



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 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.

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3 • The aim of this study was to test the effects of two smartphone-delivered treatments; one based
4 on behavioral activation and the other on mindfulness. We expected that behavioral activation
5 would be superior to mindfulness for participants suffering from more severe depression.
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8 9 2) Key Messages

- 10 • This smartphone format works well for a depressed population.
- 11 • Behavioral activation might work better for a more severely depressed population, whereas
12 mindfulness might work better for people suffering from light depression, at least in this
13 smartphone format.
- 14 • Since smartphones likely will be integrated even further in society, they may be important in
15 the future of making depression treatment and other psychological treatment more assimilated
16 into people's daily life.

17 18 19 20 21 3) Strengths and Limitations.

- 22 • One of the first to do a randomized controlled trial using smartphone applications.
- 23 • Did not control for the different components separately, so we cannot determine which parts of
24 the treatments were effective.

25 26 27 28 29 30 **Keywords**

31 Depression, Behavioral activation, Smartphone application, Mindfulness.
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34 35 36 **Abstract**

37 **Objectives**

38 Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral
39 activation and the other on mindfulness.
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42 43 **Design**

44 Parallel randomized controlled, open, trial. Participants were allocated using an online
45 randomization tool (www.random.org), handled by an independent person who was separate
46 from the staff conducting the study.
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49 50 **Setting**

51 Open trial at a university psychological center in Sweden.
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54 55 **Participants**

56 40 participants diagnosed with major depressive disorder received a behavioral activation
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3 treatment, and 41 participants received a mindfulness treatment
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5 9 participants were lost to the post-treatment.
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8 **Intervention**

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10 Behavioral activation: A 8 week long behavior program administered via a smartphone
11 application. Mindfulness: A 8 week long mindfulness program, administered via a smartphone
12 application. □
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14 **Main outcome measures**

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16 The primary outcome measures were the Beck Depression Inventory-II (BDI-II) and the 9-item
17 Patient Health Questionnaire Depression Scale (PHQ-9). □
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20 **Results**

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22 81 participants (BA n=40; Mindfulness n=41) were randomized (mean age 36.0 years
23 (SD=10.8)). All were included in the intention to treat analysis. Within-group effects from pre-
24 measurement to post-measurement on BDI-II were $d=1.83$ CI [0.27-3.38] and $d=1.21$ CI [-0.95-
25 3.38] for the behavioral activation treatment and mindfulness treatment respectively. From pre-
26 measurement to 6-month follow-up, effects were $d=1.19$ CI [-0.87-3.24] and $d=1.09$ CI [-1.32-
27 3.50] respectively.
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31 **Conclusions**

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

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40 Clinical Trials NCT01463020.
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43 **Funding**

44
45 The Swedish Research Council, 2011-2476
46
47

48 **Background**

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50 Major depressive disorder (MDD) is a major health problem, which lowers the quality of life for
51 the individual and generates enormous costs for society^{1,2}. Several forms of psychotherapy have
52 been found to be effective in the treatment of MDD³. For example, behavioral activation has an
53 established empirical base⁴. The efficacy of behavioral activation for treating MDD has been
54 established in a number of studies over the past four decades⁵. Moreover, a dismantling study
55 showed that behavioral activation could be as effective as the full cognitive behavior therapy
56 (CBT) treatment package⁶. In addition, a series of reviews and meta-analyses also show that
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3 behavioral activation is at least as effective as the full CBT packages that include both cognitive
4 and behavioral components⁴. In a later study, behavioral activation was found to be as effective
5 as antidepressant medication⁷.
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9 It is also well established that guided self-help interventions, administered through internet, can
10 have positive effects on symptoms of depression⁸⁻¹⁰. An increasing number of studies show that
11 this treatment format can be as effective as face-to-face treatment for mild to moderate MDD and
12 anxiety disorders⁹. Guided treatments distributed digitally have provided a way to reach out to
13 more patients in a manner that in most cases requires less therapist time than face-to-face
14 psychotherapy¹¹. There are, however, to our knowledge no controlled trial on internet-delivered
15 pure behavioral activation, and no study using smartphones for the delivery of behavioral
16 activation, even if studies are being conducted on smartphone-administered CBT¹².
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20 An important feature of mobile technology is the possibility for the therapist to reach the patient
21 outside of the therapy room or when not sitting in front of the computer, and thus create direct
22 incentives for behavior change in the patient's everyday life¹³. Therefore, behavioral activation
23 is a treatment that could benefit from the use of new mobile technologies (for example
24 smartphones) by creating direct incentives for behavioral activation in patient's everyday life.
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28 The same applies for mindfulness. Mindfulness is often a component in the so called third wave
29 of CBT, such as mindfulness-based cognitive therapy (MBCT;¹⁴), dialectical behavior therapy
30 (DBT;¹⁵), and acceptance and commitment therapy (ACT;¹⁶). Studies have shown a significant
31 negative correlation between mindfulness and depression^{17 18}. Moreover, a meta-analysis based
32 on 39 studies of mindfulness for depression and anxiety showed a moderate effect size of
33 Hedges's $g=0.59$ for improving mood symptoms¹⁹. The analysis also showed that mindfulness
34 was effective for individuals with depression as both the primary diagnosis and the secondary.
35 Moreover, mindfulness has been shown to be effective in relapse prevention in depression²⁰.
36 Within digitally distributed treatments, mindfulness has appeared as a component in CBT-based
37 internet treatments, but there have so far been few studies on mindfulness as a stand-alone,
38 digitally distributed treatment for depression²¹.
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43 The advantages as well as the challenges of using mobile phones in CBT have been summarized
44 by Boschen and Casey¹³. One challenge with using the mobile phone as a platform for
45 psychological treatment is that the user must be able to interact with the program in an easy way
46¹³. Both behavioral activation and mindfulness are components in multi-component treatment
47 packages, and as such they might be easier to target in smartphone applications than an entire
48 treatment program would be, due to the need of simple and fast interaction with the treatment
49 program.
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53 At the same time, research suggests that depression severity is known to be a significant
54 moderating factor in the treatment of depression. For example, some initial evidence suggests
55 that there is a difference in efficacy between two forms of CBT in the treatment of the more
56 severely depressed patients^{7 22}. There are also indications that the difference between
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3 antidepressant medication and placebo is evident in severe depression, but not in mild to
4 moderate depression²³, and that combined treatments with medication and psychotherapy are
5 more effective than single treatments²². These results suggest that baseline depression severity
6 may moderate the response to different variants of treatments. Thus, it is concluded that different
7 treatments distributed digitally can target different subgroups of depression, in terms of severity.
8 For example, Dimidjian et al. (2006) found that among more severely depressed patients,
9 behavioral activation was comparable to antidepressant medication, and significantly
10 outperformed cognitive therapy, whereas for the less severely depressed patients, no differential
11 treatment effects were observed.
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16 The aim of this study was to test the effects of two smartphone-delivered treatments; one based
17 on behavioral activation and the other on mindfulness. The study was based on our previous
18 work on guided internet-treatment for depression²⁴, but in the current study the treatment
19 content was delivered entirely via the participants personal smartphone, using recently developed
20 smartphone applications. We expected, in line with Dimidjian and coworkers' conclusions (BA
21 relative to CT $d=0.87$ on BDI), that behavioral activation would be superior to mindfulness for
22 participants suffering from more severe depression with an expected between group effect size of
23 Cohen's $d=0.50$). In order to evaluate long-term effects, we also included a 6-month follow-up
24 after the start of the treatment.
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28 **Methods**

29 **Ethics statement**

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31 The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed
32 consent was obtained from all participants by surface mail.
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36 **Recruitment and selection**

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38 The participants were mainly recruited via mass media and advertisements in large Swedish
39 newspapers. Those who were interested were directed to a web page with information about the
40 study, the treatments being tested and how to participate in the study.
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44 Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥ 5 on
45 PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last
46 month, d) not being in any concurrent psychological treatment, e) not suffering from a severe
47 comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or
48 schizophrenia, assessed during a clinical interview), f) not having other primary medical
49 problems which would need other treatments first hand, g) not having severe alcohol problems
50 and h) major depression according to the DSM-IV, with at least an episode in partial remission.
51 The diagnosis of MDD was confirmed by a structured interview (see below). The interviews
52 were made over telephone by four MSc clinical psychology students. The principal research
53 executive reviewed all the protocols from the interviews together with the interviewers.
54 Questions regarding medication and psychiatric history that came up in the interview were
55 considered before the decision on inclusion was made.
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5 Of the 231 individuals who initially expressed interest in the study, 126 completed all the
6 questions in the online screening. Of these, 29 were excluded before the telephone interview
7 started. 13 individuals were excluded after the telephone interview. Eighty-four were
8 subsequently included after the interview had been conducted. Before the study started, three
9 participants chose not to participate in the study. The reasons for exclusion are specified in the
10 flowchart found in Figure 1.
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14 Among the randomized participants there were 70.3 % women ($n=57$) and 29.6 % men ($n=24$).
15 The mean age was 36.0 years ($SD=10.8$) ranging from 20 to 61 years. See Table 1 for additional
16 demographical data. There were no significant differences in demographic characteristics
17 between the groups according to chi-square analysis.
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20 21 **Outcome measures**

22 **Primary outcome measures.** The primary outcome measures were the Beck Depression
23 Inventory-II (BDI-II; ²⁵) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9;
24 ^{26 27}) that were administered pre-treatment, at post-treatment and also six months after the
25 treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire
26 treatment phase.
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30 **Secondary outcome measures.** In addition to the BDI-II and PHQ-9, the Beck Anxiety
31 Inventory (BAI; ²⁸), the Quality of Life Inventory (QOLI; ^{29 30}), the Trimbos and Institute of
32 Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; ³¹) and the
33 Acceptance and Action Questionnaire (AAQ-II; ³²) were administered. All other outcome
34 measures were collected at pre-treatment, post-treatment and at 6-month after the start of the
35 treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the
36 treatment started.
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40 **Clinician-administered measures.** Psychiatric diagnoses were assessed using the Mini-
41 International Neuropsychiatric Interview (M.I.N.I.; ³³). The M.I.N.I. is a diagnostic interview
42 that, in contrast to several other diagnostic interviews, is completely structured, making it
43 appropriate for other assessors than experienced psychiatrists ³³. All interviews were conducted
44 by the four psychology students described above, who at post-treatment were blind to
45 participant's condition. At the 6-month follow-up, the interviews were conducted by other
46 clinical psychology students who were blind to both the participant's condition and the treatment
47 they had been given. Recovery rates were defined as no longer fulfilling the criteria for
48 depression according to M.I.N.I.
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53 **Credibility.** The credibility of the two treatments showed a mean score of 31.9 ($SD=7.1$) for the
54 behavioral activation group and at 32.1 ($SD=7.8$) for the mindfulness group on the Borkovec and
55 Nau c-Scale ³⁴.
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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 $\alpha=.79$. 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 & Hopko³⁸. 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 study³⁹. 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

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3 (SMS). The messaging system was used by the therapists to send personal encouraging messages
4 every other, or every third day to the participants, as well as weekly general educational
5 messages. The system functioned as a one-way communication, which means that the
6 participants were not able to reply the messages.
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10 Apart from this, the participants were told to write a reflection to summarize every week for their
11 therapist and send it in via e-mail, in the end of every treatment week. The participants received
12 personal feedback on their reflection from their therapist.
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15 **Mindfulness treatment.** The mindfulness intervention, also an 8-week smartphone-based
16 intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and
17 a step-by-step mindfulness practice program, administered via a smartphone application. The
18 psychoeducation for the mindfulness intervention was equivalent to that of the behavioral
19 activation intervention, except that the theoretical basis of mindfulness was presented instead of
20 the theoretical basis of behavioral activation. The text was written specially for the current
21 intervention, but inspired by⁴⁰. In all, there were three chapters, totaling 9 pages of text,
22 containing 2 927 words.
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27 The smartphone application for Iphone was an established and commercially available
28 application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of
29 the application. For other smartphones, a mobile web application was built especially for the
30 current study with the aim of mimicking the Iphone application. The application consisted of a
31 number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises
32 were both guided and unguided, and in short (three minutes) and long (30 minutes) format.
33 Through the initial psychoeducation, the participants were guided to start with short mindfulness
34 exercises.
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38 Since the mindfulness application did not have a communication system such as the behavioral
39 activation application, e-mails were used to emulate the messaging system in the behavioral
40 activation application. Hence, the therapists sent encouraging messages every other, or every
41 third day to the participants, as well as weekly general educational messages via mail.
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45 Additionally, the participants given the mindfulness intervention were also told to write a
46 reflection to summarize every week for their therapist. The participants received personal
47 feedback on their reflection from their therapist.
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51 **Therapists.** The therapists were four final-semester students from a five-year M.Sc. clinical
52 psychologist program. All therapists had completed their clinical training as well as 16 weeks of
53 internship. Each therapist was responsible for the treatment of 8 to 10 participants from the
54 behavioral activation group and an equal number of participants from the mindfulness group.
55 Therapists were randomly allocated to participants, with the restriction of not having more than
56 10 participants from each group. For the entire duration of the study the therapists received
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3 continuous supervision from an experienced psychotherapist with CBT orientation, who had
4 previous experience of working with a behavioral activation treatment manual.
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7 8 **Subgroups based on cut-off scores**

9 All randomized participants were classified into groups of either high or low severity of
10 depression. These classes were formed based on the cut-offs scores on the PHQ-9. The
11 participants were considered to suffer from higher severity of depression if they scored ≥ 10 on
12 PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of
13 moderate character ($n=51$). Participants, not fulfilling these criteria were considered to suffer
14 from lower severity of depression ($n=30$).
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17 18 **Data analysis**

19 All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t-tests and
20 χ^2 -tests were used to test for group differences in demographics, pre-treatment data and in
21 clinical significant improvement. Differences between the behavioral activation treatment and
22 the mindfulness treatment were primarily investigated by modeling interaction effects of group
23 and time. For the PHQ-9, where weekly measures were available, the continuous outcome
24 variable was analyzed using mixed effects models, given their ability to handle missing data⁴¹.
25 Random intercept models were selected. Also, several models were compared using available
26 information criteria, and the model with best fit was chosen. The covariance between the random
27 intercept and slope was not significant, and therefore was not included in the model. Error terms
28 across time were modeled with a first-order autoregressive covariance structure with
29 heterogeneous variances. Differences in average rates of growth between the two groups were
30 examined by a fixed effects interaction between group and time. Between-group differences at
31 post-treatment were analyzed using independent t-tests. Power analysis indicated an 89% chance
32 of detecting a between-group effect size of $d=0.60$ (α level=0.05). Within- and between-group
33 effect sizes (Cohen's d) were calculated by dividing the differences in means by the pooled
34 standard deviations⁴².
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42 **Results**

43 The two groups did not differ significantly on any of the measures at pretreatment ($t=0.50$ to
44 0.67 , $df=79$, $p=0.78$ to 0.50). The results will be presented in the following order: attrition and
45 adherence, self-report inventories (including effect size) both for the whole sample and the
46 subgroups, recovery rates and treatment credibility.
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49 **Attrition and adherence**

50 Of the 84 participants randomized, three participants decided not to participate in the study. Nine
51 out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these
52 (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved.
53 In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data
54 on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once
55 again, those unreachable were classified as unimproved.
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5 Adherence to treatment was defined as the number of weekly reflections the participants sent to
6 their therapist. In order to be considered as a completed week, at least one reflection had to have
7 been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere
8 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 ($M=5.8$, $SD=2.47$).

14 Primary outcome measure

15 No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found
16 between the groups, neither from pre-treatment to post-treatment, nor from pre-treatment to the
17 6-month follow up. However, as evident from Table 3, large within-group effect sizes were
18 found on PHQ-9 and BDI-II, between pre-treatment and post-treatment, as well as between pre-
19 treatment to the 6-month follow up. This was the case for both the behavioral activation
20 treatment and the mindfulness-treatment.
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24 Subgroup analyses

25 A mixed-effects model analysis on the PHQ-9 revealed significant interaction effects of group
26 and time in favor for the behavioral activation group. Thus, the results indicated a difference
27 between the groups from pre-treatment to 6-month follow-up ($F(1, 362.1)=5.2$, $p's<.05$). As seen
28 in Table 3, the effect size between the groups at 6-month follow-up was small, but close to
29 medium (Cohen's $d=0.47$; CI [-1.46, 2.40]).
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34 For the more mildly depressed participants there was a significant effect in favor of the
35 mindfulness group from pre-treatment to 6-month follow-up on PHQ-9 ($F(1, 69.3)=7.7$,
36 $p's<.01$). The effect size between the groups at 6-month follow-up was, as evident from Table 3,
37 large (Cohen's $d=0.96$)
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41 Secondary outcome measure

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

51 There were no significant differences in recovery rates between the groups, neither at post-
52 treatment nor at the 6-month follow-up. This was the case both when analyzing the whole sample
53 as well as the subgroups. When analyzing the whole sample, 73.5 % ($n=25$) in the behavioral
54 activation group recovered after treatment, compared to 53.1 % ($n=17$) in the mindfulness group
55 ($\chi^2(N=66, df=1)=2.97$, $p=.071$). At the 6-month follow-up, 30 out of 34 participants (88.2 %)
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3 from the behavioral activation group had recovered, and 26 out of 32 participants (81.3 %) from
4 the mindfulness group had recovered ($\chi^2(N=66, df=1)=.63, p=.327$).

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

14 15 16 17 **Credibility and therapist time**

18 An independent t-test showed no significant difference between the two groups on the C-scale (t
19 (78)= $0.12, p=0.90$). Furthermore, the C-scale did not correlate significantly with any of the
20 outcome measures, either for all participants combined ($r=0.13, p=0.27$), for the behavioral
21 activation group ($r=0.01, p=0.92$) or for the mindfulness group ($r=.23, p=.18$).

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

28 29 30 31 **Discussion**

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

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

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55 The result from the analysis of the higher severity participants is in line with earlier⁷ findings.
56 For example, Dimidjian et al (2006) showed that behavioral activation was comparable in
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3 efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only
4 among those patients who were more severely depressed. In line with this, Beck and colleagues
5⁴³ have long suggested that therapists should focus on behavioral strategies early in treatment
6 when patients are more depressed and return to that emphasis later if patients start to worsen.
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9 The result from the analysis of the less severely depressed participants was unexpected to us.
10 Although there is yet only initial evidence that mindfulness treatment is effective for acute or
11 severely depressed^{44 45}, mindfulness has proven to be effective for relapse prevention of
12 depression^{20 46 47}. That gives implications that a mindfulness-based treatment administered
13 through smartphone will work better for people suffering from mild depression. However, the
14 fact that the mindfulness-based treatment worked significantly better than the behavioral
15 activation-treatment was surprising to us. One explanation could be that the less severely
16 depressed participants suffered more from stress and anxiety rather than depression. This
17 population would then not be in need of a treatment that encourages more activation. Instead, a
18 mindfulness treatment could work very well for this kind of problems^{19 48}.
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24 Limitations

25 There are a number of limitations that need to be mentioned. The first and is that it is impossible
26 to determine which parts of the treatments were effective. Since we did not control for the
27 different components separately, we cannot, for example, rule out that the result was mainly an
28 effect of the therapist support. An additional treatment arm with only therapist support would
29 make it possible to rule out this question.
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32 A second limitation is that the study was underpowered. Thus, it is difficult to detect significant
33 overall differences between the two smartphone-treatments, even if significant interaction effects
34 were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc
35 power analysis revealed that a sample of 393 participants was required to detect small between-
36 group effects.
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39 A third limitation was that the participants were recruited nationally through mass media and
40 advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g.
41 an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II
42 at intake ($M=24.10$) is rather close to the limit of 29 proposed for defining severe depression²⁵.
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45 Fourth, we recruited a broad range of participants, with regards to the severity of depression (a
46 minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a
47 specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis
48 showed that participants with higher severity of depression responded to the behavioral
49 activation significantly better than the treatment based on mindfulness, whereas the treatment
50 based on mindfulness worked significantly better than the treatment based on behavioral
51 activation for the participants with lower initial. Additionally, it can be argued that these broad
52 inclusion criteria reflect a real population of individuals with depressive disorders.
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55 A fifth related concern was the large number of participants who had college- or university level
56 education (65.5 %). This might bias generalizability of the results, since it is possible that guided
57 self-help is especially well suited for educated clients. However, there are data indicating that 50
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3 % of patients seeking psychotherapy have some college education⁴⁹ and that educated patients
4 may be more inclined to seek help for mental health problems⁵⁰.
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7 Some clinical implications of this study are discussed as follows. Due to the need for simple and
8 fast interaction with the treatment program, singular treatment components such as behavioral
9 activation and mindfulness might be a better target for smartphone applications than entire multi-
10 component treatment packages. At the same time, there is a need for guided self-help treatments
11 distributed digitally that can reach out to more patients. This study is one of the first to test a
12 treatment for depression, administered via smartphone. The large within-group effects on the
13 primary outcome measures, as well as the large recovery rates for both groups, indicate that this
14 smartphone format with a small amount of text and minimal therapist support, works well for a
15 depressed population.
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19 Moreover, this study also shows that behavioral activation might work better for a more severely
20 depressed population, whereas mindfulness might work better for people suffering from light
21 depression. These results strengthen the hypothesis that different treatments distributed digitally
22 can target different subgroups of depression, in terms of severity.
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25 From a broader perspective, we believe that smartphones will be integrated even further in
26 society since they are already socially accepted as well as relatively cheap for the functionalities
27 you get¹³, and therefore may serve an important role in health care. Therefore these results,
28 showing that mild to moderate depression can be treated effectively by means of a supported
29 smartphone-application, might be important in the future of making depression treatment and
30 other psychological treatment more assimilated into people's daily life. As suggested in Ly et al.
31 (2012), the smartphone format might also help increasing the awareness of being in treatment in
32 everyday settings, and therefore better help clients create direct incentives for treatment related
33 activities in their everyday life³⁹. Using smartphones to distribute psychological treatment might
34 also help making it possible to reach out with psychological therapy to a broader group of
35 people, since their use attracts no attention¹³, allowing users to interact with a device without
36 fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones are not
37 only relevant for Swedish conditions but also for the developing countries in the world, which
38 increasingly are empowered by mobile phones with internet connection.
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42 This study might open up for a broad range of other trials conducted via smartphones, both for
43 self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a
44 substantial part of internet-based interventions in the future will be executed through
45 smartphones or at least supported by smartphones. Further studies should focus on both formats,
46 as well as expanding the treatment platform to other psychological disorders.
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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 Medication	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
	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

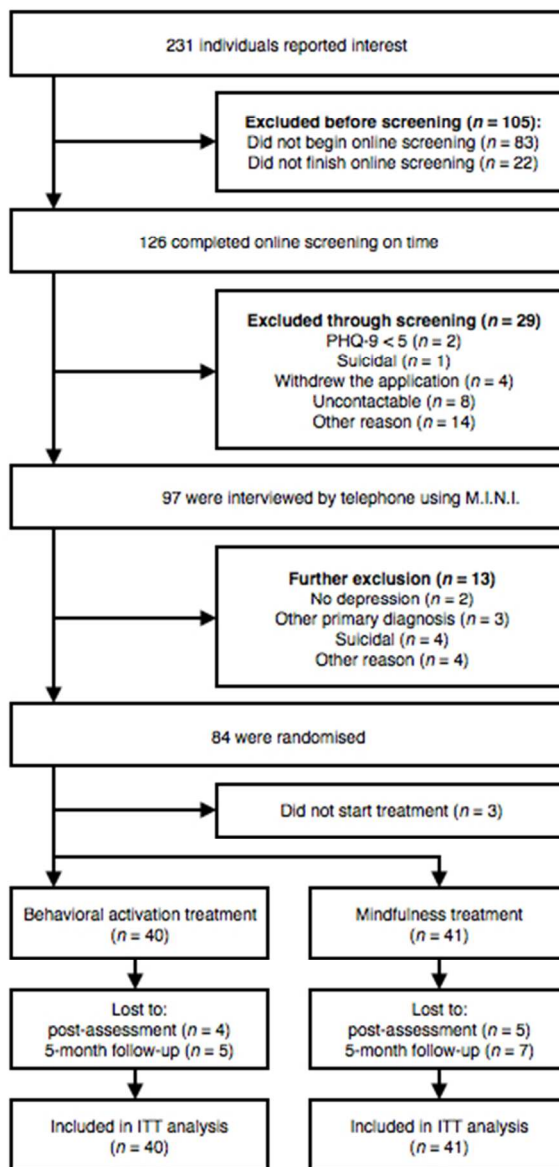
Buy or borrow a book I wanted to read
 Read at least 20 minutes out of a book
 Go to a new cafe and coffee
 Look up the nearest training center is
 Read on about training online
 Post a workout plan for the week
 Ask a friend if he / she wants to come along and train
 Spend at least 30 minutes of physical 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)			Effect size, <i>d</i> (95% CI)			
	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-	0.03 (-2.63-	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)	2.15 (0.85-	2.69 (1.69-	1.21 (-0.95-3.38)	1.09 (-1.32-3.50)
PHQ-9							
Behavioral activation	12.53 (4.43)	5.83 (3.85) (7.19 (5.84))	6.77 (5.83) (7.74 (7.33))	0.28 (-1.97-	0.15 (-1.39-	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)	1.40 (0.45-	1.69 (0.51-	1.15 (-0.02-2.32)	0.91 (-0.44-2.27)
BAI							
Behavioral activation	14.60 (9.09)	8.81 (5.77) (9.22 (7.68))	8.34 (8.50) (8.38 (7.48))	0.06 (-1.49-	0.01 (-1.86-	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)	1.61 (0.45-	1.87 (0.51-	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-	0.10 (-2.10-	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)	2.41 (0.45-	2.31 (0.51-	0.56 (-1.44-2.54)	0.87 (-1.00-2.74)
QoLI							
Behavioral activation	-0.45 (1.38)	0.92 (1.66) (0.84 (1.90))	1.15 (2.40) (1.13 (2.07))	0.05 (-0.36-	0.01 (-0.53-	0.91 (0.58-1.25) 0.62 (0.24-0.99)	0.84 (0.41-1.27) 0.75 (0.36-1.15)
Mindfulness	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)	0.45 (0.45-	0.51 (0.51-		
High level depression							
BDI-II							
Behavioral activation	26.87 (7.14)	12.00 (6.31)	11.81 (10.63)	0.42 (-2.09-	0.39 (-2.95-	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)	2.93 (0.45-	3.73 (0.51-	1.62 (-0.44-3.67)	1.32 (-1.07-3.71)
PHQ-9							
Behavioral activation	15.52 (3.29)	6.64 (4.42) (8.60 (6.29))	6.48 (5.59) (9.60 (7.71))	0.36 (-1.17-	0.47 (-1.46-	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)	1.90 (0.45-	2.40 (0.51-	1.43 (0.13-2.74)	1.05 (-0.49-2.58)
BAI							
Behavioral activation	17.43 (9.37)	9.18 (6.68) (10.68)	9.62 (8.91) (9.72 (7.91))	0.20 (-1.94-	0.01 (-2.36-	1.03 (-1.30-3.37)	0.87 (-1.77-3.52)
Mindfulness	15.57 (9.39)	8.39 (8.39)	9.72 (7.91)	2.34 (0.45-	2.38 (0.51-	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-	0.47 (-2.16-	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)	3.18 (0.45-	3.09 (0.51-	0.38 (-1.90-2.65)	0.70 (-1.40-2.80)
QoLI							
Behavioral activation	-0.51 (1.30)	0.78 (1.58) (0.38 (1.58))	1.25 (2.07) (0.53 (2.23))	0.26 (-0.70-	0.34 (-0.95-	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)	0.18 (0.45-	0.27 (0.51-	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) (6.73 (4.86))	14.07 (10.71)	-0.51 (-2.36-	-1.18 (-4.59-	1.74 (-0.25-3.72)	0.58 (-2.36-3.52)
Mindfulness	17.54 (7.09)	4.86 (4.86)	4.22 (3.63)	1.34 (0.45-	2.23 (0.51-	1.83 (-0.54-4.19)	2.35 (-0.03-4.72)
PHQ-9							
Behavioral activation	8.47 (1.59)	4.57 (2.34) (4.00 (2.86))	7.21 (6.36) (2.56 (1.51))	-0.23 (-1.20-	-0.97 (-2.94-	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)	0.74 (0.45-	1.03 (0.51-	1.38 (0.19-2.59)	2.13 (1.03-3.23)
BAI							
Behavioral activation	10.76 (7.33)	8.21 (4.10) (5.91 (4.48))	6.43 (7.80) (4.67 (4.64))	-0.56 (-2.17-	-0.27 (-2.92-	0.43 (-1.64-2.51)	0.59 (-1.98-3.16)
Mindfulness	9.08 (7.70)	4.48 (4.48)	4.67 (4.64)	1.04 (0.45-	2.38 (0.51-	0.51 (-1.95-2.98)	0.67 (-1.95-3.34)
AAQ-II							

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3	Behavioral	26.00	20.50	21.21	-0.37 (-	-0.87 (-	0.80 (-1.61-
4	activation	(6.85)	(7.34)	(9.54)	3.52-	4.26-	3.21)
5	Mindfulness	26.46	17.52	14.00	2.78)	2.52)	1.06 (-2.33-
6		(8.21)	(9.54)	(7.07)			4.44)
7	QoLI						
8	Behavioral	-0.37	1.14 (1.83)	0.97 (2.15)	-0.38 (-	-0.93 (-	0.94 (0.37-
9	activation	(1.52)	1.87 (2.24)	2.87 (2.10)	0.38-	1.77--	1.50)
10	Mindfulness	0.89 (1.61)			1.14)	0.10)	0.53 (-0.20-
11							1.14 (0.41-
12							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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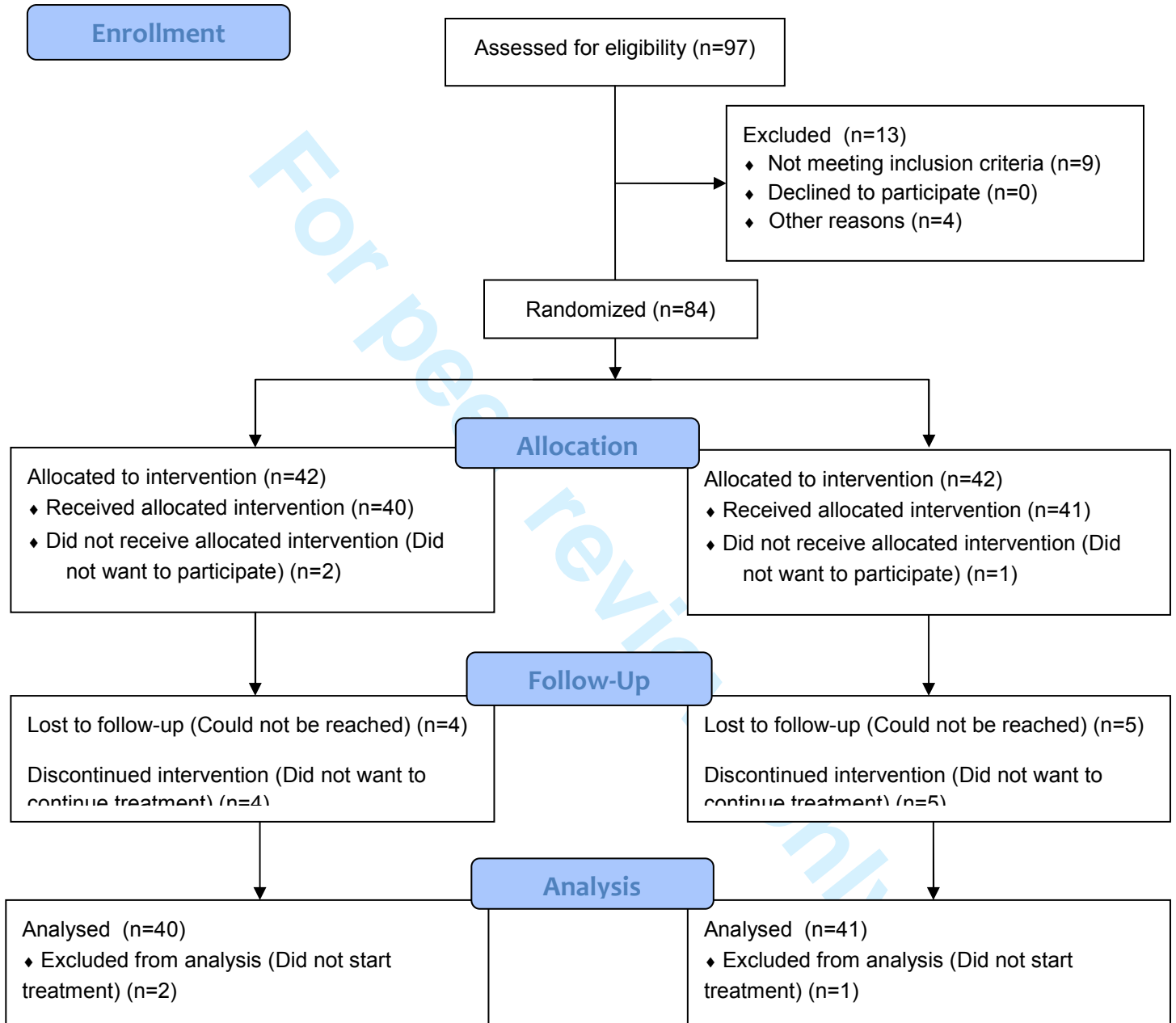
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CONSORT 2010 Flow Diagram





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

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3		11b	If relevant, description of the similarity of interventions
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
6			
7	Results		
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
9	diagram is strongly		were analysed for the primary outcome
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up
12		14b	Why the trial ended or was stopped
13			
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
16			by original assigned groups
17			
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
19	estimation		precision (such as 95% confidence interval)
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
22			pre-specified from exploratory
23			
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
25			
26	Discussion		
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
30			
31	Other information		
32	Registration	23	Registration number and name of trial registry
33	Protocol	24	Where the full trial protocol can be accessed, if available
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
35			

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37 *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

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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

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Manuscripts

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.

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3 • The aim of this study was to test the effects of two smartphone-delivered treatments; one based
4 on behavioral activation and the other on mindfulness. We expected that behavioral activation
5 would be superior to mindfulness for participants suffering from more severe depression.
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8 9 2) Key Messages

10 • The large within-group effect sizes are comparable to other depression treatment and indicate
11 that this smartphone format might work well for a depressed population.
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13 • Behavioral activation might work better for a more severely depressed population, whereas
14 mindfulness might work better for people suffering from light depression, at least in this
15 smartphone format.
16

17 • Since smartphones likely will be integrated even further in society, they may be important in
18 the future of making depression treatment and other psychological treatment more assimilated
19 into people's daily life.
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22 23 3) Strengths and Limitations.

24 • One of the first to do a randomized controlled trial using smartphone applications.
25

26 • Did not control for the different components separately, so we cannot determine which parts of
27 the treatments were effective.
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31 32 **Keywords**

33 Depression, Behavioral activation, Smartphone application, Mindfulness.
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37 38 **Abstract**

39 **Objectives**

40 Evaluating the effectiveness of two smartphone-delivered treatments; one based on behavioral
41 activation and the other on mindfulness.
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45 **Design**

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

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

The Swedish Research Council, 2011-2476

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 MDD³. For example, behavioral activation has an established empirical base⁴. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades⁵. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package⁶. 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 components⁴. In a later study, behavioral activation was found to be as effective as antidepressant medication⁷.

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression⁸⁻¹⁰. 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 disorders⁹. 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 psychotherapy¹¹. 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 CBT¹².

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 life¹³. 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 symptoms¹⁹. 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 depression²⁰. 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 depression²¹.

