**Purpose:** A randomised controlled feasibility trial (RCT) to explore the feasibility of delivering and testing a visual arts programme within stroke rehabilitation.

**Methods:** Stroke survivors receiving in-patient rehabilitation were randomised a Creative Engagement Intervention (CEI) group (n=41) or a usual care group (n=40). Recruitment, retention, preference for art participation and change in selected outcomes were evaluated at end of intervention (T2) and three month follow-up (T3).

Recruitment rate was29%. 88% (n=71) of participants completed T2 and 77% (n=62) T3 assessments. Of eight CEI group non-completers at T2, six had no preference for art participation. Outcome measure completion varied between 97% and 77%. Running groups at different sites was difficult because of randomisation timing. Between T1-T2 and T2-T3 CEI group change scores were greater for Emotion, Positive and Negative Affect Schedule (PANAS) and Self-efficacy for Art (SEfA). Effect sizes favoured the CEI group for SEfA and PANAS at T2 and T3 and PANAS at T2 and T3 (d=0.24-0.42) .

**Conclusions:** Delivering and testing an art programme within stroke rehabilitation is feasible but a cluster RCT would avoid difficulties convening art groups. Fewer measures, and better retention strategies are required**.**  Art participation may enhance art self-efficacy and affect.

**Introduction**

Stroke is the main cause of complex adult disability Annually 16 million people worldwide experience stroke1 of whom 85% experience motor, cognitive or communication impairments2. These limit independence in activities of daily living (ADL) and restrict participation in life roles2 Around 31% of survivors experience post-stroke depression within five years post-stroke3. Along with physical impairments, the psychosocial impact of stroke including depression, lower optimism, self-esteem, perceived control, and social support are associated with poorer psychosocial wellbeing and quality of life 4.

Wellbeing is viewed as balance between physical, psychological and social resources, and challenges to those resources5. Stroke presents a challenge to the balance, causing sudden and unexpected threats to resources that negatively influence wellbeing. Kirkevold 6,7 suggests wellbeing after stroke depends on mood, engagement in meaningful activities, good social relations, self-esteem and belief in own abilities. Finding ways to improve wellbeing after stroke within rehabilitation by addressing these factors is therefore vital.

Benefits of participating in meaningful leisure activities, to address wellbeing, are becoming recognised8. The importance of arts in healthcare is reflected in international healthcare policy documents 9,10 . Models of psychological care after stroke11 suggest activities including art participation within stroke rehabilitation, may enhance wellbeing, preventing escalation to more serious psychological problems. Arts programmes led by professional artists focus on benefits to wellbeing through artwork creation. These are open to all survivors and are not psychotherapeutic art therapy for specific psychological problems. Despite recent endorsement of art participation in healthcare models and policy, research evidence supporting effects of art participation on wellbeing after stroke is scant.

Two qualitative studies12,13, respectively involving sixteen and six survivors receiving in-patient rehabilitation suggest that wellbeing, rehabilitation goal achievement and renewed identity are benefits of arts participation. Two others14,15, respectively involving 20 and 24 community dwelling stroke survivors, suggest art participation may enhance self-esteem, self-efficacy and confidence. Despite these positive reports, the diverse range of reported benefits means that defining measures for evaluation of effects is challenging. We found only one RCT of art participation within stroke rehabilitation involving 118 in-patient stroke survivors16. The study demonstrated improved depression, quality of life and cognition, compared to usual care, following visual art-making combined with meditation and singing. However, it is unclear how each intervention component contributed to effects, therefore specifically evaluating effects of artmaking is warranted.

The Creative Engagement Intervention (CEI) is a person-centred arts participation programme delivered within a Scottish health board, and developed collaboratively with artists, academics and stroke survivors. In planning this study, we interviewed three artists who delivered that programme and eleven previous participants17. Findings showed the CEI enhanced sense of hope, self-efficacy and perceived control over recovery as central components of enhanced wellbeing. Other benefits included physical and communication recovery, self-esteem and mood. These benefits can be translated into measurable outcomes, congruent with models of wellbeing, as described within our related intervention model 17. The qualitative work facilitated modelling of the existing intervention into a protocol for use in a randomised controlled feasibility trial.

Feasibility trials examine key trial parameters, such as intervention feasibility, recruitment, loss to follow-up, completion and relevance of outcome measures, to optimise a subsequent large-scale RCT. They also evaluate if proceeding to full-scale trial is appropriate 18. Undertaking a feasibility evaluation of art participation is critical to inform a future trial, since so few RCTs exist.

 This study aimed examined feasibility of an RCT of a visual arts based creative engagement intervention (CEI) within in-patient stroke rehabilitation. We aimed to examine participant recruitment and retention rates, and because art participation may have limited appeal, to examine if preference for art participation influenced retention. A further aim was to explore magnitude and direction of change in selected psychosocial outcome measures to determine if progress to a large scale trial was warranted.

**Design**

This pragmatic single-blind feasibility randomised controlled trial was informed by the Medical Research Council Framework for Complex Intervention Development1920

**Methods**

East of Scotland Research Ethics Service provided approval: ref. no. 13/ES/0006. Clinicaltrials.gov. Registration number: NCT02085226

***Participants and setting***

People diagnosed with stroke admitted to two stroke rehabilitation units in North East Scotland were screened for trial inclusion within one week of admission to rehabilitation, typically less than two weeks after stroke onset. Two study researchers, the research manager, also an artist, researcher and co-author (CK) – and a psychologist (MT) conducted screening and obtained informed consent for participation from interested stroke survivors.

Medically stable survivors participating in usual rehabilitation therapies and with planned rehabilitation duration of at least three weeks were considered eligible. Stroke survivors with transient ischaemic attack; who were unconscious; medically unwell; unable to participate in usual rehabilitation activities or to provide informed consent, were excluded.

***Sample size calculation***

Formal sample size calculation was not conducted, as this was a feasibility study. The sample size, of 40 participants per group, was based on guidance that a sample of that size would provide sufficiently precise estimates of direction and magnitude of effects and of variability for later sample size calculation for a full-scale trial21.

***Randomisation***

Randomisation to usual care or intervention was conducted after baseline assessment using secure, remote, web-based, concealed computer generated randomisation. Minimisation was applied to ensure that groups were balanced. Participants were recruited from two stroke units, therefore to minimise the effects of factors within units that might affect outcomes, we included stroke unit as a minimising factor as well as age (≤60 years, 61-80 years, ≥81 years), gender, and likelihood of ADL independence, according to Barthel Index scores22, grouped as scores of 0-40, 45-55, 60-10023.

***Intervention Group***

Participants randomised to the intervention group received the modelled visual arts based CEI in addition to usual rehabilitation. Two qualified visual artists, with five and seven years of experience respectively of working in healthcare settings, delivered the CEI. The research manager (CK), a trained artist and researcher, trained the artists and assessed their performance of trial procedures, delivery of intervention stages, goal setting with participants, and progress review, prior to study commencement. Planned intervention delivery involved one session per week with the artist and one group session with other participants, to a maximum of eight sessions, because of known benefits of each approach 12,14,24 . Individual sessions lasted one hour and group sessions one hour and thirty minutes. Usual rehabilitation typically involved physiotherapy, occupational therapy, and as necessary, speech and language therapy. Approximately one half hour session was delivered by each therapy on most weekdays.

The CEI was targeted at individual survivors and included three components that we had identified as central mechanisms of action17: *Social Context* for art participation - the social setting of the group or individual sessions with the artist; *Art-making Processes* - art-making itself, individually tailored to participants’ needs and interests and *Creative Output* – the finished product. Art-making involved five carefully defined stages, allowing intervention replication, whilst facilitating tailoring of activities and materials to participants’ interests and abilities. Participants could repeat stages several times, depending on progress. Full intervention details according to TIDIER guidelines25 are reported elsewhere20. Intervention Stages are provided in Table 1

|  |  |
| --- | --- |
| **Table 1. Intervention Stages** | **Details** |
| 1. *Define initial creative goals.*
 | Artist meets participant to elicit information about their health and stroke-related impairments, to discuss interests and preferences |
| 1. *Introduction to materials and mark making*
 | Ability to handle art materials ascertained during introductory work with materials. [drawing/collage/printing/painting/mixed-media techniques]. |
| 1. *From materials and mark making to developing personal project ideas and goals.*
 | Content or subjects of personal interest considered. |
| 1. *Developing personal project ideas into creative finished pieces.*
 | Expression of content and creative interpretation facilitated by the artist.  |
| 1. *Review of completed work, mounting and display of work, celebration and future plans*
 | Completed creative piece of work as tangible output; further ideas progressed by repetition of intervention stages, facilitated by the artist |

***Control Group***

Control participants received usual stroke rehabilitation. To maintain participants’ interest in the study and reflect usual practice within those units, after baseline assessment and randomisation, a portfolio of work produced by previous participants of the Tayside CEI was provided to the control group, which provided details of available community programmes for post-discharge participation. At final outcome assessment, study researchers discussed options for participation in community art programmes.

***Measures and measurement instruments***

Measures at baseline included age, gender, stroke type (ischaemic/haemorrhagic) and side , as well as the Barthel Index 22; Montreal Cognitive Assessment26 ; NIH Stroke Scale 27; Edinburgh Handedness Inventory 28; Communication: Aphasia Severity Rating Scale 29

Our qualitative work suggested art participation may foster positive resources that contribute to wellbeing. Secondary outcome measures examined positive or negative psychological dispositions rather than absence or presence of clinical disorders such as anxiety and depression. Consultation with stroke survivors led to our final choice of outcome measures for evaluation in this feasibility study. Detailed scoring and psychometric properties are described in the trial protocol 30.

The Stroke Impact Scale questionnaire 31 was selected as apotential primary outcome measure. It measures stroke related quality of life 32. We examined Emotion, Hand Function, Communication and Social Participation, given those domains were relevant from our earlier work17,20. Items are rated on a five-point Likert scale indicating difficulty completing the item. Summative scores for domains range from 0 to 100.

ThePositive and Negative Affect Schedule33 (PANAS) measured emotional wellbeing. The focus on positive affect reflects our definition of wellbeing and the potential impact of art. Positive affect represents pleasurable engagement and includes emotions such as enthusiasm and alertness. Negative affect is characterised by subjective distress and un-pleasurable engagement. Items are scored on a five-point scale [1-5], higher scores indicate higher emotion. Total scores range from 10 to 50. The scale has high validity and reliability for use in rehabilitation.

