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“My Life After Stroke” - a feasibility study

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
22/03/2017

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Circulatory System

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

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). Survivors of stroke report many long term problems. They often feel abandoned after hospital, are unhappy with follow-up care and want more information about many aspects of stroke and stroke care. “My Life After Stroke” (MLAS) has been developed with help from stroke survivors, their carers, healthcare professionals and support groups to help address these problems. MLAS aims to help stroke survivors and their carers be better informed about stroke, help them cope with its effects, and reduce the risk of further strokes. MLAS is part of a larger research programme developing community primary care services for stroke survivors to support them and their informal carers. The aim of this study is to test the acceptability and feasibility of MLAS for stroke survivors.

Who can participate?
Stroke survivors aged 18 and over, and their carers

What does the study involve?
Participants are invited to take part in the MLAS programme. This consists of attending two individual appointments and four weekly group-based sessions covering topics of managing health, problem-solving, social needs and emotional issues. Two trained facilitators run these sessions and the researchers sit in to observe how the sessions are run. At the end of the programme participants and their carers are invited to a feedback session to give their opinions about the programme and how it can be improved. Throughout the study, information about how many participants take part and how many stay in the study until the end is recorded.

What are the possible benefits and risks of participating?
It is not known yet if there is a specific benefit of taking part in this study. It is hoped that attending the My Life After Stroke course helps build confidence. My Life After Stroke provides an opportunity to find out more information, and to gain support from others in the group sessions. The course aims to help participants find solutions to, or ways of managing, a specific problem related to stroke. Results from the questionnaires may help to monitor recovery. Information gained from this study may help to improve treatment and services in the future for people who have had a stroke. The results of this study will also inform a larger research study. There are no specific disadvantages or risks. On the course, participants are invited to share their

stories, and can say as much or as little as they would like during the course. There may be times that emotions are talked about. Talking about emotions could upset some people. If this happens, the session may be paused, and participants are free to leave any session at any point.

Where is the study run from?
Up to 4 GP practices within Leicester, Leicestershire & Rutland and Cambridgeshire (UK)

When is the study starting and how long is it expected to run for?
April 2016 to December 2017

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

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
33562

Study information

Scientific Title
“My Life After Stroke” - a feasibility study of a structured programme of support for stroke survivors living in the community

Study objectives
The aim of this study is to test the acceptability and feasibility of “My Life After Stroke” (MLAS), a program aiming to help stroke survivors and their carers be better informed about stroke, help them cope with its effects and reduce the risk of further strokes, for stroke survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - South Birmingham Research Ethics Committee, 23/02/2017, ref: 17/WM/0036

Study design
Non-randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Stroke; UKCRC code/ Disease: Stroke/ Cerebrovascular diseases

Interventions
MLAS is a self-management programme for stroke survivors and their carers, consisting of a first individual preparatory session, 4 weekly group-based sessions covering topics under the categories of stroke prevention, information, social needs and psychological issues, and a final individual session 4 weeks after the last group session. All sessions will be held at a suitable, accessible, local community facility. All stroke survivors will continue to receive usual care, as determined by their GP/hospital physician.

Group sessions will consist of stroke survivors and their carers, where relevant. Sessions will last approximately 2½ hours (including breaks). Participants will be given a handbook, which will contain educational content and further information based on the session topics. Sessions will cover a variety of topics and include risk factors for stroke and prevention, psychological well-being, problem solving and goal setting.

Individual appointments will last approximately 30-45 minutes. The introductory appointment aims to explore the stroke survivor's needs to support their active engagement in the group sessions and introduce them to key components of the programme. The final follow-up appointment will aim to address any remaining signposting that is needed, discuss goals, achievements and plans following the programme.

Intervention Type
Other

Primary outcome(s)
There is no primary outcome measure as this is a feasibility study. Attendance at sessions and uptake/withdrawal rates is captured. Descriptive analyses of outcome measures are undertaken to give insight into which outcome measures may be used as a primary outcome measure in a future RCT.

Key secondary outcome(s))
1. Feasibility and acceptability are assessed by recording attendance at each session (including number of carers), the proportion who don't respond to/decline invite letter, withdrawals (with reasons where possible) and response rates. Where possible the trialists also collect participant-reported reasons for either declining the study at initial invite or withdrawal following consent, though participants are not obliged to give this information.

Assessed at consent appointment and at final individual appointment:
2. Self-efficacy is assessed using the Stroke Self-efficacy questionnaire
3. Stroke-specific health related quality of life is assessed using the Stroke-Specific Quality of Life questionnaire and the Stroke Impact Scale
4. Self-management is assessed using the Southampton Stroke Self-management questionnaire
5. Carer's quality of life is assessed using the Caregiver Strain Index
These measures help to inform outcomes for a larger RCT as well as providing information on user-friendliness and participant burden

Completion date
06/10/2017

Eligibility

Key inclusion criteria
Stroke survivors:
1. People with a confirmed diagnosis of stroke
2. Willing and able to attend group sessions (with or without carer or appropriate support where necessary);
3. Able to provide informed consent
4. At least 18 years old
5. Gender: both

Carers:
The recruitment of carers will be via the stroke survivor initially and will be entered into the study if they are planning to accompany the stroke survivor on the MLAS programme. A carer can only take part if the stroke survivor takes part

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. No history of stroke (i.e. on a stroke register but had a TIA only)
2. Living in residential care
3. Have a terminal illness
4. Unable to understand English
5. Dementia, severe cognitive deficits or severe ongoing mental health problems that would limit their involvement
6. Currently undergoing intensive active rehabilitation (i.e. within 6 weeks of acute stroke)

Date of first enrolment
30/05/2017

Date of final enrolment
25/08/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
Up to 4 GP practices within Leicester, Leicestershire & Rutland and Cambridgeshire
United Kingdom
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Sponsor information

Organisation
NHS Cambridgeshire and Peterborough Clinical Commissioning Group

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that this was a feasibility study and no direct patient outcomes were recorded. A summary of participant feedback and how this influenced the development of the MLAS programme will be included in the final publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2022	16/08/2022	Yes	No
Basic results		06/02/2019	06/02/2019	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes