

A feasibility study of a randomised controlled trial of an Arts for Health group intervention (HeART of stroke) to support self-confidence and psychological wellbeing following a stroke

Submission date 03/04/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

16434

Study information

Scientific Title

A feasibility study of a randomised controlled trial of an Arts for Health group intervention (HeART of stroke) to support self-confidence and psychological wellbeing following a stroke

Acronym

HeART of Stroke project V1

Study objectives

How feasible is it to test the effectiveness of an Arts for Health group following stroke?

Stroke can have a major impact on the individual, physically, and also psychologically in terms of sense of self and identity. While talking therapies (such as counselling) may help they don't suit everyone, especially those with communication difficulties, who make up a third of people following stroke. In an Arts for Health (AfH) approach, people work alongside an artist in small groups and are supported to feel safe to express themselves through creative activity without needing words.

We're interested in exploring whether an AfH intervention (HeART of Stroke) offers an acceptable way for stroke survivors to explore their new sense of self alongside others. To see if it could be a beneficial addition to standard stroke care offering value for money, we need to carry out a large study. To make sure that such a study is possible we are carrying out a smaller feasibility study.

In this feasibility study 64 people up to one year post stroke will take part (32 from the Royal Bournemouth Hospital and 32 from Cambridge Community Services). They will be randomly assigned to attend a 10 session AfH group held in the community or to continue with their usual care. At the study start and end we will ask participants to complete a questionnaire booklet (with support if needed) about wellbeing, mood, quality of life, confidence and use of medication, health, social care and informal support. We will also interview some participants about their experiences of taking part, collect feedback from the artists delivering the intervention and information about the cost of providing AfH groups.

This will help us to find out if a large national study is possible, and if it is, to help us to plan it.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/SW/0136

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type, Community study

Interventions

Arts for Health group, 10 sessions over 16 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Wellbeing - Warwick-Edinburgh Mental Wellbeing Scale;

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/08/2015

Eligibility**Key inclusion criteria**

1. Patient of a) Royal Bournemouth Hospital OR b) Cambridgeshire Community Services
2. Diagnosis of stroke
3. 18 years of age or above
4. Physical, communication, or cognitive symptoms from stroke at five days post stroke
5. Be able to provide informed consent
6. Up to 1 year post stroke

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

56

Key exclusion criteria

1. Cognitive levels such that an individual would be unable to comprehend the consenting process and the intervention

2. Severe receptive aphasia which means that the person will not be able to comprehend the consenting process and the intervention
3. Already receiving a psychiatric or clinical psychology intervention We do not feel that people with long term competing health needs will benefit from this particular short term programme
4. Not being able to go to the toilet independently (this would not exclude people who use catheters /pads). This is because the artist will not be trained to assist them in the bathroom
5. Living in a residential/nursing home. An important group for a future study

Date of first enrolment

01/05/2014

Date of final enrolment

01/08/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal London House

Bournemouth

United Kingdom

BH1 3LT

Sponsor information

Organisation

Royal Bournemouth Hospital (UK)

ROR

<https://ror.org/01v14jr37>

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme; Grant Codes: PB-PG-0212-27054

Alternative Name(s)

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2019	13/03/2020	Yes	No
Protocol article	protocol	04/08/2015		Yes	No
HRA research summary			28/06/2023	No	No