afraid of not being able to control your death?

Not at all	Slightly	Moderately	Very	Extremely
1	2	3	4	5

8. (F29.4) How scared are you of dying?

Not at all	Slightly	Moderately	Very	Extremely
1	2	3	4	5

9. (F29.5) How much do you fear being in pain before you die?

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last two weeks, for example getting out as much as you would like to. If you have been able to do these things completely, circle the number next to "Completely". If you have not been able to do these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to indicate your answer lies somewhere between "Not at all" and "Completely". Questions refer to the last two weeks.

10. (F25.4) To what extent do problems with your sensory functioning (e.g. hearing, vision, taste, smell, touch) affect your ability to interact with others?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

11. (F26.3) To what extent are you able to do the things you'd like to do?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

12. (F27.3) To what extent are you satisfied with your opportunities to continue achieving in life?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

13. (F27.4) How much do you feel that you have received the recognition you deserve in life?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

14. (F28.4) To what extent do you feel that you have enough to do each day?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

The following questions ask you to say how satisfied, happy or good you have felt about various aspects of your life over the last two weeks . For example, about your participation in community life or your achievements in life. Decide how satisfied or dissatisfied you are with each aspect of your life and circle the number that best fits how you feel about this. Questions refer to the last two weeks

15. (F27.5) How satisfied are you with what you have achieved in life?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

16. (F28.1) How satisfied are you with the way you use your time?

Very dissatisfied 1	Dissatisfied 2	Neither satisfied nor dissatisfied 3	Satisfied 4	Very satisfied 5

17. (F28.2) How satisfied are you with your level of activity?

Very dissatisfied 1	Dissatisfied 2	Neither satisfied nor dissatisfied 3	Satisfied 4	Very satisfied 5

18. (F28.7) How satisfied are you with your opportunity to participate in community activities?

Very dissatisfied 1	Dissatisfied 2	Neither satisfied nor dissatisfied 3	Satisfied 4	Very satisfied 5

19. (F27.1) How happy are you with the things you are able to look forward to?

Very unhappy 1	Unhappy 2	Neither happy nor unhappy 3	Happy 4	Very happy 5

20. (F25.2) How would you rate your sensory functioning (e.g. hearing, vision, taste, smell, touch)?

Very poor 1	Poor 2	Neither poor nor good 3	Good 4	Very good 5

The following questions refer to any intimate relationships that you may have. Please consider these questions with reference to a close partner or other close person with whom you can share intimacy more than with any other person in your life

21. (F30.2) To what extent do you feel a sense of companionship in your life?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5

22. (F30.3) To what extent do you experience love in your life?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5

23. (F30.4) To what extent do you have opportunities to love?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

24. (F30.7) To what extent do you have opportunities to be loved?

Not at all	A little	Moderately	Mostly	Completely
1	2	3	4	5

Do you have any comments about the questionnaire?

THANK YOU FOR YOUR HELP

Appendix E

EQ-5D

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, Family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

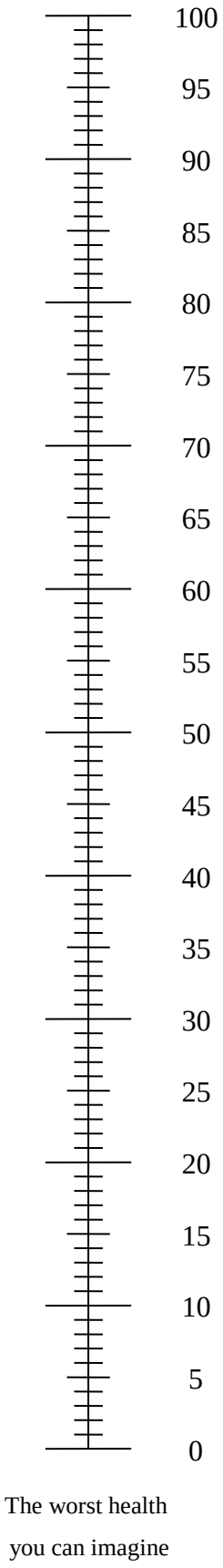
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h Walking <u>several hundred yards</u>	☐ 1	☐ 2	☐ 3
i Walking <u>one hundred yards</u>	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

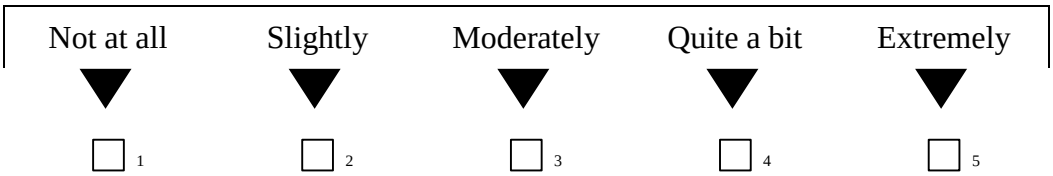
4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

