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Occupational therapy in homecare re-ablement services

Submission date	Recruitment status	[X] Prospectively registered
20/03/2014	No longer recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
31/03/2014	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
22/02/2018	Other	

Plain English summary of protocol

Background and study aims
Homecare re-ablement services help people to manage activities at home such as getting washed or dressed or preparing meals. They aim to help people regain skills they may have lost due to illness, injury or having been in hospital. Occupational therapists provide support for people to do activities they need or want to do. In homecare re-ablement services, occupational therapists assess how the person is managing at home and identify any support they may need to manage everyday tasks more easily. This may involve providing equipment or making suggestions for changing the way an activity is carried out. Some people who receive homecare re-ablement services are treated routinely by an occupational therapist. Other people do not receive input from an occupational therapist and instead are supported by homecare re-ablement staff. We do not know which of these options is best. We are carrying out a study to compare a group who receive occupational therapy as part of their homecare re-ablement with another group who do not.

Who can participate?
People using homecare re-ablement service can participate in this study.

What does the study involve?
Participants in this study will be randomly allocated into one of two groups (i.e. by chance). There is a 50% chance of being in either group. One group will receive the usual homecare re-ablement service provided, which usually lasts for six weeks. The other group will receive the usual treatment above but will also receive an occupational therapy programme within the re-ablement service. This programme will cover a range of areas to help them to do the things they wish to do on a daily basis. The occupational therapist will visit them regularly and may also provide equipment to help with their daily activities. People in both groups will complete initial assessments at the start of the study. They will also receive three follow-up visits which will take place at 2 weeks, 3 months and 6 months after finishing with the re-ablement service. These visits will be conducted by a member of the research team and will focus on the participants general health, ability to manage activities, emotional and physical abilities.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. However, the information we obtain from the

study should help us determine how to organise homecare re-ablement services in the future. The study also aims to help NHS and Social Care staff best use the resources available to them when treating people in their own homes. We do not anticipate that there are any serious risks involved in taking part. Some of the questions we need to ask will focus on activities such as washing, dressing and going to the toilet and there is a possibility that some people may find these questions upsetting or intrusive.

Where is the study run from?
This study is being run by The University of Nottingham and will take place within Nottingham City, UK.

When is the study starting and how long is it expected to run for?
The study will commence in April 2014 and will recruit participants for up to eight months.

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

Who is the main contact?
Mr Phillip Whitehead
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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

13005

Study information

Scientific Title
Can an occupational therapy intervention increase independence in activities of daily living for people who use homecare re-ablement services?

Acronym
OTHERS

Study objectives
1. It is hypothesised that a randomised controlled trial of an enhanced occupational therapy programme delivered to homecare re-ablement service users will be feasible and acceptable.
2. It is hypothesised that this intervention will improve the ability of homecare re-ablement service users to carry out activities of daily living (ADL) independently.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Social Care Research Ethics Committee, 06/03/2013, 13-IEC08-0002

Study design
Single-centre feasibility randomised controlled trial. Randomisation to parallel groups in random varying block sizes via web-based randomisation. Outcome assessor will be masked to allocation.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Homecare

Interventions
Control: Usual homecare re-ablement. Those randomised to the control group will receive the usual routine care provided by the homecare re-ablement service i.e. a six week period of homecare re-ablement provided by re-ablement workers, under the direction of a re-ablement

care team leader. The control group will not routinely receive specialist ADL assessment and intervention, or routinely access community equipment or minor adaptations provided by an occupational therapist as part of their re-ablement package. This is standard practice at the trial site.

Intervention: Enhanced occupational therapy programme. Those randomised to the intervention group will receive all routine homecare re-ablement services but, in addition, will receive an enhanced programme targeted at activities of daily living (ADL), delivered by an occupational therapist. The aim of the enhanced programme will be to maximise independence in ADL activities. A programme will be agreed with the participant which will be tailored to the needs of each individual but will include: practising activities, and/or a graded process of re-learning and building the skills to manage ADL independently; equipment provision; and environmental or activity modification. A case management approach will be adopted by the occupational therapist involving a minimum of weekly reviews and the co-ordination of aspects of the re-ablement episode and other services. Advice and information will also be provided to family members or carers.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Determination of the feasibility of conducting a larger, appropriately powered trial. The assessment of feasibility will be a composite measure of recruitment, retention, acceptability and the viability of delivering the intervention. Key aspects to be addressed are: whether the eligibility criteria are realistic; whether service users are willing to be randomised; the dropout rate; the content and scheduling of the occupational therapy treatment visits; the acceptability of the occupational therapy intervention; the most suitable primary outcome measure for the main study; the feasibility of the cost data collection.

Secondary outcome measures
The outcomes to be assessed will be:
1. Performance in personal and extended activities of daily living
2. Health and social care related quality of life
3. Number of care support hours
4. Health and social care service usage, and carer strain.

Measured by Barthel Index, Nottingham Extended Activities of Daily Living (NEADL), Short-Form 36, Adult Social Care Outcomes Toolkit (ASCOT), Euroquol EQ5D, Caregiver Strain Index (CSI). Additionally, information will be collected on: number of homecare hours, falls, admissions (to acute and residential services), and use and costs of health and community services. Acceptability of the intervention will be evaluated using a purposely designed questionnaire and qualitative interviews.

The outcomes will be measured at baseline, 2 weeks, 3 months and 6 months after the intervention has ended.

Overall study start date
01/04/2014

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. Homecare re-ablement service user
2. Able to provide informed written consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
This feasibility trial will recruit a maximum of 50 participants.

Key exclusion criteria
1. Unable to speak English
2. Receiving end of life care
3. Needing assistance of two or more people to transfer

Date of first enrolment
01/04/2014

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research & Graduate Services
King's Meadow Campus
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Doctoral Research Fellowship, DRF-2012-05-131

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	19/11/2014		Yes	No

Results article	results	16/08/2016	Yes	No