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HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention compared with usual care to increase psychological wellbeing in people following a stroke.

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Complete List of Authors:	Ellis-Hill, Caroline; Bournemouth University, Thomas, Sarah; Bournemouth University, Faculty of Health & Social Sciences Gracey, Fergus; University of East Anglia, Department of Clinical Psychology Lamont-Robinson, Catherine; University of Bristol, School of Social and Community Medicine Cant, Robin; Service User, formerly of Canterbury Christ Church University Marques, Elsa; University of Bristol, School of Social and Community Medicine Thomas, Peter; Bournemouth University, Faculty of Health and Social Sciences Grant, Mary; University of Warwick Nunn, Samantha; Cambridgeshire Community Services NHS Trust, Oliver Zangwill Centre Paling, Thomas; University of Bristol School of Social and Community Medicine Thomas, Charlotte; Bournemouth University, School of Health and Social Sciences Werson, Alessa; University of East Anglia, Department of Clinical Psychology Galvin, Kathleen; School of Health Sciences Reynolds, Frances; Brunel University London, College of Health and Life Sciences Jenkinson, Damian; Dorset County Hospital NHS Foundation Trust
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Title: HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention compared with usual care to increase psychological wellbeing in people following a stroke.

Corresponding author:

Caroline Ellis-Hill, Faculty of Health and Social Sciences; Bournemouth University, Bournemouth, UK

cehill@bournemouth.ac.uk

Co-authors:

Sarah Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Fergus Gracey, Department of Clinical Psychology, University of East Anglia, Norwich, UK

Catherine Lamont-Robinson, School of Social and Community Medicine, University of Bristol, Bristol, UK

Robin Cant, Servicer User, (formerly of Canterbury Christ Church University), Canterbury, UK

Elsa Marques, School of Clinical Sciences, University of Bristol, Bristol, UK

Peter Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Mary Grant, Warwick Clinical Trials Unit, University of Warwick, Coventry, UK

Samantha Nunn, Cambridgeshire Community Services NHS Trust, Oliver Zangwill Centre, Ely, UK

Thomas Paling, School of Clinical Sciences, University of Bristol, Bristol, UK

Charlotte Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Alessa Werson Department of Clinical Psychology, University of East Anglia, Norwich, UK

Kathleen Galvin, School of Health Sciences, University of Brighton, Brighton, UK

Frances Reynolds, formerly College of Health and Life Sciences, Brunel University London, Uxbridge, UK

Damian Jenkinson, Stroke Unit, Dorset County Hospital, Dorchester UK

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ABSTRACT

Objectives: People often experience distress following stroke due to a fundamental challenge to their identity. We evaluated (i) the acceptability of a community-based Arts & Health group intervention ('HeART of Stroke' [HoS]) to increase psychological wellbeing; (ii) the feasibility of a definitive randomised controlled trial (RCT).

Design: Two-centre 24-month parallel arm RCT with qualitative and economic components. Randomisation stratified by centre and stroke severity. Participant blinding was not possible. Outcome assessment blinding attempted.

Setting: Community

Participants: Community-dwelling adults ≤ 2 years post-stroke, recruited via hospital clinical teams/databases or community stroke/rehabilitation teams.

Interventions: HoS plus usual care (UC) versus UC. HoS is a 10-session artist-facilitated group intervention held over 14 weeks.

Outcomes: Self-reported measures of wellbeing, mood, capability, health-related quality of life, self-esteem and self-concept were administered at baseline and five months post-randomisation. Key feasibility parameters were gathered, data collection methods piloted and participant interviews (n=24) explored acceptability of the intervention/study processes.

Results: Despite a low (14%; 95% CI: 11% to 18%) recruitment rate, 88% of the recruitment target was met with 29 participants randomised to HoS and 27 to UC (57% male; mean [SD] age = 70 [12.1] years; time-since-stroke = 9 [6.1] months). Follow-up data were available for 47/56 (84%; 95% CI: 72% to 91%). Resource use questionnaire completion was 79% and 68% (NHS and societal perspectives). Five declined HoS post-randomisation; of the remaining 24, 83% attended ≥6 sessions. Preliminary effect sizes for potential primary outcomes were in the direction of benefit for the HoS arm. Participants found study

processes acceptable. The intervention cost an estimated £456 per person and was well-received. No intervention-related serious adverse events were reported.

Conclusions: Findings from this first community-based study of an Arts & Health intervention for people following stroke suggest a definitive trial is feasible and warranted. Recruitment methods will be revised.

ISRCTN 99728983

Strengths and limitations of this study

- The first feasibility study of a community-based Arts & Health group intervention to support wellbeing following a stroke.
- Participants were recruited via both hospital (Bournemouth centre) and community (Cambridgeshire centre) clinical teams.
- Incorporated mixed methods and a feasibility economic component.
- The study only included short term follow-up.
- Findings will inform a definitive randomised controlled trial of effectiveness and cost-effectiveness.

INTRODUCTION

Each year over 150,000 people in the UK experience a stroke[1] with one-third left with residual disabilities including paralysis on one side and cognitive and communication impairments.[2] Recent qualitative systematic reviews have highlighted that following a stroke or other types of brain injury people face fundamental existential challenges in terms of uncertainty and loss of their usual everyday world, leading to challenges to their sense of self and identity.[3-5] Emotional health and wellbeing following stroke have been highlighted as national priorities, featuring in the James Lind Alliance 'top ten' research priorities.[6]

Following a stroke people report a need to 'get their lives back'. Failure to do so is associated with depression (with reported accumulative incidence of 39–52% within 5 years of stroke[7]), loss of confidence,[8] people having difficulty in 'feeling part of things'[9] and becoming socially isolated.[10] This creates long-terms costs, not only for the stroke survivor, but also for their family members,[11,12] and for government, health and social services through reduced family employment and increased social and primary care needs,[13] and where untreated, depression is associated with poorer functional outcomes[14]

Ellis-Hill et al.[15] and Gracey et al.[16] have independently developed complementary theoretical models based on empirical evidence to understand the processes involved in re-establishing a positive sense of self and confidence in life following a stroke. A key factor is being able to reconstruct a sense of meaning, predictability and coherence in everyday life, when previously taken for granted assumptions often no longer hold true. In order to develop a positive sense of self and self-confidence people need to explore and develop new ways of understanding and 'being in the world'.[17,18]

While there have been great improvements in stroke care, and emotional health and wellbeing have long been seen as nationally important outcomes,[2] the stroke pathway for

long-term support is still under-researched and under-developed. A stepped approach to psychological support has been proposed[19] but this system is still in its infancy. Furthermore, a Cochrane review indicated no evidence for pharmacotherapy in prevention of post-stroke depression, and only weak evidence for psychotherapeutic approaches.[20]

Using interviews and focus groups, Harrison et al.[21] explored stroke patients', health care professionals' and carers' experiences of care provision in hospital and immediately post-discharge. They concluded that further research is required to establish the effectiveness of alternative options to formal psychological support. White et al. identified community non-participation and stroke-related disability as potentially modifiable risk factors affecting post-stroke health-related quality of life and that interventions addressing these factors should be developed and tested. [22] Thus, there is an empirical basis, in addition to a pressing need, and desire on the part of patients, for investigation of alternative options to promote wellbeing post-stroke upon return to community life.

There is growing recognition of the importance of creative approaches in health provision;[23] for example, in the United Kingdom we have seen the creation of a national Special Interest Group for Arts, Health and Wellbeing and the launch of an All-Party Parliamentary Group (APPG) inquiry into Arts, Health and Wellbeing.[24] Practical creative approaches offer new ways to explore experiences, especially those difficult to put into words.[25] There is a body of evidence that arts-based practices are of great benefit in supporting psychological and social recovery in mental health services[26] and an emerging international agenda and evidence base for 'Arts for Health' initiatives.[27,28] Concurrently, there is increasing research into the effect of art on mood and wellbeing following stroke.[29-32] This feasibility study is the first to test this approach formally in a community setting.

METHODS

Ethical approvals

The study was reviewed and given a favourable opinion by the Exeter NHS REC (Ref: 13/SW/0136). Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust (the study sponsor) and by Cambridgeshire Community Services NHS Trust.

Aims and objectives

The aims of the feasibility study were, firstly, to assess the acceptability of a 10-session community Arts & Health group intervention ('HeART of Stroke') for people following stroke and, secondly, to evaluate the feasibility of conducting a definitive randomised controlled trial to test its effectiveness and cost effectiveness when added to usual care. The specific objectives are described in detail in the published protocol[33] but, in brief, they were to:

i. assess the acceptability of aspects of study design, processes and of the HeART of Stroke (HoS) intervention;
ii. estimate key parameters such as recruitment, retention, outcome completion rates and intervention attendance;
iii. collect data on the variability of outcomes and their acceptability, to inform the selection of outcomes for the definitive trial;
iv. develop and pilot data collection tools to collect resource use and costs in the future trial, and estimate the cost of delivering HoS.

Study design

A two centre parallel arm randomised controlled feasibility study comparing the HoS group intervention plus usual care versus usual care alone (1:1 allocation ratio), with nested economic and qualitative components.

Patient and public involvement (PPI)

Patient and public involvement members were involved in the initiation and the design of the study, the development of the funding application, the design of the HoS intervention, the selection of relevant outcome measures and the design of data collection tools. During the research as well as having RC, a grant holder, who attended all steering group and dissemination meetings, we formed PPI groups in each centre. There were five PPI members in Bournemouth (four involved in the study at any one time) and three PPI members in Cambridgeshire.

As planned, patient and public involvement members were involved in three of the five study management group meetings. A newsletter kept PPI members updated with study progress. Members contributed to the study in many ways, including providing feedback about outcome measures, providing opportunities for the researchers to run through/practise aspects of the study protocol, finding a suitable venue for the intervention, providing ideas on how to enhance recruitment, helping with plain English summaries, supporting the exhibition of artwork and other dissemination activities. As part of dissemination activities, one of the study participants delivered a workshop at the UK Stroke Forum alongside CLR and CEH.

Methods

Details of our methods are published in our protocol paper.[33] We aimed to recruit a sample of 64 people (32 per centre in two blocks of 16). This would have provided an estimate of the recruitment rate with a precision of ±6% (assuming a recruitment rate of 30%) and a questionnaire return rate with a precision of ±10% (assuming a questionnaire return rate of 80%).

Participants

Participants were adults living in the community up to two years post-stroke with physical or cognitive symptoms from stroke at five days post-stroke. Exclusion criteria included severe receptive aphasia, cognitive levels that would preclude completion of outcome measures even with support, currently receiving a psychiatric or clinical psychology intervention, living in a residential or nursing home, requiring assistance with toilet needs (because the Arts & Health practitioners were not trained to support transfers).

Identification, screening and recruitment

Bournemouth Centre (Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust)

Potential participants, identified by clinical research network staff at RBCH NHS Foundation Trust, were either sent or given an invitation letter, 'Key Facts' page and reply slip and asked to return a prepaid reply slip if they were interested in participating. The study research assistant (RA) contacted those who expressed an interest and answered any queries or questions (via telephone, or face-to-face if the person had a communication disability). If they were still interested in taking part, they were sent or given a set of Participant Information Sheets (PIS).

In an attempt to improve recruitment we revised the invitation and reminder letters partway through the study via an approved substantial amendment to the NHS REC. Our PPI partners and clinical colleagues in the stroke research team at RBCH provided feedback to enhance the appeal and readability of the information via a more accessible and engaging style.

Cambridgeshire Centre (Cambridgeshire Community Services NHS Trust)

Clinical staff from the community stroke and neuro-rehabilitation teams identified potential participants in the community. In addition to the invitation letter described above, a 'consent

to contact' approach was used whereby consent to be contacted by the Cambridgeshire centre RA was sought. A member of the clinical team obtained this consent during a face-to-face consultation or verbally over the phone. If the individual remained interested, the RA gave/sent them a set of PIS.

Informed consent process

For individuals interested in taking part, the local RA arranged to visit the person at home within one month prior to the start of the HoS group. This provided an opportunity to answer any remaining questions the individual had about the study. If the person still fulfilled the eligibility criteria (a screening checklist was used) and still wished to take part, they were asked to complete and sign a consent form and complete the baseline assessment.

Randomisation

The web-based randomisation system was created by the Peninsula Clinical Trials Unit in conjunction with the study statistician. Participants were allocated to the HoS intervention plus usual care or usual care in a 1:1 ratio using minimisation to balance the numbers allocated to each arm with stratification by recruitment centre and stroke severity (Rivermead Motor Assessment – Gross Motor Subscale score ≤6 ('mild') vs. ≥7 ('moderate/severe')).[34] The study research assistants in each centre logged onto the system using a unique username and password. They were able to randomise participants individually or in batches. Individual randomisation was used to 'top up' the two trial arms if any further participants were recruited before the HoS intervention groups started.

Blinding

The nature of the intervention meant that it was not possible to blind participants and artist facilitators to group allocation. At follow-up, when support was provided/required to complete outcomes this was provided by assessors blind to group allocation.

HeART of Stroke (HoS) group intervention

The HoS intervention is described in detail in the published protocol.[33] The rationale of HoS is to provide a safe space through the medium of the Arts in which group members have the opportunity to reconnect with their internal selves though their senses and embodied knowing and connect with, and support, others. This was a face-to-face group intervention, with self-directed individual art activity opportunities between meetings. Standardisation was linked with the context and setting rather than with what the practitioners and participants did, as this was expected to vary due to the creative nature of the activity.

HoS group sessions

The HoS intervention comprised 10 two hour group sessions held over 14 weeks in the mornings (10.30-12.30) with a refreshment break. Sessions 1-3 included introductions and initial exploration. During sessions 4-7 participants were encouraged to develop their own creative practice within the sessions and at home. In sessions 8-10 links with local Arts & Health practitioners were made and potential plans for an exhibition of the participants' work discussed.

At each group, the Arts & Health practitioners encouraged members to a) explore the materials provided and arts techniques shared; b) explore their senses and support others' explorations; b) be non-judgmental of self/others; c) follow and respond to their own interests and e) develop a sense of play/improvisation. The Arts & Health practitioners prepared resources (including paints, drawing materials, clay, textiles and mixed-media) in response to the group members' individual and collective creative interests and skills. The group was offered 'stimulus' pieces such as books, poems, images, music and film and members were encouraged to share their own pieces of interest with the group.

Following each session, the Arts & Health practitioner briefly documented observations and reflected further to inform the selection of materials and activity for the following session.

Practitioners also provided participants with sketchbooks and/or paper and other arts materials to support their emerging interests between sessions.

Facilitators and venues

The groups were facilitated by Arts & Health practitioners, with at least 5 years' experience, who were able to support groups, create and hold a safe space, and who were willing and able to support arts practice where participants took the lead in their own discovery and exploration. One Arts & Health practitioner led both groups in Bournemouth (CLR) and two led one group each in Cambridgeshire. They had access to expertise in stroke (CEH) and clinical psychology (FG). For the purposes of the project a researcher was also present on site, if needed. The researcher supported study administration aspects (such as travel expenses for participants) and participant completion of a scale assessing group fit/belonging.[35]

In Bournemouth the HoS groups (iterations 1 & 2) were held in a church hall and in Cambridge they were held either in a room in a community hospital site on the edge of Cambridge city used by Headway Cambridgeshire (a local brain injury charity) (iteration 3) or a community centre in a very rural north Cambridgeshire town (iteration 4). All venues had disabled access/toilet facilities, access to water and a sink, tea/coffee-making facilities and could accommodate up to eight participants (potentially with wheelchairs) around a table. There were storage facilities (albeit limited) in Cambridgeshire but none in the Bournemouth venue. Transport was provided for those unable to make their own way to the venue.

Usual Care

In Bournemouth, support is provided by the Early Supported Discharge multidisciplinary team for 2–6 weeks after leaving hospital and then medical care via the General Practitioner (GP), with a referral to the Stroke Coordinator. People with complex medical conditions are seen by Stroke Consultants as hospital outpatients. Ongoing rehabilitation needs are met by

rehabilitation teams and day hospital service provision in some areas. In Cambridgeshire, medical care is delivered via the GP and people with complex medical conditions are seen by Stroke Consultants as hospital outpatients. All can access support from the Stroke Association 'Information, Advice and Support Coordinator' and may receive additional therapy or support via one of three locality neurorehabilitation teams. Participants in both arms of the trial received usual care, and usual care was not affected by involvement in the trial.

Descriptors and proposed outcome measures

Demographic/descriptor variables and stroke related information

At baseline the local RA collected information during a home visit about age, gender, marital status, educational qualifications, ethnicity, household composition, employment situation, comorbidities, medication, type of stroke, stroke side, time-since-stroke, mobility (Rivermead Assessment - Gross Motor subscale),[34] upper limb impairment (Motricity Index),[36] communication ability,[37] cognitive ability (Addenbrookes Cognitive Exam – Revised; ACE-R).[38]

Outcome measures

These were self-reported and presented in a booklet in a large font (pt. 14). At baseline, outcome measures were administered face-to-face by an RA in participants' homes. At approximately 5 months post-randomisation (1 month post - HoS intervention) outcome measures were administered by post, or if needed, with face-to-face or telephone support from a blinded assessor (one in each centre). At the end of the questionnaire booklet there was a question that asked whether participants had received any support from others to complete the questionnaire with the following response options possible: none, researcher on phone, researcher at house, family member/friend. Participants were asked not to disclose their allocation arm to the blinded assessors. In each centre the blinded assessors were asked to guess participants' treatment allocation.

Proposed primary outcome measures for future trial

These included the (i) Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS);[39] (ii) Hospital Anxiety and Depression Scale (HADS);[40] (iii) ICEpop CAPability measure for adults (ICECAP-A).[41]

Proposed secondary measures for future trial

These included the (i) Rosenberg Self-Esteem Scale (RSES);[42] (ii) Medical Outcomes Short Form-36 (SF-36 V.1);[43] (iii) Head Injury Semantic Differential Scale (HISDS-III).[44]

Serious adverse events and adverse events

Serious adverse events (SAEs) and adverse events (AEs) were closely monitored, documented and reported as described in the study protocol.[33]

Process measures

The Doojse scale[35] was used to measure 'sense of belonging' by participants in the HoS group at the end of the first, fifth and final session.

Identifying, measuring and valuing resource use

Resources required to deliver the HoS intervention were recorded for each session on forms completed by the artist facilitators. These included artists' preparation time, travel time to and from the venue, time spent delivering the intervention, equipment and materials used, number of participants attending the sessions, venue and venue hire costs. Resources were valued using local estimates provided by the experienced artists delivering HoS. Artist facilitators' time was valued at the fixed fee of £120 per session (to cover travel, preparation and delivery costs) with an additional £25 fee for materials and £8 for refreshments. Venue hire costs in Bournemouth (iterations 1 & 2) were £40 per session, and in Cambridgeshire, £100 per session (iteration 3) and £25 per session (iteration 4). We envisage the roll-out of

the HoS intervention would follow a similar model whereby the health care provider would pay the artist facilitators a fixed delivery fee. Participant travel costs to attend sessions were recorded and are reported.

Resources required to deliver usual care in both arms were collected via a bespoke resource use telephone-administered questionnaire that asked about resources used in the 4 months following randomisation. Participants were posted the questionnaire in advance of the telephone interview and were offered face-to-face support to complete it, if required. The questionnaire included hospital visits and admissions, use of community and social services, time off work and social activities, informal care, other sources of support, expenses incurred and medications. As service users advised us that it would be difficult to distinguish between stroke-related resource use and resource use related to co-morbidities, the questionnaire asked respondents to report resources related to all their health care needs. We assume that, in a definitive RCT, any differences between arms would result from the HoS intervention effect. To improve completion rates,[45] participants were provided with a resource use log to record health care visits prospectively, if they wished. Resources were valued using Curtis and Burns' Unit Costs of Health and Social Care[46] and the 2015 Department of Health NHS reference costs.[47] Private expenses were self-reported. Hours of informal care and time off work and social activities were valued using the Office for National Statistics (2015) average weekly earnings.[48]

Interviews

Face-to-face interviews with twelve people (8 intervention; 4 usual care) were undertaken in people's homes across both centres by CEH on two occasions: i. post-randomisation but before the HoS intervention was delivered; and ii. at study end after all outcome measures had been completed. CEH selected participants from those who had already agreed to be approached to take part in an additional qualitative study. Purposive sampling was used to capture variations that might influence perceptions including age, gender, communication

disability and severity of stroke. The pre-intervention topics included why the person decided to take part in the overall study, their views on the recruitment and initial assessment process, and for the intervention group, what they were expecting in terms of the HoS group intervention. The post-intervention topics included views on the study and outcome assessment processes and the acceptability of completing outcomes at one year follow-up in the context of a hypothetical future trial. Intervention participants were also asked about their experiences of the group, the venues, and their ability/willingness to pay their own transport costs to attend HoS.

Analysis

The analysis undertaken followed that described in the protocol unless otherwise stated.[33]

Quantitative analysis

Quantitative analysis was carried out using IBM SPSS V23.0 and STATA V14. The person undertaking the analysis was blind to allocation and group assignment was coded using 0 and 1. As this is a feasibility study, analyses are primarily descriptive and focus on baseline participant characteristics and the estimation of key feasibility parameters.[49] Estimates of recruitment, retention and questionnaire completion rates are presented with 95% confidence intervals (CIs). Intervention attendance rates are described.

Preliminary estimates of effect size with 95% CIs are presented for the four potential primary outcomes to inform the plausibility of the effect sizes used in future sample size calculations. Participants were analysed in the group they were randomised to and we attempted to collect outcome measure data from everyone randomised. Missing data were assumed to be missing completely at random (MCAR) and no imputation methods were used. Analysis of covariance was used to estimate effect size for each outcome variable at follow-up, adjusting for centre and the respective baseline values. Although stroke severity was a stratification variable in the randomisation we have not adjusted for it in the analysis because of the very

small number with a severe stroke. In the future trial we would also take into account clustering effects resulting from the group-based nature of the HoS intervention.[50] We have not taken into account clustering in the analysis presented here because (a) this is a feasibility study where the aim is not to obtain precise estimates of effect size and (b) there were just 56 participants (29 receiving the HoS intervention) and only a small number of clusters (n = 4) making it difficult to adjust for clustering. A consequence is that widths of the 95% confidence intervals are likely to be underestimated. Standardised effect sizes (Cohen's *d)* were obtained by dividing effect sizes by pooled baseline standard deviation.

Economic analysis

We report completion rates for the resource use categories. A preliminary estimate of the cost of delivering the HoS intervention was derived using macro-level costings. We also report artist facilitator time to deliver the intervention at the micro-level and patient travel expenses to the sessions.

We further report resource use units and costs per category per trial arm, for an indication of cost-drivers for the intervention for the health and social care perspective. We derived capability index scores for the ICECAP-A[51] and applied UK preference-based tariffs to the SF-6D to derive quality-adjusted life-years.[52]

Qualitative analysis

The interviews were transcribed verbatim. The responses related to the research processes such as recruitment, screening and the administration of outcome measures as well as the acceptability of the venue, the intervention, and potential willingness to pay for the intervention (latter three, intervention group only) were analysed using content analysis.[53] The accounts of the expectations and experiences of the intervention were analysed separately using thematic analysis.[54] These finding will be reported elsewhere.