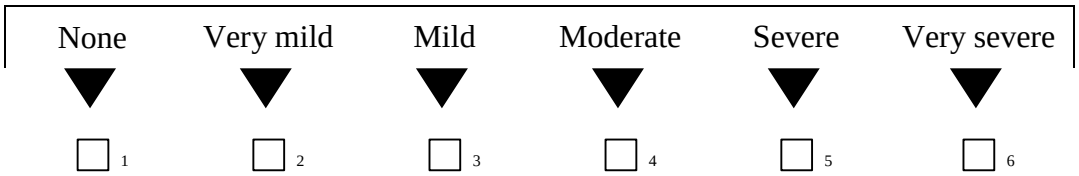
5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

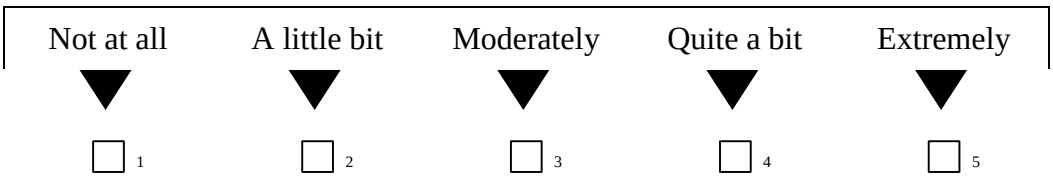
6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?



7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?



8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?



9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get ill more easily than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix G

11 Item Loneliness Scale

De Jong Gierveld 11 item Loneliness Scale (De Jong Gierveld and Kamphuis 1985; De Jong Gierveld and Van Tilburg 1999).

Scale information below taken from the online version of the Manual of the Loneliness Scale (De Jong Gierveld and Van Tilburg, 1999)

The scale may be used in face-to-face interviews, telephone interviews, self-administered (mail) questionnaires, as well as in electronic data collection. We recommend that the scale be presented somewhere in the middle of the interview or questionnaire; that is, at a moment when a considerable degree of self-disclosure from the respondents may be expected. Ideally, questions about characteristics of the respondents' networks of social relationships should precede the scale items.

The scale consists of 11 items; six are formulated negatively and five are formulated positively. The items are sometimes preceded by a short introduction.

Please indicate for each of the 11 statements, the extent to which they apply to your situation, the way you feel now. Please, circle the appropriate answer.

1. There is always someone I can talk to about my day-to-day problems
2. I miss having a really close friend
3. I experience a general sense of emptiness
4. There are plenty of people I can lean on when I have problems
5. I miss the pleasure of the company of others
6. I find my circle of friends and acquaintances too limited
7. There are many people I can trust completely
8. There are enough people I feel close to
9. I miss having people around me
10. I can call on my friends whenever I need them
11. I often feel rejected

Possible answers are "yes!", "yes", "more or less", "no", "no!"

Appendix H

LUBBEN SOCIAL NETWORK SCALE – 6 (LSNS-6)

FAMILY: Considering the people to whom you are related by birth, marriage, adoption, etc…

1. How many relatives do you see or hear from at least once a month?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

2. How many relatives do you feel at ease with that you can talk about private matters?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

3. How many relatives do you feel close to such that you could call on them for help?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

FRIENDSHIPS: Considering all of your friends including those who live in your neighbourhood

4. How many of your friends do you see or hear from at least once a month?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

5. How many friends do you feel at ease with that you can talk about private matters?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

6. How many friends do you feel close to such that you could call on them for help?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

LSNS-6 total score is an equally weighted sum of these six items. Scores range from 0 to 30

Appendix I

Social Participation Questions

How many times in the past two weeks have you done any of the following activities?

Activity	**Number of times in the past two weeks**
1) Gone to the movies, concerts, plays or sporting events	
2) Gone to fairs, museums or exhibits	
3) Attended meetings, appointments, classes or lectures	
4) Gone to church or temple services	
5) Gone on pleasure drives or picnics	
6) Played cards, bingo etc. with others	
7) Gone to family/friends house for a meal	
8) Participated in active sports or swimming	
9) Worked in the garden/yard or at a hobby	
10) Done community or volunteer work	
Total score of social participation activities in past two weeks	

Appendix J

Short Physical Performance Battery

Short Physical Performance Battery

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participant are shown in bold and should be given exactly as they are written in this script.

