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Behavioural activation therapy for depression after stroke

Submission date
10/12/2014

Recruitment status
No longer recruiting

Registration date
16/12/2014

Overall study status
Completed

Last Edited
17/09/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
One-third of people become depressed after stroke. It is important that depression is treated as it can have negative effects on recovery, quality of life and carer strain. Currently there is insufficient evidence to tell us which psychological treatment is effective and affordable. Our study aims to find out whether it is feasible to conduct a study to evaluate a psychological treatment, called behavioural activation (BA) therapy, for treating post-stroke depression. BA aims to improve mood by increasing the time people spend doing activities they enjoy.

Who can participate?
People can take part if they had their stroke between 3 months and 5 years ago and have post-stroke depression.

What does the study involve?
Participants will be divided into two groups at random. Half of the people will receive up to 15 sessions of BA over 4 months; the other half will not receive BA but will receive care as usual. No participants will have existing treatments withdrawn. Six months after joining the study participants will be visited by a researcher, who will complete questionnaires to assess the participant’s mood, activity level, quality of life, and to record other healthcare they have received. The impact on carers' health, quality of life and support provided will also be measured. We will interview eight participants and five carers from each group to ask their views on the research process and intervention.

What are the possible benefits and risks of participating?
The results of the study will tell us whether it is feasible and affordable to conduct a full-scale study evaluating BA for treating post-stroke depression, and will inform us how to design it. Behavioural activation is a safe and noninvasive intervention with minimal risks to participants. The intervention is delivered by an assistant psychologist/IAPT therapist who will receive training and regular supervision. No participants will have any existing treatments withdrawn. The benefits of BA include improved mood. It is possible that participants may experience some distress from being asked about their mood, but all therapists and researchers will be trained to

deal with distress. If at any point during the study the researcher or therapist is concerned about a participant, for example if they report severe distress or feel suicidal, then the necessary will be made.

Where is the study run from?
Sheffield Clinical Trials Research Unit (UK)

When is the study starting and how long is it expected to run for?
September 2014 to October 2016

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

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/14/01

Study information

Scientific Title
BEhavioural Activation therapy for Depression after Stroke: a parallel group feasibility multicentre randomised controlled trial with nested qualitative research and economic evaluation, comparing behavioural activation to usual stroke care for patients with post-stroke depression.

Acronym
BEADS

Study objectives
This is a pilot trial to assess the feasibility of undertaking a randomised controlled trial to investigate the clinical and cost-effectiveness of behavioural activation (BA) therapy for people with post-stroke depression. This study will provide the necessary parameters and information to plan a definitive Phase III trial to evaluate the clinical and cost-effectiveness of BA for people with post-stroke depression.
1. The primary objective is to determine the feasibility of proceeding to a definitive trial.
2. The secondary objective is to determine the feasibility of the delivery of the behavioural activation therapy intervention with people with post-stroke depression.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/131401
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/158039/PRO-13-14-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands Leicester, 29/01/2015, ref: 15/EM/0014

Study design
Parallel-group feasibility multicentre randomised controlled trial with nested qualitative research and economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Post-stroke depression

Interventions
Participants will be randomised to either Behavioural Activation Therapy or usual care.

Behavioural activation - This is a structured and individualised treatment which aims to increase people's level of activity, particularly the frequency of pleasant or enjoyable events, in order to improve mood. Participants randomised to receive BA will be treated at their place of residence by an assistant psychologist at two sites or IAPT Psychological Wellbeing Practitioner (PWP) at one site. They will be offered a maximum of 15 sessions of BA over four months, with an expected average of 10 sessions. Therapy sessions will be delivered face to face on an individual basis, at the participants' residences and will last about one hour.

Usual care - Stroke survivors are admitted to hospital, usually to a stroke unit. On discharge they may receive input from an Early Supported Discharge team or input from a community stroke /rehabilitation team. Participants in the usual care group will follow the current care pathway. Participants will receive all other services routinely available to them as local practice but will have no contact with the trial therapist. This group is the control arm and their care will be recorded to document usual care to inform the design of the definitive trial.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measures in this study relate to the feasibility of proceeding to a definitive trial, based on:
1. Feasibility of recruitment to the main trial
2. Acceptability of the research procedures and measures
3. Appropriateness of the baseline and outcome measures for assessing impact
4. Retention of participants at outcome
5. Potential value of conducting the definitive trial, based upon value of information analysis

Secondary outcome measures

The secondary objective is to determine the feasibility of the delivery of the behavioural activation therapy intervention with people with post-stroke depression, based on:
1. Acceptability of behavioural activation therapy to participants, carers and therapists
2. Feasibility of delivering the intervention by Assistant Psychologists or IAPT therapist under supervision of an experienced mental health practitioner
3. Documentation of 'usual care' using healthcare resource use questionnaire
4. Treatment fidelity of the behavioural activation therapy
5. Feasibility of delivery of behavioural activation therapy within current services and within a definitive trial

A series of other measures will be taken at 6 months to measure impact on patients' mood, health, quality of life and use of services; and carer strain, quality of life and support provided to the patient. The primary clinical outcome measure is PHQ-9. For those participants with moderate to severe language problems who are unable to complete the PHQ-9, the Visual Analog Mood Scales (VAMS) Sad item will be used

Overall study start date
01/09/2014

Completion date
31/10/2016

Eligibility

Key inclusion criteria
The criteria are designed to identify those who would be suitable for the intervention were it to be offered within clinical practice. Participants will be included in the study if they:
1. Have a diagnosis of ischaemic or haemorrhagic stroke
2. Are age 18 years or over
3. Are living in community settings, including home or nursing home
4. Are a minimum of three months and a maximum of five years post-stroke
5. Are identified as depressed, defined as:
5.1. For participants who are able to complete the Patient Health Questionnaire-9 (PHQ-9): a score of >10 on the PHQ-9
5.2. For participants with communication difficulties or severe cognitive difficulties who are unable to complete the PHQ-9: a score of at least 50/100 on Visual Analog Mood Scales (VAMS) Sad item.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

72 (36 in each arm)

Total final enrolment
48

Key exclusion criteria
Current exclusion criteria as of 27/01/2016:
Participants will be excluded from the study if they:
1. Had a diagnosis of dementia prior to the stroke (based on self-report by patient/carer)
2. Were receiving medical or psychological treatment for depression at the time at which they had their stroke (based on self-report by patient/carer)
3. Are currently receiving psychological intervention
4. Have communication difficulties that would impact on their capacity to take part in the intervention (based on assessment with the Consent Support Tool [42] for people with aphasia)
5. Have visual or hearing impairments that would impact on their capacity to take part in the intervention (based on the therapist's discretion at baseline assessment)
6. Were unable to communicate in English prior to the stroke
7. Do not have mental capacity to consent to take part in the trial.

Previous exclusion criteria:
Participants will be excluded from the study if they:
1. Had a diagnosis of dementia prior to the stroke (based on self-report by patient/carer)
2. Were receiving medical or psychological treatment for depression at the time at which they had their stroke (based on self-report by patient/carer)
3. Have communication difficulties that would impact on their capacity to take part in the intervention (based on assessment with the Consent Support Tool for people with aphasia)
4. Have visual or hearing impairments that would impact on their capacity to take part in the intervention (based on the therapist's discretion at baseline assessment)
5. Were unable to communicate in English prior to the stroke
6. Do not have mental capacity to consent to take part in the trial

Date of first enrolment
01/05/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019	17/09/2019	Yes	No
HRA research summary			28/06/2023	No	No