RESULTS

Study procedures, recruitment and retention rates

Fifty-six people were randomised (88% of our original target of 64) (see Figure 1). Nearly two-thirds of the sample was male and the mean age of the sample was 70 (SD 12.1) years and mean time-since-stroke was 9 (SD 6.1) months. Approximately 80% of participants had had ischaemic strokes. Seventy percent of the sample was retired (see Table 1). One participant who had had their stroke outside the 2 year post-stroke inclusion time window (32 months post-stroke) was erroneously recruited into the study. We included this participant's data in the analysis.

INSERT FIG 1 ABOUT HERE

INSERT TABLE 1 ABOUT HERE

Participants were enrolled into the study between August 2014 and April 2015 and the final follow-up occurred in December 2015. The recruitment rate across both centres was 14% [95% CI: 11% to 17%]. In Bournemouth, an acute hospital setting, the recruitment rate was 11% [95% CI: 8% to 14%] and in Cambridgeshire, a community setting, it was 28% [95% CI: 19% to 38%].

In total, information about the study was given or sent to 396 people (313 in Bournemouth and 83 in Cambridgeshire). Of these, 198 people declined participation, 112 did not return the reply slip, four did not meet the inclusion criteria, 26 were excluded for 'other reasons' (see Figure 1).

Six participants (11%) withdrew from both the study and follow-up data collection and three participants (5%) did not return the main outcome measures at follow-up. For two of the three proposed potential primary outcomes (HADS and ICECAP-A), 47/56 (84% (95% CI

73%, 92%)) of randomised participants had complete baseline and follow-up data and 46/56 (82% (95% CI: 70%, 91%)) had complete baseline and follow-up data for the WEMWBS.

Reasons for non-participation

Of 198 people declining participation, 89 gave reasons, the most common ones related to not being interested/feeling the intervention 'wasn't right for them' (n=27) and health reasons (n=14).

Delivery, attendance rates and group size

Five participants allocated to the HoS arm declined the intervention post-randomisation (see CONSORT diagram for reasons). Of the 29 participants randomised to HoS sessions 20 (69%, 95% CI; 51% to 84%) attended six or more of the 10 sessions.

Two HoS groups were delivered in Bournemouth (iterations 1 & 2) and two in Cambridgeshire (iterations 3 & 4). The timing of the HoS sessions deviated slightly from that specified in the original protocol (first 7 sessions held weekly, sessions 8-9 fortnightly, and session 10 held three weeks later) in three of the four iterations due to venue availability and the timing of public holidays. In Bournemouth, breaks occurred in weeks 6, 8, 9 and 13 (iteration 1) and in weeks 5, 8, 9 and 12 (iteration 2). In the Cambridgeshire centre, breaks occurred in weeks 2, 6, 10 and 13 (iteration 3). The second iteration (iteration 4) in Cambridgeshire followed the protocol.

The planned group size was 6-8 participants and this target was mostly met in iterations 1-3 with 70% (21/30) of the delivered sessions including six or more people. However, due to time pressures, and because the grant was coming to end, iteration 4 commenced before iteration 3 had finished and only six people were allocated to the intervention arm for this final iteration. Two of these subsequently declined attending the intervention and one person

withdrew from the intervention after attending the first session, with the result that in iteration 4, six of the 10 sessions included only two people.

Ratings on the domains of the Doojse Scale (measuring 'sense of belonging')[44] increased across sessions and remained high in the final session (see Table S1 in data supplement).

Support requirements for HoS group members

At the Cambridgeshire centre one of the artist facilitators discussed a HoS group member's cognitive needs with FG (clinical psychology). Subsequently, several adaptations were identified and implemented such as providing a small sketchpad when needing to wait for additional support and providing instructions one step at a time.

Suitability of the outcome measures and feasibility of the assessment strategy

The ACE-R, originally designed as a screening tool for dementia, provides a single overall functioning standardised score, and relies heavily on language abilities. It did not prove suitable for our sample, of whom nearly half (46%) had some degree of language difficulty. We have not presented the baseline descriptive data for the ACE-R as we do not feel they provide an accurate summary of the sample's cognitive abilities.

Overall, participants found the self-reported outcome measures acceptable and were able to complete them, sometimes requiring support. However, in the qualitative interviews several participants reported finding the HISDS-III[42] difficult to complete likely due to its relatively complex language demands and the way in which the bipolar adjective pairs comprising the scale vary in direction. These difficulties were reflected in some of the response patterns obtained and corroborated by the blinded assessors' experiences. For these reasons we have not presented these data.

Missing questionnaire data were followed-up via telephone by an RA (baseline) or blinded assessor (follow-up) at each centre. Levels of missing data were very low - overall, 99.8% of the questionnaire items comprising the four identified potential primary outcomes were completed (1809/1815 items at baseline and 1550/1551 items at follow-up) by those who provided outcomes (at baseline n= 55 and follow up n = 47).

Support requirements to complete outcomes

At follow-up, the self-report questionnaire booklets were administered postally by default but face-to-face support was provided if required/requested. Fifty-eight percent of those with outcomes at follow-up (26/45, data for 2 cases missing) reported that they completed the questionnaire booklet with no support, 8 (18%) received support from the researcher in the home, 10 (22%) received support from family and friends and 1 (2%) received telephone support from the blinded assessor.

Possible primary outcomes

In Table 2 we present descriptives for the four possible primary outcomes (WEMWBS, HADS-A, HADS-D, ICECAP-A) and descriptives for all other outcomes gathered are presented in Web Supplement Table S2.

INSERT TABLE 2 ABOUT HERE

Completion of resource use questionnaire

The resource use questionnaire was completed by 50/56 of participants (89%), 25/29 of patients in the HoS arm and 25/27 of patients in the usual care arm. Of these 33 (66%) were administered over the telephone, 16 (32%) face-to-face at home and 1 (2%) via the post. Although not included in the original study protocol, in the Bournemouth centre duration data were logged with the 19 telephone interviews lasting 23 minutes (SD=10) on average and the 8 face-to-face administrations in the home an average of 38 minutes (SD=13).

Completion rates of resource use categories were high and similar between the arms of the trial (Table 3). The least completed category was community based services such as primary care visits (see Table 3) with 90% complete data for this category (both trial arms combined). Seventy-nine percent complete data (out of the full sample) is available for an economic analysis from the health and social care perspective.

INSERT TABLE 3 ABOUT HERE

Assessor allocation guesses

At the Cambridgeshire centre, due to a delay in receiving approval for patient access for the blinded assessor, the unblinded RA administered outcomes to six participants. Overall 50/56 participants (Cambridgeshire = 23; Bournemouth = 27) completed questionnaire outcomes and/or telephone health use questionnaires at follow-up. In Cambridgeshire, the blinded assessor correctly guessed allocation on 9/17 (53%) occasions ($p = 1.00$ using the exact binomial test to compare with expected percentage of 50%) (NB. the six outcome assessment occasions in Cambridgeshire that were not undertaken by a blinded assessor are excluded). In Bournemouth, the blinded assessor correctly guessed allocation on 24/27 (89%) occasions ($p < .001$). Thus overall the blinded assessors correctly guessed allocation on 33/44 (75%; 95% CI 61% to 85%) occasions, $p = 0.001$.

Serious adverse events and adverse events

Five serious adverse events were reported during the study period. None was deemed related to the intervention. These included admissions to hospital for bunion removal, facial weakness and vomiting, atrial fibrillation, pneumonia, and a transient ischaemic attack.

Five adverse events were noted. None was deemed related to the intervention. Four people attended the Emergency Department but were not admitted (water retention, fall at home, fall in the road, anxiety). One person sustained a minor injury to their arm at home.

Cost of delivering the HoS intervention

The cost of delivering the HoS intervention was £1,960 in Bournemouth and £2,530 in Cambridgeshire, reflecting higher venue hire costs in Cambridgeshire (see Table 4). On average, six participants attended the two HoS iterations held in Bournemouth and four attended the two HoS iterations held in Cambridgeshire. The HoS intervention would cost the health care payer, on average, £327 per participant in Bournemouth and £657 in Cambridgeshire. The cost could be as low as £245 per participant at full capacity of 8 people.

INSERT TABLE 4 ABOUT HERE

Health-related quality of life gain, resource use and costs

Table 5 reports the quality adjusted life year (QALY) gains from baseline and resource use and costs for the HoS and usual care arms. Potential cost drivers for the intervention are inpatient and outpatient appointments and contacts with a social worker.

INSERT TABLE 5 ABOUT HERE

Qualitative

All 12 people who were purposively sampled for interview (8 intervention, 4 usual care) were interviewed on two occasions (male =7, female = 5; mean age = 70 years (range 51-83 years); mean time-since-stroke = 7 months (range 4-12 months)). Most had had a mild, and one a moderately disabling, stroke. Nine had an affected arm and five had speech difficulties. All participants found the research processes acceptable and the screening and outcome measures easy to complete with the support provided. One person commented

negatively on the cognitive assessment as her husband who lived with dementia had had to complete it in the past. One person noted they would have liked more opportunities for open answers on the questionnaires so they could provide some explanations about their responses. All interviewees would have been happy to complete outcome measures at 4 and 12 months follow up, if asked. They valued receiving the economic checklist which some completed over the specified time period and others used to supplement the telephone interviews.

Timing of sessions (held in the morning) and session duration (2 hours) were acceptable. While the venues were found to be acceptable, a few people mentioned that they would have liked access to a café where they could meet following the HoS sessions. Participants in Bournemouth were willing to pay up to £10 per session for transport if required. As all but one interviewee in Cambridgeshire drove to sessions (it was a much more rural setting than Bournemouth) and were happy to do so, transport costs were not discussed during the interviews. The one interviewee who used transport in Cambridgeshire only attended one session due to health issues (unrelated to stroke). Findings related to expectations and experiences of taking part in the groups will be reported elsewhere.

DISCUSSION

This is the first study to formally test the feasibility of an Arts & Health intervention for people post-stroke in the community. The HoS intervention was highly valued by the majority of people who took part in the HoS groups, with many reporting increased confidence both within and outside the groups. Some people reported that it was life changing. Study retention was good, data completion rates high and loss to follow-up low. While only short-term follow-up was included in this feasibility study, a future definitive study would include longer term 12 month follow-up. The main outcome measures were acceptable and mostly completed (sometimes with support). While administering the resource use questionnaire by

telephone resulted in high levels of data completeness, maintaining assessor blinding at follow-up proved challenging, particularly in the Bournemouth centre. To try to improve assessor blinding success rates, we will add instructions on the printed versions of the outcome measures that emphasise the importance of not disclosing allocation group and will reword the question in the resource use questionnaire that asks about contacts with charities, social or activity groups. We will also seek PPI advice about how we can best convey the message not to disclose allocation at the start of the telephone resource use interview and, based on this, will create a standard script. We will provide training for the blinded assessors.

We have used novel dissemination methods such as making a short film involving people who had attended the HoS groups in Bournemouth, holding an art exhibition in both Bournemouth and Cambridgeshire to showcase the creations of the HoS group members. While we did not quite reach our original recruitment target, the overall recruitment rate (14%) was not unlike that achieved in other similar studies.[55] In the current study, the recruitment rate in the community setting (28%) was higher than that via hospitals (11%). This might be because in Cambridgeshire recruitment was undertaken by clinicians working in the community who often had a long-term relationship with their clients. In contrast, at Bournemouth and Christchurch hospitals, while some potential participants were known and approached directly by the research nurses, others were identified from clinical databases and sent study information in the post.

One of the reasons that some people declined participation in the study was because they felt they were 'not artistic enough' or that 'art was not for them'. However, the HoS intervention supports people to create a new way of looking at, and develop confidence in, a new world following stroke; it is about that process of exploration rather than art per se. Modifying the name of the intervention and the way it is described to participants might be one way to increase recruitment. Additionally, we could extend the eligibility criteria by

providing additional support so that people who require support with toileting needs could attend, though this would have cost implications. Finally, we could also expand the recruitment strategy to include primary care. We will continue to consult with service users and stakeholders to seek their advice on ways of increasing recruitment rates and how best to convey the essence of the intervention to people.

The breaks structured between the HoS sessions were potentially instrumental in encouraging participants to continue art work outside the group and the links created with local arts and health practitioners led to some continuing more independent creative practice after the research ended. Other important practical considerations include ensuring that venues are on public or community transport routes, have free and disabled car parking facilities, heating/air conditioning and drink-making facilities. In the full multi-centre trial to maximise recruitment, and to be as inclusive as possible, transport will be provided, if required.

Some participants reported finding the HISDS-III difficult to complete. For these reasons we would not include this outcome in a future trial. The ACE-R also proved problematic due to its heavy reliance on language abilities. It will be important to identify a more appropriate way to evaluate specific domains of cognitive functioning for the future trial. One possibility is the recently developed Oxford Cognitive Screen[56] which has been designed specifically with a stroke population in mind and is purportedly inclusive for individuals with aphasia and neglect.

All four of the possible primary outcome measures for the future trial (WEMWBS, HADS-D, HADS-A, ICECAP-O) demonstrated change in the direction of benefit for the HoS arm. The HADS-D is the main contender for the primary outcome in a subsequent definitive trial and with medium standardised effect sizes it is likely that such a trial would be feasibly sized.

The idea for the HoS intervention originated from a stroke survivor (and co-author) (RC) who had identified a gap in service provision. Since then, Arts & Health approaches are beginning to be recognised by policy makers as a useful way to support the health and wellbeing of communities.[24] With NHS pressures and difficulties of accessing formal services[57] our relatively low cost intervention (which could be as low as £245 per person if delivered at full capacity) offers potential to form part of a comprehensive long term support pathway to reduce depression following a stroke and increase community access and participation. As we look ahead to a future definitive trial it will be important to draw upon implementation science expertise and to consult with key stakeholders. This will help us to ensure that the HoS intervention, if found to be effective and cost-effective, can be rolled out within existing health service and social care structures and is designed in such a way so as to facilitate its rapid adoption and implementation into practice.

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Contributors

CEH (Chief Investigator), FG (Principal Investigator, Cambridge Centre), CLR and RC were involved in the conception of the study and CEH, ST and FG led the design. CEH with ST and FG led the writing of initial grant application and protocol. DJ and FG advised on clinical aspects related to the grant application, PT led the statistical component of the study, EM led the economic evaluation, supported by TP and KG and FR advised on the qualitative aspects. MG and SN refined aspects of the draft protocol. MG coordinated the study on a day-to-day basis. CT and AW organised and administered the blinded assessments. ST and CEH drafted the manuscript, FG, MG, PT and EM provided detailed feedback and all other authors critically reviewed and approved the final version.

Competing interests

None

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Ethics approval

Ethics approval was granted by the Exeter NRES Committee (REC Ref 13/SW/0136) on 30/07/13. Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospital NHS Foundation Trust on 06/05/14. This Trust is the study sponsor. Local Research and Development approval was granted by Cambridgeshire Community Services NHS Trust on 29/05/14.

Provenance and peer review

Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data Sharing Statement:

Requests for de-identified data should be directed to the corresponding author.

Table 1: Baseline clinical and demographic descriptives for the sample

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
Gender [n (%)]			
▪ Female; Male	7 (26%); 20 (74%)	17 (59%); 12 (41%)	24 (43%); 32 (57%)
Age (years) Mean (SD) range	67.4 (12.83) 39-88	72.0 (11.22) 27-87	69.8 (12.1) 27-88
Ethnicity			
▪ White English	25 (93%)	23 (79%)	48 (86%)

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
▪ White other British	1 (4%)	5 (17%)	6 (11%)
▪ Mixed- white and Asian	1 (4%)	-	1 (2%)
▪ Black or Black British – African	-	1 (3%)	1 (2%)
Time since stroke (months) Median (IQR) range*	7 (5) 2-19	7 (7) 1-32	7 (5) 1-32
Stroke type [n (%)]			
▪ Ischaemic/thrombotic	6 (22%)	5 (17%)	11 (20%)
▪ Ischaemic/embolic	1 (4%)	1 (3%)	2 (4%)
▪ Haemorrhagic/Intracerebral	2 (7%)	2 (7%)	4 (7%)
▪ Haemorrhagic subarachnoid	-	1 (3%)	1 (2%)
▪ Ischaemic/type unknown	13 (48%)	16 (55%)	29 (52%)
▪ Haemorrhagic/type unknown	4 (15%)	3 (10%)	7 (13%)
▪ Type unknown	1 (4%)	1 (3%)	2 (4%)
Stroke severity (Rivermead Gross motor assessment) [n (%)]			
Total Score ≤ 6	1 (4%)	2 (7%)	3 (5%)
Total Score ≥ 7	26 (96%)	27 (93%)	53 (95%)
Stroke side [n (%)]			
▪ Left CVA	11 (42%)	15 (52%)	26 (47%)
▪ Right CVA	13 (50%)	11 (38%)	24 (44%)
▪ Both sides	1 (4%)	3 (10%)	4 (7%)
▪ Not applicable	1 (4%)	-	1 (2%)
▪ System missing	1	-	1
Centre [n (%)]			
▪ Bournemouth	16 (59%)	17 (59%)	33 (59%)
▪ Cambridgeshire	11 (41%)	12 (41%)	23 (41%)
Level of education [n (%)]			
Highest qualification achieved:			
▪ No qualifications	3 (12%)	8 (30%)	11 (20%)
▪ One or more GCSE	4 (16%)	4 (15%)	8 (14%)
▪ One or more A level	5 (20%)	1 (4%)	6 (11%)
▪ First degree or higher	1 (4%)	5 (19%)	6 11%)
▪ Other	12 (48%)	9 (33%)	21 (38%)
▪ System missing	2	2	4 (7%)
Pre-stroke employment status			
▪ Retired	14 (52%)	25 (86%)	39 (70%)
▪ Full-time employment	3 (11%)	1 (3%)	4 (7%)
▪ Part-time employment	3 (11%)	1 (3%)	4 (7%)
▪ Self-employed	2 (7%)	1 (3%)	3 (5%)
▪ Other (unemployed; homemaker)	5 (19%)	1 (3%)	6 (11%)
Marital status [n (%)]			
▪ Single	4 (15%)	3 (10%)	7 (13%)
▪ Married/cohabiting	17 (63%)	13 (45%)	30 (54%)
▪ Separated/divorced	3 (11%)	3 (10%)	6 (11%)
▪ Widowed	3 (11%)	10 (34%)	13 (23%)
Household composition			
▪ Living alone	9 (33%)	13 (45%)	23 (41%)
▪ Living with others	18 (67%)	15 (52%)	32 (57%)
▪ Sheltered housing	-	1 (3%)	1 (2%%)
Taking medication for mood			
▪ No	21 (78%)	24 (86%)	10 (18%)
▪ Yes	6 (22%)	4 (14%)	45 (82%)
▪ System missing	-	1	1
Communication difficulties†			
▪ No	18 (67%)	12 (59%)	30 (54%)
▪ Yes	9 (33%)	17 (41%)	26 (46%)
Motricity Index Total Score*			
Median (IQR) N	86.3 (27) 12-100, 27	81.0 (29) 1-100, 29	83.6 (27) 56

**NB for one case one item was missing and*

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)

was replaced by the mean

*Although the inclusion criterion for the study was ≤ 24 months post stroke we erroneously recruited one participant at 32 months post stroke and this participant's data are included in the analysis.

Table 2: Descriptives and preliminary estimates of effect size for potential primary outcomes

Outcome measure	Baseline N=56	Mean difference (95% CI)	Post N=47	Standardised Effect Size (Cohen's *d*)
Warwick and Edinburgh Mental Well Being Scale (WEMWBS) *(potential range 14-70, higher scores greater wellbeing)*				
UC mean (SD)] N	48.8 (10.64) 26		48.0 (8.40) 21	
HoS mean (SD) N	46.9 (8.94) 29		48.4 (10.28) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		2.25 [-2.83, 7.32]		0.23
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		1.14 [-3.42, 5.70]		0.12
Hospital Anxiety and Depression Scale (HADS) *Anxiety subscale* *(potential range 0-21 each subscale, higher scores greater anxiety)*				
UC mean (SD) N	7.4 (3.72) 27		7.0 (4.13) 22	
HoS mean (SD) N	7.2 (4.29) 29		6.3 (3.74) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-0.47 [-2.48, 1.54]		-0.12
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-0.55 [-2.39, 1.28]		-0.14
Hospital Anxiety and Depression Scale (HADS) *Depression subscale* *(potential range 0-21 each subscale, higher scores greater depression)*				
UC mean (SD) N	4.8 (2.68) 27		6.1 (3.33) 22	
HoS mean (SD) N	6.6 (3.76) 29		6.0 (4.18) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-1.82 [-3.42, -0.22]		-0.56
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-1.46 [-3.12, 0.21]		-0.45
ICECAP-A tariff (potential *range 0-1, higher scores greater capability)*				
UC mean (SD) N	0.81 (0.14) 26		0.78 (0.15) 21	
HoS mean (SD) N	0.75 (0.16) 29		0.76 (0.22) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		0.05 [-0.03, 0.13]		0.33
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		0.04 [-0.05, 0.12]		0.26

Where high scores indicate better outcomes, positive effect sizes suggest benefit for the HoS arm.
Where low scores indicate better outcomes, negative effect sizes suggest benefit for the HoS arm.

