Internet-based cognitive behavioural therapy for subthreshold depression in people over 50 years old: a randomized controlled clinical trial

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ABSTRACT

Background. Subthreshold depression is a highly prevalent condition and a risk factor for developing a major depressive episode. Internet-based cognitive behaviour therapy may be a promising approach for the treatment of subthreshold depression. The current study had two aims: (1) to determine whether an internet-based cognitive behaviour therapy intervention and a group cognitive behaviour therapy intervention are more effective than a waiting-list control group; and (2) to determine whether the effect of the internet-based cognitive behaviour therapy differs from the group cognitive behaviour therapy intervention.

Method. A total of 191 women and 110 men with subthreshold depression were randomized into internet-based treatment, group cognitive behaviour therapy (Lewinsohn’s Coping With Depression course), or a waiting-list control condition. The main outcome measure was treatment response after 10 weeks, defined as the difference in pre- and post-treatment scores on the Beck Depression Inventory (BDI). Missing data, a major limitation of this study, were imputed using the Multiple Imputation (MI) procedure Data Augmentation.

Results. In the waiting-list control group, we found a pre- to post-improvement effect size of 0.45, which was 0.65 in the group cognitive behaviour therapy condition and 1.00 within the internet-based treatment condition. Helmert contrasts showed a significant difference between the waiting-list condition and the two treatment conditions ($p=0.04$) and no significant difference between both treatment conditions ($p=0.62$).

Conclusions. An internet-based intervention may be at least as effective as a commonly used group cognitive behaviour therapy intervention for subthreshold depression in people over 50 years of age.

INTRODUCTION

In people over 50 years of age, the prevalence of major depression is 1–3%; the prevalence of subthreshold depression in this population is 8–16% (Cole & Dendukuri, 2003). Patients with subthreshold depression have symptoms of depression, but not enough to meet DSM-IV criteria for major depression (Cuijpers & Smit, 2004). Subthreshold depression has considerable effects on well-being and psychosocial functioning (Beekman et al. 1995; Rapaport & Judd, 1998). People with subclinical depression are reported to be similar to those with a diagnosis of major depression with regard to their psychosocial functioning (Gotlib et al. 1995). Furthermore, people with subthreshold depression experience nearly the same degree of impairment in health status, functional status...
and disability as those being diagnosed with major depression (Wagner et al. 2000).

An association between depressive symptomatology and developing a major depressive episode has been demonstrated (Cuijpers & Smit, 2004). Up to 27% of elderly people with subthreshold depression develop a major depressive episode within 3 years (Beekman et al. 2002). Late-life depression is characterized by an unfavourable prognosis, reduced quality of life, and excess mortality (Cole et al. 1999; Smit et al. 2006). Therefore, treatment of subthreshold depression is very important.

Given its high prevalence and the fact that probably less than 20% of people with depression are detected and treated (Cole & Dendukuri, 2003), new approaches are needed to treat subthreshold depression and to prevent major depressive episodes. It is important that these methods reach large populations and people who otherwise would not seek treatment.

Internet-based cognitive behaviour therapy has advantages over traditional cognitive behaviour therapy for both clients and health care. The low-threshold accessibility of the internet makes it suitable for offering and receiving help for psychological problems. Clients who are treated on the internet can avoid the stigma incurred by seeing a therapist (Gega et al. 2004). They can obtain treatment at any time and place, work at their own pace, and review the material as often as desired. In internet-based treatment, clients are guided by programmes to work on their problems. The level of therapist involvement can vary from no assistance, or minimal therapist contact by email or telephone, to the amount of involvement as seen in classic individual therapy. Thus, internet-based treatment may reduce the therapist time while maintaining efficacy (Wright et al. 2005).

A recent meta-analysis showed that these kinds of treatment programmes may be effective (Spek et al. 2007). However, more research is needed, especially studies that, within one design, include a control group, an intervention group with a proven effective therapy and an internet-based therapy. Moreover, more data are needed concerning internet-based treatment in older adults, as this has not yet been studied.

