Chapter 4

Effectiveness of Guided Self-Help for Depression and Anxiety Disorders in Primary Care: A Pragmatic Randomized Controlled Trial

Abstract

The objective of this study is to evaluate the effectiveness of (guided) self-help in primary care for patients diagnosed with a minor or major depression and/or anxiety disorder. The study population consists of 120 (screened) primary care patients aged 18-65 years with at least one depressive and/or anxiety disorder. The primary focus is the reduction of depressive and anxiety symptoms. The self-help courses (Problem-solving Treatment and exposure) took 6 weeks to complete. The self-help group reported slightly better outcomes than the care as usual group but these results were not significant: $d = -0.18$ (95% CI = -2.29 to 7.31) for symptoms of depression and $d = -0.20$ (95% CI = -0.74 to 2.29) for symptoms of anxiety. For patients with an anxiety disorder only, the anxiety symptoms decreased significantly compared to the care as usual group ($d = -0.68$; 95% CI = 0.25 to 4.77). Self-help seems only slightly superior to care as usual and therefore might not be an effective tool in general practice. But the lack of results could also be due to our selection of patients or to our selection of GPs (with interest in psychiatric disorders). Nonetheless the promising signals with respect to anxiety disorders warrant further research.

Current Controlled Trials: ISRCTN17831610.

Keywords: depression, anxiety, self-help, psychological treatment, primary care.
Introduction

Depressive and anxiety disorders are both highly prevalent.[1] Anxiety and depression can cause serious functional impairment and reduced quality of life.[2,3] Almost half of those who have ever suffered from a psychiatric disorder have had more than one disorder. Comorbid anxiety is the rule rather than the exception in depression with up to 60% of patients with major depressive disorder also suffering from an anxiety disorder.[4] Because of this high comorbidity our study is aimed at individuals with depressive disorder, anxiety disorders as well those with co-morbid depression and anxiety.

Many patients with depressive or anxiety disorders do not seek any help. It is estimated that this is true for about two thirds of cases.[5,6] Those that do seek help usually go to their general practice first.[5,7] However, they do not always present their symptoms in psychological terms, and it is well known that general practitioners (GPs) often (up to 50% of instances) fail to recognize mental health problems.[8] And those patients whose mental health problems are recognized do not always receive evidence-based treatments. Andrews et al.[9] estimate that this might be true for half of the patients in primary care. According to several studies[10-12] many patients are prescribed antidepressants immediately after the diagnosis is made; however, few patients manage to have adequate dosage and duration of (antidepressant) medication. Approximately 30% of depressed primary care patients stop using antidepressants within the first month of treatment, while only 40% reach the recommended therapeutic dosage.[13] It is also important to note that the majority of primary care patients prefer psychotherapy as a treatment.[14] Therefore it is not surprising that the research to date suggests that access to psychological treatment in primary care requires improvement. This might be achieved by a new form of treatment delivery: through self-help. Self-help can be defined as a standardized psychological treatment that a patient can work through on his/her own, possibly with some guidance.[15] Most self-help interventions are based on cognitive-behavioral therapy (CBT)[16] but nowadays other types of treatment (e.g. problem solving treatment (PST) and interpersonal therapy (IPT)) have become available as (guided) self-help interventions as well. Self-help interventions are available via books (bibliotherapy) and via the computer (web-based, CD-ROM, DVD) and they can be pure self-help or guided self-help. In pure self-help patients work on the course alone while in guided self-help patients receive feedback on their assignments, for example from a psychologist or psychiatric nurse. The guidance in guided self-help can differ in format (e.g. via telephone, face-to-face or through the Internet) as well as in the intensity (e.g. once a week or on request). It has been demonstrated convincingly that guided self-help is effective for a number of mental health problems.[17,18]

One way to offer self-help interventions is to embed them into more comprehensive care models, e.g. disease management or stepped care models. In these models patients receive evidence-based treatments and a care manager monitors their symptoms. The care manager coordinates care, monitors the treatment response and actively guides the patient through the treatment protocol. These models seem promising for the improvement of mental health care in general practice[19-21] and it is therefore important to combine the self-help with the models. One of these is a stepped care model. This model includes a number of treatments of increasing intensity.[21] All patients follow the same sequence of treatments. Accordingly all patients start with the same evidence-based minimal intervention. A self-help intervention seems an
appropriate first step in a stepped care model because it is easily accessible and is evidence-based.