Table 3: Completeness of resource use data

	N complete data	% of questionnaires filled in (n=25)	% of sample (n=29)	N complete data	% of questionnaires filled in (n=25)	% of sample (n=27)
	Intervention			Usual Care		
Health and social care						
Outpatient visits	25	100%	86%	25	100%	93%
Inpatient visits	25	100%	86%	25	100%	93%
Community based services	21	84%	72%	24	96%	89%
Personal social services	25	100%	86%	24	96%	89%
Total health and social care	21	84%	72%	23	92%	85%
Further resource use collected						
Time off work	25	100%	86%	23	92%	85%
Time off normal activities	25	100%	86%	25	100%	93%
Hours of help per week	21	84%	72%	24	96%	89%
Private therapies used	25	100%	86%	25	100%	93%
Charity/support group contacts	25	100%	86%	25	100%	93%

Table 4: HoS delivery costs

Cost of delivering HoS	**Bournemouth**	**Cambridgeshire**
Costs for 10 sessions		
Artist fee	£1,200	£1,200
Venue cost	£430	£1,000
Materials cost	£330	£330
Total	£1,960	£2,530
Mean no. of participants per session	6.0	3.85
Cost of HoS per participant (based on mean attendance)	£327	£657
Cost of HoS per participant at capacity (8 attendees)	£245	£316
Reporting micro-level resource use to deliver HoS		
Artist time (in mean hours):		
Session duration	20.0	20.5
Preparation time	20.0	10.6
Travel time	15.0	15.6
Total intervention time	55.0	46.7
Participant travel costs	£1,021	£658

Table 5: Outcomes resource use and cost of delivering care in both arms

	HoS Intervention						Usual care					
	N	N users	Mean use	SD	Mean cost	SD	N	N users	Mean use	SD	Mean cost	SD
Outcomes												
QALYs gained (SF6D)	22	-	0.18	0.03	-	-	21	-	0.17	0.02	-	-
Inpatient and A & E												
Inpatient admissions	25	3	0.9	3.0	£49	£136	25	3	0.7	2.8	£96	£308
A & E or hospital admissions	25	4	0.2	0.4	£22	£53	25	6	0.2	0.4	£34	£61
Outpatient appointments												
Stroke rehabilitation	25	1	0.0	0.2	£10	£50	25	2	0.1	0.3	£20	£69
Physiotherapy	25	3	0.3	1.2	£6	£23	25	4	1.0	2.9	£20	£56
Occupational therapy	25	1	0.0	0.2	£1	£4	25	3	0.2	0.5	£3	£9
Speech and language therapy	25	2	0.2	0.8	£4	£16	25	2	0.4	1.6	£7	£30
Psychologist	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0
Dietician	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0
Other outpatient appointments	25	14	1.2	1.5	£140	£210	25	13	2.0	3.2	£196	£393
Community-based services												
GP contacts	24	17	1.9	1.5	£92	£79	25	18	1.6	2.0	£72	£83
GP nurse contacts	25	11	1.6	3.0	£22	£44	25	16	2.0	3.1	£26	£40
Physiotherapy contacts	25	3	0.3	1.2	£6	£23	25	2	0.9	3.7	£19	£78
SALT contacts	24	3	0.4	1.3	£25	£82	25	3	1.1	3.5	£94	£308
Occupational therapy at home	25	1	0.2	0.8	£5	£25	25	2	0.2	0.9	£7	£27
Repeat prescriptions from GP	23	16	4.0	5.6	£5	£7	24	18	4.0	4.3	£5	£5
Other community-based appointments	21	2	0.4	1.4	£25	£77	24	1	0.3	1.6	£28	£143
Personal social services												
Home care worker contacts	25	0	0.0	0.0	£0	£0	24	2	0.9	3.4	£11	£41
Social worker contacts (hours)	25	2	0.4	1.6	£28	£127	25	3	0.3	0.9	£24	£72
Food at home services (meals)	25	0	0.0	0.0	£0	£0	25	1	0.6	3.2	£4	£21

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Figure Legends:

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

Figure 2: Painting by MDBD

Figure 3: Drawing by FB

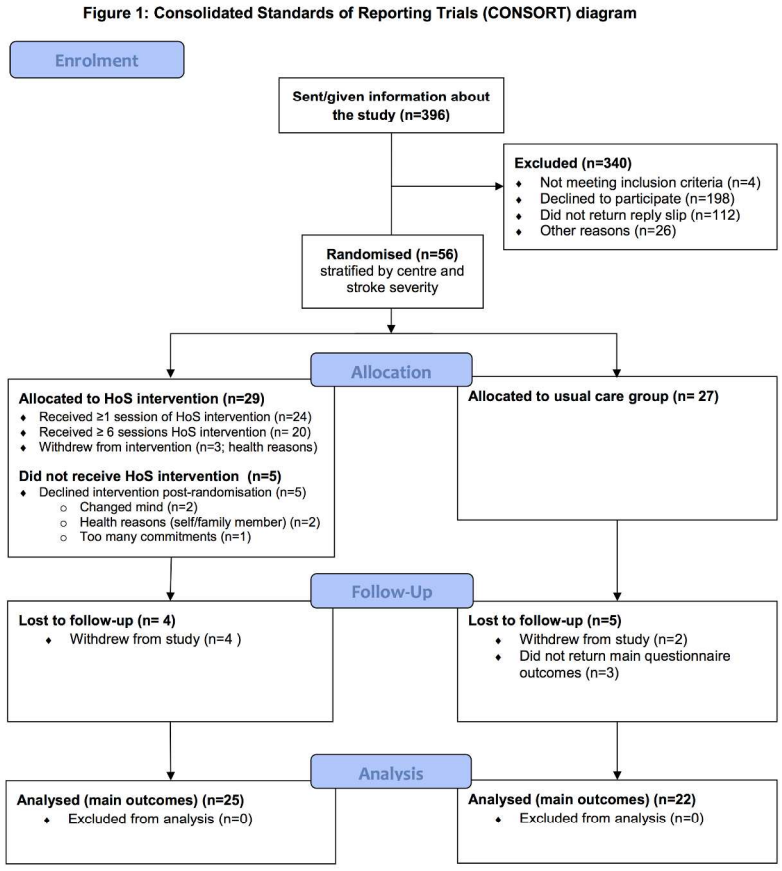
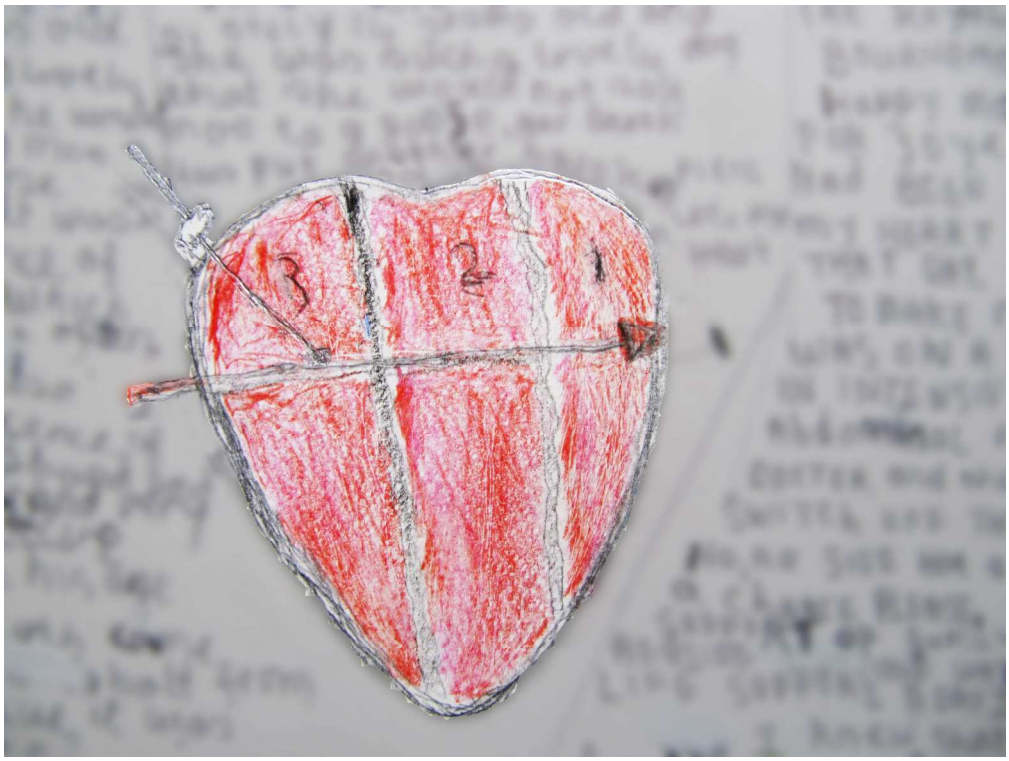


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

209x297mm (300 x 300 DPI)

Painting by MDBD

159x121mm (220 x 220 DPI)



Drawing by FB

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Supplementary Web tables

Table S1: Descriptives for Sense of Belonging

Sense of Belonging statement	**Median (IQR) range**		
(potential score range 1-7, higher scores indicate higher sense of belonging)	*Session 1 (n=24)*	*Session 5 (n=20)*	*Session 10 (n=21)*
1. I see myself as a member of the HoS group	6 (2) 1-7	7 (1) 4-7	7 (0) 6-7
2. I am pleased to be a member of the HoS group	7 (2) 1-7	7 (1) 4-7	7 (0) 4-7
3. I feel strong ties with members of the HoS group	4 (5) 1-7	5 (3) 4-7	6 (2) 3-7
4. I identify with other members of the HoS group	5 (3) 1-7	6 (2) 4-7	7 (1) 4-7

Table S2: Descriptives for potential secondary outcomes

Outcome measure	Baseline *N=56*	Post *N=47*
Rosenberg Self-Esteem Scale (RSES) *(potential score range 0-30 , higher scores indicate higher self-esteem)*		
UC mean (SD) N	20.8 (6.23) 27	20.1 (5.21) 22
HoS mean (SD) N	20.4 (5.81) 29	21.1 (5.67) 25
Medical Outcomes Short Form-36 (SF-36) - Physical functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	43.4 (24.51) 27	42.7 (23.94) 22
HoS mean (SD) N	48.3 (25.16) 27	55.3 (23.23) 23
SF-36 Role limitations - Physical subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean, SD (95% CI)	23.9 (29.36) 27	17.0 (26.03) 22
HoS mean (SD) N	35.0 (34.61) 28	27.0 (38.13) 25
SF-36 Role limitations - Emotional *(potential range 0-100, higher scores more favourable health state)*		
UC mean (SD) N	42.4 (45.05) 27	50.0 (42.10) 22
HoS mean (SD) N	45.3 (41.81) 28	49.3 (45.26) 25
SF-36 Energy/Fatigue subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	48.6 (18.01) 27	42.05 (20.45) 22
HoS mean (SD) N	45.2 (25.5) 27	43.3 (25.40) 24
SF-36 Emotional wellbeing subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD (N)	68.91 (17.19) 27	69.81 (19.51) 22
HoS mean SD (N)	67.33 (17.16) 27	68. 83 (20.43) 24
SF-36 Social functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	69.3 (26.65) 27	64.2 (29.70) 22
HoS mean (SD) N	66.5 (26.45) 28	72.00 (28.25) 25
SF-36 Pain subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	66.8 (24.45) 27	71.2 (28.32) 22
HoS mean (SD) N	61.9 (24.97) 27	69.5 (27.63) 25
SF-36 General Health subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD N	55.2 (23.68) 27	55.5 (21.49) 22
HoS mean (SD) N	51.4 (20.09) 27	57.3 (19.67) 24
SF-6D Derived health state value *(potential range -0.296 to 1.00 with higher scores indicating better health)*		
UC mean (SD) N	0.63 (0.09) 27	0.64 (0.08) 21
HoS mean, SD N	0.64 (0.12) 26	0.68 (0.12) 24

UC = Usual Care
HoS = HeART of Stroke

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6-7
	2b	Specific objectives or research questions for pilot trial	8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	10, 20
Participants	4a	Eligibility criteria for participants	10
	4b	Settings and locations where the data were collected	10, 13
	4c	How participants were identified and consented	10-11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12-14
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	14-17
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	10, 20
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	-
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	11
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	11
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	11

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11,14,23
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	17-18
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	19 + Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	19
	14b	Why the pilot trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	32
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	34
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	34
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	35-39
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	23
	19a	If relevant, other important unintended consequences	-
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25-28
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	25-28
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	25-28
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	25-28
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	Referenced
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29
	26	Ethical approval or approval by research review committee, confirmed with reference number	

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HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention plus usual care compared with usual care to increase psychological wellbeing in people following a stroke.

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Keywords:	Stroke < NEUROLOGY, Arts & Health, Identity, Wellbeing, Feasibility Study

Title: HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention plus usual care compared with usual care to increase psychological wellbeing in people following a stroke.

Corresponding author:

Caroline Ellis-Hill,* Faculty of Health and Social Sciences; Bournemouth University, Bournemouth, UK

cehill@bournemouth.ac.uk

Co-authors:

Sarah Thomas,* Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Fergus Gracey, Department of Clinical Psychology, University of East Anglia, Norwich, UK

Catherine Lamont-Robinson, School of Social and Community Medicine, University of Bristol, Bristol, UK

Robin Cant, Servicer User, (formerly of Canterbury Christ Church University), Canterbury, UK

Elsa Marques, School of Clinical Sciences, University of Bristol, Bristol, UK

Peter Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Mary Grant, Warwick Clinical Trials Unit, University of Warwick, Coventry, UK

Samantha Nunn, Cambridgeshire Community Services NHS Trust, Oliver Zangwill Centre, Ely, UK

Thomas Paling, School of Clinical Sciences, University of Bristol, Bristol, UK

Charlotte Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Alessa Werson Department of Clinical Psychology, University of East Anglia, Norwich, UK

Kathleen Galvin, School of Health Sciences, University of Brighton, Brighton, UK

Frances Reynolds, formerly College of Health and Life Sciences, Brunel University London, Uxbridge, UK

Damian Jenkinson, Stroke Unit, Dorset County Hospital, Dorchester UK

*Joint first authors

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Word count: ~ 7500

ABSTRACT

Introduction People often experience distress following stroke due to fundamental challenges to their identity.

Objectives Evaluate: (i) the acceptability of 'HeART of Stroke' (HoS), a community-based Arts & Health group intervention to increase psychological wellbeing; (ii) the feasibility of a definitive randomised controlled trial (RCT).

Design Two-centre 24-month parallel arm RCT with qualitative and economic components. Randomisation stratified by centre and stroke severity. Participant blinding was not possible. Outcome assessment blinding attempted.

Setting Community

Participants Community-dwelling adults ≤ 2 years post-stroke, recruited via hospital clinical teams/databases or community stroke/rehabilitation teams.

Interventions Artist-facilitated Arts & Health group intervention (HoS) (ten 2-hour sessions over 14 weeks) plus usual care (UC) versus UC.

Outcomes Self-reported measures of wellbeing, mood, capability, health-related quality of life, self-esteem and self-concept (baseline and five months post-randomisation). Key feasibility parameters were gathered, data collection methods piloted and participant interviews (n=24) explored acceptability of the intervention/study processes.

Results Despite a low recruitment rate (14%; 95% CI: 11% to 18%), 88% of the recruitment target was met with 29 participants randomised to HoS and 27 to UC (57% male; mean [SD] age = 70 [12.1] years; time-since-stroke = 9 [6.1] months). Follow-up data were available for 47/56 (84%; 95% CI: 72% to 91%). Completion rates for a study-specific resource use questionnaire were 79% and 68% (NHS and societal perspectives). Five people declined HoS post-randomisation; of the remaining 24 who attended, 83% attended ≥6 sessions.

Preliminary effect sizes for candidate primary outcomes were in the direction of benefit for the HoS arm. Participants found study processes acceptable. The intervention cost an estimated £456 per person and was well-received (no intervention-related serious adverse events reported).

Conclusions Findings from this first community-based study of an Arts & Health intervention for people post-stroke suggest a definitive RCT is feasible. Recruitment methods will be revised.

ISRCTN 99728983

Strengths and limitations of this study

- This is the first feasibility study of a community-based Arts & Health group intervention to support wellbeing following a stroke.
- Participants were recruited via both hospital and community clinical teams enabling recruitment rate estimates for two different recruitment approaches.
- The study incorporated mixed methods and a feasibility economic component.
- The study only included short term follow-up.
- Findings will inform a definitive randomised controlled trial of effectiveness and cost-effectiveness.

INTRODUCTION

Each year over 150,000 people in the UK experience a stroke[1] with one-third left with residual disabilities including paralysis on one side and cognitive and communication impairments.[2] Qualitative meta-syntheses have highlighted that following a stroke, or other types of brain injury, people face fundamental emotional and existential challenges. They experience challenges to their sense of self and identity and their current and future lives are filled with uncertainty.[3, 4] Emotional health and wellbeing following stroke have been highlighted as national priorities, featuring in the James Lind Alliance 'top ten' research priorities.[5]

Following a stroke people report a need to 'get their lives back'. Failure to do so is associated with depression[6,7] (with reported accumulative incidence of 39–52% within 5 years of stroke[7]), loss of confidence,[8] people having difficulty in 'feeling part of things',[9] loss of sense of self[10] and becoming socially isolated.[11] This creates long-terms costs, not only for the stroke survivor, but also for their family members,[12,13] and for government, health and social services through reduced family employment and increased social and primary care needs.[14] Where untreated, depression is associated with poorer functional outcomes[15] and higher mortality.[16,17]

While there have been great improvements in stroke care, the stroke pathway for long-term support is still under-researched and under-developed. A Cochrane review indicated no evidence for pharmacotherapy in the prevention of post-stroke depression, and only weak evidence for psychotherapeutic approaches.[18] A more recent systematic review[19] that limited inclusion to participants without a diagnosis of depression at baseline concluded that antidepressants may reduce the likelihood of depression developing post-stroke but that the optimum timing and duration of treatment was not clear. There is also evidence to suggest that pharmacological treatments can have modest benefits in the treatment of depression

post-stroke.[20-23] However, anti-depressants have side effects and may have undesirable interactions with other medications and comorbidities.[20-23]

While the evidence for the effectiveness of psychotherapeutic interventions for post-stroke depression is inconclusive,[20] two recent RCTs (motivational interviewing[24,25] and a brief psychosocial behavioural intervention plus anti-depressant[26]) demonstrated reductions in post-stroke depression. However, these trials involved people early after stroke and excluded those with severe communication or cognitive problems. The CALM trial[27] of behavioural therapy demonstrated improved mood in stroke patients with aphasia and a feasibility study of behavioural activation is now underway using a broader sample of people with depression 3-60 months post-stroke.[28] A study of cognitive behavioural therapy for post-stroke depression demonstrated no benefits over usual care or an attention control; however, the sample size was small.[29]

Around 20% of people experience clinical levels of anxiety following stroke.[30] A recent Cochrane review highlighted the need for further rigorously conducted RCTs to assess pharmacological and psychological treatments for anxiety following stroke.[30]

A stepped approach to psychological support following stroke has been proposed in the UK [31] (Step 1: awareness, watching; Step 2: low intensity services, such as guided self-help; Step 3: high intensity services, such as cognitive behavioural therapy (CBT)) but this system is still in its infancy.

Harrison et al. (2017)[32] concluded from qualitative research with service users that research is needed to test alternative options to formal psychological support. Ellis-Hill et al.[33] and Gracey et al.[34] have independently developed complementary theoretical models based on empirical evidence to understand the processes involved in re-establishing a positive sense

of self and confidence in life following a stroke. The current research draws upon two specific and related theoretical frameworks; namely, the Life Thread Model[33] and Self–discrepancy theory.[9,34] These highlight that following an acquired brain injury people often lose a sense of coherence of self and a sense of predictability in life. These existential losses can cause considerable anxiety and can lead to depression. Within neuropsychological rehabilitation, it is hypothesised that establishing a safe place where clients feel understood and supported can facilitate self-development.[34,35] When carrying out embodied creative activities (such as art), people can reconnect their past, present and future selves, recreating meaningful narratives in their lives, and new ways of 'being in the world',[36,37] leading to improvements in mood and self-confidence.

There is growing recognition of the importance of creative approaches in health provision; for example, in the UK we have seen the launch of a national Special Interest Group for Arts, Health and Wellbeing supported by the Royal Society for Public Health[38] and the All-Party Parliamentary Group (APPG) inquiry into Arts, Health and Well-being in the UK.[39] Practical creative approaches offer new ways to explore experiences, especially those which are difficult to put into words.[40] There is a growing body of evidence that art-based practices are of great benefit in supporting psychological and social recovery in health services[39] and an emerging international agenda for 'Arts for Health' initiatives.[41] An ongoing prospective observational study (2009-2016) of patients referred to an 8 or 10 week 'arts on referral' programme in UK general practice (n = 1297) found statistically significant improvements in wellbeing in those who completed their prescribed programme.[42] Boyce et al.'s (2017)[43] critical review of the value of arts in healthcare highlighted that although findings are promising, research to date has been relatively narrow both in scope (a focus on music) and methodological approach. They called for methodologically rigorous research that considers different art forms in a variety of healthcare settings and considers cost-effectiveness.

In stroke, initial findings from exploratory studies of the effect of art on mood have been promising.[44,45] To our knowledge, there are only two other RCTs of Arts and Health interventions in stroke, both of which took place in inpatient rehabilitation settings.[46,47] Konkasuwan's 2015 study in Thailand involved 118 stroke patients and compared 'creative art therapy' plus standard physiotherapy with physiotherapy only. The creative art therapy was delivered by art therapists twice a week over 4 weeks and included music, singing and meditation in addition to the creative art therapy activities. They found improvements favouring the intervention group post-treatment in measures of mood, cognition, physical functioning and quality of life. Morris et al.'s[47] United Kingdom randomised controlled feasibility study (n=81) compared an artist-delivered visual arts participation programme (up to 8 sessions including individual and group delivery formats) with usual care. They concluded that the intervention was feasible to deliver and appeared to offer promise in the domains of emotional wellbeing and self-efficacy.

White et al. (2016)[48] highlighted that community participation and stroke-related disability are potentially modifiable risk factors affecting post-stroke health-related quality of life and that interventions addressing these factors should be developed and tested. This feasibility study[49] is the first to begin to systematically test an Arts & Health intervention ('HeART of Stroke') for people post-stroke in a community setting.

METHODS

Ethical approvals

The study was reviewed and given a favourable opinion by the Exeter NHS REC (Ref: 13/SW/0136). Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust (the study sponsor) and by Cambridgeshire Community Services NHS Trust.

Aims and objectives

The aims of the feasibility study were, firstly, to assess the acceptability of a 10-session community Arts & Health group intervention ('HeART of Stroke') for people following stroke and, secondly, to evaluate the feasibility of conducting a definitive randomised controlled trial to test its effectiveness and cost effectiveness when added to usual care. The specific objectives were to:

1. Assess the acceptability of key aspects of study design, randomisation and recruitment processes, and of the HoS group intervention.
2. Estimate recruitment and short-term retention rates.
3. Estimate HoS group attendance rates.
4. Assess the suitability of the outcome measures and feasibility of the assessment strategy.
5. Refine the selection of the outcome measures; in particular, to help inform the selection of the primary outcome for the full scale RCT.
6. Explore, qualitatively, individuals' experiences of participating in the study and gather feedback about the intervention and outcome measures.
7. Collect data on the standard deviation of outcome measures to inform a sample size calculation for a larger trial and obtain a preliminary estimate of effect size.
8. Refine the HoS group intervention and its delivery.
9. Explore differences in processes between the two study centres.
10. Identify, measure and value resources required to deliver the intervention in the community.
11. Develop and pilot data collection tools to measure resource use in the follow-up period to inform the design of a future within-trial economic evaluation, and estimate the cost of delivering HoS.

Study design

A two centre parallel arm randomised controlled feasibility study comparing the HoS group intervention plus usual care versus usual care alone (1:1 allocation ratio), with nested economic and qualitative components.

For reasons of efficiency and expediency, the end point of this feasibility study was one month post-intervention, but a definitive trial would include up to 12 months follow-up post-intervention to capture the longer term health and economic impact of the HoS intervention.

Patient and public involvement

Patient and public involvement members were involved in the initiation and design of the study, the development of the funding application, the design of the HoS intervention, the selection of relevant outcome measures and the design of study materials. During the research, as well as having RC, a grant holder, who attended all steering group and dissemination meetings, we formed PPI groups in each centre. There were five patient and public involvement members in Bournemouth (four involved in the study at any one time). Members came from the local voluntary 'Different Strokes' group, the Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust stroke ward patient and public involvement group and via word of mouth from these members. Four members were several years following their stroke and one person was a caregiver. There were three patient and public involvement members in Cambridgeshire; one was identified through a previous research role, two were identified through community organisations (Stroke Association and NHS community services). All were several years post-stroke.

