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## **Positive PsychoTherapy in ABI Rehab (PoPsTAR): A pilot randomised controlled trial**

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1 **Abstract**

2 Psychological distress is common following acquired brain injury (ABI), but the evidence base for  
3 psychotherapeutic interventions is small and equivocal. Positive psychotherapy aims to foster  
4 wellbeing by increasing experiences of pleasure, engagement and meaning. In this pilot trial, we  
5 investigated the feasibility and acceptability of brief positive psychotherapy in adults with ABI and  
6 emotional distress. Participants were randomised to brief positive psychotherapy plus usual  
7 treatment, or usual treatment only. Brief positive psychotherapy was delivered over eight individual  
8 out-patient sessions, by one research psychologist. A blinded assessor administered the Depression  
9 Anxiety Stress Scales (DASS-21) and Authentic Happiness Inventory (AHI) at five, nine and 20  
10 weeks post-baseline. Of 27 participants randomised (median age 57; 63% male; 82% ischaemic  
11 stroke survivors; median 5.7 months post-injury), 14 were assigned to positive psychotherapy, of  
12 whom 8 completed treatment. The intervention was feasible to deliver with excellent fidelity, and  
13 was acceptable to participants. Retention at 20 weeks was 63% overall. A full-scale trial would need  
14 to retain n=39 per group to end-point, to detect a significant difference in change scores on the  
15 DASS-21 Depression scale of 7 points (two-tailed alpha=0.05, power=0.80). Trials including an  
16 active control arm would require larger sample sizes. We conclude that a full-scale trial to investigate  
17 efficacy is warranted.

18

19 **Keywords** Brain injury; stroke; positive psychology; psychotherapy; randomised controlled trial

## 20 **Introduction**

21 Psychological distress is common in people with acquired brain injury (ABI) such as stroke or  
22 traumatic brain injury (TBI), and impacts negatively on long-term functional outcome. Frequency of  
23 depression and anxiety are high after stroke (Campbell Burton et al., 2013; Hackett & Pickles, 2014),  
24 and post-stroke depression is associated with worse functional outcome (Pohjasvaara, Vataja,  
25 Leppavuori, Kaste, & Erkinjuntti, 2001). Depression and anxiety are also common in adults with TBI  
26 (Jorge et al., 2004; Osborn, Mathias, & Fairweather-Schmidt, 2014), and presence of psychological  
27 ill-health has been linked with poorer outcome and increased disability up to seven years following  
28 TBI (Whitnall, McMillan, Murray, & Teasdale, 2006). In light of the association between  
29 psychological morbidity and poorer outcomes, it is important to address low mood and adjustment  
30 problems during the rehabilitation process. Psychology services are a key component of ABI  
31 rehabilitation, but the evidence base for specific psychotherapeutic methods in this population is  
32 small and equivocal. There is some evidence of benefit from psychological therapies, including  
33 cognitive-behavioural therapy and mindfulness-based cognitive therapy, in people with acquired  
34 brain injury (Bedard et al., 2014; Bradbury et al., 2008; Soo & Tate, 2007), but a Cochrane review of  
35 psychological therapies for post-stroke depression found no overall beneficial effect in three trials  
36 meeting their criteria (Hackett, Anderson, House, & Xia, 2008). A more recent trial of behavioural  
37 therapy for stroke survivors with aphasia and low mood reported beneficial effects (Thomas, Walker,  
38 Macniven, Haworth, & Lincoln, 2013). There remains a need for further high quality research  
39 investigating psychological interventions which are aimed at alleviating psychological morbidity  
40 following brain injury.

41 Cognitive-behavioural therapy (CBT) is one of the most commonly used psychological  
42 therapies for the treatment of low mood, but there can be challenges in applying standard CBT  
43 methods in patients with ABI because of the concomitant presence of cognitive impairment and lack  
44 of insight. It has been argued that CBT can and should be adapted for the particular circumstances

45 and needs of people with ABI; for example, modified treatment frameworks have been described for  
46 the stroke population (Broomfield et al., 2011; Kneebone, 2015). It may also be helpful to  
47 conceptualise depression after ABI as an understandable reaction at a time when self-identity is  
48 under threat (Gracey, Evans, & Malley, 2009), and therefore to employ treatment approaches which  
49 aim to resolve this threat to the self by facilitating self-reflection and personal growth as part of the  
50 rehabilitation process.

51 In recent years, there has been an increasing emphasis on the study of positive psychological  
52 attributes and personal growth, in what has become known as ‘positive psychology’. Following  
53 Seligman and Csikszentmihalyi’s initial overview (Seligman & Csikszentmihalyi, 2000), growing  
54 interest in positive psychology has been reflected in the proliferation of books, journals, associations  
55 and conferences dedicated to the topic. Positive psychology aims to understand the factors that  
56 underlie wellbeing, and positive emotions, character traits and organisations. Positive psychotherapy  
57 is a recently developed intervention approach (Rashid & Seligman, 2013) which is intended to  
58 reduce distress and foster wellbeing by increasing experiences of pleasure, engagement and meaning.  
59 Therapeutic exercises focus on experiences such as gratitude, savouring and optimism, and using  
60 character strengths in new ways. A recent meta-analysis of various types of positive psychology  
61 interventions (Bolier et al., 2013) showed overall modest effects of interventions on measures of  
62 depression and wellbeing (standardised mean difference 0.20 to 0.34). The authors noted that many  
63 studies were of low methodological quality, and only a small number were aimed at participants with  
64 psychosocial problems (e.g. depressive symptoms). There were indications of greater effects from  
65 interventions delivered individually and over a longer duration (>8 weeks), in samples referred from  
66 clinical settings, and in samples presenting with psychosocial problems. Sample attrition ranged from  
67 0% to 29% in the seven studies that included samples with psychosocial problems. The authors  
68 recommended that further high quality research be undertaken with diverse (clinical) populations,  
69 and in countries and cultures outside North America.