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey¹³. 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 way¹³. Both behavioral activation and mindfulness are components in multi-component treatment

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3 packages, and as such they might be easier to target in smartphone applications than an entire
4 treatment program would be, due to the need of simple and fast interaction with the treatment
5 program.
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9 At the same time, research suggests that depression severity is known to be a significant
10 moderating factor in the treatment of depression. For example, some initial evidence suggests
11 that there is a difference in efficacy between different forms of CBT in the treatment of the more
12 severely depressed patients^{7,22}. There are also indications that the difference between
13 antidepressant medication and placebo is evident in severe depression, but not in mild to
14 moderate depression²³, and that combined treatments with medication and psychotherapy are
15 more effective than single treatments²². These results suggest that baseline depression severity
16 may moderate the response to different variants of treatments. Thus, it is concluded that different
17 treatments distributed digitally can target different subgroups of depression, in terms of severity.
18 For example, Dimidjian et al. (2006) found that among more severely depressed patients,
19 behavioral activation was comparable to antidepressant medication, and significantly
20 outperformed cognitive therapy, whereas for the less severely depressed patients, no differential
21 treatment effects were observed.
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26 The aim of this study was to test the effects of two smartphone-delivered treatments; one based
27 on behavioral activation and the other on mindfulness. Hence, the main question is whether
28 behavioral activation is more effective than mindfulness delivered over smartphone. The study
29 was based on our previous work on guided internet-treatment for depression²⁴, but in the current
30 study the treatment content was delivered entirely via the participants personal smartphone,
31 using recently developed smartphone applications. We expected, in line with Dimidjian and
32 coworkers' conclusions (BA relative to CT $d=0.87$ on BDI), that behavioral activation would be
33 superior to mindfulness for participants suffering from more severe depression with an expected
34 between group effect size of Cohen's $d=0.50$). In order to evaluate long-term effects, we also
35 included a 6-month follow-up after the start of the treatment.
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40 **Methods**

41 **Ethics statement**

42 The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed
43 consent was obtained from all participants by surface mail.
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48 **Recruitment and selection**

49 The participants were mainly recruited via mass media and advertisements in large Swedish
50 newspapers. Those who were interested were directed to a web page with information about the
51 study, the treatments being tested and how to participate in the study.
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55 Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥ 5 on
56 PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last
57 month, d) not being in any concurrent psychological treatment, e) not suffering from a severe
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3 comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or
4 schizophrenia, assessed during a clinical interview), f) not having other primary medical
5 problems which would need other treatments first hand, g) not having severe alcohol problems,
6 h) no assessed risk of being suicidal (see below for details) and i) major depression according to
7 the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed
8 by a structured interview (see below). Additionally, an assessment of suicidal ideation was
9 conducted. The interviews were made over telephone by four MSc clinical psychology students.
10 The principal research executive reviewed all the protocols from the interviews together with the
11 interviewers. Questions regarding medication and psychiatric history that came up in the
12 interview were considered before the decision on inclusion was made.
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17 Of the 231 individuals who initially expressed interest in the study, 126 completed all the
18 questions in the online screening (22 did not finish the screening and 83 did not begin the
19 screening). Of these, 29 were excluded before the diagnostic interview started. 13 individuals
20 were excluded after the diagnostic interview. Eighty-four were subsequently included after the
21 interview had been conducted. Before the study started, three participants chose not to participate
22 in the study. The reasons for exclusion are specified in the flowchart found in Figure 1.
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26 Among the randomized participants there were 70.3 % women ($n=57$) and 29.6 % men ($n=24$).
27 The mean age was 36.0 years ($SD=10.8$) ranging from 20 to 61 years. See Table 1 for additional
28 demographical data. There were no significant differences in demographic characteristics
29 between the groups according to chi-square analysis.
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33 Outcome measures

34 **Primary outcome measures.** The primary outcome measures were the Beck Depression
35 Inventory-II (BDI-II; ²⁵) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9;
36 ^{26 27}) that were administered pre-treatment, at post-treatment and also six months after the
37 treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire
38 treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10
39 measurements on the outcome PHQ-9.
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43 **Secondary outcome measures.** In addition to the BDI-II and PHQ-9, the Beck Anxiety
44 Inventory (BAI; ²⁸), the Quality of Life Inventory (QOLI; ^{29 30}), the Trimbos and Institute of
45 Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; ³¹) and the
46 Acceptance and Action Questionnaire (AAQ-II; ³²) were administered. The AAQ-II was
47 administered on a weekly basis during the entire treatment phase (8 weeks). All other outcome
48 measures were collected at pre-treatment, post-treatment and at 6-month after the start of the
49 treatment, except for the TIC-P that was collected at pre-treatment and at 6-month after the
50 treatment started. Hence, there were two measurements on the outcome TIC-P, three
51 measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II.
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56 **Clinician-administered measures.** Psychiatric diagnoses were assessed at pre-treatment, post-
57 treatment and at 6-month after the start of the treatment, using the Mini-International
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3 Neuropsychiatric Interview (M.I.N.I.;³³). The M.I.N.I. is a diagnostic interview that, in contrast
4 to several other diagnostic interviews, is completely structured, making it appropriate for other
5 assessors than experienced psychiatrists³³. All interviews were conducted by the four
6 psychology students described above, who at post-treatment were blind to participant's
7 condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology
8 students who were blind to both the participant's condition and the treatment they had been
9 given. Recovery rates were defined as no longer fulfilling the criteria for depression according to
10 M.I.N.I.
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14 **Treatment credibility.** To measure treatment credibility, Borkovec and Nau's
15 Credibility/expectancy scale (C-Scale)³⁴ was used. The C-scale measures the way in which
16 participants view the logic of the treatment (credibility) and the improvements that can be
17 achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after
18 the first week of treatment.
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22 23 **Procedure and design**

24 For those participants included in the study, the results from the online screening were used as
25 pre-treatment assessment. All measures used have been shown to have good psychometric
26 properties, with internal consistencies of at least $\alpha=.79$. Details of this can be found in the
27 respective references of the outcome questionnaires. The outcome measures used have
28 established good psychometric properties, also when administered via the internet^{35 36}.
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32 After the recruitment, participants were allocated using an online randomization tool
33 (www.random.org), handled by an independent person who was separate from the staff
34 conducting the study.
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38 39 **The interventions**

40 **Behavioral activation treatment.** An 8-week smartphone-based behavioral activation
41 intervention with minimal therapist contact was developed by our research group. The
42 intervention consisted of a short web-based psychoeducation, and a step-by-step behavior
43 program administered via a smartphone application. The psychoeducation aimed to introduce the
44 participants to the treatment, touching on topics like the prevalence of depression, its etiology
45 and maintenance factors based on operant conditioning, as well as the theoretical basis for
46 behavioral activation. The text was written specially for the current intervention, but inspired by
47 Martell et al.³⁷ and Lejuez, Hopko & Hopko³⁸. In all, there were three chapters, totaling 11
48 pages of text, containing 3 893 words.
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52 The smartphone application was built as a native application for Iphone and a mobile web
53 application for other smartphones. See Figure 2 for a screenshot of the application. A prototype
54 of the smartphone application was tested in a pilot study³⁹. This prototype, however, was not
55 specifically designed for depression interventions. The purpose of the behavioral activation
56 application was to make it easy for the participant to remember and register important behaviors,
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3 in order to increase everyday activation. The application contained a database of 54 behaviors,
4 divided into three different areas for the participant to add to their application. See Table 2 for
5 the list of behaviors from the database. The database aimed to provide suggestions, help, and
6 inspiration to get started with the application. Participants were also able to add their own areas
7 and behaviors into the application to start tracking. Through the initial psychoeducation, the
8 participants were guided to add few (between two and four) and easy behaviors from start,
9 mainly from the database.
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14 When a behavior was completed, the participant could mark this in the application and add a
15 short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative
16 data (i.e. reflections) were presented in the application for the participant.
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20 There was also a back-end system where all the quantitative and qualitative data from the
21 participants was accessible for the therapist. From the back-end system, the therapist could send
22 short text messages to the participants via a messaging system, similar to Short Message Service
23 (SMS). The messaging system was used by the therapists to send personal encouraging messages
24 every other, or every third day to the participants, as well as weekly general educational
25 messages. The system functioned as a one-way communication, which means that the
26 participants were not able to reply the messages.
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30 Apart from this, the participants were told to write a reflection to summarize every week for their
31 therapist and send it in via e-mail, in the end of every treatment week. The participants received
32 personal feedback on their reflection from their therapist. No sensitive data was saved on a
33 computer, in which the person providing data could be identified. In addition, all internet and
34 smartphone activities was secured, with encrypted information.
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38 **Mindfulness treatment.** The mindfulness intervention, also an 8-week smartphone-based
39 intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and
40 a step-by-step mindfulness practice program, administered via a smartphone application. The
41 psychoeducation for the mindfulness intervention was equivalent to that of the behavioral
42 activation intervention, except that the theoretical basis of mindfulness was presented instead of
43 the theoretical basis of behavioral activation. The text was written specially for the current
44 intervention, but inspired by Williams et al.⁴⁰. In all, there were three chapters, totaling 9 pages
45 of text, containing 2 927 words.
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49 The smartphone application for Iphone was an established and commercially available
50 application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of
51 the application. For other smartphones, a mobile web application was built especially for the
52 current study with the aim of mimicking the Iphone application. The application consisted of a
53 number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises
54 were both guided and unguided, and in short (three minutes) and long (30 minutes) format.
55 Through the initial psychoeducation, the participants were guided to start with short mindfulness
56 exercises.
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5 Since the mindfulness application did not have a communication system such as the behavioral
6 activation application, e-mails were used to emulate the messaging system in the behavioral
7 activation application. Hence, the therapists sent encouraging messages every other, or every
8 third day to the participants, as well as weekly general educational messages via mail. The
9 difference in how the therapists communicated in the mindfulness intervention, compared with
10 the behavioral activation intervention, was that the therapists could not give specific feedback on
11 activities or exercises that the participants had done. Otherwise, the communication was similar
12 (length and type of content).
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16 Additionally, the participants given the mindfulness intervention were also told to write a
17 reflection to summarize every week for their therapist and send it in via e-mail. The participants
18 received personal feedback on their reflection from their therapist.
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22 **Therapists.** The therapists were four final-semester students from a five-year M.Sc. clinical
23 psychologist program. All therapists had completed their clinical training as well as 16 weeks of
24 internship. Each therapist was responsible for the treatment of 8 to 10 participants from the
25 behavioral activation group and an equal number of participants from the mindfulness group.
26 Therapists were randomly allocated to participants, with the restriction of not having more than
27 10 participants from each group. For the entire duration of the study the therapists received
28 continuous supervision from an experienced psychotherapist with CBT orientation, who had
29 previous experience of working with a behavioral activation treatment manual.
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33 **Subgroups based on cut-off scores**

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

45 All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent *t*-tests and
46 χ^2 -tests were used to test for group differences in demographics, pre-treatment data and in
47 recovery rates. In order to adhere to the intention-to-treat principle, the continuous outcome
48 variables (except from TIC-P, that was not analyzed as part of this study) were analyzed using
49 mixed effects models, given their ability to handle missing data⁴¹. All analyses used Maximum
50 Likelihood estimation. Random intercept models were selected for all measures. Differences
51 between the behavioral activation treatment and the mindfulness treatment were primarily
52 investigated by modeling interaction effects of group and time. For the PHQ-9 and the AAQ-II,
53 where weekly measures were available, the covariance between the random intercept and slope
54 was not significant, and therefore was not included in the model. Hence, a random intercept
55 model was used also for these measures. Between-group differences at post-treatment were
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3 analyzed using independent *t*-tests. Power analysis indicated an 89 % chance of detecting a
4 between-group effect size of $d=0.60$ (α level=0.05). Within- and between-group effect sizes
5 (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard
6 deviations⁴². This was done both from pre-measurements to post-measurements, and from pre-
7 measurements to the 6-month follow up data.
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10 11 12 **Results**

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14 The two groups did not differ significantly on any of the measures at pretreatment ($t=0.50$ to
15 0.67 , $df=79$, $p=0.78$ to 0.50). The results will be presented in the following order: attrition and
16 adherence, self-report inventories (including effect size) both for the whole sample and the
17 subgroups, recovery rates and treatment credibility.
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20 21 **Attrition and adherence**

22 Of the 84 participants randomized, three participants decided not to participate in the study. Nine
23 out of these 81 participants (11.1 %) did not provide post-treatment data. Six out of these
24 (totaling 7.4 %) were unreachable for the telephone interview and were classified as unimproved.
25 In the 6-month follow-up, 69 participants from the two treatment groups (85.2 %) provided data
26 on the self-report measures and 59 (72.8 %) were reached for the telephone interview. Once
27 again, those unreachable were classified as unimproved.
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31 Adherence to treatment was defined as the number of weekly reflections the participants sent to
32 their therapist. In order to be considered as a completed week, at least one reflection had to have
33 been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere
34 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 ($M=5.8$, $SD=2.47$).
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40 41 **Primary outcome measure**

42 No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found
43 between the groups, neither from pre-treatment to post-treatment (PHQ-9: ($F(1, 501.47)=.28$,
44 $p's=.60$); BDI-II: ($F(1, 74.11)=.28$, $p's=.60$)), nor from pre-treatment to the 6-month follow up
45 (PHQ-9: ($F(1, 571.49)=.36$, $p's=.55$); BDI-II: ($F(1, 147.96)=.09$, $p's=.77$)). However, as evident
46 from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-
47 treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This
48 was the case for both the behavioral activation treatment and the mindfulness-treatment.
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51 52 **Subgroup analyses**

53 For the participants suffering from high severity of depression (≥ 10 on the PHQ-9 and an
54 ongoing primary diagnosis of major depression of moderate character), a mixed-effects model
55 analysis on the PHQ-9 revealed significant interaction effects of group and time in favor for the
56 behavioral activation group. Thus, the results indicated a difference between the groups from
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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: ($F(1, 76.43)=.106, p's=.31$)), 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 ($\chi^2(N=66, df=1)=2.97, p=.07$). 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 ($\chi^2(N=66, df=1)=.63, p=.33$).

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 ($\chi^2(N=51, df=1)=3.03, p=.07$). 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 ($\chi^2(N=51, df=1)=1.55, p=.20$).

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-Scale³⁴.

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3 An independent t-test showed no significant difference between the two groups on the C-scale (t
4 (78)=0.12, $p=0.90$). Furthermore, the C-scale did not correlate significantly with any of the
5 outcome measures, either for all participants combined ($r=0.13$, $p=0.27$), for the behavioral
6 activation group ($r=0.01$, $p=0.92$) or for the mindfulness group ($r = .23$, $p = .18$).
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10 The therapist time per participant and week varied depending on whether the participant had sent
11 a reflection or not. The therapists reported a span between 2 and 18 minutes per week and
12 participants. However, the therapist time did not differ between the two treatment groups.
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15 Discussion

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17 The overall aim of this study was to investigate the effects of two smartphone-delivered
18 treatments for people suffering from mild to moderate major depression; one based on behavioral
19 activation and the other on mindfulness. Hence, the main question was whether behavioral
20 activation is more effective than mindfulness delivered over smartphone. When analyzing the
21 whole sample as one entity, the result showed that the two interventions did not differ
22 significantly from one another; neither from pre-treatment to post-treatment, nor from pre-
23 treatment to the 6-month follow-up on any of the outcome measures. Also, there were no
24 significant differences in recovery rates between the groups, neither at post-treatment nor at the
25 6-month follow-up.
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32 This study also explored how different levels of initial depression severity could moderate
33 response to the different interventions. All randomized participants were classified into either
34 high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled
35 the criteria for an ongoing primary diagnosis of major depression. For participants with higher
36 severity of depression, the treatment based on behavioral activation was superior to the treatment
37 based on mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial
38 severity, the treatment based on mindfulness worked better than the treatment based on
39 behavioral activation, as measured with PHQ-9 and BDI-II.
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44 The result from the analysis of the higher severity participants is in line with earlier⁷ findings.
45 For example, Dimidjian et al (2006) showed that behavioral activation was comparable in
46 efficacy to antidepressant medication, and more efficacious than cognitive therapy - but only
47 among those patients who were more severely depressed. In line with this, Beck and colleagues
48⁴³ have long suggested that therapists should focus on behavioral strategies early in treatment
49 when patients are more depressed and return to that emphasis later if patients start to worsen.
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52 The result from the analysis of the less severely depressed participants was unexpected to us.
53 Although there is yet only initial evidence that mindfulness treatment is effective for acute or
54 severely depressed^{44 45}, mindfulness has proven to be effective for relapse prevention of
55 depression^{20 46 47}. That gives implications that a mindfulness-based treatment administered
56 through smartphone will work better for people suffering from mild depression. However, the
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3 fact that the mindfulness-based treatment worked significantly better than the behavioral
4 activation-treatment was surprising to us. One explanation could be that the less severely
5 depressed participants suffered more from stress and anxiety rather than depression. This
6 population would then not be in need of a treatment that encourages more activation. Instead, a
7 mindfulness treatment could work very well for this kind of problems^{19 48}.

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10 Moreover, the results showed that the two interventions were effective for treating depression
11 with large within-group effect sizes and large recovery rates, which are comparable to other
12 depression treatment. This indicates that this smartphone format might work well for a depressed
13 population.
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15 16 17 **Limitations**

18 There are a number of limitations that need to be mentioned. The first is that no wait list group
19 was included. However, our main research question was to assess whether behavioral activation
20 is more effective than mindfulness delivered over smartphone. Hence, we wanted to isolate all
21 other components, such as the therapist support and the psychoeducation, and only investigate
22 the two smartphone applications.
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25 A second limitation is that the study was underpowered. Thus, it is difficult to detect significant
26 overall differences between the two smartphone-treatments, even if significant interaction effects
27 were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc
28 power analysis revealed that a sample of 393 participants was required to detect small between-
29 group effects. We were not expecting that the mindfulness treatment would be as effective and
30 powered the trial as if a moderate between-group effect would be found.
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33 A third limitation was that the participants were recruited nationally through mass media and
34 advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g.
35 an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II
36 at intake ($M=24.10$) is rather close to the limit of 29 proposed for defining severe depression²⁵.
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39 Fourth, we recruited a broad range of participants, with regards to the severity of depression (a
40 minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a
41 specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis
42 showed that participants with higher severity of depression responded to the behavioral
43 activation significantly better than the treatment based on mindfulness, whereas the treatment
44 based on mindfulness worked significantly better than the treatment based on behavioral
45 activation for the participants with lower initial. Additionally, it can be argued that these broad
46 inclusion criteria reflect a real population of individuals with depressive disorders.
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49 A fifth related concern was the large number of participants who had college- or university level
50 education (65.5 %). This might bias generalizability of the results, since it is possible that guided
51 self-help is especially well suited for educated clients. However, there are data indicating that 50
52 % of patients seeking psychotherapy have some college education⁴⁹ and that educated patients
53 may be more inclined to seek help for mental health problems⁵⁰.
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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 get¹³, 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 life³⁹. 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 attention¹³, 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 Medication	Iphone	24 (60 %)	23 (56.1 %)	47 (58 %)
	Android	16 (40 %)	18 (43.9 %)	34 (42 %)
	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, <i>d</i> (95% CI)
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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-L Dep							
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 trials~~ 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

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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 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

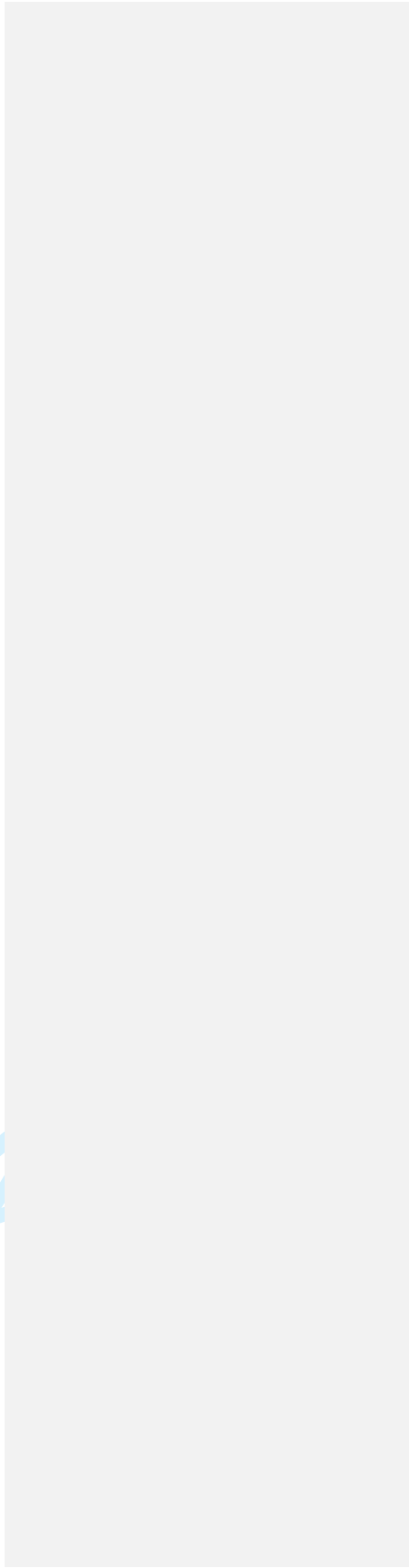
Clinical Trials NCT01463020.

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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 MDD³. For example, behavioral activation has an established empirical base⁴. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades⁵. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package⁶. 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 components⁴. In a later study, behavioral activation was found to be as effective as antidepressant medication⁷.

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression⁸⁻¹⁰. 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 disorders⁹. 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 psychotherapy¹¹. 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 CBT¹².

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 life¹³. 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 symptoms¹⁹. 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 depression²⁰. 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 depression²¹.