The current study evaluated an internet-based intervention for subthreshold depression in people over 50 years of age. Two hypotheses were tested. First, we wanted to determine whether internet-based cognitive behaviour therapy and group cognitive behaviour therapy were more effective than a waiting-list condition. Second, we tested whether the two interventions differed regarding their effectiveness.

METHOD

Participants

Participants were recruited by advertisements in free regional newspapers, and by personal letters sent by the Municipal Health Care Service of the city of Eindhoven. The letters \((n=15 697)\) were sent in cohorts to all inhabitants of Eindhoven, born between 1955 and 1949. In each mailing round, inhabitants of Eindhoven who were born in the same year received letters. The letters and advertisements provided information about the study and the address of the study homepage. The study homepage contained general information about depression, information about the study, and an application form including the screening instrument, the Edinburgh Depression Scale (EDS; Cox et al. 1987, 1996; Matthey et al. 2001). In all communications it was made clear that only people who had both depressive symptoms and internet access were eligible for the study.

Participants who scored above the cut-off score of 12 on the EDS \((n=699)\) were invited for an in-person structured clinical interview for depression, the World Health Organization Composite International Diagnostic Interview (WHO CIDI; WHO, 1997). To be included in the study, participants had to meet the following criteria: an EDS score of 12 or more, but no compliance with the DSM-IV diagnostic criteria of depression, signed informed consent, age between 50 and 75 years, access to the internet and the ability to use the internet. Exclusion criteria were suffering from any other psychiatric disorder in immediate need of treatment and suicidal ideation.

Of the 606 people who attended the interview, 301 \((49.7\%)\) were included in the study. The most important reasons for exclusion were DSM-IV diagnoses for depression \((n=125, 41.0\%\) of the exclusions; these people were referred to their general practitioner with a request for treatment), psychiatric disorders in immediate need of treatment \((n=79, 25.9\%)\),
bipolar disorder \( (n=7, 2.3\%) \), and insufficient computer skills (self-report, \( n=18 \) people, 5.9\%). The remaining exclusions (10.8\%) were based on other, less common reasons, such as relocating to another geographical area, serious physical illness, and busy work schedules. Several people were excluded on more than one criterion. Forty-three people (14.1\%) decided that they did not want to participate in the study (Fig. 1).

The study protocol was approved by the Maxima Medisch Centrum (local hospital) ethics committee, which is certified by the Central Committee on Research involving Human Subjects in The Netherlands.

**Measures**

**The Edinburgh Depression Scale (EDS)**

The EDS is a 10-item self-report scale assessing the common symptoms of depression. It was originally designed to assess post-partum depression and was called the Edinburgh Postnatal Depression Scale (EPDS; Cox *et al.* 1987). The EPDS was later validated in other age strata (Murray & Carothers, 1990; Cox *et al.* 1996; Becht *et al.* 2001; Nyklíček *et al.* 2004) and in men (Matthey *et al.* 2001) and renamed the EDS. Internal consistency (Cronbach’s \( \alpha \)) has been shown to be at least 0.80 (Cox *et al.* 1987; Matthey *et al.* 2001). The EDS was found to correlate 0.64 with the Beck Depression Inventory (BDI; Pop *et al.* 1992). With a clinical diagnosis of major depression as the criterion, the sensitivity is 84\%, the specificity 92\%, and the positive predictive value (PPV) is 46\% at cut-off point 12/13 (total scale ranges from 0 to 30) in a sample of middle-aged Dutch participants (Becht *et al.* 2001; Nyklíček *et al.* 2004). Because of its conciseness this scale was used as the screening instrument.

**BDI, 2nd edition (BDI-II)**

The 21-item BDI (Beck *et al.* 1961) is the most frequently used self-report measure for
depressive symptoms. The BDI was developed to assess the intensity of depressive symptoms. Internal consistency is high; in the Dutch manual, values for Cronbach’s $\alpha$ of 0.92 and 0.93 are reported (Van der Does, 2002). Cut-off scores, based on extensive validation studies in The Netherlands, are the following: scores of 0–13 indicate minimal symptoms, scores of 14–19 reflect light symptoms, scores of 20–28 are interpreted as moderate symptoms, and scores of 29–63 indicate serious symptoms (Dutch BDI manual; Van der Does, 2002). The BDI was used as the primary outcome measure.

