



# Help from home for depression: A randomised controlled trial comparing internet-delivered cognitive behaviour therapy with bibliotherapy for depression



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## ABSTRACT

Major Depressive Disorder (MDD) is a leading cause of the Global Burden of Disease. Cognitive Behavioural Therapy (CBT) is an effective treatment for MDD, but access can be impaired due to numerous barriers. Internet-delivered CBT (iCBT) can be utilised to overcome treatment barriers and is an effective treatment for depression, but has never been compared to bibliotherapy. This Randomised Controlled Trial (RCT) included participants meeting diagnostic criteria for MDD ( $n = 270$ ) being randomised to either: iCBT ( $n = 61$ ), a CBT self-help book (bCBT) ( $n = 77$ ), a meditation self-help book (bMED) ( $n = 64$ ) or wait-list control (WLC) ( $n = 68$ ). The primary outcome was the Patient Health Questionnaire 9-item scale (PHQ-9) at 12-weeks (post-treatment). All three active interventions were significantly more effective than WLC in reducing depression at post-treatment, but there were no significant differences between the groups. All three interventions led to large within-group reductions in PHQ-9 scores at post-treatment ( $g = 0.88$ – $1.69$ ), which were maintained at 3-month follow-up, although there was some evidence of relapse in the bMED group (within-group  $g$  [post to follow-up] =  $0.09$ – $1.04$ ). Self-help based interventions could be beneficial in treating depression, however vigilance needs to be applied when selecting from the range of materials available. Replication of this study with a larger sample is required.

## 1. Introduction

Depressive Disorders – including Major Depressive Disorder (MDD) – are a global public health concern and a leading cause of disease burden (Ferrari et al., 2013), with burgeoning individual and societal costs (Ustun et al., 2004). Recent NICE (2009) guidelines recommend non-drug interventions such as cognitive behavioural therapy (CBT) as a first line treatment for mild to moderate depression ([www.nice.org.uk/CG90](http://www.nice.org.uk/CG90)), but dissemination of CBT can be limited due to inadequate resources (Shapiro et al., 2003), particularly in certain geographical locations (Cavanagh, 2014). To address these treatment barriers, there has been a recent surge in innovative ways to deliver CBT (Andersson et al., 2012), specifically in the development of more accessible internet and computerised therapies for the treatment of common mental disorders (Marks et al., 2003).

Internet-delivered CBT (iCBT) programs are based on face-to-face CBT treatment manuals, and typically deliver psycho-education and the key CBT skills (e.g., cognitive restructuring, behavioural activation) via lessons or modules, supplemented with homework activities and practical exercises to complete between lessons. The concept of 'guided iCBT' typically takes the form of a therapist or coach supporting the patient throughout the course; this is a distinct difference to unguided iCBT which takes place without support - a purely 'self-help' format. Although unguided iCBT programs exist, recent findings indicate that guided iCBT is a more effective treatment for depression (Johansson and Andersson, 2012). Indeed, 'technician-assisted' guidance (whereby a technician provides support and encouragement to patients and responds to general questions about the course) has been shown to be equally as effective as 'clinician-assisted' guidance provided by a qualified clinical psychologist (Titov et al., 2010).

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The main strengths of iCBT include its accessibility to large amounts of people (Andersson, 2006), the privacy and convenience it invokes for the user (Wootton et al., 2011), and the ability to offer immediate feedback (Andersson et al., 2005). This treatment modality is also scalable, with the scope to be utilised within a stepped-care framework (Andrews and Williams, 2015). ICBT is cost-effective (Hedman et al., 2012) with a recent meta-analysis revealing that guided iCBT and face-to-face CBT produced equivalent overall effects in treating depression ( $g = 0.05$  (95% CI:  $-0.19$  to  $0.30$ ) (Andersson et al., 2014). Although the majority of randomised trials have found positive effects of internet and computerised CBT on depression, there are some exceptions. A recent study found that guided computerised CBT did not achieve better outcomes for people with depression compared to usual (GP) care alone (Gilbody et al., 2015), although there are some concerns with the probity of the REEACT trial (Andrews et al., 2016).

The stages in CBT for depression can be generalised and represented in manuals and ‘self-help’ books. Bibliotherapy - including self-help books - are commonly used to teach self-help tools and strategies (Den Boer et al., 2004), with their usefulness to treat depression - when compared to controls - largely supported (Gregory et al., 2004). However as numerous self-help books are widely available for depression - whereby a specific self-help program is presented and is typically worked through independently - the evidence-base to support them is relatively small (McKendree-Smith et al., 2003), making their impact difficult to establish.

