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An evaluation of the Regaining Confidence after Stroke (RCAS) course

Submission date
12/06/2013

Recruitment status
No longer recruiting

Registration date
12/06/2013

Overall study status
Completed

Last Edited
02/08/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
After stroke it can be common to feel low in mood or lacking in confidence and this can affect how much people feel like getting out and being active.. A course has been designed called Regaining Confidence After Stroke (RCAS) which aims to help stroke survivors and their carers cope with life after stroke. The course is held in the community and encourages discussion between people with similar problems. There has not been much work done to test whether the course is a useful treatment in improving mood, confidence and coping. This study aims to test the benefits of the course and identify any possible problems in the way the course is delivered.

Who can participate?
Letters inviting people to take part in the study are being sent to stroke survivors who have a Nottingham City GP and who have had a stroke within the last 2 years. They also need to be over 18 years, able to get out to group meetings and able to speak English. They will usually have been discharged from all other rehabilitation or therapy.

What does the study involve?
After agreeing to take part in the study participants are asked to answer questions about their mood, confidence and level of ability and independence. Half of the people who agree to take part are chosen at random and invited to attend the RCAS course which is a set of 11 group sessions held once a week for around 2 hours. Sessions involve an introductory talk or video followed by group discussion, with the aim of sharing problems and ideas for coping and making realistic adjustment to the after-effects of stroke.. Those who are not chosen to attend the group just continue to receive their usual care. After 3 months and 6 months everyone who agreed to take part in the study is asked to fill out the same forms that were completed at the beginning of the study. Carers of those invited to attend the group are invited to attend 3 of the sessions and asked to fill out some forms about how they are feeling and coping. Some of the stroke survivors who attend the RCAS course, and their carers, are interviewed by a member of the research team asking for their views on the course.

What are the possible benefits and risks of participating?
There are no particular risks associated with this study. We hope that by attending the RCAS course it will help improve participants' mood and confidence, but we don't know for certain whether it will.

Where is the study run from?
The study is being run from Nottingham University. The course sessions will be held in a community venue in the Nottingham City area.

When is the study starting and how long is it expected to run for?
June 2013 to November 2013

Who is funding the study?
Stroke Association and NHS Nottingham City Research Capability grant

Who is the main contact?
Kate Hooban

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14452

Study information

Scientific Title
An evaluation of the Regaining Confidence after Stroke (RCAS) course

Acronym
RCAS

Study objectives
An unfortunate common consequence of stroke is psychological distress, which refers to many negative mood states including depression and anxiety. It can have a detrimental effect upon rehabilitation. Regaining Confidence after Stroke (RCAS) is a group therapy that has been used nationwide for the last 10 years; it is designed to help stroke survivors with low mood or adjustment difficulties at the time of discharge from rehabilitation. We have received funding from the Stroke Association to conduct an initial evaluation of the RCAS course in improving mood, confidence and coping, and increasing activity levels in stroke survivors, and improving mood and coping in their carers. The study will also provide information about the most appropriate outcome measures, the number of required participants, and the acceptability of the course to stroke survivors and their carers, which will be useful for any followup studies.

Participants will be recruited from research sites in Nottingham and Leicester, and will be divided into two groups on the basis of chance. Group A will receive the RCAS course and Group B will receive usual care. The participants will be given several questionnaires before the intervention and after 3 and 6 months to determine the effectiveness of the course and at least 12 participants will be interviewed to obtain their opinions on the therapy. The stroke survivors carers will be asked to provide similar information. In addition, a sample of sessions will be recorded to check that the course is being delivered correctly. We expect that the proposed study will help to improve longterm psychological adjustment following a stroke, which may improve recovery and quality of life in stroke survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands-Nottingham1 , ref: 12/EM/0319 - 2011

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Primary Care, Rehabilitation; Disease: Community study

Interventions
Psychological intervention, Delivery of the RCAS course: Participants will be recruited from research sites in Nottingham and Leicester, and will be divided into two groups on the basis of chance. Group A will receive the RCAS course and Group B will receive usual care. The participants will be given several questionnaires before the intervention and after 3 and 6 months to determine the effectiveness of the course and at least 12 participants will be interviewed to obtain their opinions on the therapy. The stroke survivors carers will be asked to provide similar information. In addition, a sample of sessions will be recorded to check that the course is being delivered correctly.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
As of 19/09/2016:
General health, measured by GHQ-30 questionnaire at baseline, 3 months and 6 months

Initial:
General Health Questionnaire 28; Timepoint(s): Not available

Secondary outcome measures
Added 19/09/2016:
Confidence after stroke, assessed using the COPE and Confidence after Stroke Measure (CASM) questionnaire at baseline, 3 months and 6 months

Overall study start date
01/06/2013

Completion date
30/11/2013

Eligibility

Key inclusion criteria
Potential participants will be invited to take part in the study if they:
1. Have a clinical diagnosis of stroke
2. Are less than two years after stroke onset
3. Are resident in the community
4. Have been discharged from other rehabilitation therapies
5. Are not involved in other trials of psychological interventions
6. Give informed consent

7. These participants will be suffering from psychological distress or struggling to adjust to life after stroke
8. Carers will be invited to take part if they either live with or have regular contact with a stroke survivor

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

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

Total final enrolment
47

Key exclusion criteria
Potential participants will be excluded if they:
1. Have a Barthel score of less than 10
2. A Sheffield Screening Test for Acquired Language Disorders receptive score of less than 8
3. Do not speak English or have previously attended the RCAS course
4. This will exclude those who will be unable to participate in the group sessions or complete the outcome measures and also those whose previous experience of the RCAS course may affect their expectation of outcome
5. Carers will be excluded if they are under 18 years of age or do not speak English, as this would prevent them from completing the outcome measures

Date of first enrolment
01/06/2013

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Work, Health & Organisations
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Sponsor information

Organisation
University of Nottingham

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (UK)

Funder Name
NHS Nottingham City Research Capability grant

Results and Publications

Publication and dissemination plan
The study has been written up as a Masters thesis which was recently submitted to the University of Nottingham. Further plans are to be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	25/07/2019	02/08/2019	Yes	No