**WHO CIDI**

The WHO CIDI (WHO, 1997) is a fully structured interview developed to map DSM-IV and ICD-10 symptoms, and to report whether the diagnostic criteria are met. Reliability of the CIDI for mood disorders is good: the test–retest $\kappa$ coefficient is 0.71 and the inter-rater $\kappa$ coefficient is 0.95 (Wittchen, 1994). The CIDI is available in three different versions: referring to the previous 4 weeks (1-month prevalence), to the previous 12 months (1-year prevalence), and to an episode earlier in life (lifetime prevalence). The 12-month version was used in the interview to assess subthreshold depression.

**Procedure**

Participants with an EDS score of 12 or more were invited for a face-to-face clinical interview at a centre for diagnosis in primary care (Diagnostisch Centrum Eindhoven). In this interview, participants were informed about the study and the study conditions, demographic data were collected, and a structured interview was conducted to assess the DSM-IV criteria of depression. At the end of the clinical interview, eligible participants were randomized. For this purpose a random allocation sequence was generated. The randomization list was kept in an administrative office that was not related to the study. After the inclusion of a participant in the study, the interviewer made a telephone call to the ‘randomization office’ to inquire to which condition the participant was randomized. On the randomization list, the time and date of randomization were noted.

After the interview, and after randomization, the participants were asked to fill in the BDI at home. After completion of this questionnaire, the treatment started. Ten weeks after the start of the treatment or after 10 weeks on the waiting-list, participants were asked to complete the post-treatment BDI. All questionnaires were completed at home and sent to the study site.

**Interventions**

The group cognitive behaviour therapy protocol was the Coping With Depression (CWD) course (Lewinsohn et al., 1992), adapted to the Dutch situation by Cuijpers (2000). This is a highly structured cognitive behavioural treatment for depression. The course consists of 10 weekly group sessions on psycho-education, cognitive restructuring, behaviour change, and relapse prevention. It has been used for over 10 years by mental health institutions in The Netherlands and has been shown to be effective (Cuijpers, 1998; Allart-van Dam et al., 2003, 2007; Haringsma et al., 2005). The group cognitive behaviour therapy sessions were led by psychologists and trained social workers. There were always two group leaders, of which at least one was a psychologist. Groups consisted of no more than 10 participants. The sessions took place at the centre for diagnosis in primary care where the participants had been interviewed before their inclusion in the study.

The internet-based cognitive behaviour therapy intervention was developed by the Trimbos Institute, The Netherlands Institute of Mental Health and Addiction. It is a self-help intervention of eight modules with text, exercises, videos and figures. The internet-based intervention covers the same subjects as the group course, as it was based on the CWD course. The internet-based treatment was studied as a self-help intervention, and no professional support was offered to the participants of this study. The participants accessed the intervention from their home computers via the internet. The amount of time advised for completion of the course was 8 weeks, one session per week.

Participants on the waiting-list did not receive treatment immediately but were invited to participate in the intervention of their choice after the end of the trial.

**Analyses**

The target sample size of 300 participants was calculated to yield 78% power to detect a small effect (Cohen’s $f=0.10$). The study was a priori
powered to detect a small effect because we wanted to test whether there was a difference between the two interventions. The calculation was based on an analysis of variance (ANOVA) with an $\alpha$ of 0.05 (Cohen, 1988).

Preliminary analyses included checks for normality and the computation of descriptive statistics. All variables were distributed acceptably close to normal. ANOVAs, $t$ tests and $\chi^2$ tests were used to compare the following groups on baseline characteristics: (a) participants randomized to the interventions and the waiting-list, (b) people who completed all questionnaires versus people who did not, and (c) people who completed treatment versus those who did not.

Analyses regarding the main hypotheses were performed according to the intention-to-treat approach on imputed data. Missing data were imputed using the Multiple Imputation (MI) procedure Data Augmentation with the Norm library from the statistical package R (R Development Core Team, 2005) written by Schafer (1998), because Data Augmentation is currently the most sophisticated method available to create MIs (Allison, 2001). The data file was imputed five times, resulting in five new data files on which all of the analyses were performed. The five sets of outcomes were then pooled using so-called MI inference to come to a single set of results. This pooling makes use of both the variance of the outcomes within a data file and between data files. For a more extensive description of MI, see Schafer (1999). All randomized participants were included in the analyses, regardless of how many treatment modules or sessions they had completed. The effects of the interventions were tested by means of Helmert contrasts. These contrasts explicitly allow for testing hypotheses concerning differences among conditions, as opposed to ANOVA, which is an omnibus test that needs post-hoe tests to see where the differences lie.

