

2022-10-10

The efficacy of therapist-supported acceptance and commitment therapy-based bibliotherapy for psychological distress after stroke: a single-case multiple-baseline study

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<http://hdl.handle.net/10026.1/19701>

10.1017/s135246582200042x

Behavioural and Cognitive Psychotherapy

Cambridge University Press

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The efficacy of therapist-supported Acceptance and Commitment Therapy-based bibliotherapy for psychological distress after stroke: A single-case multiple-baseline study.

Journal:	<i>Behavioural and Cognitive Psychotherapy</i>
Manuscript ID	BCP-02057-21.R2
Manuscript Type:	Main
Keywords:	stroke, acceptance and commitment therapy (ACT), self-management
Abstract:	<p>Abstract</p> <p>Background: Psychological distress is common after stroke and affects recovery. However, there are few evidence-based psychological treatments. This study evaluates a bibliotherapy-based approach to their amelioration.</p> <p>Aims: To investigate a stroke-specific self-management book, based on Acceptance and Commitment Therapy (ACT), as a therapist-supported intervention for psychological distress after stroke.</p> <p>Method: The design was a single case, randomised non-concurrent multiple-baseline design (MBD). Sixteen stroke survivors, eight males and eight females (mean age 60.6 years), participated in an MBD with three phases: A (randomised-duration baseline); B (Intervention); Follow-up (at 3-weeks). During the baseline, participants received therapist contact only. In the bibliotherapy intervention, participants received bi-weekly therapist support. The primary measures of psychological distress (General Health Questionnaire-12—GHQ-12) and quality of life (Satisfaction with Life Scale--SWLS) were completed weekly. Secondary measures of mood, wellbeing and illness impact were completed pre- and post-intervention.</p> <p>Results: Omnibus whole-group TAU-U analysis was statistically significant for each primary measure with a moderate effect size on both (0.6 and 0.3 for GHQ-12 and SWLS, respectively). Individual TAU-U analyses demonstrated the majority of individuals exhibited positive change. All the secondary measures showed significant pre-post improvements. Eighty-one percent of participants reported the book was helpful and 81% also found the ACT-based sections helpful. Relative risk calculations showed finding the book helpful was associated with improvement in GHQ and SWLS scores.</p> <p>Conclusions: ACT-based bibliotherapy, with therapist support, is a promising intervention for psychological difficulties after stroke.</p>

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Running Title:
Efficacy of bibliotherapy for stroke.

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Conclusions: ACT-based bibliotherapy, with therapist support, is a promising intervention for psychological difficulties after stroke.

Key Words

Stroke, Acceptance and Commitment Therapy, Bibliotherapy, self-management

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Introduction

Stroke is accompanied by anxiety in about 25% of people (Cambell Burton et al., 2013) and by depression in 29% (Ayerbe et al., 2018). Psychological distress is associated with impeded rehabilitation (Ahn et al., 2015), impaired functional outcomes (Ayerbe et al., 2014; Chun et al., 2018a; Chun et al., 2018b), restricted activities of daily living (Tsuchiya et al., 2016) and increased mortality (Bartoli et al., 2013). Length of hospital stays (Sugawara et al., 2015) and healthcare costs (Naylor et al., 2012) are also greater in the presence of challenges such as cognition, affective disorders, fatigue and disability that are associated with psychological distress. Cognitive impairment occurs commonly after stroke (Nys et al., 2007); about 15% of stroke survivors had cognitive test scores indicative of impaired activities of daily life and the need for supported living arrangements (Liman et al., 2012). Fatigue is often another barrier to readjustment after stroke (Acciarresi et al., 2014).

Despite the importance of addressing psychological factors after stroke, several reviews (Allida et al., 2020; Campbell-Burton et al., 2011; Gillespie et al., 2015; Hackett et al., 2008; Wu, et al., 2015) identified few psychological treatment approaches with a sound evidence-base. Consequently, national guidelines (Intercollegiate Stroke Working Party---ICSWP-UK, The Royal College of Physicians, 2016; National Institute for Health and Care Excellence (NICE), 2013/2018) recommend few psychological treatments specifically for stroke. For example, the ICSWP recommends four treatments or preventative approaches for low mood: motivational interviewing based on one RCT, for which a subsequent pilot RCT failed to find any benefit (Kerr et al., 2018); behaviour therapy based on one RCT;

problems solving therapy based on two RCTs. While a meta-analysis suggested benefit of CBT after stroke for Chinese samples (Wang, et al., 2018), the authors urge caution due to heterogeneity and low quality (61%) of the studies and lack of corroboration in two European studies. To date, CBT has not been recommended for stroke-specific psychological disorders in UK stroke guidance.

Cost-effective approaches to psychological therapy after stroke are urgently needed in view of their high prevalence and impact in the context of limited resources for psychological care (The Royal College of Physicians, 2015). Transdiagnostic therapeutic approaches such as Acceptance and Commitment Therapy (ACT) (Hayes, 2004) have the potential to address a wide range of psychological and behavioural problems without requiring staff training in several diagnosis-specific therapy protocols. ACT simplifies the treatment of emotional difficulties by targeting shared aetiological processes underpinning multiple forms of emotional distress (Gros et al., 2016). Kangas and MacDonald (2011) concluded their review of CBT for acquired brain injury with a recommendation for research into ACT with this population, stimulating two Randomised Controlled Trials. For people with elevated psychological distress after brain injury, ACT therapy was beneficial in the short-term compared to a befriending control condition, although other indices of recovery did not show improvement (Whiting et al., 2020). Sander et al. (2020) found that ACT for people exhibiting psychological distress after traumatic brain injury reduced psychological distress, compared to a counselling/education intervention. However, the control intervention in this study lacked equivalence to the ACT intervention. There is now also growing evidence for ACT's effectiveness in reducing psychological distress and enhancing psychological wellbeing after stroke (Graham

et al., 2016; Majumder & Morris, 2019). Reviews have concluded that ACT is cost-effective, readily translates to different settings (Ruiz, 2010) and can be delivered in low-intensity formats (Dindo et al., 2017). In addition, stroke survivors reported that ACT helped them to adjust to the consequences of stroke (Large et al., 2019). Consistent with its transdiagnostic foundations, ACT's focus is not a single psychological difficulty or symptom. Instead, it addresses broader psychological processes encompassed as 'psychological flexibility'. Psychological flexibility derives from a capacity to engage positively with six core psychological processes that form the central tenets of the ACT model (Hayes, 2004). The relevance of psychological flexibility and its constituent processes to people with psychological distress after a stroke was succinctly summarised by Majumdar and Morris (2019). They pointed out that the health model underpinning ACT is conducive to the promotion of wellbeing rather than simply symptom reduction; the emphasis on acceptance of psychological distress and 'getting on with life' has application where there are enduring disabilities following stroke; the focus on mindfulness and 'being in the present' encourages a person to make contact with their surroundings and to experiences beyond their disability and psychological distress; building 'self-as-context', an observing self that is separate from the experience of psychological distress, counters negative changes in self-identity after stroke; the discovery of a person's core values to pursue value-driven 'committed action' may represent an improvement on current goal setting practice in stroke.

Another advantage of ACT is that it is readily disseminated and administered in different formats (Assaz et al., 2018; Dindo et al., 2017). Cost-effective delivery of psychological interventions is vital in the context of restricted healthcare funding

(Luchinskaya et al., 2017). Many of the delivery formats of existing therapies are resource intensive, requiring one-to-one delivery, coupled with adaptation and specialised training for different conditions (Majumdar & Morris, 2019). Cost savings can be made by group delivery, delivery by associate grade staff working under supervision or bibliotherapy (with therapist support or alone). Bibliotherapy has potential to be cost-effective in stroke. It was shown to be cost-effective for behavioural disorders in children when compared with therapist-led interventions (Sampaio et al., 2016) and a review, (Latchem & Greenhalgh, 2014), concluded that self-management is effective in neurological conditions including head injury, dementia and stroke. Several meta-analyses including bibliotherapy have confirmed that bibliotherapy, alone or with therapist support, is effective for psychological treatment of emotional disorders (Cuijpers et al., 2010; Den Boer et al., 2004; Hirai & Clum, 2006).

Bibliotherapy, which is the provision of psychological therapy through books or other written materials, may be particularly suited to the stroke population since it can be self-paced and is accessible by people with mobility restrictions (Jacobs & Mosco, 2008). Moreover, it can be delivered through existing public library networks (Chamberlain et al., 2008). The aim of the present study was to investigate the efficacy of a self-management book for stroke (*'Rebuilding your life after stroke'*, Morris et al., 2017) which uses ACT as its core model. The ACT section of the book was broadly based on material used in a study of group therapy (Majumdar & Morris, 2019) where it demonstrated efficacy with a group of stroke survivors. Acceptance of psychological distress is a key goal of ACT and was identified as a high research priority by a panel of stroke survivors, caregivers and health clinicians (Pollock et al.,

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2014). The ACT programme in the book aimed to increase acceptance of the effects of stroke as a facet of psychological flexibility that promotes positive outcomes (Kashdan, 2010).

It was hypothesised that bibliotherapy, used with therapist support, would reduce psychological distress and improve satisfaction with life. The bibliotherapy was self-administered and self-paced and the book consists of two distinct sections and eight chapters. Therefore, in order to facilitate its effective use over the intervention period, this study used a ‘small-N’ replicated single case, non-concurrent multiple baseline design (MBD) (Watson & Workman, 1981) with therapist support, in preference to a group-based RCT. The primary outcome measures were brief measures chosen to assess changes in distress and satisfaction with life over the course of the bibliotherapy, while the secondary outcome measures provided a more detailed assessment of change in common psychological problems after stroke as well as wellbeing and the impact of stroke.

Methods

Ethics

This study abided by the ethical principles of the BPS and BABCP. This study was approved through the integrated research applications system (IRAS) for NHS ethics, IRAS ID 232266. Research and Development Department permission was granted by four Health Boards/Trusts (three in south Wales, one in south-west England). Three stroke survivors were consulted during the design of the study. They suggested that individual support from a therapist should be included.

Design and Analysis

The study employed a small-N single case non-concurrent MBD. The design was non-concurrent to improve feasibility (Watson & Workman, 1981). In this design control for threats to internal validity are ameliorated through (1) a baseline phase of random duration and (2) frequent measurement throughout the baseline and intervention phases. Randomisation was achieved by randomising baseline duration and the start of the intervention. This staggered the intervention across participants and permitted randomised controlled comparisons. To improve sensitivity to change, outcomes were measured frequently at short time intervals.

Participants all started with a randomised, pre-determined length, baseline phase (see Supplementary Material 1 for details) so that entry into the intervention stage was staggered, and randomised, which allows quasi-control for time and maturation effects (Rhoda et al., 2011). Staggering the baseline involved some participants remaining in the baseline phase when intervention for others began. This process permits interpretation through controlling for whole-sample confounding factors e.g. alteration in general care practice in stroke and current events. Primary measures were taken weekly and secondary measures at the start and end of each phase. The statistical analysis method was designed specifically for MBDs and partialled out baseline effects from the intervention results ([//www.singlecase.org/calculators](http://www.singlecase.org/calculators)) (Vannest et al., 2016).

Sample Size and Phases

The MBD included 32 phases (16 participants, each with a baseline and intervention) and weekly observations. All the baseline and intervention phases had at least three

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observations due to practical issues with starting the intervention for some participants. Initially minimum baseline points had been set at 2 weeks following advice received by the ethical committee which advised that the feasibility of the study could be compromised through long baselines and the likelihood of dropout due to the complex nature of the participant population (see Supplementary Material 1). The interventions were self-paced and ranged from three to sixteen weeks. Based on a quality recommendation for concurrent MBDs – where overlap between phases is a part of the design (Kratochwill et al., 2013), the planned design exceeded the quality standard for the number of phases (6) and met the quality standard for data points per phase for 11 of the 16 baseline phases and 14 of 16 intervention phases. All the remaining phases (7) met the quality standard ‘with reservations’.

Recruitment

Since the problems of simultaneous recruitment in multiple baseline design are well documented (Graham et al., 2012) this study recruited participants at point of referral into the study. In line with guidelines that community interventions should be provided irrespective of time since stroke (The Royal College of Physicians, 2016), time since stroke was not used as an exclusion criterion.

Recruitment was from three Health Boards in Wales and one Health Trust in southwest England and two stroke charities. Leaflets providing brief information about the study were provided to staff and passed on to clients. Signed informed consent was obtained by the researcher. No financial/reward incentives were used. Inclusion and exclusion criteria were assessed by interview by the first author.

Inclusion:

- a clinical diagnosis of at least one stroke.
- 18 years of age or above
- reporting psychological distress to a referring clinician/key worker
- ability to read a book.

Exclusion:

- diagnosis of serious psychiatric problems such as psychosis
- diagnosis of a progressive, degenerative disorder
- serious communicative difficulties, such as aphasia
- traumatic brain injury

Further details of recruitment and attrition can be found in Supplementary Material 2.

Materials

The self-management book, '*Rebuilding your life after stroke*' (Morris et al., 2017) is available free of charge in the UK through the Reading Agency, 'Books on Prescription' Scheme (<https://reading-well.org.uk/books/books-on-prescription>). The book was written by stroke clinicians and stroke survivors to address common post-stroke psychological difficulties. The book is divided into four parts: Part 1, *Introduction* to the book, its scope, navigation and materials; Part 2, *What is happening to me?* About common psychological distress after stroke; Part 3, *Rebuilding your life after stroke*. The ACT-based content: Part 4, *Summary*. A synthesis and ideas for the future. There are also lists of stroke-related resources at the end. The book is designed with spiral binding so it can be read one-handed. (See Supplementary Material 3 for the Contents Page of the book.)

The book provides practical guidance for the management of common psychological and behavioural problems after stroke in Part 2 and takes Acceptance and Commitment Therapy (ACT) as the core model for approaching more intractable forms of psychological distress in Part 3. The book has linked audio-visual files on YouTube for practising ACT-based exercises and of interviews with stroke survivors.

Measures

Socio-demographical information

Information was collected about age, gender, date of first and most recent stroke, type of stroke, and current psychiatric/psychological treatments.

Primary measures

Since the primary measures were self-assessment measures, the standard of inter-observer agreement for MBDs (Kratochwill et al., 2013) was not applicable.

Reliability of the measures is instead attested by the demonstration of test-retest reliability in the validation of the instruments.

The primary measures were collected weekly and were chosen to cover both distress and life satisfaction.

General Health Questionnaire -12 (GHQ-12)

The GHQ-12 is a brief assessment of psychological difficulties in the general population (Goldberg & Williams, 1988) with scores ranging from 0 to 36. The validity and reliability of the GHQ-12 have been evaluated (Hankins, 2008). In the general population, Cronbach's alpha was 0.94 (Lesage et al., 2011). In stroke, the validity of the General health Questionnaire (GHQ-28, which includes the GHQ-12 questions) has been reviewed with the conclusion that it has validity as a screening instrument (Burton & Tyson, 2015). For the GHQ-12, Hilari et al. (2003) reported a correlation of (.58) with a stroke Aphasia Quality of Life Scale. It has been shown to be

acceptable as a measure of distress in over 10 studies of stroke and was recommended as a screening measure for depression after stroke (Bennett & Lincoln, 2006).

Satisfaction with Life Scale (SWLS)

The SWLS (Diener *et al.*, 1985) is a brief, global life-satisfaction instrument including five questions about level of satisfaction with current life conditions. Responses are on a 7-point scale from strongly disagree to strongly agree and the scores range from 5 to 35. A review of the SWLS (Pavot & Diener, 1993) cited high internal consistency (Alpha .87) and two-month test-retest reliability of .82. Construct validity has been demonstrated through negative correlations with tests of clinical conditions such as depression and anxiety and positive correlations with measures of positive affect. A meta-analytic reliability-generalisation-study estimated an average Cronbach's Alpha of 0.78 across 60 studies (Vassar, 2008). Internal constancy remained high in a neurological sample with Parkinson's disease (Alpha .92) and Rasch analysis supported its validity (Loveride & Hagell, 2016). There are currently no stroke validation studies of the SWLS. However, it has been used successfully with stroke survivors in several studies (e.g. Mahmoud *et al.*, 2009).

Secondary measures

Secondary measures were collected only pre- and post-intervention.

Beck Depression Inventory – II (BDI-II) Fast-Screen

The BDI-II-FS (Beck *et al.*, 1996) is a 7-item, self-report measure. Although less thoroughly validated than the longer form of the BDI-II, the fast screen version avoids

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3 confounding somatic symptoms in physical illnesses (Salter Moses et al., 2008). The
4 validity of the BDI-II-FS has been established in a review of studies of mixed medical
5 patients (Wang & Gorenstein, 2013) and it has acceptable sensitivity, 0.71,
6 specificity, 0.74 and internal consistency, 0.75 in stroke (Healy et al., 2008).
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14 *Hospital Anxiety and Depression Screen, HADS*

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16 The HADS (Zigmond & Snaith, 1983) is a 14-item mood and anxiety screening tool
17 for patients with physical illnesses. It was included to allow comparison with other
18 studies due to its widespread use in stroke research. The HADS has undergone
19 validation for use in stroke and has shown good performance: AUC = 85.9%
20 (Prisnie, et al., 2016). Sensitivity and specificity values of 0.92, 0.65 respectively are
21 established in stroke (Burton & Tyson, 2015). Cronbach's alpha has been shown to
22 be high at 0.85 in stroke survivors (Aben et al., 2002) Total scores HADS scores
23 were used for analyses in this study.
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38 *The Beck Anxiety Inventory, BAI*

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40 The BAI (Beck & Steer, 1993) is a 21-item self-report measure of symptoms of
41 anxiety. The BAI has been shown to measure general anxiety (Muntingh et al.,
42 2011). A comprehensive meta-analysis of 192 studies found the BAI to demonstrate
43 sound psychometric properties, with good reliability (cronbach's alpha) and test-
44 retest reliability (0.91 and 0.65, respectively). Sensitivity was .83 and specificity 0.89
45 in a sample of cancer patients (Bardoshi et al., 2015). There are currently no formal
46 validation studies of the BAI in stroke although one small-sample study compared it
47 with a clinical interview finding it had good sensitivity but low specificity (Goldstein et
48 al., 1998). The BAI has been also been compared with other indices of anxiety; a
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study evaluating anxiety in stroke survivors using the BAI found that the rates of anxiety correlated with published rates and somatic symptoms were not over-reported in comparison to emotional items (Barker-Collo, 2007).

The Warwick Edinburgh Mental Wellbeing Scale (WEMWS)

Wellbeing was assessed separately to psychological distress (depression and anxiety) since the absence of distress does not necessarily signify the presence of wellbeing. The WEMWS has 14 items and its validity in non-clinical populations was evidenced by a negative correlation with the GHQ-12 and high positive correlations with a range of life-satisfaction scales. It had good internal consistency and test-retest reliability (0.89 and 0.83 respectively) (Stewart-Brown et al., 2011; Tennant et al., 2007). The WEMWS has not been validated for stroke populations but has been shown to be acceptable and accessible by stroke survivors (Majumdar & Morris, 2019).

Stroke impact scale (SIS)

The SIS is a complete assessment of physical and functional disability associated with stroke (Duncan et al., 2003). It is an eight-domain measure, consisting of 59 questions. The SIS gives a composite disability score and the internal consistency of the measure ranges from 0.86 to 0.95 (Jenkinson et al., 2013). Its reliability (internal consistency and test-retest) and validity in against a wide range of cognitive and performance measures have been extensively studies and this research is reported at (<https://strokengine.ca/en/assessments/stroke-impact-scale-sis/>)

Survey

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Participants completed a brief, closed-question, survey at the completion of the study. The survey consisted of three enquiries using a Likert Scale of 0-10 (where 10 is rated as most helpful): “*how helpful was the book?*” ; “*which part of the book was found to be particularly helpful?*”; “*What aspect of wellbeing did the book help address?* “. Four options were provided for each area: [Improvements to] anxiety, depression, confidence, self-activation or other.

Study procedure

Participants started baselines as they were recruited over a 10-month period in 2018/19. Baseline lengths were randomised in advance using a randomisation programme. Randomised baseline lengths ranged from two to eight weeks. The study consisted of three phases: Baseline, intervention and a 3-week follow-up. The two primary measures were collected weekly and the five secondary measures were collected before and after the intervention phase. The survey was completed at the end of the intervention. In the baseline phase one-to-one, therapist contact occurred every two weeks in the patient’s home to control for this element in the intervention phase. During the ‘no-active-intervention’, baseline phase, therapist support consisted of person-centred support e.g. empathy, positive regard and congruence (Fazio et al., 2018). The sessions lasted 40-50 minutes. The number of therapist sessions received by each participant are given in Supplementary Material 1.

Individuals continued with any usual treatments e.g. antidepressants, GP appointments, stroke clinic appointments, specialist nurse visits, physiotherapy, etc. None were having concurrent psychological therapy. The baseline phase allowed

assessment of the effects of these treatments as well as the therapist contact. Some participants were unable to start the intervention at the end of the planned baseline stage and the baseline was extended until they could do so (see Supplementary Material 1 for details).

During the intervention phase, each stroke survivor was given the book and therapist provided support to use the book and to practise/apply its principles. The therapist was a pre-registration trainee clinical psychologist with seven years of NHS experience as a graduate psychologist and basic (non-accredited) training in a range of therapies including ACT, CBT and general counselling. The support was provided on an individual basis every two weeks by home visits and was based on the client's expressed questions and needs in relation to their use of the book. These sessions also lasted 40-50 minutes. The number of sessions received by each participant is given in the tabulation of the study phases in Supplementary Material 1. The pace of reading/applying the book material was decided in collaboration with the individuals. The intervention phase length therefore varied for individual participants (between 6-16 weeks). The book material used was also tailored to individuals. Session structure was as follows:

1. Set the agenda; ask about current difficulties for which book could be used.
2. Discuss what the book offers to manage difficulty.
3. Review psychoeducation from the book by collaboratively considering information in the book that is potentially helpful in promoting psychological flexibility.
4. Try out exercises (optional) from the book.

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3 5. Review session and set homework from the book.
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5 The follow-up used the primary measures (GHQ-12, SWLS). Follow-up was
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7 conducted by the researcher 3-weeks following the completion of the final,
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9 intervention phase.
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11 All therapist contact and measurements took place face- to- face in the participants'
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13 places of residence (apart from two contacts to the participant's home by telephone).
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15 Home visits improved recruitment and reduced the burden of travel due to stroke-
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17 related mobility restrictions. Blinding of researcher to the phase for collection of
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19 participant self-assessments and to the intervention was not feasible.
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26 **Statistical analysis**

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28 Analysis of the MBD was completed using TAU-U. TAU-U is an effect size that
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30 combines the trend from the intervention phase with non-overlap from both baseline
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32 and intervention phases and is a reliable test in multiple-baseline design analysis
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34 (Bossart, Laird & Armstrong, 2018). TAU-U provides conservative effect sizes
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36 (Bossart, Laird & Armstrong, 2018). The TAU-U employed tool is internet-based
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38 (www.singlecaseresearch.org/calculators; Vannest, Parker, Gnan & Adiguzel,
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40 2016). Baseline correction was used if baseline TAU-U exceeded 0.2 (Vannest &
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42 Ninci, 2015). This TAU-U calculator yields effect sizes for the difference in phases
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44 (Bossart, et al., 2018). Effect sizes were interpreted based on guidelines (Vannest
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46 and Ninci, 2015): <0.20 = small change; 0.20-0.60 = moderate change; 0.60-0.80 =
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48 large change.
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53 SPSS 25 was used to analyse before and after change in the secondary measures.
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55 Paired t-tests, with Bonferroni corrections, were used to evaluate change in the
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57 scores of the secondary measures between the pre- and post- intervention
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assessment points. A sample of 13 is required to detect a large effect size (D_z) with a power of 0.9 with a one-tailed test.

Survey Analysis

Relative risk can be used to determine associations in cohort studies (Viera, 2008).

Here it was defined as the rate of reported benefit if exposure to the book was found helpful (rated as $>6/10$) divided by the rate of reported benefit in those who did not find the book helpful.

Results

The flow of participants from their initial recruitment to the study is depicted in the PRIMA diagram in Supplementary Material 4.

The median number of baseline and intervention weeks were 6.0 (range 3 to 11) and 11.0 (range 3 to 16), respectively. The corresponding medians for therapist contacts and therapist time during baseline and intervention phases were 3.0 sessions (range 1 to 4) or 2.25 hours and 5.0 sessions (range 2 to 8) or 3.75 hours, respectively. (See Supplementary Material 1).

Demographical analysis

Table 1 gives a summary of the sample characteristics. The mean time since stroke was 19 months.

Insert Table 1 about here

Primary measures’ analysis: GHQ-12 and SWLS

Figures 2 to 17 (Supplementary Material 5) illustrate the effects of intervention on the GHQ-12 and SWLS. *Graphs for participants 3 and 8 are given as illustrations in Figure 1. The GHQ-12 scores were indicative of high levels of psychological distress in this sample, with 14 of 16 participants scoring 20 or over at the start of the baseline. On the SWLS only two participants scored in the very dissatisfied range at the start of baseline, but all scored below 20 which is regarded as the ‘neutral’ point on the scale.*

Insert Figure 1 about here

The whole-sample omnibus analysis of the GHQ-12 results was statistically significant with a moderate effect size (0.6, $p < 0.05$). TAU-U scores were computed for each participant; all demonstrated an effect in the positive direction and seven (43.7%) showed statistically significant effects. Due to the short baselines of some participants the absence of more individual significant effects was not unexpected. The whole-sample omnibus analysis of the SWLS results was also statistically significant ($TAU = 0.3$; $p < 0.05$) with a moderate effect size. Individual TAU-U analyses showed a positive effect of the intervention for 12 (75.0%) of the participants and five (31.3%) were statistically significant. However, two participants showed statistically significant effects in a negative direction on this measure.

Insert Table 2 about here

Follow-up

Paired sample t-tests on the 3-week follow-up results of both primary measures comparing final intervention scores and three-week follow-up scores on GHQ-12 (means 9.0(5.1) and 10.7(6.5), respectively and SWLS (means 17.1(9.2) and 18.8(8.5), respectively) were not statistically significant. This was commensurate with the maintenance of gains.

Secondary measures analysis

Paired samples, t-test, results of the pre-post, whole-group analysis of the BDI, BAI, HADS, WEMWS and SIS are presented in Table 3. At baseline mean BDI-II scores where in the normal range while BAI and HADS total scores indicated significant distress. Following Bonferroni correction (adjusted $\alpha = 0.01$), the results of the pre-post, whole-group analysis remained statistically significant.

Insert Table 3 about here

Survey results

Survey results are presented in Table 4. Eighty-one percent of the sample reported the book as very helpful. It was reported useful for anxiety, low mood, confidence, motivation, acceptance and understanding carer's role. Eighty-one percent of the sample also reported Part 3, which contains the ACT programme, as helpful.

Insert Table 4 about here

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The relative risk calculation showed that the chance of improvement on the GHQ-12 if the book was found helpful was 81% and the corresponding figure of the SWLS was 68%. The chance of improvement on GHQ-12 if the book was found helpful was increased by a factor of eight, compared to if the book was not found helpful. The corresponding factor for the SWLS approached seven.

Discussion

The TAU-U whole-sample omnibus results for both primary measures showed moderate effect sizes of the intervention on both GHQ-12 and the SWLS over a median of 11 weeks of using the book with six therapist contacts (median 4.5 hours in total). Individual analyses support the omnibus analysis with the majority of participants showing changes in a positive direction on both measures. This lends support to the hypothesis that bibliotherapy, with therapist support, was beneficial for the psychological wellbeing and quality of life of stroke survivors in the short- term. The outcome extends the conclusion of meta-analyses of bibliotherapy in the mental health context (Cuijpers et al., 2010; Den Boer et al., 2004; Hirai & Clum, 2006;) to psychological sequelae of a physical health condition. It also supports the conclusions of Majumdar & Morris (2019) that ACT-based interventions are beneficial for stroke survivors, at least in the short-term. This outcome was achieved with a medium of only 4.5 hours of therapist contact in the intervention phase and is encouraging for the development of cost-effective, low-intensity interventions for psychological distress (Latchem & Greenhalgh, 2014; Sampaio et al., 2016;) delivered through book prescription schemes (Chamberlain et al., 2008).

All secondary outcome measures showed large statistically significant change in a positive direction. Although these pre-post results may be a consequence of temporal change unconnected to the intervention, they are congruent with those of the controlled MBD and together these findings support the efficacy of bibliotherapy.

In this study, the WEMWS wellbeing scale and the SWLS quality of life measure both showed significant change over time whereas Majumdar & Morris (2019) found they did not show benefit in a controlled trial of group-based ACT. They attributed the lack of benefit to insufficient intervention time (four weeks) to develop secondary benefits in overall wellbeing. The longer study period here may have allowed sufficient time for this. The improvement on the SWLS may also reflect the individualised approach of the current study in contrast to the group-based didactic approach taken by Majumder & Morris (2019) **since the stroke survivors were able to discuss and plan individual values-based activities and social engagement during the therapist support sessions**. Generally, in the absence of psychological intervention, post-stroke life satisfaction remains low despite extensive rehabilitation (Langhammer, et al., 2017). Improving quality of life is a priority in view of the high prevalence of post-stroke disability (Carmo et al., 2015) and the bibliotherapy approach is promising in this respect.

The Stroke Impact Scale (SIS) showed positive change in perceptions and experiences of disability after stroke and includes dimensions of HRQOL (Salter et al., 2008). This finding may attest to the role of acceptance and defusion (Graham et al., 2016) in amelioration of negative psychological processes stemming from enduring disability and loss of function which are frequent consequences of stroke

(American Heart Association, 2011; Feigin et al., 2017). ACT's focus on identifying values to underpin goal setting and value-based living may be particularly helpful in promoting active engagement in the context of enduring disabilities (Clarke et al., 2014). Value-based living is associated with psychological wellbeing and improved function in people after traumatic brain injury (Pais et al., 2019).

Taken together, the results of the SWLS, WEMWS and SIS tentatively support the bibliotherapy - ACT intervention as an effective intervention for enhanced wellbeing and quality of life for stroke survivors.

The brief survey showed that the book was perceived favourably by participants, with 81% of the sample reporting part 3 (ACT intervention) as the most helpful part. ACT fits particularly well in stroke from a theoretical and practical point of view. Its therapeutic techniques do not aim primarily to alleviate psychological distress (Guadiano, 2011) but rather to enhance psychological flexibility to change the relationship between a person, their distress and the behaviours the distress engenders. This promotes the transdiagnostic nature of ACT by requiring less specificity for interventions than psychological approaches based on cognitive processes and reinforcement contingencies (Assaz et al., 2018).

The emphasis of ACT on experiential learning enables it to be used with success with generalised cognitive impairments in learning disability settings (Brown & Hooper, 2009). For example, the ACT process of defusion (distinguishing between thoughts and reality) does not require cognitive reframing of psychologically distressing thoughts in order to reduce negative responses to thoughts (Assaz et al.,

2018) and has been shown to produce more rapid change than cognitive restructuring (Deacon et al., 2011). Cognitive factors may also underpin ACT's success with complex presentations i.e. treatment resistant populations (Clarke et al., 2014).

Limitations and future research

This MBD study provided a level of experimental control but a concurrent design, where all the participants start baseline at the same time, would have provided more definitive evidence. Further research using randomised control conditions, blinding to hypotheses and phases/conditions, longer baselines and follow-up and larger samples is required to address the limitations of this study and strengthen evidence for the effectiveness of ACT-based supported bibliotherapy in stroke. Although all baselines were three weeks or longer, it would have added greater control to ensure randomised baseline lengths were set at a minimum of three weeks. However, the minimum of two weeks was dictated by ethical concerns about attrition during a non-treatment period for this fragile population. In addition, inclusion of only those with clinical levels of psychological distress would enhance generalisability to clinical populations. However, data from the current study may be valuable in establishing aspects of feasibility of future randomised studies as well as the length of intervention required. Investigations of bibliotherapy without therapist support are also required to determine if efficacy is maintained in its absence since this could limit the cost-effectiveness of the approach. Although three of the measures used had not been fully validated in stroke, all had previously been used successfully with this population. People with severe aphasia and who could not read were not

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included in the study and research using communications aids for this sample would extend the findings. The current study did not include a measure of ACT processes related to psychological flexibility since, when the study was designed, none were validated specifically for stroke or had been demonstrated to be acceptable for this population. Inclusion of validated ACT-process measures would increase confidence that ACT-specific factors are responsible for benefits. While the baselines were randomised in advance of the study, it was not possible for all participants to transfer to the intervention in the identified week due to unplanned events such as individual or family illness. In these cases, the baseline and data collection were continued (median 1 week) until the participant could start the intervention. It was considered that such unplanned extensions would not affect the conclusions since extended baseline phases allow rigorous comparisons.

Service Implications

Comorbidity of stroke and mood-based difficulties is high (Hackett & Pickles, 2014). Healthcare cost is increased by psychological comorbidity in long-term conditions (Naylor et al., 2012). The Royal College of Physicians (2016) suggest that stroke patients should be offered a choice of interventions for psychological difficulties. The results of the current study indicate that the novel ACT-based bibliotherapy, with therapist support is effective in the short-term. The intervention can be tailored to individual needs and requires less therapist time per week than traditional therapy.

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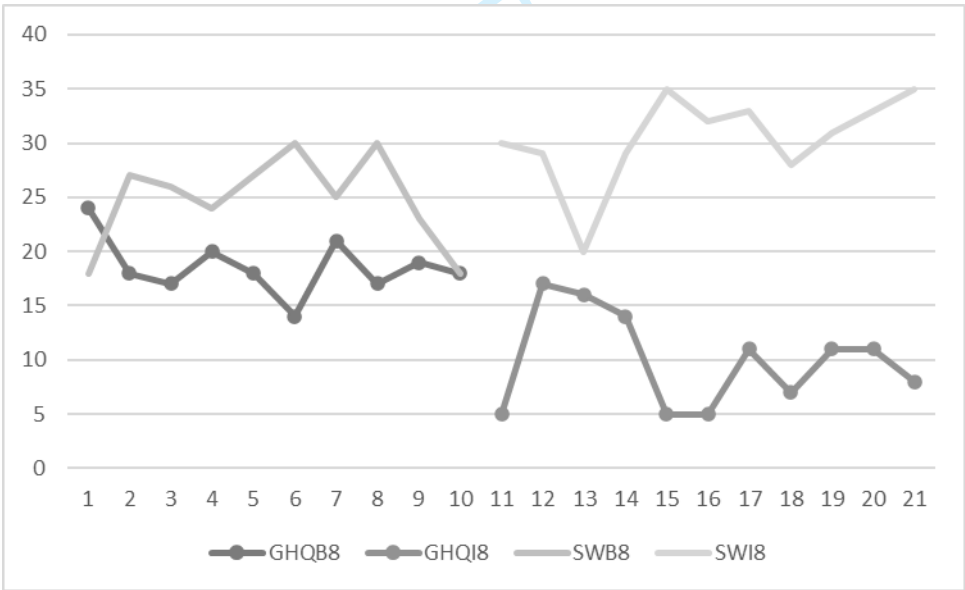
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Key: GHQBn = GHQ-12 baseline; GHQIn = GHQ-12 intervention; SWBIn = SWLS Baseline; SWIn = SWLS Intervention. Where n = the number of the participant.

Figure 1. Baseline and intervention scores for GHQ and SW for participants 3 and 8.

Participant	Age and Gender	Type of stroke	Number of strokes	Employment us (R-retired, W-working, U-unemployed)	Medication
1	53, F	Infarct, laterlisation unknown	1	U	Sertraline
2	59, M	Right-sided haemorrhage	1	U	NA
3	52, M	Right sided Ischaemic attack	1	U	Citalopram
4	84, F	Left-sided Infarct	1	R	NA
5	56, M	Left Haemorrhage & TIA	2	U	Beta-blockers
6	73, F	Right sided infarct	1	U	Carbamazepine & Lorazepam

7	29, F	Left sided Haemorrhage	1	U	Propanol
8	80, M	Cerebellar Infarct and TIA	2	R	Sertraline
9	67, M	Left sided Infarct & TIA	2	R	Citalopram
10	82, M	Mid-brain Infarct & TIA	2	R	NA
11	56, F	Left -sided infarct & TIA	2	U	Citalopram
12	56, M	Left-sided Infarct	1	E	NA
13	56, F	Left-sided Infarct & TIA	2	U	Sertraline
14	53, M	Right sided Infarct	2	U	Sertraline & Diazepam
15	34, F	Left sided Haemorrhage	1	E	NA
16	79, F	Left sided infarct	1	R	Amitriptyline

Table 1: Sample characteristics

Participant	GHQ-12			SWLS		
No.	Tau-U	Effect size	<i>p</i> value	Tau-U	Effect size	<i>p</i> value
1	0.50	Moderate	0.110	0.70	Large	0.021*
2	0.90	Large	0.000*	0.40	Moderate	0.011*
3	0.10	Small	0.717	-0.69**	Moderate	0.016*
4	0.71	Moderate	0.011*	0.58	Moderate	0.038*
5	0.70	Large	0.018*	0.66	Moderate	0.027*
6	0.42	Moderate	0.212	0.42	Moderate	0.183
7	0.70	Large	0.031*	0.28	Small	0.395
8	0.98	Large	0.000 *	0.80	Large	0.004*
9	0.50	Moderate	0.121	0.60	Moderate	0.071
10	0.60	Moderate	0.027*	0.30	Moderate	0.239
11	0.10	Very Small	0.730	0.43	Moderate	0.174
12	0.07	Very small	0.813	-0.16**	Small	0.592
13	0.60	Moderate	0.155	0.60	Large	0.110
14	0.22	Small	0.662	0.33	Moderate	0.512
15	0.14	Small	0.608	-0.94**	Large	0.007
16	0.83	Large	0.000*	-0.50**	Moderate	0.143

*alpha <0.05; ** - indicates reduced satisfaction with life.

Table 2: Individual Tau-U statistics for GHQ-12 and SWLS

For Peer Review

Measure	Pre-test Mean (SD)	Post-test Mean (SD)	Paired T-Test
BDI-II	8.4(4.7),	4.3(4.2)	p<.001
BAI	22.6(11.4),	9.9(10.5)	p<.0001
HADS	23.1(8.9),	14.7(8.6)	p<.0001
WEMWS	36.9(11.5),	48.9(11.7)	p<.0001
SIS	188.9(36.0),	218.3 (30.2)	p<.001

BDI-II = Beck Depression Inventory-II; BAI = Beck Anxiety Inventory; HADS = Hospital Anxiety and Depression Scale; WEMWS = Warwick Edinburgh Mental Wellbeing Scale; SIS = Stroke Impact Scale.

Table 3: Whole-sample pre-post analysis for secondary measures

Participant	Helpfulness rating 0-10 10 = extremely helpful	What did the book help with?	Which Part of the book was most helpful?
1	5	Anxiety: understanding burden on carer. ††	2
2	8	Confidence and low mood	1, 2, 3
3	8	Confidence: Learning that I can get through it. ††	2
4	10	Confidence	3
5	8	Anxiety	3
6	10	Confidence	3
7	10	Anxiety/low mood	2, 3
8	10	Anxiety, low mood	3
9	9	Getting motivated	3
10	10	Low mood, confidence, anxiety	3
11	7	Anxiety thoughts	3
12	9	Anxiety, motivation	3
13	Lost to follow- up†	-----	-----
14	10	Anxiety, confidence	2 & 3
15	10	Low mood, confidence, anxiety	3
16	7	Confidence: understanding and realising you are not alone. ††	1, 2, 3

† Participant's view of the book prior to drop-out due to fall was favourable 'I carry it around with me'

†† Reason given for 'other' response

Table 4: Survey results

Supplementary Material 1: Planned and actual (brackets) baseline and intervention lengths in weeks and therapist contacts (40-50 minutes each)

Participant	Randomised order of baseline lengths	Number of therapist contacts	Length of intervention phase**	Number of therapist contacts
1	4(7)	3	7	3
2	4	2	16	8
3	3(7)	3	11	6
4	7	3	12	5 (one phone call)
5	5(6)	3	11	6
6	4(5)	2	13	5**
7	4	2	15	5**
8	7(10)	4	11	6
9	2(4)	2	14	6 (one phone call)
10	8(11)	4	9	5
11	5	2	13	7
12	6	3	9	5
13	6	3	3 (lost to follow-up)	2
14	2(3)	1	3	2
15	4(5)	2	7	4
16	6 (8)	4	5	3

**intervention phase includes periods when sessions were missed but primary measures were continued.

Supplementary Material 2: Recruitment and attrition

Total no. of participants who did not enter study following referral into study = 10				
Declined to participate = 6	Reasons cited			
	bereavement	Antidepressant improved mood	Inconvenient at this time	Do not need psychological support
Count	1	1	3	1
Did not meet inclusion criteria = 3	Inclusion criteria unmet			
	Reporting Psych. distress	18 or above	Clinically diagnosed stroke	
Count	3			
No. of participants uncontactable following referral into study = 1				

Participants who dropped out after consent (n=4)	
Baseline phase (n=2)	Intervention phase (n=2)
1 family illness	1 lost to follow-up due to fall
1 carer duties prohibiting participation at this time	1 lost at commencement of intervention due to fall

For Peer Review

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Supplementary Material 3: Contents of “Rebuilding your Life after Stroke.”

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Supplementary material 4: Recruitment flow chart.