As planned, patient and public involvement members were involved in three of the five study management group meetings. A newsletter kept patient and public involvement members updated with study progress. Members contributed to the study in many ways, including providing feedback about outcome measures, providing opportunities for the researchers to

run through/practise aspects of the study protocol, helping to identify a suitable venue for the intervention, providing ideas on how to enhance recruitment, contributing to plain English summaries, supporting the exhibition of artwork and other dissemination activities. Examples of dissemination activities undertaken include a workshop at the UK Stroke Forum co-delivered by a study participant with two members of the research team (CLR and CEH), local newspaper coverage and articles in magazines.

Methods

Details of our methods are published in our protocol paper.[49] We aimed to recruit a sample of 64 people (32 per centre in two blocks of 16). This would have provided an estimate of the recruitment rate with a precision of ±6% (assuming a recruitment rate of 30%) and a questionnaire return rate with a precision of ±10% (assuming a questionnaire return rate of 80%). Reporting of this feasibility study follows the CONSORT 2010 extension for randomised pilot and feasibility trials.[50]

Participants

Participants were adults living in the community up to two years post-stroke. This time point was chosen as the peak incidence and greatest severity of depression commonly occurs between 6 months and 2 years following stroke.[51] Participants also had physical or cognitive symptoms from stroke at five days post-stroke. Severity of stroke and cognitive impairment are risk factors for the development of post-stroke depression[52] and it was felt people who had fully recovered physically and cognitively within this short time point may be less likely to benefit from the intervention. Exclusion criteria included severe receptive aphasia, cognitive levels that would preclude completion of outcome measures even with support, currently receiving a psychiatric or clinical psychology intervention, living in a residential or nursing home, requiring assistance with toilet needs (because the Arts & Health practitioners were not trained to support transfers).

Identification, screening and recruitment

Bournemouth Centre, UK (Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust)

Potential participants, identified by clinical research network staff at RBCH NHS Foundation Trust, were either sent or given an invitation letter, 'Key Facts' page and reply slip and asked to return a prepaid reply slip if they were interested in participating. The study research assistant contacted those who expressed an interest and answered any queries or questions (via telephone, or face-to-face if the person had a communication disability). If they were still interested in taking part, they were sent or given a set of participant information sheets.

In an attempt to improve recruitment we revised the invitation and reminder letters partway through the study via an approved substantial amendment to the NHS REC. Our patient and public involvement partners and clinical colleagues in the stroke research team at RBCH provided feedback to enhance the appeal and readability of the information via a more accessible and engaging style.

Cambridgeshire Centre, UK (Cambridgeshire Community Services NHS Trust)

Clinical staff from the community stroke and neuro-rehabilitation teams identified potential participants in the community. In addition to the invitation letter described above, a 'consent to contact' approach was used whereby consent to be contacted by the Cambridgeshire centre research assistant was sought. A member of the clinical team obtained this consent during a face-to-face consultation or verbally over the phone. If the individual remained interested, the research assistant gave/sent them a set of participant information sheets.

Informed consent process

For individuals interested in taking part, the local research assistant arranged to visit the person at home within one month prior to the start of the HoS group. This provided an

opportunity to answer any remaining questions the individual had about the study. If the person still fulfilled the eligibility criteria (a screening checklist was used) and still wished to take part, they were asked to complete and sign a consent form and complete the baseline assessment.

Randomisation

The web-based randomisation system was created by the Peninsula Clinical Trials Unit in conjunction with the study statistician. Participants were allocated to the HoS intervention plus usual care or usual care in a 1:1 ratio using minimisation to balance the numbers allocated to each arm with stratification by recruitment centre and stroke severity (Rivermead Motor Assessment – Gross Motor Subscale score ≤6 ('mild') vs. ≥7 ('moderate/severe')).[53] The study research assistants in each centre logged onto the system using a unique username and password. They were able to randomise participants individually or in batches. Randomisation of individuals was used to 'top up' the two trial arms if any further participants were recruited before the HoS intervention groups started.

Blinding

The nature of the intervention meant that it was not possible to blind participants and artist facilitators to group allocation. At follow-up, when support was provided/required to complete outcomes this was provided by assessors blind to group allocation.

HeART of Stroke (HoS) group intervention

The HoS intervention is described in detail in the published protocol.[49] In summary, it comprised ten two hour Arts & Health practitioner-led group sessions held in community venues over 14 weeks. Sessions were held in the mornings (10.30-12.30) with a refreshment break. Sessions 1-3 included introductions and initial exploration. During sessions 4-7 participants were encouraged to develop their own creative practice within the

sessions and at home. In sessions 8-10 links with local Arts & Health practitioners were made and potential plans for an exhibition of the participants' work discussed.

Key aspects of the group were the opportunity to be creative and the safe group atmosphere. At each group, the Arts & Health practitioners encouraged members to a) explore the materials provided and arts techniques shared; b) explore their senses and support others' explorations; b) be non-judgmental of self/others; c) follow and respond to their own interests and d) develop a sense of play/improvisation. The Arts & Health practitioners prepared resources (including paints, drawing materials, clay, textiles and mixed-media) in response to the group members' individual and collective creative interests and skills. The group was offered 'stimulus' pieces such as books, poems, images, music and film and members were encouraged to share their own pieces of interest with the group.

Following each session, the Arts & Health practitioner briefly documented observations and reflected further to inform the selection of materials and activity for the next session. Practitioners also provided participants with sketchbooks and/or paper and other arts materials to support their emerging interests between sessions.

The rationale of HoS is to provide a safe space through the medium of the Arts in which group members have the opportunity to reconnect with their internal selves though their senses and embodied knowing and connect with, and support, others. This was a face-to-face group intervention, with self-directed individual art activity opportunities between meetings. Standardisation was linked with the context and setting rather than specified activities carried out by the practitioners and participants as this was expected to vary due to the creative nature of the activity. For example, standardisation included the groups taking place in a non-medical setting, so that the Arts & Health practitioners could create and hold a safe space in which participants felt able to express themselves creatively. The focus was

the person not their stroke. The artists responded to and followed the interests of each participant, rather than solely 'teaching' arts skills.

Facilitators and venues

The groups were facilitated by Arts & Health practitioners, with at least 5 years' Arts & Health practice experience, who were able to support groups, create and hold a safe space, and who were willing and able to support arts practice where participants took the lead in their own discovery and exploration. Currently in the UK, Arts & Health practitioners are not required to undertake specific training but characteristically develop their practice within NHS initiatives working alongside experienced artist mentors or with respected 'Arts on Prescription' organisations. One Arts & Health practitioner led both groups in Bournemouth (CLR) and two led one group each in Cambridgeshire. They had access to expertise in stroke (CEH) and clinical psychology (FG). For the purposes of the project a researcher was also present on site, if needed. The researcher supported study administration aspects (such as travel expenses for participants) and participant completion of a scale (Doojse et al.'s social identification scale) assessing group fit/belonging.[54]

In Bournemouth the HoS groups (iterations 1 & 2) were held in a church hall and in Cambridgeshire they were held either in a room in a community hospital site on the edge of Cambridge city used by Headway Cambridgeshire (a local brain injury charity) (iteration 3) or a community centre in a very rural north Cambridgeshire town (iteration 4). All venues had disabled access/toilet facilities, access to water and a sink, tea/coffee-making facilities and could accommodate up to eight participants (potentially with wheelchairs) around a table. There were storage facilities (albeit limited) in Cambridgeshire but none in the Bournemouth venue. Transport was provided for those unable to make their own way to the venue.

Usual Care

In Bournemouth, support is provided by the Early Supported Discharge multidisciplinary team for 2–6 weeks after leaving hospital and then medical care via the General Practitioner (GP), with a referral to the Stroke Coordinator. People with complex medical conditions are seen by Stroke Consultants as hospital outpatients. Ongoing rehabilitation needs are met by rehabilitation teams and day hospital service provision in some areas. In Cambridgeshire, medical care is delivered via the GP and people with complex medical conditions are seen by Stroke Consultants as hospital outpatients. All can access support from the Stroke Association 'Information, Advice and Support Coordinator' and may receive additional therapy or support via one of three locality neurorehabilitation teams. Participants in both arms of the trial received usual care, and usual care was not affected by involvement in the trial.

Descriptors and proposed outcome measures

Demographic/descriptor variables and stroke related information

At baseline the local research assistant collected information during a home visit about age, sex, marital status, educational qualifications, ethnicity, household composition, employment situation, comorbidities, medication, type of stroke, stroke side, time-since-stroke, mobility (Rivermead Assessment - Gross Motor subscale),[53] upper limb impairment (Motricity Index),[55] communication ability (Boston Severity Rating Scale),[56] cognitive ability (Addenbrookes Cognitive Exam – Revised; ACE-R).[57]

Outcome measures

The outcome measures (see below) were self-reported and presented in a booklet in a large font (pt. 14). At baseline, outcome measures were administered face-to-face by a research assistant in participants' homes. At approximately 5 months post-randomisation (1 month post - HoS intervention) outcome measures were administered by post, or if needed, with face-to-face or telephone support from a blinded assessor (one in each centre). At the end of the questionnaire booklet there was a question that asked whether participants had received

any support from others to complete it with the following response options possible: none, researcher on phone, researcher at house, family member/friend. Participants were asked not to disclose their allocation arm to the blinded assessors. In each centre the blinded assessors were asked to guess participants' treatment allocation.

In line with the feasibility objectives of this study, three outcome measures were included for consideration as potential candidates for the primary outcome in a subsequent full trial, as follows:

(i) Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS)[58]

(ii) Hospital Anxiety and Depression Scale (HADS)[59]

(iii) ICEpop CAPability measure for adults (ICECAP-A)[60]

In addition, the following outcome measures were included as potential secondary outcomes:

(i) Rosenberg Self-Esteem Scale (RSES)[61]

(ii) Medical Outcomes Short Form-36 (SF-36 V.1)[62]

(iii) Head Injury Semantic Differential Scale (HISDS-III)[63]

Serious adverse events and adverse events

Serious adverse events (SAEs) and adverse events (AEs) were closely monitored, documented and reported as described in the study protocol.[49]

Process measures

Doojse et al.'s social identification self-report scale[54] was used to measure 'sense of belonging' by participants in the HoS group at the end of the first, fifth and final session.

Identifying, measuring and valuing resource use

Resources required to deliver the HoS intervention were recorded for each session on forms completed by the artist facilitators. These included artists' preparation time, travel time to and from the venue, time spent delivering the intervention, equipment and materials used, number of participants attending the sessions, venue and venue hire costs. Resources were valued using local estimates provided by the experienced artists delivering HoS. Artist facilitators' time was valued at the fixed fee of £120 per session (to cover travel, preparation and delivery costs) with an additional £25 fee for materials and £8 for refreshments. Venue hire costs in Bournemouth (iterations 1 & 2) were £40 per session, and in Cambridgeshire, £100 per session (iteration 3) and £25 per session (iteration 4). We envisage the roll-out of the HoS intervention would follow a similar model whereby the health care provider would pay the artist facilitators a fixed delivery fee. Participant travel costs to attend sessions were recorded and are reported.

Resources required to deliver usual care in both arms were collected via a bespoke telephone-administered resource use questionnaire that asked about resources used in the period following randomisation. Participants were posted the questionnaire in advance of the telephone interview and were offered face-to-face support to complete it, if required. The questionnaire included hospital visits and admissions, use of community and social services, time off work and social activities, informal care, other sources of support, expenses incurred and medications. As service users advised us that it would be difficult to distinguish between stroke-related resource use and resource use related to co-morbidities, the questionnaire asked respondents to report resources related to all their health care needs. We assume that, in a definitive RCT, any differences between arms would result from the HoS intervention effect. To improve completion rates,[64] participants were provided with a resource use log to record health care visits prospectively, if they wished. Resources were valued using Curtis and Burns' Unit Costs of Health and Social Care[65] and the 2015 Department of Health National Health Service (NHS) reference costs.[66] Private expenses

were self-reported. Hours of informal care and time off work and social activities were valued using the Office for National Statistics (2015) average weekly earnings.[67]

Qualitative descriptive interviews

Face-to-face interviews with twelve people (8 intervention; 4 usual care) were undertaken in people's homes across both centres by CEH on two occasions: i. post-randomisation but before the HoS intervention was delivered; and ii. at study end after all outcome measures had been completed. Purposive sampling was used to capture variations that might influence perceptions including age, sex, communication disability and severity of stroke. The pre-intervention topics included why the person decided to take part in the overall study, their views on the recruitment and initial assessment process, and (intervention group only) expectations in terms of the HoS group intervention. The post-intervention topics included views on the study and outcome assessment processes and the acceptability of completing outcomes at one year follow-up in the context of a hypothetical future trial. Intervention participants were also asked about their experiences of the group, the venues, and their ability/willingness to pay their own transport costs to attend HoS.

Analysis

Quantitative analysis

Quantitative analysis was carried out using IBM SPSS V23.0 and STATA V14. The person undertaking the analysis was blind to allocation and group assignment was coded using 0 and 1. As this is a feasibility study, analyses are primarily descriptive and focus on baseline participant characteristics and the estimation of key feasibility parameters.[68] Estimates of recruitment, retention and questionnaire completion rates are presented with 95% confidence intervals (CIs). Intervention attendance rates are described.

Preliminary estimates of effect size with 95% CIs are presented for the three candidate primary outcomes to inform the plausibility of the effect sizes used in future sample size calculations. Participants were analysed in the group they were randomised to and we attempted to collect outcome measure data from everyone randomised. Missing data were assumed to be missing completely at random (MCAR) and no imputation methods were used. Analysis of covariance was used to estimate effect size for each outcome variable at follow-up, adjusting for centre and the respective baseline values. Although stroke severity was a stratification variable in the randomisation we have not adjusted for it in the analysis because of the very small number with a severe stroke. In the future trial we would also take into account clustering effects resulting from the group-based nature of the HoS intervention.[69] We have not taken into account clustering in the analysis presented here because (a) this is a feasibility study where the aim is not to obtain precise estimates of effect size and (b) there were just 56 participants (29 receiving the HoS intervention) and only a small number of clusters (n = 4) making it difficult to adjust for clustering. A consequence is that widths of the 95% confidence intervals are likely to be underestimated. Standardised effect sizes (Cohen's *d)* were obtained by dividing effect sizes by pooled baseline standard deviation.

Economic analysis

We report completion rates for the resource use categories. A preliminary estimate of the cost of delivering the HoS intervention was derived using macro-level costings. We also report artist facilitator time to deliver the intervention at the micro-level and patient travel expenses to the sessions.

We further report resource use units and costs per category per trial arm, for an indication of cost drivers for the intervention for the health and social care perspective. We derived capability index scores for the ICECAP-A[70] and applied UK preference-based tariffs to the SF-6D to derive quality-adjusted life-years.[71]

Qualitative analysis

The interviews were transcribed verbatim. Responses related to the research processes such as recruitment, screening and the administration of outcome measures as well as the acceptability of the venue, the intervention, and potential willingness to pay for the intervention (latter three, intervention group only) were analysed using content analysis.[72] Accounts of the expectations and experiences of the intervention were analysed separately using thematic analysis.[73] These finding will be reported elsewhere.

RESULTS

Study procedures, recruitment and retention rates

Fifty-six people were randomised (88% of our original target of 64) (see Figure 1). Nearly two-thirds of the sample was male and the mean age of the sample was 70 (SD 12.1) years and mean time-since-stroke was 9 (SD 6.1) months. Approximately 80% of participants had had ischaemic strokes. Seventy percent of the sample was retired (see Table 1). One participant who had had their stroke outside the 2 year post-stroke inclusion time window (32 months post-stroke) was erroneously recruited into the study. We included this participant's data in the analysis.

INSERT FIG 1 ABOUT HERE

INSERT TABLE 1 ABOUT HERE

Participants were enrolled into the study between August 2014 and April 2015 and the final follow-up occurred in December 2015. The recruitment rate across both centres was 14% [95% CI: 11% to 17%]. In Bournemouth, an acute hospital setting, the recruitment rate was 11% [95% CI: 8% to 14%] and in Cambridgeshire, a community setting, it was 28% [95% CI: 19% to 38%].

In total, information about the study was given or sent to 396 people (313 in Bournemouth and 83 in Cambridgeshire). Of these, 198 people declined participation, 112 did not return the reply slip, four did not meet the inclusion criteria, 26 were excluded for 'other reasons' (see Figure 1).

Six participants (11%) withdrew from both the study and follow-up data collection and three participants (5%) did not return the main outcome measures at follow-up. For two of the three proposed potential primary outcomes (HADS and ICECAP-A), 47/56 (84% (95% CI 73% to 92%)) of randomised participants had complete baseline and follow-up data and 46/56 (82% (95% CI: 70% to 91%)) had complete baseline and follow-up data for the WEMWBS.

Reasons for non-participation

Of 198 people declining participation, 89 gave reasons, the most common ones related to not being interested/feeling the intervention 'wasn't for them' (n=27) and health reasons (n=14).

Delivery, attendance rates and group size

Five participants allocated to the HoS arm declined the intervention post-randomisation (see CONSORT diagram for reasons). Of the 29 participants randomised to HoS sessions 20 (69%, 95% CI; 51% to 84%) attended six or more of the 10 sessions.

Two HoS groups were delivered in Bournemouth (iterations 1 & 2) and two in Cambridgeshire (iterations 3 & 4). The timing of the HoS sessions deviated slightly from that specified in the original protocol in three of the four iterations due to venue availability and the timing of public holidays. The planned group size was 6-8 participants and this target was mostly met in iterations 1-3 with 70% (21/30) of the delivered sessions including six or

more people. In iteration 4 due to time pressures (the grant coming to an end) only 11 people were randomised with six allocated to the intervention. There were two drop-outs out before the group commenced and one person withdrew after the first session meaning that 90% of sessions included 3 people or fewer. A summary of attendance at the HoS groups broken down by centre and session is presented in Web Supplement Table S1. Seventy-two percent of participants randomised to the HoS arm attended the final session (session 10) of the HoS group intervention.

Self-reported ratings on the domains of the Doojse Scale (measuring 'sense of belonging')[54] increased across sessions and remained high in the final session (see Table S2 in data supplement).

Support requirements for HoS group members

At the Cambridgeshire centre one of the artist facilitators discussed a HoS group member's cognitive needs with FG (clinical psychology). Subsequently, several adaptations were identified and implemented such as providing a small sketchpad when needing to wait for additional support and providing instructions one step at a time.

Suitability of the outcome measures and feasibility of the assessment strategy

The ACE-R, originally designed as a screening tool for dementia, provides a single overall functioning standardised score, and relies heavily on language abilities. It did not prove suitable for our sample, of whom nearly half (46%) had some degree of language difficulty. We have not presented the baseline descriptive data for the ACE-R as we do not feel they provide an accurate summary of the sample's cognitive abilities.

Overall, participants found the self-reported outcome measures acceptable and were able to complete them, sometimes requiring support. However, in the qualitative interviews several participants reported finding the HISDS-III[63] difficult to complete likely due to its relatively

complex language demands and the way in which the bipolar adjective pairs comprising the scale vary in direction. These difficulties were reflected in some of the response patterns obtained and corroborated by the blinded assessors' experiences. For these reasons we have not presented these data.

Missing questionnaire data were followed-up via telephone by a research assistant (baseline) or blinded assessor (follow-up) at each centre. Levels of missing data were very low - overall, 99.8% of the questionnaire items comprising the candidate primary outcomes were completed (1809/1815 items at baseline and 1550/1551 items at follow-up) by those who provided outcomes (at baseline n= 55 and follow up n = 47).

Support requirements to complete outcomes

At follow-up, the self-report questionnaire booklets were administered postally by default but face-to-face support was provided if required/requested. Fifty-eight percent of those with follow-up data (26/45, data for 2 cases missing) reported that they completed the questionnaire booklet with no support, 8 (18%) received support from the researcher in the home, 10 (22%) received support from family and friends and 1 (2%) received telephone support from the blinded assessor.

Possible primary outcomes

In Table 2 we present descriptives for the possible primary outcomes (WEMWBS, HADS-A, HADS-D, ICECAP-A) and descriptives for all other outcomes gathered are presented in Web Supplement Table S3.

INSERT TABLE 2 ABOUT HERE

Completion of resource use questionnaire

The resource use questionnaire was completed by 50/56 of participants (89%); 25/29 of patients in the HoS arm and 25/27 of patients in the usual care arm. Of these 33 (66%) were administered over the telephone, 16 (32%) face-to-face at home and 1 (2%) via the post. Although not included in the original study protocol, in the Bournemouth centre duration data were logged with the 19 telephone interviews lasting 23 minutes (SD=10) on average and the 8 face-to-face administrations in the home an average of 38 minutes (SD=13).

Completion rates of resource use categories were high and similar between the arms of the trial (Table 3). The least completed category was community based services such as primary care visits (see Table 3) with 90% complete data for this category (both trial arms combined). Seventy-nine percent complete data (out of the full sample) is available for an economic analysis from the health and social care perspective.

INSERT TABLE 3 ABOUT HERE

Assessor allocation guesses

At the Cambridgeshire centre, due to a delay in receiving approval for patient access for the blinded assessor, the unblinded research assistant administered outcomes to six participants. Overall 50/56 participants (Cambridgeshire = 23; Bournemouth = 27) completed questionnaire outcomes and/or telephone health use questionnaires at follow-up. In Cambridgeshire, the blinded assessor correctly guessed allocation on 9/17 (53%) occasions ($p = 1.00$ using the exact binomial test to compare with expected percentage of 50%) (NB. the six outcome assessment occasions in Cambridgeshire that were not undertaken by a blinded assessor are excluded). In Bournemouth, the blinded assessor correctly guessed allocation on 24/27 (89%) occasions ($p < .001$). Thus overall the blinded assessors correctly guessed allocation on 33/44 (75%; 95% CI 61% to 85%) occasions, $p = 0.001$.

Serious adverse events and adverse events

Five serious adverse events were reported during the study period. None was deemed related to the intervention. These included admissions to hospital for bunion removal, facial weakness and vomiting, atrial fibrillation, pneumonia, and a transient ischaemic attack.

Five adverse events were noted. None was deemed related to the intervention. Four people attended the Emergency Department but were not admitted (water retention, fall at home, fall in the road, anxiety). One person sustained a minor injury to their arm at home.

Cost of delivering the HoS intervention

The cost of delivering the HoS intervention was £1,960 in Bournemouth and £2,530 in Cambridgeshire, reflecting higher venue hire costs in Cambridgeshire (see Table 4). On average, six participants attended the two HoS iterations held in Bournemouth and four attended the two HoS iterations held in Cambridgeshire. The HoS intervention would cost the health care payer, on average, £327 per participant in Bournemouth and £657 in Cambridgeshire. The cost could be as low as £245 per participant at full capacity of 8 people.

