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Research report

Randomised controlled non-inferiority trial with 3-year follow-up of internet-delivered versus face-to-face group cognitive behavioural therapy for depression

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ABSTRACT

Background: Guided internet-delivered cognitive behaviour therapy (ICBT) has been found to be effective in the treatment of mild to moderate depression, but there have been no direct comparisons with the more established group-based CBT with a long-term follow-up.
Method: Participants with mild to moderate depression were recruited from the general population and randomized to either guided ICBT ($n=33$) or to live group treatment ($n=36$). Measures were completed before and after the intervention to assess depression, anxiety, and quality of life. Follow-ups were conducted at one-year and three-year after the treatment had ended.
Results: Data were analysed on an intention-to-treat basis using linear mixed-effects regression analysis. Results on the self-rated version of the Montgomery–Åsberg Depression Scale showed significant improvements in both groups across time indicating non-inferiority of guided ICBT, and there was even a tendency for the guided ICBT group to be superior to group-based CBT at three year follow-up. Within-group effect sizes for the ICBT condition at post-treatment showed a Cohen's $d=1.46$, with a similar large effect at 3-year follow-up, $d=1.78$. For the group CBT the corresponding within-group effects were $d=0.99$ and $d=1.34$, respectively.
Limitations: The study was small with two active treatments and there was no placebo or credible control condition.
Conclusions: Guided ICBT is at least as effective as group-based CBT and long-term effects can be sustained up to 3 years after treatment.

1. Introduction

Major depression is widely acknowledged as a major health problem, with adverse consequences in terms of loss of productivity and lowered quality of life (Ebmeier et al., 2006). There is a range of treatment options for the acute phase of depression (Gotlib and Hammen, 2009), including several psychological treatments that have been developed and tested in controlled trials, often with small differences between active depression-specific treatments (Cuijpers et al., 2008a; Wampold et al., 2002).

A recent development in the psychological treatment of depression is to deliver the treatment over the internet (Andersson, 2009). Over the last decade, several controlled trials have been published on internet delivered cognitive behaviour therapy (ICBT), and reviews of the literature suggest that therapist-guided ICBT for depression can be as effective as face-to-face CBT (Andersson and Cuijpers, 2009; Johansson and Andersson, 2012). However, in order to fully establish that guided ICBT is as effective as face-to-face delivered treatment direct comparative trials are needed. In the field of anxiety disorders there are direct comparative trials, for example on panic disorder (Bergström et al., 2010; Kiropoulos et al., 2008), and social anxiety disorder (Hedman et al., 2011a), in which equivalent outcomes have been found. To our knowledge, there is only one published controlled trial in the field of depression that focused on subthreshold depression in older adults (Spek et al.,

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2007). Interestingly, that study did not find any differences between ICBT and group CBT. Another important aspect of depression treatments in general – and indeed also applicable in the case of ICBT – is how well effects are sustained over time. Again, there are studies on the long term effects of guided ICBT for anxiety disorders (Hedman et al., 2011b), and also for depression (Andersson et al., 2013), showing that effects are sustained up to 3.5 years following treatment completion. However, a serious concern is that none of the long-term follow-up studies have been controlled. One reason for the small number of trials with long-term follow-up, is that the most common research design is to include a waiting list control group that is, for ethical reasons, treated after a waiting period.

Given the lack of direct comparative studies on guided ICBT versus face-to-face CBT that have included a long-term follow-up, we decided to conduct a non-inferiority trial with two arms. We used group-based CBT as comparison condition, which is a treatment format that is frequently used and found to be equally effective as individual CBT (Cuijpers et al., 2008b), but probably more cost-effective given the saved therapist time. Outcome data were collected at pre- and post-treatment, and at 1-year, and 3-year follow-up. In addition, weekly ratings were collected during the treatment period. We expected the two treatments to be similar (non-inferior), and analyzed the data using linear mixed-effects regression.

2. Method

2.1. Design and procedure

The study was set up as a randomized controlled non-inferiority trial with two arms. Randomization was conducted by an independent person who was not otherwise involved in the research project, using an online true random-number service (www.random.org).