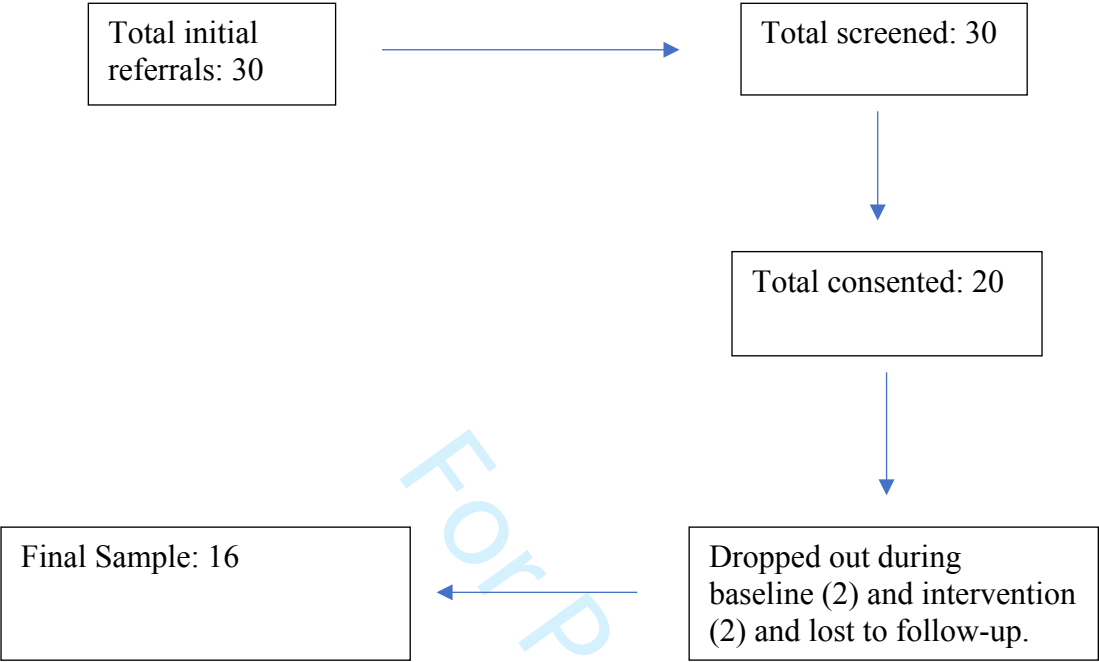




Figure 2: Participant 1

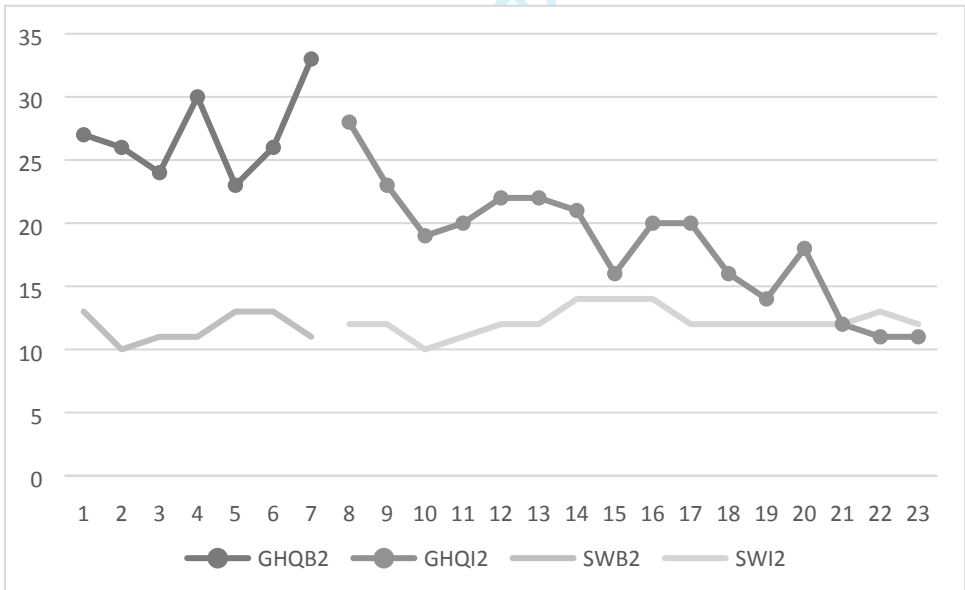


Figure 3: Participant 2

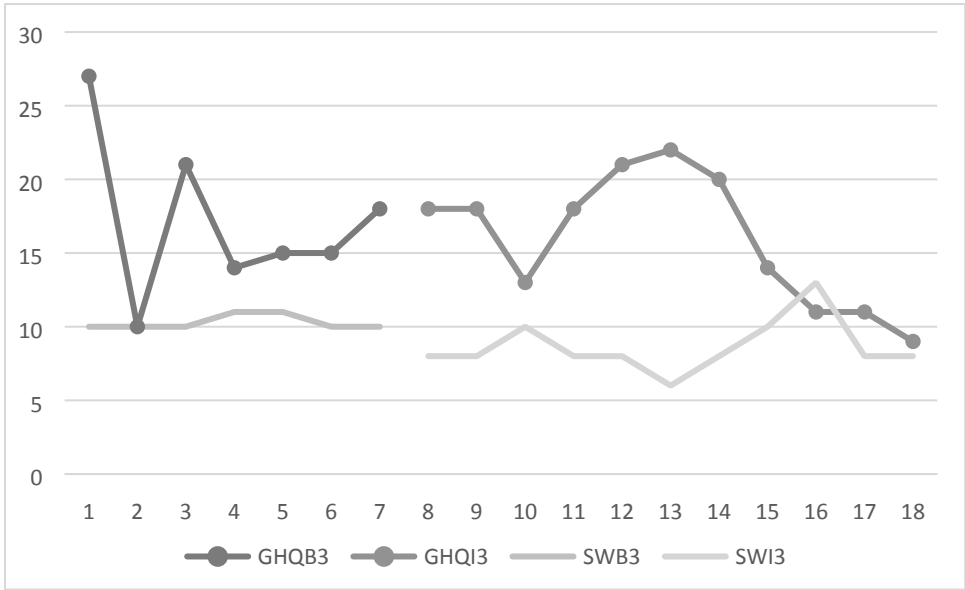


Figure 4: Participant 3

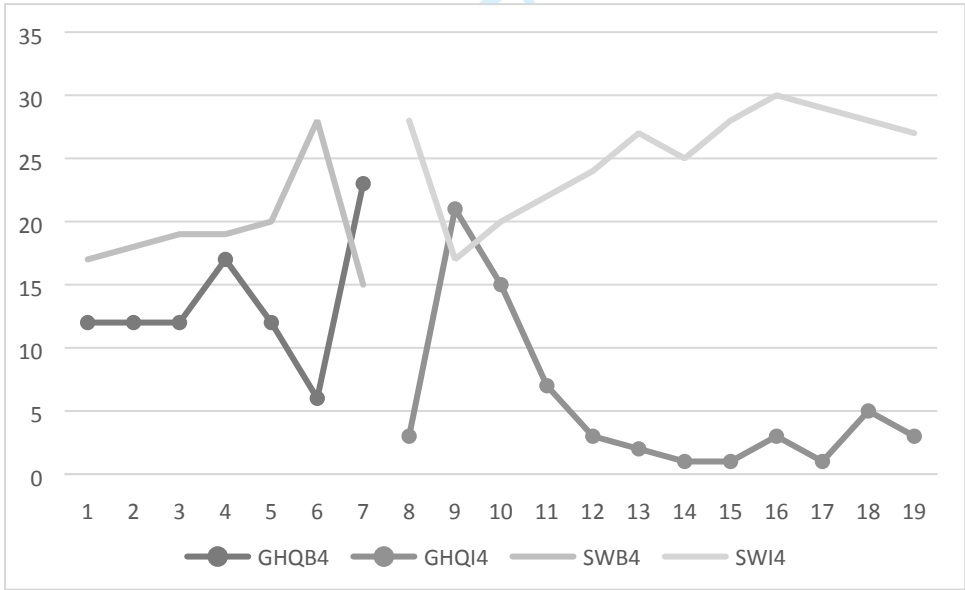


Figure 5: Participant 4



Figure 6: Participant 5



Figure 7: Participant 6

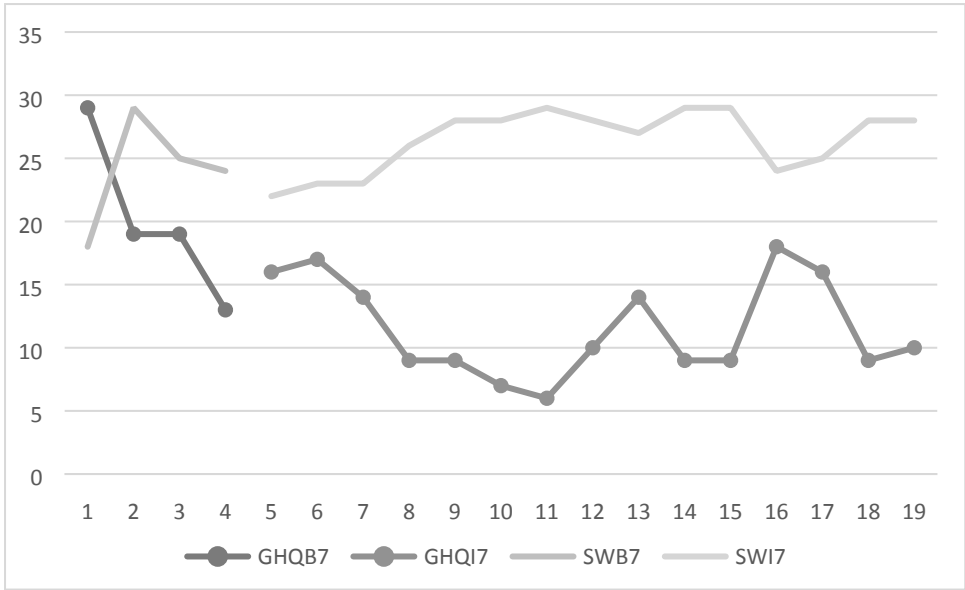


Figure 8: Participant 7



Figure 9: Participant 8

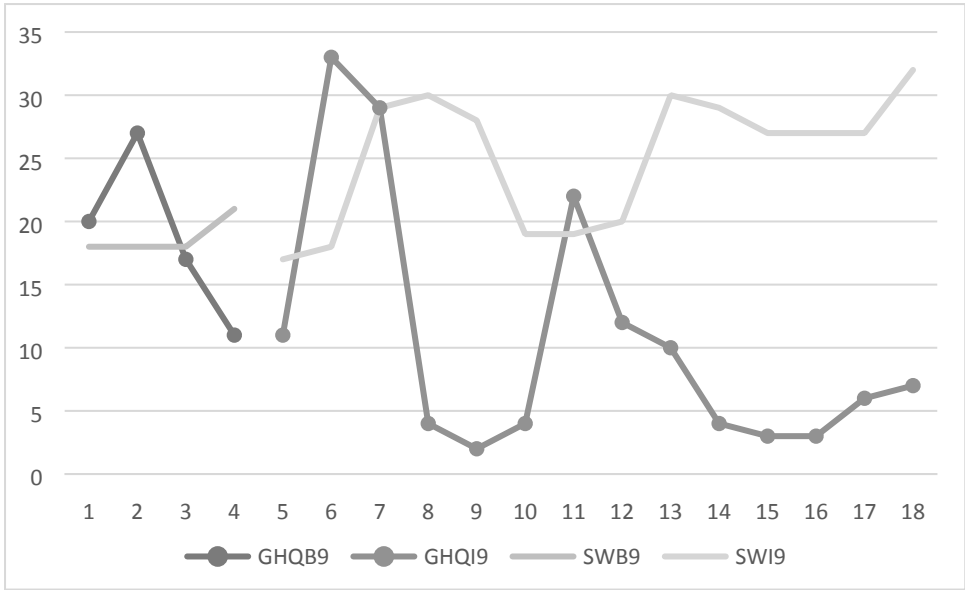


Figure 10: Participant 9



Figure 11: Participant 10

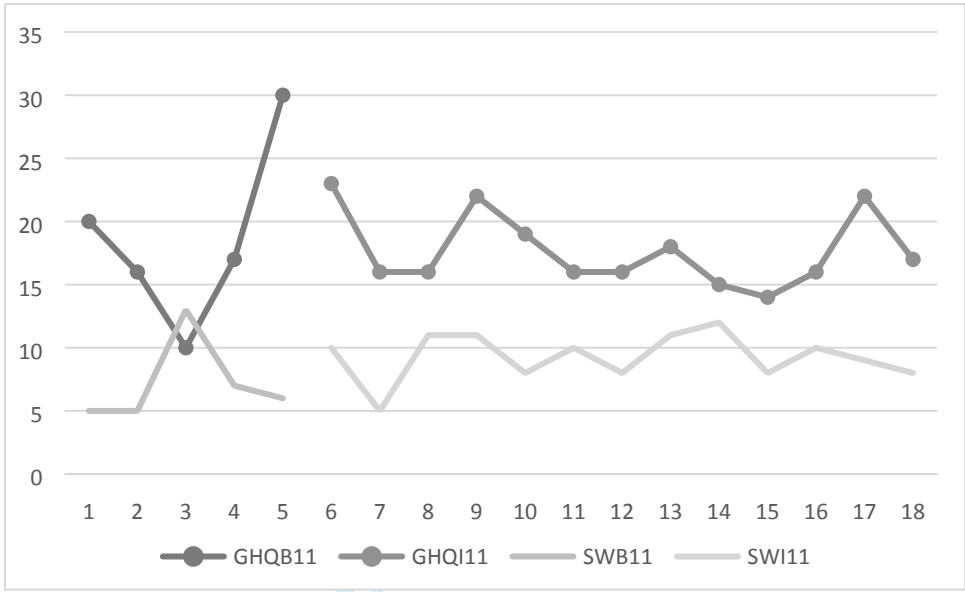


Figure 12: Participant 11

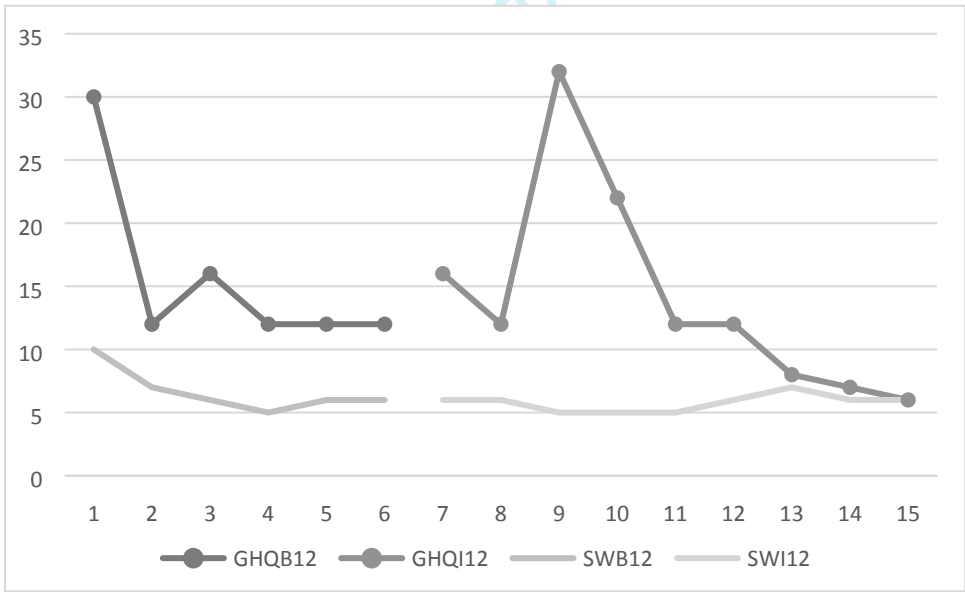


Figure 13: Participant 12

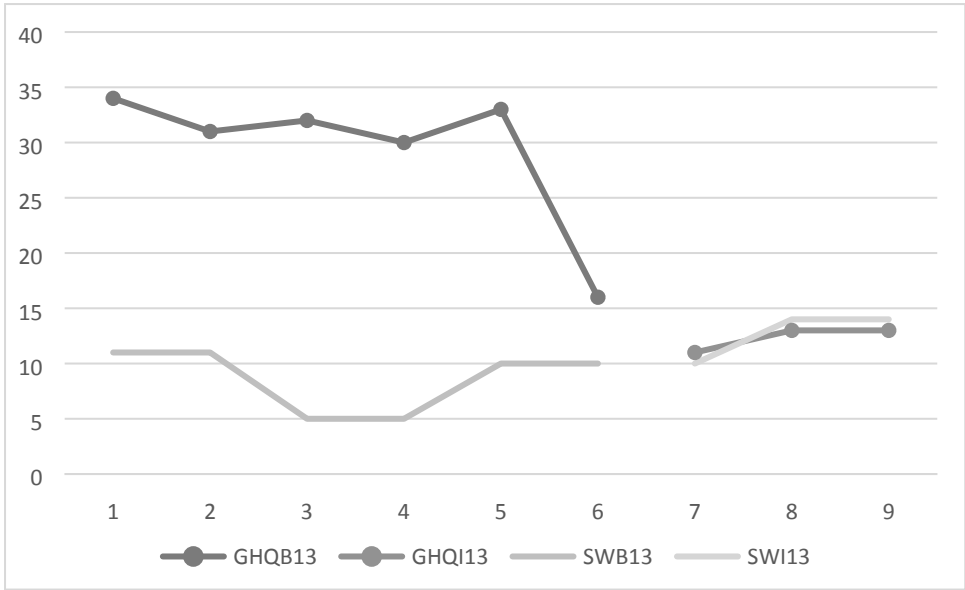


Figure 14: Participant 13

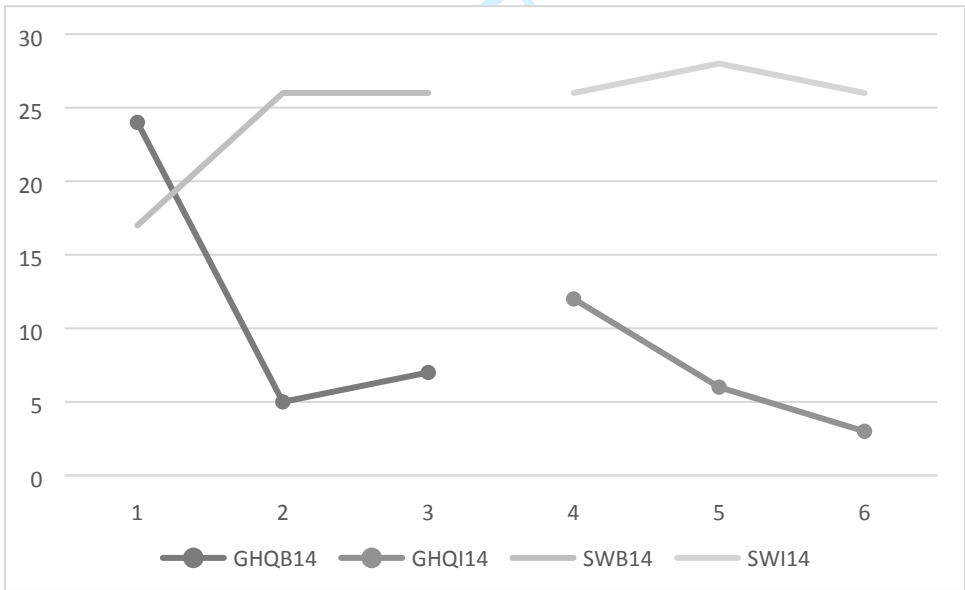


Figure 15: Participant 14

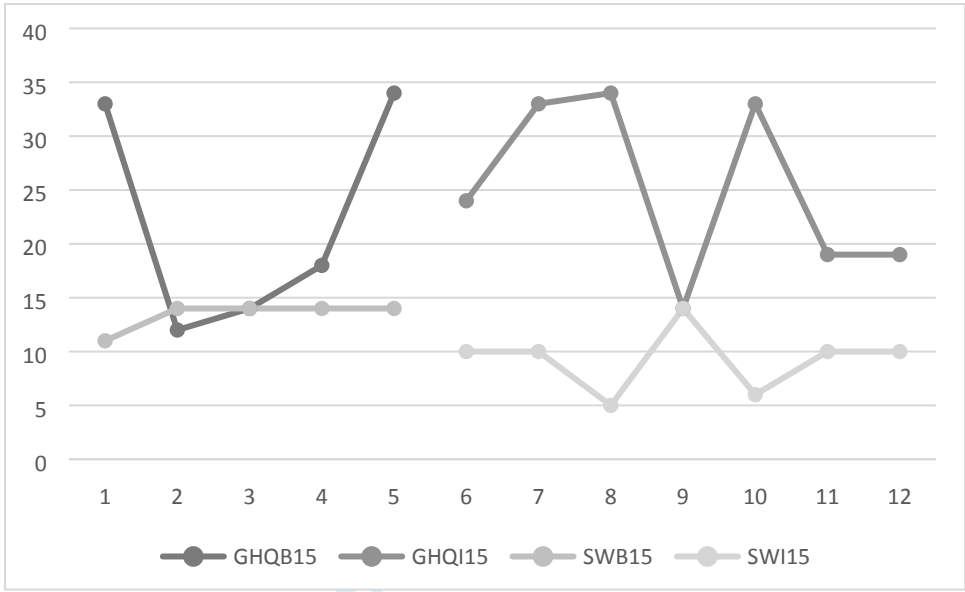


Figure 16: Participant 15

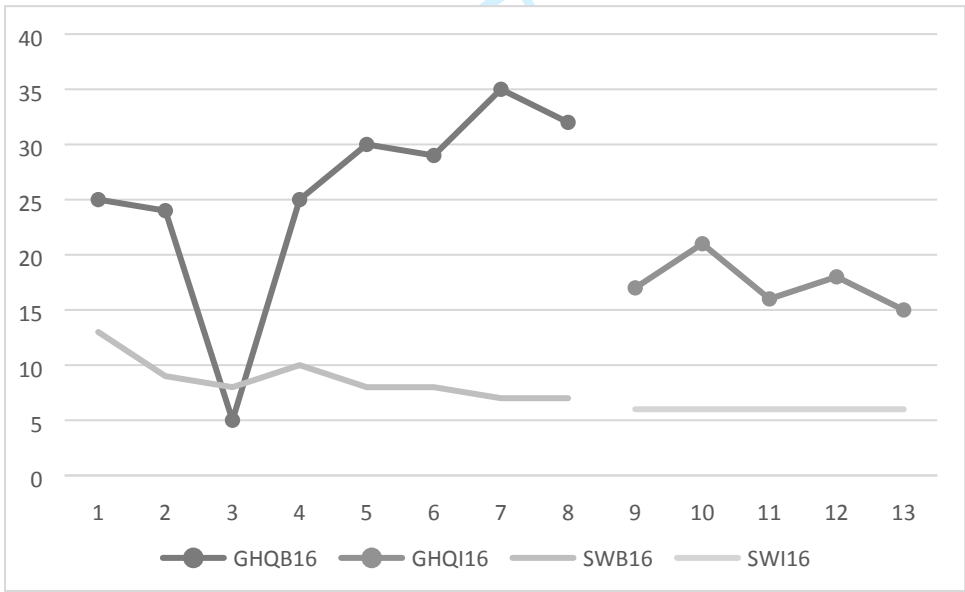


Figure 17: Participant 16

Key: GHQBn = GHQ-12 baseline; GHQIn = GHQ-12 intervention; SWBIn = SWLS Baseline; SWIn = SWLS Intervention. Where n = the number of the participant.

Supplementary material 4. Graphs for GHQ and SWB for baseline and intervention phases.

Supplementary Material 6: Scribe2016 checklist

The Single-Case Reporting guideline In Behavioural interventions (SCRIBE) 2016 Checklist

Responses are highlighted.

Item number	Topic	Item description	Notes
TITLE and ABSTRACT			
1	Title	Identify the research as a single-case experimental design in the title	Title Page
2	Abstract	Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions	Abstract