We calculated improvement effect sizes ($d_{impr}$) by dividing the absolute difference between the post-treatment average score ($M_{post}$) and the pretreatment average score ($M_{pre}$) by the pretreatment standard deviation ($s.D_{pre}$). An effect size of 0.5 thus indicates that the post-treatment average score is half a standard deviation larger than the pretreatment average score. For between-group effect sizes, we calculated effect sizes by subtracting the effect size of the experimental group from the effect size of the control group. Effect sizes of 0.56–1.2 can be assumed to be large, while effect sizes of 0.33–0.55 are moderate, and effect sizes of 0–0.32 are small (Cohen, 1988).

To assess clinically significant change, we used the definition of Jacobson et al. (1984); they defined clinically significant change as the extent to which therapy moves someone outside the range of the dysfunctional population or within the functional population. As we did not include any people with a clinical diagnosis of major depression in the study, we decided to use a cut-off score as an indication of functional status (Haringsma et al. 2005). People with a BDI score $\geq$20 have moderate to serious symptoms of depression and were considered to be dysfunctional (Dutch BDI manual; Van der Does, 2002). People scoring below 20 on the BDI have minimal to light symptoms and were considered to be in the functional population. Clinically significant change was a change from a baseline BDI score of $\geq$20 to a post-treatment BDI score of $<20$. This was assessed using the McNemar test.

RESULTS

Post-treatment measures were completed by 67 of 102 participants in the internet group, 56 of 99 participants in the group course condition and 58 of 100 participants on the waiting-list. Intention-to-treat analyses were carried out on imputed data of all 301 participants, regardless of the amount of treatment received.

There were no differences between the three conditions regarding age [$F(2,298)=0.79$, $p>0.10$], gender [$\chi^2(2)=1.63$, $p>0.10$], having a partner [$\chi^2(2)=2.62$, $p>0.10$], educational level [$\chi^2(4)=8.21$, $p>0.05$], employment status [$\chi^2(6)=6.39$, $p>0.10$], and completion of post-treatment measures [$\chi^2(2)=2.53$, $p>0.10$], EDS scores at screening [$F(2,298)=0.61$, $p>0.10$] or BDI baseline scores [$F(2,245)=0.25$, $p>0.10$] (Table 1).

Those who did not complete post-treatment measures did not differ from people who did complete post-treatment measures regarding age [$t(299)=-1.03$, $p>0.10$], gender [$\chi^2(1)=2.52$, $p>0.10$], having a partner [$\chi^2(1)=0.07$,
Those who did not complete treatment did not differ from people who did complete treatment regarding age \(t(125) = 0.35, p > 0.10\), gender \(\chi^2(1) = 2.03, p > 0.10\), having a partner \(\chi^2(1) = 0.01, p > 0.10\), educational level \(\chi^2(2) = 3.57, p > 0.10\), employment status \(\chi^2(3) = 1.33, p > 0.10\), EDS scores at screening \(t(299) = -0.326, p > 0.10\) and BDI baseline scores \(t(246) = -1.926, p = 0.06\). However, those who did not complete treatment were more often assigned to the internet course \(\chi^2(1) = 27.96, p < 0.01\) than those who did complete treatment. Completion of treatment was measured by self-report. Participant characteristics are shown in Table 1.

We found that a mean of 9.1 out of 10 sessions (98.3%) was completed in the group course and a mean of 5.5 out of eight modules (78.1%) was completed in the internet-based intervention. The group course was completed by 94.5% of the participants; the internet course was completed by 48.3% of the participants. We did not find a dose effect relationship in the internet-based treatment condition. The main reason for not completing treatment was lack of time.