We recruited participants by means of newspaper articles in regional papers, posters at the University campus, local health care facilities, and information on various web pages. Thus participants had to reside in the region of Östergötland county, Sweden, or close to the region, as they had to be able to come to group sessions. A web page was created that included an outline of the study, information about CBT in general, a short presentation of the people involved in the study, and the possibility to sign up for the study. Signing up for the study also required completion of four computerized questionnaires: Beck Depression Inventory (BDI-1) (Beck et al., 1961), Montgomery Åsberg Depression Rating Scale-Self Rated version (MADRS-S) (Svanborg and Åsberg, 1994), Beck Anxiety Inventory (BAI) (Beck et al., 1988), and the Quality of Life Inventory (QOLI) (Frisch et al., 1992). We also included other questions concerning demographic variables, prior treatments, medication, and expectations about the treatment. Participants who fulfilled the initial inclusion criteria according to a computerized screening were called to a live meeting where they were interviewed using the Structured Clinical Interview for DSM-IV—Axis I disorders, clinical version (SCID-I-CV) (First et al., 1997a). We also included the questions from SCID-II relating to avoidant, dependent, and obsessive compulsive personality disorder (First et al., 1997b).

Criteria for inclusion were (a) being at least 18 years, (b) a total between 15 and 35 points on MADRS-S, (c) <4 on Item 9 (suicidal thoughts) on MADRS-S, (d) no medication for depression or unchanged dosage of medication for depression during the last month, (e) not participating in other treatment for depression at the time, (f) not having other primary disorder that needed different treatment or that could be affected negatively by the treatment, and (g) being diagnosed with major depression with or without dysthymia according to DSM-IV in the clinical interview.

We aimed for 120 participants in order to obtain reliable estimates of within-group effects for the two treatments, but ended up with fewer participants with a total *N* of 69 (see Section 3).

2.2. Measures

All participants were evaluated before therapy, immediately following treatment, at one-year, and three-year follow up. All questionnaires were administered through the Internet, which yields reliable psychometric properties (Holländare et al., 2010). The MADRS-S (Svanborg and Åsberg, 1994) was used as the main outcome measure of depression at the different assessment points. In addition, the BDI (Beck et al., 1961) was used as a secondary depression measure. The BAI (Beck et al., 1988) was used as a measure of general anxiety, and the Quality of Life Inventory (QOLI; Frisch et al., 1992) to measure of life quality.

Three interview measures were administered. In addition to the SCID-I, an estimation of the degree of global improvement for each participant was done using the Clinical Global Impression Improvement (CGI-I) scale (Guy, 1976). Functioning at the time of the first interview was compared to functioning at the second interview using a seven-grade scale: very much improved, moderately improved, and minimally improved, no change, minimal deterioration, moderately deteriorated, and very much deteriorated. SCID-I was administered at pre-treatment, post-treatment, and at 3-years follow up. CGI-I was used at post-treatment and at six-month follow up. At follow-up (i.e., 1- and 3-year), the SCID-I and CGI-I were done through telephone. We also administered the 18-item Hamilton Rating Scale for Depression, HDRS (Hamilton, 1967) at pre-treatment and post-treatment, but did not include that measure in the follow-up interviews.

2.3. Interventions

2.3.1. ICBT

The self-help treatment was based on a programme used in earlier studies (Andersson et al., 2005; Johansson et al., 2012; Vernmark et al., 2010), and consisted of seven text modules (e.g., chapters) totalling 114 pages, including exercises. The material consisted of an introduction to CBT, depression from a CBT-perspective with a behavioural focus (Martell et al., 2001), behavioural activation, cognitive restructuring (Beck et al., 1979), sleep management (Morin, 1996), defining goals/values (Wilson and Murrell, 2004), and relapse prevention (Gortner et al., 1998). The reading level of the text was approximately eight grade (ages 12–14). The treatment was guided by an identified internet-therapist and patients were instructed to submit homework assignments each Sunday after which they received personalized feedback within 24 h. All contact with the patients was handled via a secure online contact management system resembling internet banking. Four students at their last term of the clinical psychology program (five year M.Sc.) were therapist in the ICBT condition. They were supervised by a licensed experienced therapist. Three of the students were also therapists in the group treatment.

2.3.2. Group-based face-to-face CBT

The group treatment was set up to follow the same treatment components as the ICBT manual. A manual for the group treatment was prepared which included guidelines on what to cover in psychoeducation, review of homework, in session exercises, and scheduling of the group sessions. There were eight group sessions, each lasting 2 h including a 15 min break. Three treatment groups were set up and there were two therapists for each group, with one experienced licensed clinical psychologist and one student