Our study and others indicated that art participation may enhance self-esteem14. The Visual Analogue Self-esteem Scale34 was developed for people with aphasia, and was accessible to our participants. Visually represented constructs are rated on a scale of 1-5. Item responses are summed providing a total score between 10 and 50.

Control over recovery was indicated as a positive benefit of art participation 17. The stroke specific Recovery Locus of Control Scale assessed this domain35. It is a nine-item scale measuring internal and external control beliefs relating to recovery. Degree of control is rated between 1 and 5. Summed items indicate strength of internal control, with 9 indicating minimum and 45 maximum.

Hope predicts recovery after stroke36. The Trait Hope Scale reflects hope of achieving broader life goals, an outcome that was attributed to art participation in our previous study17. It is a 12-item measure with four item subscales of agency and pathway. Pathway focuses on routes to achievement of goals; and agency focuses on motivation and confidence to achieve them. Items are scored on a four-point Likert scale. The domains of the measure captured mechanisms, suggested in our previous study, through which art participation might provide hope.

*General self-efficacy:* Art making appeared to develop confidence to achieve art-specific goal achievement *and* personal rehabilitation goals14,17. To capture general confidence we included the General Self-Efficacy Scale37, a 10-item scale assessing confidence to deal with life demands. Responses are scored 1-4 and summed to a total of 40, indicating maximum self-efficacy. The scale is widely used with stroke populations.

*Self-efficacy for art:* To assess self-efficacy for art we asked two single item questions, using an established procedure 38. The questions are: 1. How confident are you that you can express yourself through art activities? 2. How difficult do you find it to express yourself through art activities? Self-efficacy for art expression is scored on a seven-point vertical visual analogue scale with one as least confident/difficult and seven as most confident/difficult.

Because art participation may not appeal to all, preference for randomisation to doing or viewing art, or no preference, was assessed using a simple question after randomisation.

Nart were also collected

***Trial Procedures***

As per local ethical regulations, nursing and rehabilitation staff identified potential participants and provided them with study information. Those expressing interest were screened by the research team and written informed consent for participation obtained. Baseline measures were collected and participant details entered into a secure, remote, web-based randomisation system then artists were informed of group allocation. The system was password accesses only by the study team.

An assessor trained in measures and blind to group allocation conducted outcome (T2) and follow-up (T3) assessments. CEI group T2 assessment was conducted after eight art sessions – or hospital discharge if sooner. Control group T2 outcomes were assessed at four weeks, or discharge if sooner. Participants were instructed not to reveal group allocation to the assessor. T3 assessment was undertaken three months after T2 assessment in hospital or participants’ homes depending on discharge status.

Twelve participants and twelve rehabilitation staff were invited to participate in audio-recorded interviews after follow-up assessment to evaluate experiences of trial participation.

***Data analysis***

We examined proportions of survivors who were eligible, who provided consent to participate who dropped out and who had different preferences for art participation. We also described within-group change and between-group differences to inform primary outcome measure selection for a full-scale trial, however evaluation of treatment effectiveness was a secondary outcome, so statistical analysis was kept to a minimum. Data were screened for normality and transformed where required. Data for continuous outcome measures were assessed for normality prior to analysis. Where data was found to be non-normally distributed, right-skewed data were transformed by logarithm (base e) to achieve a normal distribution, while left-skewed data was transformed by squaring. Where transformation led to a normal distribution, the transformed data were analysed as a sensitivity analysis to confirm the original analysis.

 Data were summarised and changes from baseline calculated. To assess variability, magnitude and direction of mean between group difference at T2 and T3 was conducted using analysis of covariance (ANCOVA), adjusting for baseline co-variates, and 95% confidence intervals for the difference were recorded. Cohen’s d effect size was calculated by dividing group means at T2 and T3 by the pooled standard deviation. The statistician undertaking analysis was blinded to group status until after the main analysis was conducted. Data were stored in accordance with the UK Data Protection Act39.

**Results**

***Recruitment***

Over 12 months, we screened 284 stroke survivors admitted to rehabilitation units for eligibility. Of those, 117 (41%) were eligible, but chose not to participate. 86 (30%) were not eligible for a range of medical reasons. 81 (29%) provided informed consent for participation. We randomised 41 to receive CEI, and 40 to usual care. Reasons for exclusion are reported in figure 1, and participant characteristics of dropouts and completers are presented in table 1.

Insert figure 1 about here

Insert table 1 about here

***Retention***

Eight CEI (20%) and two control participants (5%) dropped out before T2. Six CEI group dropouts expressed no preference, or preferred the control option of art viewing. Although numbers were insufficient for statistical testing, baseline primary outcome measure scores for CEI group dropouts were higher at T1 (n=8) compared to T2 completers (table 2), suggesting dropouts might differ in some ways from those remaining in the study.

Insert table 2 about here

At T3 three further CEI participants and six control participants were lost to follow-up, leaving a CEI group completion rate of 73% (n=30/41) and control group of 80% (n=32/40).

The number of art sessions (Mean, Standard Deviation) received by the intervention group was 5.7 ±2.5. However, frequently only one participant per unit was randomised to receive art at any time, therefore participants received fewer group sessions (2.5±1.5) than one to one sessions (4.1±1.9)

***Outcomes***

Data transformation was only used for two outcomes, The SIS Emotion and Communication scales at T3, which were skewed towards lower scores. These were transformed by squaring (score\*\*2). All others were close to normal distribution.