INSERT TABLE 4 ABOUT HERE

Health-related quality of life gain, resource use and costs

Table 5 reports the quality adjusted life year (QALY) gains from baseline and resource use and costs for the HoS and usual care arms. Potential cost drivers for the intervention are inpatient and outpatient appointments and contacts with a social worker.

INSERT TABLE 5 ABOUT HERE

Qualitative

All 12 people who were purposively sampled for interview (8 intervention, 4 usual care) were interviewed on two occasions (male = 7, female = 5; mean age = 70 years (range 51-83

years); mean time-since-stroke = 7 months (range 4-12 months)). Most had had a mild, and one a moderately disabling, stroke. Nine had an affected arm and five had speech difficulties. All participants found the research processes acceptable and the screening and outcome measures easy to complete with the support provided. One person commented negatively on the cognitive assessment as her husband who lived with dementia had had to complete it in the past. One person noted they would have liked more opportunities for open answers on the questionnaires so they could provide some explanations about their responses. All interviewees would have been happy to complete outcome measures at 4 and 12 months follow up, if asked. They valued receiving the economic checklist which some completed over the specified time period and others used to supplement the telephone interviews.

Timing of sessions (held in the morning) and session duration (2 hours) were acceptable. While the venues were found to be acceptable, a few people mentioned that they would have liked access to a café where they could meet following the HoS sessions. Participants in Bournemouth were willing to pay up to £10 per session for transport if required. As all but one interviewee in Cambridgeshire drove to sessions (it was a much more rural setting than Bournemouth) and were happy to do so, transport costs were not discussed during the interviews. The one interviewee who used transport in Cambridgeshire only attended one session due to health issues (unrelated to stroke). Findings related to expectations and experiences of taking part in the groups will be reported elsewhere.

DISCUSSION

Main findings

This is the first study to formally test the feasibility of an Arts & Health intervention for people post-stroke in the community. While there are two other RCTs of Arts and Health interventions in stroke[46,47] both of these involved inpatients in a rehabilitation setting rather

than people living in the community. One involved a creative art intervention that, unlike HoS was highly prescribed, making direct comparisons difficult.

Attendance at the HoS intervention groups was high. The majority of people who took part in the HoS groups highly valued them, with many reporting increased confidence both within and outside the groups. The numbers who declined the intervention were similar to those reported in the Morris et al.study.[47] Study retention was good with follow-up data for available for 84% of participants and data completion rates were high (> 80% for the candidate primary outcome measures).

The structured breaks between the HoS sessions were potentially instrumental in encouraging participants to continue art work outside the group. The links created with local arts and health practitioners led to some participants continuing more independent creative practice after the research ended. Important practical considerations include ensuring that venues are on public or community transport routes, have free and disabled car parking facilities, heating/air conditioning and drink-making facilities. In the full multi-centre trial, to maximise recruitment and be as inclusive as possible, transport will be provided, if required.

The included outcome measures were mostly acceptable (but see limitations section) with some participants requiring support to complete them. The possible primary outcome measures for the future trial (WEMWBS, HADS-D, HADS-A, ICECAP-O) all demonstrated change in the direction of benefit for the HoS arm. In Morris et al.'s randomised controlled feasibility study of a visual arts participation intervention for stroke inpatients, a quality of life scale was initially envisaged to be the likely primary outcome for a future trial. However, their findings suggested that a measure of emotional wellbeing (the Positive and Negative Affect Scale) would be a more relevant primary outcome measure. Similarly, in the current study a measure of emotional wellbeing (HADS-D) is the main contender for the primary outcome in

a subsequent definitive trial and, with medium standardised effect sizes, it is likely that such a trial would be feasibly sized.

We have used novel dissemination methods such as making a short film involving people who had attended the HoS groups in Bournemouth, holding an art exhibition in both Bournemouth and Cambridgeshire to showcase the creations of the HoS group members.

Limitations; Implications for a future trial

We did not quite reach our original recruitment target and the overall recruitment rate was low (though not unlike that reported in another community-based study[74]). In the current study the recruitment rate in the community setting (28%) was higher than that via hospitals (11%). This might be because in Cambridgeshire recruitment was undertaken by clinicians working in the community who often had a long-standing relationship with their clients. In contrast, at Bournemouth and Christchurch hospitals, while some potential participants were known and approached directly by the research nurses, others were identified from clinical databases and sent study information in the post.

The most common reason for people declining participation in the current study was because they felt the intervention 'wasn't for them'. Similarly Morris et al., (2017)[46] also reported that the majority of people declined participation in their feasibility study of a visual arts participation programme because they were ambivalent about art participation. Modifying the description of the HoS intervention, such as referring to it as 'an opportunity to reconnect with and gain confidence in everyday life', rather than calling it an arts intervention could be one way to enhance recruitment. Morris et al. (2017) suggested that provision of taster sessions may be another means of improving study enrolment[47] though we note a risk of jeopardising equipoise or increasing the likelihood of resentful demoralisation. Additionally, we could extend the eligibility criteria by providing additional support so that people who require support with toileting needs could attend, though this would have cost

implications. Finally, we could also expand the recruitment strategy to include primary care. We will continue to consult with service users and stakeholders to seek their advice on ways of increasing recruitment rates and how best to convey the essence of the intervention to people.

The resource use data obtained in this feasibility study provide insights into the main potential cost drivers for the intervention meaning that we can refine and shorten the resource use questionnaire for the definitive trial. While administering the resource use questionnaire by telephone resulted in high levels of data completeness, maintaining assessor blinding at follow-up proved challenging, particularly in the Bournemouth centre. To try to increase the success of assessor blinding, we will add instructions on the printed versions of the outcome measures that emphasise the importance of not disclosing allocation group and will reword the question in the resource use questionnaire that asks about contacts with charities, social or activity groups. We will also seek patient and public involvement advice about how we can best convey the message not to disclose allocation at the start of the telephone resource use interview and, based on this, will create a standard script. We will provide training for the blinded assessors.

Some participants reported finding the HISDS-III difficult to complete. For these reasons we would not include this outcome in a future trial. The ACE-R also proved problematic due to its heavy reliance on language abilities. It will be important to identify a more appropriate way to evaluate specific domains of cognitive functioning for the future trial. One possibility is the recently developed Oxford Cognitive Screen[75] which has been designed specifically with a stroke population in mind and is purportedly inclusive for individuals with aphasia and neglect. While only short-term follow-up was included in this feasibility study, a future definitive study would include longer term 12 month follow-up.

The idea for the HoS intervention originated from a stroke survivor (and co-author) (RC) who had identified a gap in service provision. Since then, Arts & Health approaches are beginning to be recognised by policy makers as a useful way to support the health and wellbeing of communities.[39] With NHS pressures and difficulties of accessing formal services[76] our relatively low cost intervention (which could be as low as £245 per person if delivered at full capacity) offers potential to form part of a comprehensive long term support pathway to reduce depression following a stroke and increase community access and participation. As we look ahead to a future definitive trial it will be important to draw upon implementation science expertise and to consult with key stakeholders. This will help us to ensure that the HoS intervention, if found to be effective and cost-effective, can be rolled out within existing health service and social care structures and is designed in such a way so as to facilitate its rapid adoption and implementation into practice.

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Contributors

CEH and ST are equal contributors and joint first authors. CEH (Chief Investigator), FG (Principal Investigator, Cambridge Centre), CLR and RC were involved in the conception of the study and CEH, ST and FG led the design. CEH with ST and FG led the writing of initial grant application and protocol. DJ and FG advised on clinical aspects related to the grant application, PT led the statistical component of the study, EM led the economic evaluation, supported by TP and KG and FR advised on the qualitative aspects. MG and SN refined aspects of the draft protocol. MG coordinated the study on a day-to-day basis. CT and AW organised and administered the blinded assessments. ST and CEH drafted the manuscript, FG, MG, PT and EM provided detailed feedback and all other authors critically reviewed and approved the final version.

Competing interests

None

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Ethics approval

Ethics approval was granted by the Exeter NRES Committee (REC Ref 13/SW/0136) on 30/07/13. Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospital NHS Foundation Trust on 06/05/14. This Trust is the study sponsor. Local Research and Development approval was granted by Cambridgeshire Community Services NHS Trust on 29/05/14.

Provenance and peer review

Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data Sharing Statement:

Requests for de-identified data should be directed to the corresponding author.

Table 1: Baseline clinical and demographic descriptives for the sample

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
Sex [n (%)]			
▪ Female; Male	7 (26%); 20 (74%)	17 (59%); 12 (41%)	24 (43%); 32 (57%)
Age (years) Mean (SD) range	67.4 (12.83) 39-88	72.0 (11.22) 27-87	69.8 (12.1) 27-88
Ethnicity			
▪ White English	25 (93%)	23 (79%)	48 (86%)
▪ White other British	1 (4%)	5 (17%)	6 (11%)
▪ Mixed- white and Asian	1 (4%)	-	1 (2%)
▪ Black or Black British – African	-	1 (3%)	1 (2%)
Time-since-stroke (months) Median (IQR) range*	7 (5) 2-19	7 (7) 1-32	7 (5) 1-32
Stroke type [n (%)]			
▪ Ischaemic/thrombotic	6 (22%)	5 (17%)	11 (20%)
▪ Ischaemic/embolic	1 (4%)	1 (3%)	2 (4%)
▪ Haemorrhagic/Intracerebral	2 (7%)	2 (7%)	4 (7%)
▪ Haemorrhagic subarachnoid	-	1 (3%)	1 (2%)
▪ Ischaemic/type unknown	13 (48%)	16 (55%)	29 (52%)
▪ Haemorrhagic/type unknown	4 (15%)	3 (10%)	7 (13%)
▪ Type unknown	1 (4%)	1 (3%)	2 (4%)
Stroke severity (Rivermead Gross motor assessment) [n (%)]			
Total Score ≤ 6	1 (4%)	2 (7%)	3 (5%)
Total Score ≥ 7	26 (96%)	27 (93%)	53 (95%)
Stroke side [n (%)]			
▪ Left CVA	11 (42%)	15 (52%)	26 (47%)
▪ Right CVA	13 (50%)	11 (38%)	24 (44%)
▪ Both sides	1 (4%)	3 (10%)	4 (7%)
▪ Not applicable	1 (4%)	-	1 (2%)
▪ System missing	1	-	1
Centre [n (%)]			
▪ Bournemouth	16 (59%)	17 (59%)	33 (59%)
▪ Cambridgeshire	11 (41%)	12 (41%)	23 (41%)
Level of education [n (%)]			
Highest qualification achieved:			
▪ No qualifications	3 (12%)	8 (30%)	11 (20%)
▪ One or more GCSE	4 (16%)	4 (15%)	8 (14%)
▪ One or more A level	5 (20%)	1 (4%)	6 (11%)
▪ First degree or higher	1 (4%)	5 (19%)	6 11%)
▪ Other	12 (48%)	9 (33%)	21 (38%)
▪ System missing	2	2	4 (7%)
Pre-stroke employment status			
▪ Retired	14 (52%)	25 (86%)	39 (70%)
▪ Full-time employment	3 (11%)	1 (3%)	4 (7%)
▪ Part-time employment	3 (11%)	1 (3%)	4 (7%)
▪ Self-employed	2 (7%)	1 (3%)	3 (5%)
▪ Other (unemployed; homemaker)	5 (19%)	1 (3%)	6 (11%)
Marital status [n (%)]			
▪ Single	4 (15%)	3 (10%)	7 (13%)
▪ Married/cohabiting	17 (63%)	13 (45%)	30 (54%)
▪ Separated/divorced	3 (11%)	3 (10%)	6 (11%)
▪ Widowed	3 (11%)	10 (34%)	13 (23%)
Household composition			
▪ Living alone	9 (33%)	13 (45%)	23 (41%)
▪ Living with others	18 (67%)	15 (52%)	32 (57%)

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
▪ Sheltered housing	-	1 (3%)	1 (2%%)
Taking medication for mood			
▪ No	21 (78%)	24 (86%)	10 (18%)
▪ Yes	6 (22%)	4 (14%)	45 (82%)
▪ System missing	-	1	1
Communication difficulties†			
▪ No	18 (67%)	12 (59%)	30 (54%)
▪ Yes	9 (33%)	17 (41%)	26 (46%)
Motricity Index Total Score*			
Median (IQR) N **NB for one case one item was missing and was replaced by the mean*	86.3 (27) 12-100, 27	81.0 (29) 1-100, 29	83.6 (27) 56

† Boston Severity Rating Scale

*Although the inclusion criterion for the study was ≤ 24 months post stroke we erroneously recruited one participant at 32 months post stroke and this participant's data are included in the analysis.

Table 2: Descriptives and preliminary estimates of effect size for potential primary outcomes

Outcome measure	Baseline N=56	Mean difference (95% CI)	Post N=47	Standardised Effect Size (Cohen's *d*)
Warwick and Edinburgh Mental Well Being Scale (WEMWBS) *(potential range 14-70, higher scores greater wellbeing)*				
UC mean (SD)] N	48.8 (10.64) 26		48.0 (8.40) 21	
HoS mean (SD) N	46.9 (8.94) 29		48.4 (10.28) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		2.25 [-2.83, 7.32]		0.23
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		1.14 [-3.42, 5.70]		0.12
Hospital Anxiety and Depression Scale (HADS) *Anxiety subscale* *(potential range 0-21 each subscale, higher scores greater anxiety)*				
UC mean (SD) N	7.4 (3.72) 27		7.0 (4.13) 22	
HoS mean (SD) N	7.2 (4.29) 29		6.3 (3.74) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-0.47 [-2.48, 1.54]		-0.12
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-0.55 [-2.39, 1.28]		-0.14
Hospital Anxiety and Depression Scale (HADS) *Depression subscale* *(potential range 0-21 each subscale, higher scores greater depression)*				
UC mean (SD) N	4.8 (2.68) 27		6.1 (3.33) 22	
HoS mean (SD) N	6.6 (3.76) 29		6.0 (4.18) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-1.82 [-3.42, -0.22]		-0.56
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-1.46 [-3.12, 0.21]		-0.45
ICECAP-A tariff (potential *range 0-1, higher scores greater capability)*				
UC mean (SD) N	0.81 (0.14) 26		0.78 (0.15) 21	
HoS mean (SD) N	0.75 (0.16) 29		0.76 (0.22) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		0.05 [-0.03, 0.13]		0.33
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		0.04 [-0.05, 0.12]		0.26

Where high scores indicate better outcomes, positive effect sizes suggest benefit for the HoS arm.
Where low scores indicate better outcomes, negative effect sizes suggest benefit for the HoS arm.

Table 3: Completeness of resource use data

	N complete data	% of questionnaires filled in (n=25)	% of sample (n=29)	N complete data	% of questionnaires filled in (n=25)	% of sample (n=27)
	Intervention			Usual Care		
Health and social care						
Outpatient visits	25	100%	86%	25	100%	93%
Inpatient visits	25	100%	86%	25	100%	93%
Community based services	21	84%	72%	24	96%	89%
Personal social services	25	100%	86%	24	96%	89%
Total health and social care	21	84%	72%	23	92%	85%
Further resource use collected						
Time off work	25	100%	86%	23	92%	85%
Time off normal activities	25	100%	86%	25	100%	93%
Hours of help per week	21	84%	72%	24	96%	89%
Private therapies used	25	100%	86%	25	100%	93%
Charity/support group contacts	25	100%	86%	25	100%	93%

Table 4: HoS delivery costs

Cost of delivering HoS	Bournemouth	Cambridgeshire
Costs for 10 sessions		
Artist fee	£1,200	£1,200
Venue cost	£430	£1,000
Materials cost	£330	£330
Total	£1,960	£2,530
Mean no. of participants per session	6.0	3.85
Cost of HoS per participant (based on mean attendance)	£327	£657
Cost of HoS per participant at capacity (8 attendees)	£245	£316
Reporting micro-level resource use to deliver HoS		
Artist time (in mean hours):		
Session duration	20.0	20.5
Preparation time	20.0	10.6
Travel time	15.0	15.6
Total intervention time	55.0	46.7
Participant travel costs	£1,021	£658

Table 5: Outcomes resource use and cost of delivering care in both arms

	HoS Intervention						Usual care					
	N	N users	Mean use	SD	Mean cost	SD	N	N users	Mean use	SD	Mean cost	SD
Outcomes												
QALYs gained (SF6D)	22	-	0.18	0.03	-	-	21	-	0.17	0.02	-	-
Inpatient and A & E												
Inpatient admissions	25	3	0.9	3.0	£49	£136	25	3	0.7	2.8	£96	£308
A & E or hospital admissions	25	4	0.2	0.4	£22	£53	25	6	0.2	0.4	£34	£61
Outpatient appointments												
Stroke rehabilitation	25	1	0.0	0.2	£10	£50	25	2	0.1	0.3	£20	£69
Physiotherapy	25	3	0.3	1.2	£6	£23	25	4	1.0	2.9	£20	£56
Occupational therapy	25	1	0.0	0.2	£1	£4	25	3	0.2	0.5	£3	£9
Speech and language therapy	25	2	0.2	0.8	£4	£16	25	2	0.4	1.6	£7	£30
Psychologist	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0
Dietician	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0
Other outpatient appointments	25	14	1.2	1.5	£140	£210	25	13	2.0	3.2	£196	£393
Community-based services												
GP contacts	24	17	1.9	1.5	£92	£79	25	18	1.6	2.0	£72	£83
GP nurse contacts	25	11	1.6	3.0	£22	£44	25	16	2.0	3.1	£26	£40
Physiotherapy contacts	25	3	0.3	1.2	£6	£23	25	2	0.9	3.7	£19	£78
SALT contacts	24	3	0.4	1.3	£25	£82	25	3	1.1	3.5	£94	£308
Occupational therapy at home	25	1	0.2	0.8	£5	£25	25	2	0.2	0.9	£7	£27
Repeat prescriptions from GP	23	16	4.0	5.6	£5	£7	24	18	4.0	4.3	£5	£5
Other community-based appointments	21	2	0.4	1.4	£25	£77	24	1	0.3	1.6	£28	£143
Personal social services												
Home care worker contacts	25	0	0.0	0.0	£0	£0	24	2	0.9	3.4	£11	£41
Social worker contacts (hours)	25	2	0.4	1.6	£28	£127	25	3	0.3	0.9	£24	£72
Food at home services (meals)	25	0	0.0	0.0	£0	£0	25	1	0.6	3.2	£4	£21

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Figure Legends:

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

Figure 2: Painting by MDBD

Figure 3: Drawing by FB

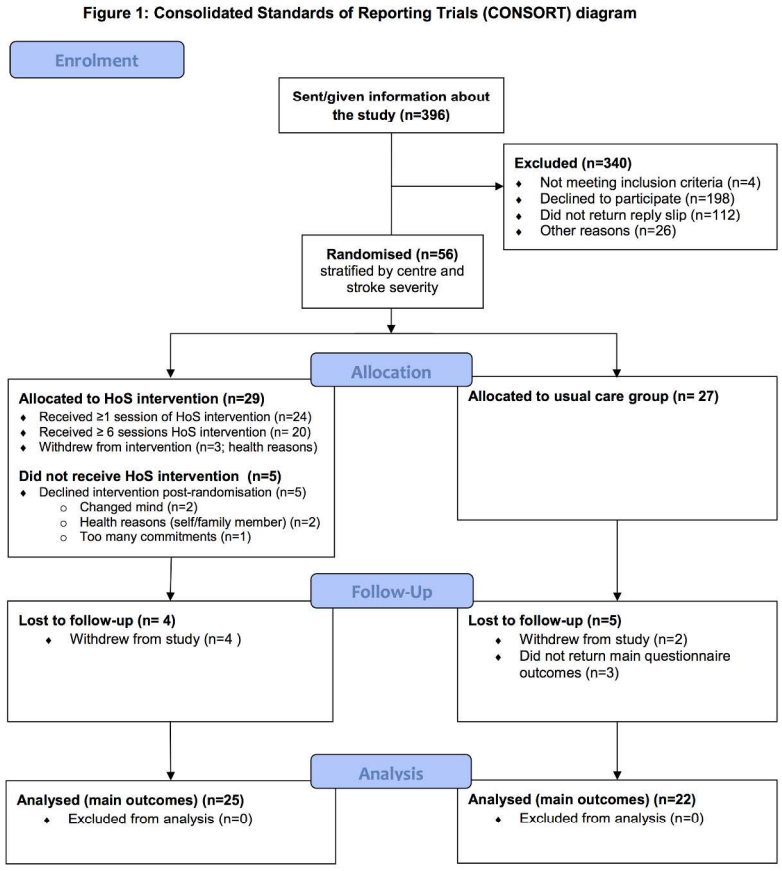

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

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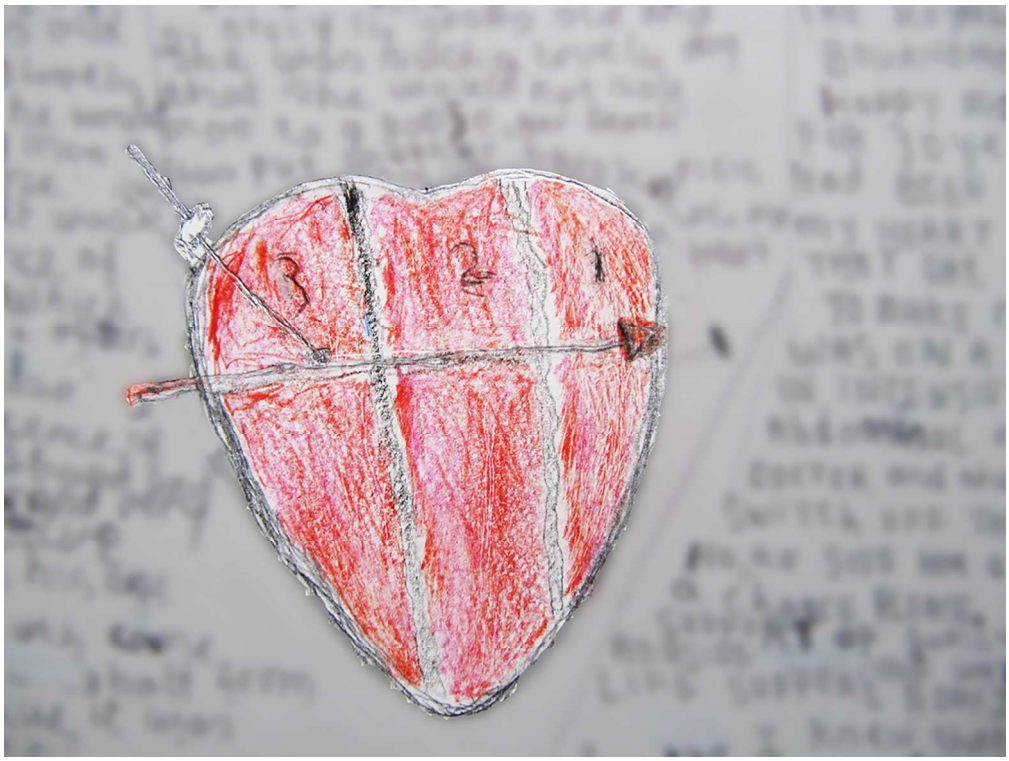

