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Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There are, however, to our knowledge no controlled trial on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• This smartphone format works well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

Setting

Open trial at a university psychological center in Sweden.

Participants

40 participants diagnosed with major depressive disorder received a behavioral activation

treatment, and 41 participants received a mindfulness treatment

9 participants were lost to the post-treatment.

Intervention

Behavioral activation: A 8 week long behavior program administered via a smartphone application. Mindfulness: A 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The primary outcome measures were the Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants (BA n=40; Mindfulness n=41) were randomized (mean age 36.0 years (SD=10.8)). All were included in the intention to treat analysis. Within-group effects from pre-measurement to post-measurement on BDI-II were *d*=1.83 CI [0.27-3.38] and *d*=1.21 CI [-0.95-3.38] for the behavioral activation treatment and mindfulness treatment respectively. From pre-measurement to 6-month follow-up, effects were *d*=1.19 CI [-0.87-3.24] and *d*=1.09 CI [-1.32-3.50] respectively.

Conclusions

The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups, indicate that this smartphone format works well for a depressed population.

Trial registration

Clinical Trials NCT01463020.

Funding

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Background

Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for the individual and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation has an established empirical base [4]. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. In addition, a series of reviews and meta-analyses also show that

behavioral activation is at least as effective as the full CBT packages that include both cognitive and behavioral components [4]. In a later study, behavioral activation was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach out to more patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy [11]. There are, however, to our knowledge no controlled trial on internet-delivered pure behavioral activation, and no study using smartphones for the delivery of behavioral activation, even if studies are being conducted on smartphone-administered CBT [12].

An important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [13]. Therefore, behavioral activation is a treatment that could benefit from the use of new mobile technologies (for example smartphones) by creating direct incentives for behavioral activation in patient's everyday life.

The same applies for mindfulness. Mindfulness is often a component in the so called third wave of CBT, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18]. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression as both the primary diagnosis and the secondary. Moreover, mindfulness has been shown to be effective in relapse prevention in depression [20]. Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based internet treatments, but there have so far been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [21].

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey [13]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [13]. Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

At the same time, research suggests that depression severity is known to be a significant moderating factor in the treatment of depression. For example, some initial evidence suggests that there is a difference in efficacy between two forms of CBT in the treatment of the more severely depressed patients [7 22]. There are also indications that the difference between

antidepressant medication and placebo is evident in severe depression, but not in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [22]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. (2006) found that among more severely depressed patients, behavioral activation was comparable to antidepressant medication, and significantly outperformed cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed.

The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. The study was based on our previous work on guided internet-treatment for depression [24], but in the current study the treatment content was delivered entirely via the participants personal smartphone, using recently developed smartphone applications. We expected, in line with Dimidjian and coworkers' conclusions (BA relative to CT d=0.87 on BDI), that behavioral activation would be superior to mindfulness for participants suffering from more severe depression with an expected between group effect size of Cohen´s d=0.50). In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems and h) major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). The interviews were made over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers. Questions regarding medication and psychiatric history that came up in the interview were considered before the decision on inclusion was made.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening. Of these, 29 were excluded before the telephone interview started. 13 individuals were excluded after the telephone interview. Eighty-four were subsequently included after the interview had been conducted. Before the study started, three participants chose not to participate in the study. The reasons for exclusion are specified in the flowchart found in Figure 1.

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data. There were no significant differences in demographic characteristics between the groups according to chi-square analysis.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [25]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [26 27]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase.

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [28]), the Quality of Life Inventory (QOLI; [29 30]), the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; [31]) and the Acceptance and Action Questionnaire (AAQ-II; [32]) were administered. All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the treatment started.

Clinician-administered measures. Psychiatric diagnoses were assessed using the Mini-International Neuropsychiatric Interview (M.I.N.I.; [33]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [33]. All interviews were conducted by the four psychology students described above, who at post-treatment were blind to participant's condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Credibility. The credibility of the two treatments showed a mean score of 31.9 (*SD*=7.1) for the behavioral activation group and at 32.1 (*SD*=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].

Procedure and design

For those participants included in the study, the results from the online screening were used as pre-treatment assessment. All measures used have been shown to have good psychometric properties, with internal consistencies of at least α=.79. Details of this can be found in the respective references of the outcome questionnaires. The outcome measures used have established good psychometric properties, also when administered via the internet [35 36].

After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based behavioral activation intervention with minimal therapist contact was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for behavioral activation. The text was written specially for the current intervention, but inspired by Martell et al. [37] and Lejuez, Hopko & Hopko [38]. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone and a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [39]. This prototype, however, was not specifically designed for depression interventions. The purpose of the behavioral activation application was to make it easy for the participant to remember and register important behaviors, in order to increase everyday activation. The application contained a database of 54 behaviors, divided into three different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application to start tracking. Through the initial psychoeducation, the participants were guided to add few (between two and four) and easy behaviors from start, mainly from the database.

When a behavior was completed, the participant could mark this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service

(SMS). The messaging system was used by the therapists to send personal encouraging messages every other, or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, which means that the participants were not able to reply the messages.

Apart from this, the participants were told to write a reflection to summarize every week for their therapist and send it in via e-mail, in the end of every treatment week. The participants received personal feedback on their reflection from their therapist.

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the behavioral activation intervention, except that the theoretical basis of mindfulness was presented instead of the theoretical basis of behavioral activation. The text was written specially for the current intervention, but inspired by [40]. In all, there were three chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in short (three minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were guided to start with short mindfulness exercises.

Since the mindfulness application did not have a communication system such as the behavioral activation application, e-mails were used to emulate the messaging system in the behavioral activation application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail.

Additionally, the participants given the mindfulness intervention were also told to write a reflection to summarize every week for their therapist. The participants received personal feedback on their reflection from their therapist.

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of internship. Each therapist was responsible for the treatment or 8 to 10 participants from the behavioral activation group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received

continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a behavioral activation treatment manual.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-offs scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants, not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in clinical significant improvement. Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9, where weekly measures were available, the continuous outcome variable was analyzed using mixed effects models, given their ability to handle missing data [41]. Random intercept models were selected. Also, several models were compared using available information criteria, and the model with best fit was chosen. The covariance between the random intercept and slope was not significant, and therefore was not included in the model. Error terms across time were modeled with a first-order autoregressive covariance structure with heterogeneous variances. Differences in average rates of growth between the two groups were examined by a fixed effects interaction between group and time. Between-group differences at post-treatment were analyzed using independent t-tests. Power analysis indicated an 89% chance of detecting a between-group effect size of d=0.60 (α level=0.05). Within- and between-group effect sizes (Cohen's d) were calculated by dividing the differences in means by the pooled standard deviations [42].

Results

The two groups did not differ significantly on any of the measures at pretreatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). The results will be presented in the following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, three participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved. In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once again, those unreachable were classified as unimproved.

Adherence to treatment was defined as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the eight weeks. Of these, 25 (63 %) were in the behavioral activation group and 32 (78 %) were in the mindfulness group. In average, participants succeeded to adhere to six weeks (*M*=5.8, *SD*=2.47).

Primary outcome measure

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow up. However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the behavioral activation treatment and the mindfulness-treatment.

Subgroup analyses

A mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the behavioral activation group. Thus, the results indicated a difference between the groups from pre-treatment to 6-month follow-up ($F(1, 362.1)=5.2$, p's<.05). As seen in Table 3, the effect size between the groups at 6-month follow-up was small, but close to medium (Cohen's d=0.47; CI [-1.46, 2.40]).

For the more mildly depressed participants there was a significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on PHQ-9 ($F(1, 69.3)=7.7$, p's<.01). The effect size between the groups at 6-month follow-up was, as evident from Table 3, large (Cohen's d=0.96)

Secondary outcome measure

As evident from Table 3 no significant interaction effects were found on the secondary measures neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow up. Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample, 73.5 % (n=25) in the behavioral activation group recovered after treatment, compared to 53.1 % (n=17) in the mindfulness group (χ^2(N=66, df=1)=2.97, p=.071). At the 6-month follow-up, 30 out of 34 participants (88.2 %)

from the behavioral activation group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, *df*=1)=.63, *p*=.327.

When analyzing only the severe depressed participants, there was a tendency in favor for the behavioral activation group. Among the severely depressed participants, 73.9 % (*n*=17) in the behavioral activation group recovered after treatment, compared to 50.0 % (*n*=14) in the mindfulness group (χ^2(N=51, *df*=1)=3.03, *p*=.072). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the behavioral activation group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, *df*=1)=1.55, *p*=.197).

Credibility and therapist time

An independent t-test showed no significant difference between the two groups on the C-scale (*t* (78)=0.12, *p*=0.90). Furthermore, the C-scale did not correlate significantly with any of the outcome measures, either for all participants combined (*r*=0.13, *p*=0.27), for the behavioral activation group (*r*=0.01, *p*=0.92) or for the mindfulness group (*r* =. 23, *p* = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participants. However, the therapist time did not differ between the two treatment groups.

Discussion

The overall aim of this study was to investigate the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on behavioral activation and the other on mindfulness. When analyzing the whole sample as one entity, the result showed that the two interventions were effective for treating depression with large within-group effect sizes and large recovery rates, but that they did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity, the treatment based on mindfulness worked better than the treatment based on behavioral activation.

The result from the analysis of the higher severity participants is in line with earlier [7] findings. For example, Dimidjian et al (2006) showed that behavioral activation was comparable in

efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. In line with this, Beck and colleagues [43] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen.

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed [44 45], mindfulness has proven to be effective for relapse prevention of depression [20 46 47]. That gives implications that a mindfulness-based treatment administered through smartphone will work better for people suffering from mild depression. However, the fact that the mindfulness-based treatment worked significantly better than the behavioral activation-treatment was surprising to us. One explanation could be that the less severely depressed participants suffered more from stress and anxiety rather than depression. This population would then not be in need of a treatment that encourages more activation. Instead, a mindfulness treatment could work very well for this kind of problems [19 48].

Limitations

There are a number of limitations that need to be mentioned. The first and is that it is impossible to determine which parts of the treatments were effective. Since we did not control for the different components separately, we cannot, for example, rule out that the result was mainly an effect of the therapist support. An additional treatment arm with only therapist support would make it possible to rule out this question.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II at intake (M=24.10) is rather close to the limit of 29 proposed for defining severe depression [25].

Fourth, we recruited a broad range of participants, with regards to the severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded to the behavioral activation significantly better that the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation for the participants with lower initial. Additionally, it can be argued that these broad inclusion criteria reflect a real population of individuals with depressive disorders.

A fifth related concern was the large number of participants who had college- or university level education (65.5 %). This might bias generalizability of the results, since it is possible that guided self-help is especially well suited for educated clients. However, there are data indicating that 50

% of patients seeking psychotherapy have some college education [49] and that educated patients may be more inclined to seek help for mental health problems [50].

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as behavioral activation and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups, indicate that this smartphone format with a small amount of text and minimal therapist support, works well for a depressed population.

Moreover, this study also shows that behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results strengthen the hypothesis that different treatments distributed digitally can target different subgroups of depression, in terms of severity.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted as well as relatively cheap for the functionalities you get [13], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate depression can be treated effectively by means of a supported smartphone-application, might be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life. As suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of being in treatment in everyday settings, and therefore better help clients create direct incentives for treatment related activities in their everyday life [39]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [13], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not only relevant for Swedish conditions but also for the developing countries in the world, which increasingly are empowered by mobile phones with internet connection.

This study might open up for a broad range of other trials conducted via smartphones, both for self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the behavioral activation application is currently developed for the open market by KHL.

Author's contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

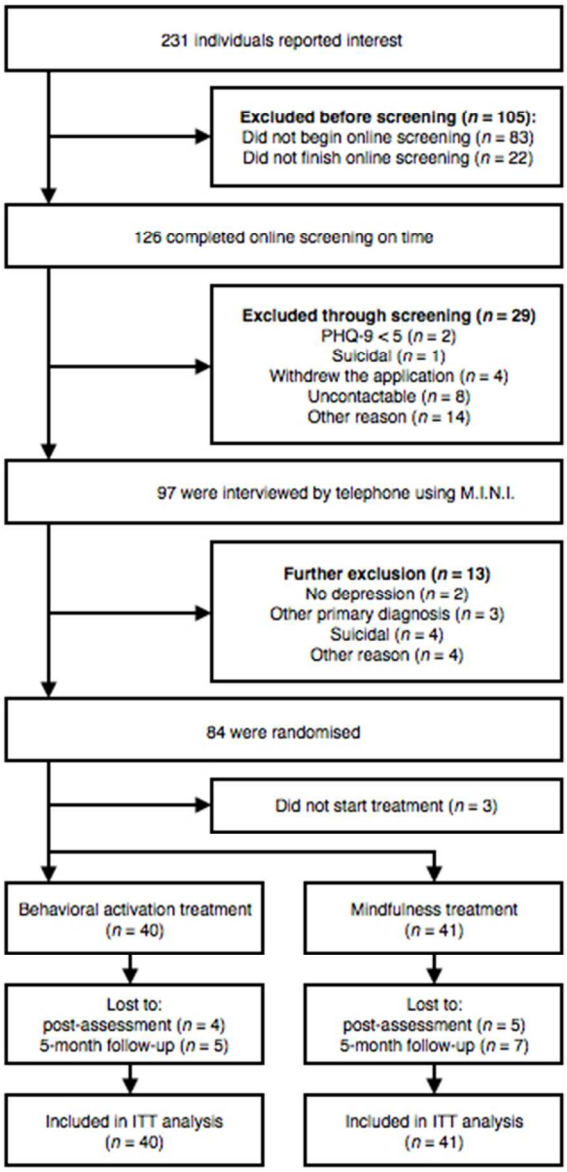
Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.

	Mean (*SD*)			Effect size, *d* (95% CI)			
Outcome measure	**Pre-treatment**	**Post-treatment**	**6-month follow-up**	**Between-group, pre-post**	**Between-group, pre-6FU**	**Within-group, pre-post**	**Within-group, pre-6FU**
Total							
BDI-II							
Behavioral activation	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25 (-1.65-2.15)	0.03 (-2.63-2.69)	1.83 (0.27-3.38)	1.19 (-0.87-3.24)
Mindfulness	24.68 (9.47)	12.94 (10.18)	13.09 (12.24)			1.21 (-0.95-3.38)	1.09 (-1.32-3.50)
PHQ-9							
Behavioral activation	12.53 (4.43)	5.83 (3.85)	6.77 (5.83)	0.28 (-0.85-1.40)	0.15 (-1.39-1.69)	1.63 (0.71-2.56)	1.14 (-0.01-2.28)
Mindfulness	13.22 (4.81)	7.19 (5.84)	7.74 (7.33)			1.15 (-0.02-2.32)	0.91 (-0.44-2.27)
BAI							
Behavioral activation	14.60 (9.09)	8.81 (5.77)	8.34 (8.50)	0.06 (-1.49-1.61)	0.01 (-1.86-1.87)	0.76 (-0.95-2.47)	0.72 (-1.25-2.69)
Mindfulness	13.51 (9.31)	9.22 (7.68)	8.38 (7.48)			0.51 (-1.39-2.40)	0.61 (-1.30-2.51)
AAQ-II							
Behavioral activation	27.28 (7.05)	21.22 (8.24)	20.09 (9.28)	0.22 (-1.97-2.41)	0.10 (-2.10-2.31)	0.80 (-0.89-2.50)	0.89 (-0.93-2.72)
Mindfulness	28.22 (7.09)	23.32 (10.82)	21.03 (9.68)			0.56 (-1.44-2.54)	0.87 (-1.00-2.74)
QoLI							
Behavioral activation	-0.45 (1.38)	0.92 (1.66)	1.15 (2.40)	0.05 (-0.36-0.45)	0.01 (-0.53-0.51)	0.91 (0.58-1.25) 0.62 (0.24-0.99)	0.84 (0.41-1.27)
Mindfulness	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)				0.75 (0.36-1.15)
High level depression							
BDI-II							
Behavioral activation	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42 (-2.09-2.93)	0.39 (-2.95-3.73)	2.25 (0.33-4.18)	1.72 (-0.87-4.31)
Mindfulness	28.00 (8.61)	15.68 (10.76)	16.28 (12.71)			1.62 (-0.44-3.67)	1.32 (-1.07-3.71)
PHQ-9							
Behavioral activation	15.52 (3.29)	6.64 (4.42)	6.48 (5.59)	0.36 (-1.17-1.90)	0.47 (-1.46-2.40)	2.34 (1.23-3.45)	2.04 (0.73-3.35)
Mindfulness	15.57 (3.35)	8.60 (6.29)	9.60 (7.71)			1.43 (0.13-2.74)	1.05 (-0.49-2.58)
BAI							
Behavioral activation	17.43 (9.37)	9.18 (6.68)	9.62 (8.91)	0.20 (-1.94-2.34)	0.01 (-2.36-2.38)	1.03 (-1.30-3.37)	0.87 (-1.77-3.52)
Mindfulness	15.57 (9.39)	10.68 (8.39)	9.72 (7.91)			0.56 (-1.80-2.92)	0.68 (-1.62-2.99)
AAQ-II							
Behavioral activation	28.27 (7.21)	21.68 (8.90)	19.33 (9.27)	0.44 (-2.30-3.18)	0.47 (-2.16-3.09)	0.83 (-1.47-3.14)	1.11 (-1.28-3.49)
Mindfulness	29.04 (6.50)	25.87 (10.52)	23.56 (9.33)			0.38 (-1.90-2.65)	0.70 (-1.40-2.80)
QoLI							
Behavioral activation	-0.51 (1.30)	0.78 (1.58)	1.25 (2.07)	0.26 (-0.70-0.18)	0.34 (-0.95-0.27)	0.91 (0.50-1.33)	1.05 (0.56-1.55)
Mindfulness	-0.71 (1.18)	0.38 (1.58)	0.53 (2.23)			0.80 (0.44-1.17)	0.72 (0.26-1.18)
Low level depression							
BDI-II							
Behavioral activation	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51 (-2.36-1.34)	-1.18 (-4.59-2.23)	1.74 (-0.25-3.72)	0.58 (-2.36-3.52)
Mindfulness	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)			1.83 (-0.54-4.19)	2.35 (-0.03-4.72)
PHQ-9							
Behavioral activation	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23 (-1.20-0.74)	-0.97 (-2.94-1.03)	2.06 (1.39-2.72)	0.30 (-1.21-1.80)
Mindfulness	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)			1.38 (0.19-2.59)	2.13 (1.03-3.23)
BAI							
Behavioral activation	10.76 (7.33)	8.21 (4.10)	6.43 (7.80)	-0.56 (-2.17-1.04)	-0.27 (-2.92-2.38)	0.43 (-1.64-2.51)	0.59 (-1.98-3.16)
Mindfulness	9.08 (7.70)	5.91 (4.48)	4.67 (4.64)			0.51 (-1.95-2.98)	0.67 (-1.95-3.34)
AAQ-II							

Behavioral activation	26.00 (6.85)	20.50 (7.34)	21.21 (9.54)	-0.37 (-3.52-2.78)	-0.87 (-4.26-2.52)	0.80 (-1.61-3.21)	0.61 (-2.17-3.39)
Mindfulness	26.46 (8.21)	17.52 (9.54)	14.00 (7.07)			1.06 (-2.33-4.44)	1.68 (-1.42-4.78)
QoLI							
Behavioral activation	-0.37 (1.52)	1.14 (1.83)	0.97 (2.15)	-0.38 (-0.38-1.14)	-0.93 (-1.77--0.10)	0.94 (0.37-1.50)	0.76 (0.13-1.38)
Mindfulness	0.89 (1.61)	1.87 (2.24)	2.87 (2.10)			0.53 (-0.20-1.27)	1.14 (0.41-1.87)

Abbreviations: BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.