70 We believe there is a good rationale to investigate the potential benefits of positive  
71 psychotherapy approaches in the context of ABI rehabilitation (Evans, 2011). Many people cope  
72 well, make adjustments, and experience positive psychological growth after brain injury (Rogan,  
73 Fortune, & Prentice, 2013). It is possible that goal-directed rehabilitation could be enhanced by  
74 focusing more explicitly on maximising wellbeing, using a positive psychology framework. If there  
75 were evidence of benefit, we envisage that such an approach could be delivered by rehabilitation  
76 staff as part of a comprehensive, individualised rehabilitation programme. One study to date  
77 (Andrewes, Walker, & O'Neill, 2014) has investigated the application of positive psychotherapy  
78 exercises in an in-patient ABI rehabilitation setting, but there has been no research in out-patient  
79 settings. Development and evaluation of novel psychological interventions should proceed  
80 incrementally, beginning with research on feasibility and acceptability, and including detailed pilot  
81 research to inform the design and conduct of controlled efficacy evaluations (Craig et al., 2008). We  
82 therefore undertook this pilot study with the aim of investigating the feasibility of a brief positive  
83 psychotherapy intervention within a randomised controlled trial (RCT) context, with out-patient ABI  
84 survivors experiencing emotional distress. In view of the lack of previous literature on the use of  
85 positive psychology assessment tools in this clinical population, we also wished to investigate the  
86 reliability of wellbeing measures. The present study was not designed to determine the efficacy of  
87 the intervention; rather, our objective was to gather essential data to plan future trials in this area.

88

89 *Primary research question*

90 (i) What are the likely recruitment, adherence and retention rates over 20 weeks for a trial comparing  
91 brief positive psychotherapy versus treatment as usual (TAU) in an out-patient setting for patients  
92 with ABI and emotional distress?

93

94 *Secondary research questions*

- 95 (ii) Is a brief positive psychotherapy intervention feasible to deliver in an out-patient setting with  
96 patients presenting with emotional distress following ABI?
- 97 (iii) Are positive psychology assessment tools reliable in people with ABI?
- 98 (iv) Is a full-scale RCT of brief positive psychotherapy indicated, and if so, what is the required  
99 sample size?

100

## 101 **Methods**

102 This was a two-arm, parallel group, single-blind pilot RCT, comparing brief positive psychotherapy  
103 plus TAU (intervention) versus TAU only (control). Reporting follows CONSORT guidelines for  
104 non-pharmacologic treatment interventions (Boutron et al., 2008). Figure 1 shows participant flow  
105 through the study. Recruitment took place between June 2013 and May 2014, and follow-up was  
106 completed by October 2014. A favourable ethical opinion was given by the West of Scotland  
107 Research Ethics Service (ref. 13/WS/0049). The study was registered with the UK Clinical Research  
108 Network (ref. 14302) and ClinicalTrials.gov (ref. NCT01867684).

109

110 [Figure 1 about here]

111

### 112 *Participants*

113 Adults aged 18 or over were recruited from stroke out-patient clinics and the stroke psychology  
114 service out-patient waiting list in NHS Greater Glasgow & Clyde, and from the Glasgow Community  
115 Treatment Centre for Brain Injury (CTCBI).

### 116 Inclusion criteria:

- 117 - Diagnosis of acquired, non-progressive brain injury (confirmed by the local clinician based  
118 on clinical and/or radiological evidence);

- 119 - Between 3 and 12 months post-injury at time of recruitment (subsequently extended up to 36
- 120 months post-injury to accommodate late first-time referrals to the recruiting services);
- 121 - Presence of emotional distress (score in moderate or above range on at least one sub-scale of
- 122 the Depression Anxiety Stress Scales; DASS-21) (Lovibond & Lovibond, 1995);
- 123 - Medically stable (based on opinion of local clinician);
- 124 - Able to consent to research.

125 Exclusion criteria:

- 126 - Significant communication impairments that would preclude participation;
- 127 - Diagnosis of mild traumatic brain injury;
- 128 - Comorbid developmental learning disability or degenerative neurological condition.

129 Pre-injury history of mood disorder did not lead to exclusion.

130

### 131 *Materials and Procedure*

132 Figure 2 shows the schedule of assessments.

#### 133 Recruitment and screening

134 Potentially eligible patients were informed about the study by a clinician in the out-patient setting or  
135 via a letter from the stroke psychology service. Patients who expressed interest met with the research  
136 assistant (RA), gave written informed consent, and were screened to determine eligibility, including  
137 administration of the DASS-21 to measure emotional distress and the Frenchay Aphasia Screening  
138 Test (Enderby, Wood, & Wade, 2013) to ascertain adequate level of communication ability. The  
139 DASS-21 scores from this assessment also served as baseline measures in the study.

#### 140 Baseline measures and randomisation (Week 0)

141 Either on the same day as the screening assessment or within the following 10 days, participants  
142 completed further baseline assessment measures: Test of Premorbid Functioning (ToPF) (Wechsler,  
143 2011a); Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) (Randolph,

144 1998); Digit Span task from the Wechsler Adult Intelligence Scale 4th edition (WAIS-IV)  
145 (Wechsler, 2010); Similarities task from the Wechsler Abbreviated Scale of Intelligence (WASI-II)  
146 (Wechsler, 2011b); letter fluency (Tombaugh, Kozak, & Rees, 1999); Awareness Questionnaire  
147 (AQ) (Sherer, 2004); and Mayo-Portland Adaptability Inventory (MPAI-4) (Malec, 2005). Informant  
148 versions of the AQ and MPAI-4 and the Modified Caregiver Strain Index (M-CSI) (Thornton &  
149 Travis, 2003) were administered to an appropriate informant (this was optional, depending on  
150 participant preference).

151 The Authentic Happiness Inventory (AHI) (Peterson, 2005) and a short inventory of  
152 Signature Strengths (based on the Brief Strengths Test) (Peterson, 2004) were administered to  
153 participants at baseline and again within one week (prior to commencing the intervention), to  
154 ascertain test-retest reliability of these positive psychology tools in this clinical population. The AHI  
155 includes 24 items assessing pleasure, meaning and engagement, with each item represented by a  
156 group of multiple-choice statements (e.g. 1 = 'My life does not have any purpose or meaning' to 5 =  
157 'I have a very clear idea about the purpose or meaning of my life'). The AHI has previously been  
158 reported to have high internal consistency ( $\alpha = 0.92$  in healthy young adults) (Schiffrin & Nelson,  
159 2010). It has been successfully used with participants with brain injury in one study (Andrewes et al.,  
160 2014), but psychometric properties were not reported. The Signature Strengths inventory was a list  
161 of brief descriptions of 24 positive character attributes. Participants used an iterative card-sorting  
162 procedure to rank the attributes, to produce a final list of the 'top five' signature strengths that they  
163 perceived to be true of themselves. This was not administered as a study outcome variable, but rather  
164 as a necessary pre-requisite to the exercises that would be introduced during the intervention.  
165 Participants were also asked to rate the acceptability of both the AHI and Signature Strengths  
166 inventories.

167 Following baseline assessment, participants were randomly allocated to study intervention or  
168 control arm.

169            Intervention phase (Weeks 1 to 8 inclusive)

170 Participants in the control arm received usual care within the clinical service. The content of usual  
171 care was not standardised; input varied between services and participants, but all participants could  
172 access clinical psychology input if required. Participants in the intervention arm received a brief  
173 positive psychotherapy intervention delivered over eight weeks, in addition to accessing usual care  
174 within the clinical service. The study intervention followed a manualised programme designed by the  
175 research team and based on aspects of Rashid and Seligman’s programme (Rashid & Seligman,  
176 2013), incorporating psychoeducation about ABI and positive psychology (Week 1), a range of  
177 therapeutic exercises and homework focused on using signature character strengths and reflecting on  
178 positive events (Weeks 2 to 7 inclusive, with mid-point review at Week 4), and final review and plan  
179 for maintenance (Week 8). The topics and exercises were based on Seligman’s PERMA framework  
180 (Seligman, 2011) and conceptualisation of the ‘Full Life’, and included character strengths, gratitude,  
181 savouring, optimism, hope, personal growth, and the ‘gift of time’. Care was taken to ensure that the  
182 treatment principles took into account the likely social and health-related challenges faced by the  
183 study population. Negative circumstances and perceptions were acknowledged and discussed but the  
184 treatment programme avoided cognitive therapy techniques, instead focusing on realistic goal-setting  
185 and action planning. The trial therapist liaised with the patient’s clinical service if appropriate, to  
186 ensure that psychological needs that were beyond the scope of the study intervention could be  
187 addressed as part of usual clinical treatment. The intervention was delivered on a one-to-one basis  
188 once per week within a clinical out-patient setting by one trial therapist (J.P.), who held a psychology  
189 PhD but no formal qualifications in psychological therapy. Participants’ travel expenses were paid. A  
190 standard treatment workbook was provided for use by participants during and between appointments,  
191 containing session summaries and space to record individualised homework information. An  
192 individualised method of prompting the completion of homework (e.g. notes, alarms etc) was agreed  
193 upon. Feasibility and acceptability of the treatment programme were measured by recording

194 appointments attended, homework tasks completed, trial therapist's ratings of the feasibility of the  
195 session content, and participants' opinions of the programme (Likert scales and comments, unseen  
196 by the trial therapist).

197 Interim and follow-up measures (Weeks 5, 9 and 20)

198 Participants in both study arms completed the DASS-21 and AHI at Weeks 5, 9 and 20. At Week 20  
199 only, the MPAI-4 was re-administered, and informants were also asked to complete this and the M-  
200 CSI. These assessments were administered by a second RA, blinded to allocation, by post or by  
201 telephone depending on participant preference. A telephone reminder was provided if postal  
202 materials had not been returned after one week.

203

204 [Figure 2 about here]

205

206 *Summary of outcome measures*

207 Primary outcome measures:

208 - Recruitment rate; treatment adherence; and sample retention at 20 weeks from baseline.

209 Secondary outcome measures:

210 - Test-retest reliability of AHI and Signature Strengths inventory;

211 - Change in DASS-21 scores at 20 weeks from baseline;

212 - Changes in AHI, MPAI-4 and M-CSI scores at 20 weeks from baseline;

213 - Ratings of participants' and therapist's experience of treatment delivery.

214 The 20-week assessment was chosen *a priori* as the primary end-point because this would provide a  
215 more robust test of efficacy in a future full-scale trial than the immediate post-intervention measures.

216

217 *Treatment fidelity*

218 All intervention sessions were audio-recorded, and a subsample of these (three randomly chosen  
219 recordings from each of the eight treatment sessions in the programme) were rated by the chief  
220 investigator (J.J.E.). Ratings were made with reference to the treatment manual, according to a three-  
221 point scale (content consistent with protocol for stage of therapy; content partially consistent but  
222 evidence of deviation into other unrelated areas or therapeutic methods; content largely inconsistent  
223 with protocol for stage of therapy). A clinical neuropsychologist (B.C.) provided regular clinical  
224 supervision input to the trial therapist. Both the chief investigator and supervisor attended positive  
225 psychotherapy training delivered by original developer Tayyab Rashid prior to study  
226 commencement.

227

#### 228 *Randomisation and bias prevention*

229 Stratified randomisation with blocking was used to allocate participants to two groups of equal size,  
230 stratified by service setting (stroke versus CTCBI). Because service setting was a proxy for injury  
231 type (stroke versus non-stroke) and for the nature of usual care that would be available to  
232 participants, either of which could have influenced outcomes, including this as a stratification factor  
233 ensured these aspects would be balanced across the intervention and control groups. The allocation  
234 system was managed by the Robertson Centre for Biostatistics and was accessed via an automated  
235 telephone service after the baseline assessment had been completed. Screening, baseline assessments,  
236 allocation and interventions were carried out by one RA (who was blinded to randomisation block  
237 length), and the interim and follow-up measures were administered by a second RA, each of whom  
238 was blind to the other's findings. The second RA was blind to participant allocation; a standard script  
239 was used to prevent unblinding during follow-up telephone calls, and postal materials included clear  
240 instructions to participants not to reveal treatment allocation information.

241

#### 242 *Sample size and statistical methods*

243 Taking into account available service information about estimated numbers of patients meeting study  
244 criteria during the planned recruitment period, and typical attrition rates from psychological therapy  
245 (Wierzbicki & Pekarik, 1993), we estimated that up to 30 participants would be randomised to each  
246 study arm and that 70% (95% confidence interval [CI] 58%-82%) would be retained to the 20-week  
247 endpoint. However, determining the actual recruitment and retention rate was the primary aim of the  
248 study.

249 Data were analysed using SAS software, following a detailed analysis plan. Recruitment,  
250 adherence and retention rates were summarised as percentages. An intra-class correlation coefficient  
251 (ICC) was calculated to determine test-retest reliability of the AHI; 95% CI was generated using a  
252 non-parametric bootstrap procedure with 500 replicates. Percent test-retest agreement on the  
253 Signature Strengths inventory was reported. Analyses were conducted on an intention to treat basis:  
254 participants were analysed in the groups to which they had been allocated (regardless of adherence),  
255 and missing data were not imputed. The study was not designed to have power to detect significant  
256 differences in outcomes between the two study arms.

257

## 258 **Results**

### 259 *Characteristics of the sample*

260 A total of 76 patients expressed interest, of whom n = 9 were ineligible, n = 17 declined to  
261 participate, and n = 13 lost contact, leaving n = 37 who enrolled in the study. A CONSORT  
262 flowchart is given in Figure 3. This shows that n = 27 completed baseline assessments and were  
263 randomised. Table 1 shows the baseline demographic and clinical characteristics of the intervention  
264 and control groups. The control group was older on average than the intervention group; this was due  
265 to the inclusion of one 25-year old in the intervention group. There were more men than women in  
266 both groups. The majority of participants were recruited from stroke services, and the most common  
267 type of injury was ischaemic stroke. Median time since injury was just under six months. Seven of

268 13 control participants and six of 14 intervention participants were receiving psychological treatment  
269 outside the study. Two-thirds of the control group and one third of the intervention group self-  
270 reported that they were taking psychotropic medications. Of those taking psychotropic medications,  
271 two were taking both an antidepressant and a sedative. The remainder were taking one medication,  
272 most commonly a selective serotonin reuptake inhibitor.

273

274 [Figure 3 about here]

275 [Tables 1 and 2 about here]

276

277 Table 2 shows the cognitive measures and self- and informant-reported questionnaires at  
278 baseline. The mean DASS-21 scores for Depression and Anxiety were in the severe range and the  
279 mean Stress score was in the moderate-severe range, with some indication of poorer scores in the  
280 control group. Participants rated their overall disability level on the MPAI-4 in the moderate-severe  
281 range relative to a typical ABI comparison group. Where AQ ratings were available for both  
282 participants and informants (n = 14), score differences indicated that the control participants’  
283 perception of their functioning was better than informants’ perceptions, whereas the reverse was true  
284 for those in the intervention arm. Cognitive scores were in the low average to average range on most  
285 measures, with slightly better performance seen in the intervention group.

286

287 *Acceptability and reliability of positive psychology measures*

288 At baseline, participants rated their experience of completing the AHI questionnaire and Signature  
289 Strengths inventory on 7-point Likert scales, where lower scores indicated more favourable opinions.  
290 Median ratings of ease, length and relevance of the AHI were 3 or lower. Several participants  
291 commented that item 15 on the AHI did not apply to them because it asked about “work (paid or  
292 unpaid)” and so they did not feel able to select an answer. For this reason, all AHI scores reported

293 here exclude item 15 from the mean calculation. A median Likert rating of 2 was given for each  
294 opinion (ease, length and relevance) of the Signature Strengths inventory. Participants commented  
295 that they found the descriptions and card-sorting procedure easy to understand, but struggled to  
296 narrow their choice down to five signature strengths.

297 The AHI and Signature Strengths exercise were re-administered after a median of 9.5 days  
298 (25th, 75th percentile = 7.0, 15.5; n = 24) to ascertain test-retest reliability. The ICC coefficient for  
299 the AHI mean score was 0.86 (95% CI = 0.81, 0.91). The median percentage agreement for the top  
300 five Signature Strengths was 60% (25<sup>th</sup>, 75<sup>th</sup> percentile = 40%, 60%).

301

### 302 *Feasibility and acceptability of the brief positive psychotherapy intervention*

303 Of the 14 participants randomised to the intervention arm, two declined to commence treatment  
304 because of perceived lack of time. Of the 12 who commenced, n = 8 attended all eight planned  
305 sessions. Two participants discontinued treatment after the first session: one ceased contact with the  
306 therapist, and one informed the therapist that they had found it distressing talking about difficulties  
307 and did not wish to continue. One participant ceased treatment after five sessions, due to significant  
308 illness. One participant ceased treatment after six sessions; this person had dropped out of contact  
309 with the therapist repeatedly throughout the treatment period, leading to long gaps between  
310 appointments, and they eventually informed the team that they did not wish to complete. Participants  
311 who did not complete treatment were still sent follow-up questionnaires, unless they indicated that  
312 they no longer wished to receive them.

313 Completion rates for assigned homework were high: across all participants who attended at  
314 least one session that involved homework, 74% of assigned tasks were fully or partly completed. All  
315 eight participants who attended the full treatment programme completed at least 70% of their  
316 assigned homework.

317 The average length of each session in the programme varied, with Session 7 being the  
318 shortest (median 25 minutes; 25th, 75th percentile = 23, 36) and Session 5 being the longest (median  
319 43 minutes; 25th, 75th percentile = 33, 46). The trial therapist rated her perception of the feasibility  
320 of each session with each participant (total of 77 sessions). Overall, 73 sessions (94.8%) were rated  
321 as feasible. Four were rated as partly feasible, with cognitive impairment, distress and fatigue noted  
322 as reasons for this. The chief investigator rated n = 24 randomly selected session recordings for  
323 fidelity; all were rated ‘consistent with protocol’.

324 At the end of Session 4 and Session 8, participants attending treatment completed a feedback  
325 form (unseen by the therapist) regarding their opinion of the convenience of appointments, relevance  
326 of treatment to their concerns, ease of using workbooks within sessions, and ease of homework  
327 completion (7-point Likert scales with lower ratings being more favourable). Median ratings for all  
328 aspects at both time-points were 2.5 or lower. The majority of comments were positive, with  
329 examples as follows:

330 “Great experience. Feel privileged to be in 'chosen' group and feel I have benefited greatly  
331 from sessions. Will try to build in maintenance and keep positive outcome ongoing.” (ID  
332 1013).

333 “Exactly what I needed after suffering a stroke at a young age - confidence and fear play a  
334 massive part - this treatment has been invaluable.” (ID 1024).

335 Participants were able to use the workbook and homework diaries but commented that lack of time  
336 and motivation impacted on homework completion. Use of frequent recapping and review sessions  
337 were viewed as helpful.

338

### 339 *Retention to Week 20 endpoint*

340 As Figure 2 shows, five participants were lost from each study arm; retention was 62% in the control  
341 group and 64% in the intervention group (63% overall). Four control participants and three

342 intervention participants failed to return their Week 20 questionnaires and were considered lost to  
343 follow-up. One control participant withdrew between baseline and Week 5, due to moving out of the  
344 area. One intervention participant withdrew between baseline and Week 5, stating they had changed  
345 their mind, and one intervention participant withdrew between Week 9 and Week 20 due to illness.

346

#### 347 *Success of blinding*

348 All post-baseline outcome measures were processed by a blinded assessor, who guessed allocation at  
349 the end of the study. These guesses were at near-chance level: 53.8% of treatment participants and  
350 58.3% of control participants were guessed correctly.

351

352 [Table 3 about here]

353

#### 354 *Sample size calculation for full-scale trial*

355 Table 3 summarises the change scores in the sample as a whole between baseline and the primary  
356 endpoint, Week 20. The variance in these change scores can be used as the basis for a sample size  
357 calculation for a full-scale trial. Further information regarding differences in change scores between  
358 the treatment and control groups is given in the Supplement.

359 The DASS-21 Depression score would be the primary outcome of interest in a future full-  
360 scale trial. A decrease of 7 points on this measure would mean that everyone scoring in the moderate  
361 or severe ranges would drop into the range below. Based on the SD of the overall change score in  
362 this pilot trial (10.84), a full-scale trial comparing brief positive psychotherapy versus TAU would  
363 require  $n = 39$  per group at end-point to detect a significant difference in change scores of 7 points  
364 (two-tailed  $\alpha = 0.05$ , power = 0.80). Assuming 63% retention,  $n = 62$  would be required per  
365 group (total  $n = 124$ ).

366           Given the known non-specific benefits of receiving a trial intervention and additional contact  
367 from the research team, it would be valuable to consider a trial design comparing the intervention  
368 with an attention control rather than TAU only. In this case, a smaller decrease on DASS-21  
369 Depression would be expected. A two-arm trial of this type would require  $n = 75$  per group at end-  
370 point to detect a significant difference in change scores of 5 points (two-tailed alpha = 0.05, power =  
371 0.80). Assuming 63% retention,  $n = 120$  would be required per group (total  $n = 240$ ). Alternatively, a  
372 three-arm trial could be undertaken to compare the study intervention against both an attention  
373 control and TAU only. This would require  $n = 100$  per group at end-point to detect a significant  
374 difference in change scores of 5 points (two-tailed alpha = 0.017, power = 0.80). Assuming 63%  
375 retention,  $n = 159$  would be required per group (total  $n = 477$ ).

376

## 377 **Discussion**

378 Recruitment to this pilot trial was challenging, but we succeeded in recruiting a small sample which  
379 was representative demographically and clinically of patients with ABI, most of whom were stroke  
380 survivors. Important information was gathered regarding recruitment strategy, and good working  
381 relationships were established with a range of recruiting services. We gained an understanding of  
382 reasons for ineligibility of potential participants; in both stroke and brain injury services this was  
383 often because of length of time since injury or lack of clear evidence of definite ABI. We took steps  
384 to address the issue of time since injury by increasing the upper limit from 12 months to 36 months,  
385 but a large number of patients were beyond even this time frame, especially in the CTCBI service. In  
386 future it may be possible to make contact with patients earlier in the post-injury pathway by  
387 recruiting from in-patient services at time of discharge, and/or by recruiting from third sector  
388 organisations.

389           A key study output was the brief positive psychotherapy treatment package, including  
390 manual, workbooks and supporting materials. The treatment programme was feasible to deliver and

391 acceptable to patients, with favourable feedback regarding usability and relevance. Therapist fidelity  
392 was excellent, although the study would have benefited from the inclusion of additional treatment  
393 process measures, e.g. of client expectations and therapeutic alliance. Homework completion rates  
394 were good, despite the cognitive challenges of self-directed task completion and independent  
395 reflection on psychological concepts.

396         The dropout rate was comparable with typical rates for psychological therapies, which have  
397 previously been estimated as 20% to 47% (Swift & Greenberg, 2012; Wierzbicki & Pekarik, 1993),  
398 and was unsurprising in this clinical population where disability and comorbidity are common.  
399 Sample attrition at endpoint was similar in both study arms. Previous studies of one-to-one positive  
400 psychology interventions in samples with emotional distress have reported attrition rates of 0% to  
401 20% in the intervention group and 40% in the control group (Bolier et al., 2013). There was no  
402 indication that treatment dropout was related to the positive psychotherapy package specifically;  
403 distress was cited by one person as a reason for dropout, but in that particular case it was felt that the  
404 participant would not have engaged with any talking therapy. We acknowledge that a positive  
405 psychotherapy approach may not be well-received by some patients, especially if they perceive the  
406 intervention as not addressing the negative aspects of their experiences; we aimed to manage  
407 expectations and maximise engagement by explaining in the first treatment session that this was not  
408 a simplistic ‘positive thinking’ intervention, and by encouraging the setting of realistic goals and  
409 action plans throughout treatment. It would be important in future studies to focus in more detail on  
410 issues of therapeutic engagement, in order to improve sample retention during the intervention phase.  
411 A future trial would also benefit from a staged approach to maximise sample follow-up, moving  
412 proactively from postal contact to telephone administration and possibly face-to-face visits  
413 depending on individual participant needs. Reducing treatment dropout and non-response at follow-  
414 up would increase study power and reduce the sample recruitment load of a future trial.

415           Some limitations were found regarding the feasibility of the AHI measure, in particular one  
416 item assessing satisfaction with work. Because this measure is scored as a mean across items, it was  
417 possible to modify this for use here by excluding that item. Test-retest reliability of the AHI was  
418 high, and it has good potential as a secondary outcome to assess psychological wellbeing alongside  
419 the DASS-21. The Signature Strengths rating showed lower test-retest agreement. This was not  
420 intended to be used as an outcome measure, however, but rather as an exercise to inform goal-setting  
421 in treatment. Participants reported that this rather abstract measure was understandable and relevant  
422 to them.

423           A limitation of the study was the self-report nature of the follow-up questionnaires. Although  
424 these were handled by a blinded assessor, they reflect subjective reporting by unblinded participants.  
425 A future trial would benefit from the addition of externally rated outcome measures.

426           We conclude that a full-scale RCT of brief positive psychotherapy for emotional distress  
427 following ABI is justified and feasible. The treatment package would be largely identical, and we  
428 therefore expect to be able to incorporate data from this pilot study into a future larger analysis. This  
429 will ensure maximum value from the present study, and contribute to the efficiency of a future trial.  
430 Although the sample size here was small, we obtained sufficient information about recruitment  
431 strategy, and detailed feedback from those participants who did complete treatment, to allow us to be  
432 confident about designing and conducting a full-scale trial with a high chance of success. This will  
433 require a multi-centre approach to achieve adequate sample sizes to detect significant treatment  
434 effects.

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**Table 1** Demographic and clinical characteristics of the sample at baseline.