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey¹³. 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 way¹³. Both behavioral activation and mindfulness are components in multi-component treatment

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

12
13 At the same time, research suggests that depression severity is known to be a significant
14 moderating factor in the treatment of depression. For example, some initial evidence suggests
15 that there is a difference in efficacy between two different forms of CBT in the treatment of the
16 more severely depressed patients^{7,22}. There are also indications that the difference between
17 antidepressant medication and placebo is evident in severe depression, but not in mild to
18 moderate depression²³, and that combined treatments with medication and psychotherapy are
19 more effective than single treatments²². These results suggest that baseline depression severity
20 may moderate the response to different variants of treatments. Thus, it is concluded that different
21 treatments distributed digitally can target different subgroups of depression, in terms of severity.
22 For example, Dimidjian et al. (2006) found that among more severely depressed patients,
23 behavioral activation was comparable to antidepressant medication, and significantly
24 outperformed cognitive therapy, whereas for the less severely depressed patients, no differential
25 treatment effects were observed.

26
27 The aim of this study was to test the effects of two smartphone-delivered treatments; one based
28 on behavioral activation and the other on mindfulness. Hence, the main question is whether
29 behavioral activation is more effective than mindfulness delivered over smartphone. The study
30 was based on our previous work on guided internet-treatment for depression²⁴, but in the current
31 study the treatment content was delivered entirely via the participants personal smartphone,
32 using recently developed smartphone applications. We expected, in line with Dimidjian and
33 coworkers' conclusions (BA relative to CT $d=0.87$ on BDI), that behavioral activation would be
34 superior to mindfulness for participants suffering from more severe depression with an expected
35 between group effect size of Cohen's $d=0.50$). In order to evaluate long-term effects, we also
36 included a 6-month follow-up after the start of the treatment.

37 38 **Methods**

39 **Ethics statement**

40
41 The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed
42 consent was obtained from all participants by surface mail.

43 44 **Recruitment and selection**

45
46 The participants were mainly recruited via mass media and advertisements in large Swedish
47 newspapers. Those who were interested were directed to a web page with information about the
48 study, the treatments being tested and how to participate in the study.

49
50 Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥ 5 on
51 PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last
52 month, d) not being in any concurrent psychological treatment, e) not suffering from a severe
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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 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; ^{31,34}) 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-

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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 psychiatrists³³. 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's C-Scale³⁴.~~

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 $\alpha=.79$. 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 & Hopko³⁸. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.

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9 The smartphone application was built as a native application for Iphone and a mobile web
10 application for other smartphones. See Figure 2 for a screenshot of the application. A prototype
11 of the smartphone application was tested in a pilot study³⁹. This prototype, however, was not
12 specifically designed for depression interventions. The purpose of the behavioral activation
13 application was to make it easy for the participant to remember and register important behaviors,
14 in order to increase everyday activation. The application contained a database of 54 behaviors,
15 divided into three different areas for the participant to add to their application. See Table 2 for
16 the list of behaviors from the database. The database aimed to provide suggestions, help, and
17 inspiration to get started with the application. Participants were also able to add their own areas
18 and behaviors into the application to start tracking. Through the initial psychoeducation, the
19 participants were guided to add few (between two and four) and easy behaviors from start,
20 mainly from the database.

21
22 When a behavior was completed, the participant could mark this in the application and add a
23 short reflection. Statistics and summaries of quantitative (i.e. behavior frequency) and qualitative
24 data (i.e. reflections) were presented in the application for the participant.

25
26 There was also a back-end system where all the quantitative and qualitative data from the
27 participants was accessible for the therapist. From the back-end system, the therapist could send
28 short text messages to the participants via a messaging system, similar to Short Message Service
29 (SMS). The messaging system was used by the therapists to send personal encouraging messages
30 every other, or every third day to the participants, as well as weekly general educational
31 messages. The system functioned as a one-way communication, which means that the
32 participants were not able to reply the messages.

33
34 Apart from this, the participants were told to write a reflection to summarize every week for their
35 therapist and send it in via e-mail, in the end of every treatment week. The participants received
36 personal feedback on their reflection from their therapist. No sensitive data was saved on a
37 computer, in which the person providing data could be identified. In addition, all internet and
38 smartphone activities was secured, with encrypted information.

39
40 **Mindfulness treatment.** The mindfulness intervention, also an 8-week smartphone-based
41 intervention with minimal therapist contact, consisted of a short web-based psychoeducation, and
42 a step-by-step mindfulness practice program, administered via a smartphone application. The
43 psychoeducation for the mindfulness intervention was equivalent to that of the behavioral
44 activation intervention, except that the theoretical basis of mindfulness was presented instead of
45 the theoretical basis of behavioral activation. The text was written specially for the current
46 intervention, but inspired by [Williams et al.](#)⁴⁰. In all, there were three chapters, totaling 9 pages
47 of text, containing 2 927 words.

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

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9 outcome variables (except from TIC-P, that was not analyzed as part of this study) were analyzed
10 using mixed effects models, given their ability to handle missing data. For the PHQ-9, where
11 weekly measures were available, the continuous outcome variable was analyzed using mixed
12 effects models, given their ability to handle missing data⁴¹. Random intercept models were
13 selected. All analyses used Maximum Likelihood estimation. Random intercept models were
14 selected for all measures. Differences between the behavioral activation treatment and the
15 mindfulness treatment were primarily investigated by modeling interaction effects of group and
16 time. For the PHQ-9 and the AAQ-II, where weekly measures were available. Also, several
17 models were compared using available information criteria, and the model with best fit was
18 chosen. (The covariance between the random intercept and slope was not significant, and
19 therefore was not included in the model. Error terms across time were modeled with a first-order
20 autoregressive covariance structure with heterogeneous variances. Hence, a random intercept
21 model was used also for these measures. Differences in average rates of growth between the two
22 groups were examined by a fixed effects interaction between group and time. Between-group
23 differences at post-treatment were analyzed using independent *t*-tests. Power analysis indicated
24 an 89% chance of detecting a between-group effect size of $d=0.60$ (α level=0.05). Within- and
25 between-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by
26 the pooled standard deviations⁴². This was done both from pre-measurements to post-
27 measurements, and from pre-measurements to the 6-month follow up data.

Results

30 The two groups did not differ significantly on any of the measures at pretreatment ($t=0.50$ to
31 0.67 , $df=79$, $p=0.78$ to 0.50). The results will be presented in the following order: attrition and
32 adherence, self-report inventories (including effect size) both for the whole sample and the
33 subgroups, recovery rates and treatment credibility.

Attrition and adherence

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

44 Adherence to treatment was defined as the number of weekly reflections the participants sent to
45 their therapist. In order to be considered as a completed week, at least one reflection had to have
46 been sent to the therapist during that week. Of the 81 participants, 57 (70 %) succeeded to adhere
47 to all the eight weeks. Of these, 25 (63 %) were in the behavioral activation group and 32 (78 %) were
48 in the mindfulness group. In average, participants succeeded to adhere to six weeks ($M=5.8$,
49 $SD=2.47$).

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 between the groups at 6-month follow-up were, as evident from Table 3, large (PHQ-9: Cohen's $d=0.986$; 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 ($\chi^2(N=66, df=1)=2.97, p=.07+$). 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 ($\chi^2(N=66, df=1)=.63, p=.327$).

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9 When analyzing only the severe depressed participants, there was a tendency in favor for the
10 behavioral activation group. Among the severely depressed participants, 73.9 % ($n=17$) in the
11 behavioral activation group recovered after treatment, compared to 50.0 % ($n=14$) in the
12 mindfulness group ($\chi^2(N=51, df=1)=3.03, p=.072$). At the 6-month follow-up, 21 out of 23
13 participants (91.3 %) from the behavioral activation group had recovered, and 22 out of 28
14 participants (78.6 %) from the mindfulness group had recovered ($\chi^2(N=51, df=1)=1.55,$
15 $p=.20197$).

16 17 **Treatment credibility and therapist time**

18 The credibility of the two treatments showed a mean score of 31.9 (SD=7.1) for the behavioral
19 activation group and at 32.1 (SD=7.8) for the mindfulness group on the Borkovec and Nau c-
20 Scale³⁴.

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23 An independent t-test showed no significant difference between the two groups on the C-scale (t
24 (78)=0.12, $p=0.90$). Furthermore, the C-scale did not correlate significantly with any of the
25 outcome measures, either for all participants combined ($r=0.13, p=0.27$), for the behavioral
26 activation group ($r=0.01, p=0.92$) or for the mindfulness group ($r = .23, p = .18$).

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

31 32 33 **Discussion**

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35 The overall aim of this study was to investigate the effects of two smartphone-delivered
36 treatments for people suffering from mild to moderate major depression; one based on behavioral
37 activation and the other on mindfulness. Hence, the main question was whether behavioral
38 activation is more effective than mindfulness delivered over smartphone. When analyzing the
39 whole sample as one entity, the result showed that the two interventions ~~were effective for~~
40 ~~treating depression with large within-group effect sizes and large recovery rates, but that they did~~
41 not differ significantly from one another; neither from pre-treatment to post-treatment, nor from
42 pre-treatment to the 6-month follow-up on any of the outcome measures. Also, there were no
43 significant differences in recovery rates between the groups, neither at post-treatment nor at the
44 6-month follow-up.

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

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

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

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

33 34 **Limitations**

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

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

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

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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.

For peer review only

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.

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60**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)			Effect size, d (95% CI)			
	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 BA	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-MF	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 BA	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-MF	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 BA	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-MF	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 BA	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-MF	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 BA	-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)	0.84 (0.41-1.27)
Mindfulness-MF	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)			0.62 (0.24-0.99)	0.75 (0.36-1.15)
H-L High level depression							
Behavioral activation BA	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-MF	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 BA	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-MF	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 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)

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Behavioral activation BA	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)
Mindfulness-MF AAQ-II	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)
Behavioral activation BA	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)
Mindfulness-MF QoLI	-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)
Behavioral activation BA	-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)
Low-L-L Delevel depression BDI-II	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51	-1.2148	1.74 (-0.25-3.72)	0.58 (-2.36-3.52)
Behavioral activation BA	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)	(-2.36-1.34)	(-2.6894-12.2371)	1.83 (-0.54-4.19)	2.35 (-0.03-4.72)
Mindfulness-MF PHQ-9	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23	-0.987	2.06 (1.39-2.72)	0.30 (-1.21-1.80)
Behavioral activation BA	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)	(-1.20-0.74)	(-4.6913-10.6372)	1.38 (0.19-2.59)	2.13 (1.03-3.23)
Mindfulness-MF BAI	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)
Behavioral activation BA	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)
Mindfulness-MF AAQ-II	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)
Behavioral activation BA	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)
Mindfulness-MF QoLI	-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)
Behavioral activation BA	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)

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

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9 | Low-level depression: BDI-II: Beck Depression Inventory-II; PHQ-9: 9-item Patient Health
10 Questionnaire Depression Scale; BAI: Beck Anxiety Inventory; AAQ-II: Acceptance and Action
11 Questionnaire; QOLI: Quality of Life Inventory.
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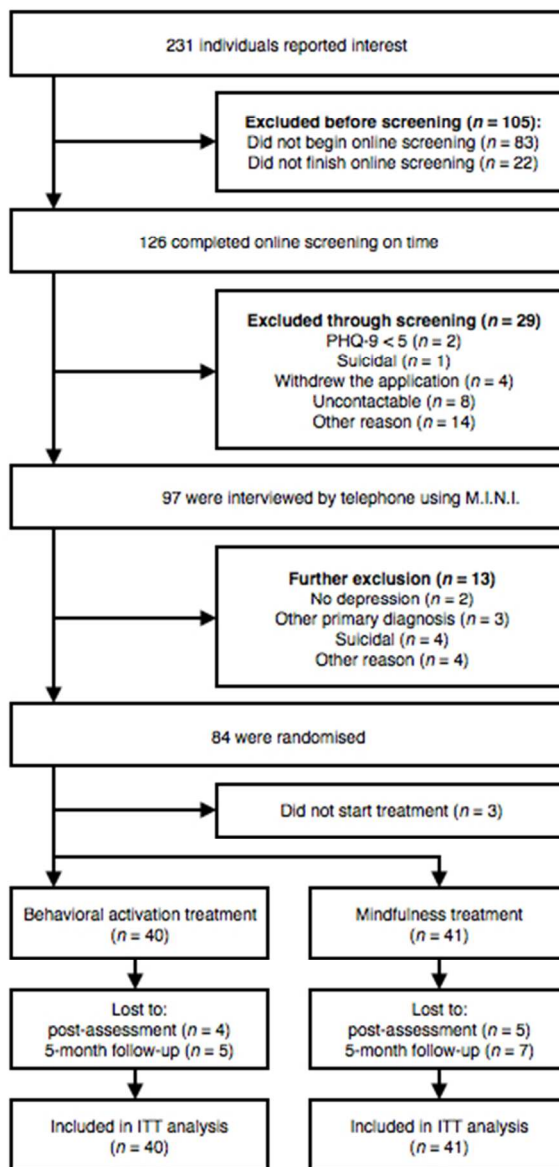
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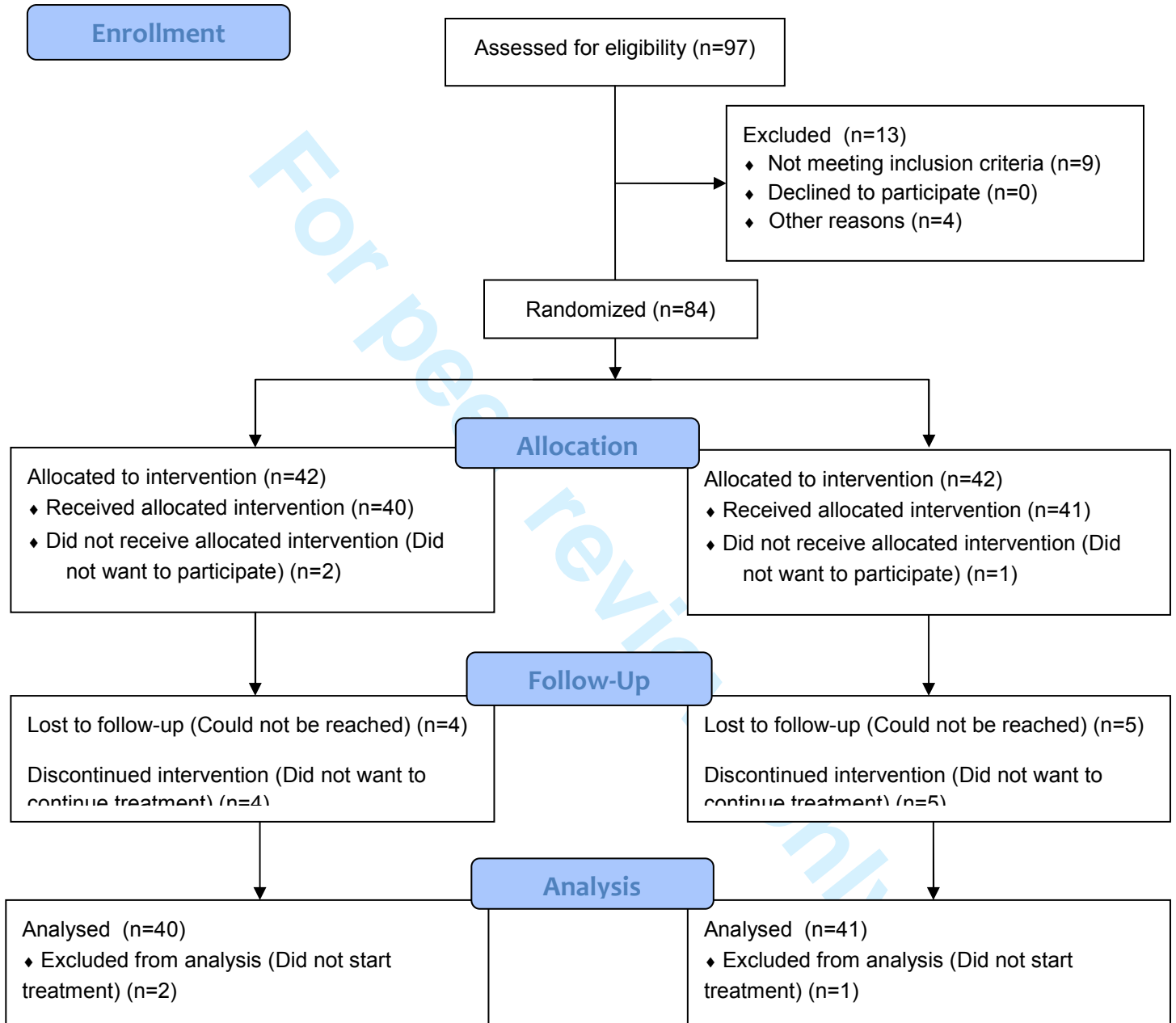
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CONSORT 2010 Flow Diagram





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

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3		11b	If relevant, description of the similarity of interventions
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
6			
7	Results		
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
9	diagram is strongly		were analysed for the primary outcome
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up
12		14b	Why the trial ended or was stopped
13			
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
16			by original assigned groups
17			
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
19	estimation		precision (such as 95% confidence interval)
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
22			pre-specified from exploratory
23			
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
25			
26	Discussion		
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
30			
31	Other information		
32	Registration	23	Registration number and name of trial registry
33	Protocol	24	Where the full trial protocol can be accessed, if available
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
35			

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37 *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

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003440.R2
Article Type:	Research
Date Submitted by the Author:	16-Oct-2013
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

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Manuscripts

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 MDD³. For example, behavioral activation (BA) has an established empirical base⁴. 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 decades⁵. Moreover, a dismantling study showed that BA could be as effective as the full cognitive behavior therapy (CBT) treatment package⁶. Moreover, in a later randomized controlled trial, BA was found to be as effective as antidepressant medication⁷.

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression⁸⁻¹⁰. 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 disorders⁹. 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 outcome¹¹. 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 CBT¹², for example in the treatment of MDD¹³.

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 symptoms¹⁹. 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 anxiety²¹. 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 depression²².