Script:

Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any movement that you feel might be unsafe.

Do you have any questions before we begin?

Balance Tests

The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

Side-By-Side Stand

Script:

Now I will show you the first movement.

(Demonstrate) **I want you to try to stand with your feet together, side-by-side, for about 10 seconds.**

You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.

Stand next to the participant to help him/her into the side-by-side position.

Supply just enough support to the participant's arm to prevent loss of balance.

*When the participant has his/her feet together, ask **"Are you ready?**"*

*Then let go and begin timing as you say, **"Ready, begin."***

*Stop the stopwatch and say **"Stop"** after 10 seconds or when the participant steps out of position or grabs your arm.*

If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

	1. Side-by-Side Score		
	Held for 10 sec	☐ 1	***Proceed to Semi-Tandem Stand***
	Not held for 10 sec	☐ 2	***Go to question #2***
	Not attempted	☐ 3	***Go to question #3***
	2. Number of seconds held if less than 10 sec: ☐ . ☐☐ (seconds) *pbsbsles* ***Proceed to Semi-Tandem Stand***		
	3. If participant did not attempt test: (Mark X for reason) *pbsbsnot*		
	a. Tried but unable	☐ 1	
	b. Participant could not hold position unassisted	☐ 2	
	c. Not attempted, you felt unsafe	☐ 3	
	d. Not attempted, participant felt unsafe	☐ 4	
	e. Participant unable to understand instructions	☐ 5	
	f. Other (specify) _____ *pbsbspfy*	☐ 6	
	g. Participant refused	☐ 998	

Semi-Tandem Stand

Script:

Now I will show you the second movement.

(Demonstrate) **I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.**

You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.

Stand next to the participant to help him/her into the semi-tandem position.

Supply just enough support to the participant's arm to prevent loss of balance.

When the participant has his/her feet together, ask **"Are you ready?"**

Then let go and begin timing as you say **"Ready, begin."**

Stop the stopwatch and say **"Stop"** after 10 seconds or when the participant steps out of position or grabs your arm.

If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

1. Semi-Tandem Stand Score		
Held for 10 sec	☐ 1	***Proceed to Tandem Stand***
Not held for 10 sec	☐ 2	***Go to question #2***
Not attempted	☐ 3	***Go to question #3***
2. Number of seconds held if less than 10 sec: ☐ . ☐☐ (seconds) *pbstsles* ***Proceed to Tandem Stand***		
3. If participant did not attempt test: (Mark X for reason) *pbstsnot*		
a. Tried but unable	☐ 1	
b. Participant could not hold position unassisted	☐ 2	
c. Not attempted, you felt unsafe	☐ 3	
d. Not attempted, participant felt unsafe	☐ 4	
e. Participant unable to understand instructions	☐ 5	
f. Other (specify) _____ *pbstspfy*	☐ 6	
g. Participant refused	☐ 998	

Tandem Stand

Script:

Now I will show you the first movement.

(Demonstrate) ***I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***

You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.

Stand next to the participant to help him/her into the tandem position.

Supply just enough support to the participant's arm to prevent loss of balance.

When the participant has his/her feet together, ask "**Are you ready?"**

Then let go and begin timing as you say, **"Ready, begin."**

Stop the stopwatch and say **"Stop"** after 10 seconds or when the participant steps out of position or grabs your arm.

	1. Tandem Stand Score		
	Held for 10 sec	☐ 1	***Proceed to Gait Speed***
	Held for 3 to 9.99 sec	☐ 2	***Go to question #2***
	Held for < than 3 sec	☐ 3	***Go to question #2***
	Not attempted	☐ 4	***Go to question #3***
	2. Number of seconds held if less than 10 sec: ☐ . ☐☐ (seconds) *pbtsless* ***Proceed to Gait Speed***		
	3. If participant did not attempt test: (Mark X for reason) *pbtsnot*		
	a. Tried but unable	☐ 1	
	b. Participant could not hold position unassisted	☐ 2	
	c. Not attempted, you felt unsafe	☐ 3	
	d. Not attempted, participant felt unsafe	☐ 4	
	e. Participant unable to understand instructions	☐ 5	
	f. Other (specify) _____ *pbtsspfy*	☐ 6	
	g. Participant refused	☐ 998	

Gait Speed Test

First Gait Speed Test

Script:

Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.

This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.

Demonstrate the walk for the participant.

Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?

Have the participant stand with both feet touching the starting line.

When I want you to start, I will say: "Ready, begin." *When the participant acknowledges this instruction say:* **"Ready, begin."**

Press the start/stop button to start the stopwatch when the participant steps over the starting line.

Walk behind and to the side of the participant.

