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Art participation for psychosocial wellbeing during stroke rehabilitation

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1 Manuscript Title: Art participation for psychosocial wellbeing during stroke
2 rehabilitation: a feasibility randomised controlled trial.

3

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5

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34 The authors report no declarations of interest.

35

36 **Trial Registration:**

37 Registry: Clinical Trials.gov

38 Date of Registration: 6th March 2014

39 Date of first participant enrollment: July 2013

40 Registration Number: NCT 02085226

41 URL: <https://clinicaltrials.gov/ct2/show/NCT02085226?term=NCT02085226&rank=1>

42 Registration was late because we had not been informed by our clinical trials unit of the
43 need to register before the start of recruitment. We registered the trial as soon as we
44 knew that we should. We have full details of our ethics protocol that provides evidence
45 of our trial history.

46

47 **Word Count:** 4208

48

49 **Tables**

50 table 1. Intervention Stages

51 table 2. Participant Characteristics

52 table 3. Baseline (T1) scores on outcome measures

53 table 4. Mean (SD) Change scores T1 to T2; estimated between group differences and
54 effect size estimation at T2

55 table 5. Mean (SD) Change scores T1 to T3; estimated between group differences and
56 effect size estimation at T3

57 figure 1. Participant flow through the study

58

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63

64

65

66 **Purpose:** To examine the feasibility of undertaking a pragmatic single-blind randomised
67 controlled trial of a visual arts participation programme to evaluate effects on survivor
68 wellbeing within stroke rehabilitation.

69

70 **Methods:** Stroke survivors receiving in-patient rehabilitation were randomised to
71 receive eight art participation sessions (n=41) or usual care (n=40). Recruitment,
72 retention, preference for art participation and change in selected outcomes were
73 evaluated at end of intervention outcome assessment and three-month follow-up.

74

75 **Results:** Of 315 potentially eligible participants 81 (29%) were recruited. 88% (n=71)
76 completed outcome and 77% (n=62) follow-up assessments. Of eight intervention group
77 non-completers, six had no preference for art participation. Outcome completion varied
78 between 97% and 77%. Running groups was difficult because of randomisation timing.
79 Effectiveness cannot be determined from this feasibility study but effects sizes suggested
80 art participation may benefit emotional wellbeing, measured on the Positive and Negative
81 Affect Schedule, and Self-efficacy for Art (d=0.24-0.42).

82

83 **Conclusions:** Undertaking a randomised controlled trial of art participation within stroke
84 rehabilitation was feasible. Art participation may enhance self-efficacy and positively
85 influence emotional wellbeing. These should be outcomes in a future definitive trial. A
86 cluster randomised controlled trial would ensure art groups could be reliably convened.
87 Fewer measures, and better retention strategies are required.

88

89 **Key words:** Stroke Rehabilitation, Art, Emotions, Affect, Wellbeing

90

91

92

93 **Introduction**

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

102

103 Wellbeing is viewed as balance between physical, psychological and social resources, and
104 challenges to those resources⁵. Stroke presents a challenge to the balance, causing sudden
105 and unexpected threats to resources that negatively influence wellbeing. Kirkevold ^{6,7}
106 suggests wellbeing after stroke depends on positive emotion, engagement in meaningful
107 activities, good social relations, self-esteem and belief in one's own abilities. Finding ways
108 to improve wellbeing after stroke within rehabilitation by addressing these factors is
109 therefore a logical avenue for exploration.

110

111 The benefits of participating in meaningful leisure activities to address wellbeing after
112 stroke, are becoming recognised⁸. The importance of arts in healthcare is reflected in
113 international healthcare policy documents ^{9,10}. Models of psychological care after stroke¹¹
114 suggest activities including art participation within stroke rehabilitation, may enhance
115 wellbeing, preventing escalation to more serious psychological problems. Arts
116 programmes led by professional artists focus on benefits to wellbeing through artwork
117 creation, by enabling people to realise their creative potential. Programmes are open to
118 all survivors and are not psychotherapeutic art therapy for specific psychological
119 problems. Despite recent endorsement of art participation in healthcare models and

120 policy, research evidence supporting benefits of art participation on wellbeing after
121 stroke is scant.

