

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

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

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9 Recruitment rate was 29%. 88% (n=71) of participants completed T2 and 77% (n=62)
10 T3 assessments. Of eight CEI group non-completers at T2, six had no preference for art
11 participation. Outcome measure completion varied between 97% and 77%. Running
12 groups at different sites was difficult because of randomisation timing. Between T1-T2
13 and T2-T3 CEI group change scores were greater for Emotion, Positive and Negative
14 Affect Schedule (PANAS) and Self-efficacy for Art (SEfA). Effect sizes favoured the CEI
15 group for SEfA and PANAS at T2 and T3 and PANAS at T2 and T3 (d=0.24-0.42) .

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

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27 **Introduction**

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

35

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

42

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

53

54 Two qualitative studies^{12,13}, respectively involving sixteen and six survivors receiving in-
55 patient rehabilitation suggest that wellbeing, rehabilitation goal achievement and
56 renewed identity are benefits of arts participation. Two others^{14,15}, respectively involving
57 20 and 24 community dwelling stroke survivors, suggest art participation may enhance
58 self-esteem, self-efficacy and confidence. Despite these positive reports, the diverse range
59 of reported benefits means that defining measures for evaluation of effects is challenging.
60 We found only one RCT of art participation within stroke rehabilitation involving 118 in-
61 patient stroke survivors¹⁶. The study demonstrated improved depression, quality of life
62 and cognition, compared to usual care, following visual art-making combined with
63 meditation and singing. However, it is unclear how each intervention component
64 contributed to effects, therefore specifically evaluating effects of artmaking is warranted.

65

66 The Creative Engagement Intervention (CEI) is a person-centred arts participation
67 programme delivered within a Scottish health board, and developed collaboratively with
68 artists, academics and stroke survivors. In planning this study, we interviewed three
69 artists who delivered that programme and eleven previous participants¹⁷. Findings
70 showed the CEI enhanced sense of hope, self-efficacy and perceived control over recovery
71 as central components of enhanced wellbeing. Other benefits included physical and
72 communication recovery, self-esteem and mood. These benefits can be translated into
73 measurable outcomes, congruent with models of wellbeing, as described within our
74 related intervention model¹⁷. The qualitative work facilitated modelling of the existing
75 intervention into a protocol for use in a randomised controlled feasibility trial.

76

77 Feasibility trials examine key trial parameters, such as intervention feasibility,
78 recruitment, loss to follow-up, completion and relevance of outcome measures, to
79 optimise a subsequent large-scale RCT. They also evaluate if proceeding to full-scale trial

80 is appropriate ¹⁸. Undertaking a feasibility evaluation of art participation is critical to
81 inform a future trial, since so few RCTs exist.

82

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

89 **Design**

90 This pragmatic single-blind feasibility randomised controlled trial was informed by the
91 Medical Research Council Framework for Complex Intervention Development¹⁹. The
92 published study protocol provides in-depth methodological details²⁰. We provide a brief
93 description below.

94

95 **Methods**

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

98 ***Participants and setting***

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

103 conducted screening and obtained informed consent for participation from interested
104 stroke survivors.

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

110 ***Sample size calculation***

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

115

116 ***Randomisation***

117 Randomisation to usual care or intervention was conducted after baseline assessment
118 using secure, remote, web-based, concealed computer generated randomisation.
119 Minimisation was applied to ensure that groups were balanced. Participants were
120 recruited from two stroke units, therefore to minimise the effects of factors within units
121 that might affect outcomes, we included stroke unit as a minimising factor as well as age
122 (≤ 60 years, 61-80 years, ≥ 81 years), gender, and likelihood of ADL independence,
123 according to Barthel Index scores²², grouped as scores of 0-40, 45-55, 60-100²³.

124 ***Intervention Group***

125 Participants randomised to the intervention group received the modelled visual arts
126 based CEI in addition to usual rehabilitation. Two qualified visual artists, with five and
127 seven years of experience respectively of working in healthcare settings, delivered the

128 CEI. The research manager (CK), a trained artist and researcher, trained the artists and
 129 assessed their performance of trial procedures, delivery of intervention stages, goal
 130 setting with participants, and progress review, prior to study commencement. Planned
 131 intervention delivery involved one session per week with the artist and one group session
 132 with other participants, to a maximum of eight sessions, because of known benefits of
 133 each approach^{12,14,24}. Individual sessions lasted one hour and group sessions one hour
 134 and thirty minutes. Usual rehabilitation typically involved physiotherapy, occupational
 135 therapy, and as necessary, speech and language therapy. Approximately one half hour
 136 session was delivered by each therapy on most weekdays.

