ISRCTN41760734 https://doi.org/10.1186/ISRCTN41760734

Developing an intervention for fall related injury in dementia

Submission date
16/11/2015

Recruitment status
No longer recruiting

Registration date
16/11/2015

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People with dementia (PWD) fall over more often than people who do not have dementia. When they fall over, they are more likely to hurt themselves. They do not get better as easily as people without dementia. After hurting themselves PWD may need a lot more help in looking after themselves. They may need to move to a care home. They and their carer may not have such a good quality of life after the fall. The NHS and social services find it is expensive to look after people with these injuries. We know that injuries cause many problems for PWD, but we do not really know the best way to look after them. This is because there are very few examples of research in this area. Each person is likely to have many different needs, but at the moment, we do not know what these needs are, or how we can meet these needs within the NHS. For instance, would it be better to have a specialist team to look after PWD who fall, or would it be better to invest in education for all staff looking after PWD in the community? We also do not know what is most important to PWD after a fall. For instance, is it more important that they can start walking quickly, or do they need to feel confident that they will not fall again? However we approach this problem, it is important to show that the approach actually works and is good value for money. We do this by carrying out a clinical trial. In this study, we plan to do the background research needed to make sure that we design a trial that has a good chance of being successful.

Who can participate?
People with dementia who live in the community and who have sustained a fall-related injury, and the carers and professionals who care for them.

What does the study involve?
In the first part of the study, the researchers search for previous studies to find out what PWD need after a fall. In the second part of the study, the researchers keep a record of every PWD who sees their GP, calls an ambulance or goes to hospital because they have hurt themselves in a fall in Newcastle, Stockton and Norwich. They check these people's records to find out if they were kept in hospital or referred to a clinic. They ask some people in each place to keep a detailed diary of all the help they had from the NHS and social services. They then ask if we can interview them and their carers to find out what help they needed after the fall. In the third part of the study, the researchers ask a group of experts, PWD and their carers to look at the things

they found out in the first two parts of the study. They ask them whether they think it is likely that they will find enough people to take part in a clinical trial and where it would be best to do it. For example, should they ask the ambulance staff to find the PWD for the trial, or should they do it at the hospital? They ask them about what sort of help people would need and how they should measure whether the PWD got better. In the fourth part of the study, the researchers practice doing the things that the expert group decided they should do. This is with just 15 people in each town and is a practice to smooth out any problems before doing the full trial. The aim is to find out how to cope with any practical problems that would make the trial difficult. They also ask the PWD, their carers and the staff looking after them whether they had any problems taking part.

What are the possible benefits and risks of participating?
At the end of the study, we will be able to say whether it is a good idea to have a full clinical trial of how to improve what happens for PWD who hurt themselves in a fall. If it is, we will be able to recommend how the trial should be done.

Where is the study run from?
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2015 to August 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Louise Allan (louise.allan@ncl.ac.uk)
Mrs Beth Edgar (beth.edgar@ncl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Louise Allan

ORCID ID
https://orcid.org/0000-0002-8912-4901

Contact details
Institute of Neuroscience
Newcastle University
Biomedical Research Building
Campus for Ageing and Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL
+44 (0)191 208 1336
louise.allan@ncl.ac.uk

Type(s)
Public

Contact name
Mrs Beth Edgar

Contact details
Institute of Neuroscience
Newcastle University
Biomedical Research Building
Campus for Ageing and Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL
+44 (0)191 208 1314
beth.edgar@ncl.ac.uk

Additional identifiers

Protocol serial number
HTA 13/78/02

Study information

Scientific Title
Is it possible to develop a complex intervention to improve the outcome of fall-related injuries in people with dementia?

Acronym
DIFRID

Study objectives
The overall aim of this study is to assess through a series of work packages (WPs) whether it is possible to design a complex intervention to improve the outcome of fall-related injuries in people with dementia living in their own homes.
The health technology to be assessed in this project is a complex intervention and is at the earliest stage of development described in the MRC guidance on developing and evaluating complex interventions. People with dementia who sustain fall-related injuries currently receive a range of health interventions, but a single model of care in the form of a complex intervention for this specific situation has not previously been described and the potential demand for such an intervention is not known. We have taken the approach that in order to develop a new, person-centred and effective complex intervention for this group of patients, we must first be able to answer the following research questions.
1. What are the health and social care needs of patients and carers which must be addressed by the complex intervention?
2. What is the likely demand for the complex intervention?
3. What are the health and social care interventions already being received by patients and carers (i.e., what is usual care)?
4. What are the best available ideas for a new complex intervention (from the perspectives of all stakeholders)?

5. What are the outcomes of importance which the complex intervention must influence (from the perspectives of all stakeholders)?
6. How should changes in these outcomes be measured with respect to clinical effectiveness and cost-effectiveness and have these been measured in any previous studies?

More details can be found here: http://www.nets.nihr.ac.uk/projects/hta/137802

Ethics approval required
Old ethics approval format

Ethics approval(s)
Service observation:
North East: Newcastle and North Tyneside 2 Research Ethics Committee, 22/01/2016, ref: 15/NE/0397

Main study:
North East: Newcastle and North Tyneside 2 Research Ethics Committee, 22/03/2016, ref: 16/NE/0011

Study design
Observational longitudinal study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improving the outcomes of fall-related injuries in dementia

Interventions
This is a feasibility study which aims to design and test the feasibility of a complex intervention

Work package 1: We will use established methods of systematic review to identify empirical evidence regarding the health and social care needs of people with dementia with fall-related injuries, outcomes of importance to patients, carers and professionals and comparative studies providing evidence on the relative effectiveness and cost effectiveness of interventions.

Work package 2: We will use both quantitative and qualitative methods in an observational study, which will describe current models of usual care and identify how the models might be adapted in a complex intervention package.

Work package 3: We will convene a consensus panel to review the findings of the prior work packages. The recommendations of the panel regarding the design of the intervention will be assimilated using methods of the RAND Nominal Group Technique (NGT-R, also known as the modified Delphi panel approach).

Work package 4: We will test the procedures for implementation of the intervention and measurement of outcomes recommended in WP3, in the form of a pre-trial evaluation. We will test the feasibility of delivery of the intervention within present NHS structures, and test acceptability, adherence to delivery of the intervention and outcome measurement.

Intervention Type
Mixed

Primary outcome(s)
The establishment of the best primary outcome measure for this group of patients is one of the research questions

Key secondary outcome(s))
The establishment of the best secondary outcome measures for this group of patients is one of the research questions

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. People with a known diagnosis of dementia who live in the community, and who present to health services having sustained a fall-related injury
2. People who care for those with a known diagnosis of dementia who live in the community, and who present to health services having sustained a fall-related injury
3. Professionals who care for those with a known diagnosis of dementia who live in the community, and who present to health services having sustained a fall-related injury

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
115

Key exclusion criteria
1. Not living in the community
2. The diagnosis of dementia cannot be established within 72 hours

Date of first enrolment
01/11/2015

Date of final enrolment

31/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle upon Tyne Hospitals NHS Trust
Biomedical Research Building
Campus for Ageing and Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
United Kingdom
TS19 8PE

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
United Kingdom
NR4 7UY

Sponsor information

Organisation
Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the trialists have not obtained consent from the individual participants for their data to be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	30/10/2019	Yes	No
Protocol article	protocol	10/11/2018		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	Intervention development	28/02/2019	29/11/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes