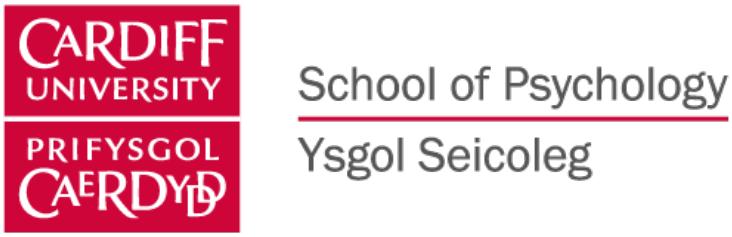


# Transdiagnostic approaches and supported-bibliotherapy for psychological problems after stroke.

Thesis submitted in partial fulfilment of the requirement

for the degree of:

**Doctorate of Clinical Psychology (DClinPsy)**

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Transdiagnostic approaches and supported-bibliotherapy after stroke.

Abstract

Stroke leads to high levels of disability, with up to a third of stroke survivors failing to regain function. Consequently, psychological distress in this group is common, and a third of stroke survivors experience depression, whilst a quarter experience an anxiety related difficulty. A high proportion of stroke survivors report that their psychological distress wasn't addressed by services. The following papers present potential stepped-care options for the provision of psychological care in stroke services.

Paper one

Paper one presents a systematic review of brief, transdiagnostic psychological approaches. The review considers both treatment and prevention of psychological difficulties. Prevention and treatment are both important because the rate of psychological difficulties in the stroke population is known to be reliably high. Prevention may also help target the high level of multimorbidity in this population since stroke more commonly occurs at chronologically higher ages. The systematic review focussed on transdiagnostic approaches. Transdiagnostic approaches target a common psychological mechanism across a range of difficulties. The benefit of transdiagnostic approaches is that they potentially result in increased clinical utility by reducing the requirement for training in a large number of approaches. The results showed that transdiagnostic approaches, such as Motivational interviewing (MI), Problem-solving therapy (PST), acceptance and commitment therapy (ACT) are helpful for psychological difficulties after stroke.

Transdiagnostic approaches and supported-bibliotherapy after stroke.

Paper two

Paper two presents a study of bibliotherapy using a stroke-specific book that was developed collaboratively by stroke clinicians and stroke survivors. The book is called '*Rebuilding your life after stroke*' and contains material to address psychological difficulties after stroke with an acceptance and commitment therapy model. The study used a multiple baseline design and reported results on a general health questionnaire (GHQ-12) and a satisfaction with life questionnaire (SWLQ). Sixteen stroke participants were recruited from clinical services and third sector organisations with expertise in stroke. The results showed that moderate-to-large effect sizes were obtained for a high proportion of the sample on both measures. The results are discussed in the context of using bibliotherapy and ACT materials to enhance provision of psychological care in stroke services.

Paper 3

Paper three is a reflective paper which considers the strengths and limitations of both papers one and two. Paper three presents a discussion of the difficulties of reviewing the evidence base for transdiagnostic approaches as studies more commonly investigated therapies using single-diagnostic criteria. Paper three also discusses the strengths and challenges of conducting multiple baseline design studies and the issues of recruitment encountered during the study.

## Transdiagnostic approaches in the treatment and prevention of psychological difficulties after stroke: a systematic review

**Abstract**: Stroke is one of the leading causes of disability in the world. Post-stroke comorbidity is high and psychological difficulties prevalent. Multiple psychological difficulties impact on recovery and rehabilitation after stroke. There is a need for transdiagnostic therapies to manage this multi-morbidity in stroke. Transdiagnostic approaches offer improved clinical utility given that therapists are unlikely to be able to master all the possible variations in manuals for the whole host of possible DSM categories. This review evaluates the evidence base for transdiagnostic therapies for psychological difficulties after stroke, which results in a high level of co-morbidity. Transdiagnostic therapies are defined as not requiring a single diagnosis for effectiveness and in stroke include mindfulness, ACT, MI, PST and integrative behavioural interventions. The results of the review show that transdiagnostic therapies for post-stroke psychological difficulties are effective. In particular, transdiagnostic approaches for post-stroke psychological difficulties improved outcomes, maintained at follow-up. The transdiagnostic approaches reviewed were also considered practicable.

### Introduction

Stroke is a type of an ABI that results in an acute, vascular, injury to the brain (Waldron, Casserley & Sullivan, 2013). Stroke is considered to be the one of the leading causes of disability in the UK (Public Health England, 2018), with

two-third stroke survivors leaving hospital markedly disabled (The Stroke Association, 2018). Psychological problems after stroke are common, with emotional problems encompassing changes to identity (Musser, Wilkinson, Gilbert & Bokhour, 2015), poor self-esteem (Vickery, Sepehri & Evans, 2008) and body-image (Keppel & Crowe, 2000) to name a few. Both anxiety and depression are also frequently reported by stroke survivors (Boakye et al., 2019). Depression in particular has received much research interest. Screening and management of post-stroke depression is vital to minimise poor stroke rehabilitation outcomes (Bartoli et al., 2013), to ameliorating the role of depression precipitating further strokes (Yuan et al., 2012) and to reduce depression-related mortality after stroke (Nickel & Thomalia, 2017).

Depression after stroke significantly impedes post-stroke rehabilitation and its treatment alongside physical rehabilitation is crucial (Nickel & Thomalia, 2017). Anxiety after stroke also impedes rehabilitation and a return to normal activities (Chun, Whiteley, Denis, Mead & Carson, 2018). Life after stroke requires concurrent adaptations in physical, psychosocial and psychological functioning (Waldron, Casserley & Sullivan, 2013), compounded by difficulties resulting from long-term functional impairments limiting successful adaptation (Nickel & Thomalia., 2017). Overall, stroke results in a complex combination of long-term difficulties (Brewer, Horgan, Hickey & Williams, 2012).

**Systematic review**

As a result of the high levels of comorbidity in stroke which includes psychological difficulties (Ofori-Osenso, 2018) and the fact that multiple post-stroke problems afflict stroke survivors (Auton et al., 2016), the aim of this review is to review the evidence base for transdiagnostic psychological therapies in stroke. Brief transdiagnostic approaches are recommended by the Royal College of Physicians (2016) although evidence for them remains tenuous. Transdiagnostic approaches don't require application to a single psychiatric diagnosis for efficacy (Norton & Philipp, 2008) and potentially simultaneously address several comorbid difficulties (Mcmanus, Shafran & Cooper, 2010). Transdiagnostic approaches target general psychological processes linked to a range of presentations. Specifically, a transdiagnostic approach targets a transdiagnostic process, which is defined as a mechanistic psychological process that occurs across a range of psychological difficulties (Dolsen, Asarnow & Harvey, 2014). Addressing a transdiagnostic mechanism may solve the issue of co/multimorbidity, which is considered to enhance the clinical utility of approaches (Mcmanus, Shafran & Cooper, 2010). It is beyond the scope of this review to provide a comprehensive summary of transdiagnostic approaches. Transdiagnostic theories relevant to transdiagnostic approaches tested in stroke will be prioritised in the next section. Transdiagnostic approaches that have been tested in stroke and included in this review are ACT, mindfulness-based approaches, integrative behavioural approaches, problem-solving therapy (PST), the solution-focussed approach and Motivational Interviewing (MI).

## Transdiagnostic approaches

Psychological distress has traditionally been classified in nosological categories with theoretically unique aetiologies and processes (Nolen-Hoeksema & Watkins, 2011). Increasingly narrowed categories in the latest editions of the DSM have correspondingly increased comorbidity rates (Clark et al., 2017). The strategy of identifying unique aspects of difficulties by shrinking categories ignores commonalities across problems (Garland & Howard, 2014). Findings show that there is a high level of comorbidity between a range of psychological difficulties (Brown, Campbell, Lehman, Grisham & Mancill, 2001). The high prevalence of comorbidity limits research and the clinical utility of uni-diagnostic approaches (Garland & Howard, 2014). The narrowing of categories has resulted in small, inconsequential variations to treatment manuals, placing a resource burden on clinical services (Boswell, 2013). The limited clinical utility of single-diagnosis treatment protocols in particular has prompted production of a unified CBT protocol incorporating transdiagnostic processes for treatment of psychological difficulties (McHugh & Barlow, 2010). Commensurate with the limitations of researching complex areas using uni-diagnostic criteria, and the lack of scientific validity of uni-diagnostic approaches, a research domain-criteria framework (RDoC) has been developed (Morris & Cuthbert, 2012). The research framework in the RDoC represents a shift from a categorical to a dimensional approach using a biobehavioural framework for the spectrum of psychological difficulties (Ford et al., 2014), and highlights the occurrence of co-existing dimensions of psychological problems (Lilienfeld & Treadway, 2016).

An overarching theory of biobehavioural-neuromodulation is based on the concept of control (Powers et al., 2011). Perceptual control theory (PCT) suggests that human behaviour is modified through controlling effects of inputs (Mansell, 2010). Many psychological difficulties can be seen as problems of control e.g. panic disorder (Mansell, 2010). According to PCT, distress results when inhibition of certain states is required (Morris, Mansell & McEvoy, 2016). Controlling one's behaviour requires top-down modulation of responses with involvement of pre-frontal cortices (Paschke et al., 2016). Conversely, a whole range of psychological difficulties can be traced to amygdala hyperactivation which results in emotion dysregulation (Simon, Adler, Kaufmann & Kathmann, 2014). Emotion dysregulation is also associated with poor control (Kelly et al., 2016).

Control conceptually overlaps with emotion regulation (Paschke et al., 2016). Emotion regulation is a transdiagnostic construct that has become popular in both research and clinical domains. Emotion regulation (ER) difficulties precipitate the development of both emotional and internalising problems (e.g. borderline personality disorder, depression and anxiety), suggesting it's transdiagnostic (Aldao, Gee, De Los Reyes & Seager, 2016). An impressive array of studies also underscores emotion regulation as a transdiagnostic process across a range of externalising problems and problems related to control (Aldao, Gee, De Los Reyes & Seager, 2016) e.g. conduct disorder (Beauchine, 2015) and eating disorders (Svaldi, Griepenstoh, Tuschen-Caffier & Ehring, 2012). A closer examination of studies shows that ER has

been demonstrated cross-sectionally across populations with a range of psychological difficulties suggesting that it is a concept with stable explanatory power (Aldao, Gee, De Los Reyes & Seager, 2016).

Maladaptive ER cognitive strategies such as rumination, avoidance, suppression and worry are influential in moderating health management strategies across a range of difficulties (Aldao, Jazaieri, Goldin & Gross, 2014). Rumination in particular involves an actionless focus on distress, and its causes, which does not promote constructive problem solving (Nolen-Hoeksema, Wisco & Lyubomirsky, 2008). Therefore, rumination significantly affects problem solving, and can lead to prolonged dwelling and disabling indecision (Ward, Lyubomirsky, Sousa & Nolen-Hoeksema, 2003).

The findings of a whole body of research suggest that disruption of meaningful goals is prevalent in a wide range of mood disorders e.g. depression, hypomania and anxiety (Dickson, Johnson, Huntley, Peckham & Taylor, 2017). Not only does rumination impair problem solving, it also leads to poor solution selection (Donaldson & Lam, 2004). Studies have found that rumination, although traditionally associated with depression, is also associated with a range of established nosological conditions such as emotional disorders, eating disorders, substance abuse (Nolen-Hoeksema, Stice, Wade & Bohon, 2007). Thus, rumination has been identified as having a pivotal role in the development of the major classes of psychological difficulties (Luca, 2019).

Intolerance of uncertainty (IU) has also been identified as a transdiagnostic emotion regulation strategy mediated by both worry and rumination (Boswell, Thompson- Hollands, Farchione & Barlowe, 2013). Emerging evidence indicates that IU has explanatory value in a range of emotional problems (McEvoy & Mahoney, 2011). IU has also been found to be associated with experiential avoidance (Lee, Orsillo, Roemer & Allen, 2010).

Experiential avoidance is implicated in maintaining a range of difficulties due to its role in accentuating negative experiences (Wenzlaff & Wagner, 2000) and fostering inaction (Hayes et al., 2004). Suppression is a particular type of experiential avoidance that leads to the development of a wide range of psychological problems e.g. GAD (Ellard, Barlow, Whitfield-Gabrieli, Ganrieli & Deckersbach, 2017), OCD (Salkovskis, 1996) and PTSD (Ehlers & Steil, 1995). Additionally, research has shown that suppression is a transdiagnostic process that mediates comorbidities across conditions (Garland & Robert-Lewis, 2012). Experiential avoidance promotes psychological inflexibility (Kato, 2016) and is demonstrated in eating disorders (Rawal, Park & Williams, 2010) and emotional problems after psychosis (White et al., 2013). Consistent with its role as a transdiagnostic mechanism, psychological inflexibility has itself been found as functionally related to a broad range of conditions emotional conditions (Levin et al., 2014),

Both psychological inflexibility and suppression can be ameliorated by mindfulness (Hooper, Villate, Neofotistou & McHugh, 2010). Mindfulness is a

transdiagnostic, adaptive emotion- regulation process that has grown in both research and clinical popularity (Gratz & Roemer, 2004). Mindfulness is a fundamental part of acceptance and commitment therapy (ACT), the effects of which have been demonstrated transdiagnostically in BPD (Perroud, Nicastro, Jermann & Hugeulot, 2012), pain (Vowles, Witkiewitz, Snowden & Ashworth, 2014) and depression (MacKenzie & Kocovski, 2016).

Mindfulness has been conceptualised as a self-regulatory process that reduces attentional biases in a wide range of clinical problems e.g. depression (Segal et al., 2010), anxiety-related difficulties such as GAD (Roemer and Orsilli, 2002) and pain (Schmidt et al., 2011). Attentional biases/distortions are common across difficulties including anxiety (Cisler & Koster, 2010), depression (Lichenstein-Vidne et al., 2017), and pain (Schoth, Nunes & Liossi, 2012). Allocation of attention can be influenced by motivational salience in relation to avoiding pain or achieving pleasure, which in turn is influenced by affective salience (Todd, Cunningham, Andersen & Thompson, 2012). Findings from neuroscience research suggest that goal approach/avoidance, innervated by the orbitofrontal cortex and amygdala, may be a transdiagnostic process across psychological difficulties (Spielberg et al., 2014). These neuroscientific findings substantiate the role of motivation in psychological difficulties (Spielberg et al., 2014). Motivation to address difficulties can be conceptualised as a transtheoretical process that impacts outcomes (Boswell et al., 2012). High levels of distress negatively impact motivation levels (Boswell et al., 2012), and motivation to address

difficulties is considered key to successful psychotherapeutic change (Fienstein, Heiman & Yager, 2015).

## Transdiagnostic approaches in stroke

This review is the first review of transdiagnostic psychological approaches in stroke and considers both treatment and prevention of psychological difficulties after stroke. Transdiagnostic approaches such as problem-solving therapy (PST), Motivational Interviewing (MI) and Acceptance commitment therapy (ACT) have demonstrated robust results in stroke populations (e.g. Robinson et al., 2007; Watkins et al., 2007; Majumdar & Morris, 2019). Table 1 provides detail of the proposed links between the evidence base for transdiagnostic concepts identified in the literature and the particular transdiagnostic approaches tested in stroke (references for the links are provided in the second column). (See Table 3 in appendix 1 which highlights the transdiagnostic emphasis of the interventions tested in stroke).

Table 1

*Proposed links between the evidence base for transtheoretical concepts and transdiagnostic approaches tested in stroke.*

| Transdiagnostic theory identified in the literature | Transdiagnostic approach tested in stroke and their links to the transdiagnostic theory identified in the literature |
|---|---|
| Control (Powers et al., 2011) | MI (Motivation impacts on control strategies e.g. Jones, Siegle & |

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| | Mandell, 2016); ACT (Control leads to greater experiential avoidance e.g. Kashdan et al., 2014). |
| Intolerance of uncertainty (IU) (Boswell, Thompson- Hollands, Farchione & Barlowe, 2013) | ACT (IU leads to excessive avoidance e.g. Flors, Cobos & Lopez, 2018); MI (IU leads to devaluing of outcome e.g. Flors, Cobos & Lopez, 2018). |
| Emotion dysregulation (Aldao, Gee, De Los Reyes & Seager, 2016) | PST (Emotion dysregulation impairs problem solving e.g. Donaldson & Lam, 2004); ACT (the goal in ACT is to achieve emotion regulation e.g. Narouzi, Zargar & Narouzi, 2017); MI (emotion affects approach/avoidance motivation e.g. Beauchaine & Zisner, 2017), integrative behavioural approaches tested in stroke include a combination of problem solving and motivational techniques (e.g. Seattle protocol adapted for stroke Teri, Logsdon & McCurry, 2008) |
| Experiential avoidance (Hayes et al., 2004) | ACT (using negative strategies to avoid emotions heightens vulnerability to psychological difficulties e.g. Narouzi, Zargar & Narouzi, 2017); PST (emotion focussed strategies as opposed to problem-solving strategies exacerbate problems e.g. Schoenmakers, Tilburg & Fokkema, 2015); MI (connection between experiential avoidance and |

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| | approach-avoidance motivation e.g. Nielsen, Sayal & Townsend, 2016); integrative behavioural approaches* Rather than alleviating distress, a solution-focussed approach promotes goal-directed behaviour (Shuttlewood & Nash, 2016). |
| Psychological inflexibility (Kato, 2016) | ACT (psychological flexibility is fundamental to ACT e.g. Kato, 2016); PST (problem solving skills improve psychological flexibility e.g. Burke et al., 2014); MI (distress impairs cognitive flexibility, in addition to which motivation and cognitive control are neurobiologically linked e.g. Chiew & Braver, 2011). |
| Mindfulness (Segal et al., 2010) | Mindfulness based approaches (e.g. Segal, 2010); ACT (mindfulness methods improve present moment connection in ACT e.g. Zhang et al., 2018). |
| Motivation (Boswell et al., 2012) | MI (emotion affects approach-avoidance motivation e.g. Beauchaine & Zisner, 2017); PST (motivation to address problems is affected by distress e.g. Boswell et al., 2012); ACT (connection between experiential avoidance and approach-avoidance motivation e.g. Nielsen, Sayal & Townsend, 2016). |

* integrative behavioural approaches e.g. the Seattle protocol include problem solving and motivational aspects, in addition to pleasant activity/event scheduling (Teri, Logsdon & McCurry, 2008).

## Method

Preferred Reporting Items for Systematic Reviews and Metaanalysis (PRISMA) guidelines (The PRISMA group, 2009) were followed for this review.

### Assessment of Methodological Quality of Included Studies:

The studies were quality appraised using the 'Effective Public Health Practice Project Quality Assessment Tool' (EPHPP; Jackson & Waters, 2005). The measure assesses the overall quality of quantitative studies through calculating domain scores. Domain scores are subsequently converted into overall markers of quality appraisal. Domains include study design, randomisation, confounders etc. The tool has been used extensively in public health research. The tool's content and construct validity are high (Thomas, Cliska, Dobbins & Micucci, 2004). The tool provides 3 potential global indicators: Strong (no weak ratings), moderate (1 weak rating) and weak (2 or more weak ratings). The Cochrane Risk of Bias tool (Higgins et al., 2011) was also used to assess issues of bias, such as blinding of psychological therapies, in randomised controlled trials.

## Literature search strategy

To be included in this review studies had to have met the following inclusion criteria: in peer-reviewed journals, in English, adult sample of stroke survivors, reported psychological distress on standardised psychological outcome measures that measure symptoms of emotional/ psychological difficulties, and studied a transdiagnostic approach with a theoretical basis consistent with the evidence-base for transdiagnostic concepts provided in the introduction (see Table 1 for proposed links; e.g. emotion dysregulation leads to ineffective problems solving (Donaldson & Lam, 2004) so a link to PST is proposed in Table 1). Studies using integrative, transdiagnostic behavioural interventions were included. Included studies had designs with pre- post outcomes as a minimum. This review used a clinical-criteria for the definition of stroke which follows other prominent review strategies (Hackett, Anderson, House & Xia, 2008). The clinical definition includes intracerebral haemorrhage and cerebral infarction. To be fully comprehensive, Transient-Ischaemic Attack (TIA) was also included. Although subarachnoid haemorrhage is an atypical stroke, trials including results for SAH were included. Studies were not excluded on the grounds of gender, ethnic background or any other demographic, except studies of non-adult samples were excluded. The review included varied designs encompassing pilot, open trials and quasi-experimental designs.

Exclusion criteria: Studies were excluded if the interventions focussed on carers, serious psychopathology predating stroke (e.g. Bipolar Disorder), and case studies. Studies reporting on mixed neurological conditions were excluded unless results for stroke could be clearly extracted. Foreign language articles, unless translated and available in English, were excluded. Qualitative studies were excluded.

**Search methods**

A scoping exercise was conducted which showed that there were no studies meeting the transdiagnostic criteria prior to the year 2000. Studies were identified by searching on Ovid, MedLine, and Psychinfo databases between January 2000- December 2018. A repeat search in April 2019 showed that there had been no additional publications of transdiagnostic psychological approaches after stroke. The following search terms were used: 'transdiagnostic,' 'mindfulness', 'Acceptance and commitment therapy' ('ACT'), 'problem solving', 'motivational interviewing', 'behavioural therapy', 'compassion focussed therapy' AND 'stroke, 'cerebral vascular accident' ('CVA'), 'Transient Ischaemic Attack' ('TIA'), 'Subarachnoid haemorrhage' ('SAH'). 'CBT' or 'cognitive behavioural therapy' weren't searched as the scoping exercise showed that the only study of CBT after stroke utilised activity scheduling for depression which is considered a uni-diagnostic approach for depression (Veale, 2008) and fails to meet the transdiagnostic criteria for this systematic review.

## Data collection and analysis

All citations and abstracts revealed through searching were reviewed on the basis of the inclusion criteria. Full-text articles were studied when all inclusion criteria were met.

## Data extraction

The primary evaluated outcome was the effect on standardised outcome measures.

Data were also extracted on the following characteristics of papers:

1. Design: including recruitment strategy, treatment assignments, adherence, follow-up, drop-out
2. Measure/s
3. Intervention
4. Sample size
5. Manualisation
6. Exclusion of aphasia

## Result

Figure 1 outlines results obtained using the search strategy

Figure 1

*Search strategy results*

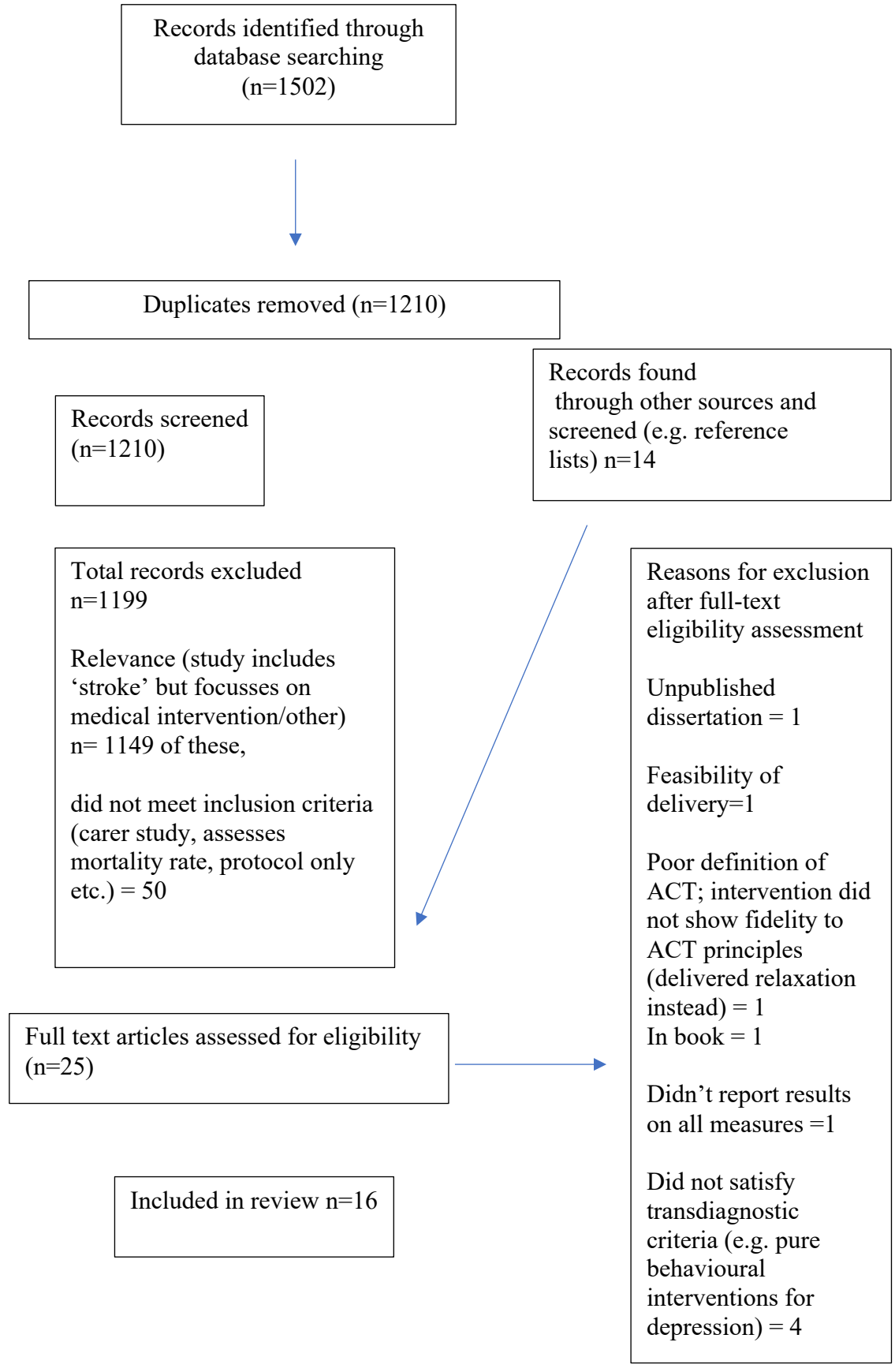

Table 2

*An overview of included studies*

| Author/s | Study intervention target | Study design and treatment or prevention | Sample characteristics | Intervention | Study period/follow-up | Manual/ clear steps for intervention? | Aphasia in exclusion criteria? | Measure of psychological distress | Summary of findings |
|---|---|---|---|---|---|---|---|---|---|
| **Robinson et al. (2008)** | Prevention of post-stroke depression (PSD)/ improvements to function. | RCT; anti-depressants vs. PST vs. placebo. Prevention study. | 127 ischemic or haemorrhagic stroke survivors (176 intention-to-treat) without depression, within 3-month of index stroke. | Individual Escitalopram and PST. | 3, 6, 9 and 12- month follow-up. | Yes. | No | Structured clinical interview for DSM-IV diagnosis of depression; Hamilton depression rating scale. Hamilton anxiety rating scale. Functional Independence measure (FIM) & Social Functioning Exam (SFE). | Patients randomised to placebo 4.5 more likely than Escitalopram and 2.2 more likely than PST to develop depression. 7.2 patients would need to be treated with Escitalopram, and 9.1 cases treated with PST, to prevent 1 case of depression. After intent-to-treat analysis Escitalopram superior to placebo and PST. No FIM & |