122

123 Two qualitative studies^{12,13}, respectively involving sixteen and six survivors who received
124 in-patient stroke rehabilitation suggest that wellbeing, rehabilitation goal achievement
125 and renewed identity are benefits of arts participation. Two others^{14,15}, respectively
126 involving 20 and 24 community dwelling stroke survivors, suggest art participation may
127 enhance self-esteem, self-efficacy and confidence. Despite these positive reports, the
128 diverse range of potential benefits means that defining measures for evaluation of effects
129 of art participation is challenging. Only one previous randomised controlled trial (RCT)
130 of art participation within stroke rehabilitation was found, involving 118 in-patient stroke
131 survivors¹⁶. The study demonstrated improved depression, quality of life and cognition,
132 compared to usual care, following visual art-making combined with meditation and
133 singing. However, it is unclear how each intervention component contributed to effects,
134 therefore specifically evaluating effects of artmaking in its own right is warranted.

135

136 A person-centred arts participation programme developed collaboratively with artists,
137 academics and stroke survivors has been routinely delivered within a Scottish health
138 board. A qualitative study with three artists who delivered that programme, and eleven
139 previous participants¹⁷ showed the programme enhanced perceptions of hope, self-
140 efficacy and perceived control over recovery as central components of enhanced
141 wellbeing. Other benefits included physical and communication recovery, self-esteem and
142 positive emotional state. These benefits were operationalised using standardised
143 outcome measures congruent with models of wellbeing, as described within the
144 intervention model identified in preliminary work to model the intervention¹⁷. The
145 qualitative work facilitated modelling of the existing intervention into a protocol for use
146 in an RCT, which was tested in a feasibility RCT.

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

152

153 The present study aimed to examine feasibility of conducting a future definitive RCT of
154 the art participation programme within in-patient stroke rehabilitation. It aimed to
155 examine participant recruitment and retention rates, and because art participation may
156 have limited appeal, to examine if preference for art participation influenced retention. A
157 further aim was to examine the appropriateness of the selected primary outcome
158 measure and other measures, and to explore magnitude and direction of change to
159 determine if progress to a definitive RCT was warranted.

160 **Design**

161 This pragmatic single-blind feasibility randomised controlled trial was informed by the
162 Medical Research Council Framework for Complex Intervention Development ¹⁹. The
163 published study protocol provides in-depth methodological details²⁰. A brief description
164 is provided below.

165

166 **Methods**

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

169

170 ***Participants and setting***

171 People diagnosed with stroke admitted to two stroke rehabilitation units in North East
172 Scotland were screened for trial inclusion within one week of admission to rehabilitation,
173 typically less than two weeks after stroke onset. Two study researchers, the research

174 manager, also an artist, researcher and co-author – and a psychologist conducted
175 screening and obtained informed consent for participation from interested stroke
176 survivors.

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

182 ***Sample size calculation***

183 Formal sample size calculation was not conducted, as this was a feasibility RCT. The
184 sample size, of 40 participants per group, was based on guidance that a sample of that size
185 was adequate to provide fairly accurate estimates of direction and magnitude of effects
186 and variability²¹.

187

188 ***Randomisation***

189 Randomisation to intervention or control was conducted after baseline assessment using
190 secure, remote, web-based, concealed computer-generated randomisation. Minimisation
191 was applied to ensure that groups were balanced. To minimise the effects of recruiting
192 from two centres stroke unit was included as a minimising factor as well as age (≤ 60
193 years, 61-80 years, ≥ 81 years), gender, and likelihood of independence in activities of
194 daily living, according to Barthel Index scores²², grouped as scores of 0-40, 45-55, 60-
195 100²³.

196

197 ***Intervention Group***

198 Participants randomised to the intervention group received the modelled visual arts
199 participation programme in addition to usual rehabilitation. Two qualified visual artists,

200 with five and seven years of experience respectively of working in healthcare settings,
201 delivered the art participation programme. The research manager, an experienced artist
202 and researcher, trained the artists and assessed their performance of trial procedures,
203 delivery of intervention stages, goal setting with participants, and progress review, prior
204 to study commencement. Planned intervention delivery involved one session per week
205 with the artist and one group session with other participants, to a maximum of eight
206 sessions, because of known benefits of each approach^{12,14,24}. Individual sessions lasted
207 one hour and group sessions one hour and thirty minutes. Usual rehabilitation typically
208 involved physiotherapy, occupational therapy, and as necessary, speech and language
209 therapy. One half hour session was delivered by each therapy on most weekdays.

210

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

220 *Insert Table 1 about here*

221

222 ***Control Group***

223 Control participants received usual stroke rehabilitation. To maintain participants'
224 interest in the study and reflect usual practice within those units, after baseline
225 assessment and randomisation, a portfolio of work produced by previous participants of

226 the existing programme was provided to the control group. No specific instruction was
227 given, other than informing them that it had been produced by other stroke survivors. At
228 final outcome assessment, study researchers discussed options for participation in
229 community art programmes.

230

231 ***Measures and measurement instruments***

232 Measures at baseline included age, gender, stroke type (ischaemic/haemorrhagic) and
233 side of hemiplegia, as well as the Barthel Index²²; Montreal Cognitive Assessment²⁶; NIH
234 Stroke Scale²⁷; Edinburgh Handedness Inventory²⁸; Communication: Aphasia Severity
235 Rating Scale²⁹

236

237 Qualitative work to inform this study suggested art participation may foster positive
238 resources that contribute to wellbeing, and guided outcome selection. Consultation with
239 stroke survivors led to the final choice of outcome measures. Detailed scoring and
240 psychometric properties are described in the trial protocol, and only brief detail is
241 provided here³⁰.

242

243 The Stroke Impact Scale questionnaire³¹ was selected as a potential primary outcome
244 measure, as it measures specific domains of stroke related quality of life³². Emotion,
245 Hand Function, Communication and Social Participation were examined, given those
246 domains were relevant from the earlier qualitative work^{17,20}. Items are rated on a five-
247 point Likert scale indicating difficulty completing the item. Summative scores for
248 domains range from 0 to 100.

249

250 The potential secondary outcome measures examined positive emotional wellbeing
251 rather than absence or presence of clinical disorders such as anxiety and depression. The
252 Positive and Negative Affect Schedule³³ measured emotional wellbeing. The focus on

253 positive affect reflects the selected definition of emotional wellbeing and the potential
254 impact of art identified from previous literature. Positive affect represents pleasurable
255 engagement and includes emotions such as enthusiasm and alertness. Negative affect is
256 characterised by subjective distress and un-pleasurable engagement. Items are scored
257 on a five-point scale [1-5], higher scores indicate higher emotion. Total scores range from
258 10 to 50.

259

260 This study and others indicated that art participation may enhance self-esteem¹⁴. The
261 Visual Analogue Self-esteem Scale³⁴ was developed for people with aphasia, and was
262 accessible to study participants. Visually represented constructs are rated on a scale of
263 1-5. Item responses are summed providing a total score between 10 and 50.

264

265 Perception of control over recovery was indicated in the qualitative work to inform this
266 study as a positive benefit of art participation¹⁷. The stroke specific Recovery Locus of
267 Control Scale assessed this domain³⁵. It is a nine-item scale measuring internal and
268 external control beliefs relating to recovery. Degree of control is rated between 1 and 5.
269 Summed items indicate strength of internal control, with 9 indicating minimum and 45
270 maximum.

271

272 Hope predicts recovery after stroke³⁶. The Trait Hope Scale reflects hope of achieving
273 broader life goals, an outcome that was attributed to art participation in previous
274 research¹⁷. It is a 12-item measure with four item Lickert subscales of agency and
275 pathway. Pathway focuses on routes to achievement of goals; and agency focuses on
276 motivation and confidence to achieve them. The domains of the measure captured
277 mechanisms through which art participation might provide hope.

278

279 Art making appeared to develop confidence to achieve art-specific goal achievement *and*
280 personal rehabilitation goals^{14,17}. To capture this general confidence, the General Self-
281 Efficacy Scale³⁷ was selected, a 10-item scale assessing confidence to deal with life
282 demands. Responses are scored 1-4 and summed to a total of 40, indicating maximum
283 self-efficacy. The scale is widely used with stroke populations.