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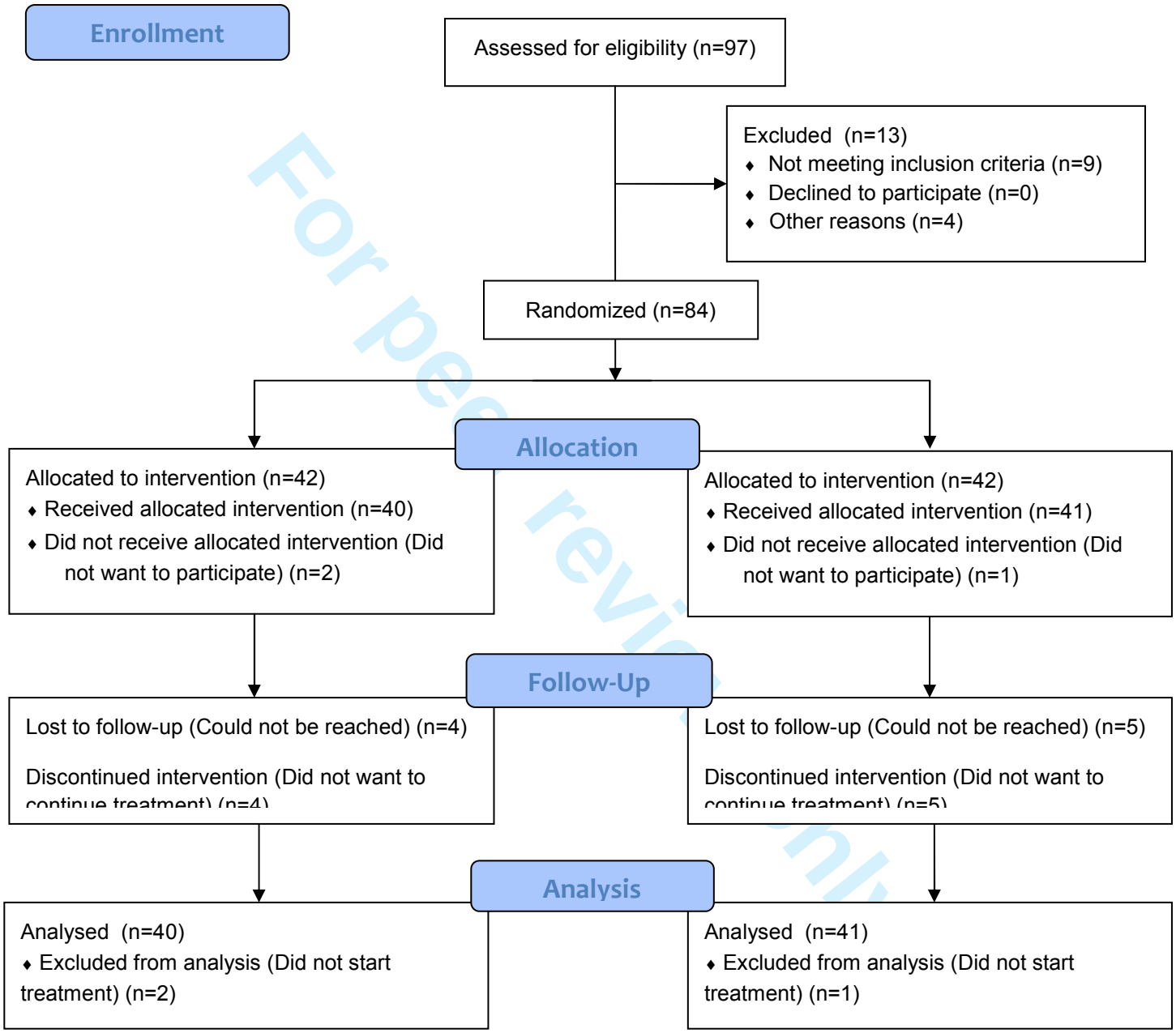
CONSORT 2010 Flow Diagram



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6

	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	14
Protocol	24	Where the full trial protocol can be accessed, if available	14
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There are, however, to our knowledge no controlled trials on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• The large within-group effect sizes are comparable to other depression treatment and indicate that this smartphone format might work well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool, handled by an independent person who was separate from the staff conducting the study.

Setting

General community, with recruitment nationally through mass media and advertisements.

Participants

40 participants diagnosed with major depressive disorder received a behavioral activation treatment, and 41 participants received a mindfulness treatment

9 participants were lost at the post-treatment.

Intervention

Behavioral activation: An 8 week long behavior program administered via a smartphone application. Mindfulness: An 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The primary outcome measures were the Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants (BA n=40; Mindfulness n=41) were randomized (mean age 36.0 years (SD=10.8)) and analyzed. Results showed large within-group effect sizes on the BDI-II for the behavioral activation treatment and mindfulness treatment respectively from pre-treatment to the 6-month follow up (d=1.19 and d=1.09), but no significant interaction effects of group and time on any of the outcome measures from pre-treatment to the 6-month follow up. Subgroup analyses showed that the behavioral activation treatment was more effective than the mindfulness treatment among participants with higher initial severity of depression, measured with the PHQ-9. In contrast, the mindfulness treatment worked better than the behavioral activation treatment among participants with lower initial severity.

Conclusions

For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness. For participants with lower initial severity, the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation.

Trial registration

Clinical Trials NCT01463020.

Funding

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Background

Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for the individual and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation has an established empirical base [4]. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. In addition, a series of reviews and meta-analyses also show that behavioral activation is at least as effective as the full CBT packages that include both cognitive and behavioral components [4]. In a later study, behavioral activation was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach out to more patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy [11]. There are, however, to our knowledge no controlled trial on internet-delivered pure behavioral activation, and no study using smartphones for the delivery of behavioral activation, even if studies are being conducted on smartphone-administered CBT [12].

An important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [13]. Therefore, behavioral activation is a treatment that could benefit from the use of new mobile technologies (for example smartphones) by creating direct incentives for behavioral activation in patient's everyday life.

The same applies for mindfulness. Mindfulness is often a component in the so called third wave of CBT, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18]. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression as both the primary diagnosis and the secondary. Moreover, mindfulness has been shown to be effective in relapse prevention in depression [20]. Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based internet treatments, but there have so far been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [21].

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey [13]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [13]. Both behavioral activation and mindfulness are components in multi-component treatment

packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

At the same time, research suggests that depression severity is known to be a significant moderating factor in the treatment of depression. For example, some initial evidence suggests that there is a difference in efficacy between different forms of CBT in the treatment of the more severely depressed patients [7 22]. There are also indications that the difference between antidepressant medication and placebo is evident in severe depression, but not in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [22]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. (2006) found that among more severely depressed patients, behavioral activation was comparable to antidepressant medication, and significantly outperformed cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed.

The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. Hence, the main question is whether behavioral activation is more effective than mindfulness delivered over smartphone. The study was based on our previous work on guided internet-treatment for depression [24], but in the current study the treatment content was delivered entirely via the participants personal smartphone, using recently developed smartphone applications. We expected, in line with Dimidjian and coworkers' conclusions (BA relative to CT d=0.87 on BDI), that behavioral activation would be superior to mindfulness for participants suffering from more severe depression with an expected between group effect size of Cohen´s d=0.50). In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe

comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems, h) no assessed risk of being suicidal (see below for details) and i) major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). Additionally, an assessment of suicidal ideation was conducted. The interviews were made over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers. Questions regarding medication and psychiatric history that came up in the interview were considered before the decision on inclusion was made.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening (22 did not finish the screening and 83 did not begin the screening). Of these, 29 were excluded before the diagnostic interview started. 13 individuals were excluded after the diagnostic interview. Eighty-four were subsequently included after the interview had been conducted. Before the study started, three participants chose not to participate in the study. The reasons for exclusion are specified in the flowchart found in Figure 1.

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data. There were no significant differences in demographic characteristics between the groups according to chi-square analysis.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [25]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [26 27]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10 measurements on the outcome PHQ-9.

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [28]), the Quality of Life Inventory (QOLI; [29 30]), the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; [31]) and the Acceptance and Action Questionnaire (AAQ-II; [32]) were administered. The AAQ-II was administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the treatment started. Hence, there were two measurements on the outcome TIC-P, three measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II.

Clinician-administered measures. Psychiatric diagnoses were assessed at pre-treatment, post-treatment and at 6-month after the start of the treatment, using the Mini-International

Neuropsychiatric Interview (M.I.N.I.; [33]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [33]. All interviews were conducted by the four psychology students described above, who at post-treatment were blind to participant's condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Treatment credibility. To measure treatment credibility, Borkovec and Nau's Credibility/expectancy scale (C-Scale)[34] was used. The C-scale measures the way in which participants view the logic of the treatment (credibility) and the improvements that can be achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after the first week of treatment.

Procedure and design

For those participants included in the study, the results from the online screening were used as pre-treatment assessment. All measures used have been shown to have good psychometric properties, with internal consistencies of at least α=.79. Details of this can be found in the respective references of the outcome questionnaires. The outcome measures used have established good psychometric properties, also when administered via the internet [35 36].

After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based behavioral activation intervention with minimal therapist contact was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for behavioral activation. The text was written specially for the current intervention, but inspired by Martell et al. [37] and Lejuez, Hopko & Hopko [38]. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone and a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [39]. This prototype, however, was not specifically designed for depression interventions. The purpose of the behavioral activation application was to make it easy for the participant to remember and register important behaviors,

in order to increase everyday activation. The application contained a database of 54 behaviors, divided into three different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application to start tracking. Through the initial psychoeducation, the participants were guided to add few (between two and four) and easy behaviors from start, mainly from the database.

When a behavior was completed, the participant could mark this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service (SMS). The messaging system was used by the therapists to send personal encouraging messages every other, or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, which means that the participants were not able to reply the messages.

Apart from this, the participants were told to write a reflection to summarize every week for their therapist and send it in via e-mail, in the end of every treatment week. The participants received personal feedback on their reflection from their therapist. No sensitive data was saved on a computer, in which the person providing data could be identified. In addition, all internet and smartphone activities was secured, with encrypted information.

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the behavioral activation intervention, except that the theoretical basis of mindfulness was presented instead of the theoretical basis of behavioral activation. The text was written specially for the current intervention, but inspired by Williams et al. [40]. In all, there were three chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in short (three minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were guided to start with short mindfulness exercises.

Since the mindfulness application did not have a communication system such as the behavioral activation application, e-mails were used to emulate the messaging system in the behavioral activation application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail. The difference in how the therapists communicated in the mindfulness intervention, compared with the behavioral activation intervention, was that the therapists could not give specific feedback on activities or exercises that the participants had done. Otherwise, the communication was similar (length and type of content).

Additionally, the participants given the mindfulness intervention were also told to write a reflection to summarize every week for their therapist and send it in via e-mail. The participants received personal feedback on their reflection from their therapist.

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of internship. Each therapist was responsible for the treatment or 8 to 10 participants from the behavioral activation group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a behavioral activation treatment manual.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-offs scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants, not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in recovery rates. In order to adhere to the intention-to-treat principle, the continuous outcome variables (expect from TIC-P, that was not analyzed as part of this study) were analyzed using mixed effects models, given their ability to handle missing data [41]. All analyses used Maximum Likelihood estimation. Random intercept models were selected for all measures. Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II, where weekly measures were available, the covariance between the random intercept and slope was not significant, and therefore was not included in the model. Hence, a random intercept model was used also for these measures. Between-group differences at post-treatment were

analyzed using independent *t*-tests. Power analysis indicated an 89 % chance of detecting a between-group effect size of d=0.60 (α level=0.05). Within- and between-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard deviations [42]. This was done both from pre-measurements to post-measurements, and from pre-measurements to the 6-month follow up data.

Results

The two groups did not differ significantly on any of the measures at pretreatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). The results will be presented in the following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, three participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved. In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once again, those unreachable were classified as unimproved.

Adherence to treatment was defined as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the eight weeks. Of these, 25 (63 %) were in the behavioral activation group and 32 (78 %) were in the mindfulness group. In average, participants succeeded to adhere to six weeks (M=5.8, SD=2.47).

Primary outcome measure

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment (PHQ-9: (F(1, 501.47)=.28, p's=.60); BDI-II: (F(1, 74.11)=.28, p's=.60)), nor from pre-treatment to the 6-month follow up (PHQ-9: (F(1, 571.49)=.36, p's=.55); BDI-II: (F(1, 147.96)=.09, p's=.77)). However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the behavioral activation treatment and the mindfulness-treatment.

Subgroup analyses

For the participants suffering from high severity of depression (≥10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate character), a mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the behavioral activation group. Thus, the results indicated a difference between the groups from

pre-treatment to 6-month follow-up (F(1, 362.1)=5.2, p's<.05). As seen in Table 3, the effect size between the groups at 6-month follow-up was small, but close to medium (Cohen's d=0.47; CI [-1.46, 2.40]).

For the more mildly depressed participants there was a significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on both the PHQ-9 (F(1, 69.3)=7.7, p's<.01) and the BDI-II (F(1, 53.60)=6.25, p's<.05). The effect sizes were, as evident from Table 3, large (PHQ-9: Cohen's d=0.98; CI [-0.72, 2.68]; BDI-II: Cohen's d=1.21; CI [-1.71, 4.13]).

Secondary outcome measure

As evident from Table 3 no significant interaction effects were found on the secondary measures neither from pre-treatment to post-treatment (BAI: (F(1, 74.05)=1.30, p's=.26); AAQ-II: (F(1, 570.00)=.07, p's=.79); QOLI: (F(1, 76.43)=.1.06, p's=.31)), nor from pre-treatment to the 6-month follow up (BAI: (F(1, 147.01)=.35, p's=.56); AAQ-II: (F(1, 639.00)=.11, p's=.74); QOLI: (F(1, 148.61)=.39, p's=.53)). Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample, 73.5 % (n=25) in the behavioral activation group recovered after treatment, compared to 53.1 % (n=17) in the mindfulness group (χ^2(N=66, df=1)=2.97, p=.07). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from the behavioral activation group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, df=1)=.63, p=.33.

When analyzing only the severe depressed participants, there was a tendency in favor for the behavioral activation group. Among the severely depressed participants, 73.9 % (n=17) in the behavioral activation group recovered after treatment, compared to 50.0 % (n=14) in the mindfulness group (χ^2(N=51, df=1)=3.03, p=.07). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the behavioral activation group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, df=1)=1.55, p=.20).

Treatment credibility and therapist time

The credibility of the two treatments showed a mean score of 31.9 (SD=7.1) for the behavioral activation group and at 32.1 (SD=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].

An independent t-test showed no significant difference between the two groups on the C-scale (t (78)=0.12, p=0.90). Furthermore, the C-scale did not correlate significantly with any of the outcome measures, either for all participants combined (r=0.13, p=0.27), for the behavioral activation group (r=0.01, p=0.92) or for the mindfulness group (r =. 23, p = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participants. However, the therapist time did not differ between the two treatment groups.

Discussion

The overall aim of this study was to investigate the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on behavioral activation and the other on mindfulness. Hence, the main question was whether behavioral activation is more effective than mindfulness delivered over smartphone. When analyzing the whole sample as one entity, the result showed that the two interventions did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity, the treatment based on mindfulness worked better than the treatment based on behavioral activation, as measured with PHQ-9 and BDI-II.

The result from the analysis of the higher severity participants is in line with earlier [7] findings. For example, Dimidjian et al (2006) showed that behavioral activation was comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. In line with this, Beck and colleagues [43] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen.

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed [44 45], mindfulness has proven to be effective for relapse prevention of depression [20 46 47]. That gives implications that a mindfulness-based treatment administered through smartphone will work better for people suffering from mild depression. However, the

fact that the mindfulness-based treatment worked significantly better than the behavioral activation-treatment was surprising to us. One explanation could be that the less severely depressed participants suffered more from stress and anxiety rather than depression. This population would then not be in need of a treatment that encourages more activation. Instead, a mindfulness treatment could work very well for this kind of problems [19 48].

Moreover, the results showed that the two interventions were effective for treating depression with large within-group effect sizes and large recovery rates, which are comparable to other depression treatment. This indicates that this smartphone format might work well for a depressed population.

Limitations

There are a number of limitations that need to be mentioned. The first is that no wait list group was included. However, our main research question was to assess whether behavioral activation is more effective than mindfulness delivered over smartphone. Hence, we wanted to isolate all other components, such as the therapist support and the psychoeducation, and only investigate the two smartphone applications.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects. We were not expecting that the mindfulness treatment would be as effective and powered the trial as if a moderate between-group effect would be found.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II at intake (M=24.10) is rather close to the limit of 29 proposed for defining severe depression [25].

Fourth, we recruited a broad range of participants, with regards to the severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded to the behavioral activation significantly better that the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation for the participants with lower initial. Additionally, it can be argued that these broad inclusion criteria reflect a real population of individuals with depressive disorders.

A fifth related concern was the large number of participants who had college- or university level education (65.5 %). This might bias generalizability of the results, since it is possible that guided self-help is especially well suited for educated clients. However, there are data indicating that 50 % of patients seeking psychotherapy have some college education [49] and that educated patients may be more inclined to seek help for mental health problems [50].

Conclusion

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as behavioral activation and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups are comparable to other depression treatments, and indicate that this smartphone format with a small amount of text and minimal therapist support, might work well for a depressed population.

Moreover, this study also shows that behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results strengthen the hypothesis that different treatments distributed digitally can target different subgroups of depression, in terms of severity.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted as well as relatively cheap for the functionalities you get [13], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate depression can be treated effectively by means of a supported smartphone-application, might be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life. As suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of being in treatment in everyday settings, and therefore better help clients create direct incentives for treatment related activities in their everyday life [39]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [13], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not only relevant for Swedish conditions but also for the developing countries in the world, which increasingly are empowered by mobile phones with internet connection.

This study might open up for a broad range of other trials conducted via smartphones, both for self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the behavioral activation application is currently developed for the open market by KHL.

Author's contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.

	Mean (*SD*)		Effect size, *d* (95% CI)	

Outcome measure	Pre-treatment	Post-treatment	6-month follow-up	Between-group, pre-post	Between-group, pre-6FU	Within-group, pre-post	Within-group, pre-6FU
Total							
BDI-II							
BA	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25	0.03	1.83 (0.27-3.38)	1.19 (-0.87-3.24)
MF	24.68 (9.47)	12.94 (10.18)	13.09 (12.24)	(-1.65-2.15)	(-2.63-2.69)	1.21 (-0.95-3.38)	1.09 (-1.32-3.50)
PHQ-9							
BA	12.53 (4.43)	5.83 (3.85)	6.77 (5.83)	0.28	0.15	1.63 (0.71-2.56)	1.14 (-0.01-2.28)
MF	13.22 (4.81)	7.19 (5.84)	7.74 (7.33)	(-0.85-1.40)	(-1.39-1.69)	1.15 (-0.02-2.32)	0.91 (-0.44-2.27)
BAI							
BA	14.60 (9.09)	8.81 (5.77)	8.34 (8.50)	0.06	0.01	0.76 (-0.95-2.47)	0.72 (-1.25-2.69)
MF	13.51 (9.31)	9.22 (7.68)	8.38 (7.48)	(-1.49-1.61)	(-1.86-1.87)	0.51 (-1.39-2.40)	0.61 (-1.30-2.51)
AAQ-II							
BA	27.28 (7.05)	21.22 (8.24)	20.09 (9.28)	0.22	0.10	0.80 (-0.89-2.50)	0.89 (-0.93-2.72)
MF	28.22 (7.09)	23.32 (10.82)	21.03 (9.68)	(-1.97-2.41)	(-2.10-2.31)	0.56 (-1.44-2.54)	0.87 (-1.00-2.74)
QoLI							
BA	-0.45 (1.38)	0.92 (1.66)	1.15 (2.40)	0.05	0.01	0.91 (0.58-1.25)	0.84 (0.41-1.27)
MF	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)	(-0.36-0.45)	(-0.53-0.51)	0.62 (0.24-0.99)	0.75 (0.36-1.15)
H-LDep							
BDI-II							
BA	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42	0.39	2.25 (0.33-4.18)	1.72 (-0.87-4.31)
MF	28.00 (8.61)	15.68 (10.76)	16.28 (12.71)	(-2.09-2.93)	(-2.95-3.73)	1.62 (-0.44-3.67)	1.32 (-1.07-3.71)
PHQ-9							
BA	15.52 (3.29)	6.64 (4.42)	6.48 (5.59)	0.36	0.47	2.34 (1.23-3.45)	2.04 (0.73-3.35)
MF	15.57 (3.35)	8.60 (6.29)	9.60 (7.71)	(-1.17-1.90)	(-1.46-2.40)	1.43 (0.13-2.74)	1.05 (-0.49-2.58)
BAI							
BA	17.43 (9.37)	9.18 (6.68)	9.62 (8.91)	0.20	0.01	1.03 (-1.30-3.37)	0.87 (-1.77-3.52)
MF	15.57 (9.39)	10.68 (8.39)	9.72 (7.91)	(-1.94-2.34)	(-2.36-2.38)	0.56 (-1.80-2.92)	0.68 (-1.62-2.99)
AAQ-II							
BA	28.27 (7.21)	21.68 (8.90)	19.33 (9.27)	0.44	0.47	0.83 (-1.47-3.14)	1.11 (-1.28-3.49)
MF	29.04 (6.50)	25.87 (10.52)	23.56 (9.33)	(-2.30-3.18)	(-2.16-3.09)	0.38 (-1.90-2.65)	0.70 (-1.40-2.80)
QoLI							
BA	-0.51 (1.30)	0.78 (1.58)	1.25 (2.07)	0.26	0.34	0.91 (0.50-1.33)	1.05 (0.56-1.55)
MF	-0.71 (1.18)	0.38 (1.58)	0.53 (2.23)	(-0.70-0.18)	(-0.95-0.27)	0.80 (0.44-1.17)	0.72 (0.26-1.18)
L-L Dep							
BDI-II							
BA	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51	-1.21	1.74 (-0.25-3.72)	0.58 (-2.36-3.52)
MF	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)	(-2.36-1.34)	(-4.13-1.71)	1.83 (-0.54-4.19)	2.35 (-0.03-4.72)
PHQ-9							
BA	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23	-0.98	2.06 (1.39-2.72)	0.30 (-1.21-1.80)
MF	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)	(-1.20-0.74)	(-2.68-0.72)	1.38 (0.19-2.59)	2.13 (1.03-3.23)
BAI							
BA	10.76 (7.33)	8.21 (4.10)	6.43 (7.80)	-0.56	-0.27	0.43 (-1.64-2.51)	0.59 (-1.98-3.16)
MF	9.08 (7.70)	5.91 (4.48)	4.67 (4.64)	(-2.17-1.04)	(-2.92-2.38)	0.51 (-1.95-2.98)	0.67 (-1.95-3.34)
AAQ-II							
BA	26.00 (6.85)	20.50 (7.34)	21.21 (9.54)	-0.37	-0.87	0.80 (-1.61-3.21)	0.61 (-2.17-3.39)
MF	26.46 (8.21)	17.52 (9.54)	14.00 (7.07)	(-3.52-2.78)	(-4.26-2.52)	1.06 (-2.33-4.44)	1.68 (-1.42-4.78)
QoLI							
BA	-0.37 (1.52)	1.14 (1.83)	0.97 (2.15)	-0.38	-0.93	0.94 (0.37-1.50)	0.76 (0.13-1.38)
MF	0.89 (1.61)	1.87 (2.24)	2.87 (2.10)	(-0.38-1.14)	(-1.77-0.10)	0.53 (-0.20-1.27)	1.14 (0.41-1.87)

Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep: Low-level depression; BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There ~~are, however, to our knowledge no controlled trial~~<u>are, however, to our knowledge no controlled trials</u> on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment

program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• ~~This~~ The large within-group effect sizes are comparable to other depression treatment and indicate that this smartphone format might work~~s~~ well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool ~~(www.random.org)~~, handled by an independent person who was separate from the staff conducting the study.