137

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

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
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148 ***Control Group***

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

155

156 ***Measures and measurement instruments***

157 Measures at baseline included age, gender, stroke type (ischaemic/haemorrhagic) and
 158 side , as well as the Barthel Index ²²; Montreal Cognitive Assessment ²⁶ ; NIH Stroke Scale
 159 ²⁷; Edinburgh Handedness Inventory ²⁸; Communication: Aphasia Severity Rating Scale ²⁹

160

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

167

168 The Stroke Impact Scale questionnaire ³¹ was selected as a potential primary outcome
 169 measure. It measures stroke related quality of life ³². We examined Emotion, Hand
 170 Function, Communication and Social Participation, given those domains were relevant

171 from our earlier work^{17,20}. Items are rated on a five-point Likert scale indicating
172 difficulty completing the item. Summative scores for domains range from 0 to 100.

173

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

181

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

186 Control over recovery was indicated as a positive benefit of art participation¹⁷. The
187 stroke specific Recovery Locus of Control Scale assessed this domain³⁵. It is a nine-item
188 scale measuring internal and external control beliefs relating to recovery. Degree of
189 control is rated between 1 and 5. Summed items indicate strength of internal control, with
190 9 indicating minimum and 45 maximum.

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

196 the measure captured mechanisms, suggested in our previous study, through which art
197 participation might provide hope.

198
199 *General self-efficacy:* Art making appeared to develop confidence to achieve art-specific
200 goal achievement *and* personal rehabilitation goals^{14,17}. To capture general confidence
201 we included the General Self-Efficacy Scale³⁷, a 10-item scale assessing confidence to deal
202 with life demands. Responses are scored 1-4 and summed to a total of 40, indicating
203 maximum self-efficacy. The scale is widely used with stroke populations.

204
205 *Self-efficacy for art:* To assess self-efficacy for art we asked two single item questions,
206 using an established procedure ³⁸. The questions are: 1. How confident are you that you
207 can express yourself through art activities? 2. How difficult do you find it to express
208 yourself through art activities? Self-efficacy for art expression is scored on a seven-point
209 vertical visual analogue scale with one as least confident/difficult and seven as most
210 confident/difficult.

211

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

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

216 ***Trial Procedures***

217 As per local ethical regulations, nursing and rehabilitation staff identified potential
218 participants and provided them with study information. Those expressing interest were
219 screened by the research team and written informed consent for participation obtained.
220 Baseline measures were collected and participant details entered into a secure, remote,

221 web-based randomisation system then artists were informed of group allocation. The
222 system was password accesses only by the study team.

223

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

230

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

234

235 ***Data analysis***

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

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

254

255 **Results**

256 ***Recruitment***

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

263 Insert figure 1 about here

264 Insert table 1 about here

265 ***Retention***

266 Eight CEI (20%) and two control participants (5%) dropped out before T2. Six CEI group
267 dropouts expressed no preference, or preferred the control option of art viewing.
268 Although numbers were insufficient for statistical testing, baseline primary outcome
269 measure scores for CEI group dropouts were higher at T1 (n=8) compared to T2

270 completers (table 2), suggesting dropouts might differ in some ways from those
271 remaining in the study.

272 Insert table 2 about here

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

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

280 ***Outcomes***

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

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

289

290 ***Change from baseline***

291 For the selected Stroke Impact Scale subscales, participants completing the intervention
292 in the CEI group had higher change scores (Mean, Standard Deviation) than the control

293 group between T1 and T2 in Social Participation (3.4 ± 27.7 vs -2.7 ± 34.0), Emotion
294 (5.8 ± 23.9 vs 5.3 ± 18.5) and Hand Function (26.7 ± 31.9 vs 25.7 ± 35.2) (table 3). However,
295 differences were small and variability was high. For communication, change was negative
296 between T1 and T2, with greatest decline in the CEI group (-10.1 ± 24.9 vs -1.4 ± 17.2). For
297 secondary outcomes the CI group had greatest improvement in Positive Affect (5.4 ± 9.2
298 vs 1.7 ± 9.9), lower increase in Negative Affect (3.2 ± 10.8 vs 4.5 ± 9.4) (table 3), and most
299 improvement in self-efficacy for art (5.4 ± 9.2 vs 1.79 ± 9.9). For all other measures change
300 was small and fairly equitable between groups (table 3). Mean between group differences
301 at T2 reflected the pattern for change scores. For self-efficacy for art (mean difference =
302 2.6; 95% CI = 1.1 to 4.2; Cohen's $d = 0.35$) mean difference favoured the intervention
303 group; and for self-esteem (mean difference = 4.3; 95% CI = -7.3 to -1.3, Cohen's $d = -0.51$)
304 and communication (mean difference = 6.4; 95% CI = -14.5 to 3.2; Cohen's $d = -0.54$) the
305 mean difference favoured the control group (table 3).

306 Insert table 3 about here

307 For overall change T1 to T3 on the Stroke Impact Scale (table 4), the control group
308 demonstrated most improvement on all domains except Emotion, where the change score
309 was slightly greater for the intervention group (3.9 ± 19.1 vs 3.5 ± 20.8). Greater
310 improvement for the intervention group for positive affect (4.3 ± 7.5 vs 2.8 ± 10.1) and
311 lower increase in negative affect (3.3 ± 11.0 vs 5.2 ± 9.8) was maintained for overall change.
312 The intervention group demonstrated greatest overall change in self-efficacy for art
313 (2.1 ± 4.1 vs 0.4 ± 3.9), otherwise change in both groups was small and similar across the
314 groups (table 4).

315 Insert table 4 about here

316 In terms of estimated mean differences at T3, the pattern was similar to T2, favouring the
317 CEI group for hand function, social participation, positive and negative affect and self-
318 efficacy for art (table 4). Although small to moderate, effect size favoured self-efficacy for

319 art in the CEI group (mean difference =2.1; 95% CI = 0.4 to 3.8; Cohen's d = 3.0) and the
320 general self-efficacy significantly in the control group (mean difference = 3.0; 95%CI =-
321 5.9 to -0.2; Cohen's d = -0.28). Other outcomes showed very small effect sizes, most
322 favouring the control group.

323

324 **Discussion**

325 Conducting an RCT to test a visual arts intervention within stroke rehabilitation was
326 feasible. Recruitment and retention were comparable to other stroke rehabilitation trials
327 ^{40,41}, however preference for art may influence study retention. The study was not
328 designed to definitively evaluate effectiveness, but indicated that expected changes in the
329 nominated primary outcome were not realised, but that positive affect and self-efficacy
330 for art, may be improved.

331

332 ***Recruitment and retention***

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

339

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

343

344

345 ***Group participation***

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

352

353 ***Potential Effects***

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

358 The RCT of art participation with stroke survivors in Thailand¹⁶ showed improved
359 depression and quality of life compared to controls receiving physiotherapy only. The
360 small effect sizes in our study probably reflect low study power, but may mean
361 intervention adjustment, or additional activities such as singing and meditation, are
362 indeed necessary for effectiveness. Our CEI involved choice and development of
363 personally meaningful artwork, but activities in that study were more prescribed and pre-
364 determined, making direct comparison difficult.

365

366 One study aim was to identify relevant outcome measures. PANAS reflected our positive
367 definition of wellbeing, however it may be insensitive to change in lower emotional
368 arousal states⁴⁶ and we may have missed intervention effects by not measuring

369 depression and anxiety. Despite these limitations, both studies indicate art may positively
370 influence mood and affect after stroke, suggesting a full-scale trial, with mood as primary
371 outcome, is probably warranted.