It is not known whether guided iCBT represents an advance in efficacy over the numerous CBT self-help books widely available for treating depression. This question is especially pertinent in an increasingly digital age; however access to the internet is not completely ubiquitous, especially for those on lower incomes (Cline and Haynes, 2001) and those living in rural and remote areas where internet access can be limited. Therefore the first aim of the current study was to compare an evidence-based guided iCBT course (Perini et al., 2009), the ‘Sadness’ program, versus unguided access to a self-help book based on CBT for depression. Participants in the CBT self-help book group were provided with a leading self-help book free of charge, ‘Beating the Blues’ (Tanner and Ball, 2012), which they completed without any form of guidance.

We also compared these two interventions to a third group who received a self-help meditation book, ‘Silence your Mind’ (Manocha, 2013). The self-help meditation book was also unguided and served as an active comparison condition to control for the effects of assessment, monitoring, and active learning and skills practice. We aimed to explore whether there were any significant differences between these active intervention groups at post-treatment. A variety of meditation-based interventions for depression are currently available; given that meditation can result in reduced psychological stress (Goyal et al., 2014), and has shown to be beneficial in treating acute and sub-acute depression (Jain et al., 2015), we expected the meditation book to have some advantageous effects on depression symptoms and to outperform a waiting list control group, but we anticipated that both CBT groups would outperform the meditation book in reducing depression. To our knowledge, this is the first study to compare guided iCBT with two self-help books, one book based on CBT and one based on meditation, for the treatment of MDD.

## 2. Method

### 2.1. Design

The current study utilised a randomised controlled trial design to compare an iCBT program, a CBT self-help book, a meditation self-help book, to a wait-list control for participants meeting diagnostic criteria for MDD. Participants were assessed at pre-treatment, mid-treatment, post-treatment and at 3 months post-treatment.

### 2.2. Inclusion/exclusion criteria

Inclusion criteria were: (i) aged over 18 years (ii) prepared to provide contact details of their General Practitioner (iii) had access to internet and printer, (iv) resident in Australia, (v) fluent in written and spoken English, (vi) a score between 5 and 23 on the Patient Health Questionnaire 9-item scale (PHQ-9), (vii) met criteria on the Mini International Neuropsychiatric Interview Version 5.0.0 (MINI) (Sheehan et al., 1998) for DSM-IV criteria for MDD on structured telephone diagnostic interview, (viii) if taking medications for anxiety or depression, were on a stable dose for at least 8 weeks at time of intake interview, and (ix) had not commenced face to face CBT within 4 weeks at time of intake interview. Exclusion Criteria included psychosis or bipolar disorder, drug or alcohol dependency, benzodiazepine use, severe depression PHQ-9 total scores  $> 24$ , or current suicidality.

### 2.3. Procedure

Participants were recruited via the Virtual Clinic ([www.virtualclinic.org.au](http://www.virtualclinic.org.au)), the research arm of the Clinical Research Unit for Anxiety and Depression, based at St Vincent's Hospital, Sydney and the University of New South Wales. Potential applicants viewed advertisements in the form of leaflets and posters and on social media. Applicants completed online screening questionnaires about demographic information and depressive symptoms as assessed on the PHQ-9 (Kroenke et al., 2001), after reading details about the study. Participants who met online screening criteria then participated in a brief telephone interview. Trained interviewers administered a structured diagnostic interview which consisted of the Mini International Neuropsychiatric Interview Version 5.0.0 (MINI) (Sheehan et al., 1998) MDD and risk assessment modules to confirm whether applicants met for DSM-IV criteria for MDD. Full risk assessment modules (where necessary) were completed by a psychiatry registrar to assess suicidal ideation and determine suitability for the study.

### 2.4. Participant flow

Details of the participant flow are displayed in Fig. 1. A total of 1143 applicants applied online for the study between May 2013 and February 2015. Of these, 549 applicants were excluded after completing initial online screening questions and received an email with information about alternative services. Five hundred and ninety four applicants passed the online screening phase and were telephoned for a diagnostic interview. A further 324 individuals were excluded at telephone interview stage, leaving 270 applicants who met inclusion criteria and were randomised.

Eligible participants were randomised based on a random number sequence generated at [www.random.org](http://www.random.org) by an independent person not involved in the study. Group allocation numbers were concealed from the interviewer with the use of opaque sealed envelopes, which were opened once the applicant was deemed eligible to participate. Participants provided electronic informed consent before being enrolled in the study. This study was approved by the Human Research Ethics Committee (HREC/13/SVH/29) of St Vincent's Hospital Sydney, Australia. The trial was prospectively registered on ANZCTR (ACTRN12613000502730).

### 2.5. Interventions

#### 2.5.1. Sadness program (iCBT)

The Sadness program was delivered through [www.virtualclinic.org.au](http://www.virtualclinic.org.au). The program has been evaluated in four previous trials and its efficacy has been established (Perini et al., 2008, 2009, Titov et al., 2010, Watts et al., 2013) (between-groups effect sizes:  $d = 0.8$ – $1.3$ , within-group pre-post effect sizes:  $d = 0.9$ – $1.0$ ). The program consisted

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