Setting

~~Open trial at a university psychological center in Sweden.~~ General community, with recruitment nationally through mass media and advertisements.

Participants

40 participants diagnosed with major depressive disorder received a behavioral activation treatment, and 41 participants received a mindfulness treatment

9 participants were lost ~~to~~ at the post-treatment.

Intervention

Behavioral activation: An 8 week long behavior program administered via a smartphone application. Mindfulness: An 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The primary outcome measures were the Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants (BA n=40; Mindfulness n=41) were randomized (mean age 36.0 years (SD=10.8)) and ~~. All were included in the intention to treat analysis~~analyzed. Results showed large within-group effect sizes on the BDI-II for the behavioral activation treatment and mindfulness treatment respectively from pre-treatment to the 6-month follow up (*d*=1.19 and *d*=1.09), but no significant interaction effects of group and time on any of the outcome measures from pre-treatment to the 6-month follow up. Subgroup analyses showed that the behavioral activation treatment was more effective than the mindfulness treatment among participants with higher initial severity of depression, measured with the PHQ-9. In contrast, the mindfulness treatment worked better than the behavioral activation treatment among participants with lower initial severity. ~~Within-group effects from pre-measurement to post-measurement on BDI-II were *d*=1.83 CI [0.27-3.38] and *d*=1.21 CI [-0.95-3.38] for the behavioral activation treatment and mindfulness treatment respectively. From pre-measurement to 6-month follow-up, effects were *d*=1.19 CI [-0.87-3.24] and *d*=1.09 CI [-1.32-3.50] respectively.~~

Conclusions

For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness. For participants with lower initial severity, the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation.

~~The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups, indicate that this smartphone format works well for a depressed population.~~

Trial registration

Clinical Trials NCT01463020.

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Background

Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for the individual and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation has an established empirical base [4]. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. In addition, a series of reviews and meta-analyses also show that behavioral activation is at least as effective as the full CBT packages that include both cognitive and behavioral components [4]. In a later study, behavioral activation was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach out to more patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy [11]. There are, however, to our knowledge no controlled trial on internet-delivered pure behavioral activation, and no study using smartphones for the delivery of behavioral activation, even if studies are being conducted on smartphone-administered CBT [12].

An important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [13]. Therefore, behavioral activation is a treatment that could benefit from the use of new mobile technologies (for example smartphones) by creating direct incentives for behavioral activation in patient's everyday life.

The same applies for mindfulness. Mindfulness is often a component in the so called third wave of CBT, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18]. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression as both the primary diagnosis and the secondary. Moreover, mindfulness has been shown to be effective in relapse prevention in depression [20]. Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based internet treatments, but there have so far been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [21].

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey [13]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [13]. Both behavioral activation and mindfulness are components in multi-component treatment

packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

At the same time, research suggests that depression severity is known to be a significant moderating factor in the treatment of depression. For example, some initial evidence suggests that there is a difference in efficacy between ~~two~~ different forms of CBT in the treatment of the more severely depressed patients [7 22]. There are also indications that the difference between antidepressant medication and placebo is evident in severe depression, but not in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [22]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. (2006) found that among more severely depressed patients, behavioral activation was comparable to antidepressant medication, and significantly outperformed cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed.

The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. Hence, the main question is whether behavioral activation is more effective than mindfulness delivered over smartphone. The study was based on our previous work on guided internet-treatment for depression [24], but in the current study the treatment content was delivered entirely via the participants personal smartphone, using recently developed smartphone applications. We expected, in line with Dimidjian and coworkers' conclusions (BA relative to CT d=0.87 on BDI), that behavioral activation would be superior to mindfulness for participants suffering from more severe depression with an expected between group effect size of Cohen´s d=0.50). In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe

comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems, h) no assessed risk of being suicidal (see below for details) and ih) major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). Additionally, an assessment of suicidal ideation was conducted. The interviews were made over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers. Questions regarding medication and psychiatric history that came up in the interview were considered before the decision on inclusion was made.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening (22 did not finish the screening and 83 did not begin the screening). Of these, 29 were excluded before the diagnostic interview ~~telephone interview~~ started. 13 individuals were excluded after the diagnostic interview~~telephone interview~~. Eighty-four were subsequently included after the interview had been conducted. Before the study started, three participants chose not to participate in the study. The reasons for exclusion are specified in the flowchart found in Figure 1.

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data. There were no significant differences in demographic characteristics between the groups according to chi-square analysis.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [25]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [26 27]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10 measurements on the outcome PHQ-9.

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [28]), the Quality of Life Inventory (QOLI; [29 30]), the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; [31]) and the Acceptance and Action Questionnaire (AAQ-II; [32]) were administered. The AAQ-II was administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the treatment started. Hence, there were two measurements on the outcome TIC-P, three measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II.

Clinician-administered measures. Psychiatric diagnoses were assessed at pre-treatment, post-

treatment and at 6-month after the start of the treatment, using the Mini-International Neuropsychiatric Interview (M.I.N.I.; [33]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [33]. All interviews were conducted by the four psychology students described above, who at post-treatment were blind to participant's condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Treatment credibility. To measure treatment credibility, Borkovec and Nau's Credibility/expectancy scale (C-Scale)[34] was used. The C-scale measures the way in which participants view the logic of the treatment (credibility) and the improvements that can be achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after the first week of treatment.

~~**Credibility.** The credibility of the two treatments showed a mean score of 31.9 (*SD*=7.1) for the behavioral activation group and at 32.1 (*SD*=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].~~

Procedure and design

For those participants included in the study, the results from the online screening were used as pre-treatment assessment. All measures used have been shown to have good psychometric properties, with internal consistencies of at least α=.79. Details of this can be found in the respective references of the outcome questionnaires. The outcome measures used have established good psychometric properties, also when administered via the internet [35 36].

After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based behavioral activation intervention with minimal therapist contact was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for behavioral activation. The text was written specially for the current intervention, but inspired by Martell et al. [37] and Lejuez, Hopko & Hopko [38]. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone and a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [39]. This prototype, however, was not specifically designed for depression interventions. The purpose of the behavioral activation application was to make it easy for the participant to remember and register important behaviors, in order to increase everyday activation. The application contained a database of 54 behaviors, divided into three different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application to start tracking. Through the initial psychoeducation, the participants were guided to add few (between two and four) and easy behaviors from start, mainly from the database.

When a behavior was completed, the participant could mark this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service (SMS). The messaging system was used by the therapists to send personal encouraging messages every other, or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, which means that the participants were not able to reply the messages.

Apart from this, the participants were told to write a reflection to summarize every week for their therapist and send it in via e-mail, in the end of every treatment week. The participants received personal feedback on their reflection from their therapist. No sensitive data was saved on a computer, in which the person providing data could be identified. In addition, all internet and smartphone activities was secured, with encrypted information.

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the behavioral activation intervention, except that the theoretical basis of mindfulness was presented instead of the theoretical basis of behavioral activation. The text was written specially for the current intervention, but inspired by Williams et al. [40]. In all, there were three chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the

current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in short (three minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were guided to start with short mindfulness exercises.

Since the mindfulness application did not have a communication system such as the behavioral activation application, e-mails were used to emulate the messaging system in the behavioral activation application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail. The difference in how the therapists communicated in the mindfulness intervention, compared with the behavioral activation intervention, was that the therapists could not give specific feedback on activities or exercises that the participants had done. Otherwise, the communication was similar (length and type of content).

Additionally, the participants given the mindfulness intervention were also told to write a reflection to summarize every week for their therapist and send it in via e-mail. The participants received personal feedback on their reflection from their therapist.

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of internship. Each therapist was responsible for the treatment or 8 to 10 participants from the behavioral activation group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a behavioral activation treatment manual.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-offs scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants, not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in recovery rates ~~clinical significant improvement~~. ~~Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time.~~ In order to adhere to the intention-to-treat principle, the continuous

outcome variables (expect from TIC-P, that was not analyzed as part of this study) were analyzed using mixed effects models, given their ability to handle missing data ~~For the PHQ-9, where weekly measures were available, the continuous outcome variable was analyzed using mixed effects models, given their ability to handle missing data~~ [41]. ~~Random intercept models were selected.~~ All analyses used Maximum Likelihood estimation. Random intercept models were selected for all measures. Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II, where weekly measures were available, ~~Also, several models were compared using available information criteria, and the model with best fit was chosen. t~~The covariance between the random intercept and slope was not significant, and therefore was not included in the model. ~~Error terms across time were modeled with a first-order autoregressive covariance structure with heterogeneous variances.~~ Hence, a random intercept model was used also for these measures. ~~Differences in average rates of growth between the two groups were examined by a fixed effects interaction between group and time.~~ Between-group differences at post-treatment were analyzed using independent *t*-tests. Power analysis indicated an 89 % chance of detecting a between-group effect size of d=0.60 (α level=0.05). Within- and between-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard deviations [42]. This was done both from pre-measurements to post-measurements, and from pre-measurements to the 6-month follow up data.

Results

The two groups did not differ significantly on any of the measures at pretreatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). The results will be presented in the following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, three participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved. In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once again, those unreachable were classified as unimproved.

Adherence to treatment was defined as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the eight weeks. Of these, 25 (63 %) were in the behavioral activation group and 32 (78 %) were in the mindfulness group. In average, participants succeeded to adhere to six weeks (M=5.8, SD=2.47).

Primary outcome measure

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment (PHQ-9: (F(1, 501.47)=.28, p's=.60); BDI-II: (F(1, 74.11)=.28, p's=.60)), nor from pre-treatment to the 6-month follow up (PHQ-9: (F(1, 571.49)=.36, p's=.55); BDI-II: (F(1, 147.96)=.09, p's=.77)). However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the behavioral activation treatment and the mindfulness-treatment.

Subgroup analyses

For the participants suffering from high severity of depression (≥10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate character), a~~A~~ mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the behavioral activation group. Thus, the results indicated a difference between the groups from pre-treatment to 6-month follow-up (F(1, 362.1)=5.2, p's<.05). As seen in Table 3, the effect size between the groups at 6-month follow-up was small, but close to medium (Cohen's d=0.47; CI [-1.46, 2.40]).

For the more mildly depressed participants there was a significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on both the PHQ-9 (F(1, 69.3)=7.7, p's<.01) and the BDI-II (F(1, 53.60)=6.25, p's<.05). The effect sizes ~~between the groups at 6-month follow-up was~~were, as evident from Table 3, large (PHQ-9: Cohen's d=0.9~~8~~6; CI [-0.72, 2.68]; BDI-II: Cohen's d=1.21; CI [-1.71, 4.13]).

Secondary outcome measure

As evident from Table 3 no significant interaction effects were found on the secondary measures neither from pre-treatment to post-treatment (BAI: (F(1, 74.05)=1.30, p's=.26); AAQ-II: (F(1, 570.00)=.07, p's=.79); QOLI: (F(1, 76.43)=.1.06, p's=.31)), nor from pre-treatment to the 6-month follow up (BAI: (F(1, 147.01)=.35, p's=.56); AAQ-II: (F(1, 639.00)=.11, p's=.74); QOLI: (F(1, 148.61)=.39, p's=.53)). Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample, 73.5 % (n=25) in the behavioral activation group recovered after treatment, compared to 53.1 % (n=17) in the mindfulness group (χ^2(N=66, df=1)=2.97, p=.07~~1~~). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from the behavioral activation group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, df=1)=.63, p=.3~~27~~.

When analyzing only the severe depressed participants, there was a tendency in favor for the behavioral activation group. Among the severely depressed participants, 73.9 % (n=17) in the behavioral activation group recovered after treatment, compared to 50.0 % (n=14) in the mindfulness group (χ^2(N=51, df=1)=3.03, p=.072). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the behavioral activation group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, df=1)=1.55, p=.201).

Treatment credibility and therapist time

The credibility of the two treatments showed a mean score of 31.9 (SD=7.1) for the behavioral activation group and at 32.1 (SD=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].

An independent t-test showed no significant difference between the two groups on the C-scale (t (78)=0.12, p=0.90). Furthermore, the C-scale did not correlate significantly with any of the outcome measures, either for all participants combined (r=0.13, p=0.27), for the behavioral activation group (r=0.01, p=0.92) or for the mindfulness group (r =. 23, p = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participants. However, the therapist time did not differ between the two treatment groups.

Discussion

The overall aim of this study was to investigate the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on behavioral activation and the other on mindfulness. Hence, the main question was whether behavioral activation is more effective than mindfulness delivered over smartphone. When analyzing the whole sample as one entity, the result showed that the two interventions ~~were effective for treating depression with large within-group effect sizes and large recovery rates, but that they~~ did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial

severity, the treatment based on mindfulness worked better than the treatment based on behavioral activation, as measured with PHQ-9 and BDI-II.

The result from the analysis of the higher severity participants is in line with earlier [7] findings. For example, Dimidjian et al (2006) showed that behavioral activation was comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. In line with this, Beck and colleagues [43] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen.

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed [44 45], mindfulness has proven to be effective for relapse prevention of depression [20 46 47]. That gives implications that a mindfulness-based treatment administered through smartphone will work better for people suffering from mild depression. However, the fact that the mindfulness-based treatment worked significantly better than the behavioral activation-treatment was surprising to us. One explanation could be that the less severely depressed participants suffered more from stress and anxiety rather than depression. This population would then not be in need of a treatment that encourages more activation. Instead, a mindfulness treatment could work very well for this kind of problems [19 48].

Moreover, the results showed that the two interventions were effective for treating depression with large within-group effect sizes and large recovery rates, which are comparable to other depression treatment. This indicates that this smartphone format might work well for a depressed population.

Limitations

There are a number of limitations that need to be mentioned. The first ~~and~~ is that ~~it is impossible to determine which parts of the treatments were effective. Since we did not control for the different components separately, we cannot, for example, rule out that the result was mainly an effect of the therapist support. An additional treatment arm with only therapist support would make it possible to rule out this question.~~ no wait list group was included. However, our main research question was to assess whether behavioral activation is more effective than mindfulness delivered over smartphone. Hence, we wanted to isolate all other components, such as the therapist support and the psychoeducation, and only investigate the two smartphone applications.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects. We were not expecting that the mindfulness treatment would be as effective and powered the trial as if a moderate between-group effect would be found.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II

at intake (*M*=24.10) is rather close to the limit of 29 proposed for defining severe depression [25].

Fourth, we recruited a broad range of participants, with regards to the severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded to the behavioral activation significantly better that the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation for the participants with lower initial. Additionally, it can be argued that these broad inclusion criteria reflect a real population of individuals with depressive disorders.

A fifth related concern was the large number of participants who had college- or university level education (65.5 %). This might bias generalizability of the results, since it is possible that guided self-help is especially well suited for educated clients. However, there are data indicating that 50 % of patients seeking psychotherapy have some college education [49] and that educated patients may be more inclined to seek help for mental health problems [50].

Conclusion

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as behavioral activation and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups are comparable to other depression treatments, and indicate that this smartphone format with a small amount of text and minimal therapist support, might work well for a depressed population.

Moreover, this study also shows that behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results strengthen the hypothesis that different treatments distributed digitally can target different subgroups of depression, in terms of severity.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted as well as relatively cheap for the functionalities you get [13], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate depression can be treated effectively by means of a supported smartphone-application, might be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life. As suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of being in treatment in everyday settings, and therefore better help clients create direct incentives for treatment related activities in their everyday life [39]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [13], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not

only relevant for Swedish conditions but also for the developing countries in the world, which increasingly are empowered by mobile phones with internet connection.

This study might open up for a broad range of other trials conducted via smartphones, both for self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the behavioral activation application is currently developed for the open market by KHL.

Author's contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

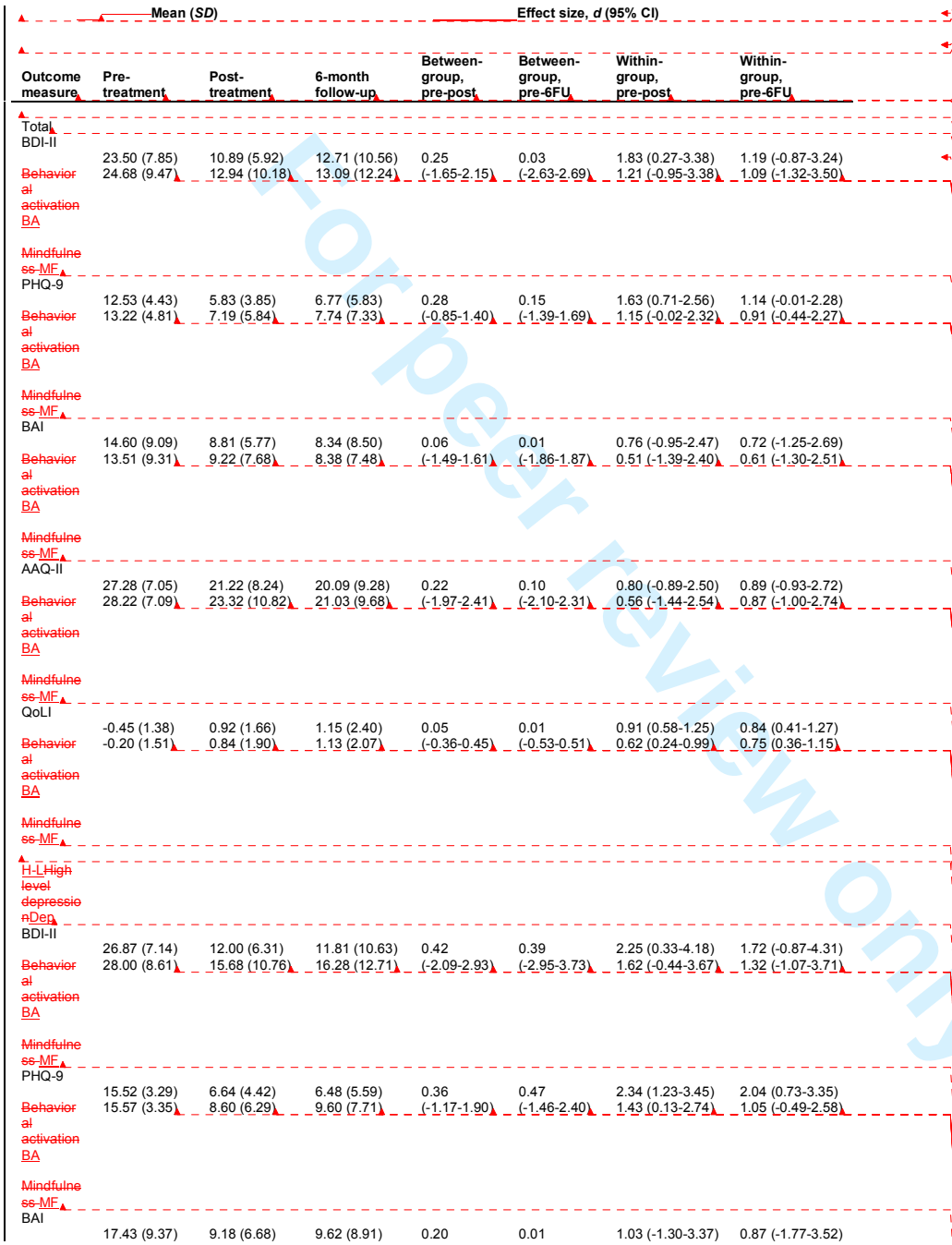
Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.