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| | | | | | | | | SFE group differences. Results reported for the overall year. |
| **Mikami et al. (2014)** | Prevention of GAD/ improvements to function. | RCT; anti-depressants vs. PST vs. placebo. Prevention study. | 149 ischemic or haemorrhagic stroke survivors without GAD, within 3 months of index stroke. | Individual Escitalopram and PST. | 12 months. | Yes. | No. | Structured clinical interview (SCID); HAM-A; FIM and Social functioning exam (SFE). | Patients in placebo 4.49 times group more likely to develop GAD than anti-depressant group and 4 times more likely to develop GAD than PST group. Numbers needed to treat (NNT) for combined Escitalopram and PST was 7.46. |
| **Mikami et al. (2013)** | Development of post-stroke apathy/ improvements to function. | RCT; anti-depressants vs. PST vs. placebo. Prevention study. | 154 ischemic or haemorrhagic stroke survivors without apathy, within 3-months of index stroke. | Individual Escitalopram and PST. | 12-month follow-up. | Yes. | No. | SCID; FIM; Apathy scale. | Time from enrolment to onset of apathy not statistically significant between groups. Cox proportional hazard showed that patients' development of apathy in both PST and escitalopram delayed compared to placebo. No significant differences between groups on FIM. |

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| **Mikami et al. (2011)** | Onset of mood difficulties. | RCT; anti-depressants vs. PST vs. placebo. Prevention study. | 108 non-depressed, ischemic or haemorrhagic stroke survivors, within 3-months of index stroke, without mood difficulties. | Individual Escitalopram and PST. | 18-month follow-up of Robinson et al. (2008). | Yes. | No. | Proportion of population using SCID and Hamilton depression rating scale (HRSD). | Rate of depression was higher in non-depressed stroke patients after cessation of anti - depressants vs. PST and placebo at 6 months. HDRS scores higher for anti-depressant group at 18 months. Odd-ratios showed an elevated risk-level of depression for antidepressant group only. No significant effect on FIM. |
| **Mitchell et al. (2009)** | Treatment of mood/ improvement to function. | RCT (Living Well with Stroke trial); Psychosocial intervention + pharmacotherapy vs. TAU. | 101 community-dwelling stroke survivors, within 4 - months of index stroke. Diagnosis of depression validated using the DISH (Diagnostic interview | Individual Brief psychosocial/behavioural intervention (Seattle Protocol) * in combination with pharmacotherapy. | 12 months duration and 24- month follow-up.. | Yes. | No. | HRSD | Greater decrease seen on HRSD for intervention group at all intervention points, and at 1-year. Greater remission rates reported for intervention group at 24 months which also predicted better functioning on Barthel Index. |

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| | | | and structure Hamilton). | | | | | | |
| **Hadidi, Lindquist, Buckwalter & Savik (2015)** | Treatment of Mood/ improvements to function. | Repeated measures experimental, randomised design (randomised to groups); PST vs. TAU. Intervention. | 22 stroke survivors. Participants recruited regardless of current status of mood difficulties, however CES-D score of >5 was used to indicate depression. <5 was classed as subsyndromal depression. | Individual PST (IMPACT model). | | Yes. | Severe aphasia excluded. | Centre for epidemiological studies – depression scale (CES-D); FIM. | No statistically significant differences in groups. PST group showed clinical significance of a greater drop in CES-D scores for 10 out of 11 participants at 10 weeks. A higher proportion of participants in PST group became subsyndromal for depression. No difference on FIM between groups. |
| **Visser et al. (2016)** | Coping, HRQOL, mood. | RCT; PST vs. TAU. Intervention. | 166 outpatient stroke survivors, including SAH. CES-D was used to determine mood difficulties. Baseline | Group-based PST (bolt-on to TAU). | 12-month follow-up. | Yes. | Moderate-to-severe aphasia exclude. | Coping Inventory for stressful situation (CISS), Short problem - solving inventory-Revised (SPSI-R), Stroke specific quality of life scale -12 (SS-QOL) and | Significant differences on CISS at 6 months. Significant differences between groups for avoidant coping and task-oriented coping, neither sustained at 12-month follow-up. No differences in groups in Emotion- |

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| | | | scores for both PST and TAU groups didn't reach cut-off for probable depression. | | | | | EURO-QOL EQ-5D-5L. CES-D as secondary outcome. | oriented coping. No overall difference in coping skills between groups. No differences in SS-QOL or EURO-QOL (both groups improved, although PST group continued to increase over time). No overall differences on overall HRQOL at 12 months. No group differences on CES-D. |
| **Moustgaard, Felteau, Beddard (2007)** | Anxiety, Depression/ quality of life. | Pre-post-design. Intervention study. | 23 general population stroke participant sample. No verification of current mood difficulties. | Group Mindfulness- based cognitive therapy. | 3-month follow-up | Yes. | No. | Hospital anxiety and depression scale (HADS), Beck anxiety inventory (BAI) & Beck depression inventory (BDI-II). Stroke specific quality of life and 36-short form general health questionnaire. MMSE. | Statistically significant improvements on all measures, including improved mobility maintained at 3 - months follow-up (with exception that p values for panic and autonomic scales on BAI weren't statistically significant). |
| **Joo et al. (2010)** | Anxiety, Depression and stress. | Pre-post effectiveness | 11 SAH stroke survivors. | Individual MBSR. | Not stated. | Yes. | No. | BDI-II (Korean Version) and state-trait | Statistically significant decrease on BDI-II. Borderline |

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| | | study. Intervention. | Verification of current status of mood difficulties not provided. | | | | | anxiety inventory (STAI). Heart-rate variability (HRV). | significant differences on STAI. Both maximum and minimum BP decreased (borderline significant difference). All indices of heart rate variability showed statistically significant differences. |
| **Watkins et al. (2007)** | Anxiety/ depression/ improvements to function. | RCT; MI vs. TAU. Intervention. | 411 stroke survivors on acute stroke registry. Mood difficulty assessed using GHQ-28 with a score >5 signifying low mood. | Individual MI. | 3 months. | Yes. | No (Severe communicative difficulties excluded). | General health questionnaire (GHQ-28), Stroke expectations recovery scale (SEQ) and Barthel Index. | Statistically significant result of MI on GHQ-28 at 3 months. A protective effect of MI on depression. No differences on SEQ or Barthel Index. |
| **Watkins et al. (2011).** | Mood and mortality. | RCT: MI vs. TAU. Intervention. | 290 stroke survivors on acute registry. Mood dichotomised on GHQ-28 (score OF>5 | Individual MI. | 12-month follow-up study of Watkins et al. (2007). | Yes. | No (Severe communicative difficulties excluded). | GHQ-28; Beliefs and expectations of recovery (SEQ) and Barthel Index. | Results as above. These results held at 3 months. At 12 months, significant effect of MI remained. |

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| | | | indicated low mood). | | | | | | |
| **Kerr, McCay, Mackey, Wijeratne (2018)** | Mood and anxiety/ QOL. | RCT; MI vs. TAU. Intervention. | 38 stroke survivors in acute setting. Depression confirmed using HADS and PHQ-9. | Individual MI. | 3-month follow-up | Yes. | No (Severe aphasia excluded) | HADS; Patient health questionnaire (PHQ-9), Quality of life (QOL index -stroke version). | In intervention group anxiety scores similar to baseline at 3-month follow-up. Depression scores increased in both groups. No differences on QOL index in groups, which was high for both groups at 3 months. |
| **Majumdar & Morris (2019)** | Mood/ anxiety/ wellbeing. | Randomised design with repeated measures; ACT vs. TAU. Intervention study. | 53 stroke survivors from medical and community settings. Verification of current status of mood difficulties not provided, except mean of baseline scores on PHQ-9 and GAD-7. | Group-based ACT. | 2-month follow-up. | Yes. | No (Severe aphasia excluded). | PHQ-9; Generalised anxiety disorder measure (GAD-7); Euro-qol (EQ)-5D-5L; Adult hope scale (AHS); Warwick Edinburgh mental wellbeing scale (WEMWS). | Statistically significant difference in groups in favour of ACT for depression, sustained at 2-month follow-up. Significant time x effect for ACT on hopefulness, self-reported health status. No significant differences for GAD-7, QOL-STROKE or WEMWS (pre-post analyses for WEMWS was significant). |

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|---|---|---|---|---|---|---|---|---|---|
| **Fang, Mpofu & Athanasu (2017)** | Mood/anxiety. | RCT; repeated measures at 1, 3 and 6-months; CPI vs. TAU. Intervention. | 42 ischemic or haemorrhagic stroke patients, within 1 week of stroke. Mood difficulties screened with HADS; patients with score >8 positive for PSA and PDA. | Individual CIPI (Constructive integrative psychosocial intervention). * | 6 months. | Yes. | No.. | HADS | Greater proportional reduction in HADS scores for intervention group at 6 months for depressed patients. Statistically significant improvements for HADS scores for anxiety patients compared to TAU group. |
| **Kirkness et al. (2017)** | Mood. | RCT; Psychosocial intervention in-person or teletherapy vs. TAU. Intervention. | 100 ischemic or haemorrhagic stroke survivors recruited from hospital settings, within 4 months of index stroke. Geriatric Depression screen used to detect | Individual Brief psychosocial intervention via. Teletherapy or in-person (adapted from Seattle protocols). ** | 12 months duration. | Yes. | No. | HRSD scale. | No difference between teletherapy or in -person so groups combined for analysis against TAU. Higher percentage decrease on HRSD scores and remission rates in combined intervention group (in-person and tele-therapy) vs. control group. But this was not statistically significant. |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | depression. Patients with >11 scores positive for depression. | | | | | | |
| **Northcott, Burns, Simpson & Hilari (2015)** | Mood/ anxiety/ social network. | Small n pilot study; repeated measures, pre-post, design. Feasibility of intervention. | 5 community -based aphasic stroke survivors, 6 -months post - stroke. Verification of current mood status not provided, except pre-post means on GHQ-12. | Individual Solution focussed brief therapy (BRIEF model). | 5 weeks duration | Yes. | No (Severe aphasia excluded) . | GHQ-12; Friendship scale of stroke social network scale; communication participation item bank (CPIB). | Trend towards improvement on GHQ-12 but not Friendship scale. All participants improved on the CPIB relative to scores prior to the intervention. |

* Classed as a transdiagnostic approach as CIPI includes problem-solving, stress management techniques in addition to activity participation **Classed as a transdiagnostic approach since Seattle protocol is an integrative transdiagnostic approach to increase activity levels, including. problem solving, goal-setting, addressing obstacles, and motivational approaches (Teri, Logsdon & McCurry, 2008).

Quality analysis results are presented in Table 3 (in order of above)

Table 3

*Quality analysis results*

| Paper | Design | Quality appraisal global rating for paper |
|---|---|---|
| Robinson et al (2007) | RCT | Strong |
| Mikami (2014) | RCT | Strong |
| Mikami (2013) | RCT | Strong |
| Mikami (2011) | RCT | Strong |
| Mitchell et al (2009) | RCT | Strong |
| Hadidi, Lindquist, Buckwalter & Savik (2014) | Repeated measures experimental design. Randomised to groups | Weak |
| Visser et al (2016) | RCT | Strong |
| Moustgaard, Felteau & Beddard (2007) | Pre-post | Weak |
| Joo et al (2010) | Pre-post | Weak |
| Watkins et al (2007) | RCT | Strong |
| Watkins et al. (2011) | RCT | Strong |
| Kerr, McCann, Mackey, Wijeratne (2018) | RCT | Strong |
| Majumdar & Morris (2019) | RCT | Strong |
| Fang, Mpofusu & Athanasu (2017) | RCT; repeated measures. | Weak |
| Kirkness et al. (2017) | RCT | Strong |
| Northcott, burns, Simpson & Hilari (2015) | Pre-Post | Weak |

## Findings

In brief, 14 out of 16 studies of transdiagnostic approaches found statistically significant differences in groups in favour of the transdiagnostic approach. These were: PST (Robinson et al. 2008; Mikami, 2011, 2013, 2014); group-based ACT (Majumdar and Morris, 2019); MI (Watkins et al. 2007; Watkins et al. 2011); brief integrative psychosocial intervention (Mitchell et al. 2009); group-based PST (Visser et al. 2016); MBCT (Moustgaard, Felteau & Beddard, 2007); MBSR (Joo et al. 2010); constructive integrative intervention (Fang, Mpofu & Athanasu, 2017) and brief solution focussed (Northcott, Burns, Simpson & Hilari, 2015) (see Table 2). Four out of sixteen studies were prevention studies (Robinson et al., 2008; Mikami et al., 2011, 2013, 2014).

Short-term (<3 months) follow-ups were uncommon, except Northcott, Simpson, Burns & Hilari (2015) without follow-up; Majumdar & Morris (2019) completed a two-month follow-up. The following studies completed 12-month follow-ups: MI (Watkins et al. 2011), brief psychosocial/behavioural integrative intervention (Mitchell et al. 2009) and PST (Visser et al. 2016). Duration of studies ranged from five weeks (Northcott, Simpson & Hilari, 2015) to 18 months (Mikami et al., 2011).

The PST studies were conducted over a long period: 12-18 months (Robinson et al., 2008; Mikami, 2011; 2013; 2014). The studies of Mitchell et al. (2009), Majumdar & Morris (2019), Visser et al. (2016), Moustgaard, Felteau & Beddard (2007) and Watkins et al. (2011) all showed beneficial effects were maintained at follow up. Only three of the 16 studies were of

group-based interventions: (Majumdar & Morris, 2019; Visser et al., 2016; Mousgaard, Felteau & Beddard, 2007) and all obtained positive results.

It is worth considering these results in greater detail. One finding of note is that the study by Kerr, MacCann, Mackey & Wijeratne (2018) didn't replicate the findings of Watkins et al. (2007) for beneficial effects of MI (p=0.03). On closer scrutiny, the Kerr, McCann, Mackey & Wijeratne (2018) used 3 shorter sessions of MI, whilst Watkins et al (2007) used four longer sessions of MI. Another possible explanation for the discrepant finding for MI is that Watkins et al. (2007) recruited stroke survivors immediately after the acute stage (two-four weeks) of stroke, whilst the sample in the Kerr, McCann, Mackey & Wijeratne (2018) study was composed of acute stroke participants. The follow-up study of MI by Watkins et al. (2011) showed that the positive effect of MI on depression held at 12-month follow-up (p=0.02).

Five of the six PST studies showed that problem-solving is beneficial both in the treatment and prevention of post-stroke psychological difficulties (Robinson et al., 2008; Mikami, 2011; 2013; 2014; Visser et al., 2016). The Robinson et al. (2008) study found that anti-depressants prescribed to a sample of *non-depressed stroke survivors* appeared to mitigate against development of depression at twelve months, compared to PST and TAU. The authors suggest that this finding illustrates the protective effect of anti-depressants against the development of post-stroke depression. However, the 18-month follow-up of this study by Mikami et al. (2011) showed that rates of depression in the anti-depressant group, after cessation of anti-depressants, exceeded rates in either PST or TAU. Their odds-ratio findings

indicated an elevated risk of depression following anti-depressant use, which warrants serious consideration (Mikami et al., 2011). The study of Hadidi, Buckwalter, Lindquist & Buckwalter (2015) failed to replicate the finding in favour of PST, for which one potential explanation is the small sample size, since they noted a clinically significant drop in CES-D scores for PST.

A range of outcome measures, and secondary measures were employed by studies. All studies utilised standardised outcome measures and reported data derived from all outcome measures. Twelve out of 16 studies used tools specifically validated for stroke samples (Northcott, Burns, Simpson & Hilari, 2015; Kirkness et al., 2017; Fang, Mopfofu & Athanasu, 2017; Majumdar & Morris, 2019; Kerr, McCann, Mackey & Wijeratne, 2018; Watkins et al., 2007; 2011; Joo et al., 2010; Moustgaard, Felteau, Beddard, 2007; Hadidi, Buckwalter, Lindquist, Savik, 2014; Mitchell et al., 2009). Four studies used a SCID interview (Robinson et al., 2008; Mikami, 2011; 2013; 2014).

Adverse events were not reported, except for medication (Robinson et al., 2008; Mikami, 2011, 2013, 2014). Randomised controlled trials were frequently employed in twelve of the 16 studies (Robinson et al., 2008; Mikami et al., 2011; Mikami, 2013; Mikami, 2014; Watkins et al., 2007, 2011; Mitchell et al., 2009; Hadidi, Buckwalter, Lindquist & Savik, 2014; Visser et al., 2016; Kerr, McCann, Mackey, Wijeratne, 2018; Majumdar & Morris, 2018; Fang, Mpofusu & Athanasu, 2017). Both studies of mindfulness were pre-post intervention studies (Joo et al., 2010; Moustgaard, Felteau & Beddard, 2007). Hadidi, Buckwalter, Lindquist & Savik (2014) randomised to groups to increase plausibility of results resulting from the experimental

design. Nine of the 13 RCT's compared the experimental intervention to TAU only (Mitchell et al., 2009; Visser et al., 2016; Watkins et al., 2007; 2011; Kerr, McCann, Mackey & Wijeratne, 2018; Majumdar & Morris, 2019; Fang, Mpofusu & Athanasu, 2017; Kirkness et al., 2017).

All studies reported on randomisation strategies, if appropriate (e.g. Robinson et al., 2008). Blinding of data collection was employed by few studies (Visser et al., 2016; Robinson et al., 2008; Mikami et al., 2014; Mikami et al., 2013; Mikami., 2011). Robinson et al. (2008) reported a breach in the blinding of the psychological intervention. The majority of the studies used standardised, published, treatment protocols (e.g. Robinson et al., 2008; Mikami, 2011, 2013, 2014; Majumdar & Morris, 2018; Watkins et al., 2007; Watkins et al., 2011; Joo et al., 2010; Mitchell et al., 2009; Hadidi, Buckwalter, Lindquist, Savik, 2014; Kerr, McCann, Mackey & Wijeratne, 2018; Northcott, Burns, Simpson & Hilari, 2015). Studies rarely reported fidelity to model with few exceptions (Watkins et al., 2007, 2011; Hadidi, Lindquist, Buckwalter & Savik, 2014). Eight studies conducted an intent-to-treat analysis (Robinson et al. 2008; Mikami, 2014, 2013, 2011; Majumdar & Morris, 2019; Watkins et al., 2007, 2011; Kerr, McCann, Mackey & Wijeratne., 2018). All 16 studies provided either illustrations or descriptions of the flow of participants through the study.

Effects of intervention

In view of the large number of heterogenous outcome measures, and designs, it was inappropriate to pool outcome data.

Findings are highlighted in Table 2.

## Discussion

This review identified 16 studies of transdiagnostic treatment of post-stroke psychological distress. There were few studies for each intervention minimising direct comparison of therapies. Since 11 out of the 16 studies scored 'strong' on the quality appraisal tool there is evidence that transdiagnostic therapies can be effective in reducing symptoms of psychological distress following stroke as measured by standardised measures. However, many studies were underpowered with small samples (n = 20-70) except Robinson et al. (2008); Mikami et al. (2011, 2013, 2014); Watkins et al. (2007, 2011); Mitchell et al. (2009); Visser et al. (2016) and Kirkness et al. (2017). The brief solution focussed study had a very small sample size (n=5), and participants had low initial scores on the GHQ-12 (mean 4.8, n=5).

In practice, each type of therapy has been under-investigated with few subjected to RCTs to date, with the exception of PST for a range of difficulties. A Cochrane risk of bias assessment confirmed that many included trials are subject to bias due to absence of blinding -to -therapy-type and the fact that attention control groups, in addition to placebo control & TAU conditions, were not implemented (Watkins et al., 2007; 2011; Mitchell et al., 2009; Visser et al., 2016; Kerr, McCann & Wijeratne, 2018; Majumdar & Morris, 2019; Fang, Mpofusu & Athanasu, 2017; Kirkness et al., 2017). Attention control groups control for non-specific effects in psychological research (Pagoto et al., 2013). The absence of adequate attention control

groups, in addition to TAU control groups, limits the conclusions that can be drawn about transdiagnostic approaches in particular. The risk bias assessment tool (Cochrane tool; Higgins et al., 2011) also confirmed that studies of psychological therapies couldn't be double blinded. Non-blinded studies increase risk biases such as the Hawthorne effect and researcher-led biases.

With the exception of two studies (Moustgaard, Bedard & Felteau, 2007; Joo et al, 2010), studies were biased as recruitment of stroke survivors was not from general population. However, 12 of the 16 studies used randomised controlled trials thus minimising the impact of recruitment biases. The lowest quality ratings were for the mindfulness (Joo et al., 2010; Moustgaard, Felteau & Beddard, 2007) and brief-solution focussed (Northcott, burns, Simpson & Hilari, 2015) studies.

All data collection measures used in reviewed studies were standardised measures, considered to have good reliability and validity, and good psychometric properties for the detection of post-stroke psychological difficulties (Burton & Tyson, 2015). However, there was a high degree of heterogeneity of outcome measures in studies making it difficult to compare cut-offs across different measures. In pre -post and repeated measured designs (without control groups), the results might equally be explained by uncontrolled confounding factors (Rush, Campbell, Jhund, Petrie & McMurray, 2018). The prevention studies (Robinson et al., 2008; Mikami et al., 2011, 2013, 2014) all utilised the SCID interview which has been validated for stroke (Robinson et al., 2008). However, Robinson et al. (2008)

failed to report findings on the HDRS and the HARS. HADS and HARS results would help verify the diagnoses, as currently there is a risk of reification with DSM diagnoses (van der Kleut & Heugten, 2015). The prevention studies indicate that there is good benefit of problem-solving compared to TAU for prevention of depression given that anti-depressants appear to increase rates of depression in previously non-depressed stroke patients (Mikami et al., 2011). It is also worth noting that in the Robinson et al. (2008) study the positive effect of anti-depressants was achieved through continued use of anti-depressants.

Only Moustgaard, Bedard & Felteau (2007), which adjusted the yoga intervention in the MBCT intervention, and Majumdar & Morris (2019), which adjusted the presentation materials according to advice provided by stroke survivors, described adjustments to accommodate stroke-related presentations.

All studies reported the number of people who declined to participate or showed attrition. However, attrition was not problematic for most studies, with the majority of the original participant population remaining intact. When attrition did occur, studies completed an intent-to- treat analysis, or a robust analysis such as last observation carried forward (e.g. Robinson et al., 2007, Mikami, 2011, 2013, 2014 and Watkins et al., 2007).

Inadequate descriptions of the different elements of interventions weren't common-place, with all sixteen studies providing manuals or descriptions of steps involved in the interventions (e.g. Fang, Mpofu & Athanasu, 2017; Robinson et al., 2008; Mikami et al., 2014, 2013, 2011; Majumdar & Morris.,

2018; Watkins et al., 2007, 2011; Hadidi, Buckwalter, Linquist & Savik, 2014; Northcott, Burns, Simpson & Hilari, 2015; Joo et al., 2010). Use of manuals maximises replicability and real-world application. In studies of multicomponent interventions without manuals, it is difficult to know which aspects are considered the active ingredients of the intervention. Therefore, a strength of reviewed studies is that all the transdiagnostic approaches were delivered generically, through basic manualised approaches, yet achieved respectable results. These results are encouraging as manualised approaches reduce requirement for extensive training. The range of therapies tested also suggests that individual differences in stroke-related psychological presentations could be accommodated. The review also provides evidence that different formats of psychological delivery can be effective e.g. one-to-one or groups. The provision of psychological interventions in the group modality may be particularly welcomed given evidence that 30% stroke survivors experience post-stroke depression and one-in-four experience post-stroke anxiety, as well as a high degree of comorbidity.

The evidence for beneficial effect has to be balanced against limitations of the studies included in this review. Limitations included short-term follow-ups and variations in outcome measures and interventions. This variability limits the potential for generalisability from studies since they may actually be measuring different facets of psychological difficulties and prevents pooling of results for metanalyses. However, a positive finding is that selective reporting of measures was limited.

Within-therapy approaches varied (e.g. Robinson et al. (2008); Mikami et al. (2011, 2013, 2014) used a 7-step PST and Mitchell et al. (2009) used a 4-step PST approach). With figures showing that the cost of even a low-intensity psychological therapy session approaches £100 (Radakrishnan et al., 2013) it is important to ensure that the least number of sessions to realise benefit are researched.

Many of the studies did not report whether psychotherapies underwent a per-protocol analysis, with the exception of Robinson et al. (2008); Mikami et al. (2011, 2013, 2014); Watkins et al., 2007; Hadidi, Buckwalter, Lindquist & Savik, 2014). Per protocol provision requires that psychotherapy is delivered through trained, supervised practitioners, and therapy is manualised. There is good evidence that psychotherapies are required to be adequately provided to realise benefit (Hackett, Anderson, House & Xia, 2008).

The lack of reporting of adverse effects is also particularly concerning, as is the limited follow-up of drop-outs or those reporting absence of benefit. Whilst adverse effects owing to medications were reported (Robinson et al., 2008; Mikami et al. 2011, 2013, 2014), no studies recorded drop-out, combined with lack of benefit from psychological therapy, as a potentially adverse effect.