		<b>Overall</b>	<b>Control</b>	<b>Intervention</b>
<b>Age (years)</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	57.0 (49.0, 61.0)	58.0 (56.0, 68.0)	54.0 (46.0, 59.0)
<b>Gender</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Male <i>n</i> (%)	17 (63.0)	8 (61.5)	9 (64.3)
<b>Years of education</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	11.0 (11.0, 15.0)	11.0 (11.0, 12.0)	11.0 (11.0, 15.0)
<b>Service setting</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	CTCBI <i>n</i> (%)	3 (11.1)	1 (7.7)	2 (14.3)
	Stroke <i>n</i> (%)	24 (88.9)	12 (92.3)	12 (85.7)
<b>Diagnosis category</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	CVA (infarct) <i>n</i> (%)	22 (81.5)	11 (84.6)	11 (78.6)
	CVA (haemorrhagic) <i>n</i> (%)	2 (7.4)	1 (7.7)	1 (7.1)
	Other ABI <i>n</i> (%)	3 (11.1)	1 (7.7)	2 (14.3)
<b>Time since injury (months)</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	5.7 (3.1, 8.4)	5.6 (3.1, 8.4)	5.8 (3.5, 8.2)
<b>Seeing a psychologist</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Yes <i>n</i> (%)	13 (48.1)	7 (53.8)	6 (42.9)
<b>Taking a psychotropic medication</b>	<i>n</i> (missing)	26 (1)	12 (1)	14 (0)
	Yes <i>n</i> (%)	13 (50.0)	8 (66.7)	5 (35.7)
<b>Informant type<sup>a</sup></b>	<i>n</i> (missing)	18 (9)	8 (5)	10 (4)
	Spouse / partner <i>n</i> (%)	14 (77.8)	5 (62.5)	9 (90.0)
	Parent <i>n</i> (%)	1 (5.6)	0	1 (10.0)
	Child <i>n</i> (%)	2 (11.1)	2 (25.0)	0
	Friend <i>n</i> (%)	1 (5.6)	1 (12.5)	0

Note: ABI, acquired brain injury; CTCBI, Community Treatment Centre for Brain Injury; CVA, cerebrovascular accident.

<sup>a</sup> Inclusion of an informant in the study was optional.

**Table 2** Cognitive and questionnaire measures at baseline.

		<b>Overall</b>	<b>Control</b>	<b>Intervention</b>
<b>ToPF estimated IQ</b>	<i>n</i> (missing)	26 (1)	12 (1)	14 (0)
	Median (25th, 75th percentile)	99.00 (94.30, 106.0)	96.60 (92.35, 108.5)	101.0 (95.40, 106.0)
<b>RBANS Immediate memory</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	83.15 (15.49)	80.15 (16.73)	85.93 (14.30)
<b>RBANS Delayed memory</b>	<i>n</i> (missing)	24 (3)	12 (1)	12 (2)
	Mean (SD)	92.75 (11.62)	90.17 (9.04)	95.33 (13.64)
<b>RBANS Attention</b>	<i>n</i> (missing)	26 (1)	13 (0)	13 (1)
	Mean (SD)	93.31 (16.07)	89.54 (16.08)	97.08 (15.77)
<b>RBANS Language</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	91.96 (11.56)	89.15 (8.77)	94.57 (13.45)
<b>RBANS Visuospatial</b>	<i>n</i> (missing)	25 (2)	12 (1)	13 (1)
	Mean (SD)	99.00 (13.00)	95.33 (11.77)	102.4 (13.60)
<b>Longest digit span forward</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25th, 75th percentile)	7.00 (5.00, 8.00)	7.00 (5.00, 7.00)	7.00 (5.00, 8.00)
<b>Longest digit span backward</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25th, 75th percentile)	4.00 (3.00, 6.00)	4.00 (3.00, 5.00)	4.50 (4.00, 6.00)
<b>Letter fluency total</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Median (25th, 75th percentile)	32.00 (25.00, 41.00)	26.00 (23.00, 37.00)	32.50 (28.00, 41.00)
<b>Similarities T-score</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	44.44 (8.25)	45.31 (11.39)	43.64 (3.88)
<b>DASS-21 Depression</b>	<i>n</i> (missing)	26 (1)	12 (1)	14 (0)
	Mean (SD)	24.19 (10.51)	27.58 (9.55)	21.29 (10.74)
<b>DASS-21 Anxiety</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	19.26 (9.51)	21.08 (9.37)	17.57 (9.68)
<b>DASS-21 Stress</b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	25.93 (7.37)	28.15 (6.08)	23.86 (8.06)
<b>AHI mean score<sup>a</sup></b>	<i>n</i> (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	2.40 (0.43)	2.39 (0.45)	2.41 (0.44)
<b>AQ score difference<sup>b,c</sup></b>	<i>n</i> (missing)	14 (13)	7 (6)	7 (7)
	Median (25th, 75th percentile)	2.00 (-7.00, 4.00)	3.00 (1.00, 7.00)	-7.00 (-13.0, 3.00)
<b>MPAI-4 total (participant)</b>	<i>n</i> (missing)	26 (1)	13 (0)	13 (1)
	Mean (SD)	54.23 (5.32)	55.92 (5.99)	52.54 (4.10)
<b>MPAI-4 total (informant)<sup>c</sup></b>	<i>n</i> (missing)	10 (17)	4 (9)	6 (8)
	Mean (SD)	49.00 (11.74)	44.00 (15.38)	52.33 (8.52)

<b>M-CSI<sup>c</sup></b>	<i>n</i> (missing)	12 (15)	6 (7)	6 (8)
	Median (25th, 75th percentile)	5.50 (2.50, 9.00)	5.00 (1.00, 13.00)	7.00 (4.00, 9.00)

Note: AHI, Authentic Happiness Inventory; AQ, Awareness Questionnaire; DASS-21, Depression Anxiety Stress Scales short form; IQR, interquartile range; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status; SD, standard deviation; ToPF IQ, Test of Premorbid Functioning intelligence quotient.

<sup>a</sup> Score from first baseline administration, excluding item 15.

<sup>b</sup> AQ score difference was calculated by subtracting the informant score from the patient score; positive values indicate better perceived functioning by the patient relative to the informant.

<sup>c</sup> Inclusion of an informant in the study was optional.

**Table 3** Change scores on outcome measures from baseline to Week 20, for both groups combined.

	<b>Mean change score</b>	<b>SD</b>	<b><i>n</i></b>
<b>DASS-21 Depression</b>	-5.87	10.84	15
<b>DASS-21 Anxiety</b>	-4.80	9.85	15
<b>DASS-21 Stress</b>	-5.20	5.80	15
<b>AHI mean score</b>	0.02	0.47	17
<b>MPAI-4 total (participant)</b>	-1.89	6.95	9
<b>MPAI-4 total (informant)<sup>a</sup></b>	0.40	10.11	5
<b>M-CSI<sup>a</sup></b>	-3.00	2.16	4

Note: AHI, Authentic Happiness Inventory; DASS-21, Depression Anxiety Stress Scales short form; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; SD, standard deviation. Negative values indicate improvement, except AHI where positive value indicates improvement. AHI mean scores exclude item 15. The mean interval between baseline and endpoint was 23.3 weeks (SD = 2.3).