284

285 Self-efficacy for art was assessed by two single item questions, using an established
286 procedure³⁸. The questions are: 1. How confident are you that you can express yourself
287 through art activities? 2. How difficult do you find it to express yourself through art
288 activities? Self-efficacy for art expression is scored on a seven-point vertical visual
289 analogue scale with one as least confident/difficult and seven as most confident/difficult.

290

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

293 Number of eligible participants, recruitment, retention, preference for art participation
294 and follow-up rates were also collected.

295

296 ***Trial Procedures***

297 As per local ethical regulations, nursing and rehabilitation staff identified potential
298 participants and provided them with study information. Those expressing interest were
299 screened by the research team to ensure they met inclusion criteria, and written informed
300 consent for participation was obtained. Baseline measures at time one (T1) were
301 collected and participant details entered into a secure, remote, web-based randomisation
302 system by the study researchers, after which artists were informed of group allocation.
303 The system was accessed by a password known only to the study team.

304

305 An assessor trained in measures and blind to group allocation conducted outcome
306 assessments at time two (T2) and follow-up assessments at time three (T3). Intervention
307 group T2 assessment was conducted at four weeks after eight art sessions - two per week
308 - had been completed, or at hospital discharge if discharge occurred before eight sessions
309 had been completed. Control group T2 outcomes were also assessed at four weeks, or
310 discharge if sooner. Participants were instructed not to reveal group allocation to the
311 assessor. T3 assessment was undertaken three months after T2 assessment in hospital or
312 participants' homes depending on discharge status.

313

314 ***Data analysis***

315 Proportions of survivors who were eligible for participation, who provided consent to
316 participate, who withdrew and who had different preferences for art participation were
317 assessed. Within-group change and between-group differences were examined to inform
318 primary outcome measure selection for a definitive RCT. Evaluation of treatment
319 effectiveness was not the purpose of this study, so statistical analysis was kept to a
320 minimum. Data were screened for normality and transformed where required. Data for
321 continuous outcome measures were assessed for normality prior to analysis. Where data
322 was found to be non-normally distributed, right-skewed data were transformed by
323 logarithm (base e) to achieve a normal distribution, while left-skewed data was
324 transformed by squaring. Where transformation led to a normal distribution, the
325 transformed data were analysed as a sensitivity analysis to confirm the original analysis.

326

327 Data were summarised and changes from baseline calculated. To assess variability,
328 magnitude and direction of mean between group difference at T2 and T3 was conducted
329 using analysis of covariance, adjusting for baseline co-variates, and 95% confidence
330 intervals for the difference were recorded. Cohen's d effect size was calculated by dividing

331 group means at T2 and T3 by the pooled standard deviation. The statistician undertaking
332 analysis was blinded to group status until after the main analysis was conducted. Data
333 were stored in accordance with the UK Data Protection Act 1998³⁹.

334

335 **Results**

336 ***Recruitment***

337 Over 12 months, 284 stroke survivors admitted to rehabilitation units for eligibility were
338 screened. Of those, 117 (41%) were eligible, but chose not to participate. 86 (30%) were
339 not eligible for a range of medical reasons. 81 (29%) provided informed consent for
340 participation. 41 were randomised to receive the intervention, 40 to the control group.
341 Reasons for exclusion are reported in figure 1, and participant characteristics are
342 presented in Table 2.

343 Insert figure 1 about here

344 Insert table 2 about here

345

346 ***Retention***

347 Eight intervention (20%) and two control participants (5%) withdrew before T2. Six of
348 those withdrawing from the intervention group expressed no preference, or preferred
349 the control option of art viewing. Although numbers were insufficient for statistical
350 testing, baseline primary outcome measure scores for intervention group dropouts were
351 higher at T1 (n=8) compared to T2 completers (table 3), suggesting dropouts might differ
352 in some ways from those remaining in the study.