Mixed populations were studied in all studies e.g. early effects of stroke vs. late effects of stroke. Different stages of the stroke-recovery-continuum are likely to be distinguished by a combination of different psychological difficulties. In the early stages, the requirement to cope with the losses brought about to life by stroke is likely to be prevalent, leading to

accompanying reduction in quality of life. At later stages, adjustment to daily life is required, leading potentially to a combination of self-esteem, identity, relationship and mood difficulties. Studying different populations at different stages therefore makes it difficult to summarise results of interventions.

Fifteen out of sixteen studies allowed inclusion of minor-moderate aphasia which is a real strength. However, the exclusion of severe cognitive and communication difficulties remains problematic. This reinforces the criticism commonly levelled at research that it is unrepresentative of clinical services in the real world (Hackett, Anderson, House & Xia, 2008). In fact, analyses show that up to a third of stroke survivors are consistently excluded from research (Turner-Stokes, 2003). The studies reviewed show limited external generalisability for 2 reasons: 1. stroke commonly strikes at higher age, making co/multimorbidities common, and 2. cognitive impairments are common following stroke, as is aphasia (The Stroke Association, 2012).

The other severe limitation is that psychological comorbidity with mild cognitive impairments was excluded from all studies. This is particularly problematic for the testing of transdiagnostic approaches; despite utilising a transdiagnostic approach none of the studies reported findings on measures of co/multimorbidity. Simply making comorbidity an exclusion criterion means that the effects of comorbidity remain unexplained (Haagsma et al., 2011). It is important that effects of co-multimorbidity are better understood as clinically the problem of co/multimorbidity presents challenges of polypharmacy and associated adverse effects, in addition to higher treatment burden (Smith et al., 2013). No studies reported on common post-stroke

effects such as issues in relationships, identity/role changes and body image issues which is also likely to limit external generalisability.

**Clinical implications**

Transdiagnostic approaches are multifaceted and aim to address co/multimorbidity by targeting the underlying issues of psychological difficulties (Rector, Man & Lerman, 2014). Transdiagnostic therapies are practical, allow parsimonious applicability and reduce requirement to create protocols for single diagnoses. The results of this review suggest that transdiagnostic therapies can be efficacious in the treatment of post-stroke psychological difficulties. However, these results must be interpreted with caution on the basis of the methodological flaws and limitations highlighted by this review.

That group delivery using didactic methods and manualised approaches are effective suggests straight forward translation into clinical practice. Absence of manuals is one of the barriers for straight-forward application of an intervention in clinical practice (Glasgow & Emmens, 2007). Additionally, the approaches tested were straight-forward. Clinicians often cite highly demanding approaches tested in ideal research settings, without margins for deviations from protocols, as limiting the practical application of research findings into clinical practice (Glasgow & Emmons, 2007). The demands on clinical staff and resources required by high intensity approaches is likely to be prohibitive in settings, such as stroke, where disability impedes recovery and resources are limited (see NAO, 2010).

Given that psychological care in stroke is poorly provisioned (NAO, 2010) and Mckevitt et al. (2011) found that 75% of stroke survivors felt their emotional needs weren't addressed, brief, manualised approaches may help bridge this gap. The fact that brief interventions were tested is also an advantage because studies which demand a high intensity of involvement by participants result in small, unrepresentative samples (Glasgow & Emmens, 2007). Transdiagnostic approaches enable realistic translation into clinical practice as, clinically, treating individual contributions to problems is suboptimal and economically disadvantageous (Lefevre et al., 2014). Taking all this together, the clinical value of a transdiagnostic approach lies in facilitating enhanced clinical utility when comorbid problems are classified as distinct entities despite potentially sharing underlying homogeneity (Meghani et al., 2013).

**Research implications**

A large proportion of reviewed studies (60% studies) were rated 'strong' following quality appraisal, suggesting that there is reasonably good evidence that transdiagnostic therapies can be helpful after stroke. The results of this review invite further testing of transdiagnostic therapies for post-stroke difficulties. However, post-stroke difficulties may include mood, fatigue, quality of life, wellbeing and functional difficulties and future studies should also include these facets of post-stroke problems.

Stroke includes comorbidity and complex interactions of effects (Brewer, Horgan, Hickey & Williams, 2012). To test an intervention that is transdiagnostic in nature, it is important that studies don't rely on uni-

diagnostic criteria, neglect wellbeing/quality of life indices, and the whole range of post-stroke comorbidities. For example, many studies used integrated scales of anxiety and depression as opposed to considering a whole range of post-stroke difficulties, thus limiting the utility of the research and its translation into clinical practice.

Studying effects on single facets of complex difficulties also potentially adversely affects the research outcomes. For example, effect sizes may be attenuated in complex problems (Fern & Monroe, 1996). This suggests that measures of single facets of co/multimorbidity are inappropriate. That comorbidities can be influenced by individual differences (Meghani et al., 2013) suggests the importance of understanding comorbidities.

One way to potentially accommodate the comorbidity and complexity is to measure psychophysiological indices alongside psychometric measures. Heart rate variability (HRV) is a potentially useful candidate for measuring psychophysiological outcomes, although its limitations should be properly understood prior to implementation. HRV is associated with impaired emotion regulation (Applehans & Luecans, 2006). Since many psychological difficulties are innervated by emotion regulation in general (see introduction for a review), HRV may provide a way of addressing the problems of *solely* using psychometric measures. HRV also partly addresses the issue of comorbidity since it's associated with interoceptive processing which appears to mediate a large number of biological processes (Khalsa et al., 2018).

One of the pressing issues in psychological research is the failure to replicate findings. Recent scrutiny has revealed that findings of various

research questions couldn't be replicated even under ideal research conditions (Owens, 2018). The current review has highlighted the limitation of heterogenous research conditions leading to inability to meta-analyse the findings. Since the purpose of meta-analysis is to clarify contrasting approaches or to root-out inconclusive findings (Gurevitch, Koricheva, Nakagawa & Stewart, 2018) the inability to meta-analyse findings is a severe problem. For example, as highlighted, the Kerr, Mccann, Mackey & Wijeratne (2018) trial failed to replicate the findings of two other trials (Watkins et al., 2007; 2011); a meta-analysis would clarify true effect of interventions (Gurevitch, Koricheva, Nagakawa & Stewart, 2018). There are therefore two implications: a concerted effort to develop replicable research in stroke is vital, and a future meta-analysis on the subject of transdiagnostic approaches in stroke is crucial. The limitation of a lack of the ability to meta-analyse findings extends to the fact that this review's search strategy may have introduced a systematic bias as unpublished studies weren't searched.

Future studies of transdiagnostic therapies should consider the following:

1. A review of beneficial quality-of-life and long-term outcomes in stroke is required to inform studies.
2. It is important that transdiagnostic therapies are tested on a *combination* of post-stroke difficulties, enhancing clinical utility and generalisability.
3. Where possible, blind data collection and analyses.
4. Conduct randomised controlled trials of adequate sample sizes (+70).

5. Carefully consider exclusion criteria and use consecutive admission to minimise selection bias and improve generalisability.
6. Provide per-protocol analyses for adequate exposure to therapy, manualisation, and adequate follow-ups.
7. Provide adverse effects data and include surveys of psychotherapy-driven adverse effects e.g. difficulties with application of techniques limiting motivation for psychotherapy in the future, or lack of effect leading to drop-out.
8. Monitor and provide clear reasons for drop-outs and conduct intent-to-treat analyses.
9. Future research should at a minimum include representative stroke samples of mild cognitive difficulties common in stroke.
10. Studies should aim to include surveys of patient groups and policy makers to design research to address issues of pressing urgency (Smith et al., 2013).

**Limitations of this review**

In order to provide a comprehensive review of the evidence-base, a wide selection-criteria was employed which increased heterogeneity of studies, particularly in respect to research methods and outcome measures. Therefore, an overall statistical analysis of the results was not possible, and a narrative review was completed. In addition, all types of studies, with the exception of case studies (n=1) were included. This is common practice as a result of the methodological variation of studies in this area. As it stands, the major weaknesses of this review are that included studies didn't

test/measure transdiagnostic approaches on co/multimorbidity in stroke and that a meta-analysis couldn’t be completed.

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## Appendix 1

Table 3

*Key features of transdiagnostic approaches*

| | MI | PST | Mindfulness | BT | ACT |
|---|---|---|---|---|---|
| Effectiveness demonstrated without significant alterations; does not require unique protocols for psychiatric diagnoses; has demonstrated outcomes across conditions. | Yes (see Mckenzie, Pierce & Gunn (2015) for review). | Yes (See references in this review e.g. Robinson et al. (2009)). | Yes (see Lawrence, Booth, Mercer & Crawford, 2013). | Yes. Behaviourally focussed positive psychology interventions (see review of BT for wellbeing irrespective of depression status- Mazzucchelli, Kane & Rees, 2010)). | Yes (see Powers, Vording & Emmelkamp, 2009 for review). |
| Original conception as model of behaviour change irrespective of psychiatric diagnosis? | Yes | Yes | Yes | Yes | Yes |

**Empirical paper**

# Investigating the efficacy of bibliotherapy in stroke: A quasi-experimental design.


## Abstract

Aim: The aim was to investigate a stroke-specific self-management book that targeted psychological issues after stroke.

Design: A quasi-experimental, multiple- baseline design was used

Measures: The GHQ-12 and SWLQ were completed weekly. Other measures, BDI-FS, BAI, HADS, SIS, WEMWS were completed pre-post.

Method: Sixteen stroke survivors participated in a randomised multiple baseline design with three phases, A (randomised- length baseline)- B(Intervention)- C (3-week follow-up). In the baseline phase, participants received therapist contact only. In the intervention phase, participants received bi-weekly therapist support during the bibliotherapy intervention. The follow-up was at three-weeks following completion of intervention.

Results: An omnibus, whole-group, TAU-U analysis was statistically significant for both primary measures with a moderate effect sizes on both measures (0.6 and 0.3 for GHQ-12 and SWLQ respectively). TAU-U analysis

for each case (singlecasecalcultors.org) of the GHQ-12 and SWLQ results showed moderate- to-large effect sizes (0.6-0.9) for 69 percent of the sample on both primary measures, GHQ-12 and SWLQ. For 43% percent of the sample (n=8) the results were statistically significant ($p<0.05$) on the GHQ-12. For 38% of the sample (n=4) SWLQ results were statistically significant ($p<0.05$).

Conclusion: The findings suggest that bibliotherapy, with support, may have promising utility as a cost-effective intervention for psychological difficulties after stroke.

## Introduction

A stroke is classed as an acute cerebral vascular event in which blood supply to a part of the brain is blocked in ischaemic stroke, or ruptured in haemorrhagic stroke (American Stroke Association, 2019). Stroke is one of the top reasons for premature mortality and lifetime morbidity all over the world (Gurol & Kim, 2018). Although medical advances have decreased the mortality rate (Lackland et al. 2014), stroke results in cognitive decline in a significant number of those who survive, with nearly 30% eventually progressing to dementia (Teasel, Salter, Faltynek, Cotoi & Eskes, 2018). Stroke limits quality of life even in the absence of overt disability (Lai, Studensky, Duncan & Perrrera, 2002) and long-term disability predicts poor quality of life (QOL) and health-related QOL (HRQOL) (Abubakar & Isezuo, 2012).

Epidemiological data confirm a high prevalence of psychological difficulties in the stroke population (Wolfe et al., 2011). Point prevalence rates of post-stroke depression indicate a 30% increase in the risk of depression in stroke survivors in the first 6-months after stroke (Hackett & Pickles, 2014), which remains stable for ten years (Ayerbe, Aysis, Wolfe & Rudd, 2013). A large stroke cohort identified a higher risk of depression after stroke compared to a matched reference sample without stroke (Jorgensen et al., 2016).

Post-stroke depression predicts worse functional outcomes at discharge (Ahn, Lee, Jeong, Kim & Park, 2015) and worse rates of recovery in activities of daily living (ADL) (Tsuchiya et al., 2016). Fifteen percent of stroke survivors score in the impaired range on the MMSE (<24), which is predictive of poor take up of ADL, instrumental ADL, and living in an institution, five years after stroke (Liman et al., 2012). Post-stroke depression has a negative impact on rehabilitation (Ahn, Lee, Jeong, Kim & Park, 2015) and longer hospital admittance (Sugawara et al., 2015). Unsurprisingly, long-term conditions, such as stroke, with accompanying depression result in higher healthcare costs (Naylor et al., 2012). Comorbidity of stroke with depression also raises mortality risk (Bartoli et al., 2013)

Post-stroke anxiety is less well-researched, but review findings reveal that it affects one-fifth of stroke survivors split equally between panic disorder and post-traumatic stress disorder (PTSD) (Chun et al. 2018). A Transient Ischemic Attack significantly predicts higher PTSD rates (Kiphuth, Utz, Martin

Kohrmann & Schenck, 2014). Anxiety after stroke has a negative impact on life outcomes even after mild stroke (Chun et al., 2018). Meta-analysis evidence has concluded that anxiety is often comorbid with depression (Campbell-Burton et al., 2012). The existence of anxiety at 3-months has been shown to lead to poorer life outcomes at 3- and 5-years post stroke (Ayerbe, Aysis, Crichton, Wolfe & Rudd, 2014). A systematic review of psychological therapies for post-stroke anxiety failed to support any particular type of psychological intervention (Campbell-Burton et al., 2011). Other less-well researched, but frequent post-stroke conditions include body image (Eilertson, Kirkevold & Bjork, 2010) self-identity (Pallesin, 2014), fatigue (Acciarresi, Bogousslavsky & Paciaroni, 2014) and barriers to returning to employment (Hartke, Trierweiler & Bode, 2011).

Addressing psychological need is considered to be vital to the stroke pathway, with importance of parity in psychological and physical disability (Royal College of Physicians, 2016). To date, there have been numerous investigations of psychological therapies post stroke, with some inconsistent results. The only RCT which investigated CBT for post stroke depression (Lincoln & Flannaghan, 2003) did not find any differences between groups. Subsequent scrutiny revealed that adjustments or adaptations to the CBT had not been made for common problems after stroke e.g. communication/speech difficulties (Thomas & Lincoln, 2006). Studies have confirmed the role of post-stroke aphasia in the development of depression (Shehata, Mistikawi, Risha & Hassan, 2015). In a randomised controlled trial of psychological therapy using a behavioural approach, which made

significant adaptations for aphasia, (Thomas, Walker, Macniven, Haworth & Lincoln, 2013) aphasic stroke survivors benefited from the intervention. A single-case-design study showed CBT to improve post-stroke anxiety in the case of two individuals with cognitive and communication problems (Kneebone & Jeffries, 2013), which also suggests adaptations to conventional formats are required. A published framework has outlined possible adaptations to psychological therapy to be inclusive of common post-stroke cognitive and speech difficulties (Kneebone, 2016). The range of difficulties and comorbidities facing stroke survivors suggest transdiagnostic therapies have a role in stroke care.

Transdiagnostic approaches simplify treatment of emotional difficulties by encompassing the shared aetiological processes in emotional distress (Gros, Allan & Szafranski, 2016). A transdiagnostic therapy of particular relevance to the current study is Acceptance and Commitment Therapy (ACT). A recent RCT investigated brief, group-based ACT, and found results in favour of ACT for depression, hope and health related quality of life in comparison to treatment as usual (Majumdar & Morris, 2019).

**ACT**

The basis of ACT is that distress is an inevitable occurrence in life. ACT centralises functional contextualism in its understanding of distress, theorising that psychological connections between experiences are idiosyncratic (Hayes, 2004). This means that ACT prioritises key individual

psychological processes. ACT has been found to elicit effect sizes of similar magnitude to CBT when applied to long-term health conditions such as pain, although the evidence base is in its nascent stages (Graham, Gouick, Krahe & Gillanders, 2016). Stroke leads to greater disability than nearly all other health conditions (The Stroke Association, 2018). However, significant differences exist in quality of life profiles in long-term health condition mediated by psychological factors (Graham, Gouick, Krahe & Gillanders, 2016). ACT is a transdiagnostic approach with good evidence of applications to populations with complex difficulties, including psychosis, with lasting effects (Bach, Steven, Hayes & Gallop, 2011). Consistent with a transdiagnostic approach, ACT's focus isn't a single psychiatric difficulty or symptom, instead it addresses broader psychological processes such as psychological flexibility (Dindo, Van Liew & Arch, 2017). Review findings indicate that ACT is cost-effective, readily translating to different settings (Ruiz, 2010) and to low-intensity delivery formats (e.g. Dindo, Van Liew & Arch, 2017).

It is vital that cost-effective psychological therapies are identified and investigated. Although the cost-effectiveness of Clinical Psychology is supported (NHS England, 2017), NHS funding has seen its slowest growth in recent years, which is particularly marked in Wales, Scotland and Northern Ireland (Luchinskaya, Simpson & Stoye, 2017). Many of the delivery formats of existing therapies are resource intensive (Majumdar & Morris, 2019). Cost-effective delivery formats include groups, upskilling basic-grade staff and bibliotherapy. Bibliotherapy has also demonstrated its cost-effectiveness

against established therapist-led interventions (Sampaio, Enebrink, Mihalopoulos & Feldman, 2016). A recent review into the benefit of bibliotherapy showed that reading a self-management book is beneficial to health outcomes for those with neurological conditions (Latchem & Greenhalgh, 2014). Several meta-analyses of bibliotherapy have summarised that bibliotherapy is effective for psychological treatment of emotional disorders (Den Boer, Wiersma, & Van Den Bosch, 2004; Hirai & Clum, 2006; Cuijpers, Donker, Van Straten & Andersson, 2010).

## **The current study*:* Efficacy of bibliotherapy using *'Rebuilding your life after stroke' stroke- specific book***

There are no studies of the books that are currently recommended in routine stroke clinical practice. The aim of the present study was to investigate the efficacy of bibliotherapy using a book called '*Rebuilding your life after stroke'*. The book is recommended as part of the 'Reading Well Books' scheme: the English scheme resulting from the Book Prescription Scheme in Wales, which received favourable appraisal from users (Frude, 2011). Bibliotherapy is particularly useful when psychiatric medication is contraindicated (Frude, 2011, or when depression is unremitting (NICE, 2009). There are also unique benefits of bibliotherapy that recommend it for stroke populations. For example, bibliotherapy can be completed at the person's own pace, and allows dissemination of psychological therapies to otherwise hard-to access, isolated populations, due to geography, or stroke-related disability (Jacobs & Mosco, 2008).

The book evaluated in this present study has many benefits. '*Rebuilding your life after stroke*' was written by stroke clinicians and stroke survivors to address common post-stroke psychological difficulties. The book also includes practical guidance on the management of common psychological problems after stroke. The book is based on Acceptance and Commitment Therapy (ACT). Acceptance of effects of stroke was rated as the highest research priority by a panel of experts, including stroke survivors, caregivers and health clinicians (Pollock, George, Fenton & Firkins, 2014). The ACT programme in the book aims to increase both acceptance of the effects of stroke and psychological flexibility, which results in positive health outcomes (Kashdan, 2010). The book was developed with considerable guidance from stroke survivors about the optimal format to increase its accessibility and facilitate good post-stroke outcomes.

**Objectives**

The aim of the current study was to investigate the efficacy of bibliotherapy in stroke using '*Rebuilding Your life After stroke.'*

It was hypothesised that the book, used with therapist support, would lead to reduced psychological difficulties as measured by the GHQ-12, a measure of psychological distress. It was also hypothesised that the book, with therapist support, would lead to improved satisfaction with life.

Since bibliotherapy is self-paced and self-administered it is difficult to evaluate using traditional methods such as randomised controlled trials. Hence, this study used a quasi-experimental design: the multiple baseline design (MBD) in which variables are tracked longitudinally (Kim, Kang & Jeon, 2015). In MBD, a sustained intervention is delivered on a staggered schedule, and control is achieved by randomising baseline lengths (Rhoda, Murray, Andridge, Pennel & Hade, 2011).

## Methods

This study was approved through the integrated research applications system (IRAS) for NHS ethics. R&D permission to conduct the study was obtained in four healthboards (three in south Wales, one in south west England).

Three stroke survivors were consulted during the design of the study and two major pieces of guidance were acted upon: to reduce the length of weekly questionnaires increasing feasibility of study, and to provide bibliotherapy, assisted by therapist, intervention in an individualised manner.

### Sample size

This study was a small n study. Hence, a power calculation was not completed. Multiple baseline studies typically recruit between 4-8 participants. Previous research suggests that the interval treatments

delivered in multiple baselines perform better under small-sample conditions (Ferron, Bell, Hess, Rendina-Gobioff & Hibbard, 2009).

**Recruitment**

This study recruited participants at point of referral, given that concurrent recruitment of the whole sample would have resulted in unacceptable delays. The problems of concurrent recruitment in multiple baseline design are well appreciated (Graham, Karmarkar & Ottenbacher, 2012) e.g. reduced feasibility. Therefore, non-concurrent recruitment was employed.

The study was promoted to three health boards in Wales and one in south west England. The study was also promoted to prominent third sector organisations. Leaflets providing brief information about the study were provided so that these could be passed on to clients. Clinicians/ coordinators were asked to request initial verbal consent from potential participants allowing researcher to make contact. Signed informed consent was obtained by the author of the study who also completed all subsequent roles of the study, including the therapist and assessor roles.

No financial/reward incentives were used to recruit/retain participants.

**Inclusion criteria**

These comprised:

- a clinical diagnosis of at least one stroke and/or TIA
- 18 years of age or above
- reporting psychological distress
- able to read a book.

**Exclusion criteria**

These comprised:

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

**Study procedure**

The study employed a small n, A-B-A multiple-baseline design. This design was applied due to its suitability for a small n study. The benefit of MBD is that variables can be measured continuously over time. Concurrent recruitment was not feasible, and participants started baselines as they were recruited, between June 2018 and March 2019.

In accordance with non-concurrent MBD, baseline lengths were randomised using an Excel randomisation programme. Randomised baseline lengths ranged from two to eight weeks (Table 1).

Table 1

*Randomised order of baselines*

| Participant no. | Randomised order of baseline lengths (weeks) |
|---|---|
| Participant 1 | 4 |
| Participant 2 | 4 |
| Participant 3 | 3 |
| Participant 4 | 7 |
| Participant 5 | 5 |
| Participant 6 | 4 |
| Participant 7 | 4 |
| Participant 8 | 7 |
| Participant 9 | 2 |
| Participant 10 | 8 |
| Participant 11 | 5 |
| Participant 12 | 6 |
| Participant 13 | 7 |
| Participant 14 | 3 |
| Participant 15 | 6 |
| Participant 16 | 7 |
| Participant 17 | 2 |
| Participant 18 | 4 |
| Participant 19 | 6 |
| Participant 20 | 8 |

As per requirement in MBD, participant entry into the intervention stage was staggered, and randomised, which allows a quasi- control for time and maturation effects (Rhoda, Murray, Andridge, Pennell & Hade, 2011).

Staggering the baseline involved some participants remaining in the baseline phase when intervention for others began in a 'step-wedged' design (Rhoda, Murray, Andridge, Pennell & Hade, 2011). This process allows researchers to make causal inference by ruling out whole-sample confounding factors e.g. alteration in UK-based -medical practice in stroke. Randomised baselines provide rigorous control for MBD (Rhoda, Murray, Andridge, Pennell & Hade, 2011).

**Study interventions**

The study consisted of three phases: Baseline, intervention and a 3-week follow-up.

In the baseline phase one-to-one, therapist contact was provided by the researcher every two weeks to control for this element in the intervention phase. During the no-active-intervention, baseline phase, therapist support consisted of person-centred ideals e.g. empathy, positive regard and congruence (see Fazio, Pace, Flinner, Kallmyer, 2018). The sessions lasted between 40-50 minutes. During the baseline phase individuals continued with their usual treatments e.g. antidepressant use, GP appointments, stroke clinic appointments, specialist nurse visits, physiotherapy etc. The baseline phase allowed a measure of the effects of these interventions (and therapist contact) on mood, anxiety and satisfaction with life levels. The baseline effects of the interventions are 'partialled' in the final analysis using a single-

cases statistical analysis package for multiple baseline design (MBD) (singlecase.org/calculators) (Vannest, Parker, Gonan & Adiguzel, 2016).

During the intervention phase the stroke survivor was given the book and the therapist provided support to use the book, and to practise/apply its principles. The support was provided on an individual basis every two weeks. Sessions lasted between 40-50 minutes. The pace of reading/applying the book material was decided in collaboration with the individual; however, the aim of the study was to complete the book. The intervention phase length therefore continued until the book had been completed and varied for individual participants (between 6-16 weeks). The focus of the book material 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 agreed as potentially helpful e.g. thought illusions (face/vase picture) to demonstrate possibility of psychological flexibility.
4. Try out exercise (optional) from the book.
5. Review session and set homework from the book.

Follow-up was completed using the primary measures (GHQ-12, SWLQ). Follow-up took place 3-weeks following the completion of the final, intervention phase, primary measures.

The prevalence of stroke disability is high, and this study aimed to be inclusive. Thus, the study was delivered in participants' places of residence to reduce the burden of travel due to stroke-related mobility restrictions.

**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 were collected every week and included:

General Health Questionnaire -12 (GHQ-12)

The GHQ-12 is a modified version of the original 60-item version. The GHQ-12 was designed to assess psychological difficulties in the general population (Goldberg & Williams, 1988). The validity and reliability of the GHQ-12 has been established (Hankins, 2008). In the general population, Cronbach's alpha has been reported as 0.94 (Lesage, Martens-Resende, Deschamps & Berjot, 2011). In stroke, the validity of the General health

Questionnaire (GHQ) has been thoroughly assessed (Lincoln, Nicholl, Flannaghan, Leonard & Van der Gucht, 2003; Burton & Tyson, 2015). The 12-item version of GHQ is suggested for routine clinical evaluation and community settings in stroke (Bennett & Lincoln, 2016).

Satisfaction with Life Questionnaire (SWLQ) (Diener, Emmons, Larsen, Griffin, 1985).

SWLQ 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. The SWLQ has been found to have good reliability for the assessment of satisfaction with life in a variety of populations (Lopez-Ortega, Torres-Castro & Rosas-Carrasco, 2016) including Parkinson's Disease (Loveride & Hagell, 2016). A meta-analytic reliability- generalisation-study estimated a Cronbach's Alpha of 0.78 across 60 studies (Vassar, 2008). There are currently no stroke validation studies of the SWLQ. However, a stroke study showed that the instrument accurately detected low SWL compared to a norm, of older community-dwelling residents, and showed a decline in the SWL score as a result of depression after stroke as predicted (Ostwald, Godwin & Cron, 2009).

Secondary measures were collected in pre-post format and included:

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

The BDI-II (Beck, Steer, Brown, 1996)- FS is a 7-item, self-report measure. The BDI-II short-form avoids confounding somatic symptoms in physical illnesses (Salter et al., 2013). The validity of the BDI-II-FS has been established (Wang & Gorenstein, 2013), with acceptable sensitivity, 0.71, and specificity, 0.74 in stroke (Healy, Kneebone, Carroll & Anderson, 2008).

Hospital Anxiety and Depression Screen, HADS (Zigmond & Snaith, 1983)

HADS is a 14-item mood and anxiety screening tool for patients with physical illnesses. HADS has undergone validation for use in stroke and has shown good performance: AUC = 85.9% (Prisnie et al., 2016). Sensitivity and specificity values of 0.92, 0.65 respectively are established in stroke (Burton & Tyson, 2015).

BAI (Beck & Steer, 1993).

The BAI is a 21-item, self-report, measure of physiological and cognitive symptoms of anxiety. BAI has been shown to measure general anxiety (Muntingh et al., 2011). A comprehensive meta-analysis of 192 studies found the BAI to demonstrate sound psychometric properties, with good reliability and validity (0.91 and 0.65 respectively) (Bardoshi, Duncan & Erford, 2016). There are currently no validation studies of the BAI in stroke. A study evaluated the anxiety endorsements by stroke survivors using the BAI and found that the rates of anxiety correlated with published rates (1 in 4) and

somatic symptoms were not over-reported, in comparison to emotional items (Barker-Collo, 2007).

### The Warwick Edinburgh Mental Wellbeing Scale (WEMWS)

The WEMWS assesses mental wellbeing using 14 items (Tennant et al., 2007). The WEMWS has been shown to have 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 precedence in psychological stroke research (Majumdar & Morris, 2019).

### Stroke impact scale (SIS)

The SIS is a complete assessment of physical and functional disability associated with stroke (Salter et al., 2013). It is an 8-domain measure, consisting of 59 scaled- questions. The SIS gives a composite disability score (Jenkinson, Fitzpatrick, Crocker & Peters, 2013). The internal consistency of the measure ranges from 0.86- 0.95 (Jenkinson, Fitzpatrick, Crocker & Peters, 2013).

### Survey

Participants completed a brief, closed-question, survey at the completion of the study. The survey consisted of 3 enquiries: "*how helpful was the book*

*using a Likert Scale of 0-10?*" (where 10 is rated as most helpful); "*which part of the book was found to be particularly helpful?" "What aspect of wellbeing did the book help address*? "(4 options were provided (improvements to): anxiety, depression, confidence, self-activation or other?)

**Statistical analysis**

Analysis was completed using TAU-U, an index measure for MBD. TAU-U calculates the rank order difference in scores between phases and is essentially a Mann-Witney-derived between-group test (Brossart,Laird & Armstrong, 2018). Tau-U combines the trend from the intervention phase with nonoverlap from both baseline and intervention phases. TAU-U has been shown to be a reliable test in multiple-baseline design analysis (Bossart, Laird & Armstrong, 2018).

The tool www.singlecaseresearch.org/calculators (Vannest, Parker, Gonan & Adiguzel, 2016) was utilised to complete the TAU-U analysis. This tool is freely available and enables analysis at the individual and group level.

The tool uses the following parameters for TAU-U= $tau_{a\ vs\ b-a}$ (Brossart, Laird & Armstrong, 2018). In this format, TAU-U shrinks the non-overlap index (needed for effect size calculation) by accounting for any overlap between phases, thus providing conservative effect sizes (Bossart, Laird & Armstrong, 2018). In this study, baseline correction, by selecting this function in the calculator, was completed if baseline TAU of baseline exceeded 0.2

(Vannest & Ninci, 2015). The selected TAU-U calculator yields effect sizes for the difference in phases (Brossart, Laird & Armstrong, 2018). The single-case TAU-U analyses did not meet the criteria for Bonferroni correction since: 1) they were planned comparisons of baseline and intervention phases; 2) each analysis represented an individual case and so was important in its own right; 3) the analyses were not based on a null hypothesis that **all** tests were non-significant. (Armstrong, 2014).

Effect sizes were interpreted on the basis of guidelines provided by Vannest and Ninci (2015):

<0.20 = small change

0.20-0.60 = moderate change

0.60-0.80 = large change

The *d* statistic is a measure of the effect size of the intervention (Faraone, 2008). This study aimed to be widely interpretable and so the *d* statistic was also calculated. Shadish, Hedges & Pustejovsky (2014) recommend that the standardised mean difference (SMD), *d*, (Busk & Serlin, 1992) statistic allows both future power calculations and meaningful inclusion of MBD in meta-analyses. SMD is particularly fitting for effect size calculations in MBD as it has the standard deviation of baseline as denominator (Gierut, Morisette & Dickinson, 2015).

SPSS 25 was used to analyse secondary measures.

## Survey Analysis

Relative risk is used to determine associations in cohort studies (Viera, 2008). Relative risk was used to determine the likelihood of gaining benefit if exposure to the book was found helpful (rated as >6/10).

## Results

Figure 1 outlines the flow of participants from initial recruitment.

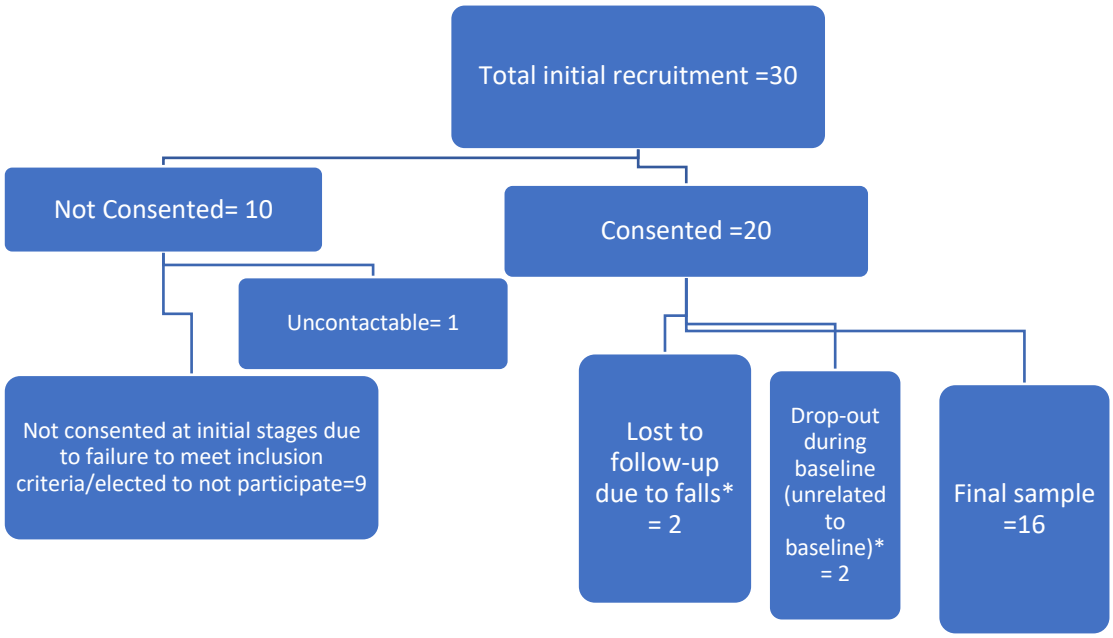



Figure 1

*Flow of participants through the study after initial recruitment*

*See appendix for further drop-out data (Table 8)

Figure 2 gives the breakdown in the final sample numbers by healthboard vs. third-sector recruitment

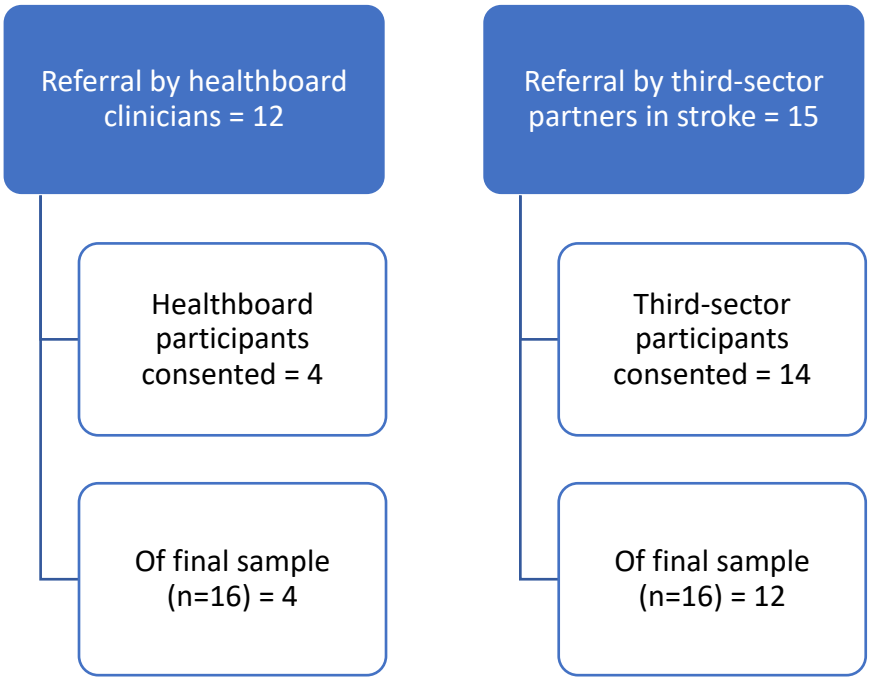



Figure 2

*Breakdown of final sample numbers by healthboard vs. third-sector partners in stroke*

**Demographical analysis**

The rate of male vs. female recruitment was fifty percent.

Eighty -two percent of the sample was from a working-class background.

The age range extended from 30 years of age to 82 years of age. The mean age was fifty- eight. The majority of the participants (88%) fell in the 50-82 bracket.

Sixty- three percent of the sample was taking psychiatric medication at the commencement of study.

Table 2 gives a summary of stroke-related indices of the sample

Table 2

*Analysis of stroke-related indices of participant population*

| Type of stroke | Number of strokes | Employment status (R-retired, W-orking, U-nemployed) | Receipt of medication for psych. difficulties |
|---|---|---|---|
| Infarct | 1 | U | Sertraline |
| Right-sided haemorrhage | 1 | U | NA |
| Right sided Ischaemic attack | 1 | U | Citalopram |
| Left-sided Infarct | 1 | R | NA |
| Left Haemorrhage & TIA | 2 | U | Beta-blockers |
| Right sided infarct | 1 | U | Carbamazepine & Lorazepam |

| | | | |
|---|---|---|---|
| Left sided Haemorrhage | 1 | U | Propanalol |
| Cerebellar Infarct and TIA | 2 | R | Sertraline |
| Left sided Infarct & TIA | 2 | R | Citalopram |
| Mid-brain Infarct & TIA | 2 | R | NA |
| Left -sided infarct & TIA | 2 | U | Citalopram |
| Left-sided Infarct | | E | NA |
| Left-sided Infarct & TIA | 2 | U | Sertraline |
| Right sided Infarct | 2 | U | Sertraline & Diazepam |
| Left sided Haemorrhage | 1 | E | NA |

Table 3 shows the length of baseline and intervention phase for each participant in the final sample

Table 3

*Baseline and intervention lengths (weeks)*

| Participant no. | Randomised order of baseline lengths (weeks) | Length of intervention phase (weeks)* |
|---|---|---|
| 1 | 4 | 7 |
| 2 | 4 | 16 |
| 3 | 3 | 11 |

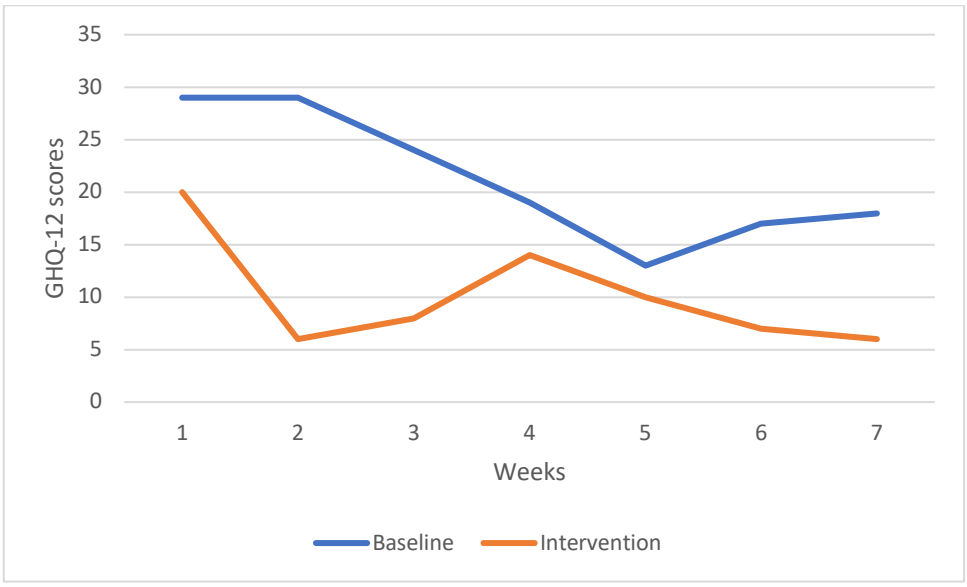
| | | |
|---|---|---|
| 4 | 7 | 12 |
| 5 | 5 | 11 |
| 6 | 4 | 13 |
| 7 | 4 | 15 |
| 8 | 7 | 11 |
| 9 | 2 | 14 |
| 10 | 8 | 9 |
| 11 | 5 | 13 |
| 12 | 6 | 9 |
| 13 | 6 | 3 (lost to follow-up due to fall) |
| 14 | 2 | 3 |
| 15 | 4 | 7 |
| 16 | 6 | 5 |

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

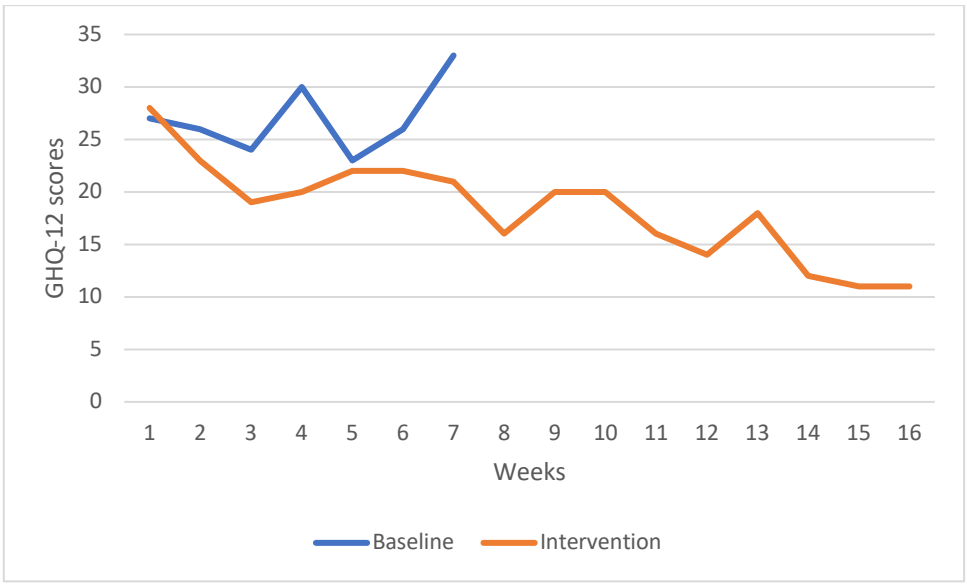
**Primary measures' analysis: GHQ-12 and SWLQ**

The following graphs illustrate the effects of intervention on GHQ-12 results. Baselines preceded intervention but are superimposed to show the effects of the intervention better.

Participant 1




Participant 2

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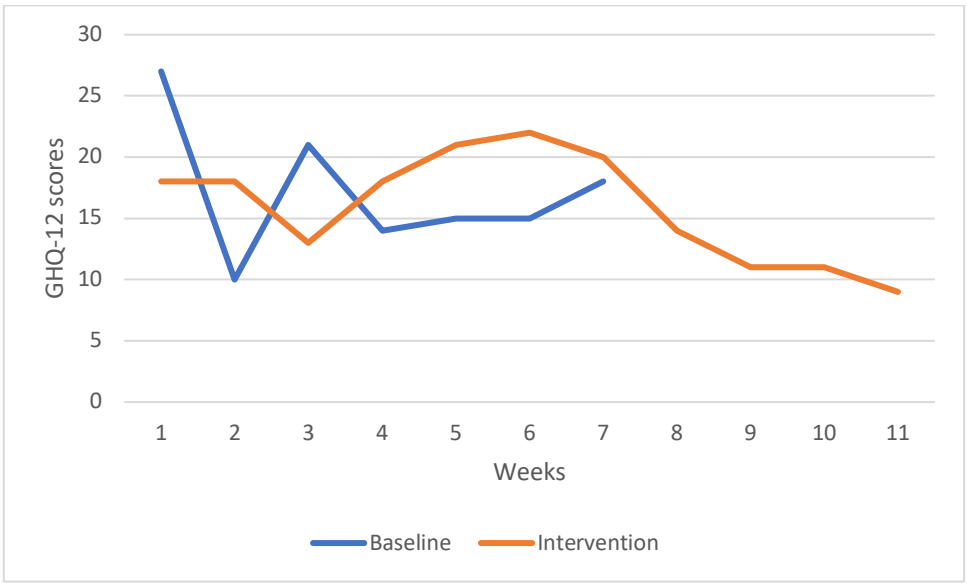


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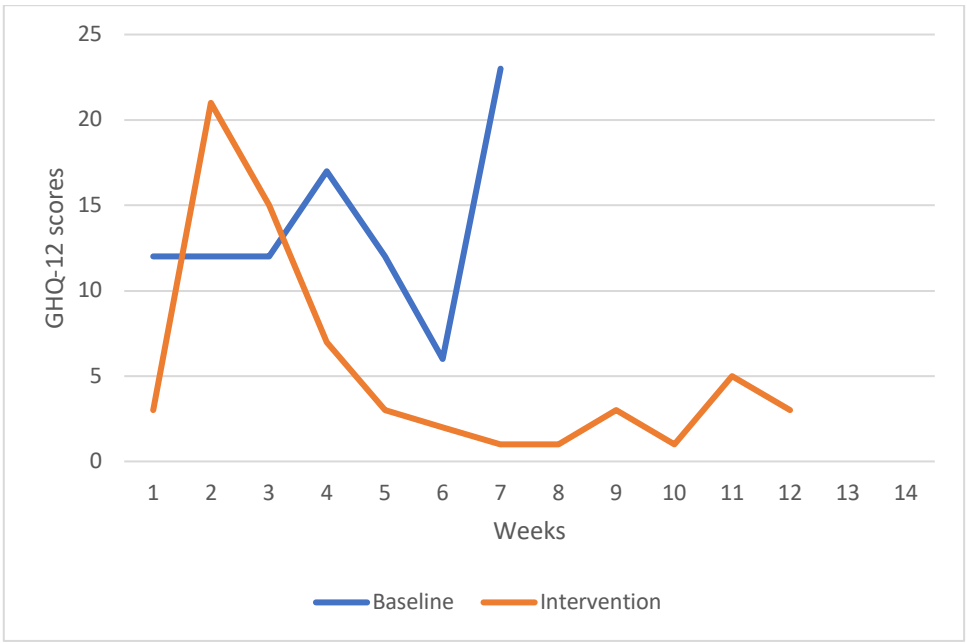


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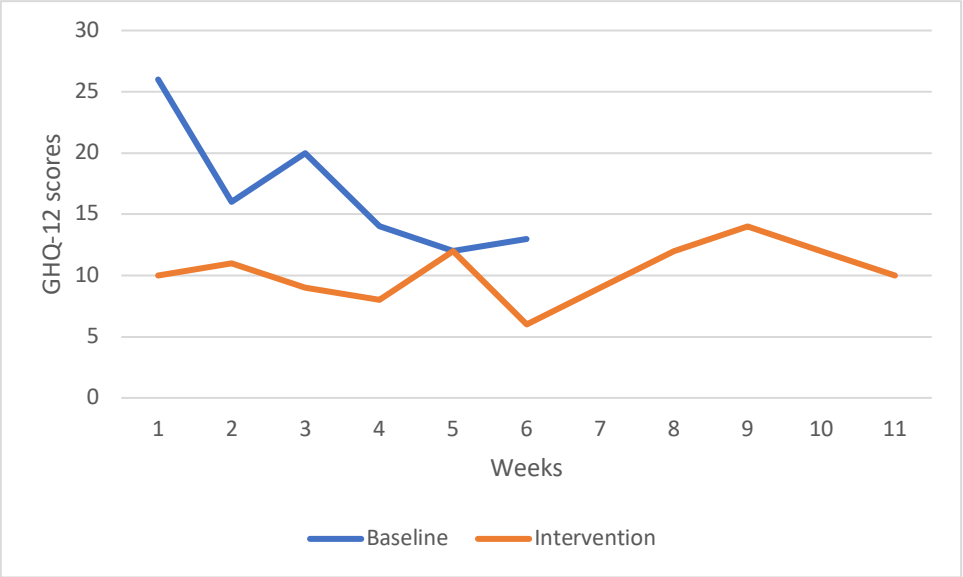


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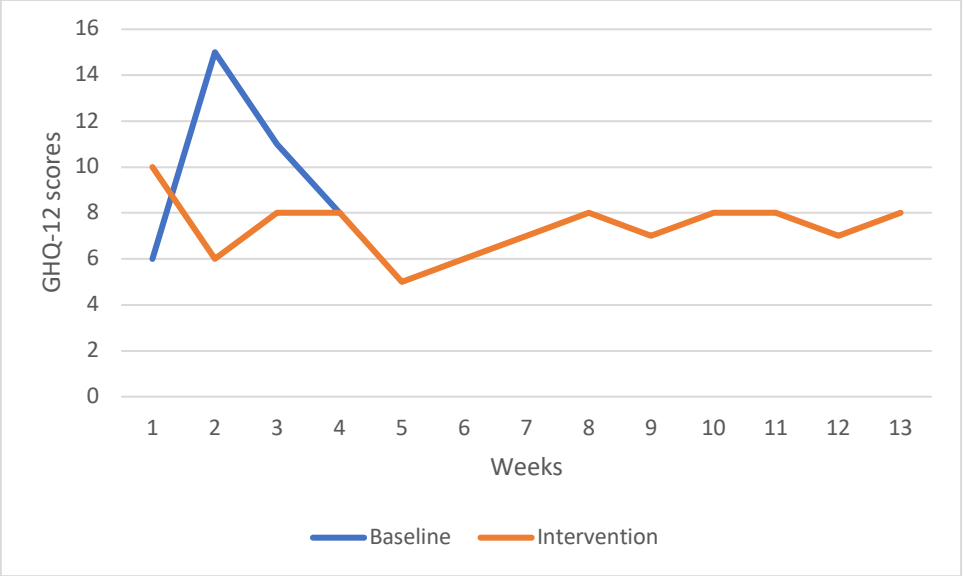
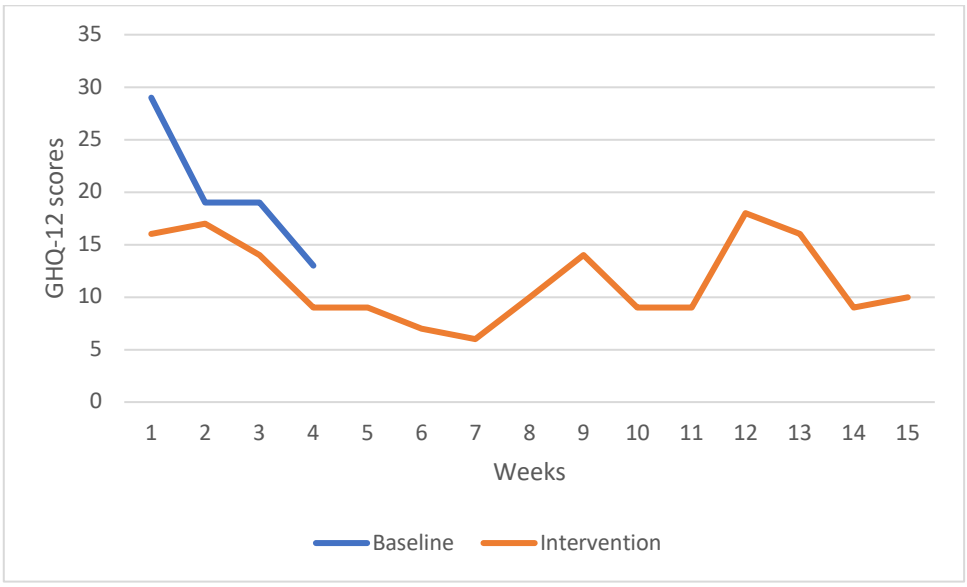



Participant 7

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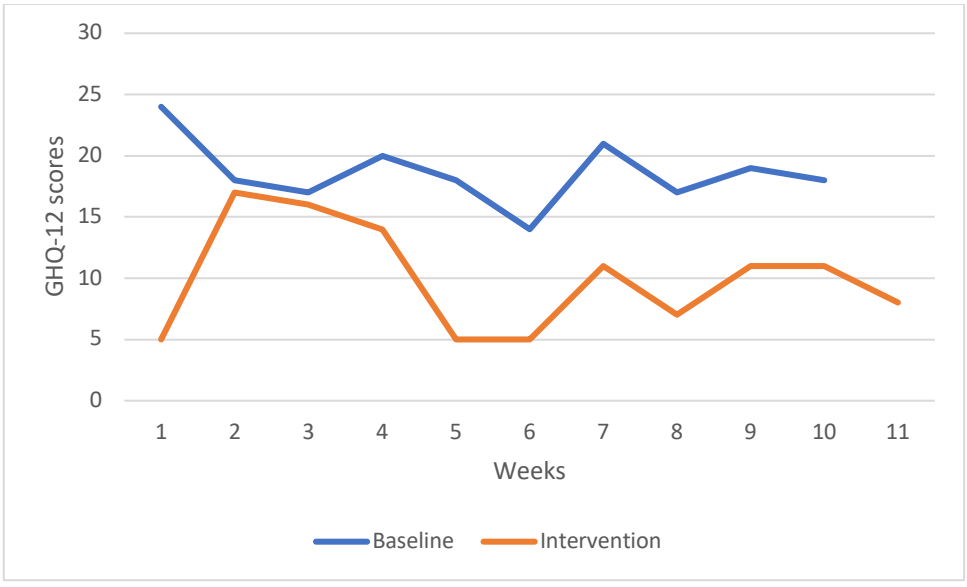