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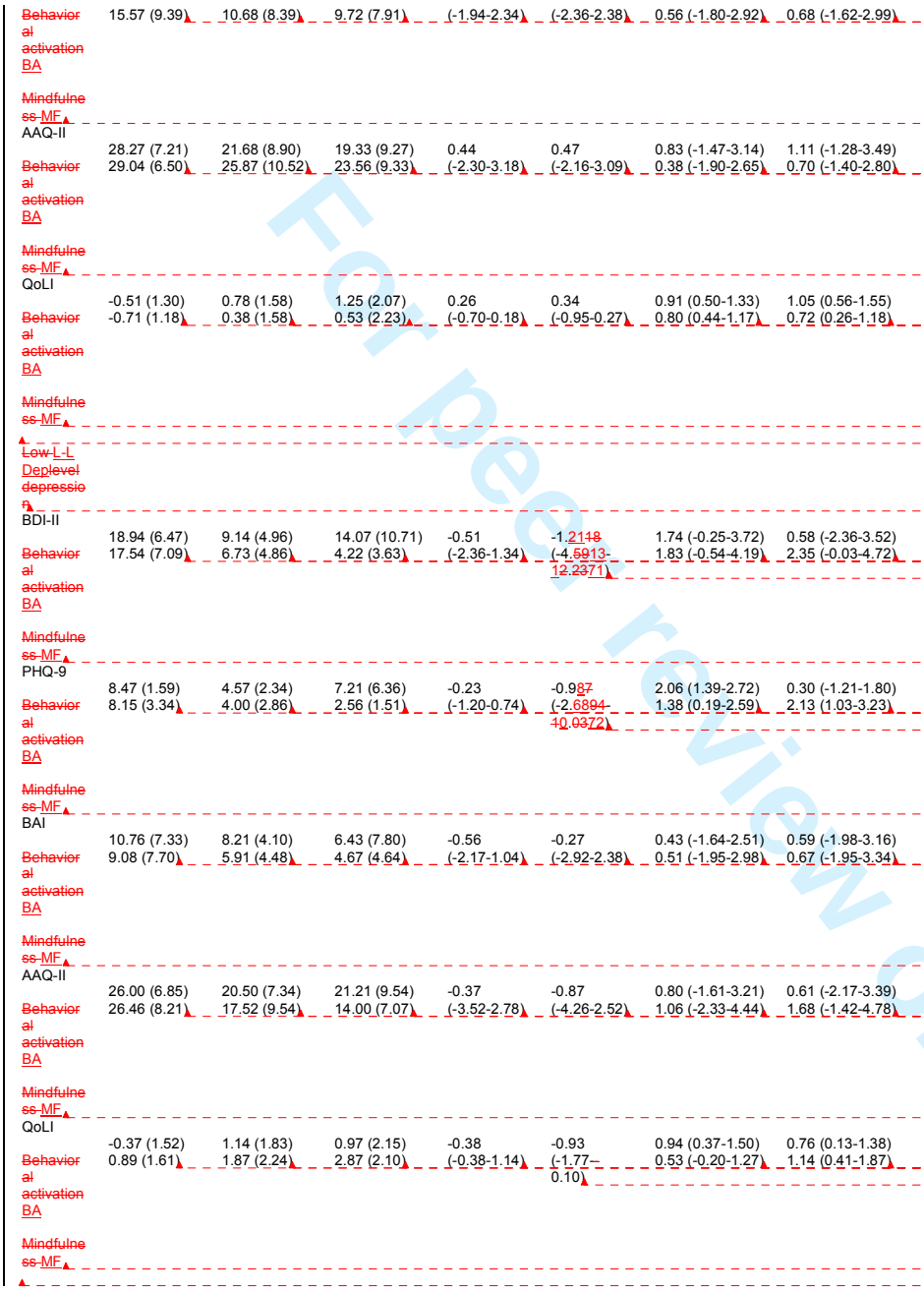

Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep:

Low-level depression; BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.

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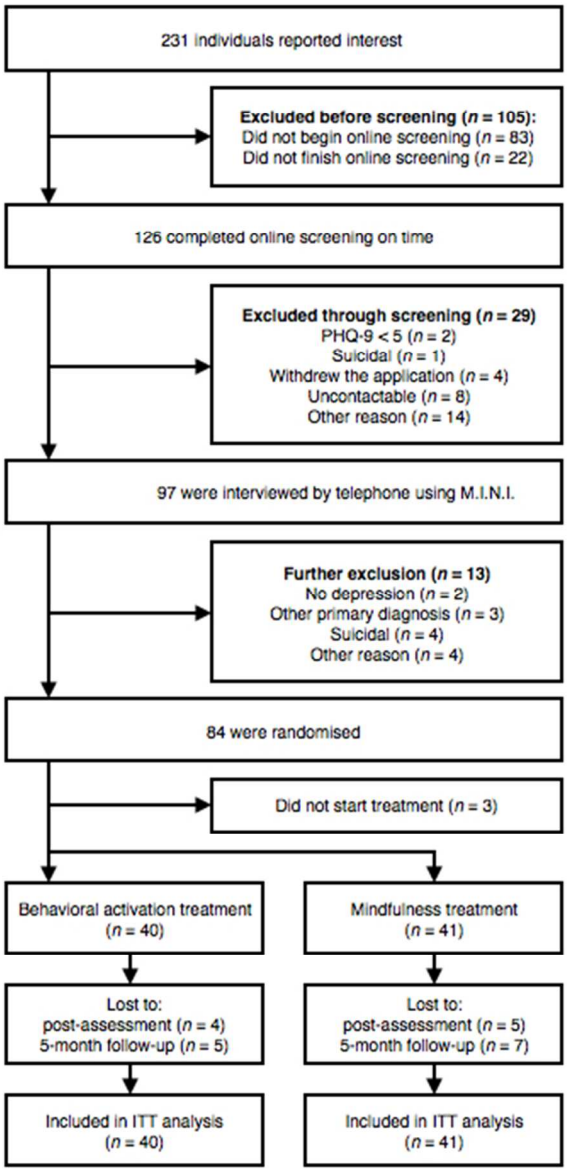

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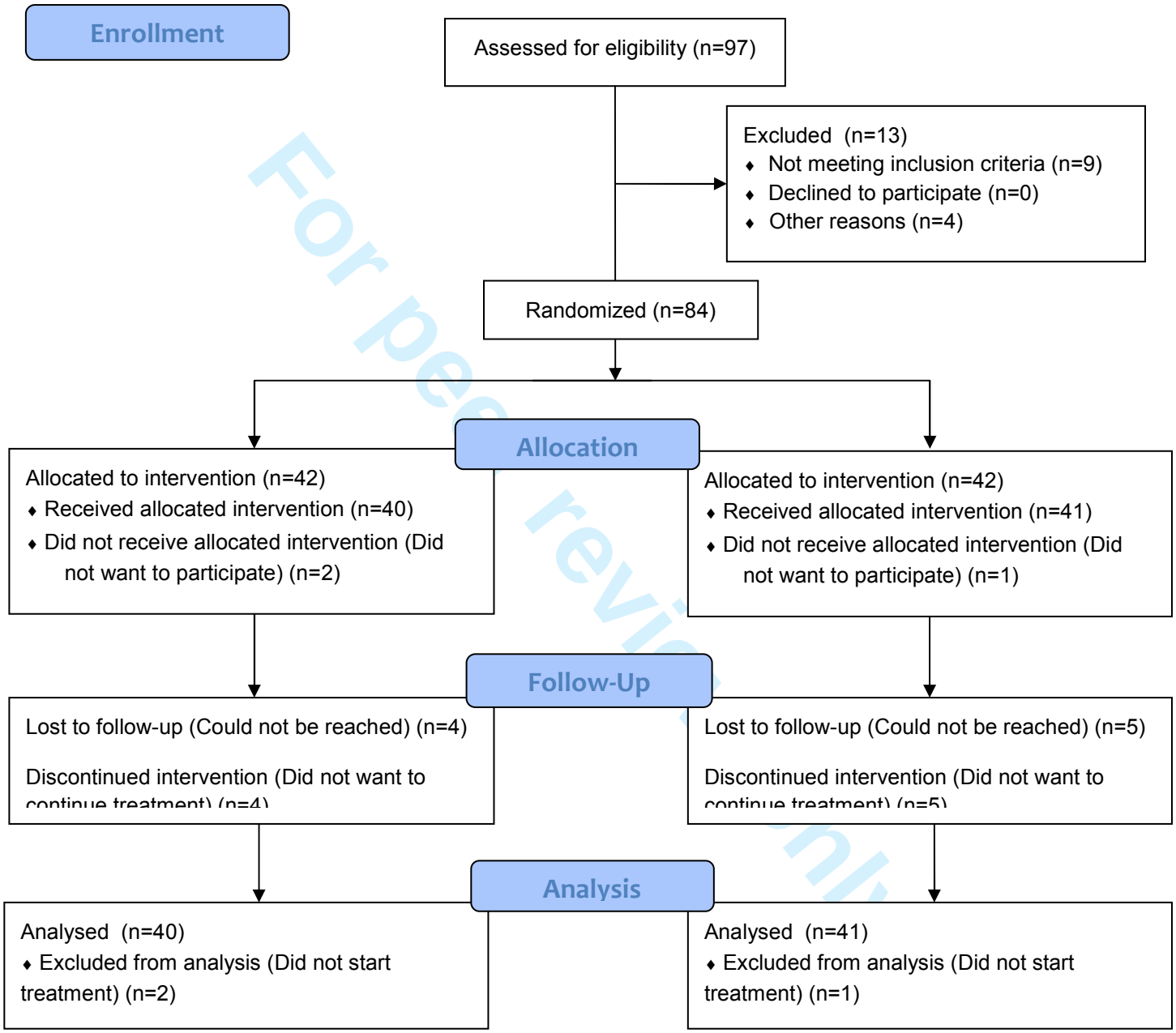
CONSORT 2010 Flow Diagram



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6

	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	14
Protocol	24	Where the full trial protocol can be accessed, if available	14
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Secondary Subject Heading:	Public health
Keywords:	Depression, Smartphone application, Behavioral activation, Mindfulness

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating and comparing the effectiveness of two smartphone-delivered treatments; one based on BA and one on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool, handled by an independent person who was separate from the staff conducting the study.

Setting

General community, with recruitment nationally through mass media and advertisements.

Participants

40 participants diagnosed with major depressive disorder received a BA treatment, and 41 participants received a mindfulness treatment. 9 participants were lost at the post-treatment.

Intervention

BA: An 8 week long behavior program administered via a smartphone application. Mindfulness: An 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants were randomized (mean age 36.0 years (SD=10.8)) and analyzed. Results showed no significant interaction effects of group and time on any of the outcome measures neither from pre-treatment to post-treatment nor from pre-treatment to the 6-month follow up. Subgroup analyses showed that the BA treatment was more effective than the mindfulness treatment among participants with higher initial severity of depression from pre-treatment to the 6-month follow up (PHQ-9: $F(1, 362.1)=5.2$, p's<.05). In contrast, the mindfulness treatment worked better than the BA treatment among participants with lower initial severity from pre-treatment to the 6-month follow up (PHQ-9: $F(1, 69.3)=7.7$, p's<.01); BDI-II: ($F(1, 53.60)=6.25$, p's<.05).

Conclusions

The two interventions did not differ significantly from one another. For participants with higher severity of depression, the treatment based on BA was superior to the treatment based on mindfulness. For participants with lower initial severity, the treatment based on mindfulness worked significantly better than the treatment based on BA.

Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There are, however, to our knowledge no controlled trials on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• The large within-group effect sizes are comparable to other depression treatment and indicate that this smartphone format might work well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Background

Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for the individual and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation (BA) has an established empirical base [4]. BA is an established psychological treatment derived from learning theory. It is aimed at increasing adequate behaviors and learning about links between behavior and mood. The efficacy of BA for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that BA could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. Moreover, in a later randomized controlled trial, BA was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach out to more patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy, but with similar clinical outcome [11]. There are, however, to our knowledge no controlled trial on internet-delivered pure BA, and no study using smartphones for the delivery of BA, even if studies are being conducted on smartphone-administered CBT [12], for example in the treatment of MDD [13].

Mindfulness is likewise BA, often used as a component in multi-component treatment packages, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18], meaning that more mindfulness practice is associated with lower levels of depression. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression both as primary and secondary diagnosis. Moreover, mindfulness has been shown to be effective in relapse prevention in depression with an overall risk ratio mean of 0.66 (95% CI [0.53, 0.82], p's<.01) [20], as well as for comorbid disorders such as anxiety [21]. Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based internet treatments, but there have so far been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [22].

Research suggests that depression severity is known to be a significant moderating factor in the treatment of depression. There are also indications that the difference between antidepressant medication and placebo is evident in severe depression, but not in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [24]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. (2006) found that among more severely depressed patients, behavioral activation was as effective as antidepressant medication, and significantly outperformed

cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed. However, in meta-analyses on BA versus cognitive therapy this has not been found [24].

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey [25]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [25]. Both BA and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program. Another important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [25]. Therefore, BA is a treatment that could benefit from the use of new mobile technologies (for example smartphones), even more than mindfulness, by creating direct incentives for BA in patient's everyday life.

In this study, we hypothesized that BA treatment delivered over smartphone would be more effective than mindfulness treatment delivered over smartphone with an expected between group effect size of Cohen´s *d*=0.50. We also expected, in line with Dimidjian and coworkers' conclusions, that BA would be superior to mindfulness for participants suffering from more severe depression. The study was based on our previous work on guided internet-treatment for depression [26], but in the current study the treatment content was delivered entirely via the participants' personal smartphone, using recently developed smartphone applications. The aim of this study was to test the effects of two smartphone-delivered treatments; one based on BA and the other on mindfulness. Hence, the main question is whether BA is more effective than mindfulness delivered over smartphone. In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or

schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems, h) no assessed risk of being suicidal (see below for details) and i) major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). Additionally, an assessment of suicidal ideation was conducted. The interviews were made over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening (22 did not finish the screening and 83 did not begin the screening). Of these, 29 were excluded before the diagnostic interview started. The most common reason for exclusion was an ongoing psychological treatment. Other reasons for exclusion were wrong type of phone and score under 5 on the PHQ-9. 13 individuals were excluded after the diagnostic interview with the most common reason that the participants were judged to be in need of another kind of treatment. Eighty-four were subsequently included after the interview had been conducted. Before the study started, three participants chose not to participate in the study. Hence, 81 participants were finally included in the data analysis. The reasons for exclusion are specified in the flowchart found in Figure 1.

[Insert Figure 1 about here]

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [27]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [28 29]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10 measurements on the outcome PHQ-9 (including pre-treatment, post-treatment and six months follow up).

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [30]), the Quality of Life Inventory (QOLI; [31 32]) and the Acceptance and Action Questionnaire (AAQ-II; [33]) were administered. The AAQ-II was administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment. Hence, there were three measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II (including pre-treatment, post-treatment and six months follow up). All outcome measures used have been shown to have good psychometric properties, with internal consistencies of at least

α=.79. Details of this can be found in the respective references of the outcome questionnaires.

Clinician-administered measures. Psychiatric diagnoses were assessed at pre-treatment, post-treatment and at 6-month after the start of the treatment, using the Mini-International Neuropsychiatric Interview (M.I.N.I.; [34]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [34]. All interviews were made over telephone by the four psychology students described above, who at post-treatment were blind to participant's condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Treatment credibility. To measure participants' perceived treatment credibility, Borkovec and Nau's Credibility/expectancy scale (C-Scale)[35] was used. The C-scale measures the way in which participants view the logic of the treatment (credibility) and the improvements that can be achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after the first week of treatment.

Administration format of self-report measures

We used an online platform to administer the BDI-II, PHQ-9, BAI, QOLI, AAQ-II and the C-scale. Previous psychometric research has validated internet-administration of self-rating scales for depression, quality of life and anxiety [36-38].

Procedure and design

For those participants included in the study, the results from the online screening were used as pre-treatment assessment. After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based BA intervention with minimal therapist contact (maximum time of 20 minutes per participant and week) was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for BA. The text in the web-based psychoeducation was written specially for the current intervention, but inspired by the BA treatment manuals of Martell et al. [39] and Lejuez, Hopko & Hopko [40]. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone, meaning that the application was coded in a specific programming language (Objective C), and a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [41]. This prototype, however, was not specifically designed for depression interventions. The purpose of the BA application was to make it easy for the participant to remember and register important behaviors, in order to increase everyday activation. The application contained a database of 54 behaviors, divided into three different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application to start tracking. Through the initial psychoeducation, the participants were guided to add few (between two and four) and easy behaviors from start, mainly from the database.

When a behavior was completed, for example: *Get ready in the morning*, the participant could register this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service (SMS). The messaging system was used by the therapists (described below) to send personal encouraging messages every other or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, meaning that the participants were not able to reply the messages. The participants were also told to write a reflection to summarize every week for their therapist and send it in via e-mail in the end of every treatment week. The participants received personal feedback on their reflection from their therapist via e-mail. No sensitive data was saved on a computer, in which the person providing data could be identified. In addition, all internet and smartphone activities were secured, with SSL-encrypted information.

[Insert Figure 2 about here]

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact (maximum time of 20 minutes per participant and week), consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the BA intervention, except that the theoretical basis of mindfulness was presented instead of the theoretical basis of BA. The text was written specially for the current intervention, but inspired by the self help book *The Mindful Way Through Depression* by Williams et al. [42]. In all, there were three chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in short (three minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were guided to start with short mindfulness exercises, such as guided three minutes mindfulness exercise, which was one of the audio tracks in the application.

Since the mindfulness application did not have a communication function such as the BA application, e-mails were used to emulate the messaging system in the BA application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail. The difference in how the therapists communicated in the mindfulness intervention, compared with the BA intervention, was that the therapists could not give specific feedback on activities or exercises that the participants had done. Otherwise, the communication was similar (length and type of guided content in the feedback). Additionally, the participants given the mindfulness intervention were also told to write a reflection to summarize every week for their therapist and send it in via e-mail. The participants received personal feedback on their reflection from their therapist.

[Insert Figure 3 about here]

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of internship. Each therapist was responsible for the treatment or 8 to 10 participants from the BA group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a BA treatment manual, as well as mindfulness in depression treatment.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-offs scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants, not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent *t*-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in recovery rates. In order to adhere to the intention-to-treat principle, the continuous outcome variables were analyzed using mixed effects models, given their ability to handle missing data [43]. All analyses used Maximum Likelihood estimation. Random intercept models were selected for all measures. Differences between the BA treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II, where weekly measures were available, the covariance between the random intercept and slope was not significant, and therefore was not included in the model. Hence, a random intercept model was used also for these measures. Between-group differences at post-treatment were analyzed using independent *t*-tests. Power analysis indicated an 89 % chance of detecting a between-group effect size of d=0.60 (α level=0.05, one tailed). Within- and between-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard deviations [44]. This was done both from pre-measurements to post-measurements, and from pre-measurements to the 6-month follow up data.

Results

The two groups did not differ significantly on any of the measures at pre-treatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). See Table 3 for all outcome measurements at pre-treatment, post-treatment and at 6-month follow-up. Also, there was no significant difference in demographic characteristics between the groups according to chi-square analysis. See Table 1 for demographical data. The results will be presented in the following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, three participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data with a distribution of four participants from the BA group and five participants from the mindfulness group. Six out of the 81 participants (totaling 7.4 %) were unreachable for the M.I.N.I. telephone interview and were classified as unimproved in the data analysis. In the 6-month follow-up, 69 participants from the two treatment groups (totaling 85.2 %) provided data on the self-report measures, with a distribution of 35 participants from the BA group and 34 participants from the mindfulness group. 59 participants (72.8 %) were reached for the M.I.N.I. telephone interview. Once again, those unreachable were classified as unimproved in the data analysis.

Adherence to treatment was defined as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the eight weeks. Of these, 25 (63 %) were in the BA group and 32 (78 %) were in the mindfulness group. No significant difference in adherence was found between the two groups (χ^2(N=81, df=1)=2.35, p=1.00). In average, participants succeeded to adhere to six weeks

(*M*=5.8, *SD*=2.47).

Primary outcome measures

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment (PHQ-9: (F(1, 501.47)=.28, p's=.60); BDI-II: (F(1, 74.11)=.28, p's=.60)), nor from pre-treatment to the 6-month follow up (PHQ-9: (F(1, 571.49)=.36, p's=.55); BDI-II: (F(1, 147.96)=.09, p's=.77)). However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the BA treatment and the mindfulness-treatment.

Subgroup analyses

For the participants (total *n*=51, BA *n*=23, MF *n*=28) suffering from high severity of depression (≥10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate character), a mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the BA group from pre-treatment to 6-month follow-up, but not on pre-treatment to post-treatment. Thus, the results indicated a difference between the groups from pre-treatment to 6-month follow-up (F(1, 362.1)=5.2, p's<.05). As seen in Table 3, the effect size between the groups at 6-month follow-up was small (Cohen's d=0.47; CI [-1.46, 2.40]). No difference between the groups from pre-treatment to post-treatment was found

For the more mildly depressed participants (total *n*=30, BA *n*=17, MF *n*=13) there was a significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on both the PHQ-9 (F(1, 69.3)=7.7, p's<.01) and the BDI-II (F(1, 53.60)=6.25, p's<.05). The effect sizes were, as evident from Table 3, large (PHQ-9: Cohen's d=0.98; CI [-0.72, 2.68]; BDI-II: Cohen's d=1.21; CI [-1.71, 4.13]). No difference between the groups from pre-treatment to post-treatment was found

Secondary outcome measures

As evident from Table 3 no significant interaction effects were found on the secondary measures neither from pre-treatment to post-treatment (BAI: (F(1, 74.05)=1.30, p's=.26); AAQ-II: (F(1, 570.00)=.07, p's=.79); QOLI: (F(1, 76.43)=.1.06, p's=.31)), nor from pre-treatment to the 6-month follow up (BAI: (F(1, 147.01)=.35, p's=.56); AAQ-II: (F(1, 639.00)=.11, p's=.74); QOLI: (F(1, 148.61)=.39, p's=.53)). Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample (*n*=81), 73.5 % (*n*=25) in the BA

group recovered after treatment, compared to 53.1 % (*n*=17) in the mindfulness group (χ^2(N=66, *df*=1)=2.97, *p*=.07). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from the BA group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, *df*=1)=.63, *p*=.33.

