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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

Registration date
03/04/2014

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 dont 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.

Were 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Wellbeing - Warwick-Edinburgh Mental Wellbeing Scale;

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64;

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
England

United Kingdom

Study participating centre
Royal London House
Bournemouth
United Kingdom
BH1 3LT

Sponsor information

Organisation

Royal Bournemouth Hospital (UK)

Sponsor details
Haematology
Bournemouth
England
United Kingdom
BH7 7DW

Sponsor type
Hospital/treatment centre

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, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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