353 Insert table 3 about here

354 At T3 three further intervention group participants and six control participants could not
355 be contacted, leaving the intervention group completion rate of 73% (n=30/41) and
356 control group of 80% (n=32/40).

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

361 ***Outcomes***

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

365

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

371

372 ***Change, between group difference and effect sizes***

373 Examination of effects was not the purpose of this study and, data is presented here to
374 illustrate change in each measure for the purpose of outcome selection for a definitive
375 trial. For the selected Stroke Impact Scale subscales, participants completing the
376 intervention had higher change scores (Mean, Standard Deviation) than the control group
377 between T1 and T2 in Social Participation (3.4 ± 27.7 vs -2.7 ± 34.0), Emotion (5.8 ± 23.9 vs
378 5.3 ± 18.5) and Hand Function (26.7 ± 31.9 vs 25.7 ± 35.2) (table 4). However, differences
379 were small and variability was high. For communication, change was negative between
380 T1 and T2, with greatest decline in the intervention group (-10.1 ± 24.9 vs -1.4 ± 17.2). For

381 secondary outcomes, the intervention group had greatest improvement in Positive Affect
382 (5.4 ± 9.2 vs 1.7 ± 9.9), lower increase in Negative Affect (3.2 ± 10.8 vs 4.5 ± 9.4) (table 4), and
383 most improvement in self-efficacy for art (5.4 ± 9.2 vs 1.79 ± 9.9). For all other measures
384 change was small and fairly equitable between groups (table 4). Mean between group
385 differences at T2 reflected the pattern for change scores. For self-efficacy for art (mean
386 difference = 2.6; 95% CI = 1.1 to 4.2; Cohen's $d = 0.35$) mean difference favoured the
387 intervention group; and for self-esteem (mean difference = 4.3; 95% CI = -7.3 to -1.3,
388 Cohen's $d = -0.51$) and communication (mean difference = 6.4; 95% CI = -14.5 to 3.2;
389 Cohen's $d = -0.54$) the mean difference favoured the control group (table 4).

390 Insert table 4 about here

391 For overall change T1 to T3 on the Stroke Impact Scale (table 5), the control group
392 demonstrated most improvement on all domains except Emotion, where the change score
393 was slightly greater for the intervention group (3.9 ± 19.1 vs 3.5 ± 20.8). Greater
394 improvement for the intervention group for positive affect (4.3 ± 7.5 vs 2.8 ± 10.1) and
395 lower increase in negative affect (3.3 ± 11.0 vs 5.2 ± 9.8) was maintained for overall change.
396 The intervention group demonstrated greatest overall change in self-efficacy for art
397 (2.1 ± 4.1 vs 0.4 ± 3.9), otherwise change in both groups was small and similar across the
398 groups (table 5).

399

400 Insert table 5 about here

401

402 In terms of estimated mean differences at T3, the pattern was similar to T2, favouring the
403 intervention group for hand function, social participation, positive and negative affect and
404 self-efficacy for art (table 5). Although small to moderate, effect size favoured self-efficacy
405 for art in the intervention group (mean difference = 2.1; 95% CI = 0.4 to 3.8; Cohen's $d =$
406 3.0) and the general self-efficacy significantly in the control group (mean difference = 3.0;

407 95%CI =-5.9 to -0.2; Cohen's d = -0.28). Other outcomes showed very small effect sizes,
408 most favouring the control group.

409

410 **Discussion**

411 Findings show that conducting a definitive RCT to test a visual arts intervention within
412 stroke rehabilitation is feasible. Recruitment and retention were comparable to other
413 stroke rehabilitation trials ^{40,41}, however preference for art may have influenced study
414 retention. The study was not designed to definitively evaluate effectiveness however data
415 analysis indicated that expected improvements in the nominated primary outcome were
416 not realised, but that positive affect and self-efficacy for art, may be improved. Findings
417 suggest that the primary outcome should be changed for a definitive RCT.