372

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

378

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

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

393

394 ***Limitations***

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

404

405 **Conclusion**

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

417

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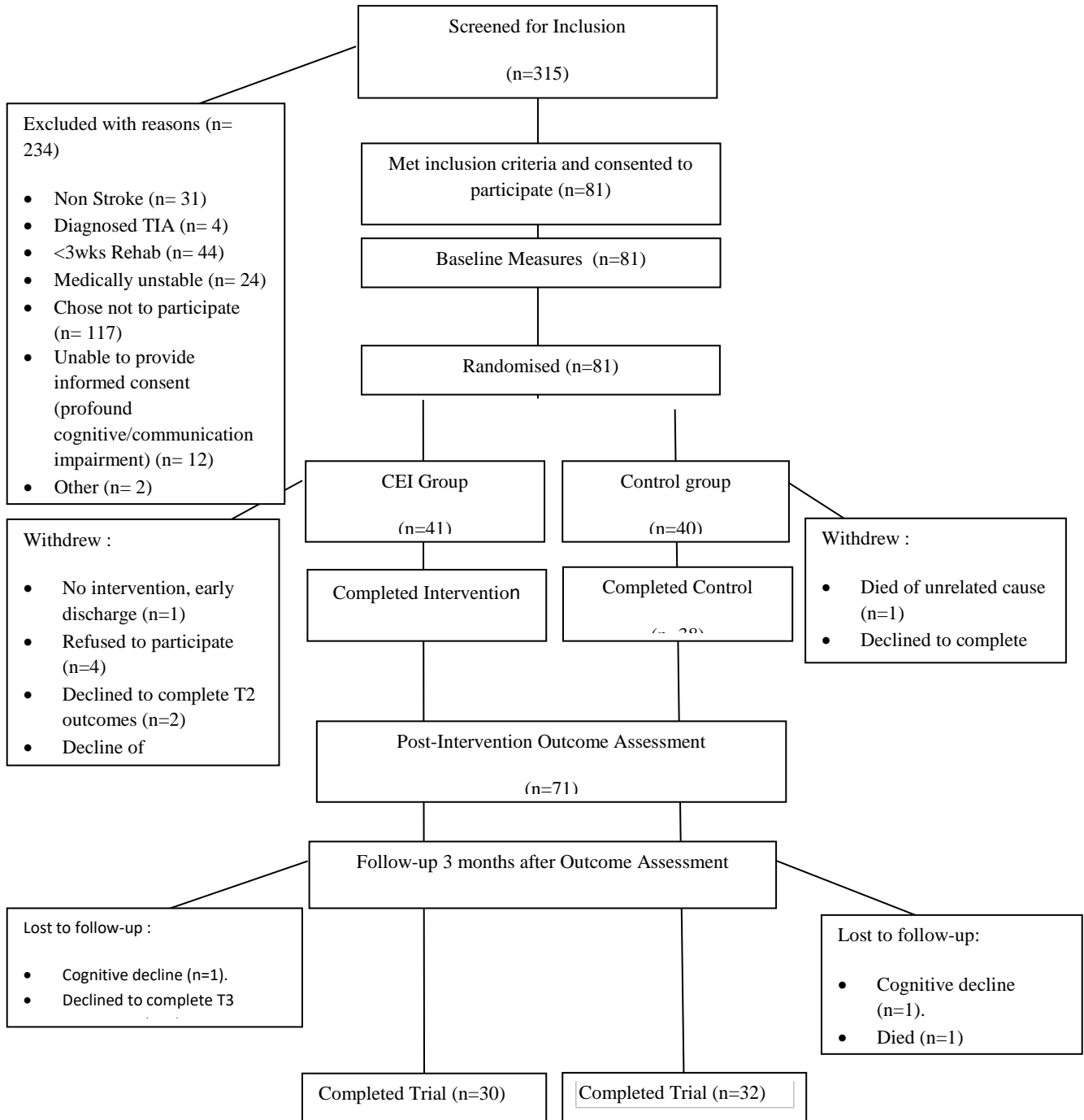
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figure 1. Consort Diagram



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)	557
Male, n (%)	19(46%)	17(42%)	
Female, n (%)	22(54%)	23(58%)	558
Ischaemic stroke, n (%)	36(88%)	35(87%)	
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 (%)			559
Left hemiplegia	22(54%)	23(57%)	
Right hemiplegia	19(46%)	16(43%)	
NIH Stroke Scale (max=15) (mean, SD)	5.4(3.3)	5.2(3.7)	561
Montreal Cognitive Assessment (max=30)(mean, SD)	18.4(5.4)	18.4(6.6)	562
Barthel Index (Max=100)	46.2(24.7)	46.0(26.8)	
On Psychotropic Drugs n (%)	2(5%)	1(2.5%)	
Intervention Sessions (Max=8)(mean, SD)	5.6(2.6)	-	563
Preference for Art, n (%)			
View	9(22)	9(23)	
Participate	18(44)	15(37)	564
None	14(34)	16(40)	
Experience of Art, n (%)			
None	22(54)	27(67)	565
A little	17(41)	12(30)	
A lot	2(5)	1(3)	

566

567

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)				
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	-

table 3. 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 Cohen's d (positive value favours CEI)
	CEI Group (n= 33)	Control Group (n=38)	Estimated mean difference T2	95% Confidence Interval	
Stroke Impact Scale (Min=0, Max=100)					
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
Social Participation	3.4(27.7)	-2.7(34.0)	0.1	-10.5 to 10.8	0.01
				to 5.8	
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
Negative Affect (lower score better)	3.2(10.8)	4.5(9.4)	3.0	-0.7 to 6.7	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

standard deviation

SD denotes

Outcome Measures	Change T1 to T3 (mean, SD)		Estimated Between Group Difference at T3		Standarised Effect Size Cohen's d (positive favours intervention)	Effect value
	CEI Group (n= 33)	Control Group (n=38)	Estimated Difference T3	Mean 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	

SD denotes standard deviation

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Declaration of Interest Statement

The authors report no conflicts of interest.