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A cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care-homes

Submission date
17/10/2009

Recruitment status
No longer recruiting

Registration date
21/10/2009

Overall study status
Completed

Last Edited
02/03/2016

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
This 4 year-long study is being carried out to assess the value of providing a targeted course of occupational therapy to people living in a residential or nursing home after stroke. This service has been found to be of value to people living in their own homes, and to people after a stroke. It has been found to be helpful in terms of improving their independence, their ability to take part in everyday activities, and their mobility. However, occupational therapy is less readily available to people living in residential or nursing homes.

Who can participate?
Residents of care/residential homes of any age, with a history of stroke or transient ischaemic attack (TIA).

What does the study involve?
All the homes that participate in the study will either receive the service of an occupational therapist or not for a three month period (on top of any services the home currently receives). If the participant decides to take part, he/she will be assessed four times-at 0 months, 3 months, 6 months and finally at 12 months. The participant may be seen by an occupational therapist, who will deliver therapy according to his/her needs. The assessments will ask the participant various questions about his/her day to day activities. The initial assessments will also look at his /her communication and clarity of thought.
The therapists providing the service will ask the participant their ability to take part in day to day activities and, if the therapist feels that he/she can help the participant to keep their mobility and or prevent them from losing their independence, they will suggest one of a number of things to help. This may include:
1. Providing a piece of equipment or adapting something (such as raising the height of their chair)
Providing advice
2. Providing activities, which he/she will practice with the participant and ask him/her to continue to practice between visits
3. Providing exercises for him/her to practice.

The therapists will arrange a time that is convenient for the participant and this will not restrict their lifestyle in any way. The therapists providing the therapy would be visiting the care/nursing home for about 3 months, but as an individual the participant may only be seen a few times (depending on his/her needs).

What are the possible benefits and risks of participating?
It is hoped that we can show that the services of an occupational therapist would be helpful to people living in either residential or nursing homes after a stroke. However, this cannot be guaranteed. The information collected from this study may help us to assist people participate in day to day activities more easily and maintain this ability for a longer period of time. The services of an occupational therapist are not thought to put individuals at risk. The therapists would not ask the participant to do things that they don't want to and they are free to stop at any time. At worst, the services the therapist offers may not have any measurable benefits.

Where is the study run from?
University of Birmingham at the Primary Care Clinical Research & Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2010 to February 2013

Who is funding the study?
NIHR - Health Technology Assessment (HTA) (UK)

Who is the main contact?
Prof. Catherine Sackley
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/14/30

Study information

Scientific Title
A cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care-homes

Acronym
OTCH

Study objectives
The purpose of the study is to conduct a phase III randomised controlled trial (RCT) to evaluate the effects of a targeted course of occupational therapy (targeted repetitive training of activities of daily living, provision of adaptive equipment and minor environmental adaptations and staff training) for people with stroke living in a care home.

In particular, the effects on:
1. Independence in self-care activities of daily living
2. Mobility

Adverse events will be recorded.
An economic evaluation will be conducted

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081430
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/52361/PRO-08-14-30.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted via Integrated Research Application System (IRAS) on 07/10/2009 (ref: 09/H1210/88). Approval pending as of 17/10/2009.

Study design
Pragmatic phase III cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Stroke rehabilitation

Interventions
This is a pragmatic phase III cluster randomised controlled trial with independent assessment. Randomisation will be conducted by the Clinical Trials Unit (CTU) and only revealed to the treating occupational therapist.

Occupational therapy is delivered to patients after stroke to improve self care independence, activity and reduce the risk of poor outcome. A package of occupational therapy intervention for a care home population has been developed using evidence and consensus and will be delivered by a qualified occupational therapist to both the individual resident and the care home staff. It will be targeted towards improving independence in personal activities of daily living such as; feeding, dressing, toileting, bathing, transferring and mobilising. The frequency and duration will be dependent on the resident and therapist's agreed goals and will be around 8 hours per resident over the three-month period. Occupational therapy will follow a routine process using a 'client centred approach' and will include a continuous process of assessment, treatment and reassessment. Affordable assistive technology and home adaptations (mean expenditure - from pilot £120) will be provided, consistent with current NHS and local authority social care. Staff will receive individual training and group education sessions on facilitating independence and mobility and the use of adaptive equipment, a description of which has been published.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Independence in activities of daily living, assessed using the Barthel Activity of Daily Living Index, a commonly used measure (toileting, dressing, feeding, continence, mobility and grooming) containing 10 items and scored from 0-20 (with 20 being more independent)

All primary and secondary outcome measures will be assessed at baseline (0 months), after the intervention (3 months) and at follow-up (6 and 12 months).

Secondary outcome measures
1. Rivermead Mobility Index (RMI), a 15 item measure of functional mobility (scored 0-15, 15 being more mobile)
2. Mood, assessed by a 15-item Geriatric Depression Scale (GDS15), and informant version
3. Adverse events
4. Staff attitude
5. Health utility will be estimated using the Euroqol EQ-5D

All primary and secondary outcome measures will be assessed at baseline (0 months), after the intervention (3 months) and at follow-up (6 and 12 months).

In addition, the Mini-Mental State Examination (MMSE) will be used at baseline to determine the level of a resident's cognitive impairment; not as an exclusion criterion.

Overall study start date
01/01/2010

Completion date
28/02/2013

Eligibility

Key inclusion criteria
Adult men and women living in a care home with a history of stroke or transient ischaemic attack (TIA)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
840

Key exclusion criteria
Active end of life care plan

Date of first enrolment
01/01/2010

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Research and Commercial Services
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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	09/07/2012		Yes	No
Results article	results	05/02/2015		Yes	No
Results article	results	01/02/2016		Yes	No