When analyzing only the severe depressed participants, there was a tendency in favor for the BA group. Among the severely depressed participants, 73.9 % (*n*=17) in the BA group recovered after treatment, compared to 50.0 % (*n*=14) in the mindfulness group (χ^2(N=51, *df*=1)=3.03, *p*=.07). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the BA group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, *df*=1)=1.55, *p*=.20).

Among the less severe depressed participants, 82.4 % (*n*=14) in the BA group recovered after treatment, compared to 92.3 % (*n*=12) in the mindfulness group (χ^2(N=30, *df*=1)=.63, *p*=.41). At the 6-month follow-up, the number of participants from the BA group that had recovered remained the same as in the post-measurement (*n*=14). In the mindfulness group all participants (*n*=13) from the mindfulness group had recovered at the 6-month follow-up (χ^2(N=30, *df*=1)=2.549, *p*=.17).

Treatment credibility and therapist time

Treatment credibility ratings (C-scale) after one week of treatment showed that participants in both groups rated their respective treatment as credible. Out of a possible total of 50, the average scores were 31.9 (*SD*=7.1) for the BA group and 32.1 (*SD*=7.8) for the mindfulness group. There was no significant difference in treatment credibility between the two groups (*t* (78)=0.12, *p*=0.90). Furthermore, treatment credibility did not correlate significantly with any of the outcome measures, either for all participants combined (*r*=0.13, *p*=0.27), for the BA group (*r*=0.01, *p*=0.92) or for the mindfulness group (*r* =. 23, *p* = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participants. However, the therapist time did not differ between the two treatment groups.

Discussion

The overall aim of this study was to evaluate and compare the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on BA and the other on mindfulness. Hence, the main question was whether BA is more effective than mindfulness delivered over smartphone. We hypothesized that BA treatment delivered over smartphone would be more effective than mindfulness treatment delivered over smartphone. We also expected that BA would be superior to mindfulness for participants suffering from more severe depression. When analyzing the whole sample as one entity, the result showed that the

two interventions did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on BA was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity, the treatment based on mindfulness worked better than the treatment based on BA, as measured with PHQ-9 and BDI-II.

The result from the analysis of the higher severity participants is in line with Dimidjian et al's finding [7]. In contrast to the meta-analysis by Cuijpers et al [24], Dimidjian et al [7] found that BA was comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. In line with this, Beck and colleagues [45] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen.

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed [46 47], mindfulness has proven to be effective for relapse prevention of recurrent depression [20 48 49]. A possible explanation to the results could be that there was a difference between the two treatment groups, although not significant, in the number of participants that were suffering from major depression. In the BA group 64.7% (n=11) were diagnosed with major depression in the initial screening, compared to 30.8 % (n=4) in the mindfulness group (χ^2(N=30, df=1)=3.39, p=.07).

Moreover, the results showed significant improvements from pre-treatment to post-treatment on the primary outcome measures in both treatment conditions with large within-group effect sizes and large recovery rates, which are comparable to other depression treatment. This might indicate that this smartphone format could work well for a depressed population. However, a replication with a waiting list group should be conducted to rule out that the effects occurred due to natural recovery.

Limitations

There are a number of limitations that need to be mentioned. The first is that no wait list group was included. Even if our main research question was to assess whether behavioral activation is more effective than mindfulness delivered over smartphone a control group would have yielded a more clear result.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects. We were not expecting that the mindfulness treatment would be as effective and powered the trial as if a moderate between-group effect would be found.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II at intake (*M*=24.10) is rather close to the limit of 29 proposed for defining severe depression [27], meaning that the depression severity in this study was comparable to an outpatient psychiatric population.

Fourth, we recruited a broad range of participants, with regards to the severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded to the BA significantly better that the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on BA for the participants with lower initial. Additionally, it can be argued that these broad inclusion criteria reflect a real population (i.e. an outpatient psychiatric population) of individuals with depressive disorders.

A fifth related concern was the large number of participants who had college- or university level education (65.5 %). This might bias generalizability of the results, since it is possible that guided self-help is especially well suited for educated clients. However, there are data indicating that 50 % of patients seeking psychotherapy have some college education [50] and that educated patients may be more inclined to seek help for mental health problems in general [51].

Conclusion

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as BA and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups are comparable to other depression treatments, and indicate that this smartphone format with a small amount of text and minimal therapist support, might work well for a depressed population. However, as mentioned above, a replication with a waiting list group should be conducted to rule out that the effects occurred due to natural recovery.

Moreover, this study also shows that BA might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results suggest that different treatments distributed digitally can target different subgroups

of depression in terms of severity. However, more studies are needed to strengthen this hypothesis before a conclusion can be drawn.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted as well as relatively cheap for the functionalities you get [25], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate major depression can be treated effectively by means of a supported smartphone-application, might be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life. As suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of being in treatment in everyday settings, and therefore better help clients create direct incentives for treatment related activities in their everyday life [41]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [25], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not only relevant for Swedish conditions but also for the developing countries in the world, which increasingly are empowered by mobile phones with internet connection.

This study might open up for a broad range of other trials conducted via smartphones, both for self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the BA application is currently developed for the open market by KHL.

Authors' contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA was the principal research executive and participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.

	Mean (*SD*)			Effect size, *d* (95% CI)			
Outcome measure	**Pre-treatment**	**Post-treatment**	**6-month follow-up**	**Between-group, pre-post**	**Between-group, pre-6FU**	**Within-group, pre-post**	**Within-group, pre-6FU**
Total							
BDI-II							
BA	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25	0.03	1.83 (0.27-3.38)**	1.19 (-0.87-3.24)**
MF	24.68 (9.47)	12.94 (10.18)	13.09 (12.24)	(-1.65-2.15)	(-2.63-2.69)	1.21 (-0.95-3.38)**	1.09 (-1.32-3.50)**
PHQ-9							
BA	12.53 (4.43)	5.83 (3.85)	6.77 (5.83)	0.28	0.15	1.63 (0.71-2.56)**	1.14 (-0.01-2.28)**
MF	13.22 (4.81)	7.19 (5.84)	7.74 (7.33)	(-0.85-1.40)	(-1.39-1.69)	1.15 (-0.02-2.32)**	0.91 (-0.44-2.27)**
BAI							
BA	14.60 (9.09)	8.81 (5.77)	8.34 (8.50)	0.06	0.01	0.76 (-0.95-2.47)**	0.72 (-1.25-2.69)**
MF	13.51 (9.31)	9.22 (7.68)	8.38 (7.48)	(-1.49-1.61)	(-1.86-1.87)	0.51 (-1.39-2.40)**	0.61 (-1.30-2.51)**
AAQ-II							
BA	27.28 (7.05)	21.22 (8.24)	20.09 (9.28)	0.22	0.10	0.80 (-0.89-2.50)**	0.89 (-0.93-2.72)**
MF	28.22 (7.09)	23.32 (10.82)	21.03 (9.68)	(-1.97-2.41)	(-2.10-2.31)	0.56 (-1.44-2.54)*	0.87 (-1.00-2.74)**
QoLI							
BA	-0.45 (1.38)	0.92 (1.66)	1.15 (2.40)	0.05	0.01	0.91 (0.58-1.25)**	0.84 (0.41-1.27) **
MF	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)	(-0.36-0.45)	(-0.53-0.51)	0.62 (0.24-0.99)**	0.75 (0.36-1.15)**
H-LDep							
BDI-II							
BA	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42	0.39	2.25 (0.33-4.18)**	1.72 (-0.87-4.31)**
MF	28.00 (8.61)	15.68 (10.76)	16.28 (12.71)	(-2.09-2.93)	(-2.95-3.73)	1.62 (-0.44-3.67)**	1.32 (-1.07-3.71)**
PHQ-9							
BA	15.52 (3.29)	6.64 (4.42)	6.48 (5.59)	0.36	0.47	2.34 (1.23-3.45)**	2.04 (0.73-3.35)**
MF	15.57 (3.35)	8.60 (6.29)	9.60 (7.71)	(-1.17-1.90)	(-1.46-2.40)*	1.43 (0.13-2.74)**	1.05 (-0.49-2.58)**
BAI							
BA	17.43 (9.37)	9.18 (6.68)	9.62 (8.91)	0.20	0.01	1.03 (-1.30-3.37)**	0.87 (-1.77-3.52)**
MF	15.57 (9.39)	10.68 (8.39)	9.72 (7.91)	(-1.94-2.34)	(-2.36-2.38)	0.56 (-1.80-2.92)*	0.68 (-1.62-2.99)**
AAQ-II							
BA	28.27 (7.21)	21.68 (8.90)	19.33 (9.27)	0.44	0.47	0.83 (-1.47-3.14)**	1.11 (-1.28-3.49)**
MF	29.04 (6.50)	25.87 (10.52)	23.56 (9.33)	(-2.30-3.18)	(-2.16-3.09)	0.38 (-1.90-2.65)	0.70 (-1.40-2.80)*
QoLI							
BA	-0.51 (1.30)	0.78 (1.58)	1.25 (2.07)	0.26	0.34	0.91 (0.50-1.33)**	1.05 (0.56-1.55)**
MF	-0.71 (1.18)	0.38 (1.58)	0.53 (2.23)	(-0.70-0.18)	(-0.95-0.27)	0.80 (0.44-1.17)**	0.72 (0.26-1.18)**
L-L Dep							
BDI-II							
BA	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51	-1.21	1.74 (-0.25-3.72)**	0.58 (-2.36-3.52)
MF	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)	(-2.36-1.34)	(-4.13-1.71)*	1.83 (-0.54-4.19)**	2.35 (-0.03-4.72)**
PHQ-9							
BA	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23	-0.98	2.06 (1.39-2.72)**	0.30 (-1.21-1.80)
MF	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)	(-1.20-0.74)	(-2.68-0.72)**	1.38 (0.19-2.59)*	2.13 (1.03-3.23)**
BAI							
BA	10.76 (7.33)	8.21 (4.10)	6.43 (7.80)	-0.56	-0.27	0.43 (-1.64-2.51)	0.59 (-1.98-3.16)
MF	9.08 (7.70)	5.91 (4.48)	4.67 (4.64)	(-2.17-1.04)	(-2.92-2.38)	0.51 (-1.95-2.98)	0.67 (-1.95-3.34)**
AAQ-II							
BA	26.00 (6.85)	20.50 (7.34)	21.21 (9.54)	-0.37	-0.87	0.80 (-1.61-3.21)**	0.61 (-2.17-3.39)
MF	26.46 (8.21)	17.52 (9.54)	14.00 (7.07)	(-3.52-2.78)	(-4.26-2.52)	1.06 (-2.33-4.44)*	1.68 (-1.42-4.78)**
QoLI							
BA	-0.37 (1.52)	1.14 (1.83)	0.97 (2.15)	-0.38	-0.93	0.94 (0.37-1.50)**	0.76 (0.13-1.38)*
MF	0.89 (1.61)	1.87 (2.24)	2.87 (2.10)	(-0.38-1.14)	(-1.77-0.10)	0.53 (-0.20-1.27)	1.14 (0.41-1.87)

Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep: Low-level depression; BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.

* $p<0.05$.

** $p<0.01$.

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There ~~are, however, to our knowledge no controlled trial~~are, however, to our knowledge no controlled trials on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment

program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• ~~This~~ The large within-group effect sizes are comparable to other depression treatment and indicate that this smartphone format might work~~s~~ well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool ~~(www.random.org)~~, handled by an independent person who was separate from the staff conducting the study.

Setting

~~Open trial at a university psychological center in Sweden.~~ General community, with recruitment nationally through mass media and advertisements.

Participants

40 participants diagnosed with major depressive disorder received a behavioral activation treatment, and 41 participants received a mindfulness treatment

9 participants were lost ~~to~~ at the post-treatment.

Intervention

Behavioral activation: An 8 week long behavior program administered via a smartphone application. Mindfulness: An 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The primary outcome measures were the Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants (BA n=40; Mindfulness n=41) were randomized (mean age 36.0 years (SD=10.8)) and ~~. All were included in the intention to treat analysis~~analyzed. Results showed large within-group effect sizes on the BDI-II for the behavioral activation treatment and mindfulness treatment respectively from pre-treatment to the 6-month follow up (*d*=1.19 and *d*=1.09), but no significant interaction effects of group and time on any of the outcome measures from pre-treatment to the 6-month follow up. Subgroup analyses showed that the behavioral activation treatment was more effective than the mindfulness treatment among participants with higher initial severity of depression, measured with the PHQ-9. In contrast, the mindfulness treatment worked better than the behavioral activation treatment among participants with lower initial severity. ~~Within-group effects from pre-measurement to post-measurement on BDI-II were *d*=1.83 CI [0.27-3.38] and *d*=1.21 CI [-0.95-3.38] for the behavioral activation treatment and mindfulness treatment respectively. From pre-measurement to 6-month follow-up, effects were *d*=1.19 CI [-0.87-3.24] and *d*=1.09 CI [-1.32-3.50] respectively.~~

Conclusions

For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness. For participants with lower initial severity, the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation.

~~The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups, indicate that this smartphone format works well for a depressed population.~~

Trial registration

Clinical Trials NCT01463020.

Funding

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Background

Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for the individual and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation has an established empirical base [4]. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. In addition, a series of reviews and meta-analyses also show that behavioral activation is at least as effective as the full CBT packages that include both cognitive and behavioral components [4]. In a later study, behavioral activation was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach out to more patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy [11]. There are, however, to our knowledge no controlled trial on internet-delivered pure behavioral activation, and no study using smartphones for the delivery of behavioral activation, even if studies are being conducted on smartphone-administered CBT [12].

An important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [13]. Therefore, behavioral activation is a treatment that could benefit from the use of new mobile technologies (for example smartphones) by creating direct incentives for behavioral activation in patient's everyday life.

The same applies for mindfulness. Mindfulness is often a component in the so called third wave of CBT, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18]. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression as both the primary diagnosis and the secondary. Moreover, mindfulness has been shown to be effective in relapse prevention in depression [20]. Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based internet treatments, but there have so far been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [21].

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey [13]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [13]. Both behavioral activation and mindfulness are components in multi-component treatment

packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

At the same time, research suggests that depression severity is known to be a significant moderating factor in the treatment of depression. For example, some initial evidence suggests that there is a difference in efficacy between ~~two~~ different forms of CBT in the treatment of the more severely depressed patients [7 22]. There are also indications that the difference between antidepressant medication and placebo is evident in severe depression, but not in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [22]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. (2006) found that among more severely depressed patients, behavioral activation was comparable to antidepressant medication, and significantly outperformed cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed.

The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. Hence, the main question is whether behavioral activation is more effective than mindfulness delivered over smartphone. The study was based on our previous work on guided internet-treatment for depression [24], but in the current study the treatment content was delivered entirely via the participants personal smartphone, using recently developed smartphone applications. We expected, in line with Dimidjian and coworkers' conclusions (BA relative to CT d=0.87 on BDI), that behavioral activation would be superior to mindfulness for participants suffering from more severe depression with an expected between group effect size of Cohen´s d=0.50). In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe

comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems, h) no assessed risk of being suicidal (see below for details) and ih) major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). Additionally, an assessment of suicidal ideation was conducted. The interviews were made over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers. Questions regarding medication and psychiatric history that came up in the interview were considered before the decision on inclusion was made.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening (22 did not finish the screening and 83 did not begin the screening). Of these, 29 were excluded before the diagnostic interview ~~telephone interview~~ started. 13 individuals were excluded after the diagnostic interview~~telephone interview~~. Eighty-four were subsequently included after the interview had been conducted. Before the study started, three participants chose not to participate in the study. The reasons for exclusion are specified in the flowchart found in Figure 1.

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data. There were no significant differences in demographic characteristics between the groups according to chi-square analysis.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [25]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [26 27]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10 measurements on the outcome PHQ-9.

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [28]), the Quality of Life Inventory (QOLI; [29 30]), the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P;- [31~~31~~]) and the Acceptance and Action Questionnaire (AAQ-II; [32]) were administered. The AAQ-II was administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the treatment started. Hence, there were two measurements on the outcome TIC-P, three measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II.

Clinician-administered measures. Psychiatric diagnoses were assessed at pre-treatment, post-

treatment and at 6-month after the start of the treatment, using the Mini-International Neuropsychiatric Interview (M.I.N.I.; [33]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [33]. All interviews were conducted by the four psychology students described above, who at post-treatment were blind to participant's condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Treatment credibility. To measure treatment credibility, Borkovec and Nau's Credibility/expectancy scale (C-Scale)[34] was used. The C-scale measures the way in which participants view the logic of the treatment (credibility) and the improvements that can be achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after the first week of treatment.

~~**Credibility.** The credibility of the two treatments showed a mean score of 31.9 (*SD*=7.1) for the behavioral activation group and at 32.1 (*SD*=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].~~

Procedure and design

For those participants included in the study, the results from the online screening were used as pre-treatment assessment. All measures used have been shown to have good psychometric properties, with internal consistencies of at least α=.79. Details of this can be found in the respective references of the outcome questionnaires. The outcome measures used have established good psychometric properties, also when administered via the internet [35 36].

After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based behavioral activation intervention with minimal therapist contact was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for behavioral activation. The text was written specially for the current intervention, but inspired by Martell et al. [37] and Lejuez, Hopko & Hopko [38]. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone and a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [39]. This prototype, however, was not specifically designed for depression interventions. The purpose of the behavioral activation application was to make it easy for the participant to remember and register important behaviors, in order to increase everyday activation. The application contained a database of 54 behaviors, divided into three different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application to start tracking. Through the initial psychoeducation, the participants were guided to add few (between two and four) and easy behaviors from start, mainly from the database.

When a behavior was completed, the participant could mark this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service (SMS). The messaging system was used by the therapists to send personal encouraging messages every other, or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, which means that the participants were not able to reply the messages.

Apart from this, the participants were told to write a reflection to summarize every week for their therapist and send it in via e-mail, in the end of every treatment week. The participants received personal feedback on their reflection from their therapist. No sensitive data was saved on a computer, in which the person providing data could be identified. In addition, all internet and smartphone activities was secured, with encrypted information.

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the behavioral activation intervention, except that the theoretical basis of mindfulness was presented instead of the theoretical basis of behavioral activation. The text was written specially for the current intervention, but inspired by Williams et al. [40]. In all, there were three chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the

current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in short (three minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were guided to start with short mindfulness exercises.

Since the mindfulness application did not have a communication system such as the behavioral activation application, e-mails were used to emulate the messaging system in the behavioral activation application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail. The difference in how the therapists communicated in the mindfulness intervention, compared with the behavioral activation intervention, was that the therapists could not give specific feedback on activities or exercises that the participants had done. Otherwise, the communication was similar (length and type of content).

Additionally, the participants given the mindfulness intervention were also told to write a reflection to summarize every week for their therapist and send it in via e-mail. The participants received personal feedback on their reflection from their therapist.

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of internship. Each therapist was responsible for the treatment or 8 to 10 participants from the behavioral activation group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a behavioral activation treatment manual.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-offs scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants, not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in recovery rates ~~clinical significant improvement~~. ~~Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time.~~ In order to adhere to the intention-to-treat principle, the continuous

outcome variables (expect from TIC-P, that was not analyzed as part of this study) were analyzed using mixed effects models, given their ability to handle missing data ~~For the PHQ-9, where weekly measures were available, the continuous outcome variable was analyzed using mixed effects models, given their ability to handle missing data~~ [41]. ~~Random intercept models were selected.~~ All analyses used Maximum Likelihood estimation. Random intercept models were selected for all measures. Differences between the behavioral activation treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II, where weekly measures were available, ~~Also, several models were compared using available information criteria, and the model with best fit was chosen.~~ t~~T~~he covariance between the random intercept and slope was not significant, and therefore was not included in the model. ~~Error terms across time were modeled with a first-order autoregressive covariance structure with heterogeneous variances.~~ Hence, a random intercept model was used also for these measures. ~~Differences in average rates of growth between the two groups were examined by a fixed effects interaction between group and time.~~ Between-group differences at post-treatment were analyzed using independent *t*-tests. Power analysis indicated an 89 % chance of detecting a between-group effect size of d=0.60 (α level=0.05). Within- and between-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard deviations [42]. This was done both from pre-measurements to post-measurements, and from pre-measurements to the 6-month follow up data.

Results

The two groups did not differ significantly on any of the measures at pretreatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). The results will be presented in the following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, three participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved. In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once again, those unreachable were classified as unimproved.

Adherence to treatment was defined as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the eight weeks. Of these, 25 (63 %) were in the behavioral activation group and 32 (78 %) were in the mindfulness group. In average, participants succeeded to adhere to six weeks (M=5.8, SD=2.47).

Primary outcome measure

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment (PHQ-9: (F(1, 501.47)=.28, p's=.60); BDI-II: (F(1, 74.11)=.28, p's=.60)), nor from pre-treatment to the 6-month follow up (PHQ-9: (F(1, 571.49)=.36, p's=.55); BDI-II: (F(1, 147.96)=.09, p's=.77)). However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the behavioral activation treatment and the mindfulness-treatment.

Subgroup analyses

For the participants suffering from high severity of depression (≥10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate character), a~~A~~ mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the behavioral activation group. Thus, the results indicated a difference between the groups from pre-treatment to 6-month follow-up (F(1, 362.1)=5.2, p's<.05). As seen in Table 3, the effect size between the groups at 6-month follow-up was small, but close to medium (Cohen's d=0.47; CI [-1.46, 2.40]).