Groups were well matched in terms of baseline characteristics and T1 scores on the outcomes of interest (tables 2 and 3). 97% of participants completed all items on outcome measures at baseline, except for the Adult Dispositional Hope Scale, where full completion was only 86.5% and Recovery Locus of Control Scale where full completion was 77%. Participants reported these measures as difficult to understand and too long.

***Change from baseline***

For the selected Stroke Impact Scale subscales, participants completing the intervention in the CEI group had higher change scores (Mean, Standard Deviation) than the control group between T1 and T2 in Social Participation (3.4±27.7 vs -2.7 ± 34.0), Emotion (5.8±23.9 vs 5.3±18.5) and Hand Function (26.7±31.9 vs 25.7 ± 35.2) (table 3). However, differences were small and variability was high. For communication, change was negative between T1 and T2, with greatest decline in the CEI group (-10.1±24.9 vs -1.4±17.2). For secondary outcomes the CI group had greatest improvement in Positive Affect (5.4±9.2 vs1.7±9.9), lower increase in Negative Affect (3.2±10.8 vs 4.5±9.4) (table 3), and most improvement in self-efficacy for art (5.4±9.2 vs 1.79±9.9). For all other measures change was small and fairly equitable between groups (table 3). Mean between group differences at T2 reflected the pattern for change scores. For self-efficacy for art (mean difference = 2.6; 95% CI = 1.1 to 4.2; Cohen’s d =0.35) mean difference favoured the intervention group; and for self-esteem (mean difference = 4.3; 95% CI = -7.3 to -1.3, Cohen’s d = -0.51) and communication (mean difference = 6.4; 95% CI = -14.5 to 3.2; Cohen’s d = -0.54) the mean difference favoured the control group (table 3).

Insert table 3 about here

For overall change T1 to T3 on the Stroke Impact Scale (table 4), the control group demonstrated most improvement on all domains except Emotion, where the change score was slightly greater for the intervention group (3.9±19.1 vs 3.5±20.8). Greater improvement for the intervention group for positive affect (4.3±7.5 vs 2.8±10.1) and lower increase in negative affect (3.3±11.0 vs 5.2±9.8) was maintained for overall change. The intervention group demonstrated greatest overall change in self-efficacy for art (2.1±4.1 vs 0.4±3.9), otherwise change in both groups was small and similar across the groups (table 4).

Insert table 4 about here

In terms of estimated mean differences at T3, the pattern was similar to T2, favouring the CEI group for hand function, social participation, positive and negative affect and self-efficacy for art (table 4). Although small to moderate, effect size favoured self-efficacy for art in the CEI group (mean difference =2.1; 95% CI = 0.4 to 3.8; Cohen’s d = 3.0) and the general self-efficacy significantly in the control group (mean difference = 3.0; 95%CI =-5.9 to -0.2; Cohen’s d = -0.28). Other outcomes showed very small effect sizes, most favouring the control group.

**Discussion**

Conducting an RCT to test a visual arts intervention within stroke rehabilitation was feasible. Recruitment and retention were comparable to other stroke rehabilitation trials 40,41, however preference for art may influence study retention. The study was not designed to definitively evaluate effectiveness, but indicated that expected changes in the nominated primary outcome were not realised, but that positive affect and self-efficacy for art, may be improved.

***Recruitment and retention***

 At 29%, recruitment reflected previous art programmes, suggesting participation in the study did not negatively influence recruitment. The 20% drop-out rate at T2 (n=8/41) for CEI was high and, and baseline scores were high for those dropping out. Most were ambivalent about art participation, possibly perceiving little need to participate. Findings indicate incorporating preference for group allocation into trial design, may enhance retention, and facilitate evaluation of preference on outcomes42.

Completion rates on some measures were low. The test battery was long and considered repetitive. A full trial should include fewer measures, examining only salient outcomes highlighted by this study.

***Group participation***

Our difficulty running groups limited opportunities for interaction between survivors. Despite this, change in SIS Social Participation was greater for the CEI group, supporting the hypothesis that art participation may enhance well-being via social interaction 14,17,43-45. A large-scale trial should randomise by clusters to ensure sufficient participants at individual sites to run groups. This design would facilitate evaluation of effects of group and individual sessions, and more robustly evaluate impact on social participation.

***Potential Effects***

The study only provided indications of magnitude and direction of change and was not a definitive effectiveness study. Between-group differences were small and variability high, however change in positive and negative affect favoured CEI indicating art participation may positively shift emotions.

The RCT of art participation with stroke survivors in Thailand16 showed improved depression and quality of life compared to controls receiving physiotherapy only. The small effect sizes in our study probably reflect low study power, but may mean intervention adjustment, or additional activities such as singing and meditation, are indeed necessary for effectiveness. Our

One study aim was to identify relevant outcome measures. PANAS reflected our positive definition of wellbeing, however it may be insensitive to change in lower emotional arousal states46 and we may have missed intervention effects by not measuring depression and anxiety. Despite these limitations, both studies indicate art may positively influence mood and affect after stroke, suggesting a full-scale trial, with mood as primary outcome, is probably warranted.

In our study, SIS communication scales worsened over time. Whilst art sessions naturally support conversation, compared to formal approaches to conversation facilitation47, communication was unstructured and incidental. The art intervention is thus unlikely to influence perceived communication, which should not be an outcome within a full-scale trial.