INTRODUCTION			
3	Scientific background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base. Pages 1-5	
4	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses	
METHODS			
DESIGN			
5	Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined <i>a priori</i> or data-driven) and, if applicable, criteria for phase change	Pages 6-7 Design & Analysis and Procedure 13-15
6	Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study. Page 14 and Supplementary Material 1, changes to baseline length due to participant constraints.	
7	Replication	Describe any planned replication. Pages 6-8. The design was replicated 16 times	
8	Randomisation	State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized	Pages 6 and 13
9	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/ masked. Page 11; Blinding was not practicable.	
PARTICIPANT/S or UNIT/S			
10	Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment.	Page 8-9 Recruitment
11	Participant characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured.	Table 1
CONTEXT			
12	Setting	Describe characteristics of the setting and location where the study was conducted. End of Procedure page 15	
APPROVALS			
13	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained. Page 6, start of Method	
MEASURES and MATERIALS			
14	Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured. Pages 10-13 Measures	
15	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions. Not applicable	
INTERVENTIONS			
16	Intervention	Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication. Pages 13 -15, Study Procedure	
17	Procedural fidelity		
ANALYSIS			

Describe how procedural fidelity was evaluated in each phase. Page 13-15. Procedure. The bibliotherapy intervention was self-paced and administered depending on needs; therapist input is described.

18 Analyses Describe and justify all methods used to analyse data. Page 15-16, Statistical and Survey Analyses

RESULTS

- 19 Sequence completed For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons. See Supplementary Material 1.
- 20 Outcomes and estimation For each participant, report results, including raw data, for each target behaviour and other outcome/s. Raw data are depicted in Figures 1-16 in Supplementary Material 4 for the primary measures;
- 21 Diverse events State whether or not any adverse events occurred for any participant and the phase in which they occurred. Figure 1 shows flow through the experiment with note of adverse events. Deviations from design are noted on p14 and supplementary Material 1.

DISCUSSION

- 22 Interpretation Summarise findings and interpret the results in the context of current evidence. Pages 19-23
- 23 Limitations Discuss limitations, addressing sources of potential bias and imprecision. Pages 23-25
- 24 Applicability Discuss applicability and implications of the study findings. Page 25

25

DOCUMENTATION

- 27 Protocol If available, state where a study protocol can be accessed. N/A
- 28 Funding Identify source/s of funding and other support; describe the role of funders. Title page

Note Page numbers refer to the submitted WORD manuscript