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 depression²³, and that combined treatments with medication and psychotherapy are more effective than single treatments²⁴. 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

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3 cognitive therapy, whereas for the less severely depressed patients, no differential treatment
4 effects were observed. However, in meta-analyses on BA versus cognitive therapy this has not
5 been found²⁴.
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9 The advantages as well as the challenges of using mobile phones in CBT have been summarized
10 by Boschen and Casey²⁵. One challenge with using the mobile phone as a platform for
11 psychological treatment is that the user must be able to interact with the program in an easy way
12²⁵. Both BA and mindfulness are components in multi-component treatment packages, and as
13 such they might be easier to target in smartphone applications than an entire treatment program
14 would be, due to the need of simple and fast interaction with the treatment program. Another
15 important feature of mobile technology is the possibility for the therapist to reach the patient
16 outside of the therapy room or when not sitting in front of the computer, and thus create direct
17 incentives for behavior change in the patient's everyday life²⁵. Therefore, BA is a treatment that
18 could benefit from the use of new mobile technologies (for example smartphones), even more
19 than mindfulness, by creating direct incentives for BA in patient's everyday life.
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24 In this study, we hypothesized that BA treatment delivered over smartphone would be more
25 effective than mindfulness treatment delivered over smartphone with an expected between group
26 effect size of Cohen's $d=0.50$. We also expected, in line with Dimidjian and coworkers'
27 conclusions, that BA would be superior to mindfulness for participants suffering from more
28 severe depression. The study was based on our previous work on guided internet-treatment for
29 depression²⁶, but in the current study the treatment content was delivered entirely via the
30 participants' personal smartphone, using recently developed smartphone applications. The aim of
31 this study was to test the effects of two smartphone-delivered treatments; one based on BA and
32 the other on mindfulness. Hence, the main question is whether BA is more effective than
33 mindfulness delivered over smartphone. In order to evaluate long-term effects, we also included
34 a 6-month follow-up after the start of the treatment.
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39 **Methods**

40 **Ethics statement**

41 The study was approved by the Regional Ethics Board of Linköping, Sweden. Written informed
42 consent was obtained from all participants by surface mail.
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47 **Recruitment and selection**

48 The participants were mainly recruited via mass media and advertisements in large Swedish
49 newspapers. Those who were interested were directed to a web page with information about the
50 study, the treatments being tested and how to participate in the study.
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54 Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥ 5 on
55 PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last
56 month, d) not being in any concurrent psychological treatment, e) not suffering from a severe
57 comorbid psychiatric condition that could interfere with the treatment (e.g. bipolar disorder or
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3 schizophrenia, assessed during a clinical interview), f) not having other primary medical
4 problems which would need other treatments first hand, g) not having severe alcohol problems,
5 h) no assessed risk of being suicidal (see below for details) and i) major depression according to
6 the DSM-IV, with at least an episode in partial remission. The diagnosis of MDD was confirmed
7 by a structured interview (see below). Additionally, an assessment of suicidal ideation was
8 conducted. The interviews were made over telephone by four MSc clinical psychology students.
9 The principal research executive reviewed all the protocols from the interviews together with the
10 interviewers.
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15 Of the 231 individuals who initially expressed interest in the study, 126 completed all the
16 questions in the online screening (22 did not finish the screening and 83 did not begin the
17 screening). Of these, 29 were excluded before the diagnostic interview started. The most
18 common reason for exclusion was an ongoing psychological treatment. Other reasons for
19 exclusion were wrong type of phone and score under 5 on the PHQ-9. 13 individuals were
20 excluded after the diagnostic interview with the most common reason that the participants were
21 judged to be in need of another kind of treatment. Eighty-four were subsequently included after
22 the interview had been conducted. Before the study started, three participants chose not to
23 participate in the study. Hence, 81 participants were finally included in the data analysis. The
24 reasons for exclusion are specified in the flowchart found in Figure 1.
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28 [Insert Figure 1 about here]
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32 Among the randomized participants there were 70.3 % women ($n=57$) and 29.6 % men ($n=24$).
33 The mean age was 36.0 years ($SD=10.8$) ranging from 20 to 61 years. See Table 1 for additional
34 demographical data.
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37 Outcome measures

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39 **Primary outcome measures.** The primary outcome measures were the Beck Depression
40 Inventory-II (BDI-II;²⁷) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9;
41 ^{28 29}) that were administered pre-treatment, at post-treatment and also six months after the
42 treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire
43 treatment phase (8 weeks). Hence, there were three measurements on the outcome BDI-II and 10
44 measurements on the outcome PHQ-9 (including pre-treatment, post-treatment and six months
45 follow up).
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49 **Secondary outcome measures.** In addition to the BDI-II and PHQ-9, the Beck Anxiety
50 Inventory (BAI;³⁰), the Quality of Life Inventory (QOLI;^{31 32}) and the Acceptance and Action
51 Questionnaire (AAQ-II;³³) were administered. The AAQ-II was administered on a weekly basis
52 during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-
53 treatment, post-treatment and at 6-month after the start of the treatment. Hence, there were three
54 measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II
55 (including pre-treatment, post-treatment and six months follow up). All outcome measures used
56 have been shown to have good psychometric properties, with internal consistencies of at least
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3 $\alpha=.79$. Details of this can be found in the respective references of the outcome questionnaires.
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7 **Clinician-administered measures.** Psychiatric diagnoses were assessed at pre-treatment, post-
8 treatment and at 6-month after the start of the treatment, using the Mini-International
9 Neuropsychiatric Interview (M.I.N.I.; ³⁴). The M.I.N.I. is a diagnostic interview that, in contrast
10 to several other diagnostic interviews, is completely structured, making it appropriate for other
11 assessors than experienced psychiatrists ³⁴. All interviews were made over telephone by the four
12 psychology students described above, who at post-treatment were blind to participant's
13 condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology
14 students who were blind to both the participant's condition and the treatment they had been
15 given. Recovery rates were defined as no longer fulfilling the criteria for depression according to
16 M.I.N.I.
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20 **Treatment credibility.** To measure participants' perceived treatment credibility, Borkovec and
21 Nau's Credibility/expectancy scale (C-Scale)³⁵ was used. The C-scale measures the way in
22 which participants view the logic of the treatment (credibility) and the improvements that can be
23 achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after
24 the first week of treatment.
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27 28 29 **Administration format of self-report measures**

30 We used an online platform to administer the BDI-II, PHQ-9, BAI, QOLI, AAQ-II and the C-
31 scale. Previous psychometric research has validated internet-administration of self-rating scales
32 for depression, quality of life and anxiety ³⁶⁻³⁸.
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35 36 **Procedure and design**

37 For those participants included in the study, the results from the online screening were used as
38 pre-treatment assessment. After the recruitment, participants were allocated using an online
39 randomization tool (www.random.org), handled by an independent person who was separate
40 from the staff conducting the study.
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43 44 **The interventions**

45 **Behavioral activation treatment.** An 8-week smartphone-based BA intervention with minimal
46 therapist contact (maximum time of 20 minutes per participant and week) was developed by our
47 research group. The intervention consisted of a short web-based psychoeducation, and a step-by-
48 step behavior program administered via a smartphone application. The psychoeducation aimed to
49 introduce the participants to the treatment, touching on topics like the prevalence of depression,
50 its etiology and maintenance factors based on operant conditioning, as well as the theoretical
51 basis for BA. The text in the web-based psychoeducation was written specially for the current
52 intervention, but inspired by the BA treatment manuals of Martell et al. ³⁹ and Lejuez, Hopko &
53 Hopko ⁴⁰. In all, there were three chapters, totaling 11 pages of text, containing 3 893 words.
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3 The smartphone application was built as a native application for Iphone, meaning that the
4 application was coded in a specific programming language (Objective C), and a mobile web
5 application for other smartphones. See Figure 2 for a screenshot of the application. A prototype
6 of the smartphone application was tested in a pilot study⁴¹. This prototype, however, was not
7 specifically designed for depression interventions. The purpose of the BA application was to
8 make it easy for the participant to remember and register important behaviors, in order to
9 increase everyday activation. The application contained a database of 54 behaviors, divided into
10 three different areas for the participant to add to their application. See Table 2 for the list of
11 behaviors from the database. The database aimed to provide suggestions, help, and inspiration to
12 get started with the application. Participants were also able to add their own areas and behaviors
13 into the application to start tracking. Through the initial psychoeducation, the participants were
14 guided to add few (between two and four) and easy behaviors from start, mainly from the
15 database.
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21 When a behavior was completed, for example: *Get ready in the morning*, the participant could
22 register this in the application and add a short reflection. Statistics and summaries of quantitative
23 (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application
24 for the participant.
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28 There was also a back-end system where all the quantitative and qualitative data from the
29 participants was accessible for the therapist. From the back-end system, the therapist could send
30 short text messages to the participants via a messaging system, similar to Short Message Service
31 (SMS). The messaging system was used by the therapists (described below) to send personal
32 encouraging messages every other or every third day to the participants, as well as weekly
33 general educational messages. The system functioned as a one-way communication, meaning
34 that the participants were not able to reply the messages. The participants were also told to write
35 a reflection to summarize every week for their therapist and send it in via e-mail in the end of
36 every treatment week. The participants received personal feedback on their reflection from their
37 therapist via e-mail. No sensitive data was saved on a computer, in which the person providing
38 data could be identified. In addition, all internet and smartphone activities were secured, with
39 SSL-encrypted information.
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47 **Mindfulness treatment.** The mindfulness intervention, also an 8-week smartphone-based
48 intervention with minimal therapist contact (maximum time of 20 minutes per participant and
49 week), consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice
50 program, administered via a smartphone application. The psychoeducation for the mindfulness
51 intervention was equivalent to that of the BA intervention, except that the theoretical basis of
52 mindfulness was presented instead of the theoretical basis of BA. The text was written specially
53 for the current intervention, but inspired by the self help book *The Mindful Way Through*
54 *Depression* by Williams et al.⁴². In all, there were three chapters, totaling 9 pages of text,
55 containing 2 927 words.
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5 The smartphone application for Iphone was an established and commercially available
6 application that could be downloaded from the Apple app store. See Figure 3 for a screenshot of
7 the application. For other smartphones, a mobile web application was built especially for the
8 current study with the aim of mimicking the Iphone application. The application consisted of a
9 number of audio tracks with exercises to facilitate the practice of mindfulness. The exercises
10 were both guided and unguided, and in short (three minutes) and long (30 minutes) format.
11 Through the initial psychoeducation, the participants were guided to start with short mindfulness
12 exercises, such as guided three minutes mindfulness exercise, which was one of the audio tracks
13 in the application.
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18 Since the mindfulness application did not have a communication function such as the BA
19 application, e-mails were used to emulate the messaging system in the BA application. Hence,
20 the therapists sent encouraging messages every other, or every third day to the participants, as
21 well as weekly general educational messages via mail. The difference in how the therapists
22 communicated in the mindfulness intervention, compared with the BA intervention, was that the
23 therapists could not give specific feedback on activities or exercises that the participants had
24 done. Otherwise, the communication was similar (length and type of guided content in the
25 feedback). Additionally, the participants given the mindfulness intervention were also told to
26 write a reflection to summarize every week for their therapist and send it in via e-mail. The
27 participants received personal feedback on their reflection from their therapist.
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31 [Insert Figure 3 about here]
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35 **Therapists.** The therapists were four final-semester students from a five-year M.Sc. clinical
36 psychologist program. All therapists had completed their clinical training as well as 16 weeks of
37 internship. Each therapist was responsible for the treatment of 8 to 10 participants from the BA
38 group and an equal number of participants from the mindfulness group. Therapists were
39 randomly allocated to participants, with the restriction of not having more than 10 participants
40 from each group. For the entire duration of the study the therapists received continuous
41 supervision from an experienced psychotherapist with CBT orientation, who had previous
42 experience of working with a BA treatment manual, as well as mindfulness in depression
43 treatment.
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46 47 **Subgroups based on cut-off scores**

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

All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent *t*-tests and χ^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 data⁴³. 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 deviations⁴⁴. 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 ($\chi^2(N=81, df=1)=2.35, p=1.00$). 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: ($F(1, 76.43)=.106$, $p's=.31$)), 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 ($\chi^2(N=66, df=1)=2.97, p=.07$). 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 ($\chi^2(N=66, df=1)=.63, p=.33$).

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 ($\chi^2(N=51, df=1)=3.03, p=.07$). 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 ($\chi^2(N=51, df=1)=1.55, p=.20$).

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 ($\chi^2(N=30, df=1)=.63, p=.41$). 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 ($\chi^2(N=30, df=1)=2.549, p=.17$).

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

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3 two interventions did not differ significantly from one another; neither from pre-treatment to
4 post-treatment, nor from pre-treatment to the 6-month follow-up on any of the outcome
5 measures. Also, there were no significant differences in recovery rates between the groups,
6 neither at post-treatment nor at the 6-month follow-up.
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10 This study also explored how different levels of initial depression severity could moderate
11 response to the different interventions. All randomized participants were classified into either
12 high or low severity of depression based on the cut-offs scores on the PHQ-9 and if they fulfilled
13 the criteria for an ongoing primary diagnosis of major depression. For participants with higher
14 severity of depression, the treatment based on BA was superior to the treatment based on
15 mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity,
16 the treatment based on mindfulness worked better than the treatment based on BA, as measured
17 with PHQ-9 and BDI-II.
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21 The result from the analysis of the higher severity participants is in line with Dimidjian et al's
22 finding⁷. In contrast to the meta-analysis by Cuijpers et al²⁴, Dimidjian et al⁷ found that BA
23 was comparable in efficacy to antidepressant medication, and more efficacious than cognitive
24 therapy - but only among those patients who were more severely depressed. In line with this,
25 Beck and colleagues⁴⁵ have long suggested that therapists should focus on behavioral strategies
26 early in treatment when patients are more depressed and return to that emphasis later if patients
27 start to worsen.
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31 The result from the analysis of the less severely depressed participants was unexpected to us.
32 Although there is yet only initial evidence that mindfulness treatment is effective for acute or
33 severely depressed^{46,47}, mindfulness has proven to be effective for relapse prevention of
34 recurrent depression^{20,48,49}. A possible explanation to the results could be that there was a
35 difference between the two treatment groups, although not significant, in the number of
36 participants that were suffering from major depression. In the BA group 64.7% ($n=11$) were
37 diagnosed with major depression in the initial screening, compared to 30.8% ($n=4$) in the
38 mindfulness group ($\chi^2(N=30, df=1)=3.39, p=.07$).
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42 Moreover, the results showed significant improvements from pre-treatment to post-treatment on
43 the primary outcome measures in both treatment conditions with large within-group effect sizes
44 and large recovery rates, which are comparable to other depression treatment. This might
45 indicate that this smartphone format could work well for a depressed population. However, a
46 replication with a waiting list group should be conducted to rule out that the effects occurred due
47 to natural recovery.
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50 51 **Limitations**

52 There are a number of limitations that need to be mentioned. The first is that no wait list group
53 was included. Even if our main research question was to assess whether behavioral activation is
54 more effective than mindfulness delivered over smartphone a control group would have yielded a
55 more clear result.
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3 A second limitation is that the study was underpowered. Thus, it is difficult to detect significant
4 overall differences between the two smartphone-treatments, even if significant interaction effects
5 were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc
6 power analysis revealed that a sample of 393 participants was required to detect small between-
7 group effects. We were not expecting that the mindfulness treatment would be as effective and
8 powered the trial as if a moderate between-group effect would be found.
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11 A third limitation was that the participants were recruited nationally through mass media and
12 advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g.
13 an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II
14 at intake ($M=24.10$) is rather close to the limit of 29 proposed for defining severe depression²⁷,
15 meaning that the depression severity in this study was comparable to an outpatient psychiatric
16 population.
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19 Fourth, we recruited a broad range of participants, with regards to the severity of depression (a
20 minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a
21 specific group for whom the treatments would be effective. Nevertheless, a subgroup analysis
22 showed that participants with higher severity of depression responded to the BA significantly
23 better than the treatment based on mindfulness, whereas the treatment based on mindfulness
24 worked significantly better than the treatment based on BA for the participants with lower initial.
25 Additionally, it can be argued that these broad inclusion criteria reflect a real population (i.e. an
26 outpatient psychiatric population) of individuals with depressive disorders.
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30 A fifth related concern was the large number of participants who had college- or university level
31 education (65.5 %). This might bias generalizability of the results, since it is possible that guided
32 self-help is especially well suited for educated clients. However, there are data indicating that 50
33 % of patients seeking psychotherapy have some college education⁵⁰ and that educated patients
34 may be more inclined to seek help for mental health problems in general⁵¹.
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37 38 **Conclusion**

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40 Some clinical implications of this study are discussed as follows. Due to the need for simple and
41 fast interaction with the treatment program, singular treatment components such as BA and
42 mindfulness might be a better target for smartphone applications than entire multi-component
43 treatment packages. At the same time, there is a need for guided self-help treatments distributed
44 digitally that can reach out to more patients. This study is one of the first to test a treatment for
45 depression, administered via smartphone. The large within-group effects on the primary outcome
46 measures, as well as the large recovery rates for both groups are comparable to other depression
47 treatments, and indicate that this smartphone format with a small amount of text and minimal
48 therapist support, might work well for a depressed population. However, as mentioned above, a
49 replication with a waiting list group should be conducted to rule out that the effects occurred due
50 to natural recovery.
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55 Moreover, this study also shows that BA might work better for a more severely depressed
56 population, whereas mindfulness might work better for people suffering from light depression.
57 These results suggest that different treatments distributed digitally can target different subgroups
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3 of depression in terms of severity. However, more studies are needed to strengthen this
4 hypothesis before a conclusion can be drawn.
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7 From a broader perspective, we believe that smartphones will be integrated even further in
8 society since they are already socially accepted as well as relatively cheap for the functionalities
9 you get ²⁵, and therefore may serve an important role in health care. Therefore these results,
10 showing that mild to moderate major depression can be treated effectively by means of a
11 supported smartphone-application, might be important in the future of making depression
12 treatment and other psychological treatment more assimilated into people's daily life. As
13 suggested in Ly et al. (2012), the smartphone format might also help increasing the awareness of
14 being in treatment in everyday settings, and therefore better help clients create direct incentives
15 for treatment related activities in their everyday life ⁴¹. Using smartphones to distribute
16 psychological treatment might also help making it possible to reach out with psychological
17 therapy to a broader group of people, since their use attracts no attention ²⁵, allowing users to
18 interact with a device without fear of judgment or stigma. Lastly, psychological treatments
19 distributed via smartphones are not only relevant for Swedish conditions but also for the
20 developing countries in the world, which increasingly are empowered by mobile phones with
21 internet connection.
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26 This study might open up for a broad range of other trials conducted via smartphones, both for
27 self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a
28 substantial part of internet-based interventions in the future will be executed through
29 smartphones or at least supported by smartphones. Further studies should focus on both formats,
30 as well as expanding the treatment platform to other psychological disorders.
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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

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5 Get out of bed when the bell rings in the morning
6 Take a shower
7 Get ready in the morning
8 Eat breakfast
9 Read the newspaper
10 Make a meal plan for each day of the week
11 Make a shopping list for meals
12 Buy food for the meals you have planned
13 Prepare a simple meal
14 Clean a part of my home
15 Clean at least 15 minutes
16 Washing dishes immediately after a meal
17 Wash my clothes
18 Plan my TV viewing from TV schedules
19 Turn off the TV before 21:00 if I'm still watching TV
20 Turn off the computer before 21:00 if I'm still on the Internet
21 Take a brisk walk for 10 minutes
22 Log in to my online banking and pay a bill
23 Entering my weekly activities in my calendar
24

Social behaviors

25 Texting a friend and ask what he / she does
26 Call a friend and ask what the situation is
27 Take a walk with a friend
28 Book a meeting with someone in my family
29 Suggest a coffee with a friend or family member
30 Suggest a lunch with a friend or family member
31 Go to the playground with my kids
32 Bake something with my children
33 Meet a friend in the evening and ask how your day was
34 Watching an episode of a TV series with a friend
35 Go to the movies with a friend
36 Cooking with someone
37

New activities

38 Buy or borrow a book I wanted to read
39 Read at least 20 minutes out of a book
40 Go to a new cafe and coffee
41 Look up the nearest training center is
42 Read on about training online
43 Post a workout plan for the week
44 Ask a friend if he / she wants to come along and train
45 Spend at least 30 minutes of physical activity
46 Listen to a radio program
47 Watch a documentary on TV
48 Eat a good meal out
49 Write down at least two good things that happened around me
50 Rent a movie and have a night in
51 Look up the exhibits that are in my city
52 See an exhibition at a museum
53 Look up the concerts that are relevant right now
54 Go to a concert
55 Look up current things happening in my city
56 Attend a church service
57 Solve a crossword
58 Make a Sudoku
59 Listen to music without doing anything else and focus on what I hear
60 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)			Effect size, <i>d</i> (95% CI)			
	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-L Dep							
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 trials~~ 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

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9 program.

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

14 2) Key Messages

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

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

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

25 3) Strengths and Limitations.