Drawing by FB

169x127mm (300 x 300 DPI)

Painting by MDBD

84x84mm (300 x 300 DPI)

Supplementary Web tables

Table S1: Attendance at HoS by centre and session

	Bournemouth		Cambridge		Total
	Iteration 1	Iteration 2	Iteration 3	Iteration 4	
No. randomised to HoS group	8	9	6	6	29
HoS session					
1	6	7	5	4	23
2	6	7	5	1	19
3	6	6	6	2	20
4	6	6	5	2	19
5	5	7	5	2	19
6	5	6	5	2	18
7	6	5	6	3	20
8	6	6	4	2	18
9	6	6	6	2	20
10	6	6	6	3	21

Table S2: Descriptives for Doojse's et al.'s social identification scale

Sense of Belonging statement	**Median (IQR) range**		
(potential score range 1-7, higher scores indicate higher sense of belonging)	*Session 1 (n=24)*	*Session 5 (n=20)*	*Session 10 (n=21)*
1. I see myself as a member of the HoS group	6 (2) 1-7	7 (1) 4-7	7 (0) 6-7
2. I am pleased to be a member of the HoS group	7 (2) 1-7	7 (1) 4-7	7 (0) 4-7
3. I feel strong ties with members of the HoS group	4 (5) 1-7	5 (3) 4-7	6 (2) 3-7
4. I identify with other members of the HoS group	5 (3) 1-7	6 (2) 4-7	7 (1) 4-7

Table S3: Descriptives for potential secondary outcomes

Outcome measure	Baseline *N=56*	Post *N=47*
Rosenberg Self-Esteem Scale (RSES) *(potential score range 0-30 , higher scores indicate higher self-esteem)*		
UC mean (SD) N	20.8 (6.23) 27	20.1 (5.21) 22
HoS mean (SD) N	20.4 (5.81) 29	21.1 (5.67) 25
Medical Outcomes Short Form-36 (SF-36) - Physical functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	43.4 (24.51) 27	42.7 (23.94) 22
HoS mean (SD) N	48.3 (25.16) 27	55.3 (23.23) 23
SF-36 Role limitations - Physical subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean, SD (95% CI)	23.9 (29.36) 27	17.0 (26.03) 22
HoS mean (SD) N	35.0 (34.61) 28	27.0 (38.13) 25
SF-36 Role limitations - Emotional *(potential range 0-100, higher scores more favourable health state)*		
UC mean (SD) N	42.4 (45.05) 27	50.0 (42.10) 22
HoS mean (SD) N	45.3 (41.81) 28	49.3 (45.26) 25
SF-36 Energy/Fatigue subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	48.6 (18.01) 27	42.05 (20.45) 22
HoS mean (SD) N	45.2 (25.5) 27	43.3 (25.40) 24
SF-36 Emotional wellbeing subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD (N)	68.91 (17.19) 27	69.81 (19.51) 22
HoS mean SD (N)	67.33 (17.16) 27	68. 83 (20.43) 24
SF-36 Social functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	69.3 (26.65) 27	64.2 (29.70) 22
HoS mean (SD) N	66.5 (26.45) 28	72.00 (28.25) 25
SF-36 Pain subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	66.8 (24.45) 27	71.2 (28.32) 22
HoS mean (SD) N	61.9 (24.97) 27	69.5 (27.63) 25
SF-36 General Health subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD N	55.2 (23.68) 27	55.5 (21.49) 22
HoS mean (SD) N	51.4 (20.09) 27	57.3 (19.67) 24
SF-6D Derived health state value *(potential range -0.296 to 1.00 with higher scores indicating better health)*		
UC mean (SD) N	0.63 (0.09) 27	0.64 (0.08) 21
HoS mean, SD N	0.64 (0.12) 26	0.68 (0.12) 24

UC = Usual Care
HoS = HeART of Stroke

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6-10
	2b	Specific objectives or research questions for pilot trial	13
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	13
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	16, 27
Participants	4a	Eligibility criteria for participants	15
	4b	Settings and locations where the data were collected	16, 19-20
	4c	How participants were identified and consented	15-17
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	17-20
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	20-23
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	-
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	-
Sample size	7a	Rationale for numbers in the pilot trial	15
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	17
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	17
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	17
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	17

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	17,21,24
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	24-25
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	25 + Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	26
	14b	Why the pilot trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	39
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	41
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	41
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	42-44;72-73
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	30
	19a	If relevant, other important unintended consequences	-
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	33-35
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	33-35
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	32-36
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	34-35
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	Referenced
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	37
	26	Ethical approval or approval by research review committee, confirmed with reference number	38

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HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention plus usual care compared with usual care to increase psychological wellbeing in people following a stroke.

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Title: HeART of Stroke: Randomised controlled parallel arm feasibility study of a community-based Arts & Health intervention plus usual care compared with usual care to increase psychological wellbeing in people following a stroke.

Corresponding author:

Caroline Ellis-Hill,* Faculty of Health and Social Sciences; Bournemouth University, Bournemouth, UK

cehill@bournemouth.ac.uk

Co-authors:

Sarah Thomas,* Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Fergus Gracey, Department of Clinical Psychology, University of East Anglia, Norwich, UK

Catherine Lamont-Robinson, School of Social and Community Medicine, University of Bristol, Bristol, UK

Robin Cant, Servicer User, (formerly of Canterbury Christ Church University), Canterbury, UK

Elsa Marques, School of Clinical Sciences, University of Bristol, Bristol, UK

Peter Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Mary Grant, Warwick Clinical Trials Unit, University of Warwick, Coventry, UK

Samantha Nunn, Cambridgeshire Community Services NHS Trust, Oliver Zangwill Centre, Ely, UK

Thomas Paling, School of Clinical Sciences, University of Bristol, Bristol, UK

Charlotte Thomas, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, UK

Alessa Werson Department of Clinical Psychology, University of East Anglia, Norwich, UK

Kathleen Galvin, School of Health Sciences, University of Brighton, Brighton, UK

Frances Reynolds, formerly College of Health and Life Sciences, Brunel University London, Uxbridge, UK

Damian Jenkinson, Stroke Unit, Dorset County Hospital, Dorchester UK

*Joint first authors

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Word count: ~ 7500

ABSTRACT

Introduction People often experience distress following stroke due to fundamental challenges to their identity.

Objectives Evaluate: (i) the acceptability of 'HeART of Stroke' (HoS), a community-based Arts & Health group intervention, to increase psychological wellbeing; (ii) the feasibility of a definitive randomised controlled trial (RCT).

Design Two-centre 24-month parallel arm RCT with qualitative and economic components. Randomisation stratified by centre and stroke severity. Participant blinding was not possible. Outcome assessment blinding attempted.

Setting Community

Participants Community-dwelling adults ≤ 2 years post-stroke, recruited via hospital clinical teams/databases or community stroke/rehabilitation teams.

Interventions Artist-facilitated Arts & Health group intervention (HoS) (ten 2-hour sessions over 14 weeks) plus usual care (UC) versus UC.

Outcomes Self-reported measures of wellbeing, mood, capability, health-related quality of life, self-esteem and self-concept (baseline and five months post-randomisation). Key feasibility parameters were gathered, data collection methods piloted and participant interviews (n=24) explored acceptability of the intervention/study processes.

Results Despite a low recruitment rate (14%; 95% CI: 11% to 18%), 88% of the recruitment target was met with 29 participants randomised to HoS and 27 to UC (57% male; mean [SD] age = 70 [12.1] years; time-since-stroke = 9 [6.1] months). Follow-up data were available for 47/56 (84%; 95% CI: 72% to 91%). Completion rates for a study-specific resource use questionnaire were 79% and 68% (NHS and societal perspectives). Five people declined HoS post-randomisation; of the remaining 24 who attended, 83% attended ≥6 sessions.

Preliminary effect sizes for candidate primary outcomes were in the direction of benefit for the HoS arm. Participants found study processes acceptable. The intervention cost an estimated £456 per person and was well-received (no intervention-related serious adverse events reported).

Conclusions Findings from this first community-based study of an Arts & Health intervention for people post-stroke suggest a definitive RCT is feasible. Recruitment methods will be revised.

ISRCTN 99728983

Strengths and limitations of this study

- This is the first feasibility study of a community-based Arts & Health group intervention to support wellbeing following a stroke.
- Participants were recruited via both hospital and community clinical teams enabling recruitment rate estimates for two different recruitment approaches.
- The study incorporated mixed methods and a feasibility economic component.
- The study only included short term follow-up.
- Findings will inform a definitive randomised controlled trial of effectiveness and cost-effectiveness.

INTRODUCTION

Each year over 150,000 people in the UK experience a stroke[1] with one-third left with residual disabilities including paralysis on one side and cognitive and communication impairments.[2] Qualitative meta-syntheses have highlighted that following a stroke, or other types of brain injury, people face fundamental emotional and existential challenges. They experience challenges to their sense of self and identity and their current and future lives are filled with uncertainty.[3, 4] Emotional health and wellbeing following stroke have been highlighted as national priorities, featuring in the James Lind Alliance 'top ten' research priorities.[5]

Following a stroke people report a need to 'get their lives back'. Failure to do so is associated with depression[6,7] (with reported accumulative incidence of 39–52% within 5 years of stroke[7]), loss of confidence,[8] people having difficulty in 'feeling part of things',[9] loss of sense of self[10] and becoming socially isolated.[11] This creates long-terms costs, not only for the stroke survivor, but also for their family members,[12,13] and for government, health and social services through reduced family employment and increased social and primary care needs.[14] Where untreated, depression is associated with poorer functional outcomes[15] and higher mortality.[16,17]

While there have been great improvements in stroke care, the stroke pathway for long-term support is still under-researched and under-developed. A Cochrane review indicated no evidence for pharmacotherapy in the prevention of post-stroke depression, and only weak evidence for psychotherapeutic approaches.[18] A more recent systematic review[19] that limited inclusion to participants without a diagnosis of depression at baseline concluded that antidepressants may reduce the likelihood of depression developing post-stroke but that the optimum timing and duration of treatment was not clear. There is also evidence to suggest that pharmacological treatments can have modest benefits in the treatment of depression

post-stroke.[20-23] However, anti-depressants have side effects and may have undesirable interactions with other medications and/or comorbidities.[20-23]

While the evidence for the effectiveness of psychotherapeutic interventions for post-stroke depression is inconclusive,[20] two recent RCTs (motivational interviewing[24,25] and a brief psychosocial behavioural intervention plus anti-depressant[26]) demonstrated reductions in post-stroke depression. However, these trials involved people early after stroke and excluded those with severe communication or cognitive problems. The CALM (Communication and Low Mood) trial[27] of behavioural therapy demonstrated improved mood in stroke patients with aphasia and a feasibility study of behavioural activation is now underway using a broader sample of people with depression 3-60 months post-stroke.[28] A study of cognitive behavioural therapy for post-stroke depression demonstrated no benefits over usual care or an attention control; however, the sample size was small.[29]

Around 20% of people experience clinical levels of anxiety following stroke.[30] A recent Cochrane review highlighted the need for further rigorously conducted RCTs to assess pharmacological and psychological treatments for anxiety following stroke.[30]

A stepped approach to psychological support following stroke has been proposed in the UK [31] (Step 1: awareness, watching; Step 2: low intensity services, such as guided self-help; Step 3: high intensity services, such as cognitive behavioural therapy (CBT)) but this system is still in its infancy.

Harrison et al. (2017)[32] concluded from qualitative research with service users that research is needed to test alternative options to formal psychological support. Ellis-Hill et al.[33] and Gracey et al.[34] have independently developed complementary theoretical models based on empirical evidence to understand the processes involved in re-establishing a positive sense

of self and confidence in life following a stroke. The current research draws upon two specific and related theoretical frameworks; namely, the Life Thread Model[33] and Self–discrepancy theory.[9,34] These highlight that following an acquired brain injury people often lose a sense of coherence of self and a sense of predictability in life. These existential losses can cause considerable anxiety and can lead to depression. Within neuropsychological rehabilitation, it is hypothesised that establishing a safe place where clients feel understood and supported can facilitate self-development.[34,35] When carrying out embodied creative activities (such as art), people can reconnect their past, present and future selves, recreating meaningful narratives in their lives, and new ways of 'being in the world',[36,37] leading to improvements in mood and self-confidence.

There is increasing recognition of the importance of creative approaches in health provision; for example, in the UK we have seen the launch of a national Special Interest Group for Arts, Health and Wellbeing supported by the Royal Society for Public Health[38] and the All-Party Parliamentary Group (APPG) inquiry into Arts, Health and Well-being in the UK.[39] Practical creative approaches offer new ways to explore experiences, especially those which are difficult to put into words.[40] There is a growing body of evidence that art-based practices are of great benefit in supporting psychological and social recovery in health services[39] and an emerging international agenda for 'Arts for Health' initiatives.[41] An ongoing prospective observational study (2009-2016) of patients referred to an 8 or 10 week 'arts on referral' programme in UK general practice (n = 1297) found statistically significant improvements in wellbeing in those who completed their prescribed programme.[42] Boyce et al.'s (2017)[43] critical review of the value of arts in healthcare highlighted that although findings are promising, research to date has been relatively narrow both in scope (a focus on music) and methodological approach. They called for methodologically rigorous research that considers different art forms in a variety of healthcare settings and considers cost-effectiveness.

In stroke, initial findings from exploratory studies of the effect of art on mood have been promising.[44,45] To our knowledge, there are only two other RCTs of Arts and Health interventions in stroke, both of which took place in inpatient rehabilitation settings.[46,47] Konkasuwan's 2015 study in Thailand involved 118 stroke patients and compared 'creative art therapy' plus standard physiotherapy with physiotherapy only.[46] The creative art therapy was delivered by art therapists twice a week over 4 weeks and included music, singing and meditation in addition to the creative art therapy activities. They found improvements favouring the intervention group post-treatment in measures of mood, cognition, physical functioning and quality of life. Morris et al.'s[47,48] United Kingdom randomised controlled feasibility study (n=81) compared an artist-delivered visual arts participation programme (up to 8 sessions including individual and group delivery formats) with usual care. They concluded that the intervention was feasible to deliver and appeared to offer promise in the domains of emotional wellbeing and self-efficacy.

White et al. (2016)[49] highlighted that community participation and stroke-related disability are potentially modifiable risk factors affecting post-stroke health-related quality of life and that interventions addressing these factors should be developed and tested. This feasibility study[50] is the first to begin to systematically test an Arts & Health intervention ('HeART of Stroke') for people post-stroke in a community setting.

METHODS

Ethical approvals

The study was reviewed and given a favourable opinion by the Exeter NHS REC (Ref: 13/SW/0136). Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust (the study sponsor) and by Cambridgeshire Community Services NHS Trust.

Aims and objectives

The aims of the feasibility study were, firstly, to assess the acceptability of a 10-session community Arts & Health group intervention ('HeART of Stroke') for people following stroke and, secondly, to evaluate the feasibility of conducting a definitive randomised controlled trial to test its effectiveness and cost effectiveness when added to usual care. The specific objectives were to:

1. Assess the acceptability of key aspects of study design, randomisation and recruitment processes, and of the HoS group intervention.
2. Estimate recruitment and short-term retention rates.
3. Estimate HoS group attendance rates.
4. Assess the suitability of the outcome measures and feasibility of the assessment strategy.
5. Refine the selection of the outcome measures; in particular, to help inform the selection of the primary outcome for the full scale RCT.
6. Explore, qualitatively, individuals' experiences of participating in the study and gather feedback about the intervention and outcome measures.
7. Collect data on the standard deviation of outcome measures to inform a sample size calculation for a larger trial and obtain a preliminary estimate of effect size.
8. Refine the HoS group intervention and its delivery.
9. Explore differences in processes between the two study centres.
10. Identify, measure and value resources required to deliver the intervention in the community.
11. Develop and pilot data collection tools to measure resource use in the follow-up period to inform the design of a future within-trial economic evaluation, and estimate the cost of delivering HoS.

Study design

A two centre parallel arm randomised controlled feasibility study comparing the HoS group intervention plus usual care versus usual care alone (1:1 allocation ratio), with nested economic and qualitative components.

For reasons of efficiency and expediency, the end point of this feasibility study was one month post-intervention, but a definitive trial would include up to 12 months follow-up post-intervention to capture the longer term health and economic impact of the HoS intervention. One month post-treatment was chosen as the study end point rather than end of treatment because i. some of the outcome measures include items with 4-week recall periods (e.g. the SF-36) and ii. to reduce the likelihood of capturing transient disappointment about the group coming to an end in those who attended a HoS group.

Patient and public involvement

Patient and public involvement members were involved in the initiation and design of the study, the development of the funding application, the design of the HoS intervention, the selection of relevant outcome measures and the design of study materials. During the research, as well as having RC, a grant holder, who attended all steering group and dissemination meetings, we formed PPI groups in each centre. There were five patient and public involvement members in Bournemouth (four involved in the study at any one time). Members came from the local voluntary 'Different Strokes' group, the Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust stroke ward patient and public involvement group and via word of mouth from these members. Four members were several years following their stroke and one person was a caregiver. There were three patient and public involvement members in Cambridgeshire; one was identified through a previous research role, two were identified through community organisations (Stroke Association and NHS community services). All were several years post-stroke.

As planned, patient and public involvement members were involved in three of the five study management group meetings. A newsletter kept patient and public involvement members updated with study progress. Members contributed to the study in many ways, including providing feedback about outcome measures, providing opportunities for the researchers to run through/practise aspects of the study protocol, helping to identify a suitable venue for the intervention, providing ideas on how to enhance recruitment, contributing to plain English summaries, supporting the exhibition of artwork and other dissemination activities. Examples of dissemination activities undertaken include a workshop at the UK Stroke Forum co-delivered by a study participant with two members of the research team (CLR and CEH), local newspaper coverage and articles in magazines.

Methods

Details of our methods are published in our protocol paper.[50] We aimed to recruit a sample of 64 people (32 per centre in two blocks of 16). This would have provided an estimate of the recruitment rate with a precision of ±6% (assuming a recruitment rate of 30%) and a questionnaire return rate with a precision of ±10% (assuming a questionnaire return rate of 80%). Reporting of this feasibility study follows the CONSORT 2010 extension for randomised pilot and feasibility trials.[51]

Participants

Participants were adults living in the community up to two years post-stroke. This time point was chosen as the peak incidence and greatest severity of depression commonly occurs between 6 months and 2 years following stroke.[52] Participants also had physical or cognitive symptoms from stroke at five days post-stroke. Severity of stroke and cognitive impairment are risk factors for the development of post-stroke depression.[53] People who have fully recovered physically and cognitively within this short time point may be less likely to benefit from the intervention. Exclusion criteria included severe receptive aphasia, cognitive levels that would preclude completion of outcome measures even with support, currently receiving

a psychiatric or clinical psychology intervention, living in a residential or nursing home, requiring assistance with toilet needs (because the Arts & Health practitioners were not trained to support transfers).

Identification, screening and recruitment

Bournemouth Centre, UK (Royal Bournemouth and Christchurch Hospitals (RBCH) NHS Foundation Trust)

Potential participants, identified by clinical research network staff at RBCH NHS Foundation Trust, were either sent or given an invitation letter, 'Key Facts' page and reply slip and asked to return a prepaid reply slip if they were interested in participating. The study research assistant contacted those who expressed an interest and answered any queries or questions (via telephone, or face-to-face if the person had a communication disability). If they were still interested in taking part, they were sent or given a set of participant information sheets.

In an attempt to improve recruitment we revised the invitation and reminder letters partway through the study via an approved substantial amendment to the NHS REC. Our patient and public involvement partners and clinical colleagues in the stroke research team at RBCH provided feedback to enhance the appeal and readability of the information via a more accessible and engaging style.

Cambridgeshire Centre, UK (Cambridgeshire Community Services NHS Trust)

Clinical staff from the community stroke and neuro-rehabilitation teams identified potential participants in the community. In addition to the invitation letter described above, a 'consent to contact' approach was used whereby consent to be contacted by the Cambridgeshire centre research assistant was sought. A member of the clinical team obtained this consent during a face-to-face consultation or verbally over the phone. If the individual remained interested, the research assistant gave/sent them a set of participant information sheets.

Informed consent process

For individuals interested in taking part, the local research assistant arranged to visit the person at home within one month prior to the start of the HoS group. This provided an opportunity to answer any remaining questions the individual had about the study. If the person still fulfilled the eligibility criteria (a screening checklist was used) and still wished to take part, they were asked to complete and sign a consent form and complete the baseline assessment.

Randomisation

The web-based randomisation system was created by the Peninsula Clinical Trials Unit in conjunction with the study statistician. Participants were allocated to the HoS intervention plus usual care or usual care in a 1:1 ratio using minimisation to balance the numbers allocated to each arm with stratification by recruitment centre and stroke severity (Rivermead Motor Assessment – Gross Motor Subscale score ≤6 ('mild') vs. ≥7 ('moderate/severe')).[54] The study research assistants in each centre logged onto the system using a unique username and password. They were able to randomise participants individually or in batches. Randomisation of individuals was used to 'top up' the two trial arms if any further participants were recruited before the HoS intervention groups started.

Blinding

The nature of the intervention meant that it was not possible to blind participants and artist facilitators to group allocation. At follow-up, when support was provided/required to complete outcome measures this was provided by assessors blind to group allocation.

HeART of Stroke (HoS) group intervention

The HoS intervention is described in detail in the published protocol.[50] In summary, it comprised ten two hour Arts & Health practitioner-led group sessions held in community

venues over 14 weeks. Sessions were held in the mornings (10.30-12.30) with a refreshment break. Sessions 1-3 included introductions and initial exploration. During sessions 4-7 participants were encouraged to develop their own creative practice within the sessions and at home. In sessions 8-10 links with local Arts & Health practitioners were made and potential plans for an exhibition of the participants' work discussed.

Key aspects of the group were the opportunity to be creative and the safe group atmosphere. At each group, the Arts & Health practitioners encouraged members to a) explore the materials provided and arts techniques shared; b) explore their senses and support others' explorations; b) be non-judgmental of self/others; c) follow and respond to their own interests and d) develop a sense of play/improvisation. The Arts & Health practitioners prepared resources (including paints, drawing materials, clay, textiles and mixed-media) in response to the group members' individual and collective creative interests and skills. The group was offered 'stimulus' pieces such as books, poems, images, music and film and members were encouraged to share their own pieces of interest with the group. Examples of artwork produced can be seen at the beginning of the paper (Figure 1) and below (Figure 2).

Following each session, the Arts & Health practitioner briefly documented observations and reflected further to inform the selection of materials and activity for the next session. Practitioners also provided participants with sketchbooks and/or paper and other arts materials to support their emerging interests between sessions.

The rationale of HoS is to provide a safe space through the medium of the Arts in which group members have the opportunity to reconnect with their internal selves though their senses and embodied knowing and connect with, and support, others. This was a face-to-face group intervention, with self-directed individual art activity opportunities between meetings. Standardisation was linked with the context and setting rather than specified

activities carried out by the practitioners and participants as this was expected to vary due to the creative nature of the activity. For example, standardisation included the groups taking place in a non-medical setting, so that the Arts & Health practitioners could create and hold a safe space in which participants felt able to express themselves creatively. The focus was the person not their stroke. The artists responded to and followed the interests of each participant, rather than solely 'teaching' arts skills.

Facilitators and venues

The groups were facilitated by Arts & Health practitioners, with at least 5 years' Arts & Health practice experience, who were able to support groups, create and hold a safe space, and who were willing and able to support arts practice where participants took the lead in their own discovery and exploration. Currently in the UK, Arts & Health practitioners are not required to undertake specific training but characteristically develop their practice within NHS initiatives working alongside experienced artist mentors or with respected 'Arts on Prescription' organisations. One Arts & Health practitioner led both groups in Bournemouth (CLR) and two led one group each in Cambridgeshire. They had access to expertise in stroke (CEH) and clinical psychology (FG). For the purposes of the project a researcher was also present on site, if needed. The researcher supported study administration aspects (such as travel expenses for participants) and participant completion of a scale (Doojse et al.'s social identification scale) assessing group fit/belonging.[55]

In Bournemouth the HoS groups (iterations 1 & 2) were held in a church hall and in Cambridgeshire they were held either in a room in a community hospital site on the edge of Cambridge city used by Headway Cambridgeshire (a local brain injury charity) (iteration 3) or a community centre in a very rural north Cambridgeshire town (iteration 4). All venues had disabled access/toilet facilities, access to water and a sink, tea/coffee-making facilities and could accommodate up to eight participants (potentially with wheelchairs) around a table.

There were storage facilities (albeit limited) in Cambridgeshire but none in the Bournemouth venue. Transport was provided for those unable to make their own way to the venue.

Usual Care

In Bournemouth, support is provided by the Early Supported Discharge multidisciplinary team for 2–6 weeks after leaving hospital and then medical care via the General Practitioner (GP), with a referral to the Stroke Coordinator. People with complex medical conditions are seen by Stroke Consultants as hospital outpatients. Ongoing rehabilitation needs are met by rehabilitation teams and day hospital service provision in some areas. In Cambridgeshire, medical care is delivered via the GP and people with complex medical conditions are seen by Stroke Consultants as hospital outpatients. All can access support from the Stroke Association 'Information, Advice and Support Coordinator' and may receive additional therapy or support via one of three locality neurorehabilitation teams. Participants in both arms of the trial received usual care, and usual care was not affected by involvement in the trial.

Descriptors and proposed outcome measures

Demographic/descriptor variables and stroke related information

At baseline the local research assistant collected information during a home visit about age, sex, marital status, educational qualifications, ethnicity, household composition, employment situation, comorbidities, medication, type of stroke, stroke side, time-since-stroke, mobility (Rivermead Assessment - Gross Motor subscale),[54] upper limb impairment (Motricity Index),[56] communication ability (Boston Severity Rating Scale),[57] and cognitive ability (Addenbrookes Cognitive Exam – Revised; ACE-R).[58]

Outcome measures

The outcome measures (see below) were self-reported and presented in a booklet in a large font (pt. 14). At baseline, outcome measures were administered face-to-face by a research

assistant in participants' homes. At approximately 5 months post-randomisation (1 month post - HoS intervention) outcome measures were administered by post, or if needed, with face-to-face or telephone support from a blinded assessor (one in each centre). At the end of the questionnaire booklet there was a question that asked whether participants had received any support from others to complete it with the following response options possible: none, researcher on phone, researcher at house, family member/friend. Participants were asked not to disclose their allocation arm to the blinded assessors. In each centre the blinded assessors were asked to guess participants' treatment allocation.

In line with the feasibility objectives of this study, three outcome measures were included for consideration as potential candidates for the primary outcome in a subsequent full trial, as follows:

(i) Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS)[59]

(ii) Hospital Anxiety and Depression Scale (HADS)[60]

(iii) ICEpop CAPability measure for adults (ICECAP-A)[61]

In addition, the following outcome measures were included as potential secondary outcomes:

(i) Rosenberg Self-Esteem Scale (RSES)[62]

(ii) Medical Outcomes Short Form-36 (SF-36 V.1)[63]

(iii) Head Injury Semantic Differential Scale (HISDS-III)[64]

Serious adverse events and adverse events

Serious adverse events (SAEs) and adverse events (AEs) were closely monitored, documented and reported as described in the study protocol.[50]

Process measures

Doojse et al.'s social identification self-report scale[55] was used to measure 'sense of belonging' by participants in the HoS group at the end of the first, fifth and final session.

Identifying, measuring and valuing resource use

Resources required to deliver the HoS intervention were recorded for each session on forms completed by the artist facilitators. These included artists' preparation time, travel time to and from the venue, time spent delivering the intervention, equipment and materials used, number of participants attending the sessions, venue and venue hire costs. Resources were valued using local estimates provided by the experienced artists delivering HoS. Artist facilitators' time was valued at the fixed fee of £120 per session (to cover travel, preparation and delivery costs) with an additional £25 fee for materials and £8 for refreshments. Venue hire costs in Bournemouth (iterations 1 & 2) were £40 per session, and in Cambridgeshire, £100 per session (iteration 3) and £25 per session (iteration 4). We envisage the roll-out of the HoS intervention would follow a similar model whereby the health care provider would pay the artist facilitators a fixed delivery fee. Participant travel costs to attend sessions were recorded and are reported.

Resources required to deliver usual care in both arms were collected via a bespoke telephone-administered resource use questionnaire that asked about resources used in the period following randomisation. Participants were posted the questionnaire in advance of the telephone interview and were offered face-to-face support to complete it, if required. The questionnaire included hospital visits and admissions, use of community and social services, time off work and social activities, informal care, other sources of support, expenses incurred and medications. As service users advised us that it would be difficult to distinguish between stroke-related resource use and resource use related to co-morbidities, the questionnaire asked respondents to report resources related to all their health care needs. We assume that, in a definitive RCT, any differences between arms would result from the HoS intervention effect. To improve completion rates,[65] participants were provided with a

resource use log to record health care visits prospectively, if they wished. Resources were valued using Curtis and Burns' Unit Costs of Health and Social Care[66] and the 2015 Department of Health National Health Service (NHS) reference costs.[67] Private expenses were self-reported. Hours of informal care and time off work and social activities were valued using the Office for National Statistics (2015) average weekly earnings.[68]

Qualitative descriptive interviews

Face-to-face interviews with twelve people (8 intervention; 4 usual care) were undertaken in people's homes across both centres by CEH on two occasions: i. post-randomisation but before the HoS intervention was delivered; and ii. at study end after all outcome measures had been completed Purposive sampling was used to capture variations that might influence perceptions including age, sex, communication disability and severity of stroke. The pre-intervention topics included why the person decided to take part in the overall study, their views on the recruitment and initial assessment process, and (intervention group only) expectations in terms of the HoS group intervention. The post-intervention topics included views on the study and outcome assessment processes and the acceptability of completing outcomes at one year follow-up in the context of a hypothetical future trial. Intervention participants were also asked about their experiences of the group, the venues, and their ability/willingness to pay their own transport costs to attend HoS.

Analysis

Quantitative analysis

Quantitative analysis was carried out using IBM SPSS V23.0 and STATA V14. The person undertaking the analysis was blind to allocation and group assignment was coded using 0 and 1. As this is a feasibility study, analyses are primarily descriptive and focus on baseline participant characteristics and the estimation of key feasibility parameters.[69] Estimates of recruitment, retention and questionnaire completion rates are presented with 95% confidence intervals (CIs). Intervention attendance rates are described.

Preliminary estimates of effect size with 95% CIs are presented for the three candidate primary outcomes to inform the plausibility of the effect sizes used in future sample size calculations. Participants were analysed in the group they were randomised to and we attempted to collect outcome measure data from everyone randomised. Missing data were assumed to be missing completely at random (MCAR) and no imputation methods were used. Analysis of covariance was used to estimate effect size for each outcome variable at follow-up, adjusting for centre and the respective baseline values. Although stroke severity was a stratification variable in the randomisation we have not adjusted for it in the analysis because of the very small number with a severe stroke. In the future trial we would also take into account clustering effects resulting from the group-based nature of the HoS intervention.[70] We have not taken into account clustering in the analysis presented here because (a) this is a feasibility study where the aim is not to obtain precise estimates of effect size and (b) there were just 56 participants (29 receiving the HoS intervention) and only a small number of clusters (n = 4) making it difficult to adjust for clustering. A consequence is that widths of the 95% confidence intervals are likely to be underestimated. Standardised effect sizes (Cohen's *d)* were obtained by dividing effect sizes by pooled baseline standard deviation.

Economic analysis

We report completion rates for the resource use categories. A preliminary estimate of the cost of delivering the HoS intervention was derived using macro-level costings. We also report artist facilitator time to deliver the intervention at the micro-level and patient travel expenses to the sessions.

We further report resource use units and costs per category per trial arm, for an indication of cost drivers for the intervention for the health and social care perspective. We derived

capability index scores for the ICECAP-A[71] and applied UK preference-based tariffs to the SF-6D to derive quality-adjusted life-years.[72]

Qualitative analysis

The qualitative analysis consisted of two aspects i). a content analysis[73] of participants' views of the research processes which are presented in this paper and ii). a thematic analysis[74] about participants' expectations and experiences of the HeART of stroke group which will be reported in a future paper. The interviews were transcribed verbatim.

For the content analysis CEH read each transcript and for each transcript noted the response to the specific focused questions relating to the research processes such as recruitment, screening and the administration of outcome measures as well as the acceptability of the venue, the intervention, and potential willingness to pay for the intervention (latter three, intervention group only). These specific responses were then collated together across all participants by CEH and formed the findings presented below.

RESULTS

Study procedures, recruitment and retention rates

Fifty-six people were randomised (88% of our original target of 64) (see Figure 3). Nearly two-thirds of the sample was male and the mean age of the sample was 70 (SD 12.1) years and mean time-since-stroke was 9 (SD 6.1) months. Approximately 80% of participants had had ischaemic strokes. Seventy percent of the sample was retired (see Table 1). One participant who had had their stroke outside the 2 year post-stroke inclusion time window (32 months post-stroke) was erroneously recruited into the study. We included this participant's data in the analysis.

INSERT TABLE 1 ABOUT HERE

Participants were enrolled into the study between August 2014 and April 2015 and the final follow-up occurred in December 2015. The recruitment rate across both centres was 14% [95% CI: 11% to 17%]. In Bournemouth, an acute hospital setting, the recruitment rate was 11% [95% CI: 8% to 14%] and in Cambridgeshire, a community setting, it was 28% [95% CI: 19% to 38%].

In total, information about the study was given or sent to 396 people (313 in Bournemouth and 83 in Cambridgeshire). Of these, 198 people declined participation, 112 did not return the reply slip, four did not meet the inclusion criteria, 26 were excluded for 'other reasons' (see Figure 3).

Six participants (11%) withdrew from both the study and follow-up data collection and three participants (5%) did not return the main outcome measures at follow-up. For two of the three proposed potential primary outcomes (HADS and ICECAP-A), 47/56 (84% [95% CI 73% to 92%]) of randomised participants had complete baseline and follow-up data and 46/56 (82% [95% CI: 70% to 91%]) had complete baseline and follow-up data for the WEMWBS.

Reasons for non-participation

Of 198 people declining participation, 89 gave reasons, the most common ones related to not being interested/feeling the intervention 'wasn't for them' (n=27) and health reasons (n=14).

Delivery, attendance rates and group size

Five participants allocated to the HoS arm declined the intervention post-randomisation (see CONSORT diagram for reasons). Of the 29 participants randomised to HoS sessions 20 (69% [95% CI; 51% to 84%]) attended six or more of the 10 sessions.

Two HoS groups were delivered in Bournemouth (iterations 1 & 2) and two in Cambridgeshire (iterations 3 & 4). The timing of the HoS sessions deviated slightly from that specified in the original protocol in three of the four iterations due to venue availability and the timing of public holidays. The planned group size was 6-8 participants and this target was mostly met in iterations 1-3 with 70% (21/30) of the delivered sessions including six or more people. In iteration 4 due to time pressures (the grant coming to an end) only 11 people were randomised with six allocated to the intervention. There were two drop-outs out before the group commenced and one person withdrew after the first session meaning that 90% of sessions included 3 people or fewer. A summary of attendance at the HoS groups broken down by centre and session is presented in Web Supplement Table S1. Seventy-two percent of participants randomised to the HoS arm attended the final session (session 10) of the HoS group intervention.

Self-reported ratings on the domains of the Doojse Scale (measuring 'sense of belonging')[55] increased across sessions and remained high in the final session (see Table S2 in data supplement).

Support requirements for HoS group members

At the Cambridgeshire centre one of the artist facilitators discussed a HoS group member's cognitive needs with FG (clinical psychology). Subsequently, several adaptations were identified and implemented such as providing a small sketchpad when needing to wait for additional support and providing instructions one step at a time.

Suitability of the outcome measures and feasibility of the assessment strategy

The ACE-R was originally designed as a screening tool for dementia and provides a single overall total score with higher scores indicating better cognitive functioning. It relies heavily on language abilities meaning that people with aphasia can perform poorly on domains such

as memory because of language impairments.[75] It did not prove suitable for our sample, of whom nearly half (46%) had some degree of language difficulty. For this reason we have not presented the baseline descriptive data for the ACE-R as we do not feel they provide an accurate summary of the sample's cognitive abilities given that some of the domains rely on verbal fluency and expression.

Overall, participants found the self-reported outcome measures acceptable and were able to complete them, sometimes requiring support. However, several participants noted to the blinded assessors that they had found the HISDS-III difficult to complete (in terms of understanding the meaning of some of the bipolar adjective pairs and also in understanding the response format of the scale). These difficulties were reflected in some of the polarised response patterns obtained and corroborated by the blinded assessors' experiences. For these reasons we have not presented these data.

Missing questionnaire data were followed-up via telephone by a research assistant (baseline) or blinded assessor (follow-up) at each centre. Levels of missing data were very low - overall, 99.8% of the questionnaire items comprising the candidate primary outcomes were completed (1809/1815 items at baseline and 1550/1551 items at follow-up) by those who provided outcomes (at baseline n= 55 and follow up n = 47).

Support requirements to complete outcomes

At follow-up, the self-report questionnaire booklets were administered via post by default but face-to-face support was provided if required/requested. Fifty-eight percent of those with follow-up data (26/45, data for 2 cases missing) reported that they completed the questionnaire booklet with no support, 8 (18%) received support from the researcher in the home, 10 (22%) received support from family and friends and 1 (2%) received telephone support from the blinded assessor.

Possible primary outcomes

In Table 2 we present descriptives for the possible primary outcomes (WEMWBS, HADS-A, HADS-D, ICECAP-A) and descriptives for all other outcomes gathered are presented in Web Supplement Table S3.

INSERT TABLE 2 ABOUT HERE

Completion of resource use questionnaire

The resource use questionnaire was completed by 50/56 of participants (89%); 25/29 of patients in the HoS arm and 25/27 of patients in the usual care arm. Of these 33 (66%) were administered over the telephone, 16 (32%) face-to-face at home and 1 (2%) via the post. Although not included in the original study protocol, in the Bournemouth centre duration data were logged with the 19 telephone interviews lasting 23 minutes (SD=10) on average and the 8 face-to-face administrations in the home an average of 38 minutes (SD=13).

Completion rates of resource use categories were high and similar between the arms of the trial (Table 3). The least completed category was community based services such as primary care visits (see Table 3) with 90% complete data for this category (both trial arms combined). Seventy-nine percent complete data (out of the full sample) is available for an economic analysis from the health and social care perspective.

INSERT TABLE 3 ABOUT HERE

Assessor allocation guesses

At the Cambridgeshire centre, due to a delay in receiving approval for patient access for the blinded assessor, the unblinded research assistant administered outcomes to six participants. Overall 50/56 participants (Cambridgeshire = 23; Bournemouth = 27) completed questionnaire outcomes and/or telephone health use questionnaires at follow-up. In

Cambridgeshire, the blinded assessor correctly guessed allocation on 9/17 (53%) occasions (p = 1.00 using the exact binomial test to compare with expected percentage of 50%) (NB. the six outcome assessment occasions in Cambridgeshire that were not undertaken by a blinded assessor are excluded). In Bournemouth, the blinded assessor correctly guessed allocation on 24/27 (89%) occasions (p <.001). Thus overall the blinded assessors correctly guessed allocation on 33/44 (75% [95% CI 61% to 85%]) occasions, p = 0.001.

Serious adverse events and adverse events

Five serious adverse events were reported during the study period. None was deemed related to the intervention. These included admissions to hospital for bunion removal, facial weakness and vomiting, atrial fibrillation, pneumonia, and a transient ischaemic attack.

Five adverse events were noted. None was deemed related to the intervention. Four people attended the Emergency Department but were not admitted (water retention, fall at home, fall in the road, anxiety). One person sustained a minor injury to their arm at his/her home.

Cost of delivering the HoS intervention

The cost of delivering the HoS intervention was £1,960 in Bournemouth and £2,530 in Cambridgeshire, reflecting higher venue hire costs in Cambridgeshire (see Table 4). On average, six participants attended the two HoS iterations held in Bournemouth and four attended the two HoS iterations held in Cambridgeshire. The HoS intervention would cost the health care payer, on average, £327 per participant in Bournemouth and £657 in Cambridgeshire. The cost could be as low as £245 per participant at full capacity of 8 people.

INSERT TABLE 4 ABOUT HERE

Health-related quality of life gain, resource use and costs

Table 5 reports the quality adjusted life year (QALY) gains from baseline and resource use and costs for the HoS and usual care arms. Potential cost drivers for the intervention are inpatient and outpatient appointments and contacts with a social worker.

INSERT TABLE 5 ABOUT HERE

Qualitative

All 12 people who were purposively sampled for interview (8 intervention, 4 usual care) were interviewed on two occasions (male = 7, female = 5; mean age = 70 years (range 51-83 years); mean time-since-stroke = 7 months (range 4-12 months); mean interview duration 40 mins (range 10-65 mins). Most had had a mild, and one a moderately disabling, stroke. Nine had an affected arm and five had speech difficulties. Participants were positive about the research processes and reported finding the screening and baseline measures easy to complete with the support provided ('not too bad, or 'no trouble, it was quite straightforward'). One person commented negatively on the cognitive assessment as her husband who lived with dementia had had to complete it in the past. Participants found the outcome measures and resource use questionnaire acceptable ('it was all right, yeah'; 'no problems, no problems at all'). Some people valued receiving the resource use log to complete as they went along saying 'it was helpful to do it beforehand' or using the paper versions of questionnaires that were sent in advance to supplement telephone interviews saying it was not a problem due to 'the fact that I had it in front of me as well.' One person noted they would have liked more opportunities for open answers on the questionnaires so he/she could provide some explanations about his/her responses. All interviewees would have been happy to complete outcome measures at 4 and 12 months follow up, if asked.

Timing of sessions (held in the morning) and session duration (2 hours) were acceptable. While the venues were found to be acceptable, a few people mentioned that they would have liked access to a café where they could meet following the HoS sessions. Participants in Bournemouth were willing to pay up to £10 per session for transport if required. As all but

one interviewee in Cambridgeshire drove to sessions (it was a much more rural setting than Bournemouth) and were happy to do so, transport costs were not discussed during the interviews. The one interviewee who used transport in Cambridgeshire only attended one session due to health issues (unrelated to stroke). Findings related to expectations and experiences of taking part in the groups will be reported elsewhere.

DISCUSSION

Main findings

This is the first study to formally test the feasibility of an Arts & Health intervention for people post-stroke in the community. While there are two other RCTs of Arts and Health interventions in stroke[46-48] both of these involved inpatients in a rehabilitation setting rather than people living in the community. One involved a creative art intervention that, unlike HoS was highly prescribed, making direct comparisons difficult.

Attendance at the HoS intervention groups was high. The majority of people who took part in the HoS groups highly valued them, with many reporting increased confidence both within and outside the groups. The numbers who declined the intervention were similar to those reported in the Morris et al. study.[47,48] Study retention was good with follow-up data available for 84% of participants and data completion rates were high (> 80% for the candidate primary outcome measures).

The structured breaks between the HoS sessions were potentially instrumental in encouraging participants to continue art work outside the group. The links created with local arts and health practitioners led to some participants continuing more independent creative practice after the research ended. Important practical considerations include ensuring that venues are on public or community transport routes, have free and disabled car parking

facilities, heating/air conditioning and drink-making facilities. In the full multi-centre trial, to maximise recruitment and be as inclusive as possible, transport will be provided, if required.

The included outcome measures were mostly acceptable (but see limitations section) with some participants requiring support to complete them. The possible primary outcome measures for the future trial (WEMWBS, HADS-D, HADS-A, ICECAP-O) all demonstrated change in the direction of benefit for the HoS arm. In Morris et al.'s randomised controlled feasibility study of a visual arts participation intervention for stroke inpatients, a quality of life scale was initially was initially suggested as the likely primary outcome for a future trial. However, their findings suggested that a measure of emotional wellbeing (the Positive and Negative Affect Scale) would be a more relevant primary outcome measure. Similarly, in the current study a measure of emotional wellbeing (HADS-D) is being considered as the primary outcome for a subsequent definitive trial and, with medium standardised effect sizes, it is likely that such a trial would be feasibly sized.

We have used novel dissemination methods such as making a short film involving people who had attended the HoS groups in Bournemouth, holding an art exhibition in both Bournemouth and Cambridgeshire to showcase the creations of the HoS group members.

Limitations; Implications for a future trial

We did not quite reach our original recruitment target and the overall recruitment rate was low (though not unlike that reported in another community-based study[76]). In the current study the recruitment rate in the community setting (28%) was higher than that via hospitals (11%). This might be because in Cambridgeshire recruitment was undertaken by clinicians working in the community who often had a long-standing relationship with their clients. In contrast, at Bournemouth and Christchurch hospitals, while some potential participants were known and approached directly by the research nurses, others were identified from clinical databases and sent study information in the post.

The most common reason for people declining participation in the current study was because they felt the intervention 'wasn't for them'. Similarly Morris et al., (2017)[48] also reported that the majority of people declined participation in their feasibility study of a visual arts participation programme because they were ambivalent about art participation. Modifying the description of the HoS intervention, such as referring to it as 'an opportunity to reconnect with and gain confidence in everyday life', rather than calling it an arts intervention could be one way to enhance recruitment. Morris et al. (2017) suggested that provision of taster sessions may be another means of improving study enrolment[48] though we note a risk of jeopardising equipoise or increasing the likelihood of resentful demoralisation. Additionally, we could extend the eligibility criteria by providing additional support so that people who require support with toileting needs could attend, though this would have cost implications. Finally, we could also expand the recruitment strategy to include primary care. We will continue to consult with service users and stakeholders to seek their advice on ways of increasing recruitment rates and how best to convey the essence of the intervention to people.