<sup>a</sup> Inclusion of an informant in the study was optional.

## Figure legends

### Figure 1 Participant flow through study.

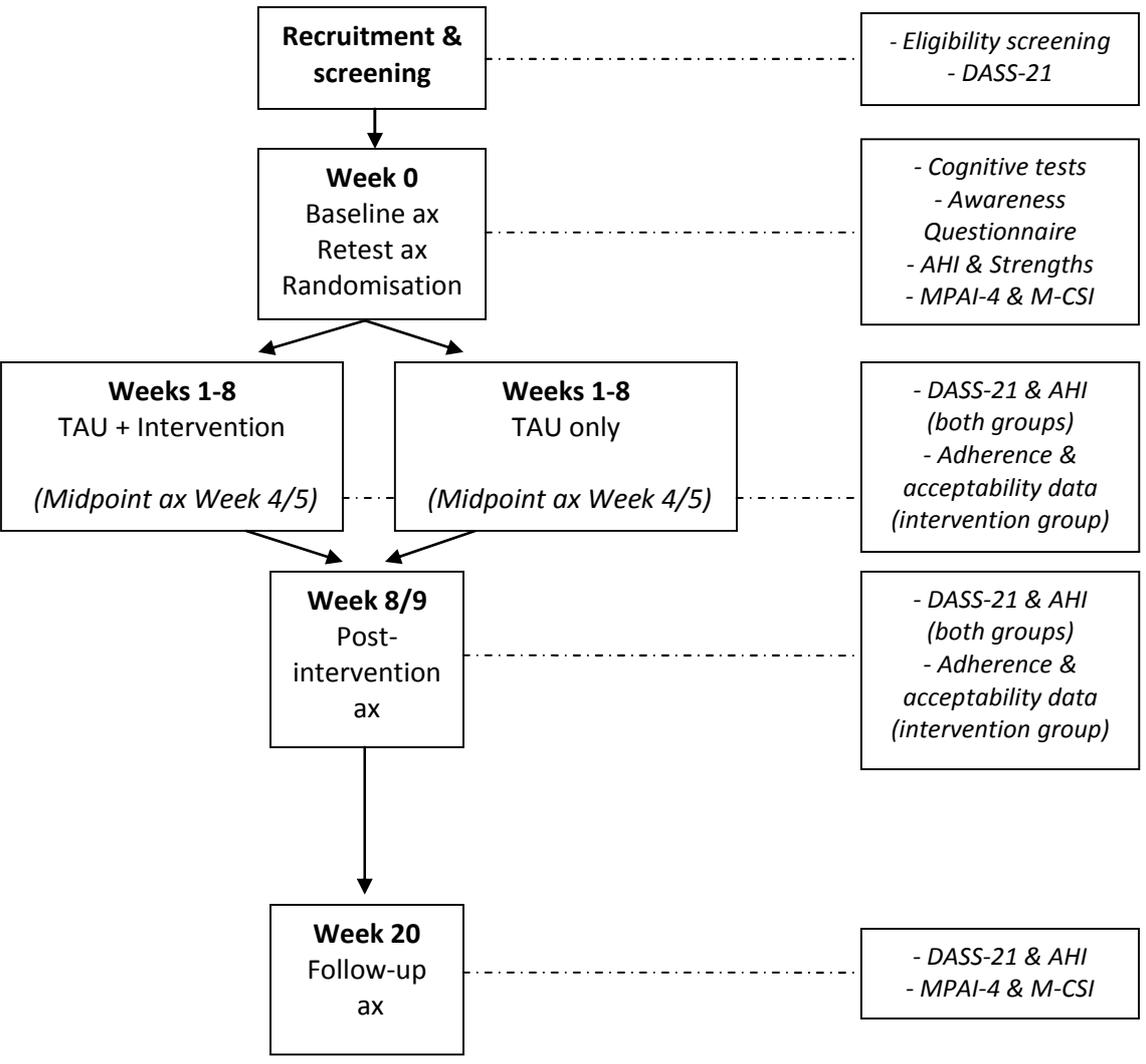
Note: AHI, Authentic Happiness Inventory; Ax, assessment; DASS-21, Depression Anxiety Stress Scales short form; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; TAU, treatment as usual.