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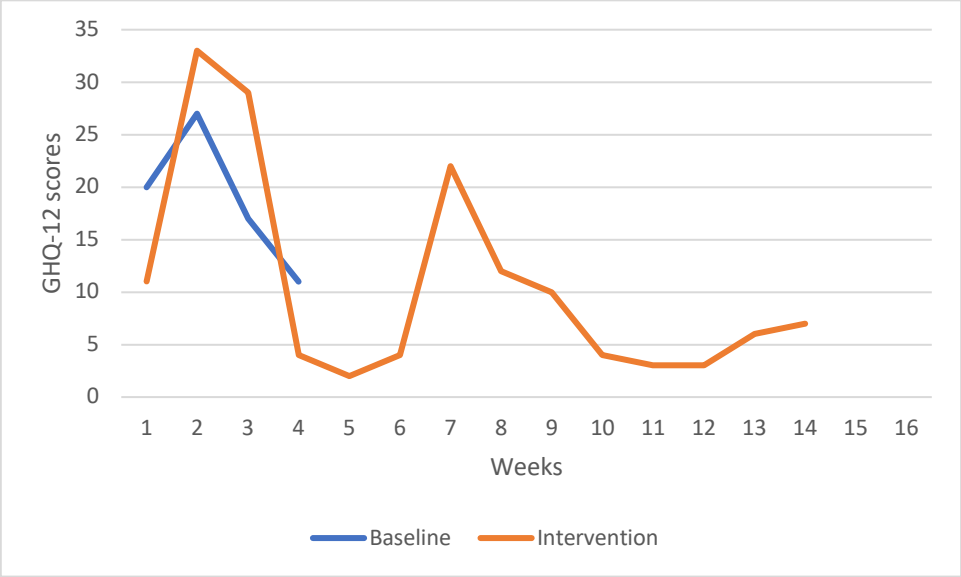


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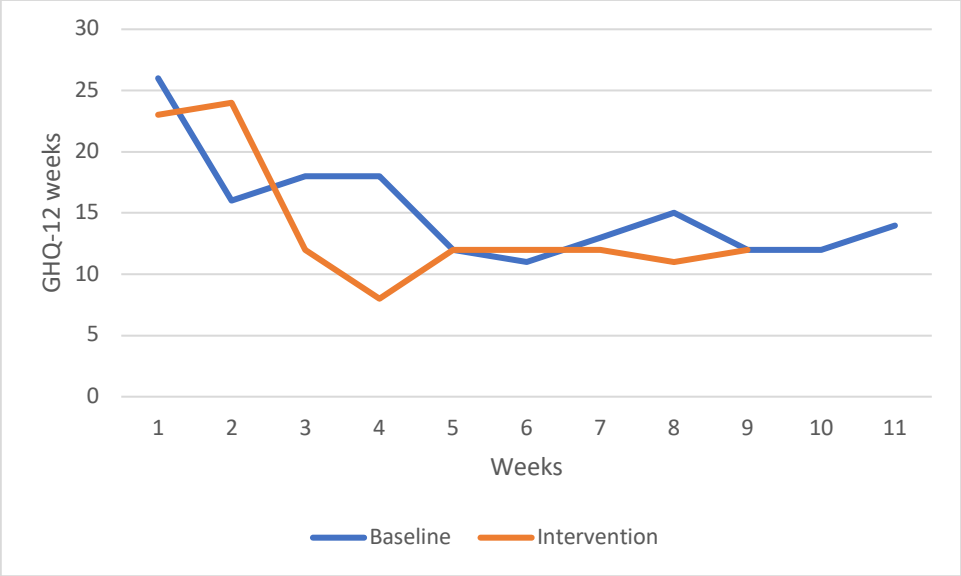


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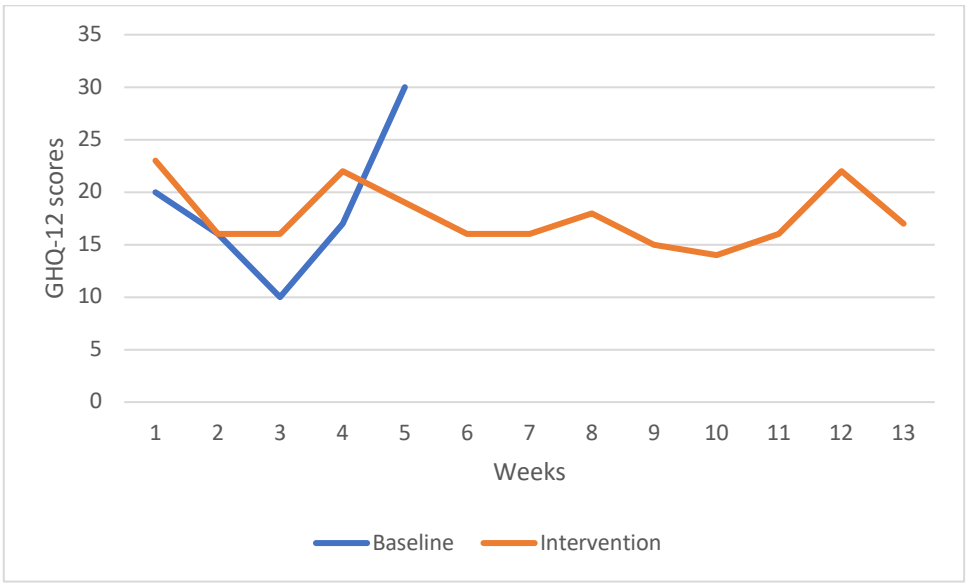


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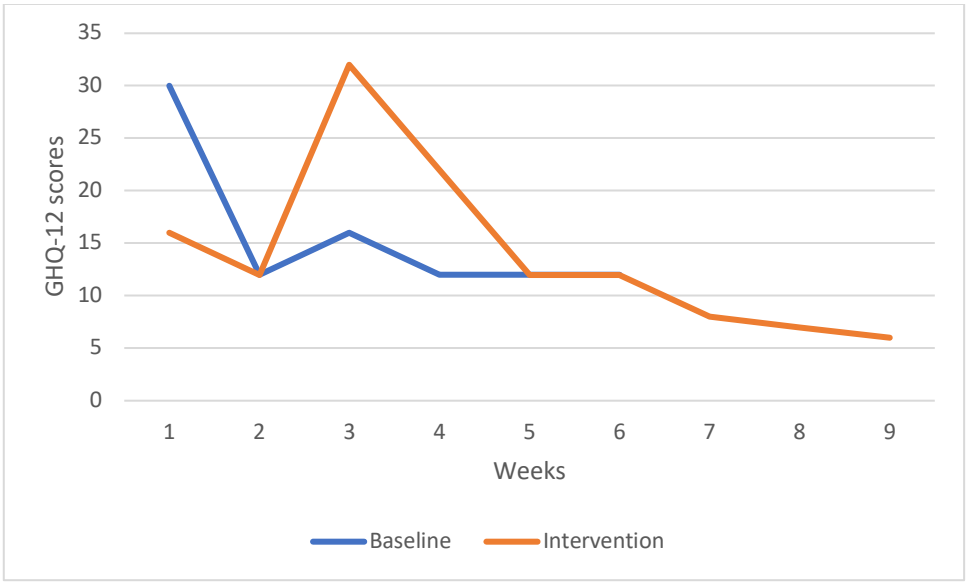


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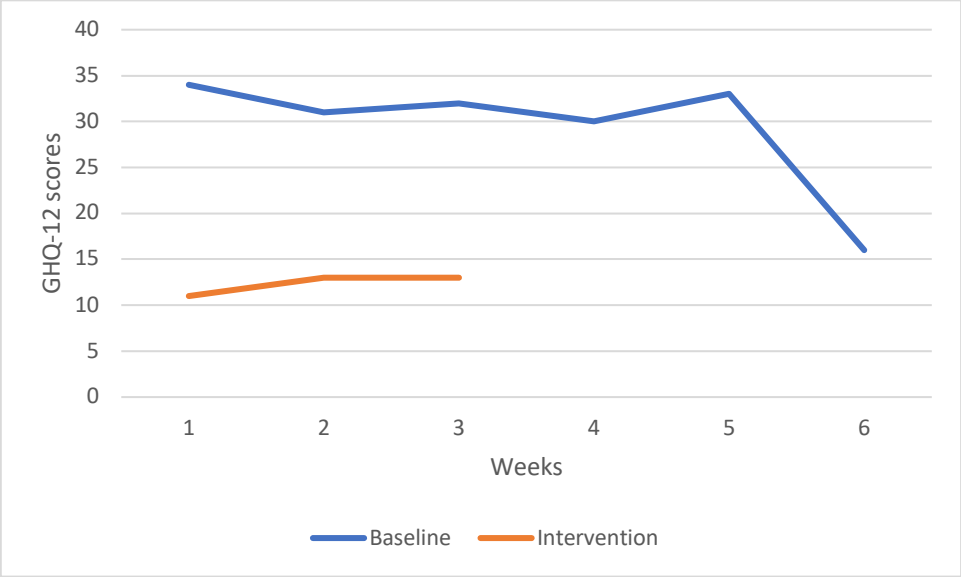


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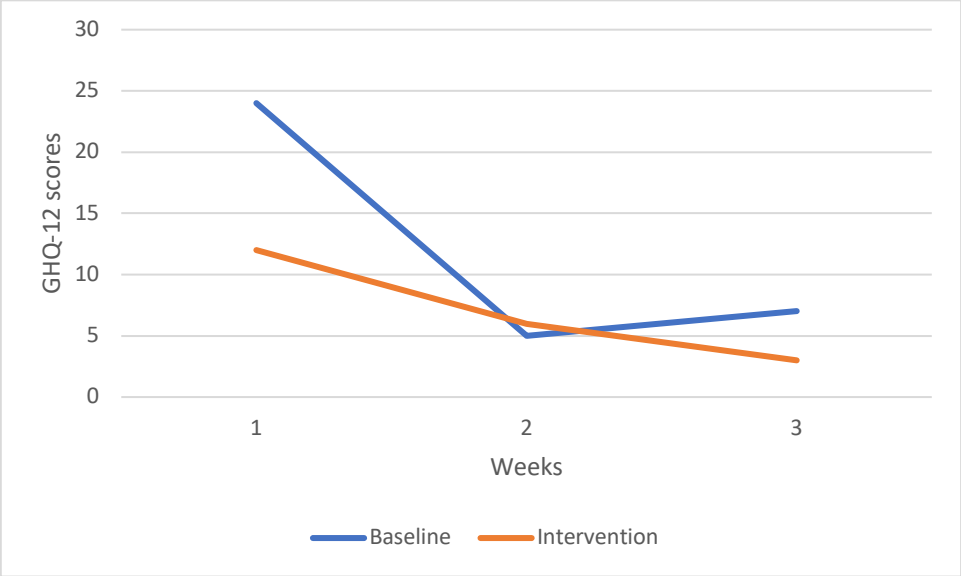
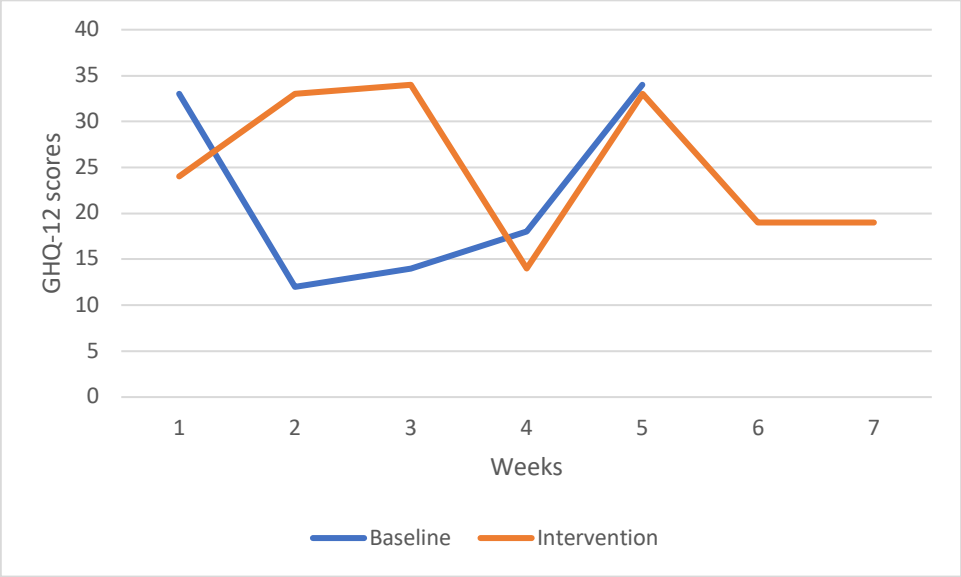
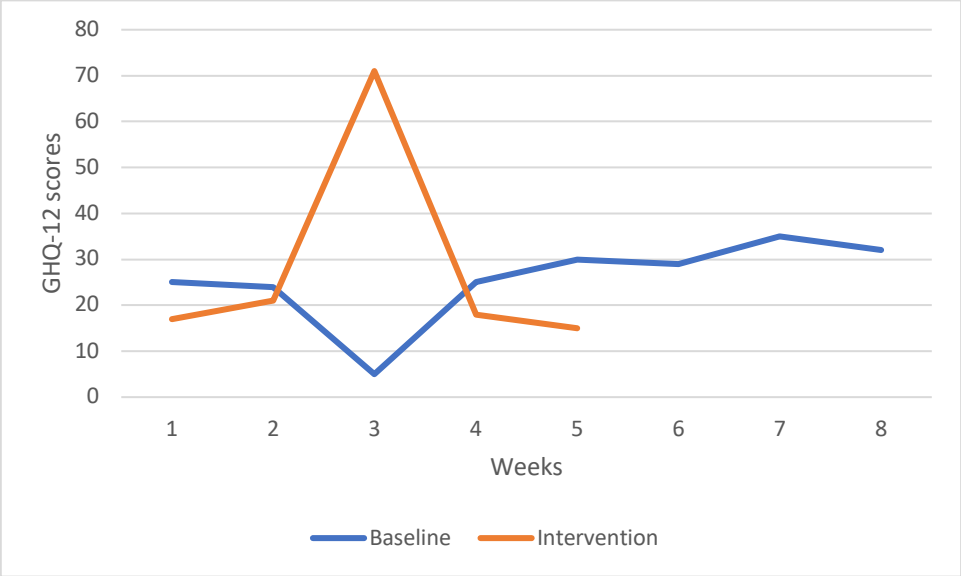



Participant 15




Participant 16




Results of TAU analysis for GHQ-12 are shown in Table 3. The whole-sample omnibus analysis of the GHQ-12 results was statistically significant with a moderate

effect size (0.6, $p<0.05$). Generally, moderate-to-large effect sizes on the GHQ-12 were obtained. The whole sample SMD, *d,* effect size for GHQ-12 was 0.7.

Table 3

*TAU U effect sizes for results of the GHQ-12*

| Participant no. | Tau U | Effect size | *p* value | SMD (mean of int- mean of BL+Int/SD baseline. (Busk & Serlin, 1992). |
|---|---|---|---|---|
| Participant 1 | 0.50 | Moderate | *0.110* | 0.9 |
| Participant 2 | 0.90* | Large | *0.000** | 1.7 |
| Participant 3 | 0.10 | Small | *0.717* | 0.2 |
| Participant 4 | 0.71 | Moderate | *0.011** | 0.9 |
| Participant 5 | 0.70* | Large | *0.018** | 0.8 |
| Participant 6 | 0.42 | Moderate | *0.212* | 0.5 |
| Participant 7 | 0.70* | Large | *0.031** | 1.0 |
| Participant 8 | 0.98 | Large | *0.000 ** | 1.6 |
| Participant 9 | 0.50 | Moderate | *0.121* | 0.4 |
| Participant 10 | 0.60 | Moderate | *0.027** | -0.2** |
| Participant 11 | 0.10 | Very Small | *0.730* | 0.1 |
| Participant 12 | 0.07 | Very small | *0.813* | 1.0 |
| Participant 13 | 0.60 | Moderate | *0.155* | 0.8 |
| Participant 14 | 0.22 | Small | *0.662* | 0.2 |
| Participant 15 | 0.14 | Small | *0.608* | 0.3 |
| Participant 16 | 0.83 | Large | *0.000** | 0.2 |

*alpha <0.05 ** negative sign indicates increased distress

The following graphs show results of intervention on SWLQ. SWLQ results are expected to be higher if satisfaction with life is improved by intervention

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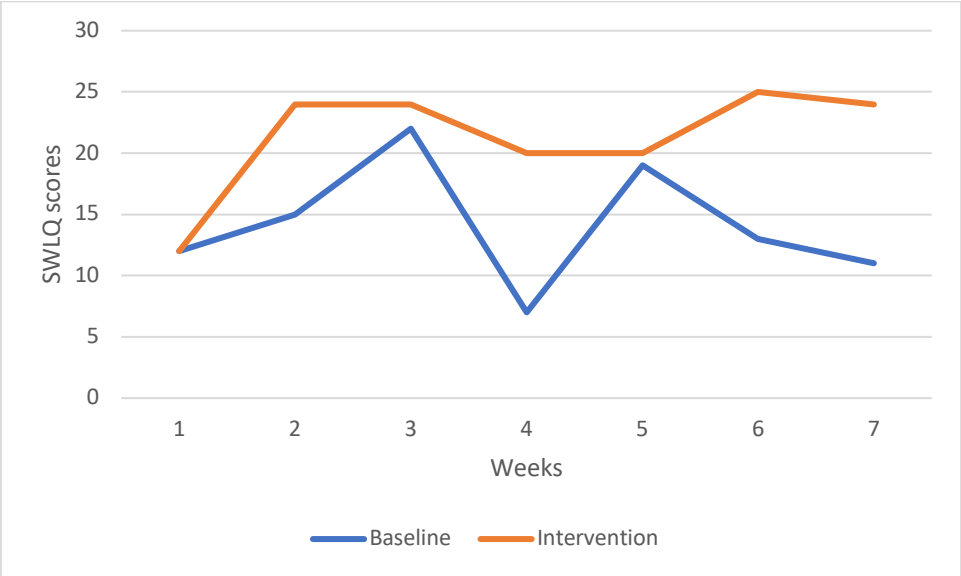
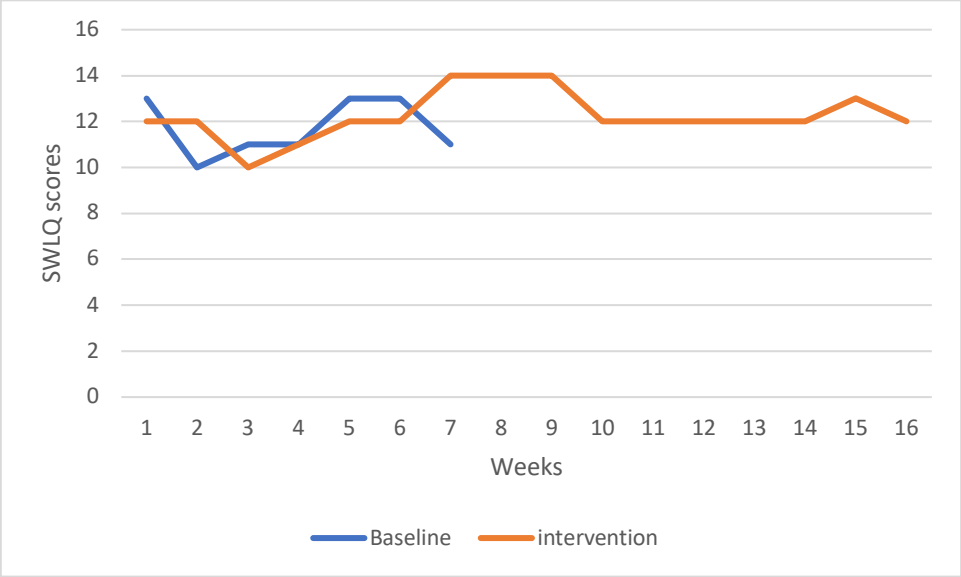
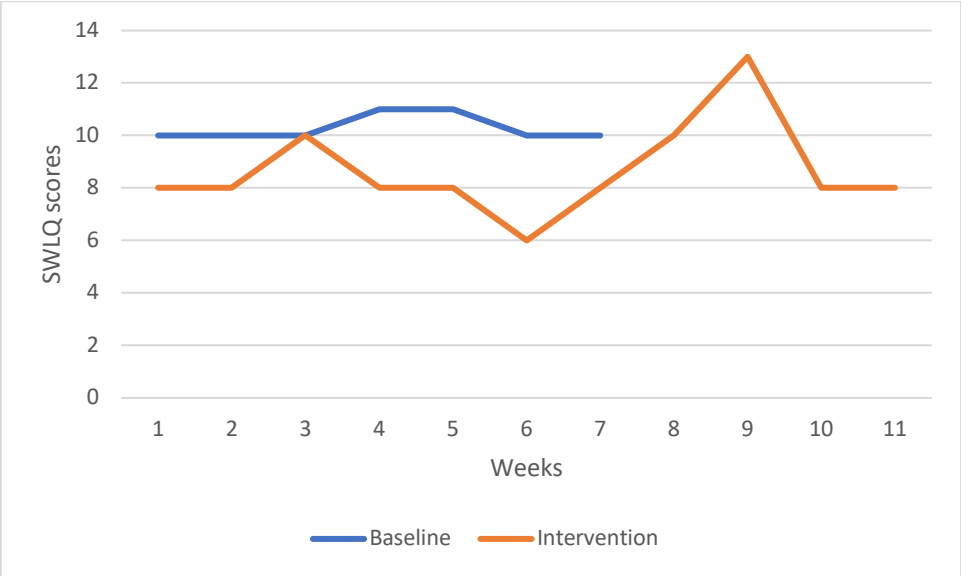



Participant 2




Participant 3



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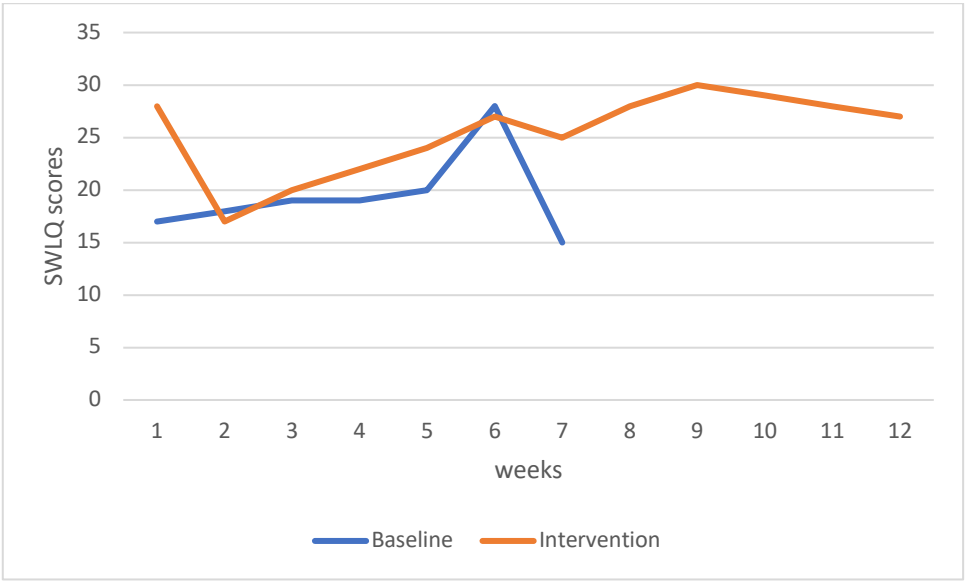


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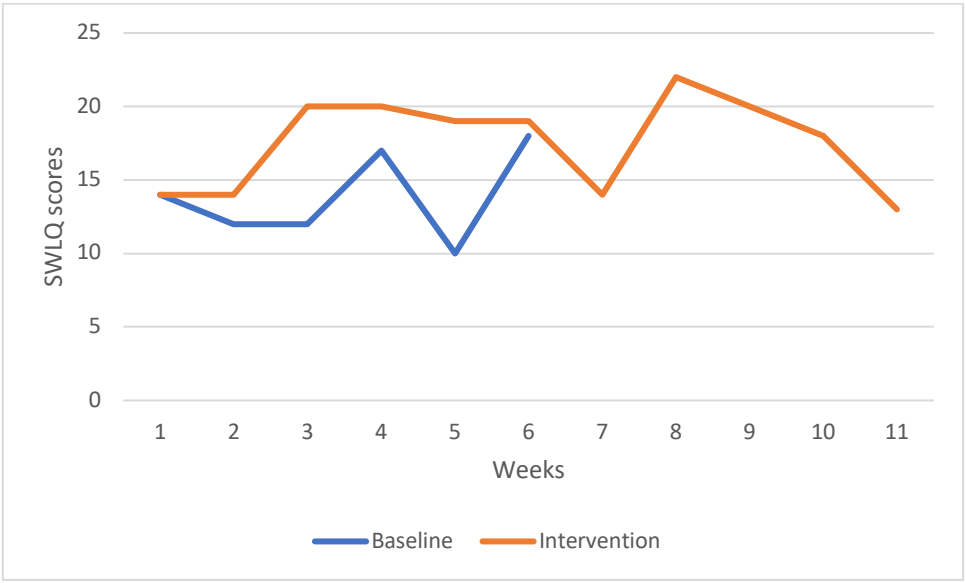

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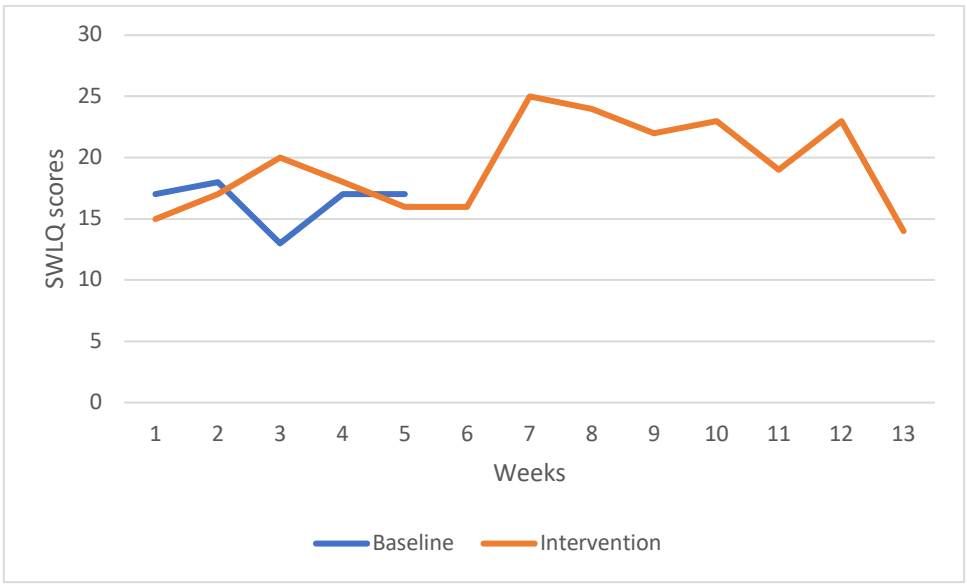


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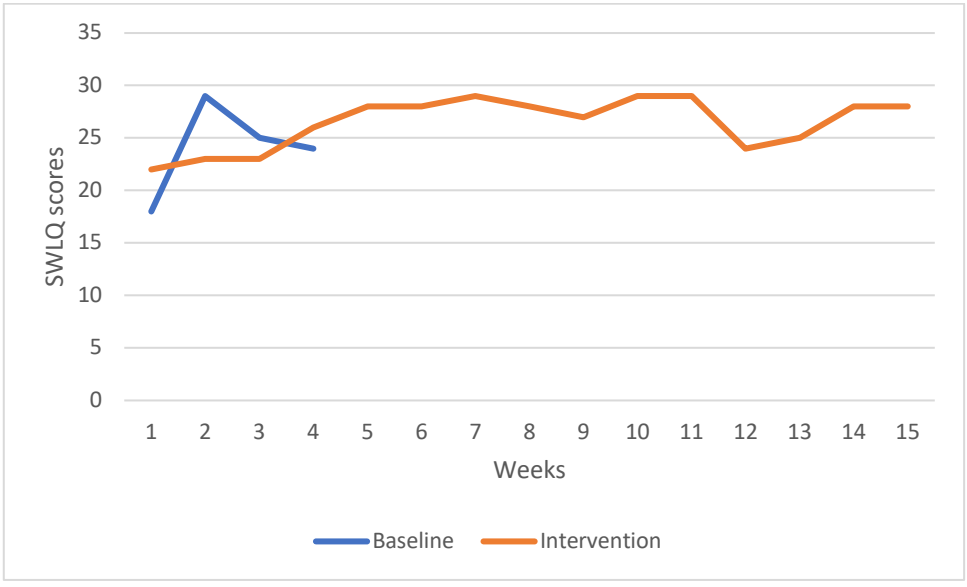

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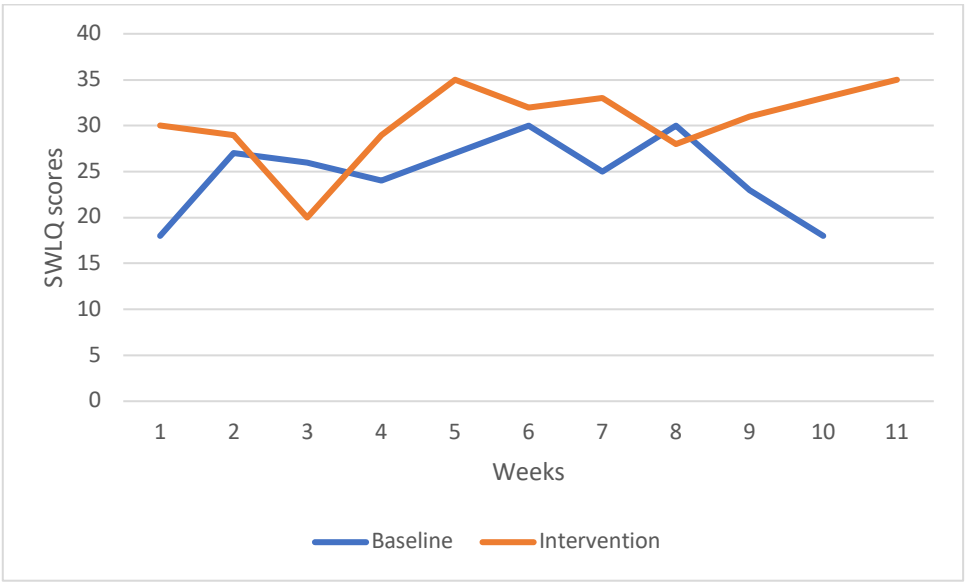
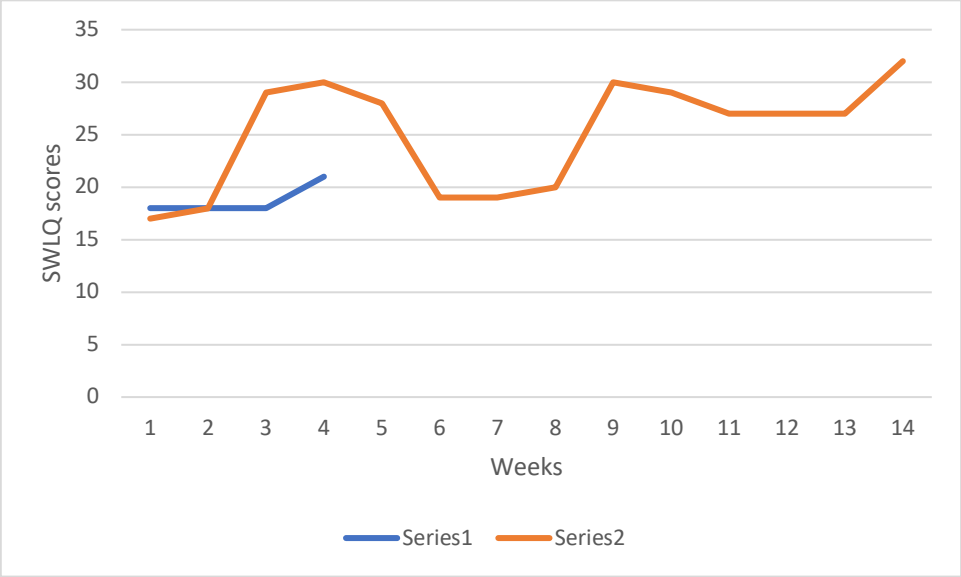
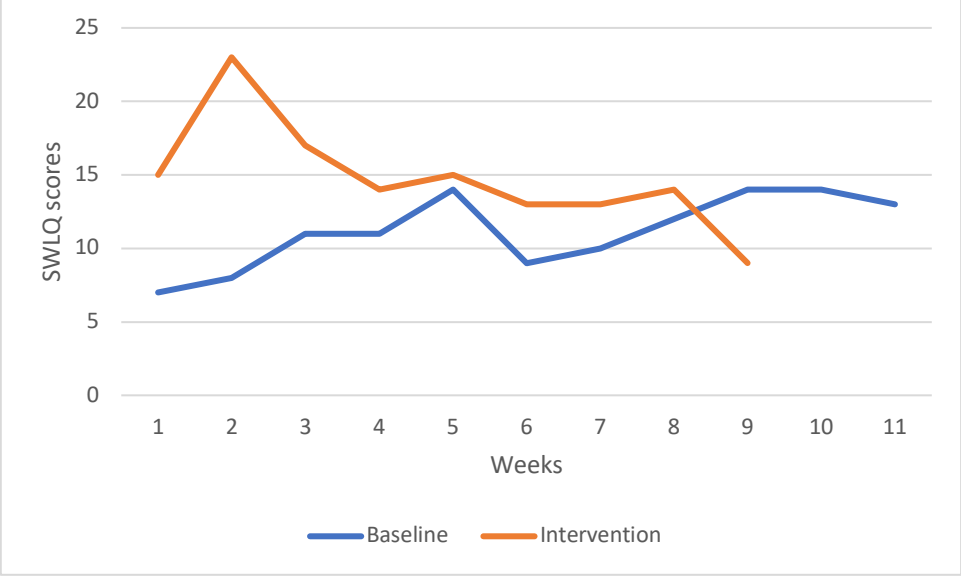


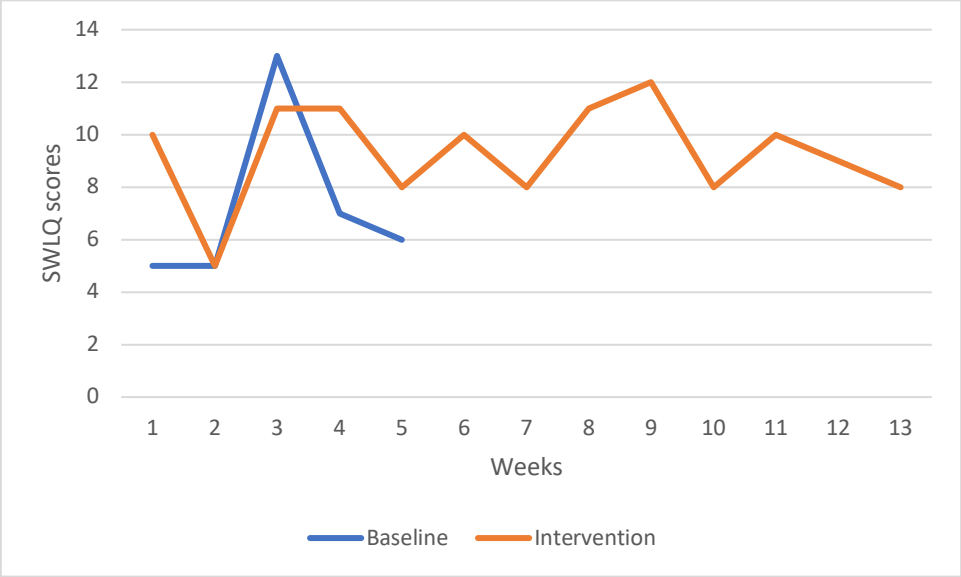

Participant 9



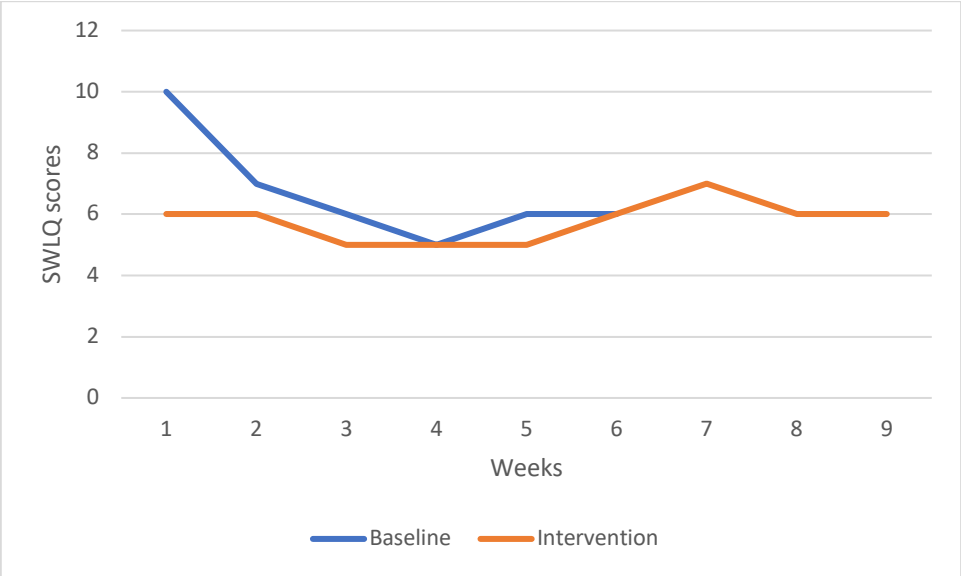

Participant 10



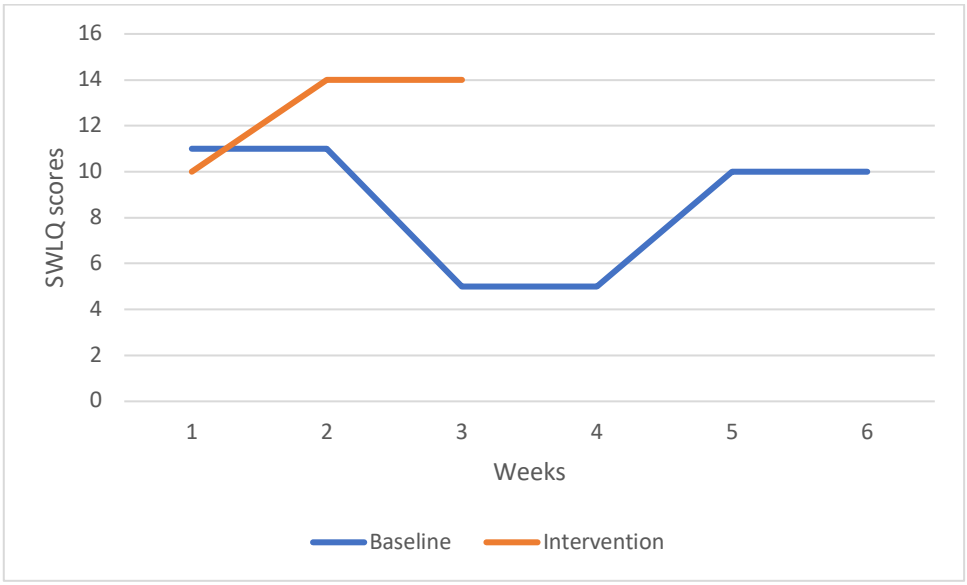

Participant 11



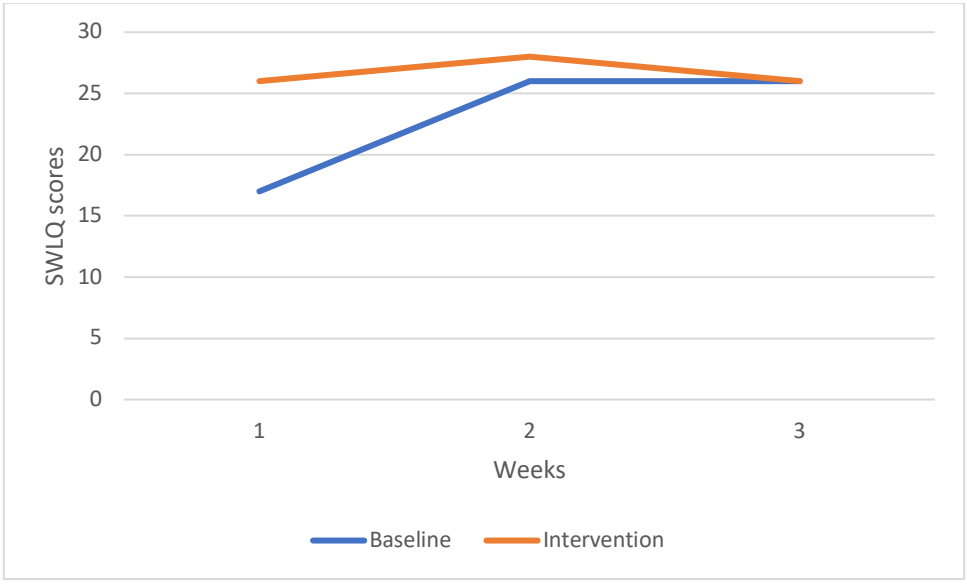

Participant 12



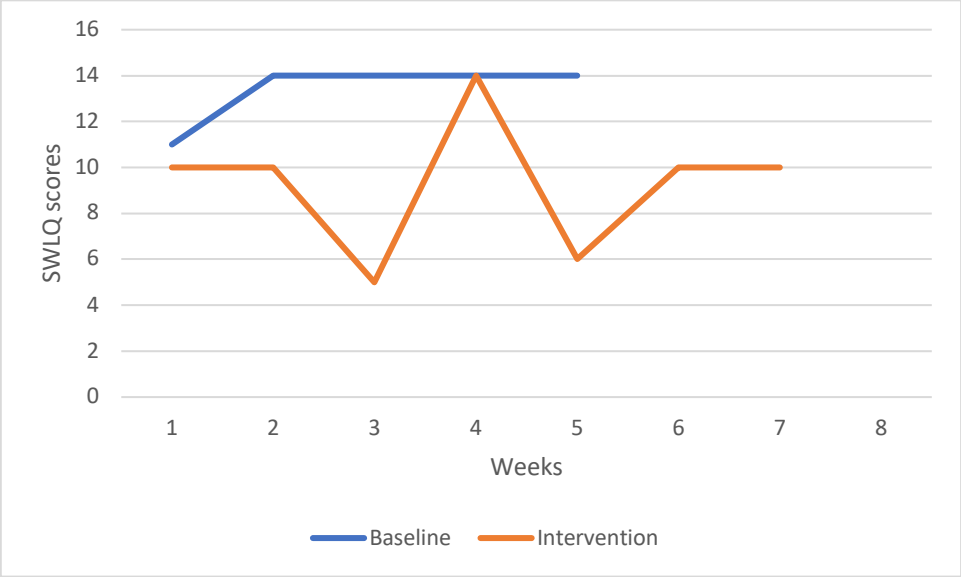
Participant 13



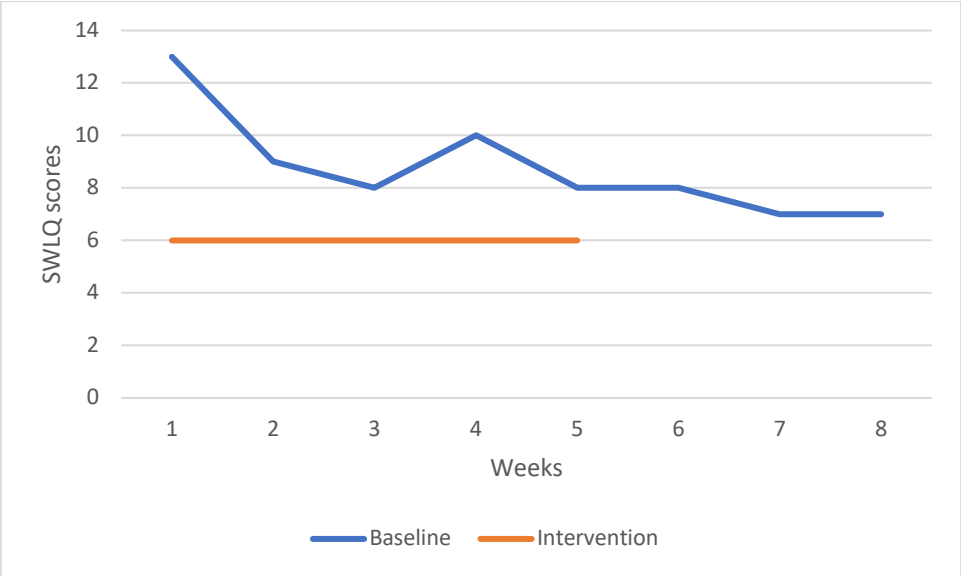

Participant 14




Participant 15




Participant 16




Results of TAU U analysis of the SWLQ results are shown in Table 4. The whole-sample omnibus analysis of the SWLQ results was statistically

significant (*TAU = 0.3; p< 0.05*) with a moderate effect size. The whole-sample SMD, *d,* effect size for SWLQ was 0.3.

Table 4

*TAU U effect sizes for results of SWLQ*

| Participant no. | Tau U | Effect size | *P* value | SMD (mean of int- mean of BL+Int/SD baseline. Busk & Serlin, 1992. |
|---|---|---|---|---|
| Participant 1 | 0.70 | Large | *0.021** | 0.7 |
| Participant 2 | 0.40 | Moderate | *0.011** | 0.3 |
| Participant 3 | -0.69** | Moderate | *0.016** | -2.2*** |
| Participant 4 | 0.58 | Moderate | *0.038** | 0.9 |
| Participant 5 | 0.66 | Moderate | *0.027** | 0.7 |
| Participant 6 | 0.42 | Moderate | *0.183* | 1.1 |
| Participant 7 | 0.28 | Small | *0.395* | 0.4 |
| Participant 8 | 0.80 | Large | *0.004** | 0.6 |
| Participant 9 | 0.60 | Moderate | *0.071* | 3.3 |
| Participant 10 | 0.30 | Moderate | *0.239* | 0.4 |
| Participant 11 | 0.43 | Moderate | *0.174* | 0.5 |
| Participant 12 | -0.16** | Small | *0.592* | -0.4*** |
| Participant 13 | 0.60 | Large | *0.110* | 0.5 |
| Participant 14 | 0.33 | Moderate | *0.512* | 0.3 |
| Participant 15 | -0.94** | Large | *0.007* | -1*** |
| Participant 16 | -0.50** | Moderate | *0.143* | 0.5*** |

*alpha <0.05, ** - indicates reduced satisfaction with life, *** - indicates SWLQ declined

**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 and SWLQ) were not statistically significant, which is commensurate with the maintenance of gains (Table 5)

Table 5

*Follow-up analysis on GHQ-12 and SWLQ primary outcome measures*

| | *p value* | Means (post, follow-up) | Standard Deviation (post, follow-up) |
|---|---|---|---|
| GHQ-12 | *0.3* | 9.0, 10.7 | 5.1, 6.5 |
| SWLQ | *0.2* | 17.1, 18.8 | 9.2, 8.5 |

**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 6.

Table 6

*Whole-sample pre-post analysis*

| Measure | *p* value, t statistic (degrees of freedom) | Mean (pre, post) | Standard Deviation (pre, post) |
|---|---|---|---|
| BDI | *0.000*,* 5.0 (14) | 7.8, 4.2 | 4.5, 4.2 |
| BAI | *0.000*,* 4.4 (14) | 21.2, 9.9 | 11.5, 12.5 |
| HADS | *0.000*,* 6.8 (14) | 22.6, 15.7 | 8.4, 8.6 |
| WEMWS | *0.000*,* 5.1 (14) | 37.8, 48.9 | 11.3, 11.7 |
| SIS | *0.001*,* 4.0 (14) | 193.4, 218.2 | 36.0, 30.2 |

*Results are statistically significant*, p< 0.05*

Following a Bonferroni correction (*p<0.01)* the results of the pre-post, whole-group analysis remained statistically significant.

**Survey results**

Survey results are presented in Table 7

Table 7

*Survey results*

| Participant no. | Helpfulness rating (0-10). | What did the book help with? | Which part of the book was most helpful? (Key: 1= Part 1, 2= part 2, 3= part 3) |
|---|---|---|---|
| Participant 1 | 5 | Anxiety: understanding burden on carer. | 2 |

| | | | |
|---|---|---|---|
| Participant 2 | 8 | Confidence and low mood | 1, 2, 3 |
| Participant 3 | 8 | Confidence: Learning that I can get through it | 2 |
| Participant 4 | 10 | Confidence | 3 |
| Participant 5 | 8 | Anxiety | 3 |
| Participant 6 | 10 | Confidence | 3 |
| Participant 7 | 10 | Anxiety/low mood | 2, 3 |
| Participant 8 | 10 | Anxiety, low mood | 3 |
| Participant 9 | 9 | Getting motivated | 3 |
| Participant 10 | 10 | Low mood, confidence, anxiety | 3 |
| Participant 11 | 7 | Anxiety thoughts | 3 |
| Participant 12 | 9 | Anxiety, motivation | 3 |
| Participant 13 | Lost to follow-up* | | |
| Participant 14 | 10 | Anxiety, Confidence | 2 & 3 |
| Participant 15 | 10 | Low mood, confidence, anxiety | 3 |
| Participant 16 | 7 | Confidence: understanding and realising you are not alone | 1, 2, 3 |

*Participant view of the book prior to drop-out due to fall was favourable ‘I carry it around with me’

Eighty-one percent of the sample reported the book as very helpful. The helpfulness of the book was reported for a range of difficulties including anxiety, low mood, confidence, motivation, acceptance and understanding carer’s role. Eighty one percent of the sample reported part 3, which contains the ACT programme, as helpful.

The relative risk calculation showed that the chance of improvement on the GHQ-12 if the book was found helpful was eight-one percent. This means that the chance of improvement on GHQ-12 if the book was found helpful is increased by nearly 8 times, compared to if the book was not found helpful. The chance of improvement on SWLQ if book was found helpful was sixty-eight percent. This means that the chance of improvement if exposure to the book was found helpful is increased by approximately seven times, compared to if the book was not found helpful.

## Discussion

The aim of this study was to evaluate the efficacy of bibliotherapy in the stroke context. The whole-sample omnibus results for both primary measures showed moderate effect sizes on both GHQ-12 (0.6, $p<0.05$) and SWLQ (0.3, $p<0.05$) primary measures. The fact that this study achieved an overall (omnibus analysis) statistically significant effect on the GHQ-12 and a measure of satisfaction with life is encouraging, as are the substantial number of individual participants that showed dependable benefit on primary measures. The results of both primary measures showed that bibliotherapy contributed moderate- to-large effect sizes for 69% (n=11) of the sample on both measures. For 43% (n=7) of the sample GHQ-12 results were statistically significant. SWLQ results were statistically significant for 38% (n=6) of the sample. It is worth noting that *p* values were attenuated by overlap between baseline and intervention scores, which has to be expected as a lag in the psychological realisation of the intervention results in overlap

in scores. *P* values were also attenuated for shorter baselines as shorter baselines result in higher unreliability.

In the absence of a control group, the effects in the positive direction on the GHQ-12 and SWLQ, and other measures, can't definitely be attributed to the bibliotherapy intervention. There were several control procedures, however, that increase the plausibility of the intervention effect. The baseline phase was implemented as quasi-experimental control condition to both guard against inflated results and control against effects of time and maturation. The baseline phase also included an attention-control procedure, through equivalent level of therapist-support in both phases. The randomised entry into intervention protected against potential recruitment biases, whilst the varied-length and staggered baselines (in randomised order) increased internal validity and provided an overall baseline extended in time to rule out confounding factors.