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

27
28 • Did not control for the different components separately, so we cannot determine which parts of
29 the treatments were effective.

31 **Keywords**

32 Depression, Behavioral activation, Smartphone application, Mindfulness.

34 **Abstract**

35 **Objectives**

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

38 **Design**

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

42 **Setting**

43 Open trial at a university psychological center in Sweden. General community, with recruitment
44 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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10 **Funding**

11 The Swedish Research Council, 2011-2476
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For peer review only

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 MDD³. For example, behavioral activation has an established empirical base⁴. The efficacy of behavioral activation for treating MDD has been established in a number of studies over the past four decades⁵. Moreover, a dismantling study showed that behavioral activation could be as effective as the full cognitive behavior therapy (CBT) treatment package⁶. 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 components⁴. In a later study, behavioral activation was found to be as effective as antidepressant medication⁷.

It is also well established that guided self-help interventions, administered through internet, can have positive effects on symptoms of depression⁸⁻¹⁰. 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 disorders⁹. 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 psychotherapy¹¹. 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 CBT¹².

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 life¹³. 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 symptoms¹⁹. 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 depression²⁰. 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 depression²¹.

The advantages as well as the challenges of using mobile phones in CBT have been summarized by Boschen and Casey¹³. 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 way¹³. Both behavioral activation and mindfulness are components in multi-component treatment

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

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13 At the same time, research suggests that depression severity is known to be a significant
14 moderating factor in the treatment of depression. For example, some initial evidence suggests
15 that there is a difference in efficacy between two different forms of CBT in the treatment of the
16 more severely depressed patients^{7,22}. There are also indications that the difference between
17 antidepressant medication and placebo is evident in severe depression, but not in mild to
18 moderate depression²³, and that combined treatments with medication and psychotherapy are
19 more effective than single treatments²². These results suggest that baseline depression severity
20 may moderate the response to different variants of treatments. Thus, it is concluded that different
21 treatments distributed digitally can target different subgroups of depression, in terms of severity.
22 For example, Dimidjian et al. (2006) found that among more severely depressed patients,
23 behavioral activation was comparable to antidepressant medication, and significantly
24 outperformed cognitive therapy, whereas for the less severely depressed patients, no differential
25 treatment effects were observed.

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27 The aim of this study was to test the effects of two smartphone-delivered treatments; one based
28 on behavioral activation and the other on mindfulness. Hence, the main question is whether
29 behavioral activation is more effective than mindfulness delivered over smartphone. The study
30 was based on our previous work on guided internet-treatment for depression²⁴, but in the current
31 study the treatment content was delivered entirely via the participants personal smartphone,
32 using recently developed smartphone applications. We expected, in line with Dimidjian and
33 coworkers' conclusions (BA relative to CT $d=0.87$ on BDI), that behavioral activation would be
34 superior to mindfulness for participants suffering from more severe depression with an expected
35 between group effect size of Cohen's $d=0.50$). In order to evaluate long-term effects, we also
36 included a 6-month follow-up after the start of the treatment.

37 38 **Methods**

39 **Ethics statement**

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

43 44 **Recruitment and selection**

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

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50 Inclusion criteria for the study were a) being at least 18 years old, b) having a point total of ≥ 5 on
51 PHQ-9, c) reported unchanged dosage of medication for depression and anxiety during the last
52 month, d) not being in any concurrent psychological treatment, e) not suffering from a severe
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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 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; ^{31,34}) 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-

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9 | treatment and at 6-month after the start of the treatment, using the Mini-International
10 Neuropsychiatric Interview (M.I.N.I.;³³). The M.I.N.I. is a diagnostic interview that, in contrast
11 to several other diagnostic interviews, is completely structured, making it appropriate for other
12 assessors than experienced psychiatrists³³. All interviews were conducted by the four
13 psychology students described above, who at post-treatment were blind to participant's
14 condition. At the 6-month follow-up, the interviews were conducted by other clinical psychology
15 students who were blind to both the participant's condition and the treatment they had been
16 given. Recovery rates were defined as no longer fulfilling the criteria for depression according to
17 M.I.N.I.

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

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26 Credibility. The credibility of the two treatments showed a mean score of 31.9 (SD=7.1) for the
27 behavioral activation group and at 32.1 (SD=7.8) for the mindfulness group on the Borkovec and
28 Nau e Scale³⁴.

30 Procedure and design

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

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

42 The interventions

43 **Behavioral activation treatment.** An 8-week smartphone-based behavioral activation
44 intervention with minimal therapist contact was developed by our research group. The
45 intervention consisted of a short web-based psychoeducation, and a step-by-step behavior
46 program administered via a smartphone application. The psychoeducation aimed to introduce the
47 participants to the treatment, touching on topics like the prevalence of depression, its etiology
48 and maintenance factors based on operant conditioning, as well as the theoretical basis for
49 behavioral activation. The text was written specially for the current intervention, but inspired by
50 Martell et al.³⁷ and Lejuez, Hopko & Hopko³⁸. In all, there were three chapters, totaling 11
51 pages of text, containing 3 893 words.

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9 The smartphone application was built as a native application for Iphone and a mobile web
10 application for other smartphones. See Figure 2 for a screenshot of the application. A prototype
11 of the smartphone application was tested in a pilot study³⁹. This prototype, however, was not
12 specifically designed for depression interventions. The purpose of the behavioral activation
13 application was to make it easy for the participant to remember and register important behaviors,
14 in order to increase everyday activation. The application contained a database of 54 behaviors,
15 divided into three different areas for the participant to add to their application. See Table 2 for
16 the list of behaviors from the database. The database aimed to provide suggestions, help, and
17 inspiration to get started with the application. Participants were also able to add their own areas
18 and behaviors into the application to start tracking. Through the initial psychoeducation, the
19 participants were guided to add few (between two and four) and easy behaviors from start,
20 mainly from the database.

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

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

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

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

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

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

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24 Additionally, the participants given the mindfulness intervention were also told to write a
25 reflection to summarize every week for their therapist and send it in via e-mail. The participants
26 received personal feedback on their reflection from their therapist.
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29 **Therapists.** The therapists were four final-semester students from a five-year M.Sc. clinical
30 psychologist program. All therapists had completed their clinical training as well as 16 weeks of
31 internship. Each therapist was responsible for the treatment of 8 to 10 participants from the
32 behavioral activation group and an equal number of participants from the mindfulness group.
33 Therapists were randomly allocated to participants, with the restriction of not having more than
34 10 participants from each group. For the entire duration of the study the therapists received
35 continuous supervision from an experienced psychotherapist with CBT orientation, who had
36 previous experience of working with a behavioral activation treatment manual.

37 38 **Subgroups based on cut-off scores**

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

45 46 **Data analysis**

47 All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t -tests and
48 χ^2 -tests were used to test for group differences in demographics, pre-treatment data and in
49 recovery rates- clinical significant improvement. Differences between the behavioral activation
50 treatment and the mindfulness treatment were primarily investigated by modeling interaction
51 effects of group and time. In order to adhere to the intention-to-treat principle, the continuous
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~~outcome variables (except 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 data⁴¹. 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. (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 deviations⁴². 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 between the groups at 6-month follow-up were, as evident from Table 3, large (PHQ-9: Cohen's $d=0.986$; 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 ($\chi^2(N=66, df=1)=2.97, p=.07+$). 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 ($\chi^2(N=66, df=1)=.63, p=.327$).

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 ($\chi^2(N=51, df=1)=3.03, p=.072$). 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 ($\chi^2(N=51, df=1)=1.55, p=.2097$).

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-Scale³⁴.

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

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

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

18
19 The result from the analysis of the less severely depressed participants was unexpected to us.
20 Although there is yet only initial evidence that mindfulness treatment is effective for acute or
21 severely depressed ^{44 45}, mindfulness has proven to be effective for relapse prevention of
22 depression ^{20 46 47}. That gives implications that a mindfulness-based treatment administered
23 through smartphone will work better for people suffering from mild depression. However, the
24 fact that the mindfulness-based treatment worked significantly better than the behavioral
25 activation-treatment was surprising to us. One explanation could be that the less severely
26 depressed participants suffered more from stress and anxiety rather than depression. This
27 population would then not be in need of a treatment that encourages more activation. Instead, a
28 mindfulness treatment could work very well for this kind of problems ^{19 48}.

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

33 34 **Limitations**

35
36 There are a number of limitations that need to be mentioned. The first ~~and is that it is impossible~~
37 ~~to determine which parts of the treatments were effective. Since we did not control for the~~
38 ~~different components separately, we cannot, for example, rule out that the result was mainly an~~
39 ~~effect of the therapist support. An additional treatment arm with only therapist support would~~
40 ~~make it possible to rule out this question. no wait list group was included. However, our main~~
41 ~~research question was to assess whether behavioral activation is more effective than mindfulness~~
42 ~~delivered over smartphone. Hence, we wanted to isolate all other components, such as the~~
43 ~~therapist support and the psychoeducation, and only investigate the two smartphone applications.~~

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

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

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

11 This study might open up for a broad range of other trials conducted via smartphones, both for
12 self-help interventions as well as adjunct tools in face-to-face treatments. We believe that a
13 substantial part of internet-based interventions in the future will be executed through
14 smartphones or at least supported by smartphones. Further studies should focus on both formats,
15 as well as expanding the treatment platform to other psychological disorders.
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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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Outcome measure	Mean (SD)			Effect size, d (95% CI)			
	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 BA	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-MF	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 BA	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-MF	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 BA	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-MF	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 BA	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-MF	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 BA	-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)	0.84 (0.41-1.27)
Mindfulness-MF	-0.20 (1.51)	0.84 (1.90)	1.13 (2.07)			0.62 (0.24-0.99)	0.75 (0.36-1.15)
H-L High level depression							
Behavioral activation BA	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-MF	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 BA	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-MF	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 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)

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Behavioral activation BA	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)
Mindfulness-MF AAQ-II	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)
Behavioral activation BA	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)
Mindfulness-MF QoLI	-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)
Behavioral activation BA	-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)
Mindfulness-MF BDI-II	18.94 (6.47)	9.14 (4.96)	14.07 (10.71)	-0.51	-1.2148	1.74 (-0.25-3.72)	0.58 (-2.36-3.52)
Behavioral activation BA	17.54 (7.09)	6.73 (4.86)	4.22 (3.63)	(-2.36-1.34)	12.2371	1.83 (-0.54-4.19)	2.35 (-0.03-4.72)
Mindfulness-MF PHQ-9	8.47 (1.59)	4.57 (2.34)	7.21 (6.36)	-0.23	-0.987	2.06 (1.39-2.72)	0.30 (-1.21-1.80)
Behavioral activation BA	8.15 (3.34)	4.00 (2.86)	2.56 (1.51)	(-1.20-0.74)	-2.6894	1.38 (0.19-2.59)	2.13 (1.03-3.23)
Mindfulness-MF BAI	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)
Behavioral activation BA	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)
Mindfulness-MF AAQ-II	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)
Behavioral activation BA	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)
Mindfulness-MF QoLI	-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)
Behavioral activation BA	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)

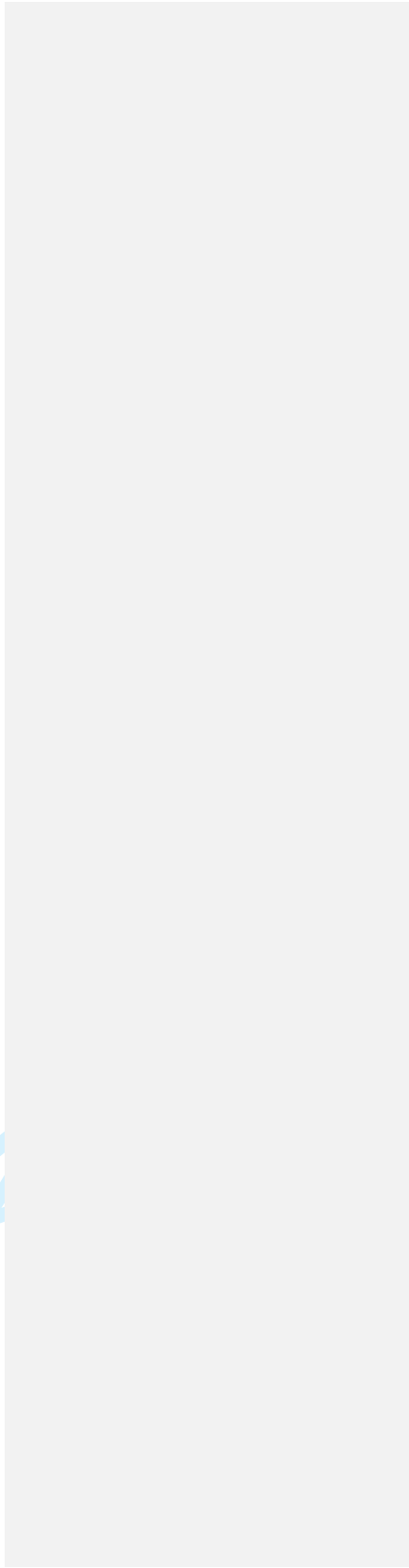
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Abbreviations: BA: Behavioral activation; MF: Mindfulness; H-L Dep: High-level depression; L-L Dep:

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| 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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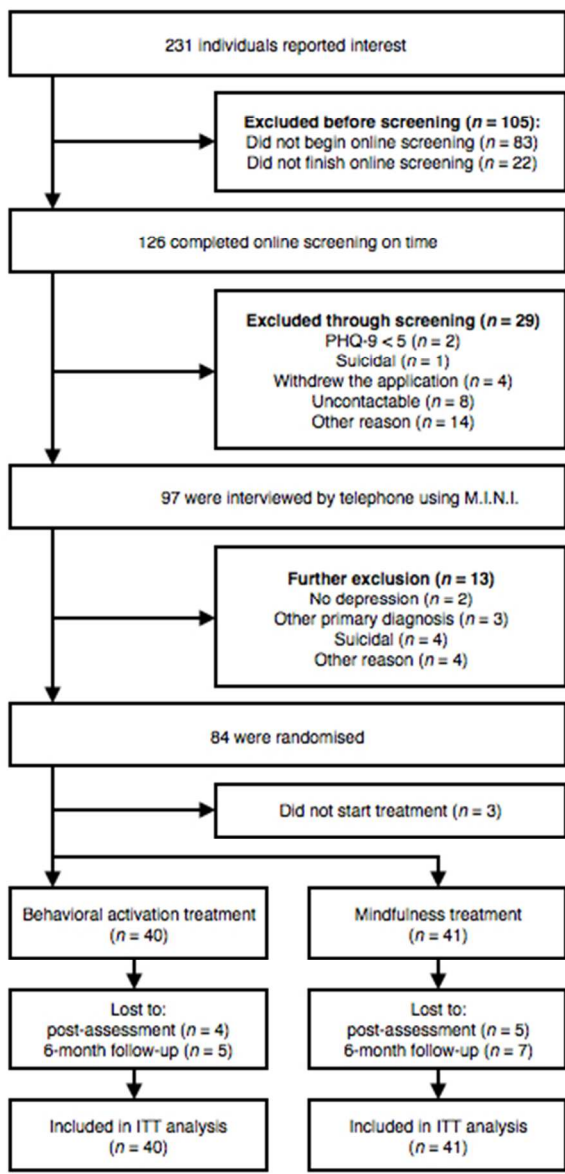
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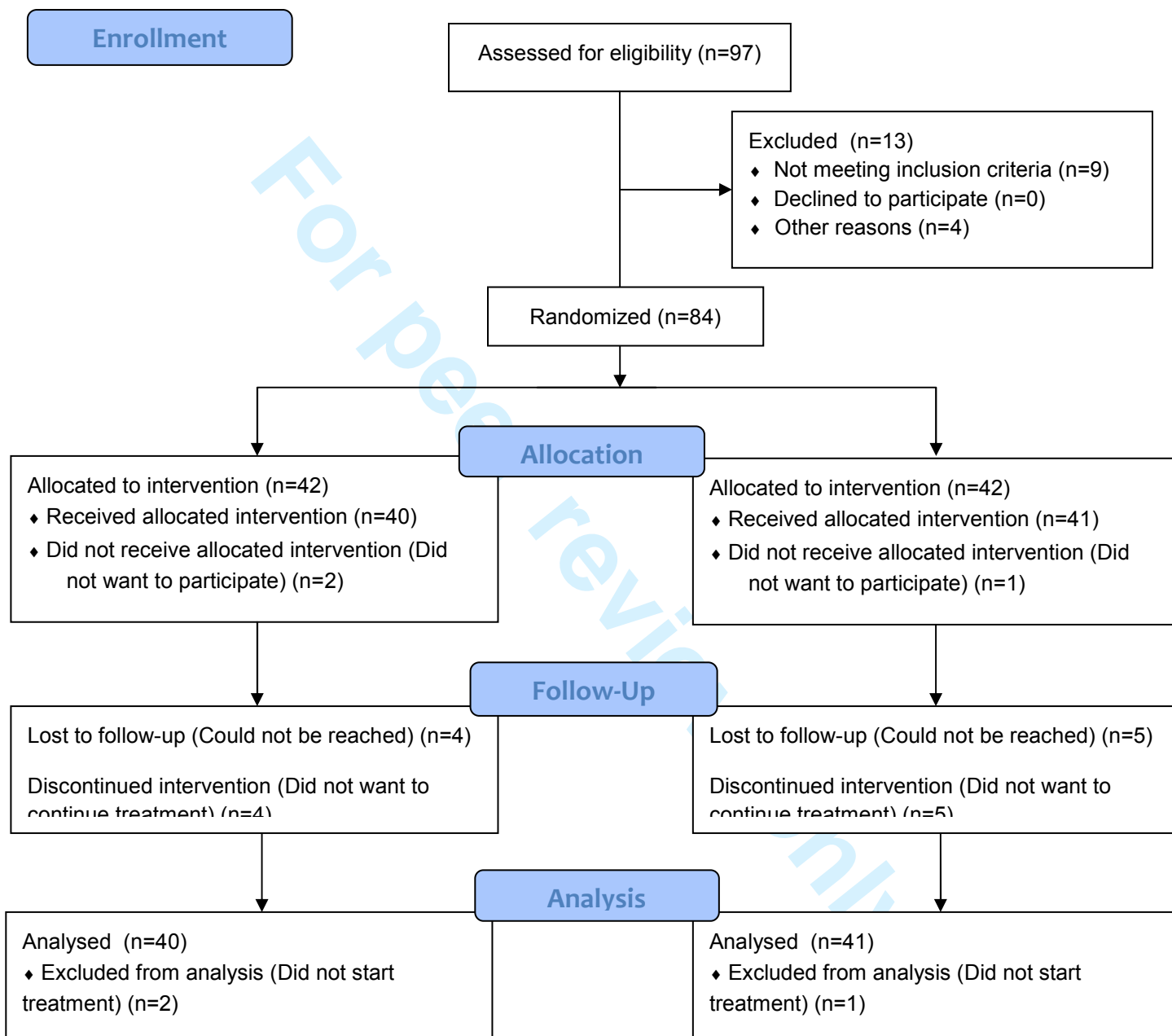
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CONSORT 2010 Flow Diagram





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

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2			
3		11b	If relevant, description of the similarity of interventions
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
6			
7	Results		
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
9	diagram is strongly		were analysed for the primary outcome
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up
12		14b	Why the trial ended or was stopped
13			
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
16			by original assigned groups
17			
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
19	estimation		precision (such as 95% confidence interval)
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
22			pre-specified from exploratory
23			
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
25			
26	Discussion		
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
30			
31	Other information		
32	Registration	23	Registration number and name of trial registry
33	Protocol	24	Where the full trial protocol can be accessed, if available
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
35			

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

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Manuscripts

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 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

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3 severity of depression, the treatment based on BA was superior to the treatment based on
4 mindfulness. For participants with lower initial severity, the treatment based on mindfulness
5 worked significantly better than the treatment based on BA.
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8 **Trial registration**

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10 Clinical Trials NCT01463020.
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13 **Article Summary**

14 1) Article Focus

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19 • It is well established that guided self-help interventions, administered through internet, can
20 have positive effects on symptoms of depression. There are, however, to our knowledge no
21 controlled trials on smartphone-delivered behavioral activation, neither on mindfulness.
22
23 • Both behavioral activation and mindfulness are components in multi-component treatment
24 packages, and as such they might be easier to target in smartphone applications than an entire
25 treatment program would be, due to the need of simple and fast interaction with the treatment
26 program.
27
28 • The aim of this study was to test the effects of two smartphone-delivered treatments; one based
29 on behavioral activation and the other on mindfulness. We expected that behavioral activation
30 would be superior to mindfulness for participants suffering from more severe depression.
31
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33 2) Key Messages

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35 • The large within-group effect sizes are comparable to other depression treatment and indicate
36 that this smartphone format might work well for a depressed population.
37
38 • Behavioral activation might work better for a more severely depressed population, whereas
39 mindfulness might work better for people suffering from light depression, at least in this
40 smartphone format.
41
42 • Since smartphones likely will be integrated even further in society, they may be important in
43 the future of making depression treatment and other psychological treatment more assimilated
44 into people's daily life.
45
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47 3) Strengths and Limitations.