418

419 ***Recruitment and retention***

420 29% of potentially eligible participants were recruited, however 41% declined to provide
421 consent for participation. Others were not included for clinical reasons. We did not have
422 ethical approval to collect sociodemographic or clinical data from those declining to
423 participate, so it is not clear if their characteristics differed clinically from those
424 consenting to participate. However most declined because they had little interest in art
425 participation. This ambivalence could be addressed by provision of taster sessions,
426 allowing people to try art participation before consenting to trial participation and
427 randomisation. Given earlier qualitative research conducted by this team, suggesting that
428 people were surprised about what they could achieve in terms of art participation, such
429 exposure may enhance recruitment rates.

430

431 The 20% withdrawal rate at T2 (n=8/41) was similar to that in other studies of
432 psychological interventions⁴¹. Baseline scores were high for those dropping out and most
433 of those dropping out were also ambivalent about art participation, possibly perceiving

434 little need to participate. Together these findings indicate incorporating preference into
435 trial design may enhance recruitment and retention, and facilitate evaluation of the
436 impact of preference for art participation on outcomes⁴².

437

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

441

442 ***Group participation***

443 Difficulty running groups limited opportunities for interaction between survivors.
444 Despite this, change in Social Participation was greater for the intervention group,
445 suggesting as reported elsewhere, that art participation may enhance well-being via
446 social interaction ^{14,17,43-45}. A definitive trial, randomising by clusters would ensure
447 sufficient participants at individual sites to conduct group sessions. This design could
448 facilitate evaluation of effects of group and individual sessions, and more robustly
449 evaluate impact on social participation.

450

451 ***Change in Outcomes***

452 Data was normally distributed in all outcomes except in two domains of the Stroke Impact
453 Scale at T3, suggesting that there was unlikely to be recruitment bias in the sample in
454 terms of outcomes of interest¹⁸. The study only provided indications of magnitude and
455 direction of change and was not a definitive effectiveness study. Between-group
456 differences were small and variability high, however change in positive and negative
457 affect favoured the intervention indicating art participation may positively influence
458 emotions.

459

460 The RCT of art participation with stroke survivors in Thailand¹⁶ showed improved
461 depression and quality of life compared to controls receiving physiotherapy only. That
462 there was no indication of effects on the selected quality of life measure using a similar
463 art participation activity probably reflects low study power, or differences in concepts
464 evaluated by the measures. The difference may also indicate that activities such as singing
465 and meditation in addition to art participation, are indeed necessary for effectiveness. The
466 present intervention involved choice and development of personally meaningful artwork,
467 but activities in the other study were more prescribed and pre-determined, making direct
468 comparison to this study difficult.

469

470 One study aim was to determine if the identified outcomes were relevant. The Positive
471 and Negative Affect Scale reflected the selected definition of wellbeing and the positive
472 emotional changes art participation was anticipated would confer. This contrasts with
473 measures reflecting the absence of negative emotions such as anxiety and depression, as
474 examined in the Thai study. Insensitivity of Positive and Negative Affect Scale to change
475 in lower emotional arousal states⁴⁶ may explain why effect size in the present study was
476 not larger, but probably also reflects the small sample size in this feasibility study.
477 Potential intervention effects may have been missed by not measuring other less
478 transient psychological consequences of stroke including anxiety and depression. Despite
479 these limitations, both studies indicate art may positively influence emotional
480 consequences of stroke. A future definitive RCT should include Positive and Negative
481 Affect Scale as the primary outcome, probably with measures of anxiety and depression
482 as secondary outcomes to capture these effects.

483

484 Stroke Impact Scale domains representing aspects of quality of life were influenced less
485 by the art intervention than anticipated. Survivor perceived communication worsened
486 over time, particularly in the intervention group. It is unlikely however that the

487 intervention caused poorer communication. Baseline clinical assessment of
488 communication was not undertaken so there is no reliable estimate of actual rather than
489 perceived communication. It is nonetheless probable that the intervention group
490 experienced initial communication that became more apparent to them over time. Whilst
491 art sessions were designed to support conversation, compared to formal approaches to
492 conversation facilitation⁴⁷, communication was unstructured and incidental and thus
493 likely to be insufficient to promote change. Communication should not be an outcome
494 within a full-scale trial. Other SIS domains may have not been sufficiently sensitive to
495 detect small changes conferred by art participation, and should not be included as an
496 outcome in a future definitive trial.

