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Investigating the feasibility of a group self-management program after stroke

Submission date
15/12/2016

Recruitment status
No longer recruiting

Registration date
20/12/2016

Overall study status
Completed

Last Edited
24/05/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is impaired mobility due to weakness or paralysis on one side of the body. In order to regain mobility, extensive physiotherapy is required, however many patients only receive this for a short time. There is therefore a need to better support stroke survivors with the long-term management of their condition. One way to address this need would be through self-management programmes. Self-management provides a set of techniques to help stroke survivors successfully manage different aspects of their condition. Bridges is a one-to-one self-management programme which is used within the NHS. Importantly, it can increase a person' s belief in their own ability to manage their stroke. Before a properly designed clinical trial to investigate whether group self-management training works for stroke survivors can be done, it is important to find out whether it is feasible – in other words whether it would be possible to conduct a larger research project of group self-management post stroke. The aim of this study is to test the feasibility of delivering a self-management programme called the Bridges self-management programme to stroke survivors.

Who can participate?
Adults who have had a stroke and have been discharged from community rehabilitation services.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the Bridges self-management programme immediately. This involves two-hourly sessions once a week for four weeks. The programme is delivered by trained facilitators and takes place in groups of 5-8 stroke patients. It is made up of content such as problem solving, reflection and future hopes. Each participant receives a work book to work through during the programme. Those in the second group receive the programme after six months of being on a waiting list. At the start of the study and then after the programme (four weeks), two weeks later and six months later, participants in both groups are followed up in order to assess their quality of life,

self-efficiency, mood and activities of daily living. The acceptability of the programme is also assessed through follow up interviews with participants.

What are the possible benefits and risks of participating?
Current evidence suggests self-management programmes may improve quality of life in stroke survivors, as well as build confidence. No effects are evidenced for this particular programme as it is new. However, similar effects have been found in group self-management programmes for other conditions so may be found for those taking part in this study. A group programme will also enable participants to meet other peers in similar positions. As there are no risks reported from the one-to-one programme or group self-management programmes and so this study is considered minimal risk.

Where is the study run from?
Hyper Acute Stroke Survivor in University College London Hospitals (UK)

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

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

Who is the main contact?
Miss Ella Clark
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19817

Study information

Scientific Title
Is it feasible to deliver a group self-management programme for stroke survivors? Exploring changes in outcomes as compared to a waitlist control group and pre-post intervention in quality of life, self-efficacy, activities of daily living and self-efficacy as well as qualitative outcomes

Acronym
GUSTO

Study objectives
The aim of this study is to evaluate whether it is feasible to deliver the Bridges self-management programme in a group setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside 1, 07/10/2015, ref: 15/NE/0341

Study design
Randomised; Interventional; Design type: Process of Care, Education or Self-Management

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Stroke, Primary sub-specialty: Rehabilitation

Interventions
Eligible participants will be randomised to either the intervention or the wait-list control group by the
projects statistician. Due to the nature of the study it is not possible to blind participants to the condition they are in, but those in the control group will receive the intervention after a delay.

Individuals randomised to the intervention group will complete the intervention as soon as they are enrolled. The intervention involves a group self-management programme (GSMP) for stroke based on Bridges. The GSMP will provide individuals with a range of SM tools they can apply to their own lives in order to enable better management of stroke. Each participant will receive a Bridges work book (available through http:// www.bridgesselfmanagement.org.uk/). Key components of Bridges make up the content such as problem solving, reflection and future hopes. The intervention is delivered in groups of 5-8 face-to-face by one stroke facilitator, one speech and language therapist and one facilitator trained in Bridges in community venues as local to participants as possible. The programme runs once a week for four weeks. Each session lasts two hours and includes a break in the middle. The intervention will be personalised with each individual. For example goals being set by the individuals to ensure they are tailored. Groups will be observed by an impartial observer and linked to core Bridges principles to enable researchers to see how closely they adhered to the design.

Participants will complete baseline measures before the intervention starts. Once they finish the intervention they will complete outcome measures at three time points; at the end of intervention, and then at 2-weeks and 6-months post intervention.

The waitlist control group will not receive any interaction with the research team during a 6-month wait period. They will continue to engage with standard practice as they would if not taking part in research. They will complete baseline measures at the start and the end of the waitlist period (prior to the intervention). Once the wait period is complete they will take part in the intervention. Outcome measures for this group will be completed at the end of the intervention and again at two weeks post intervention.

Intervention Type
Other

Primary outcome measure
Quantitative outcomes:
1. Quality of life is measured using the stroke and aphasia quality of life scale at end of the waitlist period (if applicable), end of intervention as well at 2 weeks and 6 months (intervention group only) post intervention
2. Self-efficacy is measured using the Stroke Self-efficacy Scale at end of the waitlist period (if applicable), end of intervention as well at 2 weeks and 6 months (intervention group only) post intervention
3. Mood measured using the Hospital Anxiety and Depression Scale at end of the waitlist period (if applicable), end of intervention as well at 2 weeks and 6 months (intervention group only) post intervention
4. Activities of daily living measured using the Nottingham Activities of Daily Living Scale at end of the waitlist period (if applicable), end of intervention as well at 2 weeks and 6 months (intervention group only) post intervention

Feasibility outcomes:
1. SAQoL variability is assessed at baseline and end of the waitlist period (if applicable), end of intervention as well at 2 weeks and 6 months (intervention group only) post intervention
2. Attrition is assessed using session attendance logs kept throughout the trial period
3. Eligibility rate is assessed using recruitment logs during the recruitment period.
4. Follow up completion rate is assessed by recording the number of participants who complete all follow up measures at the end of the trial
5. Willingness of participants to be randomised is assessed using interviews post intervention.

Qualitative outcomes:
Acceptability and mechanisms of change are measured using interviews and focus groups which take place in the community.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2015

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of stroke
2. Able to understand a 2-stage command either verbally or non-verbally
3. Able to understand English
4. At least 18 years' old
5. Discharged from community rehabilitation services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Any previous access or support from Bridges self-management programme
2. Severe aphasia and unable to understand a 2 stage command
3. Severe comorbidities such as malignancy or unstable cardiovascular condition
4. Clinically depressed
5. Unable to understand English and no family supporter/friend available

Date of first enrolment
01/04/2015

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hyper Acute Stroke Survivor in University College London Hospitals
Floor 7
235 Euston Road
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research

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
Results will be published in late 2018. Participants will be given a copy of the findings.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to data protection and ethical approval terms.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/01/2018		Yes	No
HRA research summary			28/06/2023	No	No