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49 • One of the first to do a randomized controlled trial using smartphone applications.
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51 • Did not control for the different components separately, so we cannot determine which parts of
52 the treatments were effective.
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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 MDD³. For example, behavioral activation (BA) has a strong empirical basis⁴. 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 decades⁵. Moreover, a dismantling study showed that BA could be as effective as the full cognitive behavior therapy (CBT) treatment package⁶. Moreover, in a later randomized controlled trial, BA was found to be as effective as antidepressant medication⁷.

It is also well established that guided self-help interventions, administered through the internet, can have positive effects on symptoms of depression⁸⁻¹⁰. 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 disorders⁹. 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 outcome¹¹. 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 CBT¹², for example in the treatment of MDD¹³.

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 symptoms¹⁹. 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 interventions²¹. 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 depression²².

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 depression²³, and that combined treatments with medication and psychotherapy are more effective than single treatments²⁴. 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

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3 activation was as effective as antidepressant medication, and significantly outperformed
4 cognitive therapy, whereas for the less severely depressed patients, no differential treatment
5 effects were observed. However, in meta-analyses on BA versus cognitive therapy this has not
6 been found²⁴.
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10 The advantages as well as the challenges of using mobile phones in CBT treatment have been
11 summarized by Boschen and Casey²⁵. One challenge with using the mobile phone as a platform
12 for psychological treatment is that the user must be able to interact with the program in an easy
13 way²⁵. In order to attain this simple and fast interaction, it might be easier to target specific
14 treatment components than entire treatment programs in smartphone applications. This would
15 make BA and mindfulness, both components in more extensive treatment packages, suitable
16 targets for smartphone-based interventions. Another important feature of mobile technology is
17 the possibility for the therapist to reach the patient outside of the therapy room or when not
18 sitting in front of the computer, and thus create direct incentives for behavior change in the
19 patient's everyday life²⁵. Therefore, BA is a treatment that could benefit from the use of new
20 mobile technologies (for example smartphones), even more than mindfulness, by creating direct
21 incentives for BA in patient's everyday life.
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26 In this study, we hypothesized that BA treatment delivered over smartphone would be more
27 effective than mindfulness treatment delivered over smartphone. A meta-analysis by
28 Mazzucchelli, Kane, and Rees²⁶ detected a significant moderate pooled effect size of Hedges's
29 $g=0.33$ (Cohen's $d=0.31$) when comparing BA with other psychological interventions, such as
30 psychoeducation about depression, problem solving, assertiveness training and brief
31 interventions. As such, we expected a moderate between group effect size (Cohen's $d=0.50$ ²⁷) in
32 this study. We also expected, in line with Dimidjian and coworkers' conclusion⁷, that BA would
33 be superior to mindfulness for participants suffering from more severe depression (scored ≥ 10 on
34 PHQ-9 and fulfilled the criteria for an ongoing primary diagnosis of major depression of
35 moderate character). Since we did not test the effects of a full MBCT program but rather a brief
36 version with fewer exercises, the mindfulness application was not hypothesized to be as effective
37 as the BA. In addition, research has shown that depressed individuals in greater extent have
38 deficits in cognitive functioning such as concentration difficulties, distractibility and
39 impairments in memory, as well as problem in engaging in effortful cognitive processes²⁸⁻³¹.
40 Therefore, we concluded that the BA intervention would be more suitable for the more severely
41 depressed participants since mindfulness require more cognitive functioning in initial stages,
42 such as the ability to control attention in order to focus on the present moment^{32 33}.
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48 The study was based on our previous work on guided internet-treatment for depression³⁴, but in
49 the current study the treatment content was delivered entirely via the participants' personal
50 smartphones, using recently developed smartphone applications. The aim of this study was to
51 test the effects of two smartphone-delivered treatments; one based on BA and the other one on
52 mindfulness. Hence, the main question is whether BA is more effective than mindfulness
53 delivered through a smartphone application. In order to evaluate long-term effects, we also
54 included a 6-month follow-up after the start of the treatment.
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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

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3 **Primary outcome measures.** The primary outcome measures were the Beck Depression
4 Inventory-II (BDI-II; ³⁵) and the 9-item Patient Health Questionnaire Depression Scale (PHQ-9;
5 ^{36 37}) that were administered pre-treatment, at post-treatment and also six months after the
6 treatment had ended. The PHQ-9 was also administered on a weekly basis during the entire
7 treatment phase (8 weeks). Hence, there were 3 measurements on the outcome BDI-II and 10
8 measurements on the outcome PHQ-9 (including pre-treatment, post-treatment and six months
9 follow up).
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13 **Secondary outcome measures.** In addition to the BDI-II and PHQ-9, the Beck Anxiety
14 Inventory (BAI; ³⁸), the Quality of Life Inventory (QOLI; ^{39 40}) and the Acceptance and Action
15 Questionnaire (AAQ-II; ⁴¹) were administered. The AAQ-II was administered on a weekly basis
16 during the entire treatment phase (8 weeks). All other outcome measures were collected at pre-
17 treatment, post-treatment and at 6-month after the start of the treatment. Hence, there were 3
18 measurements on the outcomes BAI and QOLI and 10 measurements on the outcome AAQ-II
19 (including pre-treatment, post-treatment and six months follow up). All outcome measures used
20 have been shown to have good psychometric properties, with internal consistencies of at least
21 $\alpha = .79$. Details of this can be found in the respective references of the outcome questionnaires.
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26 **Clinician-administered measures.** Psychiatric diagnoses were assessed at pre-treatment, post-
27 treatment and at follow-up 6 months after the start of the treatment, using the Mini-International
28 Neuropsychiatric Interview (M.I.N.I.; ⁴²). The M.I.N.I. is a diagnostic interview that, in contrast
29 to several other diagnostic interviews, is completely structured, making it appropriate for other
30 assessors than experienced psychiatrists ⁴². All interviews were conducted over telephone by the
31 four psychology students described above, which at post-treatment were blind to participants'
32 treatment condition. At the 6-month follow-up, the interviews were conducted by other clinical
33 psychology students who were blind to both the participant's condition and the treatment they
34 had been given. Recovery rates were defined as no longer fulfilling the criteria for depression
35 according to M.I.N.I.
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40 **Treatment credibility.** To measure participants' perceived treatment credibility, Borkovec and
41 Nau's Credibility/expectancy scale (C-Scale)⁴³ was used. The C-scale measures the way in
42 which participants view the logic of the treatment (credibility) and the improvements that can be
43 achieved (expectancy) and includes five items on a 10-point scale. Assessment was made after
44 the first week of treatment.
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48 **Administration format of self-report measures**

49 We used an online platform to administer the BDI-II, PHQ-9, BAI, QOLI, AAQ-II and the C-
50 scale. Previous psychometric research has validated internet-administration of self-rating scales
51 for depression, quality of life and anxiety ⁴⁴⁻⁴⁶.
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55 **Procedure and design**

56 For those participants included in the study, the results from the online screening were used as
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3 pre-treatment assessment. After the recruitment, participants were allocated using an online
4 randomization tool (www.random.org), handled by an independent person who was separate
5 from the staff conducting the study.
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8 9 **The interventions**

10 **Behavioral activation treatment.** An 8-week smartphone-based BA intervention with minimal
11 therapist contact (maximum time of 20 minutes per participant and week) was developed by our
12 research group. The intervention consisted of a short web-based psychoeducation, and a step-by-
13 step behavior program administered via a smartphone application. The psychoeducation aimed to
14 introduce the participants to the treatment and establish a minimum level of knowledge
15 concerning MDD, touching on topics like the prevalence of depression, its etiology and
16 maintenance factors based on operant conditioning, as well as the theoretical basis for BA. The
17 text in the web-based psychoeducation was written specially for the current intervention, but
18 inspired by the BA treatment manuals of Martell et al.⁴⁷ and Lejuez, Hopko & Hopko⁴⁸. In all,
19 there were 3 chapters, totaling 11 pages of text, containing 3 893 words.
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24 The smartphone application was built as a native application for Iphone, meaning that the
25 application was coded in a specific programming language (Objective C), and as a mobile web
26 application for other smartphones. See Figure 2 for a screenshot of the application. A prototype
27 of the smartphone application was tested in a pilot study⁴⁹. This prototype, however, was not
28 specifically designed for depression interventions. The purpose of the BA application was to
29 make it easy for the participant to remember and register important behaviors, in order to
30 increase everyday activation. The application contained a database of 54 behaviors, divided into
31 3 different areas for the participant to add to their application. See Table 2 for the list of
32 behaviors from the database. The database aimed to provide suggestions, help, and inspiration to
33 get started with the application. Participants were also able to add their own areas and behaviors
34 into the application and start performing and registering these Through the initial
35 psychoeducation, the participants were advised to add only a few (between two and four)
36 behaviors initially, mainly from the existing database, and to choose behaviors that were easy to
37 perform.
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43 When a behavior was completed, for example: *Get ready in the morning*, the participant could
44 register this in the application and add a short reflection. Statistics and summaries of quantitative
45 (i.e. behavior frequency) and qualitative data (i.e. reflections) were presented in the application
46 for the participant.
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49 There was also a back-end system where all the quantitative and qualitative data from the
50 participants was accessible from a website for the therapist. From the back-end system, the
51 therapist could send short text messages to the participants via a messaging system, similar to
52 Short Message Service (SMS). The messaging system was used by the therapists (described
53 below) to send personal encouraging messages every other or every third day to the participants,
54 as well as weekly general educational messages. The system functioned as a one-way
55 communication, meaning that the participants were not able to reply to the messages. The
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3 participants were also told to write a reflection to summarize every week for their therapist, and
4 send it via e-mail by the end of every treatment week. The participants received personal
5 feedback on their reflection from their therapist via e-mail. No sensitive data, through which the
6 person providing data could be identified, was saved. In addition, all internet (including the
7 therapists' back-end system) and smartphone activities (including the participants' mobile
8 application) were secured, with SSL-encrypted information.
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12 [Insert Figure 2 about here]
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16 **Mindfulness treatment.** The mindfulness intervention, also an 8-week smartphone-based
17 intervention with minimal therapist contact (maximum time of 20 minutes per participant and
18 week), consisted of a short web-based psychoeducation, and a step-by-step mindfulness practice
19 program, administered via a smartphone application. The psychoeducation for the mindfulness
20 intervention was equivalent to that of the BA intervention, except that the theoretical basis for
21 mindfulness was presented instead of the theoretical basis for BA. The text was written
22 especially for the current intervention, with inspiration from the self help book *The Mindful Way*
23 *Through Depression* by Williams et al.⁵⁰. In all, there were 3 chapters, totaling 9 pages of text,
24 containing 2 927 words.
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28 The smartphone application for Iphone was an established and commercially available
29 application that could be downloaded from the internet. See Figure 3 for a screenshot of the
30 application. For other smartphones, a mobile web application was built especially for the current
31 study with the aim of mimicking the Iphone application. The application consisted of a number
32 of audio tracks with exercises to facilitate the practice of mindfulness. The exercises were both
33 guided and unguided, and in both short (3 minutes) and long (30 minutes) format. Through the
34 initial psychoeducation, the participants were advised to begin with short mindfulness exercises,
35 such as a guided 3-minute mindfulness exercise, which was one of the audio tracks in the
36 application.
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40 Since the mindfulness application did not have a communication function such as the BA
41 application, e-mails were used to emulate the messaging system in the BA application. Hence,
42 the therapists sent encouraging messages every other, or every third day to the participants, as
43 well as weekly general educational messages via mail. The difference in how the therapists
44 communicated in the mindfulness intervention, compared to the BA intervention, was that the
45 therapists could not give specific feedback on activities or exercises that the participants had
46 performed. Otherwise, the communication was similar (length and type of guided content in the
47 feedback). Additionally, the participants given the mindfulness intervention were also asked to
48 write a weekly reflection to summarize their work and thoughts on the current treatment week,
49 and send this reflection to their therapist via e-mail. The participants received personal feedback
50 on their reflection from their therapist.
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3 **Therapists.** The therapists were four final-semester students from a five-year M.Sc. clinical
4 psychologist program. All therapists had completed their clinical training as well as 16 weeks of
5 practice. Each therapist was responsible for the treatment of 8 to 10 participants from the BA
6 group and an equal number of participants from the mindfulness group. Therapists were
7 randomly allocated to participants, with the restriction of not having more than 10 participants
8 from each group. For the entire duration of the study the therapists received continuous
9 supervision from an experienced psychotherapist with CBT orientation, who had previous
10 experience of working with a BA treatment manual, as well as mindfulness in depression
11 treatment.
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14 15 16 **Subgroups based on cut-off scores**

17 All randomized participants were classified into groups of either high or low severity of
18 depression. These classes were formed based on the cut-off scores on the PHQ-9. The
19 participants were considered to suffer from higher severity of depression if they scored ≥ 10 on
20 PHQ-9 and if they fulfilled the criteria for an ongoing primary diagnosis of major depression of
21 moderate character ($n=51$). Participants not fulfilling these criteria were considered to suffer
22 from lower severity of depression ($n=30$).
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25 26 27 28 **Data analysis**

29 All analyses were performed using SPSS 20 (SPSS, Inc., Chicago, IL). Independent t -tests and
30 χ^2 -tests were used to test for group differences in demographics, pre-treatment data and in
31 recovery rates. In order to adhere to the intention-to-treat principle, the continuous outcome
32 variables were analyzed using mixed effects models, given their ability to handle missing data⁵¹.
33 All analyses used Maximum Likelihood estimation. Random intercept models were selected for
34 all measures. Differences between the BA treatment and the mindfulness treatment were
35 primarily investigated by modeling interaction effects of group and time. For the PHQ-9 and the
36 AAQ-II, where weekly measures were available, the covariance between the random intercept
37 and slope was not significant, and therefore was not included in the model. Hence, a random
38 intercept model was used also for these measures. Between-group differences at post-treatment
39 were analyzed using independent t -tests. Power analysis indicated an 89 % chance of detecting a
40 between-group effect size of $d=0.60$ (α level=0.05, one tailed). Within- and between-group effect
41 sizes (Cohen's d) were calculated by dividing the differences in means by the pooled standard
42 deviations⁵². This was done both from pre-measurements to post-measurements, and from pre-
43 measurements to the 6-month follow up data.
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50 51 **Results**

52 The two groups did not differ significantly on any of the measures at pre-treatment ($t=0.50$ to
53 0.67 , $df=79$, $p=0.78$ to 0.50). Also, there was no significant difference in demographic
54 characteristics between the groups according to chi-square analysis ($\chi^2=0.01$ to 1.03 , $df=1$,
55 $p=0.22$ to 0.57). See Table 1 for demographical data. See Table 3 for all outcome measurements
56 at pre-treatment, post-treatment and at 6-month follow-up. The results will be presented in the
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3 following order: attrition and adherence, self-report inventories (including effect size) both for
4 the whole sample and the subgroups, recovery rates and treatment credibility.
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7 **Attrition and adherence**

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9 Of the 84 participants randomized, 3 participants decided not to participate in the study. Nine out
10 of these 81 participants (11.1 %) did not provide post-treatment data with a distribution of four
11 participants from the BA group and five participants from the mindfulness group. Six out of the
12 81 participants (totaling 7.4 %) were unreachable for the M.I.N.I. telephone interview and were
13 classified as unimproved in the data analysis. In the 6-month follow-up, 69 participants from the
14 two treatment groups (totaling 85.2 %) provided data on the self-report measures, with a
15 distribution of 35 participants from the BA group and 34 participants from the mindfulness
16 group. 59 participants (72.8 %) were reached for the M.I.N.I. telephone interview. Once again,
17 those unreachable were classified as unimproved in the data analysis.
18

19
20 In a study by Andersson et al⁵³, the number of postings in a discussion group was used as a
21 process factor. Therefore, we defined adherence to treatment as the number of weekly reflections
22 the participants sent to their therapist. In order to be considered as a completed week, at least one
23 reflection had to have been sent to the therapist during that week. Of the 81 participants, 57
24 (70 %) succeeded to adhere to all the 8 weeks. Of these, 25 (63 %) were in the BA group and 32
25 (78 %) were in the mindfulness group. No significant difference in adherence was found between
26 the two groups ($\chi^2(N=81, df=1)=2.35, p=1.00$). In average, participants succeeded to adhere to
27 six weeks ($M=5.8, SD=2.47$).
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30 **Primary outcome measures**

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32 No significant interaction effects of group and time on the PHQ-9 and the BDI-II were found
33 between the groups, neither from pre-treatment to post-treatment (PHQ-9: ($F(1, 501.47)=.28,$
34 $p's=.60$); BDI-II: ($F(1, 74.11)=.28, p's=.60$)), nor from pre-treatment to the 6-month follow up
35 (PHQ-9: ($F(1, 571.49)=.36, p's=.55$); BDI-II: ($F(1, 147.96)=.09, p's=.77$)). However, as evident
36 from Table 3, large within-group effect sizes were found on PHQ-9 and BDI-II, between pre-
37 treatment and post-treatment, as well as between pre-treatment to the 6-month follow up. This
38 was the case for both the BA treatment and the mindfulness-treatment.
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42 **Subgroup analyses**