497

498 General self-efficacy, self-esteem and hope have been associated with better stroke
499 recovery ^{48,49}. There was no indication that art participation may influence these
500 outcomes. High variability in scores and limited sensitivity to change in the measures may
501 explain findings. However previous qualitative findings may have been over-interpreted,
502 and these outcomes may not be relevant to this intervention.

503

504 As expected, self-efficacy for art was higher in the intervention group at T2 and T3, and,
505 as predicted by Bandura's Social Cognitive Theory⁴¹, illustrates confidence and mastery
506 through specific skills development. Self-efficacy for broader life activities was another
507 key benefit identified in qualitative art participation studies ^{12,14,17}. There was no
508 indication that art participation might influence general self-efficacy, suggesting, as
509 predicted by Bandura, that self-efficacy is specific to mastery of particular activities. The
510 earlier qualitative studies involved longer programmes of community based art
511 participation than this study^{12,14}. Potential effects may not have been realised in the short
512 timescale of the present study, and within the narrower social confines of the hospital
513 environment.

514

515 ***Limitations***

516 Although psychotropic drug use at baseline was recorded baseline levels of depression
517 were not assessed to examine if those with initial depression improved more. A future
518 trial should include this evaluation, to determine participants most likely to benefit.
519 Furthermore, the control group received an art portfolio because usual practice on those
520 units was to have artwork available from previous art programmes. The portfolio was
521 assumed to be an inert intervention, to maintain study continued participation. However,
522 it may have provided some confounding effects. A future trial should include usual
523 intervention controls only. Group dynamics were not assessed, nor were effects of art on
524 sense of identity, which may clarify intervention mechanisms of action. These should be
525 included in a definitive trial.

526

527 **Conclusion**

528 Delivering and testing an art intervention in stroke rehabilitation was feasible. Art
529 participation is a complex intervention that *may* enhance aspects of wellbeing after
530 stroke, as defined by Kirkevold⁷. Positive affect and self-efficacy for art appeared to be
531 enhanced in this feasibility study however study adjustments would be important for a
532 definitive trial. These include a more targeted test battery with change of primary
533 outcome to affect, and detailed screening to ensure participants are interested enough in
534 art participation and complete the intervention. A cluster or stepped wedge design with
535 site level randomisation would guarantee group sessions. Given the intervention may
536 improve positive affect, it could be enhanced to specifically target improvement in this
537 domain, and should be the primary outcome for a future study. Whilst retaining the
538 primary purpose of a creative experience with artists, elements of art therapy,
539 particularly techniques known to be effective at improving positive emotions could be
540 included.

541

542

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- 681

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

table 2. Participant characteristics

Baseline Characteristics	Intervention Group (n= 41)	Control Group (n= 40)	
Days admission to randomisation (mean, SD)	11.2(7.6)	12.4(9.5)	685
Age (years) (mean, SD)	77.0(9.1)	75.6(8.8)	
Male, n (%)	19(46%)	17(42%)	686
Female, n (%)	22(54%)	23(58%)	
Ischaemic stroke, n (%)	36(88%)	35(87%)	687
Haemorrhagic stroke, n (%)	5(12%)	5(13%)	
Edinburgh Handedness Inventory, n (%)			
Left Handed	3(7)	6(15)	
Ambidextrous	2(5)	1(2.5)	
Right handed	36(88)	33(82)	
Side of hemiplegia, n (%)			
Left hemiplegia	22(54%)	23(57%)	689
Right hemiplegia	19(46%)	16(43%)	
NIH Stroke Scale (max=15) (mean, SD)	5.4(3.3)	5.2(3.7)	
Montreal Cognitive Assessment (max=30) (mean, SD)	18.4(5.4)	18.4(6.6)	690
Barthel Index (Max=100)	46.2(24.7)	46.0(26.8)	691
On Psychotropic Drugs n (%)	2(5%)	1(2.5%)	
Intervention Sessions (Max=8) (mean, SD)	5.6(2.6)	-	692
Preference for Art, n (%)			
View	9(22)	9(23)	
Participate	18(44)	15(37)	
None	14(34)	16(40)	693
Experience of Art, n (%)			
None	22(54)	27(67)	
A little	17(41)	12(30)	
A lot	2(5)	1(3)	694