All secondary outcome measures showed large clinically and statistically significant change in a positive direction. However, unlike the primary measures used during the MBD, in which there was a temporal control procedure (randomisation), these pre-post results may be a consequence of temporal change unconnected to the intervention. These results are secondary measures and need to be treated with caution. In the context of the results of the SWLQ, it is interesting to note that the WEMWS also showed clinically and statistically significant change over time. In the Majumdar & Morris (2018) ACT trial the WEMWS didn't show change in

wellbeing to occur, which they attributed to insufficient time (four weeks) to embed changes to overall wellbeing. Possibly in the current study there was more scope for change on the WEMWS and SWLQ because in the MBD the intervention took place over a longer period of time and was targeted at individual difficulties. Targeting quality of life is a priority in view of the high prevalence of post-stroke disability (Carmo, Morelato, Pinto & de Oliviera, 2015). In the absence of psychological intervention, post-stroke life satisfaction remains low despite extensive rehabilitation after stroke (Langhammer, Sunnerhagen & Stanghelle, 2017).

The results of the SIS analysis are also worth exploring in detail. The SIS is a composite disability measure for stroke, measuring perceptions and experiences of disability after stroke, in which a higher score indicates greater self-reported wellbeing. Additionally, the SIS includes dimensions of HRQOL (Salter, Moses, Foley & Teasell, 2008). The analysis of the SIS results was statistically significant, suggesting that for this sample of stroke survivors, perception and experience of disability improved. This is a potentially significant finding as stroke remains one of the main causes of disability globally (Feigin, Norvving & Mensah, 2017). There is a large body of research showing that psychological factors are particularly influential in mediating wellbeing in chronic conditions (Graham, Gouick, Krahe & Gillanders, 2016). ACT aims to reduce the influence of negative psychological processes on function and behaviour through the processes of acceptance and defusion (Graham, Gouick, Krahe & Gillanders, 2016).

The rates of enduring disability in stroke are high, with up to thirty percent of cases failing to fully recover function (American Heart Association, 2011). In the stroke context, the principle of focussing on values in ACT (Clarke, Kingston, James, Bolderston & Remington, 2014) may be particularly helpful as the effects of stroke can be long-term (Wolfe et al., 2011). In addition, ACT's focus on values may help develop an acceptance of the effects of stroke (Majumdar & Morris, 2019). Therefore, ACT's focus on increasing value-based living may be more effective than traditional therapies as it promotes active engagement through increased psychological flexibility (Clarke, Kingston, James, Bolderston & Remington, 2014).

Taken together, the results of the SWLQ, WEMWS and SIS tentatively support the bibliotherapy ACT intervention as an effective intervention for enhanced wellbeing and quality of life for this sample of stroke survivors. However, in the absence of a control group it isn't possible to definitively attribute the positive change to ACT principles in the current study.

The brief survey showed that the book utilised in the therapist supported bibliotherapy intervention was perceived favourably by participants, with eighty one percent 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. ACT is based on functional contextualism which considers distress as a natural by-product of the human propensity to achieve goals (Guadiano, 2011). On this basis, ACT therapeutic techniques

don't aim primarily to completely alleviate distress and have their roots in a pragmatic philosophy of psychological difficulties (Guadiano, 2011).

ACT is grounded in contextual behavioural science (CBS) research principles which prioritise 'middle level' concepts. Middle-level concepts are clinically useful functional links between the person and environmental contingencies, which require less specificity for intervention than traditional psychological concepts such as reinforcement contingencies (Assaz, Roche, Kanter & Oshiro, 2018). This means that ACT is recommended as a model of therapy that is readily disseminated and administered (Assaz, Roche, Kanter & Oshiro, 2018). For example, a systematic review of web-based apps utilising ACT revealed that web-based ACT is effective for depression (Brown, Glendenning, Hoon & John, 2016). Both motor impairments and psychological difficulties affect stroke survivors' ability to regain independence after stroke (Obembe, Mapayi, Johnson, Agunbiade & Emechete, 2013). As a result, individually-focussed, intensive therapy may be too challenging for stroke survivors to access. In addition to web-apps as a way of increasing accessibility, this study also suggests the potential of supported bibliotherapy.

Standard psychological treatments, without significant adaptations (Kneebone, 2016), have limitations in stroke due to cognitive and language impairments (Kneebone & Jeffries, 2013). In contrast, ACT is proposed as more accessible for those with cognitive impairments as it puts greater emphasis on experiential learning, as a result of which its effects have been

demonstrated for a learning- disabled case (Brown & Hooper, 2009). An example of the experiential nature of ACT is the skill of defusion, which doesn't require cognitive reframing of distressing thoughts, and has been shown to successfully reduce the level of negative responses to thoughts (Assaz, Roche, Kanter & Oshiro, 2018). Defusion has been shown to result in immediate improvements in responses to self-focussed negative thoughts compared to cognitive restructuring, which took longer to take effect (Deacon, Fawzy, Lickel & Wolitzky-Taylor, 2011), suggesting ACT may be cost-effective. ACT has also been more successful with complex presentations i.e. treatment resistant populations (Clarke, Kingston, James, Bolderston & Remmington, 2014) suggesting that ACT has good benefits when there are obstacles to recovery.

The relative risk ratio of exposure to the book reported as helpful and gaining benefit was eighty-one and sixty- eight percent for the GHQ-12 and SWLQ respectively. This analysis tentatively suggests that a positive experience of the book increases the chance of improvement to wellbeing. The book is currently recommended by the 'Book Prescription Scheme' in England. The book is utilised by healthcare services and stroke survivors alike in Wales and England and this study presents an important investigation of the book's efficacy.

The intervention in this study was adapted to the needs of the participants e.g. experience of pain led to utilisation of pain-based ACT interventions from the book. Onset of stroke for stroke survivors recruited into the study varied

and the bibliotherapy intervention was provided in the community. Therefore, this study enacted guidance that community intervention should be provided irrespective of time of stroke (The Royal College of Physicians, 2016). This study is the first to investigate a tailored, transdiagnostic, community-based intervention in stroke, and adds to the extant evidence-base for brief, pragmatic psychological interventions in stroke.

**Limitations and future research**

Future studies with randomised controlled conditions and larger samples are required to further determine the effectiveness of supported bibliotherapy in stroke. Investigations of bibliotherapy without support are also necessitated. The current study did not have a bibliotherapy-without-support condition, which means it's not possible to reliably conclude that the active intervention was the ACT bibliotherapy intervention. However, the purpose of providing support during the baseline phase was to complete a TAU U between-phases analysis of support only vs. supported bibliotherapy.

There was also no separate randomised control group in addition to randomised baselines. Testing bibliotherapy using an RCT would be challenging because the inherent variable pacing of bibliotherapy limits standardisation. The inherent variability in bibliotherapy was the primary reason for the implementation of an MBD in the current study. Future studies could aim to address the variability by using the modal weeks of intervention from this study to determine a maximum number of sessions and the addition

of a control group could help enhance the inferences drawn from the study. A further limitation of the current study is that data collection wasn't completed by an independent assessor. Data completion took place through self-report, but the possibility of demand characteristics during data collection can't be ruled out.

Analysis of the demographical information obtained showed that people in the 18-30 bracket were underrepresented in the study (12% of the sample). Stroke is becoming more prevalent in younger cohorts (Kissela et al., 2012) and presents considerable challenges to this cohort due to economic issues more common at younger age (Smajlovic, 2015), with loss of employment rates of 80-90% (Morris, 2011). Future studies should also pay attention to recruitment from younger cohorts as stroke rates in the younger cohort are increasing (Kissela et al., 2012).

A future study of the book could include aphasic individuals by increasing support to use the book, by emphasising the experiential aspects. Indeed, aphasic individuals are frequently excluded from psychological studies due to the nature of talk-based therapies. A trial of MI (Watkins et al., 2011) which included aphasic stroke survivors yielded statistically significant results, as did a trial of behavioural therapy which included aphasic stroke survivors (Thomas et al., 2013). The results of this study invite further developments to the book, for example, visual aids, and online tools to be inclusive of varied post-stroke difficulties.

In this study practical limitations precluded weekly intervention. Future studies should aim to investigate weekly bibliotherapy to enhance delivery, and possibly strengthen effect sizes. Internet-based programs such as Skype, could be used to provide this enhancement. Future studies of ACT interventions should also include validated measures of ACT processes such as the AAQ (Bond et al., 2011). However, since the original validation in a sample of university students (Bond et al., 2011), the AAQ-II has been validated in rheumatoid arthritis, infertility and the general population (Costa, Maroco, Pinto-Gouveia & Galhardo, 2014), but not stroke.

**Service Implications**

Comorbidity of stroke and mood-based difficulties is high (Hackett & Pickles, 2014). The King's Fund report into comorbidities showed that healthcare cost is increased by 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 efficacious with moderate-large effect sizes. The guidance in stroke also suggests that a variety of interventions should be available, which are responsive to client needs (The Royal college of physicians, 2016). During therapist- supported- bibliotherapy there was careful consideration of client needs and its didactic nature facilitates ease of delivery in an area where there is a high unmet need for psychological provision.

## Conclusion

This study provides evidence that bibliotherapy with therapist support is effective for the management of post-stroke psychological difficulties. Generally moderate effect sizes were obtained with limited, bi-weekly, therapist support. This study adds to the evidence-base for transdiagnostic approaches, such as ACT, and suggests a useful avenue for up-skilling staff to use therapist-supported bibliotherapy in stroke.

**Appendix 2**

Table 8

*Complete reasons for non-recruitment of those who didn't complete consent or dropped out*

| | | | | |
|---|---|---|---|---|
| **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**<br>**1 carer duties prohibiting participation at this time** | **1 lost to follow-up due to fall**<br>**1 lost at commencement of intervention due to fall** |

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## Appendix 3

NHS ethics and HRA approval letters

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

**Gwasanaeth Moeseg Ymchwil**
**Research Ethics Service**

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

**Wales Research Ethics Committee 4**
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13 February 2018

Mrs Misbah Gladwyn-Khan
South Wales Doctorate in Clinical Psychology
Cardiff University
Tower Building, Floor 11
Cardiff
CF10 3AT misbah.khan@wales.nhs.uk

Dear Mrs Gladwyn-Khan,

| | |
|---|---|
| **Study title:** | **Bibliotherapy to reduce distress and improve wellbeing after stroke: A quasi-experimental study** |
| **REC reference:** | **18/WA/0045** |
| **IRAS project ID:** | **232266** |

The Research Ethics Committee reviewed the above application at the meeting held on 07 February 2018. The Committee wishes to thank you and your Academic Supervisor for attending the meeting in teleconference to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.
Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

**Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

NHS
Health Research Authority

Mrs Misbah Gladwyn-Khan
South Wales Doctorate in Clinical Psychology
Cardiff University
Tower Building, Floor 11
CF10 3AT

Email: hra.approval@nhs.net

06 April 2018

Dear Mrs Gladwyn-Khan

**Letter of HRA Approval**

| | |
|---|---|
| **Study title:** | **Bibliotherapy to reduce distress and improve wellbeing after stroke: A quasi-experimental study** |
| **IRAS project ID:** | **232266** |
| **Protocol number:** | **NA** |
| **REC reference:** | **18/WA/0045** |
| **Sponsor** | **Cardiff University** |

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further from the HRA.

**How should I continue to work with participating NHS organisations in England?**
You should now provide a copy of this letter to all participating NHS organisations in England, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of HRA assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

**How should I work with participating NHS/HSC organisations in Northern Ireland, Scotland and Wales?**
HRA Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland, Scotland and Wales.

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**Appendix 4**

Contents



Version 2.

# Study Protocol

Evaluating the efficacy of a guided stepped care approach to enhancing Psychological wellbeing post-stroke by bibliotherapy using 'Rebuilding Your Life After Stroke'

**Sponsor:** Cardiff University

**Sponsor ref:**

**Funder:** Cardiff University Studentship

**IRAS ref:** Submission requires Sponsorship details

**Supervisors:** Professor Reginald Morris

**Student:** Misbah Gladwyn-Khan (Trainee Clinical Psychologist)

**Collaborators:** Professor Reginald Morris

## Study summary

**Design:** Multiple Baseline Design

**Aims:** To evaluate the efficacy of a guided stepped care approach to enhance psychological wellbeing post-stroke using a book entitled 'Rebuilding Your Life after Stroke'. Specifically, the aim is to evaluate whether guided self-help using the book enhances mental wellbeing and quality of life post-stroke.

Transdiagnostic approaches and supported-bibliotherapy after stroke.

**Population:** Stroke survivors

**Duration of study:** 12-14 months

## 1. Introduction and background

Purpose of the project and academic rationale: We propose to study the efficacy of a guided stepped care approach to enhance psychological wellbeing post-stroke using 'Rebuilding your Life after stroke,' a book that was developed by clinicians, alongside carers and stroke survivors. This book aims to help stroke survivors and carers tackle common psychological difficulties arising post-stroke. There has been no formal research as yet to consider usefulness or efficacy of bibliotherapy in stroke.

Additionally, clinicians and service users have suggested that there is a gap in the service regarding Psychological input enabling service-users and carers to improve their psychological wellbeing post-stroke. This is thought to become a greater problem when the clinical care that is initially provided tails off. The book incorporates Acceptance and Commitment Therapy, ACT, which has a well-established evidence base for reducing psychological distress in individuals with mental illness (Ruiz, 2012).

In general, Stroke is one of the major causes of acquired adult disability in the UK (Scarborough, et al., 2009). Many psychological problems often result including: depression (Hacket et al., 2005), and anxiety (Campbell Burton et al., 2013). This has a significant impact on health service use (Naylor et al., 2012). The national guidelines have incorporated Psychological intervention for post stroke care (Royal College of Physicians [RCP], 2016). In England and Wales, nearly one million people are living with stroke, which is an illness of chronic prognosis and can cause sufferers to become highly dependent on others for care (National Audit Office [NAO], 2005).

It has been reported that a wide range of psychological problems can develop post stroke e.g. low mood (Hacket et al., 2005; Campbell, Burton et al., 2013) leading to a pronounced effect on health services, which are ill-equipped to tackle psychological outcomes (Naylor et al., 2012). Despite the incorporation of psychological interventions in the guidelines, there is a lack of a robust evidence-base for the efficacy of psychological interventions for commonly reported difficulties post-stroke (Lincoln et al., 2011), such as depression (Hackett et al., 2008), anxiety (Kneebone & Jeffries, 2013) and posttraumatic stress disorder (Edmondson et al., 2013).

Although the evidence is beginning to accumulate that some psychological interventions lead to improvements in wellbeing post-stroke (e.g. Kneebone et al., 2014), in order to embed psychological interventions in stroke services, further research is required to establish the effectiveness of psychological interventions post-stroke (NAO, 2010; Care Quality Commission, 2011). This is of particular urgency as medications for psychological difficulties are reported to increase adverse events (Hackett et al.,2008). The lack of an established evidence base for

psychological approaches has a negative impact on the quality of stroke care as psychological interventions are not established in services (Watkins & French, 2009).

In summary: This research aims to further explore the efficacy of psychological interventions post-stroke using the self-management book. The book teaches psychological skills to tackle common psychological problems arising post-stroke. The book aims to promote positive adjustment and reduce levels of distress as measured by GHQ-12.

## 1.1. Aims and Objectives

### 1.1.1. Aims:

Does the use of the book, which uses principles of ACT, provide an efficacious intervention for reducing Psychological distress in stroke survivors as measured by the GHQ-12? Does the book, which uses principles of ACT, provide an efficacious intervention for improving the wellbeing of Stroke survivors as measured by SWLQ? Is the book an efficacious intervention for enhancing the quality of life of stroke survivors? Subsidiary questions: How do findings of this study compare to findings of other studies of psychological interventions post-Stroke? Is this book an efficacious intervention for enhancing the wellbeing of stroke survivors?

**1.1.2. Objectives-** to evaluate the self-management book so that services can consider use bibliotherapy and the book when there is a psychological difficulty arising post-stroke. To further build on the evidence for the efficacy of Psychological interventions.

## 2. Study Design

**2.1. Theoretical Framework:** Multiple Baseline Design (Cook & Campbell, 1979, Shadish et al., 2002). The theoretical framework of this design is based on the idea that it is not always possible to randomise participants in clinical services. Therefore, this design entails the development of baseline for each participant so that any changes can be attributed to the intervention. Furthermore, by developing an extended baseline for each participant in time it helps us develop a 'quasi- control group': one which involves participants forming a control 'group' for themselves and for others. The benefit of this design is that the external validity is maximised.

**2.2. Patient sample-** Stroke survivors, adults.

**2.2.1. Participant selection:** Purposive, homogenous sampling, through Stroke clinics and third sector stroke partners

#### 2.2.1.1. Inclusion criteria

Principal inclusion criteria: All participants must be of adult age: 18 years of age or older. All participants must be able to read a book, with support if necessary. There must be a clinical diagnosis of stroke. Participants must be able to understand English and communicate responses in English. The participant must have been referred to this research by a clinician or stroke coordinator.

#### 2.2.1.2. Exclusion criteria

Principal exclusion criteria: Patients with any other acquired brain injuries, such as traumatic brain injury, encephalitis, tumours, etc. will not be allowed to enter the study. Patients with a diagnosed degenerative condition e.g. dementia will also be excluded. Cognitive / language impairment would be assessed and if necessary those with significant disability in these areas excluded as they would prevent them from reading, and benefiting from, the book. Those experiencing severe psychotic symptoms would also be excluded. Those who are receiving other Psychological therapies would be excluded to minimise confounding of results (with the exception of medicines used post-stroke or medications used for depression and anxiety). Generally: Participants must be aged over 18 years and must not have severe communication or moderate- to severe cognitive impairments that would prevent them from participating fully or from providing their informed consent. Participants' capacity to remain in the study will be monitored throughout the study.

2.3. **Setting-** Stroke clinics. However, if necessary, if for example there is limited mobility, the researcher will visit the participant at home, if this is convenient. This will be checked out with participant.

2.4. **Recruitment plans and timelines-** Begin recruitment once ethical approval has been received from NHS. We estimate that submission of ethics form would take place following confirmation of sponsorship (estimate conformation of sponsorship 2x weeks from 29/10/17. Submission of NHS ethics form on 13/11/17. We estimate 4-6 weeks for receipt of ethical approval. Begin study January 2018. Begin recruitment).

Potential participants will be identified by clinical staff. Participants will be recruited using the inclusion / exclusion criteria stipulated above. We will be working closely with the clinical psychologists in each of the Health Boards (Cardiff and Vale, and Bristol) and they will assist in recruitment within these areas. Professor Reginald Morris, Consultant Clinical Psychologist (and Academic Supervisor for this project) has strong links with the Bristol Area Stroke Association (BASF) and clinical teams across both of the Stroke Bristol NHS Trusts.

The clinical team will notify patients of this study. A participant information sheet will be provided or sent via post if interest is expressed. This information sheet will outline the nature and purpose of the study, as well as any potential risks and benefits, and rights. The patient will be given at least 24 hours to read the information sheet. Contact will then be made, and they be given the opportunity to ask any questions or discuss any concerns about the study. If participants choose to be involved in the study, they will be asked to sign a consent form. Contact will then be made to complete initial assessment and to detail what the next steps are e.g. details of the book, and meeting with a member of the research team for setting of goals and targets for use of book. Details will also be provided of the link of the online program, ' Qualtrics,' the study will employ to administer measures for questionnaire data. Physical copies of the measures can also be provided. Freedom to withdraw at any stage of the study will be made explicitly clear. Participant information sheets will also clearly explain the limits of confidentiality.

2.5. **Investigations and assessments-** Primary outcomes will be obtained from GHQ-12 (Goldberg & Blackwell, 1970) and Satisfaction with Life Scale (Diener et al., 1985). Other measures to address the secondary questions about quality of life will also be utilised. However, these measures will only be utilised at the start and at end of the study, as opposed to on a weekly basis, as is the case for the GHQ-12 and the Satisfaction with Life Scale. Proposed secondary measures are: The Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) (Tennanct et al., 2007),

## 3. Study data

### 3.1. Access to medical records

There is no planned access to medical records for this study.

**3.2. Anonymisation and access to personal data-** Anonymisation of data will take place shortly after introduction of participant to the study and confirmation of consent. Codes will be generated to anonymise. However, the researchers will know identities of participants so that incoming data is matched to correct codes. Use of personal data is minimal.

**3.3. Analysis plan-** The data will be analysed using Tau U which is the statistical method for a Multiple Baseline Design.

**3.4. Data storage & retention**

Anonymised study data will be kept for a period of 15 years on a secure server of the Cardiff University network. Electronic data will be encrypted and kept on a secure server of the Cardiff University network. Once study has been completed there will be no retention of personal data.

## 4. Regulatory issues

**4.1. Ethical approval-** We are in process of applying for NHS ethical approval for which we await conformation of sponsorship.

**4.2. Consent-**Verbal and written consent will be sought

**4.2.1. Withdrawal from the study-** Participants are free to withdraw at any stage. We will also withdraw participant's data if weekly measures are not completed and if problems evolve, such as risk, or development of Stroke condition in a way that affects ability to continue to participate.

Potential risks to participants- Completing questionnaires and reading a book that highlight distressing issues, and completion of measures in which issues around stroke/psychological wellbeing might be raised, have the potential to cause distress. To minimise the risks to participants, the potential for distress will be clearly outlined in the participant information sheet provided before they give consent to take part in the study. If participants find completing the questionnaires distressing, they will be offered time with the researcher who is a clinical psychology trainee, or if necessary with her supervisor (a registered clinical psychologist). Participants will be clearly informed of their rights to discontinue participation in the study at any stage of the research. Information detailing local support services (e.g. The Stroke Association Wales, BASF and availability of routine NHS based outpatient's services, for example G.P.) will also be provided. In order to minimise risks associated with breaches of data protection, personal identifiable information will be stored securely in a locked cabinet on NHS premises. There is also a small potential for disclosure of risk issues during completion of the questionnaires. The consent form will explain the circumstances when confidentiality would be broken, such as risk to themselves or others, in accordance with NHS policy and procedures. Should the potential for risk arise, the Clinical Supervisor, will be notified immediately for further assessment and management of the risk.

### 4.3. Study management

Professor Reginald Morris is lead supervisor. Misbah Gladwyn –Khan will act as the Chief investigator. The supervisors will closely supervise and support the research student (Chief Investigator) to achieve the study objectives. Formal supervision between all supervisors and the student will occur on a monthly basis to monitor progress, and to plan work stages. The team will also draw on the expertise and advice of project collaborators who have agreed to support the study.

**4.4. Funding-** The doctorate training, of which this research is in fulfilment of, is fully funded

### 4.5. Sponsorship

Cardiff University will act as a sponsor for the study.

### 4.6. Confidentiality

The Chief Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998. Participants will be assured that their data will not be used for any purposes beyond this study.

5. **Planned outputs-** One published article and one systematic review. Dissemination via clinical teams.

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Patient Information Sheet
Version 2 – 15/12/2017

Contact Details of Chief Investigator:
Misbah Gladwyn-Khan
School of Psychology
Doctorate in Clinical Psychology
Cardiff University
Tower Building
Floor 11
CF10 3AT
Gladwyn-Khan.M@cardiff.ac.uk

Study title:
The study for which we are requesting your participation is called 'Evaluating the efficacy of bibliotherapy using 'Rebuilding your life after Stroke'.

Funding:
This study is part of doctorate level training in Clinical Psychology at Cardiff University, which is funded by the Welsh Government.

Background:
The book 'Rebuilding your life after Stroke' was developed by people who have experienced stroke, alongside clinicians. The book was developed in response to concerns about the lack of psychological support available following a stroke for common psychological difficulties that might arise, such as depression or anxiety. The book is available free to stroke affected people in Wales and is already in the boo prescription scheme in England. The book is not-for-profit, and all author proceeds from the sale of the book go to NHS Wales.

Why are we doing this research?
The reason we are evaluating the book is because we think it could provide a valuable resource for individuals who are experiencing psychological difficulties following a stroke. The book may be used alone or with carers. By evaluating the book, we would be able to build an argument for its inclusion in services. This evaluation would help us ensure that those who require some psychological support following a stroke are offered the book as a first step towards tackling psychological difficulties post-stroke.

What is your role in the research and what are you being asked to do in brief?
As a potential participant your role would be to help us evaluate this book by reading and using the book. We would also that you complete a brief survey, involving 17 questions, on a weekly basis. The responses on the questionnaire are in the format of a simple scale. People who have experienced stroke were consulted during the design of this study. The feedback we received was that the survey was not thought to be overly time-consuming, challenging or difficult.

How will we contact you?

Clinicians will speak to you about whether you are interested in taking part in this study. Subsequently you will be asked to give permission to be contacted by a member of the research team. As part of the study we will be asking clinicians to give us the details of people who have experienced stroke and have shown interest in taking part in the study.

How will your consent be received?
We will meet with you, explain the study in detail and your verbal and written consent will be sought.

How will your data be treated?
Once we have received your consent we will fully anonymise your data using codes. All data subsequently provided by you will be stored anonymously, though researchers will be aware of your identity. This is so that we can match up the data that is received with your code. Cardiff University policy is to store anonymised data for 15 years.

Inclusion criteria
We will be recruiting stroke survivors, who are reporting post-stroke psychological difficulties such as anxiety and/or depression. The book can be used with the support of a carer.

Exclusion criteria
Those who cannot read the book in Welsh or English will not be invited to participate. We will also not be recruiting people with other severe mental health difficulties such as psychosis.

The method in detail:
Once you provide consent, your participation will involve meeting with a member of the research team 1-2 times in the beginning. This is when we will obtain your consent and complete some initial measures.
It will not necessarily be the case that if you are recruited first, you get to have the intervention sooner than others and **the intervention will not begin immediately**.
We ask that you respond to a survey on a weekly basis, before the intervention with the book begins. This period is called the baseline phase. The baseline phase could be as long as 8 weeks. You will complete the survey online. If you do not have access to the internet we will organise it so that you receive physical copies of the forms.
You will also meet with a member of the research team every fortnight during baseline and intervention phases. The purpose of meeting with the researcher in the intervention phase is to develop goals and targets for your use of the book and to support you with the use of the book.
The goals can be extended if necessary. It is important to state that we are not interested in how fast people get through their reading goals.
The book also includes some very brief exercises such as meditation or breathing exercises and problem-solving techniques. During your reading of the book we will also ask that you complete the measures every week.