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44 For the participants (total $n=51$, BA $n=23$, MF $n=28$) suffering from high severity of depression
45 (≥ 10 on the PHQ-9 and an ongoing primary diagnosis of major depression of moderate
46 character), a mixed-effects model analysis on the PHQ-9 revealed significant interaction effects
47 of group and time in favor for the BA group from pre-treatment to 6-month follow-up, but not on
48 pre-treatment to post-treatment. Thus, the results indicated a difference between the BA group
49 and the mindfulness group from pre-treatment to 6-month follow-up ($F(1, 362.1)=5.2, p's<.05$)
50 for the participants suffering from higher severity of depression. As seen in Table 3, the effect
51 size between the groups at 6-month follow-up was moderate (Cohen's $d=0.47$; CI [-1.46, 2.40]).
52 No difference between the groups from pre-treatment to post-treatment was found
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57 For the more mildly depressed participants (total $n=30$, BA $n=17$, MF $n=13$) there was a
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3 significant effect in favor of the mindfulness group from pre-treatment to 6-month follow-up on
4 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
5 sizes were, as evident from Table 3, large (PHQ-9: Cohen's $d=0.98$; CI [-0.72, 2.68]; BDI-II:
6 Cohen's $d=1.21$; CI [-1.71, 4.13]). No difference between the groups from pre-treatment to post-
7 treatment was found.
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10 11 **Secondary outcome measures**

12 As evident from Table 3 no significant interaction effects were found on the secondary measures
13 between the groups, neither from pre-treatment to post-treatment (BAI: ($F(1, 74.05)=1.30,$
14 $p's=.26$); AAQ-II: ($F(1, 570.00)=.07, p's=.79$); QOLI: ($F(1, 76.43)=1.06, p's=.31$)), nor from
15 pre-treatment to the 6-month follow up (BAI: ($F(1, 147.01)=.35, p's=.56$); AAQ-II: ($F(1,$
16 $639.00)=.11, p's=.74$); QOLI: ($F(1, 148.61)=.39, p's=.53$)). Nevertheless, as shown in table 3,
17 medium to large within-group effect sizes were revealed on all secondary outcome measures.
18 This was evident for both groups, and on pre-treatment to post-treatment, as well as on pre-
19 treatment to the 6-month follow up.
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24 **Recovery rates**

25 Recovery rates were defined as no longer fulfilling the criteria for depression according to
26 M.I.N.I. There were no significant differences in recovery rates between the groups, neither at
27 post-treatment nor at the 6-month follow-up. This was the case both when analyzing the whole
28 sample as well as the subgroups. When analyzing the whole sample ($n=81$), 73.5 % ($n=25$) in the
29 BA group recovered at post-treatment, compared to 53.1 % ($n=17$) in the mindfulness group
30 ($\chi^2(N=66, df=1)=2.97, p=.07$). At the 6-month follow-up, 30 out of 34 participants (88.2 %) from
31 the BA group had recovered, and 26 out of 32 participants (81.3 %) from the mindfulness group
32 had recovered ($\chi^2(N=66, df=1)=.63, p=.33$).
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37 When analyzing only the severe depressed participants, there was a tendency in favor for the BA
38 group. Among the severely depressed participants, 73.9 % ($n=17$) in the BA group recovered at
39 post-treatment, compared to 50.0 % ($n=14$) in the mindfulness group ($\chi^2(N=51, df=1)=3.03,$
40 $p=.07$). At the 6-month follow-up, 21 out of 23 participants (91.3 %) from the BA group had
41 recovered, and 22 out of 28 participants (78.6 %) from the mindfulness group had recovered
42 ($\chi^2(N=51, df=1)=1.55, p=.20$).
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46 Among the less severe depressed participants, 82.4 % ($n=14$) in the BA group recovered at post-
47 treatment, compared to 92.3 % ($n=12$) in the mindfulness group ($\chi^2(N=30, df=1)=.63, p=.41$). At
48 the 6-month follow-up, the number of participants from the BA group that had recovered
49 remained the same as in the post-measurement ($n=14$). In the mindfulness group all participants
50 ($n=13$) from the mindfulness group had recovered at the 6-month follow-up ($\chi^2(N=30,$
51 $df=1)=2.549, p=.17$), however no significant differences in recovery rates between the groups
52 was found when analyzing only the less severe depressed participants.
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56 **Treatment credibility and therapist time**

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3 Treatment credibility ratings (C-scale) after one week of treatment showed that participants in
4 both groups rated their respective treatment as credible. Out of a possible total of 50, the average
5 scores were 31.9 ($SD=7.1$) for the BA group and 32.1 ($SD=7.8$) for the mindfulness group. There
6 was no significant difference in treatment credibility between the two groups ($t(78)=0.12$,
7 $p=0.90$). Furthermore, treatment credibility did not correlate significantly with any of the
8 outcome measures, either for all participants combined ($r=0.13$, $p=0.27$), for the BA group
9 ($r=0.01$, $p=0.92$) or for the mindfulness group ($r=.23$, $p=.18$).
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14 The therapist time per participant and week varied depending on whether the participant had sent
15 a reflection or not. The therapists reported a span between 2 and 18 minutes per week and
16 participant. The therapists reported that the time they spent did not differ between the two
17 treatment groups.
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20 Discussion

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22 The overall aim of this study was to evaluate and compare the effects of two smartphone-
23 delivered treatments for people suffering from mild to moderate major depression; one based on
24 BA and the other on mindfulness. Hence, the main question was whether BA is more effective
25 than mindfulness delivered through a smartphone application. We hypothesized that BA
26 treatment delivered via smartphone would be more effective than mindfulness treatment
27 delivered via smartphone. We also expected that BA would be superior to mindfulness for
28 participants suffering from more severe depression. When analyzing the whole sample as one
29 entity, the result showed that the two interventions did not differ significantly from one another;
30 neither from pre-treatment to post-treatment, nor from pre-treatment to the 6-month follow-up on
31 any of the outcome measures. Also, there were no significant differences in recovery rates
32 between the groups, neither at post-treatment nor at the 6-month follow-up.
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38 This study also explored how different levels of initial depression severity could moderate
39 response to the different interventions. All randomized participants were classified into either
40 high or low severity of depression based on the cut-offs scores on the PHQ-9 and whether they
41 fulfilled the criteria for an ongoing primary diagnosis of major depression. For participants with
42 higher severity of depression, the treatment based on BA was superior to the treatment based on
43 mindfulness, as measured with PHQ-9. In contrast, for participants with lower initial severity,
44 the treatment based on mindfulness was more effective than the treatment based on BA, as
45 measured with PHQ-9 and BDI-II.
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50 The result from the analysis of the higher severity participants is in line with Dimidjian et al's
51 finding⁷. In contrast to the meta-analysis by Cuijpers et al²⁴, Dimidjian et al⁷ found that BA
52 was comparable in efficacy to antidepressant medication, and more efficacious than cognitive
53 therapy - but only among those patients who were more severely depressed. Since it is known
54 that depressed individuals in greater extent have concentration difficulties, distractibility and
55 problems in engaging in effortful cognitive processes²⁸⁻³¹, Beck and colleagues⁵⁴ have long
56 suggested that therapists should focus on behavioral strategies early in treatment when patients
57 are more depressed and return to that emphasis later if patients start to worsen. We expected that
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3 the BA intervention would be more suitable for the more severely depressed participants since
4 mindfulness require more cognitive functioning in initial stages, such as the ability to control
5 attention in order to focus on the present moment^{32 33}.
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8 The result from the analysis of the less severely depressed participants was unexpected to us.
9 Although there is yet only initial evidence that mindfulness treatment is effective for acute or
10 severely depressed patients^{55 56}, mindfulness has proven to be effective for relapse prevention of
11 recurrent depression^{20 57 58}. A possible explanation of the results could be that there was a
12 difference between the two treatment groups, although not significant, in the number of
13 participants that were suffering from major depression. In the BA group 64.7% ($n=11$) were
14 diagnosed with major depression in the initial screening, compared to 30.8 % ($n=4$) in the
15 mindfulness group ($\chi^2(N=30, df=1)=3.39, p=.07$).
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19 Moreover, the results showed significant improvements from pre-treatment to post-treatment on
20 the primary outcome measures in both treatment conditions with large within-group effect sizes
21 and large recovery rates, comparable to other depression treatments^{59 60}. This might indicate that
22 the smartphone format used in this study could work well for a depressed population. However, a
23 replication with a waiting list group should be conducted to rule out the possibility that the
24 effects occurred due to natural recovery.
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28 **Limitations**

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30 There are a number of limitations that need to be mentioned. The first is that no waiting list
31 group was included. Although our main research question was to assess whether behavioral
32 activation is more effective than mindfulness delivered via smartphone, a control group given no
33 intervention would have yielded a more clear result.
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36 A second limitation is that the study was underpowered. Thus, it is difficult to detect significant
37 overall differences between the two smartphone-treatments, even if significant interaction effects
38 were found when using mixed effects models with PHQ-9 in the subgroup analyses. A post-hoc
39 power analysis revealed that a sample of 393 participants was required to detect small between-
40 group effects. We did not expect that the mindfulness treatment would be as effective and
41 powered the trial as if a moderate between-group effect would be found.
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44 A third limitation was that the participants were recruited nationally through mass media and
45 advertisements. Thus, we cannot be sure that this treatment would work in a clinical setting, e.g.
46 an outpatient psychiatric facility. However, mean depression severity as measured by the BDI-II
47 at intake ($M=24.10$) is rather close to the limit of 29, proposed for defining severe depression³⁵,
48 meaning that the depression severity in this study was comparable to an outpatient psychiatric
49 population.
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52 Fourth, we recruited a broad range of participants, with regards to severity of depression (a
53 minimum of 8 and a maximum of 44 on BDI-II at intake). This makes it difficult to target a
54 specific group for whom the treatments would be most effective. Nevertheless, a subgroup
55 analysis showed that participants with higher severity of depression responded significantly
56 better to the BA than to the treatment based on mindfulness, whereas the treatment based on
57 mindfulness worked significantly better than the treatment based on BA for the participants with
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3 lower initial depression severity. Additionally, it can be argued that these broad inclusion criteria
4 reflect a real population (i.e. an outpatient psychiatric population) of individuals with depressive
5 disorders. However, this contributed to power limitations as well.
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8 A fifth related concern was the large number of participants that had college- or university level
9 education (65.5 %). This might compromise generalizability of the results, since it is possible
10 that guided self-help is especially well suited for educated patients. However, there is data
11 indicating that 50 % of patients seeking psychotherapy have some college education⁶¹ and that
12 educated patients may be more inclined to seek help for mental health problems in general⁶².
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15 16 **Conclusion**

17 Some clinical implications of this study are discussed as follows. Due to the need for simple and
18 fast interaction with the treatment program, singular treatment components such as BA and
19 mindfulness might be a better target for smartphone applications than entire multi-component
20 treatment packages. At the same time, there is a need for guided self-help treatments distributed
21 digitally that can reach out to more patients. This study is one of the first to test a treatment for
22 depression, administered via smartphone. The large within-group effects on the primary outcome
23 measures, as well as the large recovery rates for both groups, are comparable to other depression
24 treatments and indicate that this smartphone format with a small amount of text and minimal
25 therapist support might work well for a depressed population. However, as mentioned above, a
26 replication with a waiting list group should be conducted to rule out that the effects occurred due
27 to natural recovery.
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32 Moreover, this study also shows that BA might work better for a more severely depressed
33 population, whereas mindfulness might work better for people suffering from light depression.
34 These results suggest that different treatments distributed digitally can target different subgroups
35 of depressed patients in terms of severity. However, more studies are needed to strengthen this
36 hypothesis before any conclusions can be drawn.
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40 From a broader perspective, we believe that smartphones will be integrated even further in
41 society since they are already socially accepted and come at relatively low costs considering their
42 functionalities²⁵, and therefore may serve an important role in health care. Therefore these
43 results, showing that mild to moderate major depression can be treated effectively by means of a
44 supported smartphone-application, might be important in making depression treatment and other
45 psychological treatments more assimilated into people's daily life. As suggested in Ly et al.⁴⁹,
46 the smartphone format might also help increasing patients' awareness of being in treatment, even
47 in everyday settings, and therefore better help patients create direct incentives for treatment
48 related activities in their everyday life⁴⁹. Using smartphones to distribute psychological
49 treatment might also help making it possible to reach out with psychological therapy to a broader
50 group of people, since their use attracts no attention²⁵, allowing users to interact with a device
51 without fear of judgment or stigma. Lastly, psychological treatments distributed via smartphones
52 are not only relevant for Swedish conditions but also for the developing countries of the world,
53 which increasingly are empowered by mobile phones with internet connection.
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3 This study might pave the way for a broad range of other trials conducted via smartphones, both
4 self-help interventions and face-to-face treatments with the smartphone as an adjunct tool. We
5 believe that a substantial part of internet-based interventions in the future will be executed
6 through smartphones or at least supported by smartphones. Further studies should focus on both
7 formats, as well as expanding the treatment platform to other psychological disorders.
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For peer review only

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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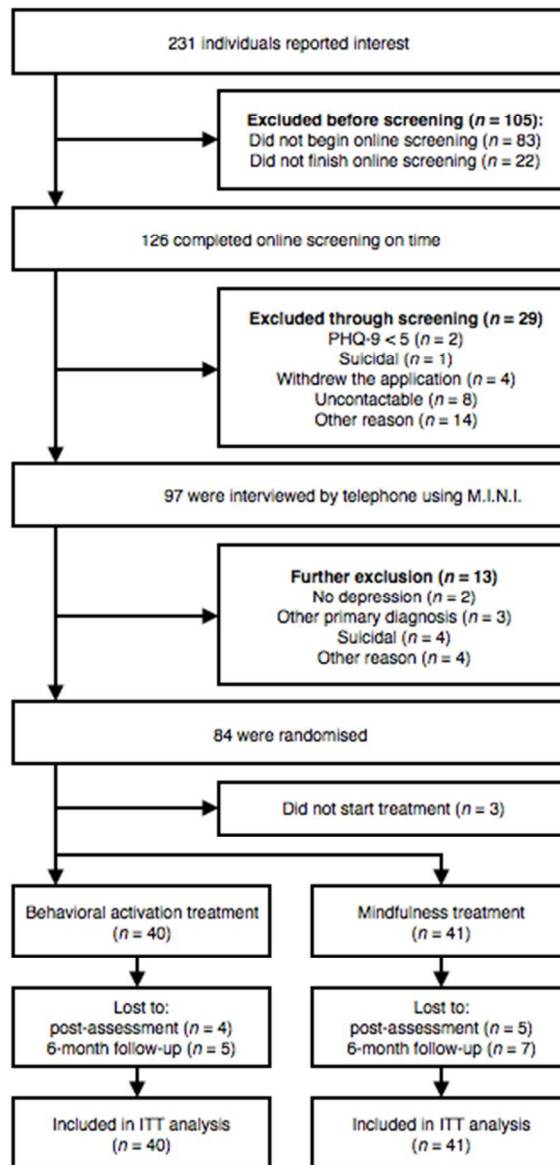
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For peer review only



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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.

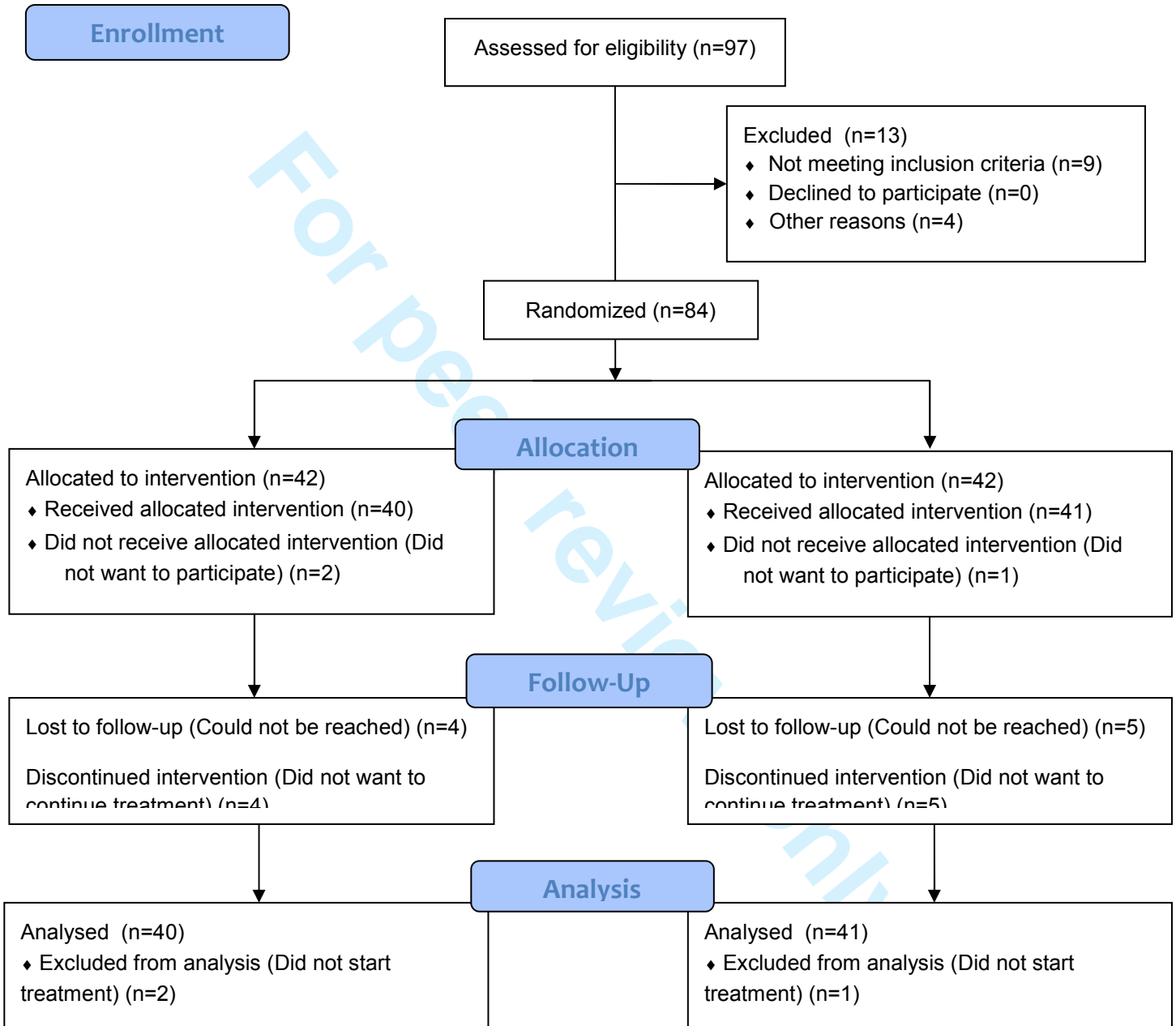
Outcome measure	Mean (SD)			Effect size, <i>d</i> (95% CI)			
	Pre-treatment	Post-treatment	6-month follow-up	Between-group, pre-post	Between-group, pre-6FU	Within-group, pre-post	Within-group, pre-6FU
Total							
BDI-II							
BA	23.50 (7.85)	10.89 (5.92)	12.71 (10.56)	0.25	0.03	1.83 (0.27-3.38)**	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-L Dep							
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

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3		11b	If relevant, description of the similarity of interventions
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
6			
7	Results		
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
9	diagram is strongly		were analysed for the primary outcome
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up
12		14b	Why the trial ended or was stopped
13			
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
16			by original assigned groups
17			
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
19	estimation		precision (such as 95% confidence interval)
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
22			pre-specified from exploratory
23			
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
25			
26	Discussion		
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
30			
31	Other information		
32	Registration	23	Registration number and name of trial registry
33	Protocol	24	Where the full trial protocol can be accessed, if available
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
35			

*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.