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A feasibility study of a self-management stroke management programme

Submission date
23/02/2012

Recruitment status
No longer recruiting

Registration date
23/02/2012

Overall study status
Completed

Last Edited
08/01/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Stroke affects people in different ways. It can lead to difficulties with communication, mobility and other aspects of life such as memory and concentration. Over a third of people who have a stroke have a long-term disability and some can experience reduced quality of life. We know that despite improvements in stroke care, some people do not feel prepared to cope with the experience of living with stroke particularly after rehabilitation stops. Self management programmes (SMPs) have been successful for people with arthritis or diabetes, but the value for people with stroke is not known. SMPs consist of working in groups or one to one with a healthcare professional to build confidence with independent activities such as setting small goals, planning daily tasks, getting into the community. A SMP delivered by health professionals on a one-to-one basis with stroke survivors has been developed. It is introduced after discharge from hospital during rehabilitation at home. A patient held workbook is used to record progress and learn about ways to manage. The evidence suggests patients view the programme positively and find the workbook helpful in planning future goals and progress.
We aim to test if the SMP can be used within stroke rehabilitation, so healthcare professionals can use it as part of their normal practice. This could be a more efficient way of delivering the SMP and encourage professionals to work together with patients to set goals and plan activities when rehabilitation stops. We will evaluate if the SMP is acceptable to patients, carers and community stroke teams, cost effective and has any impact on quality of life.

Who can participate?
Patients will be eligible to take part if they: have a confirmed diagnosis of stroke, can follow a two-stage command and can read simple text and/or have a carer or supporter to assist.

What does the study involve?
You will continue to receive your same rehabilitation within the community setting. If you participate in this study you will be assessed at three different time points (2 weeks, 6 weeks and 3 months after starting your rehabilitation). During these assessments you will be asked to complete a questionnaire about different aspects of living with a stroke; a researcher will support you to do this. You may also be asked to take part in an interview to find out about your experiences of rehabilitation. There may also be an occasion when the researcher will observe one of your rehabilitation sessions with your therapist. This will not change your treatment in

anyway and will be done with the full consent of you and the therapist. We would also request your permission to gather details of your medical history and care needs since your stroke. With your permission a letter will be sent to your GP informing them of your involvement in the study. Participants will be randomly allocated to one of two groups: the active group or the control group. If you are in the control group you will receive your usual rehabilitation. If you are in the active group you will receive your usual rehabilitation but this will include one to one time with the stroke team to work with the workbook to help your self-management.

What are the possible benefits and risks of participating?
Participants in the intervention group will receive a copy of the patient held workbook, and their interactions with clinicians will be more focused on the development of self-management skills. Patients in the control group will be given a copy of the workbook after the study has completed. Participants in the intervention arm will be receiving the stroke self-management programme as part of their usual care, so they should not note any undue change in treatment.

Where is the study run from?
St Georges University of London, Cranmer Terrace, London, UK.

When is study starting and how long is it expected to run for?
February 2012 to December 2013.

Who is funding the study?
This study is funded by the NIHR Research for Patient Benefit Programme (RfPB).

Who is the main contact?
Dr Fiona Jones
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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
11167

Study information

Scientific Title
A feasibility study of a stroke self management programme (SMP): a cluster randomised controlled trial

Study objectives
This study is designed to determine feasibility of integrating and evaluating the delivery of an SMP included within a stroke rehabilitation programme. This study will inform the next stage of research which will test the clinical effectiveness of the SMP in a fully powered cluster randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11L01450

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Self management programme - workbook helping with collborative goal setting

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Stroke and Aphasia Quality of life (SAQOL) scale

Secondary outcome measures
1. Nottingham Extended Activities of Daily Living Scale (NEADL)
2. The Stroke Self-Efficacy Questionnaire (SSEQ)
3. The Hospital Anxiety and Depression Scale (HAD)
4. The Short form 12 (SF12)
5. Qualitative Evaluation:
There will be an embedded process evaluation to assess fidelity, quality and feasibility of implementation of the SMP, clarify causal mechanisms, and identify contextual factors associated with variation in outcomes to include:
5.1. Patients in intervention clusters will be interviewed to explore their perceptions and experiences of using the SMP
5.2. Patients in control sites will be interviewed at the same time point to explore their experiences of rehabilitation and how they have been supported to self-manage
5.3. Carers or supporters of stroke participants in both intervention and control clusters will be interviewed to explore perceptions of how their partner/friend has been assisted to self-manage either through using the SMP (intervention site) or through usual rehabilitation
5.4. Clinicians in intervention clusters will be interviewed in focus groups at the end of the trial to explore; key components barriers and enablers to using the SMP as part of current rehabilitation
5.5. Clinicians at control sites will be interviewed in focus groups to explore attitudes and beliefs about current practice and how they support self-management.
6. Economic evaluation:
This will focus primarily on resource implications of the integrated SMP, calculating:
6.1. The cost of integrating SMP
6.2. The impact of SMP on service utilisation in the 3 months rehabilitation period post stroke

Overall study start date
01/05/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Team:
Community stroke teams are eligible to take part if they:
1. Receive a regular number of stroke referrals (equivalent to number of referrals in previous pilot work) and contain
team members with recognised stroke expertise
2. Where possible have not taken part in any previous training in self management e.g. Bridges /Gaining confidence after
stroe

Patient:
Patients will be eligible to take part if they have a confirmed diagnosis of stroke, can follow a two stage commandcan read simple text and/or have a carer or supported to assist The patient held stroke workbook is used as an adjunct to the SMP. Previous research has reported the workbook is
problematic if a participant is unable to read or follow a twostage
command, particularly if there is supporter.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 80

Key exclusion criteria
Decisions to exclude participants will be made with
the cluster guardian in consultataion with a speech and language therapist or psychologist of participating teams.

Date of first enrolment
01/05/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's University of London (UK)

Sponsor details
Centre for Clinical Neuroscience
Cranmer Terrace
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Sponsor type
University/education

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

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Research for Patient Benefit Programme (RfPB)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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?
Results article	results	06/01/2016		Yes	No