695

696

1 table 3. Baseline T1 scores on outcome measures, Mean, SD: Intervention Group, Control Group, dropouts at T2 assessment.
2

Outcome Measures	T1 score (mean, SD)		Participants who withdrew	
	Intervention Group (n= 41)	Control Group (n=40)	Intervention Group (n= 8)	Control Group (n=2)
Stroke Impact Scale (Min=0, Max=100)				
Emotion	69.6(19.5)	72.4(20.4)	87.6(9.5)	77.8(31.4)
Communication	75.5(21.6)	69.5(24.9)	73.2(16.1)	32.1(5.0)
Hand Function	16.1(27.3)	17.1(26.8)	52.0(30.3)	30.0 (0.0)
Social Participation	37.0(26.5)	39.5(26.3)	54.7(25.8)	18.7(0.0)
Positive and Negative Affect Schedule (min=0, max=50)				
Positive Affect (higher score better)	23.5(8.2)	24.3(7.8)	27.9 (7.1)	27.5 (2.1)
Negative Affect (lower score better)	20.2(7.8)	20.4 (8.1)	13.0(2.9)	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 preference			3	1
Preference not met			3	1
Preference met			2	-

1 table 4. Mean (SD) Change scores T1 to T2; estimated between group differences and effect size estimation at T2

Outcome Measures	Change T1 to T2 (mean, SD)		Estimated Between Group Difference at T2		Standardised Effect Size	
	Intervention Group (n= 33)	Control Group (n=38)	Estimated mean difference T2	95% Confidence Interval	Cohen's d (positive value favours Intervention)	
Stroke Impact Scale (Min=0, Max=100)						5
Emotion	5.8(23.9)	5.3(18.5)	2.8	-11.3 to 5.7	-0.35	
Communication	-10.1(24.9)	-1.4 (17.2)	6.4	-14.5 to 3.2	-0.54	
Hand Function	26.7(31.9)	25.7(35.2)	0.5	-14.4 to 13.4	-0.05	6
Social Participation	3.4(27.7)	-2.7(34.0)	0.1	-10.5 to 10.8	0.01	
						7
Positive and Negative Affect Schedule (min=0, max=50)						
Positive Affect (higher score better)	5.4(9.2)	1.7(9.9)	1.6	-2.2 to 5.3	0.24	8
Negative Affect (lower score better)	3.2(10.8)	4.5(9.4)	3.0	-0.7 to 6.7	0.42	
						9
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	10
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	11
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	12
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	13

14 SD denotes standard deviation

15

1 table 5. Mean (SD) Change scores T1 to T2; estimated between group differences and effect size estimation at T2

Outcome Measures	Change T1 to T3 (mean, SD)		Estimated Between Group Difference at T3		Standardised Effect Size Cohen's d (positive value favours intervention)
	Intervention Group (n= 33)	Control Group (n=38)	Estimated Mean Difference T3	95% Confidence Interval	
Stroke Impact Scale (Min=0, Max=100)					
Emotion	3.9 (19.1)	3.5(20.8)	2.3	-10.3 to 5.8	-0.18
Communication	1.1 (21.8)	9.3(21.8)	4.4	-13.9 to 5.2	-0.11
Hand Function	29.8 (31.3)	34.5(41.3)	2.2	-20.5 to 15.7	-0.12
Social Participation	18.3 (30.3)	19.5(33.9)	5.2	-18.8 to 8.3	-0.17
Positive and Negative Affect Schedule (min=0, max=50)					
Positive Affect (higher score better)	4.3(7.5)	2.8(10.1)	0.5	-4.5 to 3.4	0.07
Negative Affect (lower score better)	3.3(11.0)	5.2 (9.8)	3.0	-0.4 to 6.4	0.18
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

14

15 SD denotes standard deviation

16

1 Figure Caption: figure 1: Flow of Participants through the study

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5 **Declaration of Interest Statement**

6 The authors report no conflicts of interest.

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