ISRCTN58683841 https://doi.org/10.1186/ISRCTN58683841

Getting Out of The House: a multicentre trial to evaluate an outdoor mobility intervention for people who have had a stroke

Submission date
30/01/2009

Recruitment status
No longer recruiting

Registration date
09/02/2009

Overall study status
Completed

Last Edited
05/12/2017

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
A stroke is a serious, life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. Stroke can have a devastating effect on people's lives, with half of survivors being dependent on others six months later, one third feeling socially isolated, and half not getting out of their houses as much as they would like. The number of people living in the community after having a stroke is set to rise over the forthcoming decades, and the cost of stroke to the NHS is estimated to be over £2.5 billion per year. It is important therefore that new interventions are demonstrated to be good value for money before they are implemented. Research has shown that people living at home with stroke have felt neglected, not been given the correct information and received patchy levels of rehabilitation. Being able to get out of the house is an important rehabilitation target after stroke as it improves psychological and functional outcomes. A new outdoor mobility rehabilitation intervention has been developed and tested in one UK city. The study found that people who had received the new intervention, which involved the patient practicing outside with a therapist, were twice as likely to go out afterwards as those who had received the routine rehabilitation programme. The routine programme was verbal advice and written information. However, the study was undertaken in only one city and used only one therapist to provide the new programme. We now wish to find out if this new type of rehabilitation can have a similar positive affect on the quality of life for people in other areas, with other therapists, and whether it is a cost effective intervention.

Who can participate?
Patients aged 18 or over who had a stroke at least six weeks ago.

What does the study involve?
Participants are randomly allocated into one of two groups: the intervention group or the control group. Those who are in the intervention group are assessed by a therapist and mobility goals are set together. Over a series of about six treatment sessions the therapist works with the participant to realize the goals. This could be getting on and off a bus or walking to a friend's house. Those in the control group receive the routine intervention of verbal and written advice. The intervention is considered a success if we are able to show that intervention participants

have a better quality of life than the control participants six months after recruitment. Quality of life, mobility, activities of daily living, mood, home care use, hospital admissions and attendance at the GP are assessed with questionnaires. To collect this information mobility diaries are sent monthly and questionnaires six and twelve months after recruitment. In addition an independent assessor visits the participant at home, collects any outstanding assessments and carries out a mobility assessment. The results from the assessments are used to compare the outcomes for both groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Queens Medical Centre (UK)

When is the study starting and how long is it expected to run for?
August 2009 to July 2012

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Pip Logan
pip.logan@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Pip Logan

Contact details
B98, Community Health Sciences
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH
-
pip.logan@nottingham.ac.uk

Additional identifiers

Protocol serial number
HTA 08/14/51

Study information

Scientific Title

A multicentre randomised controlled trial of rehabilitation aimed at improving outdoor mobility for people who have had a stroke

Acronym
TOMAS (Trial of Outdoor Mobility After Stroke)

Study objectives
What is the clinical effectiveness and cost effectiveness of treating outdoor mobility limitations after stroke with a novel targeted rehabilitation therapy intervention?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081451
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/52371/PRO-08-14-51.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee (REC) 1, 15/06/2009, ref: 09/H0403/55

Primary study design
Interventional

Study design
Multicentre parallel-group individually randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
A novel rehabilitation technique (intervention) group will be compared to a usual care (control) group:

Intervention group:
Specifically designed outdoor mobility training and practice with a skilled health professional. Intervention group participants will receive up to 7 rehabilitation outdoor mobility sessions of about an hour each over 4 months. The main component of the intervention is that therapists go repeatedly with patients to try outdoor mobility, including buses, taxis, walking, voluntary drivers and mobility scooters until they feel confident to go alone or with a companion.

Control group:
Standard verbal and written information about outdoor mobility from a skilled health professional. Control Group participants will receive what is considered clinically to be routine intervention for outdoor mobility limitations. That is, verbal advice and provision of leaflets provided over one 1-hour session.

Intervention Type

Behavioural

Primary outcome(s)
Social Function domain of the health related quality of life measure SF-36v2™ Health Survey at 6 months.

Key secondary outcome(s)
The following will be assessed at 6 and 12 months:
1. Functional ability, measured by the Nottingham Extended Activities of Daily Living Scale
2. Mobility using the Rivermead Mobility Index
3. Modified 15/09/09: The number of journeys (travel diaries) - was previously: The number and duration of journeys from the travel diaries
4. Satisfaction with outdoor mobility, assessed using one yes/no question: "Do you get out of the house as much as you would like?"
5. Mood, using the General Health Questionnaire 12
6. Carer psychological distress, measured using the General Health Questionnaire 12pt
7. EuroQol EQ-5D
8. Resource use of health and social care
9. Provision of equipment
10. Participant mortality will be collected from medical records

Completion date
31/07/2012

Eligibility

Key inclusion criteria
Amended as of 12/03/2010:
Point 2 below has been amended to read as follows:
2. At least six weeks since stroke

Amended as of 15/09/2009:
1. Age 18 years or over
2. At least six weeks but no longer than five years since stroke
3. Wishing to get out of the house more often
4. The participant must give informed consent before completing any study-related procedure, which means any assessment or evaluation that would not have formed part of their normal care.

Amended as of 13/07/2009:
1. Aged 18 years or over, either sex
2. At least six weeks but no longer than five years since stroke
3. Wishing to get out of the house more often
4. Able to comply with the requirements of the protocol and therapy programme
5. The participant must give informed consent before completing any study-related procedure, which means any assessment or evaluation that would not have formed part of their normal care

Initial information at time of registration:
1. Both males and females, aged 18 years or over
2. At least six weeks since stroke
3. Wishing to get out of the house more often
4. Able to comply with the requirements of the protocol and therapy programme

5. The participant or legal representative must give informed consent before completing any study-related procedure, which means any assessment or evaluation that would not have formed part of their normal care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Amended as of 15/09/2009:
1. Not able to comply with the requirements of the protocol and therapy programme, in the opinion of the assessor
2. Still in post-stroke intermediate care or active rehabilitation
3. Previous enrolment in this study

Amended as of 13/07/2009:
1. Significant cognitive impairment which will impede ability to complete the assessments
2. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. terminal illness
3. Still in post-stroke intermediate care or active rehabilitation
4. Previous enrolment in this study

Initial information at time of registration:
1. Significant cognitive impairment which will impede ability to complete the assessments
2. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. terminal illness
3. Previous enrolment in this study

Date of first enrolment
01/08/2009

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014		Yes	No
Protocol article	protocol	21/06/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes