

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	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.
AUTHORS	Ellis-Hill, Caroline; Thomas, Sarah; Gracey, Fergus; Lamont-Robinson, Catherine; Cant, Robin; Marques, Elsa; Thomas, Peter; Grant, Mary; Nunn, Samantha; Paling, Thomas; Thomas, Charlotte; Werson, Alessa; Galvin, Kathleen; Reynolds, Frances; Jenkinson, Damian

VERSION 1 – REVIEW

REVIEWER	Sarah Munce Toronto Rehabilitation Institute-University Health Network
REVIEW RETURNED	19-Jan-2018

GENERAL COMMENTS	<p>Thank you for the opportunity to review this interesting paper. My comments and suggestions are outlined below.</p> <p>INTRODUCTION</p> <p>The following sentences reads as very long and should be shortened/simplified: “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”. Also 2 of 3 studies cited are qualitative meta-syntheses, not all three (references 3 and 5 only). Furthermore, they should be referred to as qualitative meta-syntheses and not qualitative systematic reviews.</p> <p>With respect to the sentence, “A stepped approach to psychological support has been proposed¹⁹ but this system is still in its infancy”, it would be helpful if the authors could provide an example what it is meant by a “stepped approach” to psychological support”.</p> <p>The authors indicate that, “Furthermore, a Cochrane review indicated no evidence for pharmacotherapy in prevention of post-stroke depression, and only weak evidence for psychotherapeutic approaches”.²⁰ This review is 10 years old – does more recent evidence provide (more) support for psychotherapeutic interventions?</p> <p>METHODS</p> <p>The authors should indicate that the reporting of this feasibility trial is consistent with the CONSORT guidelines.</p> <p>It would be helpful if the authors could provide more information</p>
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about “patient and public involvement members” – e.g., did this include individuals from community-based organizations? What kinds of patients were involved (i.e., individuals with many years post-stroke?) Were caregivers involved?

In general, it is suggested that the authors avoid introducing acronyms in their titles (e.g., PPI) and the overuse of acronyms (it can be difficult for a reader to remember what an uncommon acronym stands for).

The authors should specify the name of the country after the city names (e.g., Bournemouth).

It would be helpful if the authors could provide a rationale for the specific selection of “two years post-stroke” as well having physical or cognitive symptoms from stroke at “five days post-stroke”.

The authors should clarify what they mean/provide an example(s) of “...standardisation was linked with the context and setting...”

D should be used instead of E: c) follow and respond to their own interests and e) develop a sense of play/improvisation.

It is suggested that the authors provide more detail on the “...Arts & Health practitioners, with at least 5 years’ experience” (e.g., what were some of their educational backgrounds? 5 years of experience in what?)

The sentence, “These were self-reported and presented in a booklet in a large font (pt. 14)” should be replaced with “The outcome measures were self-reported...”

The qualitative approach should be specified (e.g., qualitative descriptive, etc.)

The authors should use the term sex instead of gender.

The authors should specify why 5 months was selected as the time point for outcome administration.

RESULTS

The results – including those reported in the narrative and tables – seem reasonable and transparent and no edits/changes are requested.

DISCUSSION

The sentence, “Some people reported that it was life changing” should be removed as it is unclear which result(s) this sentence is referring to (and it sounds a little “colloquial”).

The sentence, “Study retention was good, data completion rates high and loss to follow-up low” reads awkwardly and should be revised (and should re-iterate the specific percentages).

With respect to the sentences, “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”, again, it is unclear where these specific results are located in the manuscript and should not be appearing for the first time in the Discussion section. Furthermore, the authors indicated in the Qualitative Analysis section of the Methods section that findings on the expectations and experiences of the intervention would be reported elsewhere, so the inclusion of these quotes/findings is confusing. The authors should either include these results (i.e., in the Results section) or remove this narrative from the Discussion section. Lastly, the sentence, “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”, if it remains, needs clarification/reads too colloquially (i.e., what is

	<p>meant by “a new world following stroke”?)</p> <p>The authors should also provide an example(s) of how they would modify the way the intervention is described to increase recruitment.</p> <p>The authors should indicate whether the current intervention and relationship to the suggested outcomes are based on a specific theoretical framework. If not, did the qualitative component of the study reveal the mechanism of action of the intervention and its impact on mood?</p> <p>It is also suggested that the authors include a more thorough summary of the previous literature on Arts-based interventions in stroke (or other conditions).</p> <p>The authors need to include a Limitations section.</p>
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REVIEWER	Simone Dorsch Australian Catholic University, Australia
REVIEW RETURNED	30-Jan-2018

GENERAL COMMENTS	<p>Summary This is a randomised controlled study investigating the acceptability and feasibility of an arts based activity in improving measures of mental health and quality of life in stroke survivors. There appears to be some good effects of this intervention and it is acceptable. This study lays the groundwork for a larger study investigating the effects of this intervention.</p> <p>Major issues:</p> <ul style="list-style-type: none"> • There are many gaps in information in this manuscript and much of it needs to be written more clearly. This manuscript should contain sufficient information for the reader to understand the intervention and the outcome measures without referring to other publications. The manuscript often appears to be written in an abbreviated form in which much relevant information is missing. The Results section is extremely unclear. The Discussion section needs to be written in the usual format of a Discussion of a study. <p>Title</p> <ul style="list-style-type: none"> • The word “parallel” is not required as this is implied in a randomised controlled trial. The intervention is not compared to usual care as both groups receive the same amount of usual care and the experimental intervention is additional. <p>Abstract</p> <ul style="list-style-type: none"> • More information is needed in the abstract including: <ul style="list-style-type: none"> o Lines 13-14 – is the RCT of the same intervention? o What is the intervention? No information here about what it is o What is the primary outcome measure o What are the secondary outcome measures o What feasibility parameters? o What data collection methods were piloted? • Results – what is the recruitment rate measuring – how does it become a percentage? Line 50 – how does the follow up rate have a 95% confidence interval? Lines 51 and 52 – name the questionnaires within the sentence. Line 52 – Five who declined? • Line 24, 24 who attended? • What is meant by potential primary outcomes – why were these not
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	<p>decided a priori – they could then be later changed for a larger study</p> <ul style="list-style-type: none"> • Conclusion – clear and concise • Strengths and limitations – the authors need to indicate which are strengths and which are limitations – this is not at all clear. Line 28 what incorporated? <p>Introduction</p> <ul style="list-style-type: none"> • The Intro would benefit from further clarification of the concept and rationale of the study. Where there is existing research in this area – the results of the existing research need to be discussed so that it is clear to the reader what the current gaps in the research are and the need for this study can be made evident. • Lines 32 -34 – new sentence needed to discuss depression • Line 3 – what is meant by a “stepped approach”? • Line 9 – but what is this evidence for psychotherapeutic approaches and what is missing? • Line 20 –missing reference number • Lines 47-48 – what is this evidence base – what effects have been shown? • Line 29 – what is the evidence for people with stroke? – why is this study different? <p>Methods</p> <ul style="list-style-type: none"> • Page 7; Lines 27-28 – the objectives should be described in full here so the reader does not need to look up the protocol paper • Lines 34-35 – surely this study will allow to establish key parameters rather than estimate them • Lines 38 – what do the authors mean here – what is meant by the variability of outcomes?– do existing objective outcome measures not already have established psychometric properties and data for the variability of outcomes in this population? • Lines 41-42 – are the authors also developing new tools? Or do they simply mean they are collecting data • Page 8; Line 11 - ?design of data collection tools – what is meant • Lines 34-35 – what is meant by dissemination activities? • Line 37 – who are CLR and CEH? • Lines 46-47 – the recruitment rate is a percentage of what? • Page 10; lines 42-43 – what is meant by individual randomisation? • Lines 54-55 – does this mean outcome measures? • Page 11; lines 8-12 – this requires more explanation for those not familiar with this type of intervention • Lines 13-17 – very unclear • Page 12; line 25 – what is the scale called? • Lines 30-45 – is this information necessary? • Page 13; lines 38 onwards - what are these questionnaires – are they existing ones? Did the authors make up new ones? Are they the ones mentioned at the top of page 14 • Page 15; lines 10 onwards – are there not existing questionnaires about health resource utilisation that could have been used? • Page 16; Analysis – data analysis should be described in this paper • Page 17; line 44 onwards – why mention the qualitative analysis if none of it is to be described here • Page 18; lines 54-56 – it is very unclear what the authors are using as proposed primary outcomes, it would be better to list the outcome measures that were used, the results for these outcome measures and then discuss the merits of the various outcome measures in the discussion • Page 19; line 20 onwards – this level of detail appears
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	<p>unnecessary and could be summarised further and written more clearly</p> <ul style="list-style-type: none"> • Page 20; lines 8-11 – does this result belong here? • Lines 26 onwards – does this section belong in Results or Discussion? • Page 21; lines 20-21 – very unclear – what is meant by “those with outcomes at follow-up”? what does 26/45 data mean? • Page 23; lines 33-39 – a written summary of these results should be provided • Page 24; lines 18-34 – are these results from the entire cohort or those that took part in the interviews? <p>Discussion</p> <ul style="list-style-type: none"> • The authors should look at guidelines for writing a Discussion. The first paragraph should be a summary of results, second paragraph should be a comparison of their results with existing research etc... • Page 26; lines 32 onwards – is there really no existing validated outcome measurement tool for cognitive function after stroke?
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

INTRODUCTION

The following sentences reads as very long and should be shortened/simplified: “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”.

This has been replaced with the text below which we hope is clearer.

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}

Also 2 of 3 studies cited are qualitative meta-syntheses, not all three (references 3 and 5 only). Furthermore, they should be referred to as **qualitative meta-syntheses** and not qualitative systematic reviews.

We have made this change.

With respect to the sentence, “A stepped approach to psychological support has been proposed¹⁹ but this system is still in its infancy”, it would be helpful if the authors could provide an example what it is meant by a “stepped approach” to psychological support”.

This has been changed to:

A stepped approach to psychological support following stroke has been proposed in the UK³¹ (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.

The authors indicate that, “Furthermore, a Cochrane review indicated no evidence for pharmacotherapy in prevention of post-stroke depression, and only weak evidence for psychotherapeutic approaches”.²⁰ This review is 10 years old – does more recent evidence provide (more) support for psychotherapeutic interventions?

We have added additional detail as follows:

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 approaches¹⁸. While there is evidence to suggest that pharmacological treatments

can have modest benefits in the treatment of depression post-stroke, anti-depressants have side effects and may have undesirable interactions with other medications and comorbidities.¹⁹⁻²³

While the evidence for the effectiveness of psychotherapeutic interventions for post-stroke depression is inconclusive,¹⁹ two recent trials (motivational interviewing^{24,25} and a brief psychosocial behavioural intervention plus anti-depressant²⁶) 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 trial²⁷ 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.³ A recent Cochrane review highlighted the need for further rigorously conducted RCTs to assess pharmacological and psychological treatments for anxiety following stroke.³⁰

The authors should indicate that the reporting of this feasibility trial is consistent with the CONSORT guidelines.

Thank you for spotting this omission on our part. We have added the following sentence:
*Reporting of this feasibility study follows the CONSORT 2010 extension for randomised pilot and feasibility trials.*⁵¹

It would be helpful if the authors could provide more information about “patient and public involvement members” – e.g., did this include individuals from community-based organizations? What kinds of patients were involved (i.e., individuals with many years post-stroke?) Were caregivers involved? This has been changed to:

There were five patient and public involvement PPI 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 Hospital’s stroke ward patient and public involvement group and via word of mouth from these members. All were several years following their stroke and one person was in the role of a caregiver. There were three patient and public involvement PPI members in Cambridgeshire, one was identified through a previous research role, two were identified through community organisations (Stroke Association and NHS community services). All three were several years post-stroke.

In general, it is suggested that the authors avoid introducing acronyms in their titles (e.g., PPI) and the overuse of acronyms (it can be difficult for a reader to remember what an uncommon acronym stands for).

We have gone through the paper and reduced the use of acronyms.

The authors should specify the name of the country after the city names (e.g., Bournemouth). We have made this addition.

It would be helpful if the authors could provide a rationale for the specific selection of “two years post-stroke” as well as having physical or cognitive symptoms from stroke at “five days post-stroke”.

This has been changed to:

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 depression⁵³ 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.

The authors should clarify what they mean/provide an example(s) of “...standardisation was linked with the context and setting...”

This has been changed to:

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 just 'teaching' arts skills.

D should be used instead of E: c) follow and respond to their own interests and e) develop a sense of play/improvisation.

Thank you for spotting - we have corrected this error.

It is suggested that the authors provide more detail on the "...Arts & Health practitioners, with at least 5 years' experience" (e.g., what were some of their educational backgrounds? 5 years of experience in what?)

This has been changed to:

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.

The sentence, "These were self-reported and presented in a booklet in a large font (pt. 14)" should be replaced with "The outcome measures were self-reported..."

Thank you for this helpful suggestion - we have made the suggested change.

The qualitative approach should be specified (e.g., qualitative descriptive, etc.)

We have changed the heading to:

Qualitative Descriptive Interviews

The authors should use the term sex instead of gender.

We have made the suggested change.

The authors should specify why 5 months was selected as the time point for outcome administration. We have added the following sentence under 'Design'

For reasons of efficiency and expediency, the end point of this feasibility study was 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.

RESULTS

The results – including those reported in the narrative and tables – seem reasonable and transparent and no edits/changes are requested.

Thank you. We are pleased you found the presentation of the results clear and transparent.

DISCUSSION

The sentence, "Some people reported that it was life changing" should be removed as it is unclear which result(s) this sentence is referring to (and it sound a little "colloquial").

We have removed this sentence.

The sentence, "Study retention was good, data completion rates high and loss to follow-up low" reads awkwardly and should be revised (and should re-iterate the specific percentages).

We have revised this as follows:

Study retention was good with follow-up data for available for 84% of participants and data completion rates were high (> 80% for the three candidate primary outcome measures).

With respect to the sentences, "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", again, it is unclear where these specific results are located in the manuscript and should not be appearing for the first time in the Discussion section. Furthermore, the authors indicated in the Qualitative Analysis section of the Methods section that findings on the expectations and experiences of the intervention would be reported elsewhere, so the inclusion of these quotes/findings is

confusing. The authors should either include these results (i.e., in the Results section) or remove this narrative from the Discussion section.

Thank you for pointing out this inconsistency. We have rewritten the paragraph as follows:

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 every day life', rather than calling it an arts intervention could be one way to enhance recruitment. Morris et al., suggested that provision of taster sessions may be another means of improving study enrolment⁴⁷ though we note a risk of jeopardising equipoise or increasing the likelihood of resentful demoralisation.

Lastly, the sentence, "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", if it remains, needs clarification/reads too colloquially (i.e., what is meant by "a new world following stroke"?)

We have removed this sentence.

The authors should also provide an example(s) of how they would modify the way the intervention is described to increase recruitment.

We have added the following sentence:

Modifying the description of the HeART of Stroke intervention, such as referring to it as 'an opportunity to reconnect with and gain confidence in every day life', rather than calling it an arts intervention might be one way to increase recruitment.

The authors should indicate whether the current intervention and relationship to the suggested outcomes are based on a specific theoretical framework. If not, did the qualitative component of the study reveal the mechanism of action of the intervention and its impact on mood?

The following paragraph has been added to the introduction to describe the theoretical underpinnings of HoS:

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, the Life Thread Model³³ and Self-discrepancy theory.^{89,34} 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.

It is also suggested that the authors include a **more thorough summary of the previous literature on Arts-based interventions in stroke (or other conditions).**

We have undertaken further searches for relevant literature but the relevant evidence base is small. To our knowledge, there are only 2 RCTs of Arts and Health Interventions in stroke. We have described both of these in the introduction as below:

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 group 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 UK 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.

The authors need to include a Limitations section.

We have added a section heading 'Limitations and implications for a future trial' and have restructured the discussion in line with the BMJ Open guidance and the CONSORT extension for Pilot and Feasibility studies.

Reviewer: 2

Title

- The word "parallel" is not required as this is implied in a randomised controlled trial. The intervention is not compared to usual care as both groups receive the same amount of usual care and the experimental intervention is additional.

We prefer to retain the word 'parallel' as it differentiates the parallel arm study design from other types of design - for example multi-stage, cluster, factorial, crossover designs etc. We feel this is an important distinction.

We have added 'plus usual care' to indicate the HoS group received the intervention in addition to their usual care - thank you for noting our omission.

Abstract

- More information is needed in the abstract including:

- o Lines 13-14 – is the RCT of the same intervention?

We have reworded the objectives from "We evaluated" to "To evaluate" to make it clearer that this relates to the same RCT.

- What is the intervention? No information here about what it is

We have amended as follows but note the 300 word limit for the abstract is quite challenging when trying to meet the CONSORT reporting criteria for abstracts.

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

- o What is the primary outcome measure

There was not a primary outcome. As this was a feasibility study one of the objectives was to inform the selection of a suitable primary outcome for a future full scale trial. We have specified three candidate primary outcomes for the future trial. We have added the following text later on in the 'methods' section of the main paper:

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

- What are the secondary outcome measures

We have added the following sentence later on in the 'methods' section of the main paper:

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

What feasibility parameters?

We have tried to adhere closely to the requirements of the CONSORT guidance for the reporting of abstracts. Given these reporting requirements, the 300 word limit for abstracts in the BMJ Open precludes the addition of further detail in the abstract.

- What data collection methods were piloted?

The 300 word limit for abstracts precludes further detail here if we are to fulfil CONSORT guidance for the reporting of abstracts.

- Results – what is the recruitment rate measuring – how does it become a percentage? Line 50 – how does the follow up rate have a 95% confidence interval?

While not technically correct to use a percentage to describe a rate (usually involves time), it is common practice in the field of clinical trials to do so. For example, see:

Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, *et al.* Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study. *Health Technol Assess* 2007;**11**(48).

Cooper CL, Hind D, Duncan R, Walters S, Lartey A, Lee E, Bradburn M. A rapid review indicated higher recruitment rates in treatment trials than in prevention trials. *J Clin Epidemiol* 2015; 68:347-354.

Lines 51 and 52 – name the questionnaires within the sentence. Line 52 – Five who declined? This was a bespoke/tailored resource use questionnaire designed by the study health economist. We have added ‘study-specific’ to clarify this.

We have added in the word ‘people’ to clarify ‘five who declined’

- Line 24, 24 who attended?

We have added ‘who attended’ as suggested.

- What is meant by potential primary outcomes – why were these not decided a priori – they could then be later changed for a larger study
In line with the feasibility nature of the current study we included three outcome measures (the HADS, WEMWBS & the ICECAP-A) for consideration as candidate primary outcomes for a future full scale trial. One of the objectives of this feasibility study was to inform the selection of the primary outcome for a future trial. We have clarified this by replacing the word ‘potential’ with ‘candidate’. The 300 word limit for the abstract restricts how much explanation we can provide.

- Conclusion – clear and concise

Thank you

- Strengths and limitations – the authors need to indicate which are strengths and which are limitations – this is not at all clear. Line 28 what incorporated?

We have reworded this section and hope it is clearer.

- *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

- The Intro would benefit from **further clarification of the concept and rationale of the study**. Where there is existing research in this area – **the results of the existing research need to be discussed so that it is clear to the reader what the current gaps in the research are and the need for this study can be made evident**.

We have added additional clarification and provided further detail about the existing (albeit limited) research.

- Lines 32 -34 – new sentence needed to discuss depression

As suggested we have changed this into two sentences.

- Line 3 – what is meant by a “stepped approach”?

We have rewritten this as follows:

A stepped approach to psychological support following stroke has been proposed in the UK³¹ (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.

- Line 9 – but what is this evidence for psychotherapeutic approaches and what is missing?
We have added further detail.

- Line 20 –missing reference number

The reference (22) was there at the end of the sentence. It is now reference 48.

- Lines 47-48 – what is this evidence base – what effects have been shown?

We have added more detail.

- Line 29 – what is the evidence for people with stroke? – why is this study different?
We have added further detail about why this study is different – i.e. that it is community-based rather than based in an inpatient setting.

Methods

- Page 7; Lines 27-28 – the objectives should be described in full here so the reader does not need to look up the protocol paper
We have added objectives in full as described in the protocol paper.

- Lines 34-35 – surely this study will allow to establish key parameters rather than estimate them

A common objective of feasibility studies is to provide point estimates (sample estimates) (along with 95% CIs to indicate uncertainty/imprecision of the estimate) of key unknown population parameters to help plan a possible future definitive trial.

e.g., from National Institute for Health Research:

*Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to **estimate important parameters** that are needed to design the main study. The design of a feasibility study generally involves listing those parameters which are uncertain and describing the methods for improving their precision so that the main study will have a better chance of success. Examples of such parameters include:*

- *standard deviation of the outcome measure, which is needed in some cases to estimate sample size*
- *willingness of participants to be randomised*
- *willingness of clinicians to recruit participants*
- *number of eligible patients; carers or other appropriate participants*
- *characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure*
- *follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.*
- *availability of data needed or the usefulness and limitations of a particular database; and*
- *time needed to collect and analyse data.*

- Lines 38 – what do the authors mean here – what is meant by the variability of outcomes?– do existing objective outcome measures not already have established psychometric properties and data for the variability of outcomes in this population?
This refers to the standard deviation which is required to inform the sample size. We have clarified as below:

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.

- Lines 41-42 – are the authors also developing new tools? Or do they simply mean they are collecting data

These tools include a bespoke telephone resource use questionnaire, a prospectively completed resource use log and a form for artists to complete to record resources required to deliver HoS. These are all described in more detail later on in the paper as well as in the published protocol.

- Page 8; Line 11 - ?design of data collection tools – what is meant
We have amended this to ‘study materials’ to make it clearer.

- Lines 34-35 – what is meant by dissemination activities?

We feel that ‘dissemination activities’ is a phrase that will be generally understood but have added additional examples which we hope aids clarity.

Examples of dissemination activities 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.

- Line 37 – who are CLR and CEH?
We have reworded to ‘*with two members of the research team (CLR and CEH)*’.
- Lines 46-47 – the recruitment rate is a percentage of what?
The recruitment rate is a percentage of those people sent or given information about the study (see CONSORT diagram).
- Page 10; lines 42-43 – what is meant by individual randomisation?
We have changed this to ‘*randomisation of individuals*’ to reduce ambiguity.
- Lines 54-55 – does this mean outcome measures?
We have added in the word ‘measures’.
- Page 11; lines 8-12 – this requires more explanation for those not familiar with this type of intervention
Thank you. The following text has been added:
In summary it comprised ten two hour Arts & Health practitioner-led group sessions held in community venues over 14 weeks. Key aspects of the group were the opportunity to be creative and the safe group atmosphere. Members were encouraged to a) explore their sense of self and support others’ explorations; b) be non-judgmental of self/others; c) exercise personal choice; d) develop a sense of play/improvisation. Activities included the use of paints, drawing materials, clay, textiles and mixed-media.
- Lines 13-17 – very unclear
Thank you. This has been clarified and the text now reads:
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.
- Page 12; line 25 – what is the scale called?
Thank you for drawing this omission to our attention. We have added the name of the scale.
- Lines 30-45 – is this information necessary?
According to the TIDieR reporting guideline these details are important so our preference is to retain them.
- Page 13; lines 38 onwards - what are these questionnaires – are they existing ones? Did the authors make up new ones? Are they the ones mentioned at the top of page 14
We have added in ‘*see below*’ to make it clear that the outcome measures are described.
- Page 15; lines 10 onwards – are there not existing questionnaires about health resource utilisation that could have been used?
There is no existing validated measure of resource use for this particular patient group. The study health economist designed this study-specific resource use questionnaire drawing upon other existing resources so that it could be piloted in this feasibility study prior to a future trial. One of the feasibility study objectives (which we achieved) was to identify the main cost drivers pertaining to the HoS intervention.
- Page 16; Analysis – data analysis should be described in this paper
We have removed this sentence [*The analysis undertaken followed that described in the protocol unless otherwise stated.*³³] which is unnecessary as the analysis is fully described and no changes were made.
- Page 17; line 44 onwards – why mention the qualitative analysis if none of it is to be described here

We have described some data from the qualitative interviews relating to more practical aspects. The in-depth data relating to expectations and experiences of the intervention will be described separately.

As the qualitative component has associated objectives in our published protocol we feel it is important to make it clear that the in-depth qualitative study has been completed and will be reported in a separate paper.

- Page 18; lines 54-56 – it is very unclear what the authors are using as proposed primary outcomes, it would be better to list the outcome measures that were used, the results for these outcome measures and then discuss the merits of the various outcome measures in the discussion. Our preference is to keep our description consistent with our published protocol.
- Page 19; line 20 onwards – this level of detail appears unnecessary and could be summarised further and written more clearly. These details are required by CONSORT and TIDieR and were feasibility objectives of the study so we prefer to retain them but have reduced the detail. We have added an additional supplementary table (S2) to summarise participant attendance.
- Page 20; lines 8-11 – does this result belong here? We considered this and our preference is to keep this here as it is a process outcome and so it seems appropriate for it to follow information about attendance.
- Lines 26 onwards – does this section belong in Results or Discussion? One of our feasibility objectives was the suitability of the outcome measures and so we feel these findings belong in the results section but we have discussed their implications for the future trial in the discussion section.
- Page 21; lines 20-21 – very unclear – what is meant by “those with outcomes at follow-up”? what does 26/45 data mean? Thank you for pointing this out. We have changed to ‘those with follow-up data’
- Page 23; lines 33-39 – a written summary of these results should be provided. We would prefer not to provide additional description here as the main objective of the feasibility study was to demonstrate the feasibility of collecting these data and identify the main cost drivers looking ahead to designing an economic evaluation for a future trial [*“Potential cost drivers for the intervention are inpatient and outpatient appointments and contacts with a social worker”*]. We have already summarised the main cost drivers and feel further detail is not relevant at this stage.
- Page 24; lines 18-34 – are these results from the entire cohort or those that took part in the interviews? We have clarified that these were results from the interviews.

Discussion

- The authors should look at guidelines for writing a Discussion. The first paragraph should be a summary of results, second paragraph should be a comparison of their results with existing research etc...

We have restructured and redrafted the discussion in line with the BMJ Open guidance and the CONSORT extension for Pilot and Feasibility studies.

- Page 26; lines 32 onwards – is there really no existing validated outcome measurement tool for cognitive function after stroke? We have described the recently developed Oxford Cognitive Screen in the discussion which has been designed specifically with a stroke population in mind and is purportedly inclusive for individuals with aphasia and neglect.

VERSION 2 – REVIEW

REVIEWER	Sarah Munce Toronto Rehabilitation Institute, University Health Network, Toronto,
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	Ontario, Canada.
REVIEW RETURNED	07-May-2018

GENERAL COMMENTS	<p>“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”.</p> <p>The authors need to provide a stronger rationale for this one month timepoint.</p> <p>Spell out all acronyms including RC, CALM, etc.</p> <p>Remove emotive verbs such as felt.</p> <p>In the blinding section, “At follow-up, when support was provided/required to complete outcomes this was provided by assessors blind to group allocation”. The word measures should be inserted after outcomes.</p> <p>Under the Descriptors and proposed outcome measures section, an “and” should be added before cognitive ability.</p> <p>Further details about the qualitative analysis would be beneficial e.g., coding and development of themes. Also, was the analysis performed in duplicate etc? Do the authors have quotes to share from the qualitative component of the study? It would also be helpful to have further information about the data collection methods related to the qualitative component e.g., average length of interviews.</p> <p>Suitability of the outcome measures and feasibility of the assessment strategy (in the Results section): The authors indicate, “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.</p> <p>We have not presented the baseline descriptive data for the ACE-R</p>
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	<p>as we do not feel they provide an accurate summary of the sample's cognitive abilities". It is suggested that the authors expand on this versus "...we do not feel they provide an accurate summary of the sample's cognitive abilities".</p> <p>Similarly, the authors indicate, "However, in the qualitative interviews several participants reported finding the HISDS-III⁶³ 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". Please clarify this statement. The qualitative interviews should reveal the difficulty participants experienced completing the measure (or not i.e., not "...likely due to...") Do the authors have some quotes to support this statement?</p> <p>"Administered postally" (page 24) sounds awkward – please revise.</p> <p>"One person sustained a minor injury to their arm at home". This sentence should be revised to "his/her home" (page 26).</p> <p>The sentence on page 27, "One person noted they would have liked more opportunities for open answers on the questionnaires so they could provide some explanations about their responses" should read "...so he/she could provide...about his/her responses".</p> <p>On page 28, there is an extra "for" in the sentence starting with "Study retention was good..."</p> <p>One page 28, the phrase, "...envisioned to be..." sounds awkward and should be revised "suggested as". Similarly, the phrase "main contender" on the same page sounds awkward/colloquial. This reviewer would suggest "being considered as" instead.</p>
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VERSION 2 – AUTHOR RESPONSE

1. "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 postintervention to capture the longer term health and economic impact of the HoS intervention". The authors need to provide a stronger rationale for this one month timepoint.

We have added the following text:

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.

2. Spell out all acronyms including RC, CALM, etc.

We have done so (with the exception of RC as these are the initials of one of the co-authors).

3. Remove emotive verbs such as felt.

We have done so.

4. In the blinding section, "At follow-up, when support was provided/required to complete outcomes this was provided by assessors blind to group allocation". The word measures should be inserted after outcomes.

We have made this amendment.

5. Under the Descriptors and proposed outcome measures section, an "and" should be added before cognitive ability.

This has been added

6. Further details about the qualitative analysis would be beneficial e.g., coding and development of themes. Also, was the analysis performed in duplicate etc? Do the authors have quotes to share from the qualitative component of the study? It would also be helpful to have further information about the data collection methods related to the qualitative component e.g., average length of interviews.

Thank-you for your comment. The qualitative analysis consisted of two aspects a) content analysis about the participant's views of the research process which are presented in this paper and b) a thematic analysis about their expectations and experiences of the HeART of Stroke group which will be presented in a future paper. This has been clarified in the paper.

The steps involved in undertaking the content analysis are now specified in the paper.

The findings have been expanded to include short quotations from the content analysis.

7. Suitability of the outcome measures and feasibility of the assessment strategy (in the Results section): The authors indicate, "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 ACER as we do not feel they provide an accurate summary of the sample's cognitive abilities". It is suggested that the authors expand on this versus "...we do not feel they provide an accurate summary of the sample's cognitive abilities".

We have expanded on this as follows and added a reference.

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.

8. Similarly, the authors indicate, "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". Please clarify

this statement. The qualitative interviews should reveal the difficulty participants experienced completing the measure (or not i.e., not "...likely due to...") Do the authors have some quotes to support this statement?

We realise we made an error here and apologise for the confusion. We have clarified these sentences to indicate that the participant feedback about the HISDS-III was provided to the blinded assessors rather than during the qualitative interviews.

We have revised the text in the manuscript as follows:

However, several participants noted to the blinded assessors that they had found the HISDS-III [65] 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.

9. "Administered postally" (page 24) sounds awkward – please revise.
We have amended this to "administered by post".

10. "One person sustained a minor injury to their arm at home". This sentence should be revised to "his/her home" (page 26).
We have amended as suggested.

11. The sentence on page 27, "One person noted they would have liked more opportunities for open answers on the questionnaires so they could provide some explanations about their responses" should read "...so he/she could provide...about his/her responses".
We have amended as suggested.

12. On page 28, there is an extra "for" in the sentence starting with "Study retention was good..."
Thank you for spotting – we have corrected this.

13. On page 28, the phrase, "...envisioned to be..." sounds awkward and should be revised "suggested as".
We have amended as suggested.

14. Similarly, the phrase "main contender" on the same page sounds awkward/colloquial. This reviewer would suggest "being considered as" instead.
We have amended as suggested.