General self-efficacy, self-esteem and hope are associated with better stroke recovery 48,49. Art participation appeared not to influence these outcomes. High variability in scores and limited sensitivity to change in the measures may explain findings. We may also have over-interpreted our qualitative findings when selecting relevant measures and these outcomes may simply not be relevant to this intervention.

As expected, self-efficacy for art was higher in the intervention group at T2 and T3, and, as predicted by Bandura’s Social Cognitive Theory41, illustrates confidence and mastery through specific skills development. Self-efficacy that translated to broader life activities was a key benefit identified in several qualitative art participation studies 12,14,17. We found no indication, however, that general self-efficacy was influenced by art participation, suggesting, as predicted by Bandura, that self-efficacy is specific to mastery of particular activities. Longer exposure to art making within other qualitative studies12,14, may have promoted perceptions of enhanced general self-efficacy over time, that were not realised in the short timescale of this study.

***Limitations***

We did not measure baseline levels of depression to examine if those with initial depression improved more. A future trial should include this evaluation, to determine participants most likely to benefit. Furthermore, the control group received an art portfolio because usual practice on those units was to have artwork available from previous CEI cohorts. We also viewed it as an inert intervention to maintain study participation. However, it may have confounded effects. A future trial should include usual intervention controls only. We did not measure group dynamics or identity, which may clarify intervention mechanisms of action. These should be included for a full-scale trial.

***Conclusion***

Delivering and testing an art intervention in stroke rehabilitation was feasible. Art participation *may* enhance positive affect, social participation and self-efficacy for art, however study adjustments are important for a full trial. These include a targeted test battery and change of primary outcome to affect, a preference study design and detailed screening to ensure participants are interested in art participation and complete the intervention. A cluster or stepped wedge design with site level randomisation would guarantee group sessions. Given the intervention may improve positive affect, it could be enhanced to specifically target improvement in this domain, and should be the primary outcome for a future study. Whilst retaining the primary purpose of a creative experience with artists, elements of art therapy, particularly techniques known to be effective at improving mood and affect could be included.

**References**

1. Mukherjee D, Patil C. **Epidemiology and the global burden of stroke**. *World Neurosurgery*. 2011;76(6):S85-S86-S90.

2. The Stroke Association. Stroke statistics. . 2013;Resource Sheet 11(1):1-2014.

3. Hackett ML, Köhler S, O'Brien JT, Mead GE. Neuropsychiatric outcomes of stroke. *The Lancet Neurology*. 2014;13(5):525-534.

4. Teoh V, Sims J, Milgrom J. Psychosocial predictors of quality of life in a sample of community-dwelling stroke survivors: A longitudinal study.
. *Topics in Stroke Rehabilitation*. 2009;16(2):157-158-166.

5. Dodge R, Daly A, Huyton J, Sanders L. The challenge of defining wellbeing. *International Journal of Wellbeing,*. 2012;2(3):5th May 2017-222-235.

6. Kirkevold M, Martinsen R, Bronken BA, Kvigne K. Promoting psychosocial wellbeing following stroke using narratives and guided self-determination: A feasibility study. *BMC Psychology*. 2014;2(1):4.

7. Kirkevold M, Bronken BA, Martinsen R, Kvigne K. Promoting psychosocial well-being following a stroke: Developing a theoretically and empirically sound complex intervention. *Int J Nurs Stud*. ;49(4):386-397.

8. Dorstyn D, Roberts R, Kneebone I, Kennedy P, Lieu C. Systematic review of leisure therapy and its effectiveness in managing functional outcomes in stroke rehabilitation. *Topics in Stroke Rehabilitation*. 2014;21(1):40-51.

9. Cayton H. Report of the review of arts and health working group. . . 2007.

10. American Heart Association T, American Stroke Association T. **American heart association/american stroke association strategic policy agenda**
**2014-2017**. [http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\_466100.pdf](http://www.heart.org/idc/groups/heart-public/%40wcm/%40adv/documents/downloadable/ucm_466100.pdf). Updated 2013. Accessed Sept/11, 2015.

11. Kneebone II. Stepped psychological care after stroke. *Disabil Rehabil*. 2016;38(18):1836-1843.

12. Symons J, Clark H, Williams K, Hansen E, Orpin P. Visual art in physical rehabilitation: Experiences of people with neurological conditions. *British Journal of Occupational Therapy*. 2011;74:44-45-52.

13. Ali K, Gammidge T, Waller D. Fight like a ferret: A novel approach of using art therapy to reduce anxiety in stroke patients undergoing hospital rehabilitation. *Medical Humanities*. 2014;40(1):56-60.

14. Beesley K, White JH, Alston MK, Sweetapple AL, Pollack M.   Art after stroke: The qualitative experience of community dwelling stroke survivors in a group art programme.
. *Disabil Rehabil*. 2011;33(23-24):2346-2347-2355.

15. Sit JW, Chan AW, So WK, et al. Promoting holistic well-being in chronic stroke patients through leisure art-based creative engagement. *Rehabil Nurs*. 2014.

16. Kongkasuwan R, Voraakhom K, Pisolayabutra P, Maneechai P, Boonin J, Kuptniratsaikul V. Creative art therapy to enhance rehabilitation for stroke patients: A randomized controlled trial. *Clin Rehabil*. 2015.

17. Morris J, Toma M, Kelly C, et al. Social context, art making processes and creative output: A qualitative study exploring how psychosocial benefits of art participation during stroke rehabilitation occur. *Disabil Rehabil*. 2015:1-12.

18. - Is referral of postsurgical colorectal cancer survivors to cardiac rehabilitation feasible and acceptable? A pragmatic pilot randomised controlled trial with embedded qualitative study. *- BMJ Open*. (- 1).

19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: New guidance. . 2008.

20. Morris JH, Kelly C, Kroll T, et al. Art as a creative intervention after stroke: A single blind feasibility randomised controlled trial to examine effects on psychosocial outcomes of art participation during stroke rehabilitation compared to usual care. *Trials*. 2014;(in press).

21. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the united kingdom registered in the united kingdom clinical research network database. *BMC Med Res Methodol*. 2013;13:104-2288-13-104.

22. Granger CV, Dewis LS, Peters NC, Sherwood CC, Barrett JE. Stroke rehabilitation: Analysis of repeated barthel index measures. *Arch Phys Med Rehabil*. 1979;60(1):14-17.

23. Nakao S, Takata S, Uemura H, et al.       Relationship between barthel index scores during theacute phase of rehabilitation and subsequent ADL in stroke patients. *J Med Invest*. 2010;57:81-82-88.

24. Baumann M, Peck S, Collins C, Eades G. The meaning and value of taking part in a person-centred arts programme to hospital-based stroke patients: Findings from a qualitative study. *Disability Rehabilitation*. 2013;35(3):244-245-256.

25. Hoffmann TC, Glasziou PP, Boutron I, et al. *BMJ*. 2014;348. doi: 10.1136/bmj.g1687.

26. Nasreddine ZS, Phillips NA, Bédirian V, et al. **The montreal cognitive assessment** (**MoCA): A brief screening tool for mild cognitive impairment**. *Journal of the American Geriatrics Society*. 2005;53:695-699.

27. Brott T, Adams HP,Jr, Olinger CP, et al. Measurements of acute cerebral infarction: A clinical examination scale. *Stroke*. 1989;20(7):864-870.

28. Oldfield RC. The assessment and analysis of handedness: The edinburgh inventory. *Neuropsychologia*. 1971;9(1):97-113.

29. Goodglass H, Kaplan E. *Assessment of aphasia and related disorders.* Philadephia: Lea and Febiger; 1976.

30. Morris JH, Kelly C, Toma M, et al. Feasibility study of the effects of art as a creative engagement intervention during stroke rehabilitation on improvement of psychosocial outcomes: Study protocol for a single blind randomized controlled trial: The ACES study. *Trials*. 2014;15:380-6215-15-380.

31. Duncan PW, Bode RK, Min Lai S, Perera S. Rasch analysis of a new stroke-specific outcome scale: The stroke impact scale. *Arch Phys Med Rehabil*. 2003;84(7):950-963.

32. Richardson M, Campbell N, Allen L, Meyer M, Teasell R. The stroke impact scale: Performance as a quality of life measure in a community-based stroke rehabilitation setting. *Disabil Rehabil*. 2016;38(14):1425-1430.

33. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS scales. *J Pers Soc Psychol*. 1988;54(6):1063-1070.

34. Brumfitt SM, Sheeran P. The development and validation of the visual analogue self-esteem scale (VASES). *Br J Clin Psychol*. 1999;38 ( Pt 4)(Pt 4):387-400.

35. Partridge C, Johnston M. Perceived control of recovery from physical disability: Measurement and prediction. *British Journal of Clinical Psychology*. 1989;28(1):53-59.

36. Kortte KB, Stevenson JE, Hosey MM, Castillo R, Wegener ST. Hope predicts positive functional role outcomes in acute rehabilitation populations. *Rehabil Psychol*. 2012;57(3):248-255.

37. Schwarzer R, Jerusalem M. Generalized self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. *Measures in health psychology: A user’s portfolio. causal and control beliefs.* UK: NFER-NELSON; 1995:35-36-37.

38. Francis J, Eccles M, Johnston M, et al. Constructing questionnaires based on the theory of planned behaviour: A manual for health services resarchers. <http://pages.bangor.ac.uk/~pes004/exercise_psych/downloads/tpb_manual.pdf>. Updated 2004. Accessed 04/04, 2014.

39. The Government of the United Kingdom. The data protection act. . 1998.

40. Morris JH, van Wijck F, Joice S, Ogston SA, Cole I, MacWalter RS. A comparison of bilateral and unilateral upper-limb task training in early poststroke rehabilitation: A randomized controlled trial. *Arch Phys Med Rehabil*. 2008;89(7):1237-1245.

41. Mitchell PH, Veith RC, Becker KJ, et al. Brief Psychosocial–Behavioral intervention with antidepressant reduces poststroke depression significantly more than usual care with antidepressant. *Stroke*. 2009;40(9):3073.

42. Preference Collaborative Review Group. Patients' preferences within randomised trials: Systematic review and patient level meta-analysis. *BMJ*. 2008;337:a1864.

43. Makin S, Gask L. 'Getting back to normal': The added value of an art-based programme in promoting 'recovery' for common but chronic mental health problems. *Chronic Illn*. 2012;8(1):64-75.

44. PERRUZZA N, KINSELLA EA.
**Creative arts occupations in therapeutic practice: A review of the literature** *The British Journal of Occupational Therapy*. 2010;73(6):261-262-268.