### Figure 2 Schedule of assessments.

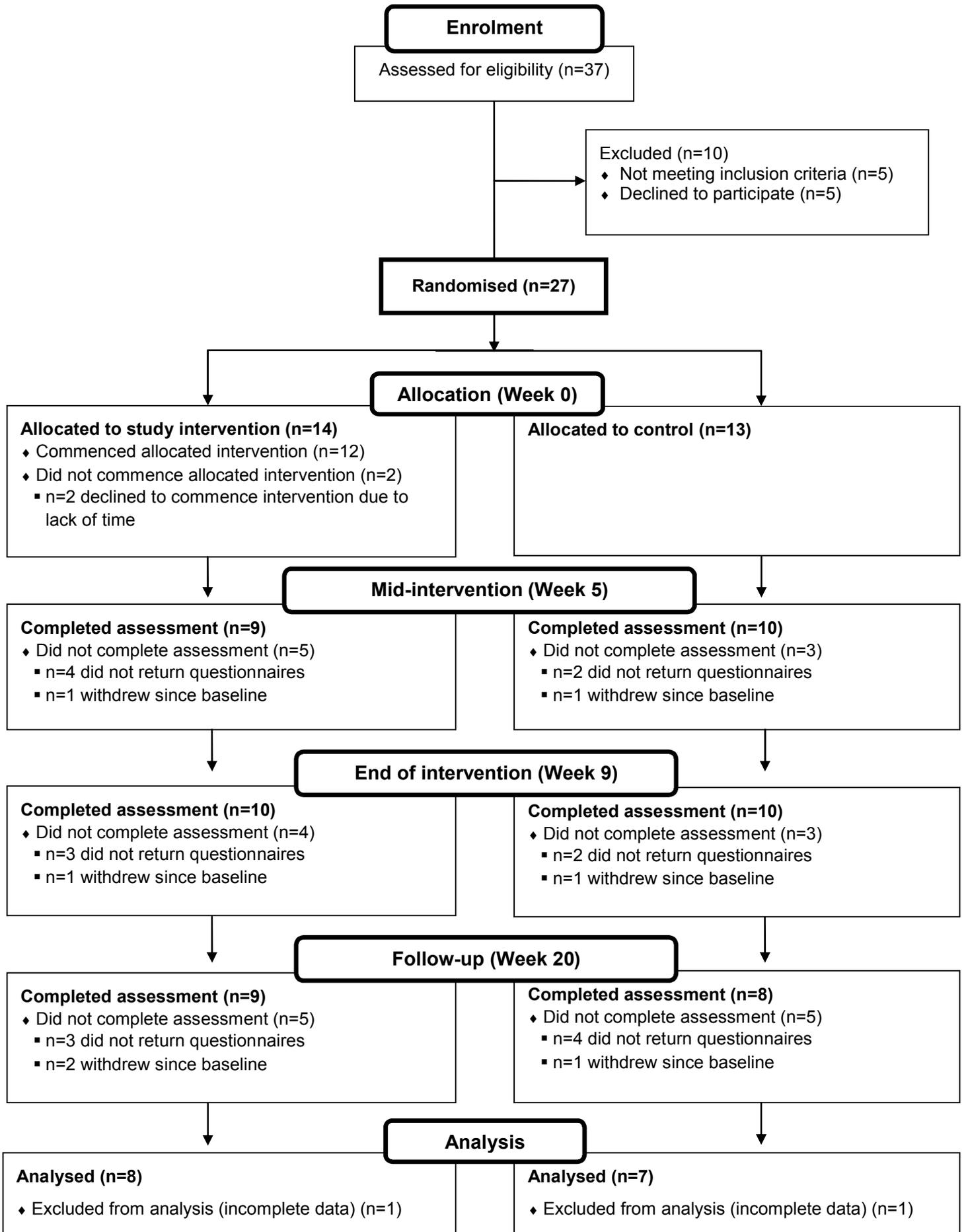
Note: AHI, Authentic Happiness Inventory; AQ, Awareness Questionnaire; DASS-21, Depression Anxiety Stress Scales short form; FAST, Frenchay Aphasia Screening Test; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status; ToPF, Test of Premorbid Functioning; WAIS-IV, Wechsler Adult Intelligence Scale 4<sup>th</sup> edition; WASI-II, Wechsler Abbreviated Scale of Intelligence 2<sup>nd</sup> edition.

### Figure 3 CONSORT flowchart.

Note: The sample size for analysis (total  $n = 15$ ) refers to the analysis of sample size calculations for a future full-scale trial, based on the DASS-21 outcome data. The analysis sample for other results reported was  $n = 17$ .



Assessment	Construct	Screen	Week 0	Re-test	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 20
DASS-21	Emotional distress	X							X				X	X
FAST	Aphasia	X												
ToPF	Premorbid ability		X											
RBANS	Cognitive function		X											
WAIS-IV Digit Span	Cognitive function		X											
WASI-II Similarities	Cognitive function		X											
Letter fluency	Cognitive function		X											
AQ (patient)	Awareness		X											
AQ (informant)	Awareness		X											
MPAI-4 (patient)	Overall function		X											X
MPAI-4 (informant)	Overall function		X											X
M-CSI (informant)	Carer strain		X											X
AHI	Wellbeing		X	X					X				X	X
Signature Strengths	Character strengths		X	X										
Feedback on AHI and Signature Strengths	Acceptability			X										
Attendance/homework/content feasibility (intervention arm only)	Acceptability, feasibility				X	X	X	X	X	X	X	X		
Feedback on treatment acceptability (intervention arm only)	Acceptability							X				X		



## Supplementary Results

### *Change on outcome measures at primary endpoint (Week 20)*

This study was not designed or powered to test the efficacy of the positive psychotherapy intervention. We include the additional results below to illustrate how such an analysis would be undertaken in a future full-scale trial with adequate sample size.

Table S1 below shows differences in mean change scores between baseline and Week 20 on each outcome measure, adjusted using analysis of covariance for service setting (stroke vs CTCBI) and baseline scores. Participants were grouped on an intention to treat basis. Mean time between assessments was 23.3 weeks (SD = 2.3). Participants with complete questionnaire data at both timepoints were included. Results for the M-CSI and the informant MPAI-4 are not reported due to very small sample sizes.

**Table S1** Differences in change scores between baseline and Week 20.

	Control change score M (SD)	Intervention change score M (SD)	Adjusted mean difference <sup>a</sup> (95% CI)	Effect size <i>d</i> (95% CI)	<i>p</i>	Control <i>n</i>	Intervention <i>n</i>
<b>DASS-21 Depression</b>	-3.71 (10.16)	-7.75 (11.73)	-7.96 (-19.7, 3.78)	0.73 (-0.34, 1.80)	0.250	7	8
<b>DASS-21 Anxiety</b>	0.57 (10.63)	-9.50 (6.57)	-9.64 (-16.6, -2.66)	1.09 (0.30, 1.88)	0.030	7	8
<b>DASS-21 Stress</b>	-2.29 (5.35)	-7.75 (5.18)	-5.78 (-10.9, -0.69)	1.10 (0.13, 2.06)	0.066	7	8
<b>AHI mean score</b>	-0.23 (0.32)	0.24 (0.49)	0.45 (0.08, 0.83)	1.11 (0.20, 2.02)	0.050	8	9
<b>MPAI-4 total (participant)</b>	0.50 (8.89)	-3.80 (5.22)	-3.07 (-16.7, 10.53)	0.42 (-1.44, 2.29)	0.676	4	5

Note: AHI, Authentic Happiness Inventory; CI, confidence interval; DASS-21, Depression Anxiety Stress Scales short form; M, mean; MPAI-4, Mayo-Portland Adaptability Inventory; SD, standard deviation. Decreases on scores indicate improvement, except AHI where increase indicates improvement. Positive *d* values favour intervention. AHI mean scores exclude item 15.

<sup>a</sup> Adjusted using analysis of covariance for service setting (stroke vs CTCBI) and baseline scores.

A sensitivity analysis was carried out including imputed scores for missing questionnaire items; this resulted in a small increase in sample sizes but did not alter the substance of the results. It should be noted that although Week 20 was intended to be a follow-up assessment (12 weeks after the end of the treatment phase), several intervention participants had completed their treatment programme later than planned as a result of appointment cancellations and breaks in contact with the therapist. Consequently, the effects reported above may be post-treatment rather than follow-up effects for some participants.