What is the total study duration expected to be?

The longest duration period of the study could last as long as an estimated 30 weeks. The shortest duration of the study will be a minimum of an estimated 10 weeks.

How will participation affect my routine care?
Your participation in the research study will not impact on any routine clinical services you might be receiving. The researchers will not replace your clinicians. When the research stops your clinicians may decide to refer you to other appropriate services. Any other services that you are already receiving e.g. medication support with your G.P. would continue during the research period.

What support would be available to you?
During the baseline phase, we will ensure you are aware of all of the contact details of clinical services that you might need to use. You will also be provided with the contact details of the members of the research team. We will make any referrals that on your behalf if you require them. We are also willing to meet with you should you require it or want it.
We do not believe the book is itself upsetting as it simply provides tried-and –tested ways of helping people tackle psychological difficulties. However, if you experience distress during the intervention stage, you will initially be met with Misbah Gladwyn-Khan, and subsequently with Professor Reginald Morris, who has worked in stroke services for many years.
We will also ensure that you are receiving support through your routine clinical services and your G.P. You will also be able to meet with Misbah Gladwyn-Khan more often than fortnightly to support your use of the book should you require it.

How will risk be handled during the study period?
If you disclose to us that you are in immediate risk, we have a responsibility to keep you and others safe and will therefore contact the appropriate agencies to get suitable help for you.

How will sensitive disclosures be handled during the study?
If you disclose to us that you have experienced malpractice or abuse within NHS services, we will also have a duty to report this.

What happens if I no longer want to take part in the study?
If you no longer wish to take part in the study, you would be free to withdraw at any stage. Cardiff University policy is that anonymised data will be held for fifteen years. In the event that you choose to self-exclude yourself we would seek your permission to continue to use any data you have already provided.

What happens if I do not routinely complete the survey?
If you elect to miss the weekly completion of the survey for a significant period of time we will ask if you wish to self-exclude yourself. We will also seek your permission to continue to use any data you have already provided. If you miss completion of data for a significant period of time, but wish to remain in the study, we will ask you to continue with completion of data. If you are in the baseline phase, this will mean continuing within this phase for a little longer. If you are in intervention phase this will simply continue up to a reasonable time frame, until you have completed your reading goals,

How many participants will be involved?
We are hoping to recruit at least 16 people into the study. All the reading and the survey will be done at your home, so you won't meet with other participants at any point.

What are the benefits to you of taking part in this study?
Currently we know that there are few psychological services available clinically to help people tackle psychological difficulties arising post-stroke in stroke services. Therefore, one of the benefits of taking part in this study is that you will be receiving some support for psychological difficulties. It is also likely that you might find the book helpful as it incorporates techniques drawn from psychological therapies that have been shown to be helpful.

What are the disadvantages of taking part in this study?
You will be asked to complete the brief ten-minute survey every week. There is a baseline phase during which you would be expected to complete measures but will not be in receipt of the intervention.
The research does not entail the provision of a therapy in a one-to-one fashion for psychological difficulties.

Accessing your records
As part of this research, we will not be accessing your medical records.

Who reviewed the development of this study?
Both academic staff, who are also clinicians in stroke services, and service users who have experienced stroke have been involved in reviewing the details of this study.

Debrief
You will be given a verbal debrief at the commencement and closure of the study. During the debrief you will also be given the opportunity to ask any questions you may have.

Consent form- Version 2

Consent form

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

**CONSENT FORM**

Title of Project: Evaluating the Efficacy of a guided stepped care approach to enhancing Psychological wellbeing post-stroke using 'Rebuilding Your Life After Stroke'

Name of Researcher: Misbah Gladwyn-Khan (Trainee Clinical Psychologist)

| | Please initial box |
|---|---|
| 1. I confirm that I have read the information sheet dated 15/12/2017 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | ☐ |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. | ☐ |
| 3. I agree to take part in the above study. | ☐ |

| Name of Participant | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |

Appendix 5

Journal submission criteria

Proposed target journal for publication of both papers: British journal of Psychology.

The main criteria are as following:

- 8000 word-limit (excluding abstract, diagrams, figures, tables and references)
- Double-spacing
- Numbered pages
- Abstract of up to 200 words
- APA style referencing

Paper 3

A critical evaluation of work completed as part the large-scale research project.

**Evaluating the efficacy of bibliotherapy in stroke**

I chose stroke as an area of research due to my interest in researching problems that can occur across the lifespan. I also have an interest in the application of psychological knowledge in health settings and alongside biomedical approaches. I wanted to complete a study of high clinical relevance, the results of which may facilitate promotion of psychological wellbeing for stroke patients in the NHS. The strategy for my research was developed in collaboration with my supervisor who is an esteemed researcher in the field, from whom I appreciated learning. This experience taught me that collaboration in research is invaluable as completing this study alone would have been challenging.

**Strengths and weaknesses of study**

One of the strengths of the study is that it investigated the effectiveness of a book that is routinely utilised in current stroke clinical psychology practice. The book is currently recommended by clinicians and is sometimes used in the place of a clinical service for people reporting psychological difficulties after stroke as a cost-saving measure. This was concerning and so my study aimed to improve this practice.

The strength of the study extends to ensuring that bibliotherapy is efficacious and to ensuring that the intervention is offered in line with research findings (the effect sizes were generally in the moderate range and so patients may require more support than could be offered in the study). Therefore, an investigation into the efficacy of bibliotherapy was timely.

An additional strength of the line of enquiry in my study is that it was timed to coincide with a particularly difficult phase in the NHS for funding of psychological services, especially in Wales where funding has lagged behind other UK nations (Luchinskaya, Simpson & Stoye, 2017). As my study showed that the intervention was helpful, there is mileage to apply for funding and grants to conduct a larger study. One of the limitations of my study is that it was labour, resource and time intensive due to utilisation of a multiple baseline design (MBD), and as NHS ethics and R&D were both required. Therefore, larger numbers of participants couldn't be recruited into the study. Given that time was pressed due to the delay in starting recruitment, I wouldn't have been able to provide the intervention to a larger sample due to other DclinPsy demands and pressures on my time.

On many occasions the feasibility of the study was severely threatened by issues of resource and labour intensity requirements of MBD. For these reasons the study was very stressful. To offset problems that may occur if the requirements of MBD weren't fulfilled, I wasn't able to take annual leave or weekends for myself for the duration of the study. This is to say, that MBD studies should be well planned and the limitations and practicalities considered in advance. A disadvantage of the line of enquiry in my study as a whole is that results from

MBD can't be used to make definitive generalisations about the book's efficacy. Yet, a significant level of time was expended to ensure baselines were representative by ensuring that participants received therapist support during the baseline.

When we first designed the study, the feasibility of the study was decided on the basis of providing therapist support during only the intervention phase. However, early critical appraisal of the study protocol by a DClinPsy research panel led to the concern that the book's efficacy couldn't be determined without also providing therapist support during the baseline phase. One of the strengths of the design I used in my study is that baselines allow control for placebo effects, like empathy and being given attention. In many cases, there was a reduction in test scores due to support provision during the baseline phase, so without baselines the effect sizes would have been artificially elevated.

One of the limitations of my study is that participants could not be recruited concurrently as R&D /ethics processes were significantly long, accounting for one year of the total time available to complete the study. There was the possibility of earlier recruitment through third sector stroke partner organisations; however, I decided that NHS ethics provided my study with a higher standard of approval, and so I didn't begin recruitment until NHS ethical approval for my study had been obtained. However, third-sector partners also appeared to value scrutiny by an NHS ethics panel. All referrals of participants were taken from experienced clinicians and stroke advisors. All participants were screened through standardised measures. However, a problem which affected the rigour of the

study is that stroke survivors from the general population couldn't be recruited and the sample was small. This means the study is in fact a cross-sectional study.

Another limitation of the line of enquiry as a whole is that bulk of the recruitment did not take place in the acute phase of the stroke as psychological difficulties often become apparent in the chronic phase of illness. This means that it is likely that the distress reported by participants could be considered to be a 'normal' part of the difficulty. However, this is to be expected as my study focussed on improving quality of life through ACT as opposed to treating distress only. In addition, psychological problems are common in the stroke population and good treatments are not widely available.

**Strengths and limitations of the design**

I chose multiple baseline design to complete my study, which is a type of quasi-experimental single-case design. In Single-case experimental design research (SCED), participants provide their own data during a baseline phase which approximates a control condition, and the data is used in a within-subjects analysis. Typically, there are two phases to this research design. A baseline phase is completed which is representative of a typical period in someone's life. The treatment phase, during which the same measures are continued, investigates the efficacy of the intervention. The baseline phase is subsequently compared to the intervention phase using analytical methods that parse out the relative difference between the two phases such that conclusions can be made

about the intervention's efficacy. The goal of single-case design is to help researchers decide whether a functional relationship exists between the independent and dependent variables. MBD provides a way of conducting first-stage research, at minimal cost. The next stage would be to plan and conduct a larger clinical study to establish effectiveness and generalisability.

The credibility of single case is enhanced by measuring the dependent variable repeatedly. The repetition adds to the experimental control of single case as it means that a sustained effect is necessary before the intervention can be said to be effective (non-overlap in measures). This approach is particularly useful for interventions that can't be removed afterwards, and for interventions that can't easily be masked, or readily delivered in double-blind studies. A book is a physical product and can't readily be delivered as a blinded intervention exclusively in an intervention group. In contrast, a single-ingredient intervention like medication or a brand- new, previously unpublicised therapy, could potentially be tested in a blinded study.

One of the advantages of MBD is that rather than only obtaining an average estimate of effect for the whole group, the effect sizes are relevant to individuals which means that those gaining less benefit can be evaluated in post-hoc analyses if required. Post-hoc analyses may be a helpful way of advancing psychological research. Enquiry at the individual level for stroke is important because there is a diverse presentation of post-stroke difficulties including psychological difficulties, body-image, relationship factors, cognitive and communication difficulties etc. One of the benefits of this experience of research

is that I am really pleased to have learned about a design that may be used in clinical practice when I qualify.

It could be argued that I should have completed a randomised controlled trial (RCT). The book used in the bibliotherapy intervention has received wide publicity in Wales and England, as it was launched in patient conferences, and is available as part of the 'Reading Well Scheme' in England. Indeed, patients were involved in its production, and it is widely available both within NHS services and partner organisations such as The Stroke Association in Wales. Therefore, it couldn't be delivered in a masked, blinded manner in an RCT, aside from the fact that psychological interventions are not generally easily blinded in RCTs. The difficulty of blinding is illustrated by the fact that none of the studies reviewed as part of my systematic review successfully blinded the delivery of the psychological interventions. Another difficulty of completing an RCT was that, within the timeframe of the doctorate the requisite funding, resource, time, were not available. Indeed, R&D processes for a multiple-baseline design presented considerable challenge to deadlines. An RCT was also not considered feasible as the nature of bibliotherapy means that it is often variably paced.

A disadvantage of MBD is that it is a quasi-experimental design and it is difficult, without a control group, to form definitive conclusions about the intervention and to conclusively rule out effects of time and maturation. Given that the study has been a big part of my life for nearly two years, this limitation saddens me. RCT designs in which whole groups are subjected to an intervention (vs. an, ideally, matched, control condition) are thought to be more reliable as threats to internal

validity are reduced. Single-case designs on the other hand have to go to great lengths to reduce threats to internal validity, as well as external validity threats. This is why a huge effort was expended during my research to develop lengthy baselines. This feature of MBD also limited the number of participants recruited into my study as therapist support was provided during the baseline phase, in addition to intervention phase. The baseline lengths for individuals were also randomised to add further rigour to the process. The baselines were varied length (2-8 weeks) and staggered so that the overall length of the total baseline in the group across participants was extended in time. Varied-length, staggered baselines allows researchers to rule out spurious and systematic effects on the sample. A spurious-uncontrolled effect might include, for example, individuals recently discharged from hospital receiving physiotherapy during the intervention phase, whilst others discharged prior to study commencement not receiving physiotherapy. A systematic effect might be something like a terrorist attack in the area in which all participants are treated leading to higher levels of anxiety, which naturally remits over time.

Without randomised, varied-length, staggered baselines it would be difficult to parse the effects of the intervention from other events, making conclusions unreliable. Additionally, with non-staggered, non-randomised baselines the timing of the intervention, as opposed to the intervention itself, could become relevant. Both staggered and randomised baselines help minimise such effects. Maturation could also become relevant as stroke survivors learn to adapt to their difficulties over time.

On the other hand, although single-case research presents complex challenges e.g. tackling nonindependence of data, autocorrelation, tackling the challenges of constructing a representative baseline, and dealing with missing data, it also provides a way of overcoming some of the challenges that may hinder psychological research e.g. costs of an RCT, manualisation, resource burden etc.

In stroke there is a good case for ensuring therapies are tailored, which isn't the standard approach in an RCT. Therefore, another advantage is that single case designs may help enhance the ecological validity of research, which I am particularly passionate about. On the other hand, a disadvantage of the method and of the research itself is that the psychological program is in final part of the book and so the change was gradual, and difficult to illustrate in one single instance. Therefore, the analysis was carefully selected to manage this issue i.e. by completing inferential analysis rather than visual analysis. The gradual change means, however, that there were also significant levels of overlap between phases. This resulted in difficulty with completing a single graph to illustrate the results as is conventional. The overlap also attenuated the effect sizes which is to be expected and welcomed as this leads to a rigorous analysis. Something that surprised me is that short baselines also resulted in attenuated p values, which requires some thought in future studies.

One of the problems with the available statistical analysis tools for multiple baseline design is that they all use slightly different ways of analysing single case designs. It is therefore imperative that the particular method of statistical analysis is transparently reported. In the absence of transparency, my research would be

difficult to compare to other similar research making consensus about efficacy of interventions challenging, in addition to which meta-syntheses are challenging with SCED. Research that is not widely disseminated becomes redundant and this is why I decided that it is important to me that my research could be interpreted by the wider research community and clinicians. If the method of statistical analysis is not transparent, effect sizes become meaningless as meta-analyses and replicability are diminished. For this reason, I converted effect sizes to the standardised mean difference, d, statistic so that my research could be analysed alongside other research in the field, which is important to me.

In MBD considerations of statistical analyses include non-independence of data and autocorrelation. Non-independence of data and autocorrelation are statistical problems, which result in potentially erroneous conclusions about interventions since data from different phases may be connected by undefined variables. For example, data may be connected simply through unmeasured behavioural responses to data, such as the Hawthorne effect. The TAU U analysis I chose is considered to be highly conservative as it attenuates p values and effect sizes due to overlap even if only one data point is overlapping. If data in the phases represents movement in the unexpected direction i.e. if GHQ-12 data reduces during baseline and increases during intervention the TAU-U analysis again attenuates the p values and effect sizes.

The tool was chosen as it provides a conservative estimate of the effect of the intervention as it results in a non-statistically significant result if there is significant overlap between baseline and intervention, or if there is too much uncertainty due

to fluctuation in phases. However, despite being attenuated the effect sizes still provide information about possible strength of effect of intervention, and the APA has suggested that effect sizes may be more valuable than only testing for statistical significance since for large samples the p value may become significant simply by chance (Sullivan & Feinn, 2012). Other challenges to the method include tackling missing data, which I handled by ensuring that participants remained in the baseline phase if baseline measurement points were missed.

**Research implications**

One of the biggest challenges of my study was the low recruitment numbers. Studies have identified the importance of community collaborations in research to maximise recruitment both in respect of diversity and rates (Griener et al., 2015). During recruitment, I realised that sampling biases can become endemic. For example, non-response can result in an inherently biased sample. This is why a sufficiently large sample is required to maximise the chance of recruiting anybody at random. I also realised that the proportion of the representative sample that agrees to participate in the study can affect the research integrity if recruitment is vulnerable to processes that may be inherently biased e.g. referrals through clinicians who review complex patients with high motivation to elicit medical care. The people who don't agree to participate may simply be more disabled by their problem. One of the problems in my study was the low level of recruitment from NHS healthboards, which may indicate a systemic issue, such as higher levels of disability. Conversely, it may indicate that those receiving continued medical

attention experience less psychological distress. These are potentially good questions for future studies.

I tried to recruit through as many venues as possible, including through third sector partnership but the sample remained small, despite ongoing efforts to recruit. The recruitment challenges resulted in logistical problems for the completion of my study and I required an extension, which was stressful and disappointing. Large samples are necessary to ensure that valuable research resources are prudently spent. GP practice recruitment was not possible because R&D processes to obtain necessary permissions would have led to further significant delays.

Arguably the characteristics of people motivated to take part in research can have a significant effect on the direction of research. For instance, people of certain characteristics may have preferences that are not representative of broader samples. This may cause challenges when an intervention is eventually offered to wider samples of patients. It is a recommendation that recruitment strategies are decided early on. However, the reality of a clinical psychology doctorate is that staff simply may not have resources to complete ethics applications in advance to maximise recruitment.

In the future, advance, pre-planned ethics' applications may be a necessity to avoid the pitfalls of poor recruitment (low recruitment numbers). For the profession to remain valid and valuable it is also imperative that the research adds value to the profession, particularly in terms of enhancing credibility of

clinical psychology in the NHS. However, if recruitment remains challenging, except when studies are planned well in advance, the research products are likely to reflect the pressures of deadlines (short studies, poor recruitment levels, questionnaire-based studies administered via. Facebook, general population, non-clinical studies). For all of these types of studies, extensive translational research is required to implement findings. Therefore, I passionately believe that my study stands out as immediately relevant and applicable in the NHS.

An important factor of consideration is that It is likely that had support not been provided during baseline, take-up of my study may have been affected. In addition, it's likely that measures wouldn't have been completed during baseline phase. I think it's important to consider that research is always personal. Whether one takes part as a participant because they care about outcomes for other patients, or whether one is a researcher who wants to see a better world through scientific advancement, it is important to value the human cost of research. For example, by visiting participants as strictly as I did, including on Christmas eve, I conveyed the importance of participants in my study. Additionally, it conveys that the data they provide is invaluable. I believe this increased the rates of data obtained. Personally, it was challenging to withhold an intervention. However, it was important to me to advance the science in this area for the greater good.

I was pleased to find that very few people dropped out of my study once they were embedded into the study, except due to serious illness resulting from falls. However, this means that the validity of the study was affected through drop-out, which I was able to partly correct by using partial intervention data from one drop-

out. This helped slightly mitigate the biasing effect of drop-out. One of the shortcomings of my study is that due to time pressures the people who dropped-out due to illness could not be followed-up.

The choice to utilise questionnaires to collect data was decided on the basis of costs, psychometric standards and to reduce burden of completing lengthy questionnaires. The choice of questionnaire utility was also facilitated by consultation with stroke survivors who highlighted the importance of striking a balance between cost and ease of completion. Generally, a trade-off is required between costs, complexity of responses and ensuring that response rate isn't affected by obstacles to completing data forms. The questionnaires that were selected as primary measures were also selected due to rigorous demonstration of robust psychometric properties. Consultation with the stroke survivors was an aspect of the research I particularly enjoyed as I learned a lot through this process, which helped me make my research protocol more inclusive.

One of the limitations of the enquiry as a whole is that we did not complete targeted promotion of the study to Welsh speakers, although we didn't exclude Welsh speakers. However, it is likely that Welsh speakers were unlikely to come forward as all of the publicity for the study was in English and it wasn't explicitly stated that the study could be completed in Welsh. Realistically, the study couldn't be completed without an interpreter if a Welsh speaker required all interventions in Welsh, and this is also true for speakers of other languages. The added step of needing an interpreter would have necessarily changed the dynamic of the intervention. Therefore, one of the limitations of the study is that

the findings can't be used to infer efficacy of bibliotherapy for non-English-speaking stroke survivors. Another limitation of the enquiry is that there was no existing evidence base that bibliotherapy after stroke could be helpful, although ACT has been found to be efficacious in stroke.

The systematic review question was chosen on the basis of a gap in the literature. The gap I identified is that there has been an increased trend of research into 'third wave' therapies, which are transdiagnostic in nature, in recent years. However, to date there hasn't been a review of these therapies in stroke to inform evidence-based practice. One of the difficulties with my review was that many studies, despite utilising transdiagnostic approaches, studied efficacy for anxiety or depression which are singular diagnoses. Another challenge for the SR was how we should operationalise and define transdiagnostic therapy. To better define transdiagnostic approaches I completed a literature review for transdiagnostic approaches. I personally found this aspect of the systematic review particularly enjoyable and interesting. It prompted thoughts about how future DClinPsy teaching could potentially become transdiagnostically-focussed, given the poor validity for DSM categories. I decided that there was a good rationale to focus on transdiagnostic approaches as they focus on improving quality of life as opposed to 'curing' distress.

The EPHP tool was utilised as a quality appraisal tool because it has good validity and reliability and is suitable for quantitative intervention studies. One of the problems with the EPHP tool is that it doesn't provide statistics on the sample size that is deemed to be an adequate sample in studies for particular designs.

This made it difficult to gauge whether an RCT with 50 participants is as good as an RCT with 30 participants. However, the EPHP does not score for sample size and therefore studies with a sample of 30 were coded equally as studies with a sample of 70. I also wanted to particularly focus on attention control issues of psychological research which the EPHPP doesn't address.

Another challenging aspect of the systematic review was that the search engines all required a separate search for all the different types of interventions that could be classed as potentially transdiagnostic in approach e.g. mindfulness, ACT etc. This is because the term transdiagnostic is not in common use in stroke, although its popularity has grown in the field of mental health in general. This creates a potential challenge for the title of the review. Since research is most valuable when it is disseminated, and has an influence on practice, a review with an unsearchable title is problematic. This means that the dissemination process is critical.

**Limitations of studies included in review**

The review is not a comprehensive review of transdiagnostic therapies since there hadn't been any studies, at the point of writing this reflection, that had investigated the efficacy of compassion -focussed therapy. As a result, all studies, even those with small samples such as the study on brief solution focussed, were included to provide a more comprehensive review of transdiagnostic therapies. The heterogeneity of studies, however, precluded a meta-analysis which is a severe short-coming of my review.

## Dissemination

The study was disseminated to all stake holders, including clinical teams and third sector organisations. There is a plan to disseminate the findings of my study at the stroke conference in October 2019.

## Implications for theory

The study showed that bibliotherapy is reasonably efficacious, which invites further studies of bibliotherapy in stroke. The findings of the study suggest that acceptance and commitment therapy (ACT) may be a way of bypassing the difficulties of cognitive disputation following stroke. In particular, stroke commonly leads to disability that requires adjustment. After stroke, individuals are likely to report psychological difficulties arising as a result of challenges to adapting to disability. This means that potential negative or anxious cognitions may be part of an adjustment process to difficulties.

In these circumstances, cognitive disputation may not be helpful. The only RCT to date of CBT in stroke showed no group differences (Lincoln & Flannaghan, 2003) which indicates that CBT may not be helpful post-stroke. However, a study which utilised ACT in just 4 group-based sessions showed that it was efficacious for improvements to depression, hope and HRQOL (Majumdar & Morris, 2019). Additionally, the current study showed that ACT is helpful for a sample composed of a mixture of difficulties. Therefore, there are now at least 2 studies

demonstrating ACT's efficacy post-stroke. This indicates that the theoretical framework of ACT may be more amenable to working with post-stroke psychological distress. Perhaps the biggest strength of ACT is that it is a contextually -based therapy which in stroke is pertinent since current difficulties are the source of distress.

**Implications for practice**

The results of a body of research in stroke, including studies reviewed in SR and my empirical study, suggest that it may be helpful to use a transdiagnostic approach. Transdiagnostic approaches may be a more powerful way of intervening after stroke as challenges and difficulties may result in thoughts about difficulties that are realistic. My experience during this study has taught me that it isn't enough to simply challenge cognitions in a logical-rational way as this can lead to greater distress through not finding evidence against future-related worries, or even current worries etc. It also may be the case that attempting to alleviate distress is limited as an approach since distress may be a valid response to current circumstances; the effects of stroke are often experienced 'in a stroke' which can be devastating. People inevitably wonder if it could have been prevented through their own actions/choices. ACT is premised on the idea that distress can't always be ameliorated and is understandable. Therefore, acceptance of the effects of stroke and using ACT principles to create the best possible life despite post-stroke difficulties may be more helpful. In fact, the findings of the systematic review showed that transdiagnostic therapies that aim to help people live the best possible life they can despite difficulties are

efficacious in general. My study suggests a useful role for stroke practitioners, such as Stroke Association coordinators, to be skilled up to deliver bibliotherapy. In fact, it's noteworthy that stroke coordinators provide generic support and therefore represent an untapped resource.

**Suggestions for further research**

Given the results of both the empirical paper and systematic review, it is important that further research is undertaken to establish the effectiveness of transdiagnostic therapies. For example, some papers reviewed as part of the systematic review were not conducted in an RCT format. At minimum, multiple baseline designs can be made more rigorous through addition of a convenient, matched, control group e.g. waiting lists, or TAU. It would also be important to complete dismantling designs as it is possible that therapies have elements in common thus simplifying the choice for services.

**Summary**

One of the advantages of my study is that it investigated the efficacy of bibliotherapy in which the intervention is manualised. In the future, a larger study with an MBD design is required to further test the efficacy of bibliotherapy using the particular stroke specific materials tested in my research. MBDs are a cost-effective way of investigating psychological therapies, but future studies should aim to act upon the knowledge developed through my study. In particular, larger

samples, recruited by concurrent, advanced recruitment, are required; the addition of a comparison control group could enhance inferential analyses.

It is also important that future studies develop closer links with referring clinicians to ascertain difficulties with referral into studies, and to offer contemporaneous solutions. For instance, for the current study, clinicians had developed the opinion that participants with existing access to the book couldn't be referred to my study. Many participants, however, reported to not have read the book due to pressures of adjustment to life after stroke. This information suggests that provision of the book alone, without support, may not be a prudent intervention. Given the evidence that unremitting mood difficulties may impact on recovery outcomes (Ayerbe, Aysis, Wolfe & Rudd, 2013), it is important that interventions are meaningful and address psychological problems with post-stroke adjustment, rather than attempting to cure distress alone.

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