For the more mildly depressed participants there was a significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on both the PHQ-9 (F(1, 69.3)=7.7, p's<.01) and the BDI-II (F(1, 53.60)=6.25, p's<.05). The effect sizes ~~between the groups at 6-month follow-up was~~were, as evident from Table 3, large (PHQ-9: Cohen's d=0.9~~8~~6; CI [-0.72, 2.68]; BDI-II: Cohen's d=1.21; CI [-1.71, 4.13]).

Secondary outcome measure

As evident from Table 3 no significant interaction effects were found on the secondary measures neither from pre-treatment to post-treatment (BAI: (F(1, 74.05)=1.30, p's=.26); AAQ-II: (F(1, 570.00)=.07, p's=.79); QOLI: (F(1, 76.43)=.1.06, p's=.31)), nor from pre-treatment to the 6-month follow up (BAI: (F(1, 147.01)=.35, p's=.56); AAQ-II: (F(1, 639.00)=.11, p's=.74); QOLI: (F(1, 148.61)=.39, p's=.53)). Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample, 73.5 % (n=25) in the behavioral activation group recovered after treatment, compared to 53.1 % (n=17) in the mindfulness group (χ^2(N=66, df=1)=2.97, p=.07~~1~~). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from the behavioral activation group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, df=1)=.63, p=.3~~27~~.

When analyzing only the severe depressed participants, there was a tendency in favor for the behavioral activation group. Among the severely depressed participants, 73.9 % (n=17) in the behavioral activation group recovered after treatment, compared to 50.0 % (n=14) in the mindfulness group (χ^2(N=51, df=1)=3.03, p=.072). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the behavioral activation group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, df=1)=1.55, p=.20197).

Treatment cCredibility and therapist time

The credibility of the two treatments showed a mean score of 31.9 (SD=7.1) for the behavioral activation group and at 32.1 (SD=7.8) for the mindfulness group on the Borkovec and Nau c-Scale [34].

An independent t-test showed no significant difference between the two groups on the C-scale (t (78)=0.12, p=0.90). Furthermore, the C-scale did not correlate significantly with any of the outcome measures, either for all participants combined (r=0.13, p=0.27), for the behavioral activation group (r=0.01, p=0.92) or for the mindfulness group (r =. 23, p = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participants. However, the therapist time did not differ between the two treatment groups.

Discussion

The overall aim of this study was to investigate the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on behavioral activation and the other on mindfulness. Hence, the main question was whether behavioral activation is more effective than mindfulness delivered over smartphone. When analyzing the whole sample as one entity, the result showed that the two interventions were effective for treating depression with large within-group effect sizes and large recovery rates, but that they did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on behavioral activation was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial

severity, the treatment based on mindfulness worked better than the treatment based on behavioral activation, as measured with PHQ-9 and BDI-II.

The result from the analysis of the higher severity participants is in line with earlier [7] findings. For example, Dimidjian et al (2006) showed that behavioral activation was comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. In line with this, Beck and colleagues [43] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen.

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed [44 45], mindfulness has proven to be effective for relapse prevention of depression [20 46 47]. That gives implications that a mindfulness-based treatment administered through smartphone will work better for people suffering from mild depression. However, the fact that the mindfulness-based treatment worked significantly better than the behavioral activation-treatment was surprising to us. One explanation could be that the less severely depressed participants suffered more from stress and anxiety rather than depression. This population would then not be in need of a treatment that encourages more activation. Instead, a mindfulness treatment could work very well for this kind of problems [19 48].

Moreover, the results showed that the two interventions were effective for treating depression with large within-group effect sizes and large recovery rates, which are comparable to other depression treatment. This indicates that this smartphone format might work well for a depressed population.

Limitations

There are a number of limitations that need to be mentioned. The first ~~and~~ is that ~~it is impossible to determine which parts of the treatments were effective. Since we did not control for the different components separately, we cannot, for example, rule out that the result was mainly an effect of the therapist support. An additional treatment arm with only therapist support would make it possible to rule out this question.~~ no wait list group was included. However, our main research question was to assess whether behavioral activation is more effective than mindfulness delivered over smartphone. Hence, we wanted to isolate all other components, such as the therapist support and the psychoeducation, and only investigate the two smartphone applications.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects. We were not expecting that the mindfulness treatment would be as effective and powered the trial as if a moderate between-group effect would be found.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II

at intake (*M*=24.10) is rather close to the limit of 29 proposed for defining severe depression [25].

Fourth, we recruited a broad range of participants, with regards to the severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded to the behavioral activation significantly better that the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on behavioral activation for the participants with lower initial. Additionally, it can be argued that these broad inclusion criteria reflect a real population of individuals with depressive disorders.

A fifth related concern was the large number of participants who had college- or university level education (65.5 %). This might bias generalizability of the results, since it is possible that guided self-help is especially well suited for educated clients. However, there are data indicating that 50 % of patients seeking psychotherapy have some college education [49] and that educated patients may be more inclined to seek help for mental health problems [50].

Conclusion

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as behavioral activation and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups are comparable to other depression treatments, and indicate that this smartphone format with a small amount of text and minimal therapist support, might work well for a depressed population.

Moreover, this study also shows that behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results strengthen the hypothesis that different treatments distributed digitally can target different subgroups of depression, in terms of severity.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted as well as relatively cheap for the functionalities you get [13], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate depression can be treated effectively by means of a supported smartphone-application, might be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life. As suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of being in treatment in everyday settings, and therefore better help clients create direct incentives for treatment related activities in their everyday life [39]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [13], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not

only relevant for Swedish conditions but also for the developing countries in the world, which increasingly are empowered by mobile phones with internet connection.

This study might open up for a broad range of other trials conducted via smartphones, both for self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the behavioral activation application is currently developed for the open market by KHL.

Author's contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.

Outcome measure	Mean (*SD*) Pre-treatment	Post-treatment	6-month follow-up	Effect size, *d* (95% CI) Between-group, pre-post	Between-group, pre-6FU	Within-group, pre-post	Within-group, pre-6FU
Total BDI-II	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25	0.03	1.83 (0.27-3.38)	1.19 (-0.87-3.24)
~~Behavioral activation~~ BA	24.68 (9.47)	12.94 (10.18)	13.09 (12.24)	(-1.65-2.15)	(-2.63-2.69)	1.21 (-0.95-3.38)	1.09 (-1.32-3.50)
~~Mindfulness~~ MF							
PHQ-9	12.53 (4.43)	5.83 (3.85)	6.77 (5.83)	0.28	0.15	1.63 (0.71-2.56)	1.14 (-0.01-2.28)
~~Behavioral activation~~ BA	13.22 (4.81)	7.19 (5.84)	7.74 (7.33)	(-0.85-1.40)	(-1.39-1.69)	1.15 (-0.02-2.32)	0.91 (-0.44-2.27)
~~Mindfulness~~ MF							
BAI	14.60 (9.09)	8.81 (5.77)	8.34 (8.50)	0.06	0.01	0.76 (-0.95-2.47)	0.72 (-1.25-2.69)
~~Behavioral activation~~ BA	13.51 (9.31)	9.22 (7.68)	8.38 (7.48)	(-1.49-1.61)	(-1.86-1.87)	0.51 (-1.39-2.40)	0.61 (-1.30-2.51)
~~Mindfulness~~ MF							
AAQ-II	27.28 (7.05)	21.22 (8.24)	20.09 (9.28)	0.22	0.10	0.80 (-0.89-2.50)	0.89 (-0.93-2.72)
~~Behavioral activation~~ BA	28.22 (7.09)	23.32 (10.82)	21.03 (9.68)	(-1.97-2.41)	(-2.10-2.31)	0.56 (-1.44-2.54)	0.87 (-1.00-2.74)
~~Mindfulness~~ MF							
QoLI	-0.45 (1.38)	0.92 (1.66)	1.15 (2.40)	0.05	0.01	0.91 (0.58-1.25)	0.84 (0.41-1.27)
~~Behavioral activation~~ BA	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)	(-0.36-0.45)	(-0.53-0.51)	0.62 (0.24-0.99)	0.75 (0.36-1.15)
~~Mindfulness~~ MF							
~~H-L~~ ~~High level depression~~ Dep. BDI-II	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42	0.39	2.25 (0.33-4.18)	1.72 (-0.87-4.31)
~~Behavioral activation~~ BA	28.00 (8.61)	15.68 (10.76)	16.28 (12.71)	(-2.09-2.93)	(-2.95-3.73)	1.62 (-0.44-3.67)	1.32 (-1.07-3.71)
~~Mindfulness~~ MF							
PHQ-9	15.52 (3.29)	6.64 (4.42)	6.48 (5.59)	0.36	0.47	2.34 (1.23-3.45)	2.04 (0.73-3.35)
~~Behavioral activation~~ BA	15.57 (3.35)	8.60 (6.29)	9.60 (7.71)	(-1.17-1.90)	(-1.46-2.40)	1.43 (0.13-2.74)	1.05 (-0.49-2.58)
~~Mindfulness~~ MF							
BAI	17.43 (9.37)	9.18 (6.68)	9.62 (8.91)	0.20	0.01	1.03 (-1.30-3.37)	0.87 (-1.77-3.52)

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Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep:

Low-level depression; BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.

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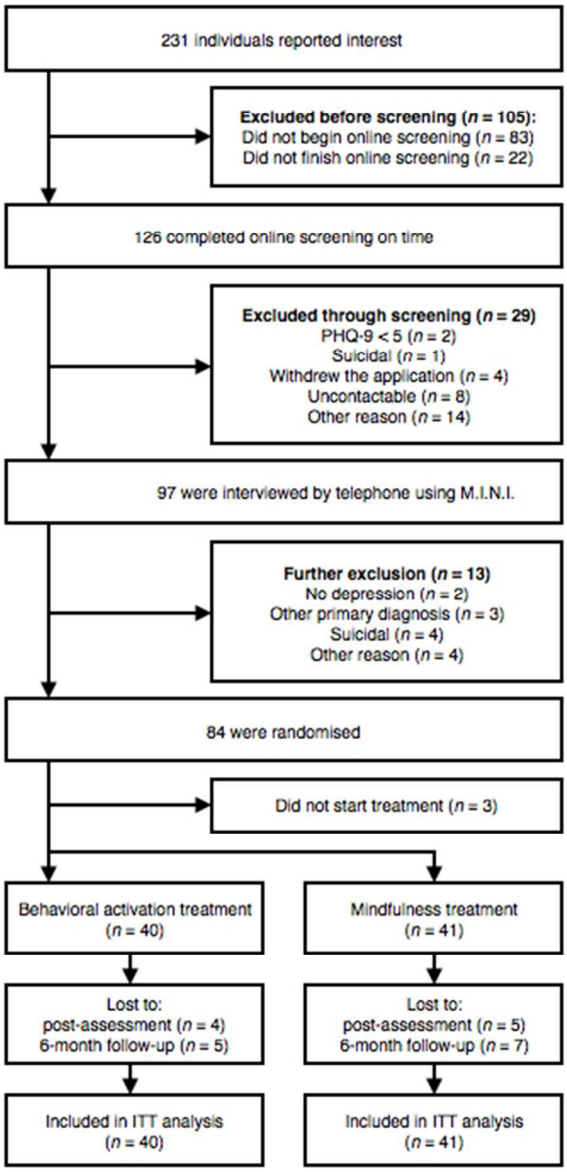

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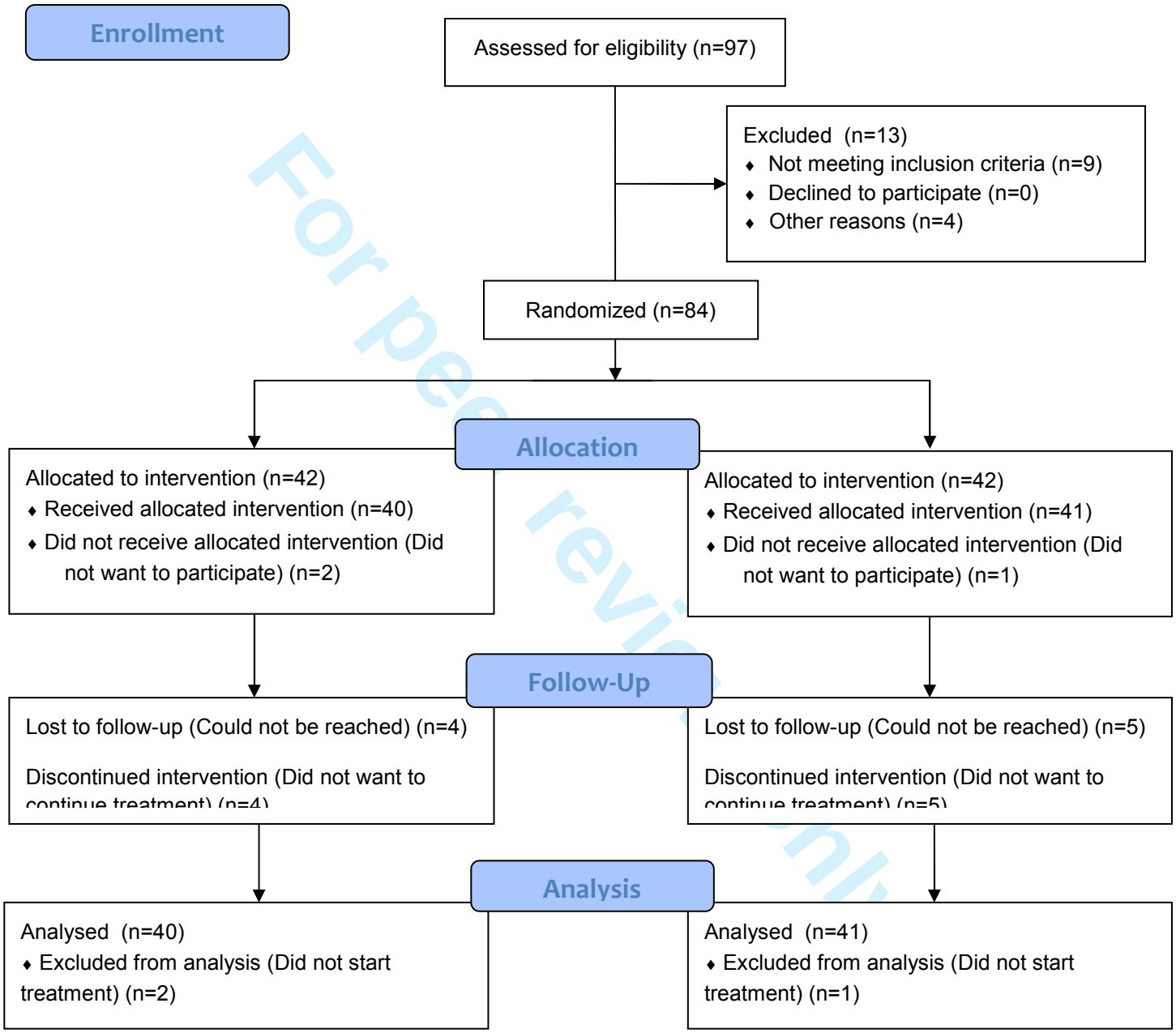
CONSORT 2010 Flow Diagram



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6

	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	14
Protocol	24	Where the full trial protocol can be accessed, if available	14
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

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Manuscript ID:	bmjopen-2013-003440.R3
Article Type:	Research
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Complete List of Authors:	Ly, Kien Hoa; Linköping University, Department of Behavioural Sciences and Learning Trüschel, Anna; Linköping University, Department of Behavioural Sciences and Learning Jarl, Linnea; Linköping University, Department of Behavioural Sciences and Learning Magnusson, Susanna; Linköping University, Department of Behavioural Sciences and Learning Windahl, Tove; Linköping University, Department of Behavioural Sciences and Learning Johansson, Robert; Linköping University, Department of Behavioural Sciences and Learning Carlbring, Per; Stockholm University, Department of Psychology Andersson, Gerhard; Karolinska Institutet, Department of Clinical Neuroscience, Center for Psychiatry Research
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health
Keywords:	Depression, Smartphone application, Behavioral activation, Mindfulness

Behavioral activation vs. Mindfulness-based guided self-help treatment administered through a smartphone application: a randomized controlled trial

Kien Hoa Ly[1§], Anna Trüschel[1], Linnea Jarl[1], Susanna Magnusson[1], Tove Windahl[1], Robert Johansson[1], Per Carlbring[2], Gerhard Andersson[1, 3]

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Keywords

Depression, Behavioral activation, Smartphone application, Mindfulness.

Abstract

Objectives

Evaluating and comparing the effectiveness of two smartphone-delivered treatments; one based on behavioral activation (BA) and one on mindfulness.

Design

Parallel randomized controlled, open, trial. Participants were allocated using an online randomization tool, handled by an independent person who was separate from the staff conducting the study.

Setting

General community, with recruitment nationally through mass media and advertisements.

Participants

40 participants diagnosed with major depressive disorder received a BA treatment, and 41 participants received a mindfulness treatment. 9 participants were lost at the post-treatment.

Intervention

BA: An 8 week long behavior program administered via a smartphone application. Mindfulness: An 8 week long mindfulness program, administered via a smartphone application.

Main outcome measures

The Beck Depression Inventory-II (BDI-II) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9).

Results

81 participants were randomized (mean age 36.0 years (SD=10.8)) and analyzed. Results showed no significant interaction effects of group and time on any of the outcome measures neither from pre-treatment to post-treatment nor from pre-treatment to the 6-month follow up. Subgroup analyses showed that the BA treatment was more effective than the mindfulness treatment among participants with higher initial severity of depression from pre-treatment to the 6-month follow up (PHQ-9: $F(1, 362.1)=5.2$, p's<.05). In contrast, the mindfulness treatment worked better than the BA treatment among participants with lower initial severity from pre-treatment to the 6-month follow up (PHQ-9: $F(1, 69.3)=7.7$, p's<.01); BDI-II: ($F(1, 53.60)=6.25$, p's<.05).

Conclusions

The two interventions did not differ significantly from one another. For participants with higher

severity of depression, the treatment based on BA was superior to the treatment based on mindfulness. For participants with lower initial severity, the treatment based on mindfulness worked significantly better than the treatment based on BA.

Trial registration

Clinical Trials NCT01463020.

Article Summary

1) Article Focus

• It is well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression. There are, however, to our knowledge no controlled trials on smartphone-delivered behavioral activation, neither on mindfulness.

• Both behavioral activation and mindfulness are components in multi-component treatment packages, and as such they might be easier to target in smartphone applications than an entire treatment program would be, due to the need of simple and fast interaction with the treatment program.

• The aim of this study was to test the effects of two smartphone-delivered treatments; one based on behavioral activation and the other on mindfulness. We expected that behavioral activation would be superior to mindfulness for participants suffering from more severe depression.

2) Key Messages

• The large within-group effect sizes are comparable to other depression treatment and indicate that this smartphone format might work well for a depressed population.

• Behavioral activation might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression, at least in this smartphone format.

• Since smartphones likely will be integrated even further in society, they may be important in the future of making depression treatment and other psychological treatment more assimilated into people's daily life.

3) Strengths and Limitations.

• One of the first to do a randomized controlled trial using smartphone applications.

• Did not control for the different components separately, so we cannot determine which parts of the treatments were effective.

Background

Major depressive disorder (MDD) is a major health problem, which causes significant detrimental effects on the individual's quality of life and generates enormous costs for society [1 2]. Several forms of psychotherapy have been found to be effective in the treatment of MDD [3]. For example, behavioral activation (BA) has a strong empirical basis [4]. BA is an established psychological treatment derived from learning theory. It is aimed at increasing adequate behaviors and learning about the relations between behavior and mood. The efficacy of BA for treating MDD has been established in a number of studies over the past four decades [5]. Moreover, a dismantling study showed that BA could be as effective as the full cognitive behavior therapy (CBT) treatment package [6]. Moreover, in a later randomized controlled trial, BA was found to be as effective as antidepressant medication [7].

It is also well established that guided self-help interventions, administered through the internet, can have positive effects on symptoms of depression [8-10]. An increasing number of studies show that this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and anxiety disorders [9]. Guided treatments distributed digitally have provided a way to reach a larger number of patients in a manner that in most cases requires less therapist time than face-to-face psychotherapy, but with similar clinical outcome [11]. There are, however, to our knowledge no controlled trial of an internet-delivered intervention based solely on BA, and no study using smartphones for the delivery of BA, even if studies are being conducted on smartphone-administered CBT [12], for example in the treatment of MDD [13].

Like BA, mindfulness is often used as a component in multi-component treatment packages, such as mindfulness-based cognitive therapy (MBCT; [14]), dialectical behavior therapy (DBT; [15]), and acceptance and commitment therapy (ACT; [16]). Studies have shown a significant negative correlation between mindfulness and depression [17 18], meaning that more mindfulness practice is associated with lower levels of depression. Moreover, a meta-analysis based on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of Hedges's g=0.59 for improving mood symptoms [19]. The analysis also showed that mindfulness was effective for individuals with depression both as primary and secondary diagnosis. Moreover, mindfulness has been shown to be effective in relapse prevention in depression with an overall risk ratio mean of 0.66 (95% CI [0.53, 0.82], p's<.01) [20]. Comorbid disorders such as anxiety have also been shown to be sensitive to mindfulness-based interventions [21]. Mindfulness has also appeared as a component in internet-based CBT treatments, but there have been few studies on mindfulness as a stand-alone, digitally distributed treatment for depression [22].