The resource use data obtained in this feasibility study provide insights into the main potential cost drivers for the intervention meaning that we can refine and shorten the resource use questionnaire for the definitive trial. While administering the resource use questionnaire by telephone resulted in high levels of data completeness, maintaining assessor blinding at follow-up proved challenging, particularly in the Bournemouth centre. To try to increase the success of assessor blinding, we will add instructions on the printed versions of the outcome measures that emphasise the importance of not disclosing allocation group and will reword the question in the resource use questionnaire that asks about contacts with charities, social or activity groups. We will also seek patient and public involvement advice about how we can best convey the message not to disclose allocation at

the start of the telephone resource use interview and, based on this, will create a standard script. We will provide training for the blinded assessors.

Some participants reported finding the HISDS-III difficult to complete. For these reasons we would not include this outcome in a future trial. The ACE-R also proved problematic due to its heavy reliance on language abilities. It will be important to identify a more appropriate way to evaluate specific domains of cognitive functioning for the future trial. One possibility is the recently developed Oxford Cognitive Screen[75] which has been designed specifically with a stroke population in mind and is purportedly inclusive for individuals with aphasia and neglect. While only short-term follow-up was included in this feasibility study, a future definitive study would include longer term 12 month follow-up.

The idea for the HoS intervention originated from a stroke survivor (and co-author) (RC) who had identified a gap in service provision. Since then, Arts & Health approaches are beginning to be recognised by policy makers as a useful way to support the health and wellbeing of communities.[39] With NHS pressures and difficulties of accessing formal services[77] our relatively low cost intervention (which could be as low as £245 per person if delivered at full capacity) offers potential to form part of a comprehensive long term support pathway to reduce depression following a stroke and increase community access and participation. As we look ahead to a future definitive trial it will be important to draw upon implementation science expertise and to consult with key stakeholders. This will help us to ensure that the HoS intervention, if found to be effective and cost-effective, can be rolled out within existing health service and social care structures and is designed in such a way so as to facilitate its rapid adoption and implementation into practice.

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Contributors

CEH and ST are equal contributors and joint first authors. CEH (Chief Investigator), FG (Principal Investigator, Cambridge Centre), CLR and RC were involved in the conception of the study and CEH, ST and FG led the design. CEH with ST and FG led the writing of initial grant application and protocol. DJ and FG advised on clinical aspects related to the grant application, PT led the statistical component of the study, EM led the economic evaluation, supported by TP and KG and FR advised on the qualitative aspects. MG and SN refined aspects of the draft protocol. MG coordinated the study on a day-to-day basis. CT and AW organised and administered the blinded assessments. ST and CEH drafted the manuscript, FG, MG, PT and EM provided detailed feedback and all other authors critically reviewed and approved the final version.

Competing interests

None

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Ethics approval

Ethics approval was granted by the Exeter NRES Committee (REC Ref 13/SW/0136) on 30/07/13. Local Research and Development approval was granted by the Royal Bournemouth and Christchurch Hospital NHS Foundation Trust on 06/05/14. This Trust is the study sponsor. Local Research and Development approval was granted by Cambridgeshire Community Services NHS Trust on 29/05/14.

Provenance and peer review

Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data Sharing Statement:

Requests for de-identified data should be directed to the corresponding author.

Table 1: Baseline clinical and demographic descriptives for the sample

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
Sex [n (%)]			
▪ Female; Male	7 (26%); 20 (74%)	17 (59%); 12 (41%)	24 (43%); 32 (57%)
Age (years) Mean (SD) range	67.4 (12.83) 39-88	72.0 (11.22) 27-87	69.8 (12.1) 27-88
Ethnicity			
▪ White English	25 (93%)	23 (79%)	48 (86%)
▪ White other British	1 (4%)	5 (17%)	6 (11%)
▪ Mixed- white and Asian	1 (4%)	-	1 (2%)
▪ Black or Black British – African	-	1 (3%)	1 (2%)
Time-since-stroke (months) Median (IQR) range*	7 (5) 2-19	7 (7) 1-32	7 (5) 1-32
Stroke type [n (%)]			
▪ Ischaemic/thrombotic	6 (22%)	5 (17%)	11 (20%)
▪ Ischaemic/embolic	1 (4%)	1 (3%)	2 (4%)
▪ Haemorrhagic/Intracerebral	2 (7%)	2 (7%)	4 (7%)
▪ Haemorrhagic subarachnoid	-	1 (3%)	1 (2%)
▪ Ischaemic/type unknown	13 (48%)	16 (55%)	29 (52%)
▪ Haemorrhagic/type unknown	4 (15%)	3 (10%)	7 (13%)
▪ Type unknown	1 (4%)	1 (3%)	2 (4%)
Stroke severity (Rivermead Gross motor assessment) [n (%)]			
Total Score ≤ 6	1 (4%)	2 (7%)	3 (5%)
Total Score ≥ 7	26 (96%)	27 (93%)	53 (95%)
Stroke side [n (%)]			
▪ Left CVA	11 (42%)	15 (52%)	26 (47%)
▪ Right CVA	13 (50%)	11 (38%)	24 (44%)
▪ Both sides	1 (4%)	3 (10%)	4 (7%)
▪ Not applicable	1 (4%)	-	1 (2%)
▪ System missing	1	-	1
Centre [n (%)]			
▪ Bournemouth	16 (59%)	17 (59%)	33 (59%)
▪ Cambridgeshire	11 (41%)	12 (41%)	23 (41%)
Level of education [n (%)]			
Highest qualification achieved:			
▪ No qualifications	3 (12%)	8 (30%)	11 (20%)
▪ One or more GCSE	4 (16%)	4 (15%)	8 (14%)
▪ One or more A level	5 (20%)	1 (4%)	6 (11%)
▪ First degree or higher	1 (4%)	5 (19%)	6 11%)
▪ Other	12 (48%)	9 (33%)	21 (38%)
▪ System missing	2	2	4 (7%)
Pre-stroke employment status			
▪ Retired	14 (52%)	25 (86%)	39 (70%)
▪ Full-time employment	3 (11%)	1 (3%)	4 (7%)
▪ Part-time employment	3 (11%)	1 (3%)	4 (7%)

Descriptor	Usual Care (UC) (n=27)	HeART of Stroke (HoS) (n=29)	Entire cohort (n=56)
▪ Self-employed	2 (7%)	1 (3%)	3 (5%)
▪ Other (unemployed; homemaker)	5 (19%)	1 (3%)	6 (11%)
Marital status [n (%)]			
▪ Single	4 (15%)	3 (10%)	7 (13%)
▪ Married/cohabiting	17 (63%)	13 (45%)	30 (54%)
▪ Separated/divorced	3 (11%)	3 (10%)	6 (11%)
▪ Widowed	3 (11%)	10 (34%)	13 (23%)
Household composition			
▪ Living alone	9 (33%)	13 (45%)	23 (41%)
▪ Living with others	18 (67%)	15 (52%)	32 (57%)
▪ Sheltered housing	-	1 (3%)	1 (2%%)
Taking medication for mood			
▪ No	21 (78%)	24 (86%)	10 (18%)
▪ Yes	6 (22%)	4 (14%)	45 (82%)
▪ System missing	-	1	1
Communication difficulties†			
▪ No	18 (67%)	12 (59%)	30 (54%)
▪ Yes	9 (33%)	17 (41%)	26 (46%)
Motricity Index Total Score*			
Median (IQR) N	86.3 (27) 12-100, 27	81.0 (29) 1-100, 29	83.6 (27) 56
**NB for one case one item was missing and was replaced by the mean*			

† Boston Severity Rating Scale

*Although the inclusion criterion for the study was ≤ 24 months post stroke we erroneously recruited one participant at 32 months post stroke and this participant's data are included in the analysis.

Table 2: Descriptives and preliminary estimates of effect size for potential primary outcomes

Outcome measure	Baseline N=56	Mean difference (95% CI)	Post N=47	Standardised Effect Size (Cohen's *d*)
Warwick and Edinburgh Mental Well Being Scale (WEMWBS) *(potential range 14-70, higher scores greater wellbeing)*				
UC mean (SD)] N	48.8 (10.64) 26		48.0 (8.40) 21	
HoS mean (SD) N	46.9 (8.94) 29		48.4 (10.28) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		2.25 [-2.83, 7.32]		0.23
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		1.14 [-3.42, 5.70]		0.12
Hospital Anxiety and Depression Scale (HADS) *Anxiety subscale* *(potential range 0-21 each subscale, higher scores greater anxiety)*				
UC mean (SD) N	7.4 (3.72) 27		7.0 (4.13) 22	
HoS mean (SD) N	7.2 (4.29) 29		6.3 (3.74) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-0.47 [-2.48, 1.54]		-0.12
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-0.55 [-2.39, 1.28]		-0.14
Hospital Anxiety and Depression Scale (HADS) *Depression subscale* *(potential range 0-21 each subscale, higher scores greater depression)*				
UC mean (SD) N	4.8 (2.68) 27		6.1 (3.33) 22	
HoS mean (SD) N	6.6 (3.76) 29		6.0 (4.18) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		-1.82 [-3.42, -0.22]		-0.56

Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		-1.46 [-3.12, 0.21]	-0.45
ICECAP-A tariff (potential *range 0-1, higher scores greater capability)*			
UC mean (SD) N	0.81 (0.14) 26	0.78 (0.15) 21	
HoS mean (SD) N	0.75 (0.16) 29	0.76 (0.22) 25	
Mean diff [95% CI] in change from baseline (unadjusted)		0.05 [-0.03, 0.13]	0.33
Mean diff [95% CI] in change from baseline (adjusted for centre & baseline score)		0.04 [-0.05, 0.12]	0.26

Where high scores indicate better outcomes, positive effect sizes suggest benefit for the HoS arm.
Where low scores indicate better outcomes, negative effect sizes suggest benefit for the HoS arm.

Table 3: Completeness of resource use data

	N complete data	% of questionnaires filled in (n=25)	% of sample (n=29)	N complete data	% of questionnaires filled in (n=25)	% of sample (n=27)
	Intervention			Usual Care		
Health and social care						
Outpatient visits	25	100%	86%	25	100%	93%
Inpatient visits	25	100%	86%	25	100%	93%
Community based services	21	84%	72%	24	96%	89%
Personal social services	25	100%	86%	24	96%	89%
Total health and social care	21	84%	72%	23	92%	85%
Further resource use collected						
Time off work	25	100%	86%	23	92%	85%
Time off normal activities	25	100%	86%	25	100%	93%
Hours of help per week	21	84%	72%	24	96%	89%
Private therapies used	25	100%	86%	25	100%	93%

Charity/support group contacts	25	100%	86%	25	100%	93%

Table 4: HoS delivery costs

Cost of delivering HoS	**Bournemouth**	**Cambridgeshire**
Costs for 10 sessions		
Artist fee	£1,200	£1,200
Venue cost	£430	£1,000
Materials cost	£330	£330
Total	£1,960	£2,530
Mean no. of participants per session	6.0	3.85
Cost of HoS per participant (based on mean attendance)	£327	£657
Cost of HoS per participant at capacity (8 attendees)	£245	£316
Reporting micro-level resource use to deliver HoS		
Artist time (in mean hours):		
Session duration	20.0	20.5
Preparation time	20.0	10.6
Travel time	15.0	15.6
Total intervention time	55.0	46.7

Participant travel costs	£1,021	£658

Table 5: Outcomes resource use and cost of delivering care in both arms

	HoS Intervention						Usual care					
	N	N users	Mean use	SD	Mean cost	SD	N	N users	Mean use	SD	Mean cost	SD
Outcomes												
QALYs gained (SF6D)	22	-	0.18	0.03	-	-	21	-	0.17	0.02	-	-
Inpatient and A & E												
Inpatient admissions	25	3	0.9	3.0	£49	£136	25	3	0.7	2.8	£96	£308
A & E or hospital admissions	25	4	0.2	0.4	£22	£53	25	6	0.2	0.4	£34	£61
Outpatient appointments												
Stroke rehabilitation	25	1	0.0	0.2	£10	£50	25	2	0.1	0.3	£20	£69
Physiotherapy	25	3	0.3	1.2	£6	£23	25	4	1.0	2.9	£20	£56
Occupational therapy	25	1	0.0	0.2	£1	£4	25	3	0.2	0.5	£3	£9
Speech and language therapy	25	2	0.2	0.8	£4	£16	25	2	0.4	1.6	£7	£30
Psychologist	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0

Dietician	25	0	0.0	0.0	£0	£0	25	0	0.0	0.0	£0	£0
Other outpatient appointments	25	14	1.2	1.5	£140	£210	25	13	2.0	3.2	£196	£393
Community-based services												
GP contacts	24	17	1.9	1.5	£92	£79	25	18	1.6	2.0	£72	£83
GP nurse contacts	25	11	1.6	3.0	£22	£44	25	16	2.0	3.1	£26	£40
Physiotherapy contacts	25	3	0.3	1.2	£6	£23	25	2	0.9	3.7	£19	£78
SALT contacts	24	3	0.4	1.3	£25	£82	25	3	1.1	3.5	£94	£308
Occupational therapy at home	25	1	0.2	0.8	£5	£25	25	2	0.2	0.9	£7	£27
Repeat prescriptions from GP	23	16	4.0	5.6	£5	£7	24	18	4.0	4.3	£5	£5
Other community-based appointments	21	2	0.4	1.4	£25	£77	24	1	0.3	1.6	£28	£143
Personal social services												
Home care worker contacts	25	0	0.0	0.0	£0	£0	24	2	0.9	3.4	£11	£41
Social worker contacts (hours)	25	2	0.4	1.6	£28	£127	25	3	0.3	0.9	£24	£72
Food at home services (meals)	25	0	0.0	0.0	£0	£0	25	1	0.6	3.2	£4	£21

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Figure Legends:

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

Figure 2: Painting by MDBD

Figure 3: Drawing by FB

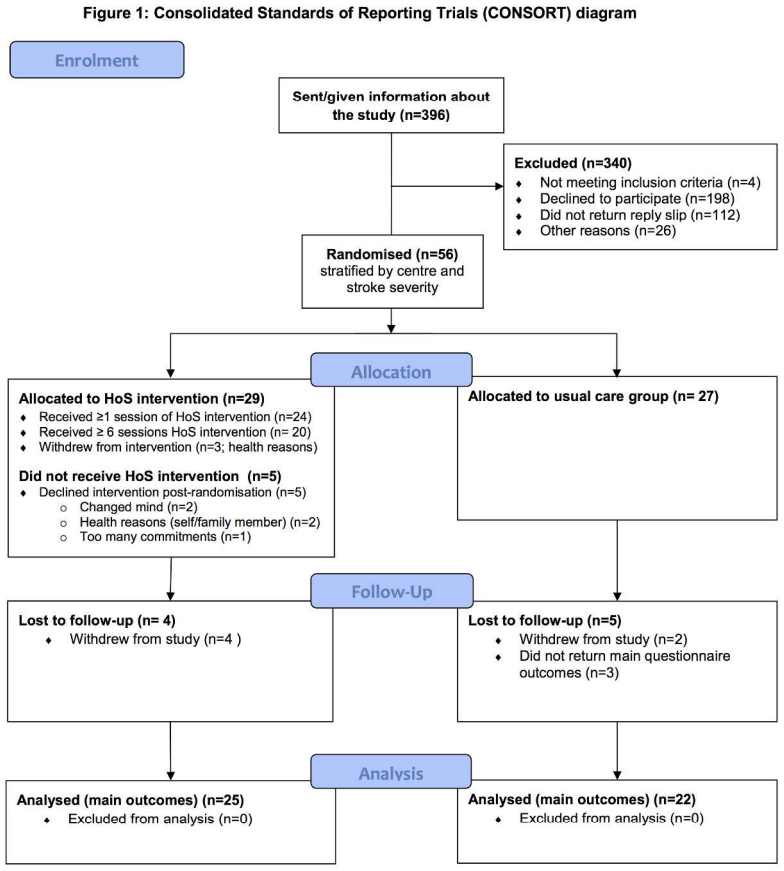
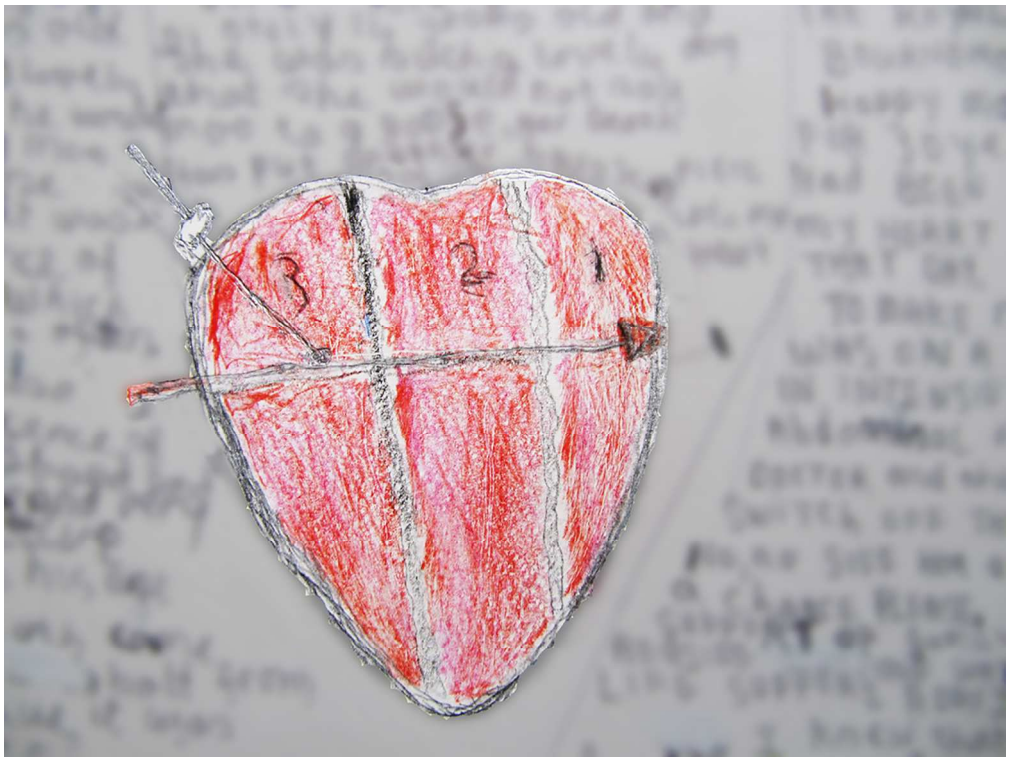


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram

209x297mm (300 x 300 DPI)



Drawing by FB

169x127mm (300 x 300 DPI)

Painting by MDBD

84x84mm (300 x 300 DPI)

Supplementary Web tables

Table S1: Attendance at HoS by centre and session

	Bournemouth		Cambridge		Total
	Iteration 1	Iteration 2	Iteration 3	Iteration 4	
No. randomised to HoS group	8	9	6	6	29
HoS session					
1	6	7	5	4	23
2	6	7	5	1	19
3	6	6	6	2	20
4	6	6	5	2	19
5	5	7	5	2	19
6	5	6	5	2	18
7	6	5	6	3	20
8	6	6	4	2	18
9	6	6	6	2	20
10	6	6	6	3	21

Table S2: Descriptives for Doojse's et al.'s social identification scale

Sense of Belonging statement	**Median (IQR) range**		
(potential score range 1-7, higher scores indicate higher sense of belonging)	*Session 1 (n=24)*	*Session 5 (n=20)*	*Session 10 (n=21)*
1. I see myself as a member of the HoS group	6 (2) 1-7	7 (1) 4-7	7 (0) 6-7
2. I am pleased to be a member of the HoS group	7 (2) 1-7	7 (1) 4-7	7 (0) 4-7
3. I feel strong ties with members of the HoS group	4 (5) 1-7	5 (3) 4-7	6 (2) 3-7
4. I identify with other members of the HoS group	5 (3) 1-7	6 (2) 4-7	7 (1) 4-7

Table S3: Descriptives for potential secondary outcomes

Outcome measure	Baseline *N=56*	Post *N=47*
Rosenberg Self-Esteem Scale (RSES) *(potential score range 0-30 , higher scores indicate higher self-esteem)*		
UC mean (SD) N	20.8 (6.23) 27	20.1 (5.21) 22
HoS mean (SD) N	20.4 (5.81) 29	21.1 (5.67) 25
Medical Outcomes Short Form-36 (SF-36) - Physical functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	43.4 (24.51) 27	42.7 (23.94) 22
HoS mean (SD) N	48.3 (25.16) 27	55.3 (23.23) 23
SF-36 Role limitations - Physical subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean, SD (95% CI)	23.9 (29.36) 27	17.0 (26.03) 22
HoS mean (SD) N	35.0 (34.61) 28	27.0 (38.13) 25
SF-36 Role limitations - Emotional *(potential range 0-100, higher scores more favourable health state)*		
UC mean (SD) N	42.4 (45.05) 27	50.0 (42.10) 22
HoS mean (SD) N	45.3 (41.81) 28	49.3 (45.26) 25
SF-36 Energy/Fatigue subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	48.6 (18.01) 27	42.05 (20.45) 22
HoS mean (SD) N	45.2 (25.5) 27	43.3 (25.40) 24
SF-36 Emotional wellbeing subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD (N)	68.91 (17.19) 27	69.81 (19.51) 22
HoS mean SD (N)	67.33 (17.16) 27	68. 83 (20.43) 24
SF-36 Social functioning subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	69.3 (26.65) 27	64.2 (29.70) 22
HoS mean (SD) N	66.5 (26.45) 28	72.00 (28.25) 25
SF-36 Pain subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean (SD) N	66.8 (24.45) 27	71.2 (28.32) 22
HoS mean (SD) N	61.9 (24.97) 27	69.5 (27.63) 25
SF-36 General Health subscale *(potential range 0-100, higher scores more favourable health)*		
UC mean SD N	55.2 (23.68) 27	55.5 (21.49) 22
HoS mean (SD) N	51.4 (20.09) 27	57.3 (19.67) 24
SF-6D Derived health state value *(potential range -0.296 to 1.00 with higher scores indicating better health)*		
UC mean (SD) N	0.63 (0.09) 27	0.64 (0.08) 21
HoS mean, SD N	0.64 (0.12) 26	0.68 (0.12) 24

UC = Usual Care
HoS = HeART of Stroke

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6-10
	2b	Specific objectives or research questions for pilot trial	13
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	13
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	16, 27
Participants	4a	Eligibility criteria for participants	15
	4b	Settings and locations where the data were collected	16, 19-20
	4c	How participants were identified and consented	15-17
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	17-20
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	20-23
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	-
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	-
Sample size	7a	Rationale for numbers in the pilot trial	15
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	17
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	17
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	17
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	17

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	17,21,24
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	24-25
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	25 + Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	26
	14b	Why the pilot trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	39
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	41
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	41
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	42-44;72-73
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	30
	19a	If relevant, other important unintended consequences	-
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	33-35
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	33-35
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	32-36
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	34-35
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	Referenced
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	37
	26	Ethical approval or approval by research review committee, confirmed with reference number	38

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