For the intention-to-treat analyses, we fitted Helmert contrasts to the imputed data to test hypotheses about the differences between conditions. The first contrast tested whether both treatments differed from the waiting-list control group. The second contrast tested whether the internet-based treatment and the group CBT were different from one another. The first fitted contrast showed a significant difference between the waiting-list condition on the one hand and the two treatment conditions on the other \(p = 0.04\). The two treatment conditions did not differ significantly \(p = 0.62\). The observed power of the contrasts was 0.68 for the first contrast and 0.12 for the second contrast. For means and standard deviations of all conditions, see Table 2.

For improvement within the waiting-list control group, we found a moderate improvement effect size of 0.45. The group cognitive
behaviour therapy condition had a large improvement effect size of 0.65, while an even larger improvement effect size of 1.00 was found within the internet-based treatment condition. When comparing the two treatments with the waiting-list group, we found an effect size of 0.20 for the group treatment and 0.55 for the internet-based treatment.

In both treatment groups, a significant proportion of participants achieved clinically significant change in functional status from moderate to serious symptoms at baseline to minimal to light symptoms at post-treatment BDI (McNemar, \( p < 0.01 \)). In the group cognitive behaviour therapy condition, 28 out of 42 people who scored BDI \( \geq 20 \) at baseline achieved a clinically significant change (14 out of 42 people who scored BDI \( \geq 20 \) at baseline remained at \( \geq 20 \) at post-treatment, 55 scored below 20 at baseline and remained below 20, and two participants worsened from below 20 at baseline to \( \geq 20 \) at post-treatment). In the internet-based treatment condition 30 out of 45 people who scored BDI \( \geq 20 \) at baseline achieved a clinically significant change (15 out of 45 people who scored BDI \( \geq 20 \) at baseline remained at \( \geq 20 \) at post-treatment, 48 scored below 20 at baseline and remained below 20, and eight participants worsened from below 20 at baseline to \( \geq 20 \) at post-treatment). In the waiting-list group, there was no significant proportion of participants who showed a significant change in status (McNemar, \( p = 0.103 \)). Only 17 out of 39 participants who scored BDI \( \geq 20 \) at baseline achieved a clinically significant change (22 out of 39 people who scored BDI \( \geq 20 \) at baseline remained at \( \geq 20 \) at post-treatment, 52 scored below 20 at baseline and remained below 20, and eight participants worsened from below 20 at baseline to \( \geq 20 \) at post-treatment).

DISCUSSION

In this study, both internet-based cognitive behaviour therapy and group cognitive behaviour therapy were significantly more effective than a waiting-list in people over 50 years of age with subthreshold depression. Furthermore, the effect of internet-based treatment did not significantly differ from that of standard group cognitive behaviour therapy. For the internet-based cognitive behaviour therapy, we found a moderate effect size of 0.55, compared to the waiting-list condition. When looking at clinically significant changes, we found that in both treatments a significant proportion of participants had made a change from moderate to serious symptoms at baseline to minimal to light symptoms post-treatment.

In this study we were faced with a large amount of missing data. This is a common problem in trials on internet-based treatment for symptoms of depression, as shown in a recent meta-analysis (Spek et al. 2007). Two studies on internet-based treatment for depression with very similar designs also obtained post-treatment data for 66% of participants (Clarke et al. 2002, 2005). A study with a follow-up period of 6 weeks obtained post-treatment data for 83% of participants (Christensen et al. 2004), and a study on an intervention that included therapist assistance obtained post-treatment data for 73% of participants (Andersson et al. 2005). There is only one study on minimal contact internet-based interventions for depression in which an extremely low drop-out rate has been observed (3%), but the way that drop-out was defined was not clearly mentioned (Patten, 2003).

As we were examining a self-help intervention, we were very careful with the amount of attention individual participants received. Therefore, we were reluctant to contact participants personally when they were late completing assessments. We sent the first three reminders by email. This was not always effective, as some people did not access their email account regularly. If, after three emails, the assessment was still not completed, we telephoned participants once. After this reminder, we did not contact participants again.