Research suggests that depression severity is a significant moderating factor in the treatment of depression. There are also indications of a distinct difference between antidepressant medication and placebo in severe depression. Such a difference has not been verified in mild to moderate depression [23], and that combined treatments with medication and psychotherapy are more effective than single treatments [24]. These results suggest that baseline depression severity may moderate the response to different variants of treatments. Thus, it is concluded that different treatments distributed digitally can target different subgroups of depression, in terms of severity. For example, Dimidjian et al. [7] found that among more severely depressed patients, behavioral

activation was as effective as antidepressant medication, and significantly outperformed cognitive therapy, whereas for the less severely depressed patients, no differential treatment effects were observed. However, in meta-analyses on BA versus cognitive therapy this has not been found [24].

The advantages as well as the challenges of using mobile phones in CBT treatment have been summarized by Boschen and Casey [25]. One challenge with using the mobile phone as a platform for psychological treatment is that the user must be able to interact with the program in an easy way [25]. In order to attain this simple and fast interaction, it might be easier to target specific treatment components than entire treatment programs in smartphone applications. This would make BA and mindfulness, both components in more extensive treatment packages, suitable targets for smartphone-based interventions. Another important feature of mobile technology is the possibility for the therapist to reach the patient outside of the therapy room or when not sitting in front of the computer, and thus create direct incentives for behavior change in the patient's everyday life [25]. Therefore, BA is a treatment that could benefit from the use of new mobile technologies (for example smartphones), even more than mindfulness, by creating direct incentives for BA in patient's everyday life.

In this study, we hypothesized that BA treatment delivered over smartphone would be more effective than mindfulness treatment delivered over smartphone. A meta-analysis by Mazzucchelli, Kane, and Rees [26] detected a significant moderate pooled effect size of Hedges's g=0.33 (Cohen's d=0.31) when comparing BA with other psychological interventions, such as psychoeducation about depression, problem solving, assertiveness training and brief interventions. As such, we expected a moderate between group effect size (Cohen´s d=0.50 [27]) in this study. We also expected, in line with Dimidjian and coworkers' conclusion [7], that BA would be superior to mindfulness for participants suffering from more severe depression (scored ≥10 on PHQ-9 and fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character). Since we did not test the effects of a full MBCT program but rather a brief version with fewer exercises, the mindfulness application was not hypothesized to be as effective as the BA. In addition, research has shown that depressed individuals in greater extent have deficits in cognitive functioning such as concentration difficulties, distractibility and impairments in memory, as well as problem in engaging in effortful cognitive processes [28-31]. Therefore, we concluded that the BA intervention would be more suitable for the more severely depressed participants since mindfulness require more cognitive functioning in initial stages, such as the ability to control attention in order to focus on the present moment [32 33].

The study was based on our previous work on guided internet-treatment for depression [34], but in the current study the treatment content was delivered entirely via the participants' personal smartphones, using recently developed smartphone applications. The aim of this study was to test the effects of two smartphone-delivered treatments; one based on BA and the other one on mindfulness. Hence, the main question is whether BA is more effective than mindfulness delivered through a smartphone application. In order to evaluate long-term effects, we also included a 6-month follow-up after the start of the treatment.

Methods

Ethics statement

The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed consent was obtained from all participants by surface mail before the study started.

Recruitment and selection

The participants were mainly recruited via mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study, the treatments being tested and how to participate in the study.

Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥5 on PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last month, d) not being in any concurrent psychological treatment, e) not suffering from a severe comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or schizophrenia, assessed during a clinical interview), f) not having other primary medical problems which would need other treatments first hand, g) not having severe alcohol problems, h) no assessed risk of being suicidal (see below for details) and i) suffering from major depression according to the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed by a structured interview (see below). Additionally, an assessment of suicidal ideation was conducted. The interviews were conducted over telephone by four MSc clinical psychology students. The principal research executive reviewed all the protocols from the interviews together with the interviewers.

Of the 231 individuals who initially expressed interest in the study, 126 completed all the questions in the online screening (22 did not finish the screening and 83 did not begin the screening). Of these, 29 were excluded before the diagnostic interview started. The most common reason for exclusion was an ongoing psychological treatment. Other reasons for exclusion were wrong type of mobile phone (i.e. not having access to a smartphone) and score under 5 on the PHQ-9. 13 individuals were excluded after the diagnostic interview. The most common reason was that the participant was considered to be in need of another kind of treatment. 84 participants were subsequently included.. Before the study started, 3 participants chose not to participate. Hence, 81 participants were finally included in the data analysis. The reasons for exclusion are specified in the flowchart found in Figure 1.

[Insert Figure 1 about here]

Among the randomized participants there were 70.3 % women (*n*=57) and 29.6 % men (*n*=24). The mean age was 36.0 years (*SD*=10.8) ranging from 20 to 61 years. See Table 1 for additional demographical data.

Outcome measures

Primary outcome measures. The primary outcome measures were the Beck Depression Inventory-II (BDI-II; [35]) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; [36 37]) that were administered pre-treatment, at post-treatment and also six months after the treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire treatment phase (8 weeks). Hence, there were 3 measurements on the outcome BDI-II and 10 measurements on the outcome PHQ-9 (including pre-treatment, post-treatment and six months follow up).

Secondary outcome measures. In addition to the BDI-II and PHQ-9, the Beck Anxiety Inventory (BAI; [38]), the Quality of Life Inventory (QOLI; [39 40]) and the Acceptance and Action Questionnaire (AAQ-II; [41]) were administered. The AAQ-II was administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-treatment, post-treatment and at 6-month after the start of the treatment. Hence, there were 3 measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II (including pre-treatment, post-treatment and six months follow up). All outcome measures used have been shown to have good psychometric properties, with internal consistencies of at least α=.79. Details of this can be found in the respective references of the outcome questionnaires.

Clinician-administered measures. Psychiatric diagnoses were assessed at pre-treatment, post-treatment and at follow-up 6 months after the start of the treatment, using the Mini-International Neuropsychiatric Interview (M.I.N.I.; [42]). The M.I.N.I. is a diagnostic interview that, in contrast to several other diagnostic interviews, is completely structured, making it appropriate for other assessors than experienced psychiatrists [42]. All interviews were conducted over telephone by the four psychology students described above, which at post-treatment were blind to participants' treatment condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to both the participant's condition and the treatment they had been given. Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I.

Treatment credibility. To measure participants' perceived treatment credibility, Borkovec and Nau's Credibility/expectancy scale (C-Scale)[43] was used. The C-scale measures the way in which participants view the logic of the treatment (credibility) and the improvements that can be achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after the first week of treatment.

Administration format of self-report measures

We used an online platform to administer the BDI-II, PHQ-9, BAI, QOLI, AAQ-II and the C-scale. Previous psychometric research has validated internet-administration of self-rating scales for depression, quality of life and anxiety [44-46].

Procedure and design

For those participants included in the study, the results from the online screening were used as

pre-treatment assessment. After the recruitment, participants were allocated using an online randomization tool (www.random.org), handled by an independent person who was separate from the staff conducting the study.

The interventions

Behavioral activation treatment. An 8-week smartphone-based BA intervention with minimal therapist contact (maximum time of 20 minutes per participant and week) was developed by our research group. The intervention consisted of a short web-based psychoeducation, and a step-by-step behavior program administered via a smartphone application. The psychoeducation aimed to introduce the participants to the treatment and establish a minimum level of knowledge concerning MDD, touching on topics like the prevalence of depression, its etiology and maintenance factors based on operant conditioning, as well as the theoretical basis for BA. The text in the web-based psychoeducation was written specially for the current intervention, but inspired by the BA treatment manuals of Martell et al. [47] and Lejuez, Hopko & Hopko [48]. In all, there were 3 chapters, totaling 11 pages of text, containing 3 893 words.

The smartphone application was built as a native application for Iphone, meaning that the application was coded in a specific programming language (Objective C), and as a mobile web application for other smartphones. See Figure 2 for a screenshot of the application. A prototype of the smartphone application was tested in a pilot study [49]. This prototype, however, was not specifically designed for depression interventions. The purpose of the BA application was to make it easy for the participant to remember and register important behaviors, in order to increase everyday activation. The application contained a database of 54 behaviors, divided into 3 different areas for the participant to add to their application. See Table 2 for the list of behaviors from the database. The database aimed to provide suggestions, help, and inspiration to get started with the application. Participants were also able to add their own areas and behaviors into the application and start performing and registering these Through the initial psychoeducation, the participants were advised to add only a few (between two and four) behaviors initially, mainly from the existing database, and to choose behaviors that were easy to perform.

When a behavior was completed, for example: *Get ready in the morning*, the participant could register this in the application and add a short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application for the participant.

There was also a back-end system where all the quantitative and qualitative data from the participants was accessible from a website for the therapist. From the back-end system, the therapist could send short text messages to the participants via a messaging system, similar to Short Message Service (SMS). The messaging system was used by the therapists (described below) to send personal encouraging messages every other or every third day to the participants, as well as weekly general educational messages. The system functioned as a one-way communication, meaning that the participants were not able to reply to the messages. The

participants were also told to write a reflection to summarize every week for their therapist, and send it via e-mail by the end of every treatment week. The participants received personal feedback on their reflection from their therapist via e-mail. No sensitive data, through which the person providing data could be identified, was saved. In addition, all internet (including the therapists' back-end system) and smartphone activities (including the participants' mobile application) were secured, with SSL-encrypted information.

[Insert Figure 2 about here]

Mindfulness treatment. The mindfulness intervention, also an 8-week smartphone-based intervention with minimal therapist contact (maximum time of 20 minutes per participant and week), consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice program, administered via a smartphone application. The psychoeducation for the mindfulness intervention was equivalent to that of the BA intervention, except that the theoretical basis for mindfulness was presented instead of the theoretical basis for BA. The text was written especially for the current intervention, with inspiration from the self help book *The Mindful Way Through Depression* by Williams et al. [50]. In all, there were 3 chapters, totaling 9 pages of text, containing 2 927 words.

The smartphone application for Iphone was an established and commercially available application that could be downloaded from the internet. See Figure 3 for a screenshot of the application. For other smartphones, a mobile web application was built especially for the current study with the aim of mimicking the Iphone application. The application consisted of a number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both guided and unguided, and in both short (3 minutes) and long (30 minutes) format. Through the initial psychoeducation, the participants were advised to begin with short mindfulness exercises, such as a guided 3-minute mindfulness exercise, which was one of the audio tracks in the application.

Since the mindfulness application did not have a communication function such as the BA application, e-mails were used to emulate the messaging system in the BA application. Hence, the therapists sent encouraging messages every other, or every third day to the participants, as well as weekly general educational messages via mail. The difference in how the therapists communicated in the mindfulness intervention, compared to the BA intervention, was that the therapists could not give specific feedback on activities or exercises that the participants had performed. Otherwise, the communication was similar (length and type of guided content in the feedback). Additionally, the participants given the mindfulness intervention were also asked to write a weekly reflection to summarize their work and thoughts on the current treatment week, and send this reflection to their therapist via e-mail. The participants received personal feedback on their reflection from their therapist.

[Insert Figure 3 about here]

Therapists. The therapists were four final-semester students from a five-year M.Sc. clinical psychologist program. All therapists had completed their clinical training as well as 16 weeks of practice. Each therapist was responsible for the treatment or 8 to 10 participants from the BA group and an equal number of participants from the mindfulness group. Therapists were randomly allocated to participants, with the restriction of not having more than 10 participants from each group. For the entire duration of the study the therapists received continuous supervision from an experienced psychotherapist with CBT orientation, who had previous experience of working with a BA treatment manual, as well as mindfulness in depression treatment.

Subgroups based on cut-off scores

All randomized participants were classified into groups of either high or low severity of depression. These classes were formed based on the cut-off scores on the PHQ-9. The participants were considered to suffer from higher severity of depression if they scored ≥10 on PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of moderate character (n=51). Participants not fulfilling these criteria were considered to suffer from lower severity of depression (n=30).

Data analysis

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and X^2-tests were used to test for group differences in demographics, pre-treatment data and in recovery rates. In order to adhere to the intention-to-treat principle, the continuous outcome variables were analyzed using mixed effects models, given their ability to handle missing data [51]. All analyses used Maximum Likelihood estimation. Random intercept models were selected for all measures. Differences between the BA treatment and the mindfulness treatment were primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II, where weekly measures were available, the covariance between the random intercept and slope was not significant, and therefore was not included in the model. Hence, a random intercept model was used also for these measures. Between-group differences at post-treatment were analyzed using independent t-tests. Power analysis indicated an 89 % chance of detecting a between-group effect size of d=0.60 (α level=0.05, one tailed). Within- and between-group effect sizes (Cohen's d) were calculated by dividing the differences in means by the pooled standard deviations [52]. This was done both from pre-measurements to post-measurements, and from pre-measurements to the 6-month follow up data.

Results

The two groups did not differ significantly on any of the measures at pre-treatment (t=0.50 to 0.67, df=79, p=0.78 to 0.50). Also, there was no significant difference in demographic characteristics between the groups according to chi-square analysis (χ^2=0.01 to 1.03, df=1, p=0.22 to 0.57). See Table 1 for demographical data. See Table 3 for all outcome measurements at pre-treatment, post-treatment and at 6-month follow-up. The results will be presented in the

following order: attrition and adherence, self-report inventories (including effect size) both for the whole sample and the subgroups, recovery rates and treatment credibility.

Attrition and adherence

Of the 84 participants randomized, 3 participants decided not to participate in the study. Nine out of these 81 participants (11.1 %) did not provide post-treatment data with a distribution of four participants from the BA group and five participants from the mindfulness group. Six out of the 81 participants (totaling 7.4 %) were unreachable for the M.I.N.I. telephone interview and were classified as unimproved in the data analysis. In the 6-month follow-up, 69 participants from the two treatment groups (totaling 85.2 %) provided data on the self-report measures, with a distribution of 35 participants from the BA group and 34 participants from the mindfulness group. 59 participants (72.8 %) were reached for the M.I.N.I. telephone interview. Once again, those unreachable were classified as unimproved in the data analysis.

In a study by Andersson et al [53], the number of postings in a discussion group was used as a process factor. Therefore, we defined adherence to treatment as the number of weekly reflections the participants sent to their therapist. In order to be considered as a completed week, at least one reflection had to have been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere to all the 8 weeks. Of these, 25 (63 %) were in the BA group and 32 (78 %) were in the mindfulness group. No significant difference in adherence was found between the two groups (χ^2(N=81, *df*=1)=2.35, *p*=1.00). In average, participants succeeded to adhere to six weeks (*M*=5.8, *SD*=2.47).

Primary outcome measures

No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found between the groups, neither from pre-treatment to post-treatment (PHQ-9: (*F*(1, 501.47)=.28, *p*'s=.60); BDI-II: (*F*(1, 74.11)=.28, *p*'s=.60)), nor from pre-treatment to the 6-month follow up (PHQ-9: (*F*(1, 571.49)=.36, *p*'s=.55); BDI-II: (*F*(1, 147.96)=.09, *p*'s=.77)). However, as evident from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This was the case for both the BA treatment and the mindfulness-treatment.

Subgroup analyses

For the participants (total *n*=51, BA *n*=23, MF *n*=28) suffering from high severity of depression (≥10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate character), a mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the BA group from pre-treatment to 6-month follow-up, but not on pre-treatment to post-treatment. Thus, the results indicated a difference between the BA group and the mindfulness group from pre-treatment to 6-month follow-up (*F*(1, 362.1)=5.2, *p*'s<.05) for the participants suffering from higher severity of depression. As seen in Table 3, the effect size between the groups at 6-month follow-up was moderate (Cohen's *d*=0.47; CI [-1.46, 2.40]). No difference between the groups from pre-treatment to post-treatment was found

For the more mildly depressed participants (total *n*=30, BA *n*=17, MF *n*=13) there was a

significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on both the PHQ-9 (F(1, 69.3)=7.7, p's<.01) and the BDI-II (F(1, 53.60)=6.25, p's<.05). The effect sizes were, as evident from Table 3, large (PHQ-9: Cohen's d=0.98; CI [-0.72, 2.68]; BDI-II: Cohen's d=1.21; CI [-1.71, 4.13]). No difference between the groups from pre-treatment to post-treatment was found.

Secondary outcome measures

As evident from Table 3 no significant interaction effects were found on the secondary measures between the groups, neither from pre-treatment to post-treatment (BAI: (F(1, 74.05)=1.30, p's=.26); AAQ-II: (F(1, 570.00)=.07, p's=.79); QOLI: (F(1, 76.43)=.1.06, p's=.31)), nor from pre-treatment to the 6-month follow up (BAI: (F(1, 147.01)=.35, p's=.56); AAQ-II: (F(1, 639.00)=.11, p's=.74); QOLI: (F(1, 148.61)=.39, p's=.53)). Nevertheless, as shown in table 3, medium to large within-group effect sizes were revealed on all secondary outcome measures. This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-treatment to the 6-month follow up.

Recovery rates

Recovery rates were defined as no longer fulfilling the criteria for depression according to M.I.N.I. There were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample as well as the subgroups. When analyzing the whole sample (n=81), 73.5 % (n=25) in the BA group recovered at post-treatment, compared to 53.1 % (n=17) in the mindfulness group (χ^2(N=66, df=1)=2.97, p=.07). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from the BA group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group had recovered (χ^2(N=66, df=1)=.63, p=.33.

When analyzing only the severe depressed participants, there was a tendency in favor for the BA group. Among the severely depressed participants, 73.9 % (n=17) in the BA group recovered at post-treatment, compared to 50.0 % (n=14) in the mindfulness group (χ^2(N=51, df=1)=3.03, p=.07). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the BA group had recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered (χ^2(N=51, df=1)=1.55, p=.20).

Among the less severe depressed participants, 82.4 % (n=14) in the BA group recovered at post-treatment, compared to 92.3 % (n=12) in the mindfulness group (χ^2(N=30, df=1)=.63, p=.41). At the 6-month follow-up, the number of participants from the BA group that had recovered remained the same as in the post-measurement (n=14). In the mindfulness group all participants (n=13) from the mindfulness group had recovered at the 6-month follow-up (χ^2(N=30, df=1)=2.549, p=.17), however no significant differences in recovery rates between the groups was found when analyzing only the less severe depressed participants.

Treatment credibility and therapist time

Treatment credibility ratings (C-scale) after one week of treatment showed that participants in both groups rated their respective treatment as credible. Out of a possible total of 50, the average scores were 31.9 (*SD*=7.1) for the BA group and 32.1 (*SD*=7.8) for the mindfulness group. There was no significant difference in treatment credibility between the two groups (t (78)=0.12, p=0.90). Furthermore, treatment credibility did not correlate significantly with any of the outcome measures, either for all participants combined (r=0.13, p=0.27), for the BA group (r=0.01, p=0.92) or for the mindfulness group (r =. 23, p = .18).

The therapist time per participant and week varied depending on whether the participant had sent a reflection or not. The therapists reported a span between 2 and 18 minutes per week and participant. The therapists reported that the time they spent did not differ between the two treatment groups.

Discussion

The overall aim of this study was to evaluate and compare the effects of two smartphone-delivered treatments for people suffering from mild to moderate major depression; one based on BA and the other on mindfulness. Hence, the main question was whether BA is more effective than mindfulness delivered through a smartphone application. We hypothesized that BA treatment delivered via smartphone would be more effective than mindfulness treatment delivered via smartphone. We also expected that BA would be superior to mindfulness for participants suffering from more severe depression. When analyzing the whole sample as one entity, the result showed that the two interventions did not differ significantly from one another; neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no significant differences in recovery rates between the groups, neither at post-treatment nor at the 6-month follow-up.

This study also explored how different levels of initial depression severity could moderate response to the different interventions. All randomized participants were classified into either high or low severity of depression based on the cut-offs scores on the PHQ-9 and whether they fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with higher severity of depression, the treatment based on BA was superior to the treatment based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity, the treatment based on mindfulness was more effective than the treatment based on BA, as measured with PHQ-9 and BDI-II.

The result from the analysis of the higher severity participants is in line with Dimidjian et al's finding [7]. In contrast to the meta-analysis by Cuijpers et al [24], Dimidjian et al [7] found that BA was comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only among those patients who were more severely depressed. Since it is known that depressed individuals in greater extent have concentration difficulties, distractibility and problems in engaging in effortful cognitive processes [28-31], Beck and colleagues [54] have long suggested that therapists should focus on behavioral strategies early in treatment when patients are more depressed and return to that emphasis later if patients start to worsen. We expected that

the BA intervention would be more suitable for the more severely depressed participants since mindfulness require more cognitive functioning in initial stages, such as the ability to control attention in order to focus on the present moment [32 33].

The result from the analysis of the less severely depressed participants was unexpected to us. Although there is yet only initial evidence that mindfulness treatment is effective for acute or severely depressed patients [55 56], mindfulness has proven to be effective for relapse prevention of recurrent depression [20 57 58]. A possible explanation of the results could be that there was a difference between the two treatment groups, although not significant, in the number of participants that were suffering from major depression. In the BA group 64.7% (n=11) were diagnosed with major depression in the initial screening, compared to 30.8 % (n=4) in the mindfulness group (χ^2(N=30, df=1)=3.39, p=.07).