Stop timing when one of the participant's feet is completely across the end line.

Length of walk test course:

1. ☐ 1 **4 meters** (in all clinical assessments)
☐ 2 **3 meters** (if 4 meter course is unavailable)

2. Was test attempted? ☐1 Yes ☐0 No
(If Yes, answer 3 & 4) ***(If No, go to 5)***

3. Time for 3 or 4 meters ☐☐.☐☐ (seconds) *pbgstime*

4. Aids used for first walk: *pbgsaid*

a. None	☐ 1
b. Cane	☐ 2
c. Other (specify)_____ *y*	☐ 3

Proceed to Second Gait Speed Test

5. If participant did not attempt test: (Mark X for reason

a. Tried but unable	☐ 1
b. Participant could not hold position unassisted	☐ 2
c. Not attempted, you felt unsafe	☐ 3
d. Not attempted, participant felt unsafe	☐ 4
e. Participant unable to understand instructions	☐ 5
f. Other (specify) _____	☐ 6
g. Participant refused	☐ 998

Proceed to Chair Stand

Second Gait Speed Test

Script:

Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.

Have the participant stand with both feet touching the starting line.

When I want you to start, I will say: "Ready, begin." *When the participant acknowledges this instruction say:* **"Ready, begin."**

Press the start/stop button to start the stopwatch when the participant steps over the starting line.

Walk behind and to the side of the participant.

Stop timing when one of the participant's feet is completely across the end line.

Second Gait Speed Test Score

1. Was test attempted? ☐1 Yes ☐0 No
(If yes, answer 2 & 3) ***(If no, go to 4)***

2. Time for 3 or 4 meters ☐☐.☐☐ seconds *pbsgs2*

3. Aids used for second walk:

a. None	☐ 1
b. Cane	☐ 2
c. Other (specify)_____	☐ 3

Proceed to Chair Stand

4. If participant did not attempt test: (Mark X for reason) *pbsgsnot*

a. Tried but unable	☐ 1
b. Participant could not hold position unassisted	☐ 2
c. Not attempted, you felt unsafe	☐ 3
d. Not attempted, participant felt unsafe	☐ 4
e. Participant unable to understand instructions	☐ 5
f. Other (specify) _____	☐ 6
g. Participant refused	☐998

Chair Stand Test

Single Chair Stand

Script:

Let's do the last movement test. Do you think it would be safe for you to try to

stand up from a chair?

The next test measures the strength in your legs.

(Demonstrate and explain the procedure) **First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest. Please stand up keeping your arms folded across your chest.** *(record result).*

If the participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."***

Single Chair Stand Test Questions

1. Safe to stand without help	☐ 1 **Yes** ☐ 0 **No**	
2. Was test attempted?	☐ 1 **Yes** ☐ 0 **No** ***(If yes, answer 3)*** ***(If no, go to 4)***	
3. Results		
a. Participant stood without using arms	☐ 1	→ Proceed to Repeated Chair Stand Test
b. Participant used arms to stand	☐ 2	→ End Test
c. Test not completed	☐ 3	→ End Test ***(If yes, answer 4)***
4. If participant did not attempt or failed: (Mark X for reason) *pbscsnot*		
a. Tried but unable		☐ 1
b. Participant could not stand unassisted		☐ 2
c. Not attempted, you felt unsafe		☐ 3
d. Not attempted, participant felt unsafe		☐ 4
e. Participant unable to understand instructions		☐ 5
f. Other (specify) _____ *pbscspfy*		☐ 6
g. Participant refused		☐ 998

Repeated Chair Stand Test Script:

Do you think it would be safe for you to try to stand up from a chair five times without using your arms?

(Demonstrate and explain the procedure): **Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.**

When the participant is properly seated, say: **"Ready? Stand"** *and begin timing.*

Count out loud as the participant arises each time, up to five times.

Stop if participant becomes tired or short of breath during repeated chair stands.

Stop the stopwatch when he/she has straightened up completely for the fifth time.