45. REYNOLDS F, VIVAT B, PRIOR S. Women's experiences of increasing subjective well-being in CFS/ME through leisure-based arts and crafts activities: A qualitative study. *Disabil Rehabil*. 2008;30(17):1279-1280-1288.

46. . Forgeard, M. J. C., Jayawickreme E, Kern ML, Seligman M, E. P. Doing the right thing: Measuring wellbeing for public policy. *International Journal of Wellbeing*. 2011;1(1):09/05/2017-79-106.

47. MCVICKER S, PARR S, POUND C, DUCHAN J. **The communication partner scheme: A project to develop long‐term, low‐cost access to conversation for people living with aphasia** . *Aphasiology*. 2009;23(1):52-53-71.

48. Chung ML, Bakas T, Plue LD, Williams LS. Effects of self-esteem, optimism, and perceived control on depressive symptoms in stroke survivor-spouse dyads. *J Cardiovasc Nurs*. 2016;31(2):E8-E16.

49. Lewin A, Jobges M, Werheid K. The influence of self-efficacy, pre-stroke depression and perceived social support on self-reported depressive symptoms during stroke rehabilitation. *Neuropsychol Rehabil*. 2013;23(4):546-562.

 **figure 1. Consort Diagram**

Screened for Inclusion

(n=315)

Baseline Measures (n=81)

Met inclusion criteria and consented to participate (n=81)

Excluded with reasons (n= 234)

* Non Stroke (n= 31)
* Diagnosed TIA (n= 4)
* <3wks Rehab (n= 44)
* Medically unstable (n= 24)
* Chose not to participate

(n= 117)

* Unable to provide informed consent (profound cognitive/communication impairment) (n= 12)
* Other (n= 2)

Randomised (n=81)

CEI Group

(n=41)

Control group

(n=40)

Withdrew :

* No intervention, early discharge (n=1)
* Refused to participate (n=4)
* Declined to complete T2 outcomes (n=2)
* Decline of communication (n=1)

Completed Intervention

(n=33)

Post-Intervention Outcome Assessment

(n=71)

Withdrew :

* Died of unrelated cause (n=1)
* Declined to complete T2 outcomes (n=1)

Follow-up 3 months after Outcome Assessment

(n=62)

Lost to follow-up :

* Cognitive decline (n=1).
* Declined to complete T3 assessment(n=2)

Lost to follow-up:

* Cognitive decline (n=1).
* Died (n=1)
* Declined to complete T3 assessment (n=4)

Completed Trial (n=30)

Completed Trial (n=32)

Completed Control

(n=38)

|  |  |  |  |
| --- | --- | --- | --- |
| **Baseline Characteristics** | **CEI Group****(n= 41)** |  | **Control Group****(n= 40)** |
| Days admission to randomisation (mean, SD) | 11.2(7.6) |  | 12.4(9.5) |
| Age (years)(mean, SD) | 77.0(9.1) |  | 75.6(8.8) |
| Male, n (%)Female, n (%) | 19(46%)22(54%) |  | 17(42%)23(58%) |
| Ischaemic stroke, n (%)Haemorrhagic stroke, n (%) | 36(88%) 5(12%) |  | 35(87%) 5(13%) |
| Edinburgh Handedness Inventory, n (%)Left HandedAmbidextrous Right handed |  3(7) 2(5)36(88) |  |  6(15) 1(2.5)33(82) |
| Side of hemiplegia, n (%)Left hemiplegia Right hemiplegia NIH Stroke Scale (max=15) (mean, SD)Montreal Cognitive Assessment (max=30)(mean, SD)Barthel Index (Max=100)On Psychotropic Drugs n (%)Intervention Sessions (Max=8)(mean, SD)Preference for Art, n (%)ViewParticipateNoneExperience of Art, n (%)NoneA littleA lot | 22(54%)19(46%)5.4(3.3)18.4(5.4)46.2(24.7) 2(5%) 5.6(2.6) 9(22)18(44)14(34)22(54)17(41) 2(5) |  | 23(57%)16(43%)5.2(3.7)18.4(6.6)46.0(26.8) 1(2.5%)- 9(23)15(37)16(40)27(67)12(30) 1(3) |

table 1. Participant characteristics

SD denotes standard deviation

table 2**.** Baseline T1 scores on outcome measures, Mean, SD: CEI Group, Control Group, dropouts at T2 assessment.

|  |  |  |
| --- | --- | --- |
| **Outcome Measures**  | **T1 score (mean, SD)** | **Dropouts** |
|  | CEI Group(n= 41) | Control Group(n=40) | CEI Group (n= 8) | Control Group (n=2) |
| **Stroke Impact Scale** (Min=0, Max=100)EmotionCommunicationHand FunctionSocial Participation | 69.6(19.5)75.5(21.6)16.1(27.3)37.0(26.5) | 72.4(20.4)69.5(24.9)17.1(26.8)39.5(26.3) | 87.6(9.5)73.2(16.1)52.0(30.3)54.7(25.8) | 77.8(31.4)32.1(5.0)30.0 (0.0)18.7(0.0) |
| **Positive and Negative Affect Schedule** (min=0, max=50)Positive Affect (higher score better)Negative Affect (lower score better) | 23.5(8.2)20.2(7.8) | 24.3(7.8)* 1. (8.1)
 | 27.9 (7.1)13.0(2.9) | 27.5 (2.1)15.5 (7.8) |
| **Visual Analogue Self-Esteem Score** (min=0, max=50) | 37.6(7.6) | 37.4(8.5) | 43.9(3.9) | 40.0 (12.7) |
| **Adult Dispositional Hope Scale** (min=8, max=64) | 25.9(3.0) | 26.4(3.7) | 26.9(2.6) | 25.0(7.1) |
| **General Self-efficacy Scale** (min=10, max=40) | 31.4(5.0) | 32.5(4.3) | 32.1(5.4) | 27.0(7.1) |
| **Self-efficacy for Art** (min=2, max=14) | 6.7(3.5) | 6.1(3.6) | 4.7(2.6) | 6.0(2.8) |
| **Recovery Locus of Control Scale** (min=9, max=45) | 36.4(5.1) | 35.5(6.4) | 38.8(2.68) | 34.0 (0.0) |
| **Preference for ART Participation** (n)No preferencePreference not metPreference met |  |  | 332 | 11- |