Moreover, the results showed significant improvements from pre-treatment to post-treatment on the primary outcome measures in both treatment conditions with large within-group effect sizes and large recovery rates, comparable to other depression treatments [59 60]. This might indicate that the smartphone format used in this study could work well for a depressed population. However, a replication with a waiting list group should be conducted to rule out the possibility that the effects occurred due to natural recovery.

Limitations

There are a number of limitations that need to be mentioned. The first is that no waiting list group was included. Although our main research question was to assess whether behavioral activation is more effective than mindfulness delivered via smartphone, a control group given no intervention would have yielded a more clear result.

A second limitation is that the study was underpowered. Thus, it is difficult to detect significant overall differences between the two smartphone-treatments, even if significant interaction effects were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc power analysis revealed that a sample of 393 participants was required to detect small between-group effects. We did not expect that the mindfulness treatment would be as effective and powered the trial as if a moderate between-group effect would be found.

A third limitation was that the participants were recruited nationally through mass media and advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g. an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II at intake (M=24.10) is rather close to the limit of 29, proposed for defining severe depression [35], meaning that the depression severity in this study was comparable to an outpatient psychiatric population.

Fourth, we recruited a broad range of participants, with regards to severity of depression (a minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a specific group for whom the treatments would be most effective. Nevertheless, a subgroup analysis showed that participants with higher severity of depression responded significantly better to the BA than to the treatment based on mindfulness, whereas the treatment based on mindfulness worked significantly better than the treatment based on BA for the participants with

lower initial depression severity. Additionally, it can be argued that these broad inclusion criteria reflect a real population (i.e. an outpatient psychiatric population) of individuals with depressive disorders. However, this contributed to power limitations as well.

A fifth related concern was the large number of participants that had college- or university level education (65.5 %). This might compromise generalizability of the results, since it is possible that guided self-help is especially well suited for educated patients. However, there is data indicating that 50 % of patients seeking psychotherapy have some college education [61] and that educated patients may be more inclined to seek help for mental health problems in general [62].

Conclusion

Some clinical implications of this study are discussed as follows. Due to the need for simple and fast interaction with the treatment program, singular treatment components such as BA and mindfulness might be a better target for smartphone applications than entire multi-component treatment packages. At the same time, there is a need for guided self-help treatments distributed digitally that can reach out to more patients. This study is one of the first to test a treatment for depression, administered via smartphone. The large within-group effects on the primary outcome measures, as well as the large recovery rates for both groups, are comparable to other depression treatments and indicate that this smartphone format with a small amount of text and minimal therapist support might work well for a depressed population. However, as mentioned above, a replication with a waiting list group should be conducted to rule out that the effects occurred due to natural recovery.

Moreover, this study also shows that BA might work better for a more severely depressed population, whereas mindfulness might work better for people suffering from light depression. These results suggest that different treatments distributed digitally can target different subgroups of depressed patients in terms of severity. However, more studies are needed to strengthen this hypothesis before any conclusions can be drawn.

From a broader perspective, we believe that smartphones will be integrated even further in society since they are already socially accepted and come at relatively low costs considering their functionalities [25], and therefore may serve an important role in health care. Therefore these results, showing that mild to moderate major depression can be treated effectively by means of a supported smartphone-application, might be important in making depression treatment and other psychological treatments more assimilated into people's daily life. As suggested in Ly et al. [49], the smartphone format might also help increasing patients' awareness of being in treatment, even in everyday settings, and therefore better help patients create direct incentives for treatment related activities in their everyday life [49]. Using smartphones to distribute psychological treatment might also help making it possible to reach out with psychological therapy to a broader group of people, since their use attracts no attention [25], allowing users to interact with a device without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not only relevant for Swedish conditions but also for the developing countries of the world, which increasingly are empowered by mobile phones with internet connection.

This study might pave the way for a broad range of other trials conducted via smartphones, both self-help interventions and face-to-face treatments with the smartphone as an adjunct tool. We believe that a substantial part of internet-based interventions in the future will be executed through smartphones or at least supported by smartphones. Further studies should focus on both formats, as well as expanding the treatment platform to other psychological disorders.

Authors' contributions

KHL was the project manager and has developed the application. KHL also participated in the drafting of the treatment manuals, and participated in analysis and interpretation of data. GA was the principal research executive and participated in the conception of the study and its design. GA also participated in the drafting of treatment manuals, analysis and interpretation of data, and performed statistical analysis. PC participated in the conception of the study and its design. RJ participated in analysis and interpretation of data, and performed statistical analysis. AT, LJ, SM and TW participated in the drafting of treatment manuals and performed the treatments. KHL and GA drafted the current manuscript. PC and RJ participated in revision of the current manuscript. All authors read and approved the final manuscript.

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Trial protocol

The full trial protocol can be found at: http://www.trialsjournal.com/content/13/1/62

Trial registration

Clinical Trials NCT01463020

Competing interests

A related version of the BA application is currently developed for the open market by KHL.

Data Sharing Statement

Additional unpublished data from the study includes answers from the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P), which is used to measure cost data from a psychological treatment. This extra data is available by emailing kien.hoa.ly@liu.se

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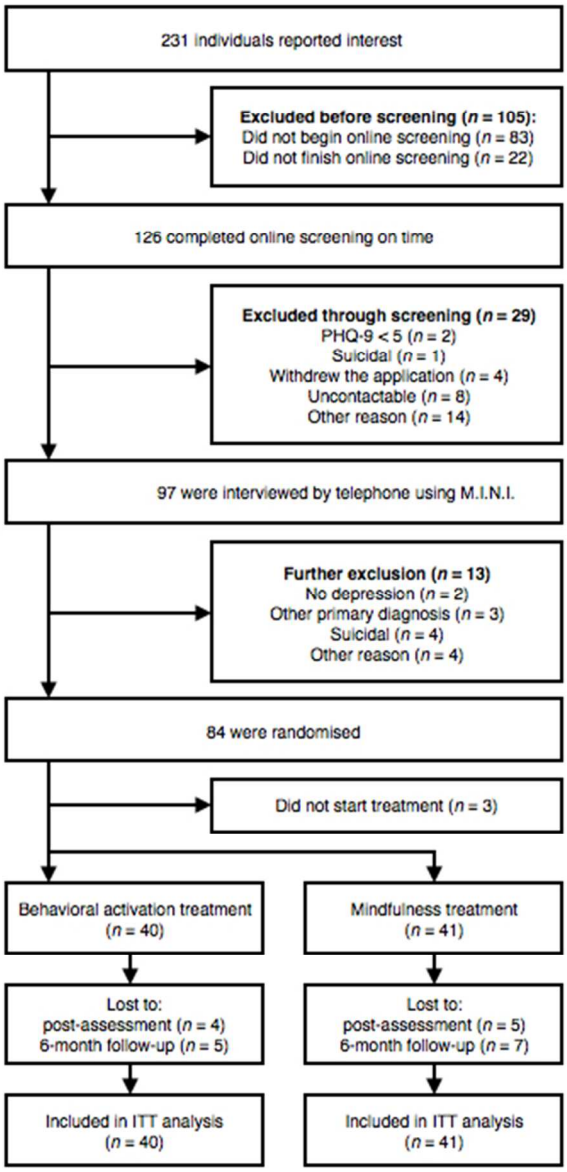

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Table 1. Demographic description of the participants at randomization.

		Behavioral activation (*N* = 40)	Mindfulness (*N* = 41)	Total (*N* = 81)
Age	Mean (*SD*)	36.6 (10.5)	35.6 (11.3)	36.1 (10.8)
	Min-Max	20-59	21-61	20-61
Gender	Female	28 (70 %)	29 (70.7 %)	57 (70 %)
	Male	12 (30 %)	12 (29.3 %)	24 (30 %)
Marital status	Single	15 (37.5 %)	15 (36.6 %)	30 (37 %)
	Married	19 (47.5 %)	24 (58.6 %)	43 (53.2 %)
	Divorced/widow/widower	5 (12.5 %)	1 (2.4 %)	6 (7.4 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.4 %)
Highest educational level	Nine year compulsory school	1 (2.5 %)	2 (4.9 %)	3 (3.8 %)
	Secondary school	11 (27.5 %)	14 (34.1 %)	25 (30.9 %)
	College/university	27 (67.5 %)	24 (58.5 %)	51 (63 %)
	Other	1 (2.5 %)	1 (2.4 %)	2 (2.5 %)
Employment status	Employed/student	35 (87.5 %)	30 (73.2 %)	65 (80.2 %)
	Unemployed	3 (7.5 %)	3 (7.3 %)	6 (7.4 %)
	Retired	0 (0 %)	1 (2.4 %)	1 (1.2 %)
	Other	2 (6.3 %)	7 (17.1 %)	9 (11.1 %)
Type of Smartphone	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
Medication	Yes, earlier	10 (25 %)	13 (31.7 %)	23 (28.4 %)
	Yes, present	12 (30 %)	14 (34. 1%)	26 (32.1 %)
	None	18 (45 %)	14 (34.1 %)	32 (39.5 %)
Psychological treatment	Yes, earlier	19 (47.5 %)	23 (56.1 %)	42 (51.9 %)
	None	21 (52.5 %)	18 (43.9 %)	39 (48.1 %)
Experience of self-help literature	Yes	12 (30 %)	13 (31.7 %)	25 (30.9 %)
	None	28 (70 %)	28 (68.3 %)	56 (69.1 %)
Diagnosis	Depression	34 (85 %)	32 (78 %)	66 (82.5 %)
	With dysthymia	22 (55 %)	18 (44 %)	40 (49 %)
	Earlier episodes	31 (77.5 %)	34 (83 %)	65 (80 %)
	Panic disorder	1 (2.5 %)	3 (7.5 %)	4 (5 %)
	Social phobia	6 (15 %)	7 (17 %)	13 (16 %)
	GAD	19 (47.5 %)	10 (24.5 %)	29 (36 %)

Table 2. List of behaviors in the database.

Everyday structure

Get out of bed when the bell rings in the morning
Take a shower
Get ready in the morning
Eat breakfast
Read the newspaper
Make a meal plan for each day of the week
Make a shopping list for meals
Buy food for the meals you have planned
Prepare a simple meal
Clean a part of my home
Clean at least 15 minutes
Washing dishes immediately after a meal
Wash my clothes
Plan my TV viewing from TV schedules
Turn off the TV before 21:00 if I'm still watching TV
Turn off the computer before 21:00 if I'm still on the Internet
Take a brisk walk for 10 minutes
Log in to my online banking and pay a bill
Entering my weekly activities in my calendar

Social behaviors

Texting a friend and ask what he / she does
Call a friend and ask what the situation is
Take a walk with a friend
Book a meeting with someone in my family
Suggest a coffee with a friend or family member
Suggest a lunch with a friend or family member
Go to the playground with my kids
Bake something with my children
Meet a friend in the evening and ask how your day was
Watching an episode of a TV series with a friend
Go to the movies with a friend
Cooking with someone

New activities

Buy or borrow a book I wanted to read
Read at least 20 minutes out of a book
Go to a new cafe and coffee
Look up the nearest training center is
Read on about training online
Post a workout plan for the week
Ask a friend if he / she wants to come along and train
Spend at least 30 minutes of physical activity
Listen to a radio program
Watch a documentary on TV
Eat a good meal out
Write down at least two good things that happened around me
Rent a movie and have a night in
Look up the exhibits that are in my city
See an exhibition at a museum
Look up the concerts that are relevant right now
Go to a concert
Look up current things happening in my city
Attend a church service
Solve a crossword
Make a Sudoku
Listen to music without doing anything else and focus on what I hear
Go to town and buy something nice for myself

Table 3. Means, SDs and effect sizes (Cohen's d) for measures of depression, anxiety, psychological flexibility and quality of life.

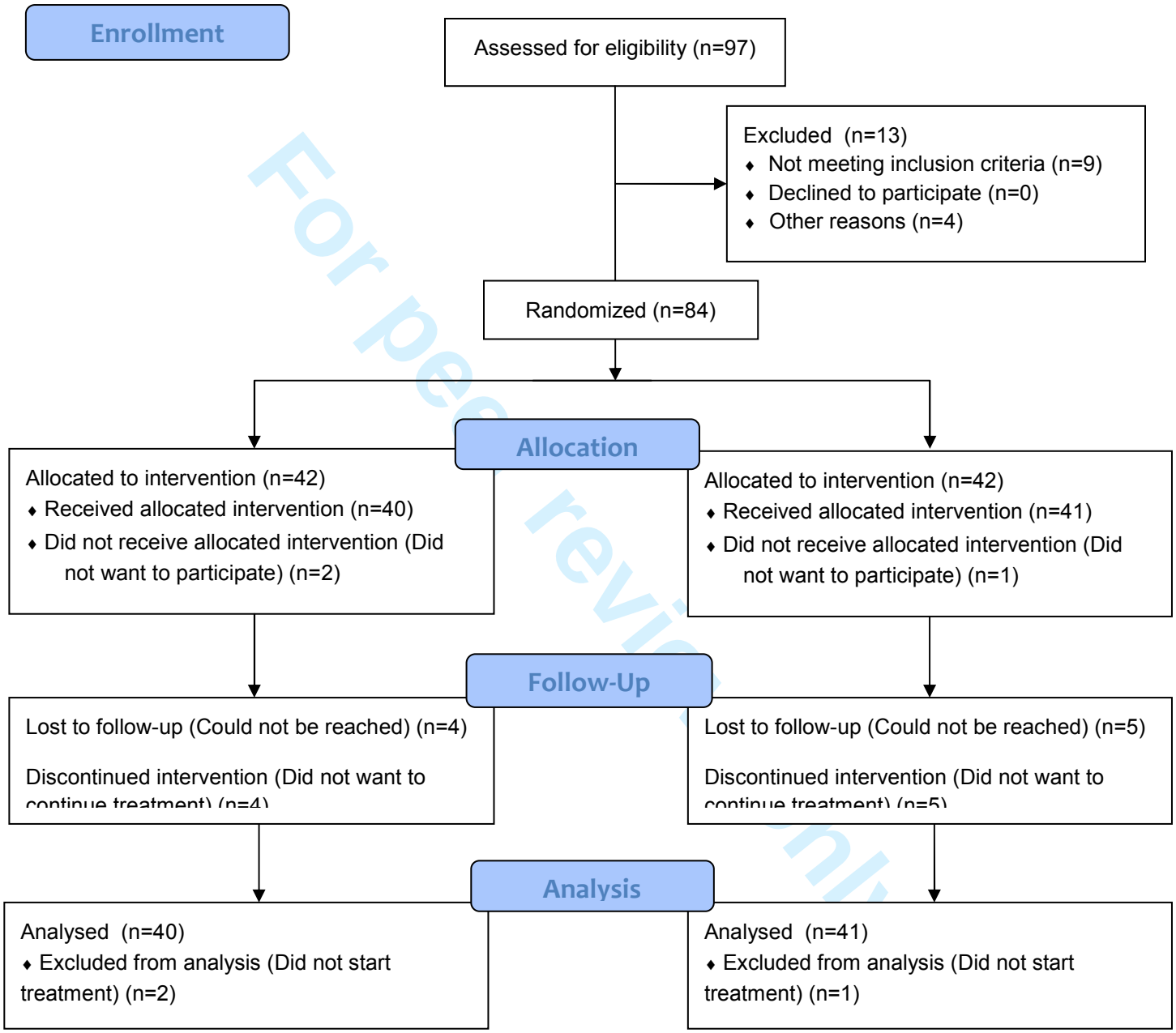
	Mean (*SD*)			Effect size, *d* (95% CI)			
Outcome measure	**Pre-treatment**	**Post-treatment**	**6-month follow-up**	**Between-group, pre-post**	**Between-group, pre-6FU**	**Within-group, pre-post**	**Within-group, pre-6FU**
Total							
BDI-II							
BA	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25	0.03	1.83 (0.27-3.38)**	1.19 (-0.87-3.24)**
MF	24.68 (9.47)	12.94 (10.18)	13.09 (12.24)	(-1.65-2.15)	(-2.63-2.69)	1.21 (-0.95-3.38)**	1.09 (-1.32-3.50)**
PHQ-9							
BA	12.53 (4.43)	5.83 (3.85)	6.77 (5.83)	0.28	0.15	1.63 (0.71-2.56)**	1.14 (-0.01-2.28)**
MF	13.22 (4.81)	7.19 (5.84)	7.74 (7.33)	(-0.85-1.40)	(-1.39-1.69)	1.15 (-0.02-2.32)**	0.91 (-0.44-2.27)**
BAI							
BA	14.60 (9.09)	8.81 (5.77)	8.34 (8.50)	0.06	0.01	0.76 (-0.95-2.47)**	0.72 (-1.25-2.69)**
MF	13.51 (9.31)	9.22 (7.68)	8.38 (7.48)	(-1.49-1.61)	(-1.86-1.87)	0.51 (-1.39-2.40)**	0.61 (-1.30-2.51)**
AAQ-II							
BA	27.28 (7.05)	21.22 (8.24)	20.09 (9.28)	0.22	0.10	0.80 (-0.89-2.50)**	0.89 (-0.93-2.72)**
MF	28.22 (7.09)	23.32 (10.82)	21.03 (9.68)	(-1.97-2.41)	(-2.10-2.31)	0.56 (-1.44-2.54)*	0.87 (-1.00-2.74)**
QoLI							
BA	-0.45 (1.38)	0.92 (1.66)	1.15 (2.40)	0.05	0.01	0.91 (0.58-1.25)**	0.84 (0.41-1.27) **
MF	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)	(-0.36-0.45)	(-0.53-0.51)	0.62 (0.24-0.99)**	0.75 (0.36-1.15)**
H-LDep							
BDI-II							
BA	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42	0.39	2.25 (0.33-4.18)**	1.72 (-0.87-4.31)**
MF	28.00 (8.61)	15.68 (10.76)	16.28 (12.71)	(-2.09-2.93)	(-2.95-3.73)	1.62 (-0.44-3.67)**	1.32 (-1.07-3.71)**
PHQ-9							
BA	15.52 (3.29)	6.64 (4.42)	6.48 (5.59)	0.36	0.47	2.34 (1.23-3.45)**	2.04 (0.73-3.35)**
MF	15.57 (3.35)	8.60 (6.29)	9.60 (7.71)	(-1.17-1.90)	(-1.46-2.40)*	1.43 (0.13-2.74)**	1.05 (-0.49-2.58)**
BAI							
BA	17.43 (9.37)	9.18 (6.68)	9.62 (8.91)	0.20	0.01	1.03 (-1.30-3.37)**	0.87 (-1.77-3.52)**
MF	15.57 (9.39)	10.68 (8.39)	9.72 (7.91)	(-1.94-2.34)	(-2.36-2.38)	0.56 (-1.80-2.92)*	0.68 (-1.62-2.99)**
AAQ-II							
BA	28.27 (7.21)	21.68 (8.90)	19.33 (9.27)	0.44	0.47	0.83 (-1.47-3.14)**	1.11 (-1.28-3.49)**
MF	29.04 (6.50)	25.87 (10.52)	23.56 (9.33)	(-2.30-3.18)	(-2.16-3.09)	0.38 (-1.90-2.65)	0.70 (-1.40-2.80)*
QoLI							
BA	-0.51 (1.30)	0.78 (1.58)	1.25 (2.07)	0.26	0.34	0.91 (0.50-1.33)**	1.05 (0.56-1.55)**
MF	-0.71 (1.18)	0.38 (1.58)	0.53 (2.23)	(-0.70-0.18)	(-0.95-0.27)	0.80 (0.44-1.17)**	0.72 (0.26-1.18)**
L-L Dep							
BDI-II							
BA	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51	-1.21	1.74 (-0.25-3.72)**	0.58 (-2.36-3.52)
MF	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)	(-2.36-1.34)	(-4.13-1.71)*	1.83 (-0.54-4.19)**	2.35 (-0.03-4.72)**
PHQ-9							
BA	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23	-0.98	2.06 (1.39-2.72)**	0.30 (-1.21-1.80)
MF	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)	(-1.20-0.74)	(-2.68-0.72)**	1.38 (0.19-2.59)*	2.13 (1.03-3.23)**
BAI							
BA	10.76 (7.33)	8.21 (4.10)	6.43 (7.80)	-0.56	-0.27	0.43 (-1.64-2.51)	0.59 (-1.98-3.16)
MF	9.08 (7.70)	5.91 (4.48)	4.67 (4.64)	(-2.17-1.04)	(-2.92-2.38)	0.51 (-1.95-2.98)	0.67 (-1.95-3.34)**
AAQ-II							
BA	26.00 (6.85)	20.50 (7.34)	21.21 (9.54)	-0.37	-0.87	0.80 (-1.61-3.21)**	0.61 (-2.17-3.39)
MF	26.46 (8.21)	17.52 (9.54)	14.00 (7.07)	(-3.52-2.78)	(-4.26-2.52)	1.06 (-2.33-4.44)*	1.68 (-1.42-4.78)**
QoLI							
BA	-0.37 (1.52)	1.14 (1.83)	0.97 (2.15)	-0.38	-0.93	0.94 (0.37-1.50)**	0.76 (0.13-1.38)*
MF	0.89 (1.61)	1.87 (2.24)	2.87 (2.10)	(-0.38-1.14)	(-1.77-0.10)	0.53 (-0.20-1.27)	1.14 (0.41-1.87)

Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep: Low-level depression; BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action Questionnaire; QOLI: Quality of Life Inventory.

* $p<0.05$.

** $p<0.01$.

CONSORT 2010 Flow Diagram



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6

	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	14
Protocol	24	Where the full trial protocol can be accessed, if available	14
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.