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

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Abstract

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

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

Introduction

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

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

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

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

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

Primary research question

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

Secondary research questions

(ii) Is a brief positive psychotherapy intervention feasible to deliver in an out-patient setting with patients presenting with emotional distress following ABI?

(iii) Are positive psychology assessment tools reliable in people with ABI?

(iv) Is a full-scale RCT of brief positive psychotherapy indicated, and if so, what is the required sample size?

Methods

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

[Figure 1 about here]

Participants

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

Inclusion criteria:

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

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

Exclusion criteria:

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

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

Materials and Procedure

Figure 2 shows the schedule of assessments.

Recruitment and screening

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

Baseline measures and randomisation (Week 0)

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

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

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

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

Intervention phase (Weeks 1 to 8 inclusive)

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

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

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

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

[Figure 2 about here]

Summary of outcome measures

Primary outcome measures:

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

Secondary outcome measures:

- Test-retest reliability of AHI and Signature Strengths inventory;
- Change in DASS-21 scores at 20 weeks from baseline;
- Changes in AHI, MPAI-4 and M-CSI scores at 20 weeks from baseline;
- Ratings of participants' and therapist's experience of treatment delivery.

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

Treatment fidelity

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

Randomisation and bias prevention

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

Sample size and statistical methods

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

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

Results

Characteristics of the sample

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

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

[Figure 3 about here]

[Tables 1 and 2 about here]

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

Acceptability and reliability of positive psychology measures

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

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

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

Feasibility and acceptability of the brief positive psychotherapy intervention

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

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

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

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

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

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

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

Retention to Week 20 endpoint

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

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

Success of blinding

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

[Table 3 about here]

Sample size calculation for full-scale trial

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

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

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

Discussion

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

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

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

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

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

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

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

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

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

Note: ABI, acquired brain injury; CTCBI, Community Treatment Centre for Brain Injury; CVA, cerebrovascular accident.
[a] Inclusion of an informant in the study was optional.

Table 2 Cognitive and questionnaire measures at baseline.

		Overall	Control	Intervention
ToPF estimated IQ	*n* (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)
RBANS Immediate memory	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	83.15 (15.49)	80.15 (16.73)	85.93 (14.30)
RBANS Delayed memory	*n* (missing)	24 (3)	12 (1)	12 (2)
	Mean (SD)	92.75 (11.62)	90.17 (9.04)	95.33 (13.64)
RBANS Attention	*n* (missing)	26 (1)	13 (0)	13 (1)
	Mean (SD)	93.31 (16.07)	89.54 (16.08)	97.08 (15.77)
RBANS Language	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	91.96 (11.56)	89.15 (8.77)	94.57 (13.45)
RBANS Visuospatial	*n* (missing)	25 (2)	12 (1)	13 (1)
	Mean (SD)	99.00 (13.00)	95.33 (11.77)	102.4 (13.60)
Longest digit span forward	*n* (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)
Longest digit span backward	*n* (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)
Letter fluency total	*n* (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)
Similarities T-score	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	44.44 (8.25)	45.31 (11.39)	43.64 (3.88)
DASS-21 Depression	*n* (missing)	26 (1)	12 (1)	14 (0)
	Mean (SD)	24.19 (10.51)	27.58 (9.55)	21.29 (10.74)
DASS-21 Anxiety	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	19.26 (9.51)	21.08 (9.37)	17.57 (9.68)
DASS-21 Stress	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	25.93 (7.37)	28.15 (6.08)	23.86 (8.06)
AHI mean score[a]	*n* (missing)	27 (0)	13 (0)	14 (0)
	Mean (SD)	2.40 (0.43)	2.39 (0.45)	2.41 (0.44)
AQ score difference[b,c]	*n* (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)
MPAI-4 total (participant)	*n* (missing)	26 (1)	13 (0)	13 (1)
	Mean (SD)	54.23 (5.32)	55.92 (5.99)	52.54 (4.10)
MPAI-4 total (informant)[c]	*n* (missing)	10 (17)	4 (9)	6 (8)
	Mean (SD)	49.00 (11.74)	44.00 (15.38)	52.33 (8.52)

M-CSI[c]	*n* (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.

[a] Score from first baseline administration, excluding item 15.

[b] 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.

[c] 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.

	Mean change score	SD	*n*
DASS-21 Depression	-5.87	10.84	15
DASS-21 Anxiety	-4.80	9.85	15
DASS-21 Stress	-5.20	5.80	15
AHI mean score	0.02	0.47	17
MPAI-4 total (participant)	-1.89	6.95	9
MPAI-4 total (informant)[a]	0.40	10.11	5
M-CSI[a]	-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).

[a] Inclusion of an informant in the study was optional.

Figure legends

Figure 1 Participant flow through study.

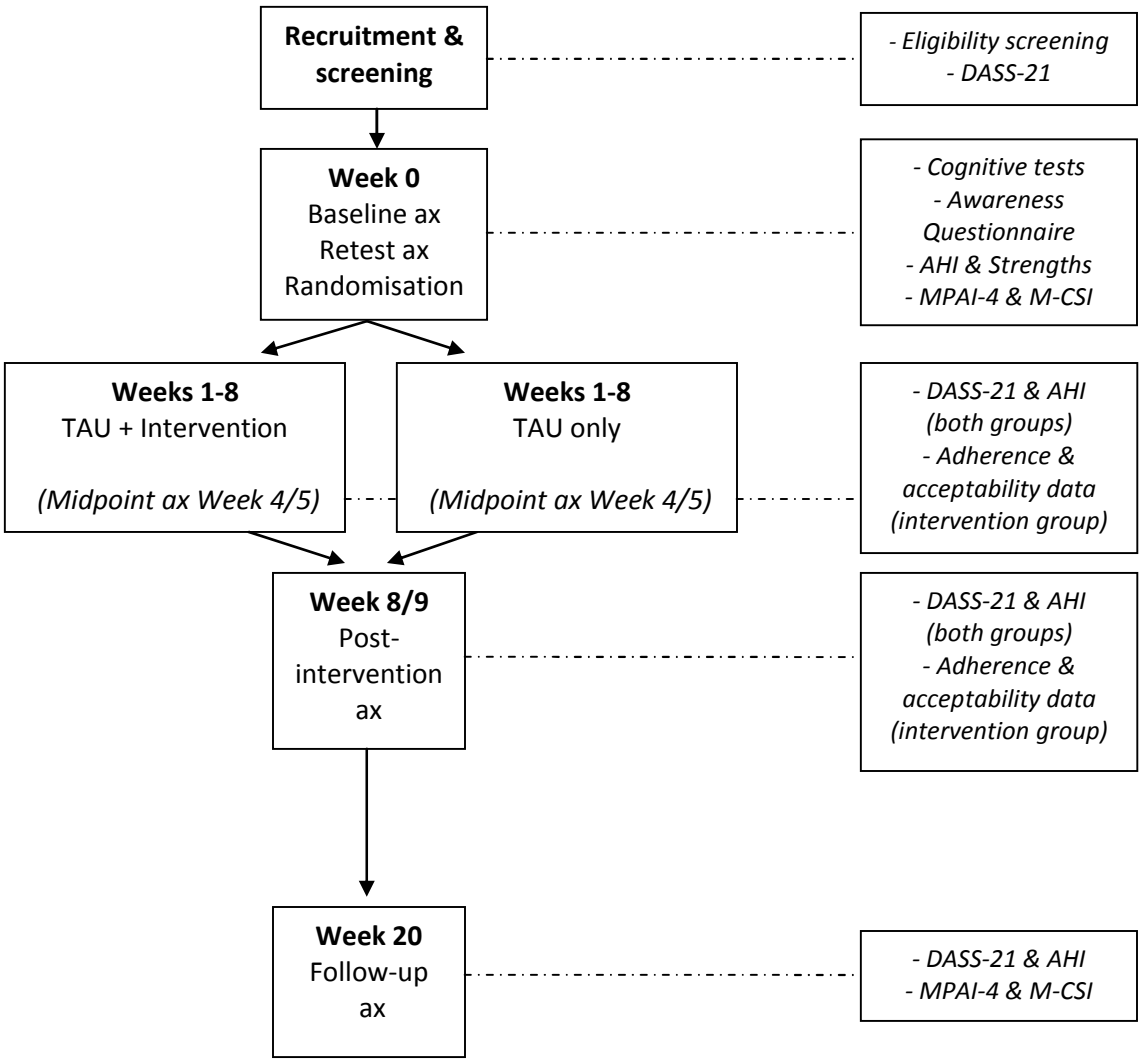
Note: AHI, Authentic Happiness Inventory; Ax, assessment; DASS-21, Depression Anxiety Stress Scales short form; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; TAU, treatment as usual.

Figure 2 Schedule of assessments.

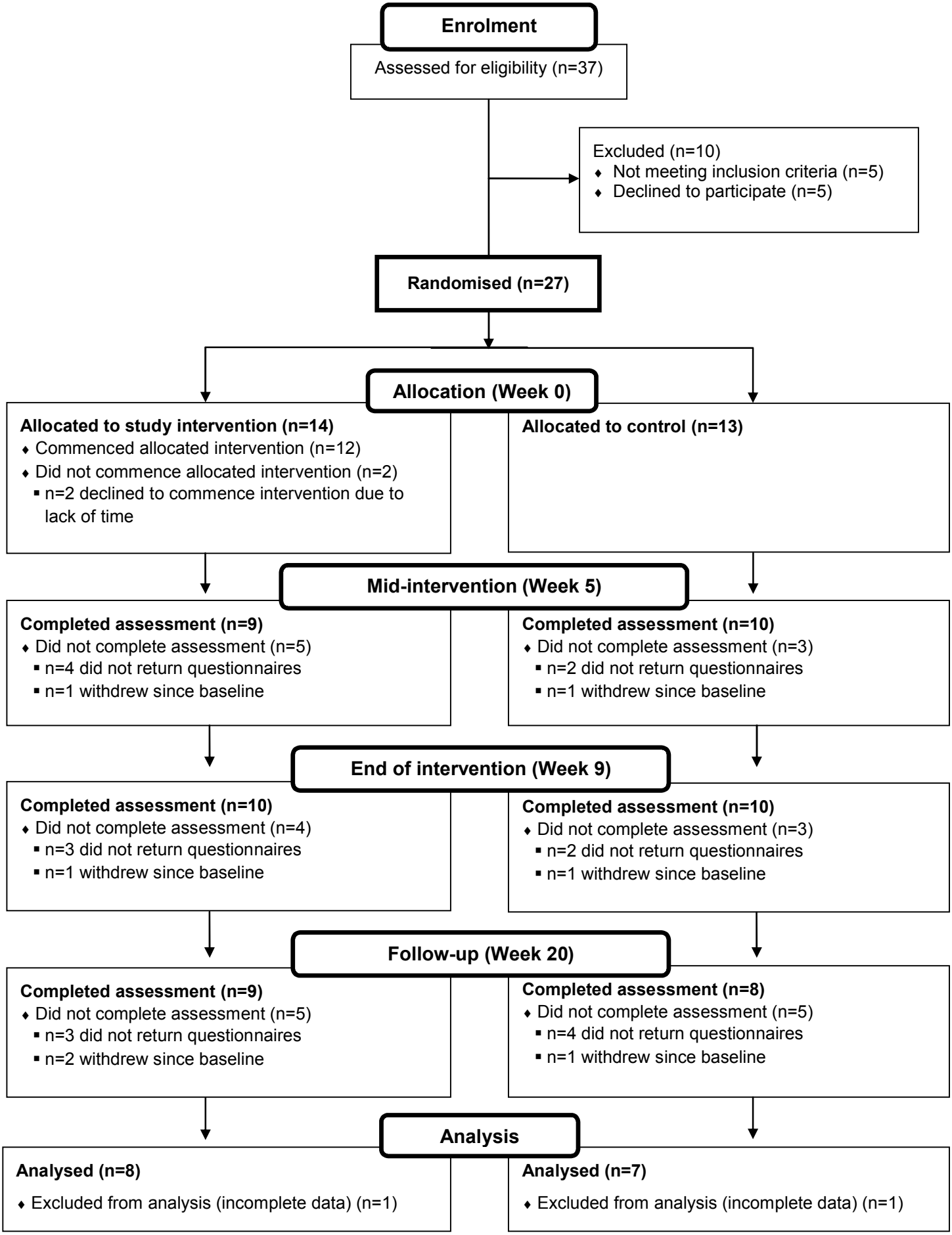
Note: AHI, Authentic Happiness Inventory; AQ, Awareness Questionnaire; DASS-21, Depression Anxiety Stress Scales short form; FAST, Frenchay Aphasia Screening Test; M-CSI, Modified Caregiver Strain Index; MPAI-4, Mayo-Portland Adaptability Inventory; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status; ToPF, Test of Premorbid Functioning; WAIS-IV, Wechsler Adult Intelligence Scale 4th edition; WASI-II, Wechsler Abbreviated Scale of Intelligence 2nd 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 $n = 17$.


