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STrategies to incRease confidence InDependence and Energy (STRIDE)

Submission date	Recruitment status	[X] Prospectively registered
17/05/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/05/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Many older people have worries and concerns about falls and balance, either through having a fall or through worrying about having one. These worries are called "fear of falling". We have developed a new talking treatment which consists of cognitive behavioural therapy sessions to help people who have fear of falling. The main aim of this study is to decide whether the addition of the talking treatment, to the standard care routinely given, reduces the fear of falling.

Who can participate?
We will be asking older adults (aged 60 years and over) attending the North Tyneside Falls Prevention Service, Galleries Day Unit Washington and Falls and Syncope service RVI with significant fear of falling to participate.

What does the study involve?
Participants will be asked to complete some questionnaires and physical assessments at the initial visit. Participants will then be randomly allocated to receive either standard care or standard care plus cognitive behavioural therapy sessions. The questionnaires and physical assessments will then be repeated at 8 weeks, 6 months and 12 months after entry into the study. Participants will also be asked to record any falls they experience in a diary.

What are the possible benefits and risks of participating?
We do not know if cognitive behavioural therapy delivered on a one to one basis plus standard care is beneficial for people with a fear of falling, though it may be. However, the information we get from this study is likely to be useful for future patients with a fear of falling. The only possible risk is for participants receiving cognitive behavioural therapy to gain confidence before they are physically ready to carry out certain activities.

Where is the study run from?
Participants will be recruited from the North Tyneside Falls Prevention Service, Galleries Day Unit Washington and Falls and Syncope service RVI.. The study is being organised by Newcastle University and the Newcastle upon Tyne Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
The study will begin recruiting participants in June 2012 for about 12 months. Participants will be followed up for 12 months.

Who is funding the study?
The National Institute for Health Research (NIHR) Health Technology Assessment programme (UK).

Who is the main contact?
Dr Steve Parry via Helen Walker (Project Secretary)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11866

Study information

Scientific Title
Cognitive behavioural therapy-based intervention to reduce fear of falling in the elderly attending a community falls service. Therapy development and phase II randomised controlled trial.

Acronym

STRIDE

Study objectives
Falls cause fear, anxiety and loss of confidence resulting in activity avoidance, social isolation and increasing frailty. The umbrella term for these problems is 'fear of falling'.

In the first part of this study (MREC reference 11/NE/0090) we developed a cognitive behavioural therapy treatment package which can be delivered by Health Care Assistants. In this study (Part 2) we aim to compare in a patient randomised controlled trial; the new cognitive behavioural therapy based intervention plus usual care versus usual care alone in individuals with a fear of falling. We will measure the impact of the intervention on fall and injury rates, quality of life, social isolation and social participation. We will also look at the costs and outcomes of the intervention in this setting. We aim to recruit 412 patients from the multi-disciplinary North Tyneside Falls Prevention Service, Galleries Day Unit Washington and Falls and Syncope service RVI.

To help us to understand what works and what does not in the trial from all perspectives, researchers within the project team are going to be continuously observing the process of developing the treatment. This started in Part 1 of the study and will continue in Part 2. Interviews will be held with a subsample of patients and carers/family members, professionals involved with the treatment of patients with a fear of falling and also observations of the project development will be recorded.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/097004
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/54669/PRO-09-70-04.pdf
Further details can also be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11866

On 10/04/2014 the following changes were made to the trial record:
1. The overall trial end date was changed from 30/04/2014 to 31/01/2015.
2. The target number of participants was changed from 582 to 412.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 1 First MREC, 16/02/2012, ref: 12/NE/0006

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Age and ageing

Interventions
Cognitive behavioural therapy delivered by trained healthcare assistants.

Followed up after 12 month(s)

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Change in fear of falling as measured by the Falls Efficacy Scale International (FES-I) measured at 12 months.

Secondary outcome measures
1. Cost Effectiveness measured at 6 months and 12 months post randomisation
2. EUROHIS-QOL-8 and WHO QOL OLD measured at 8 weeks, 6 months and 12 months post randomisation
3. EuroQoL-5 Dimensions Scale measured at 8 weeks, 6 months and 12 months post randomisation
4. Falls measured throughout follow-up
5. Functional Reach measured at 8 weeks, 6 months and 12 months post randomisation
6. Hospital Anxiety & Depression Score (HADS) measured at 8 weeks, 6 months and 12 months post randomisation
7. Isometric Hand Grip Strength measured at 8 weeks, 6 months and 12 months post randomisation; Lubben Social Network Scale 6; Timepoint(s): 8 weeks, 6 months and 12 months post randomisation
8. Numeric rating scale for fear of falling when walking measured at 8 weeks, 6 months and 12 months post randomisation
9. Patient Generated Index (PGI) measured at 8 weeks, 6 months and 12 months post randomisation
10. Short Form 36 (SF-36) measured at 8 weeks, 6 months and 12 months post randomisation
11. Short Physical Performance Battery measured at 8 weeks, 6 months and 12 months post randomisation
12. Social Participation Questionnaire measured at 8 weeks, 6 months and 12 months post randomisation
13. The De Jong-Gierveld Loneliness Scale measured at 8 weeks, 6 months and 12 months post randomisation

Overall study start date

01/05/2012

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. Patient has provided written informed consent for participation in the study
2. Age 60 years and over
3. Clinically significant fear of falling as defined by a Falls Efficacy ScaleInternational Version score of greater than 23
4. Male and female participants

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 412

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

Date of first enrolment
01/06/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Victoria Infirmary
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Sponsor type
University/education

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK), ref: 09/70/04

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/06/2014		Yes	No
Results article	results	01/07/2016		Yes	No