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Motivational interviewing for low mood after stroke

Submission date
08/11/2017

Recruitment status
No longer recruiting

Registration date
16/11/2017

Overall study status
Completed

Last Edited
01/10/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke can have a devastating effect on people, not only physically and mentally, but emotionally too. A stroke occurs when the blood supply to the brain is cut off. This research intends to help stroke survivors come to terms with the stroke and prevent depression, a common problem after stroke. Depression affects about one in three stroke survivors. Depressed patients are less motivated to take part in rehabilitation when they are in hospital, resulting in longer hospital stay and poorer recovery.
A type of talking therapy (counselling) called Motivational Interviewing (MI) could be beneficial in helping stroke patients adapt to life after a stroke. The aim of this study is to explore if it MI is a feasible approach to helping patients who have had a stroke.

Who can participate?
Adults aged 18 and older who have had a stroke

What does the study involve?
Participants are randomly allocated to receive either sessions of motivational interviewing (a talking therapy) with a trained therapist, or sessions of attention control which involves spending time with a trained visitor. The sessions are up to an hour long, and held weekly in the participants' home or in hospital, for up to four weeks. Participant's complete questionnaires about they are feeling before starting their first session, and again at three months after their stroke.

What are the possible benefits and risks of participating?
Participants may benefit from engaging in either MI or AC sessions by being able to talk to someone individually. Participants may also value being involved in improving psychological support services for future patients. While engaging in MI, participants may become distressed. If therapists or ward staff feel concerned about participants, patient are referred on to an appropriate person with the patient's consent. Should patients disclose information that concerns staff regarding the health and safety of the participant or those around the participant, again the staff member reports this to the lead researcher and the patient is referred to an appropriate person. Participants are made aware of these confidentiality issues before consenting to participate in the study.

Where is the study run from?
Countess of Chester Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2012- November 2015

Who is funding the study?
Northern Stroke Research Fund (UK)

Who is the main contact?
1. Miss Kulsum Patel (Public)
2. Dr Liz Lightbody (Scientific)

Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
105693

Study information

Scientific Title
Motivational interviewing for low mood and adjustment early after stroke: A feasibility randomised trial

Study objectives
The aim of this study is to explore the feasibility of delivering MI using members of the clinical team, and using an attention control, to inform the protocol for a future definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES North West Committee - Preston, 31/08/2012, ref: 12/NW/0633

Study design
Mixed methods single centre feasibility study non-blinded parallel-group randomised controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

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

Interventions
Following completion of baseline assessment, eligible participants are randomised early after stroke on a 1:1 ratio (stratified by response to Yale question "Do you often feel sad or depressed?" Yes or No) to:

1. Motivational Interviewing (MI) [intervention arm],
2. Attention Control (AC) [control arm].

MI is a talking therapy, the techniques of which have been applied to facilitate adjustment after stroke. Participants in the MI group received up to four, hour-long, individual MI sessions held weekly with a trained MI therapist, in hospital or at home.

AC was designed to provide participants with social attention of the same duration and intensity to the MI therapy and involved general conversation and activities not focused on mood (e.g. playing cards). Participants in the AC group receive up to four, hour-long, individual AC sessions held weekly with a trained AC visitor, in hospital or at home.

Participants in both groups are followed up at three months post-stroke.

Intervention Type
Other

Primary outcome measure
Feasibility of a future definitive trial is measured using:
1. Recruitment and three-month retention of participants, through examination of screening logs and follow up completion;
2. Completeness of data capture in study measures;
3. Acceptability of MI and AC, through interviews with participants;
4. Implementation of MI and AC, through interviews with staff delivering MI and AC;
5. Fidelity to MI and AC, through monitoring of audio recordings of sessions.

Secondary outcome measures
1. Mood is measured using the GHQ12, Yale, DISCs scores at baseline and three months
2. Survival is measured using status (alive/dead) at three months
3. Function is measured using Barthel at baseline and 3 months, and NEADL at three months
4. Quality of life is measured using the EQ5D at three months
5. Adjustment is measured using CIR at three months
6. Community integration is measured using CIQ at three months

Overall study start date
01/06/2012

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Medical diagnosis of stroke (from WHO criteria)
3. Medically stable
4. No severe communication difficulties
5. Having capacity to consent
6. No current psychological input
7. Live in hospital catchment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Aged under 18
2. Non diagnosis of stroke (from WHO criteria)
3. Medically unstable
4. Severe communication difficulties
5. Lacking capacity to consent
6. Patient receiving current psychological input
7. Live outside hospital catchment

Date of first enrolment
01/12/2012

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Countess of Chester Hospital
United Kingdom
CH2 1UL

Sponsor information

Organisation

Countess of Chester NHS Foundation Trust

Sponsor details
Chester Health Park
Liverpool Road
Chester
England
United Kingdom
CH2 1UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0149cpy58

Funder(s)

Funder type
Charity

Funder Name
Northern Stroke Research Fund

Results and Publications

Publication and dissemination plan
Publish results in Pilot and Feasibility Studies. The study protocol is not available online but can be obtained from the study contact on request.

Intention to publish date
30/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Liz Lightbody, University of Central Lancashire, email: celightbody@uclan.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/09/2018		Yes	No