SD denotes standard deviation

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome Measures** | **Change T1 to T2****(mean, SD)** | **Estimated Between****Group Difference at T2** | **Standarised****Effect Size** |
|  | CEI Group(n= 33) | Control Group(n=38) | Estimated meandifference T2 | 95%Confidence Interval | Cohen’s d(positive value favours CEI) |
| **Stroke Impact Scale** (Min=0, Max=100)EmotionCommunicationHand FunctionSocial Participation | 5.8(23.9)-10.1(24.9)26.7(31.9)3.4(27.7) | 5.3(18.5)-1.4 (17.2)25.7(35.2)-2.7(34.0) | 2.86.40.50.1 | -11.3 to 5.7-14.5 to 3.2-14.4 to 13.4-10.5 to 10.8 to 5.8 | -0.35-0.54-0.05 0.01 |
| **Positive and Negative Affect Schedule**(min=0, max=50)Positive Affect (higher score better)Negative Affect (lower score better) | 5.4(9.2)3.2(10.8) | 1.7(9.9)4.5(9.4) | 1.63.0 | -2.2 to 5.3-0.7 to 6.7 |  0.24 0.42 |
| **Visual Analogue Self-Esteem Score**(min=0, max=50) | -0.4 (6.7) | 2.1(8.4) | 4.3 | -7.3 to -1.3 | -0.51 |
| **Adult Dispositional Hope Scale** (min=8, max=64) | -0.9(3.5) | 1.5(4.9) | 0.8 | -3.2 to 1.5 | -0.12 |
| **General Self-efficacy Scale** (min=10, max=40) | -2.6(7.1) | 1.5(6.6) | 2.5 | -5.8 to 0.7 | -0.28 |
| **Self-efficacy for Art** (min=2, max=14) | 1.4(4.1) | 0.4(3.7) | 2.6 | 1.12 to 4.2 |  0.35 |
| **Recovery Locus of Control Scale** (min=9, max=45) | 1.3(6.7) | 1.2(6.6) | 0.4 | -3.22 to 2.4 |  0.06 |

table 3. Mean (SD) Change scores T1 to T2; estimated between group differences and effect size estimation at T2

 SD denotes standard deviation

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome Measures** | **Change T1 to T3****(mean, SD)** | **Estimated Between Group Difference at T3** | **Standarised Effect Size** |
|  | CEI Group(n= 33) | Control Group(n=38) | Estimated Mean Difference T3 | 95% Confidence Interval | Cohen’s d(positive value favours intervention) |
| **Stroke Impact Scale** (Min=0, Max=100)EmotionCommunicationHand FunctionSocial Participation |  3.9 (19.1) 1.1 (21.8)29.8 (31.3)18.3 (30.3) |  3.5(20.8) 9.3(21.8)34.5(41.3)19.5(33.9) | 2.34.42.25.2 | -10.3 to 5.8-13.9 to 5.2-20.5 to 15.7-18.8 to 8.3 | -0.18-0.11-0.12-0.17 |
| **Positive and Negative Affect Schedule**(min=0, max=50)Positive Affect (higher score better)Negative Affect (lower score better) |  4.3(7.5) 3.3(11.0) |  2.8(10.1) 5.2 (9.8) | 0.53.0 | -4.5 to 3.4-0.4 to 6.4 | 0.070.18 |
| **Visual Analogue Self-Esteem Score** (min=0, max=50) | -0.3(6.6) | -0.2(7.5) | 1.9 | -5.1 to 1.2 | -0.06 |
| **Adult Dispositional Hope Scale** (min=8, max=64) | -0.7(3.8) | -1.7(5.1) | 0.4 | -2.5 to 1.7 | -0.06 |
| **General Self-efficacy Scale** (min=10, max=40) | -2.0(6.4) | -0.7(6.5) | 3.0 | -5.9 to -0.2 | -0.28 |
| **Self-efficacy for Art** (min=2, max=14) |  2.1(4.1) |  0.4(3.9) | 2.1 | 0.4 to 3.8 | 0.30 |
| **Recovery Locus of Control Scale** (min=9, max=45) |  0.7(7.7) |  1.3(7.9) | 0.7 | -2.4 to 3.7 | -0.09 |

table 4. Mean (SD) Change Scores Baseline to T3; estimated between group differences and effect size estimation at T3

SD denotes standard deviation

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**Declaration of Interest Statement**

The authors report no conflicts of interest.