Recruitment & screening
- Eligibility screening
- DASS-21
Week 0
Baseline ax
Retest ax
Randomisation
- Cognitive tests
- Awareness Questionnaire
- AHI & Strengths
- MPAI-4 & M-CSI
Weeks 1-8
TAU + Intervention
(Midpoint ax Week 4/5)
Weeks 1-8
TAU only
(Midpoint ax Week 4/5)
- DASS-21 & AHI (both groups)
- Adherence & acceptability data (intervention group)
Week 8/9
Post-intervention ax
- DASS-21 & AHI (both groups)
- Adherence & acceptability data (intervention group)
Week 20
Follow-up ax
- DASS-21 & AHI
- MPAI-4 & M-CSI

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		


Enrolment
Assessed for eligibility (n=37)
Excluded (n=10)
♦ Not meeting inclusion criteria (n=5)
♦ Declined to participate (n=5)
Randomised (n=27)
Allocation (Week 0)
Allocated to study intervention (n=14)
♦ Commenced allocated intervention (n=12)
♦ Did not commence allocated intervention (n=2)
▪ n=2 declined to commence intervention due to lack of time
Allocated to control (n=13)
Mid-intervention (Week 5)
Completed assessment (n=9)
♦ Did not complete assessment (n=5)
▪ n=4 did not return questionnaires
▪ n=1 withdrew since baseline
Completed assessment (n=10)
♦ Did not complete assessment (n=3)
▪ n=2 did not return questionnaires
▪ n=1 withdrew since baseline
End of intervention (Week 9)
Completed assessment (n=10)
♦ Did not complete assessment (n=4)
▪ n=3 did not return questionnaires
▪ n=1 withdrew since baseline
Completed assessment (n=10)
♦ Did not complete assessment (n=3)
▪ n=2 did not return questionnaires
▪ n=1 withdrew since baseline
Follow-up (Week 20)
Completed assessment (n=9)
♦ Did not complete assessment (n=5)
▪ n=3 did not return questionnaires
▪ n=2 withdrew since baseline
Completed assessment (n=8)
♦ Did not complete assessment (n=5)
▪ n=4 did not return questionnaires
▪ n=1 withdrew since baseline
Analysis
Analysed (n=8)
♦ Excluded from analysis (incomplete data) (n=1)
Analysed (n=7)
♦ Excluded from analysis (incomplete data) (n=1)

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[a] (95% CI)	Effect size *d* (95% CI)	*p*	Control *n*	Intervention *n*
DASS-21 Depression	-3.71 (10.16)	-7.75 (11.73)	-7.96 (-19.7, 3.78)	0.73 (-0.34, 1.80)	0.250	7	8
DASS-21 Anxiety	0.57 (10.63)	-9.50 (6.57)	-9.64 (-16.6, -2.66)	1.09 (0.30, 1.88)	0.030	7	8
DASS-21 Stress	-2.29 (5.35)	-7.75 (5.18)	-5.78 (-10.9, -0.69)	1.10 (0.13, 2.06)	0.066	7	8
AHI mean score	-0.23 (0.32)	0.24 (0.49)	0.45 (0.08, 0.83)	1.11 (0.20, 2.02)	0.050	8	9
MPAI-4 total (participant)	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.
[a] 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.