Also stop:
- If participant uses his/her arms
- After 1 minute, if participant has not completed all 5 rises
- At your discretion, if concerned for participant's safety

If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking **"Can you continue?"**

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Repeated Chair Stand Test Questions

1. Safe to stand without help	☐ 1 **Yes** ☐ 0 **No**
2. Was test attempted?	☐ 1 **Yes** ***(If yes, answer 3)*** ☐ 0 **No** ***(If no, go to 4)***
3. Time to complete five stands *(Only enter if participant completes 5 stands)* ☐☐.☐☐ seconds ***(If participant failed test answer 4)***	
4. If participant did not attempt or failed: (Mark X for reason)	
a. Tried but unable	☐ 1
b. Participant could not stand unassisted	☐ 2
c. Not attempted, you felt unsafe	☐ 3
d. Not attempted, participant felt unsafe	☐ 4
e. Participant unable to understand instructions	☐ 5
f. Other (specify) _____	☐ 6
g. Participant refused	☐ 998

Appendix K

FES-I

FES-I Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		Not at all concerned 1	Somewhat concerned 2	Fairly concerned 3	Very concerned 4
1	Cleaning the house (e.g. sweep, vacuum or dust)	1 □	2 □	3 □	4 □
2	Getting dressed or undressed	1 □	2 □	3 □	4 □
3	Preparing simple meals	1 □	2 □	3 □	4 □
4	Taking a bath or shower	1 □	2 □	3 □	4 □
5	Going to the shop	1 □	2 □	3 □	4 □
6	Getting in or out of a chair	1 □	2 □	3 □	4 □
7	Going up or down stairs	1 □	2 □	3 □	4 □
8	Walking around in the neighbourhood	1 □	2 □	3 □	4 □
9	Reaching for something above your head or on the ground	1 □	2 □	3 □	4 □
10	Going to answer the telephone before it stops ringing	1 □	2 □	3 □	4 □
11	Walking on a slippery surface (e.g. wet or icy)	1 □	2 □	3 □	4 □
12	Visiting a friend or relative	1 □	2 □	3 □	4 □
13	Walking in a place	1 □	2 □	3 □	4 □

	with crowds				
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)	1 □	2 □	3 □	4 □
15	Walking up or down a slope	1 □	2 □	3 □	4 □
16	Going out to a social event (e.g. religious service, family gathering or club meeting)	1 □	2 □	3 □	4 □

Appendix L

Resource Utilisation Form

The following questions are about the number of times you visited or talked to health care professionals. They are only about either your difficulties in walking and going about your usual activities or because of any falls you might have had. There is also a question about the amount of help and support you required from family and friends.

1. Over the last six months how many times have you visited your general practitioner (GP) because of a fall or because of your difficulties in walking and going about your usual activities?

    a. GP visits because of difficulties in walking and going about your usual activities

    b. GP visits due to a fall

2. Over the last six months how many times have you visited other health professionals at your general practice, for instance the practice nurse, because of a fall or because of your difficulties in walking and going about your usual activities?

    a. Other general practice visits because of difficulties in walking and going about your usual activities

    b. Other general practice visits because of a fall

3. Over the last six months how many times has your GP, or other doctor, visited you at home because of a fall or because of your difficulties in walking and going about your usual activities?

    a. GP home visits because of difficulties in walking and going about your usual activities

    b. GP home visits due to a fall

4. Over the last six months how many times have other health care workers, for example district nurses, visited you at home because of a fall or because of your difficulties in walking and going about your usual activities?

    a. Other healthcare workers home visits because of difficulties in walking and going about your usual activities

    b. Other healthcare workers home visits due to a fall

5. Over the last six months, have you been admitted to hospital because of a fall? (if you were not admitted to hospital for either of these reasons please go to question 7)

a. Number of hospital admissions because of a fall

6. For each hospital admission
    a. Number of days spent in hospital?
    b. What was the name of the hospital?
    c. What injury did you suffer when you fell
    (A fractured hip, for example)

7. Over the last six months, have you visited hospital as an outpatient because of your difficulties in walking and going about your usual activities or because of a fall? (if you were not admitted to hospital for either of these reasons please go to question 9)

    a. Number of visits because difficulties in walking and going about your usual activities

    b. Number of visits because of a fall

8. During an average week over the past six months how much time do your family and friends spend helping you with activities that you would otherwise be able to undertake were it not for your difficulties in walking and going about your usual activities or because of a fall?

    a. Average number of hours spent per week because of difficulties in walking and going about your usual activities

    b. Average number of hours spent per week due to having fallen

Appendix M Numeric rating scale for pain when walking

Numeric rating scale for pain when walking

Q1) How much **pain** do you experience when walking? Please circle **one** number below that best describes your pain. A zero (0) would mean 'no pain' and a ten (10) would mean 'pain as bad as it could be'. Please circle only one number.

No pain	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Pain as bad as it could be

Appendix N Numeric rating scale for fear of falling when walking

Numeric rating scale for fear of falling when walking

Q1) How much **fear of falling** do you experience when walking? Please circle **one** number below that best describes your fear. A zero (0) would mean 'no fear of falling' and a ten (10) would mean 'fear of falling as bad as it could be'. Please circle only one number.

No fear of falling	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	Fear of falling as bad as it could be