Participants who did not provide post-treatment data did not differ from those who did. However, for BDI baseline scores \( t(246) = -1.926, p=0.06 \) we found a trend for higher scores in people who did not provide post-treatment data. This might indicate that people with more serious symptoms did not complete treatment but, at least for the internet-based treatment, we cannot be certain that all people who did not provide post-treatment data also did not complete treatment.

We dealt with missing values through the application of Data Augmentation, multiply
imputing the unobserved values. The assumption of this method is that the probability of a participant having missing values may depend on observed values (such as covariates and pre-treatment measures) but not on missing ones (i.e. the values of the post-treatment measures had they been recorded). By contrast, other methods that are often used, such as last observation carried forward and complete case analysis, are based on stronger and more unrealistic assumptions; namely, that the probability of drop-out does not depend on anything, and is purely random. As the missing post-treatment measures are unobserved, it is impossible to test by what mechanism drop-out occurred; only assumptions can be made. MI has weaker assumptions concerning the missing data than other methods such as complete case analysis. Consequently, MI provides better outcomes than the alternative methods. Moreover, MI methods have been said to reduce missing data bias even when their assumptions are not strictly valid. Therefore, we assume that the imputed values of the post-treatment measures and subsequent analyses are sound.

When looking at the rate of completion of the courses, it becomes clear that the internet-based treatment is less often completed. When started, the group cognitive behaviour therapy is usually completed: drop-out from the study among participants randomized into the group course was due to participants not being willing or able to start with group cognitive behaviour therapy within the desired time period. The completion rate for the internet-based intervention, however, was only 50%. We believe that social interaction might be a reason for this difference in completion. If starting a group treatment of 10 sessions, it is common to finish it. Group treatment involves social support and social control. Participants get to know each other and the course leaders. It does not seem appropriate to end treatment once one feels better. However, in internet-based self-help, it is much easier to end or postpone treatment when an effect is noticed or when the symptoms become less urgent. As this kind of treatment is exclusively the participant’s responsibility, there are no expectations of others regarding continuation of the treatment. It has been found that, in internet-based treatment, regular telephone calls from a therapist enhance participants’ completion of internet-based treatment (Kenwright et al. 2005). This supports our hypothesis regarding the role of social support and social control.

The effect size we found for internet-based cognitive behaviour therapy roughly corresponds with effect sizes found in a recent meta-analysis (Spek et al. 2007). For internet-based treatment without therapist support for symptoms of depression, we found effect sizes (compared to inactive control groups) from 0 to 0.4 (Clarke et al. 2002, 2005; Patten, 2003; Christensen et al. 2004). The effect size for the control condition in our study roughly corresponds with effect sizes found in other studies on internet-based treatment for symptoms of depression: we found effect sizes ranging from 0.35 to 0.70 (Clarke et al. 2002, 2005; Andersson et al. 2005).

Apart from the above-mentioned drop-out, this study has several limitations. As the post-treatment assessment was directly after treatment, we cannot draw any conclusions about long-term effects. Another limitation is the fact that participants could only be included in the study if they had computer skills and access to internet. The participants of this study were more highly educated than the general population in this age group (Statistics Netherlands, 2006). Therefore, it is uncertain whether the results of this study can be generalized to people with lower educations. Furthermore, all participants were self-referred. A recent study (Mataix-Cols et al. 2006) showed that self-referred patients are more likely to benefit from computerized cognitive behaviour treatment than patients referred by mental health professionals. This implies that the results might not be generalizable to populations with other sources of referral. Finally, as our participants suffered from subthreshold depression, we cannot draw any conclusions about the effects both treatments might have had on major depressive episodes.

More research on internet-based cognitive behaviour therapy is needed, especially research into the predictors of improvement after treatment, in order to be able to tailor effective interventions to specific subgroups of clients.

Despite these limitations, our findings suggest that people over 50 can benefit at least as much from internet-based treatment for subthreshold depression as from the commonly used CWD
course. As this internet-based intervention is a self-help intervention, there is less therapist time involved; therefore, this may be a very efficient approach in treating subthreshold depression and in preventing major depressive episodes. Furthermore, in this study many participants reported not seeking help through the regular health-care system because they were very concerned about being stigmatized. This suggests that internet-based interventions for depression might reach patients who otherwise would not seek help.

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DECLARATION OF INTEREST
None.

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