Previous RCTs on the effectiveness of (online) self-help treatment\textsuperscript{[22,23]}, with varying types and amount of guidance, were performed on community samples. A review showed that while self-help CBT is effective for depression, there is not sufficient data that specifically refers to self-help CBT for the treatment of depression in primary care.\textsuperscript{[24]} However, other RCTs in primary care testing (online) self-care in primary care show varying results. A randomized controlled trial comparing a guided self-help intervention with waiting list control for patients with anxiety and depression shows that guided self-help did not provide additional benefit to patients on a waiting list.\textsuperscript{[25]} Another study found no differences between three groups: computerized cognitive-behavioral therapy (CCBT) for depression, treatment as usual (TAU) and combined CCBT and TAU in primary care. They found medium improvement effect sizes in depressive severity for all interventions.\textsuperscript{[26]} Another randomized trial found that treating general practice patients suffering from anxiety and/or depression with a computerized cognitive-behavioral therapy program led to significant improvement on all response variables measured. For example, depression and anxiety decreased, and work and social adjustment improved.\textsuperscript{[27]}

We performed a stepped care randomized controlled trial (RCT) for patients with minor and major depression and/or anxiety disorders in primary care. The stepped care model consisted of the following steps: watchful waiting, self-help treatment, brief individual therapy and longer-term individual therapy and/or medication. In this paper we will report our findings on effectiveness after the self-help step.

**Methods**

**Study Design**

This self-help intervention effectiveness study is part of a stepped care model that is examined in a pragmatic randomized controlled trial. For the full study design we refer to the study protocol.\textsuperscript{[28]} In short, 120 participants were recruited through 32 primary care physicians. They were randomly assigned into two groups: stepped care or care as usual. We chose a pragmatic design because this increases external validity.\textsuperscript{[29]} In a pragmatic trial, patients and therapists are the same as those seen in daily practice. This means that the sample of patients may be quite heterogeneous (may have mild to severe depression/anxiety with or without psychiatric or somatic co-morbidity) and that the therapists (psychiatric nurses or psychologists) have average qualifications (instead of top level therapists from an academic center). This enhances external validity, which means that the results of this study will reflect the ‘real’ effects of daily practice. Recruitment took place between April 2007 and May 2008. The study was approved by the Medical Ethics Committee of the VU Medical Center and all participants signed informed consent.

**Inclusion and Exclusion Criteria**

We included adults aged 18-65 years with one or more of the following diagnosis from the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV)\textsuperscript{[30]}; major depression (single episode or recurrent), dysthymia, panic disorder (with or without
agoraphobia), social phobia or generalized anxiety disorder, including comorbid diagnoses. We also included patients with a minor depression or a minor anxiety disorder. We used the DSM-IV research diagnostic criteria to define minor depression (two to four out of the nine DSM-IV symptoms have to be present, of which at least one has to be a core symptom). As there are no DSM criteria for minor anxiety disorder, we defined it as a score of 12 or more on the Hospital Anxiety and Depression Scale\[31\] and dysfunctioning in daily life (household tasks, work and/or social relations). Patients were excluded when they were psychotic or suffered from bipolar disorder, were receiving current (less than 2 months) treatment (medical/psychotherapy) for psychological problems, had prominent suicide ideation, had severe alcohol problems (> 20 on the Alcohol Use Disorders Identification Test (AUDIT)\[32\], indicated having no motivation for treatment or had insufficient knowledge of the Dutch language.

**Recruitment**

**Recruitment of GPs**

In the stepped care study we collaborated with two mental health centers in Amsterdam (GGZ inGeest and Mentrum). Both of these mental health centers employ psychiatric nurses and psychologists, who work for a few hours per week in a general practice. Usually, GPs refer patients to these psychiatric nurses/psychologists for short-term treatments. First we approached the psychiatric nurses and psychologists and secondly we invited the corresponding GPs to collaborate in the study. In total we included 32 GPs from 18 general practices.

**Recruitment of Patients**

Subjects were recruited by sending all patients of the participating GPs a questionnaire during the inclusion period of 1.5 year. All patients with a positive score for depression and/or anxiety were assigned to a watchful waiting period of 4 weeks. After 4 weeks these patients were screened again to exclude those who recovered spontaneously. This second screener is the baseline questionnaire (T0) and was sent to the patients together with general information about the project and an informed consent form. Two weeks later these patients were approached for a diagnostic telephone interview (Composite International Diagnostic Interview (CIDI)\[33\]) to check for inclusion and exclusion criteria. Patients who met the inclusion criteria and returned their informed consent were randomized. A meta-analysis on the effects of psychological treatment on patients with sub-clinical depression shows an effect size of 0.40.\[34\] Based on a power of 0.80 in a two-tailed test and an α of 0.05, we needed 100 patients in each condition. Therefore, the total sample size was set at 200. We send out 34,906 screeners, which produced a very low response rate (17.4%); as a result, the inclusion period took six times as long as we expected. One hundred twenty patients were included in total [Figure 1].
Figure 1. Flowchart inclusion and randomization

Screeners sent: \( n = 34,906 \)

- Screeners received: \( n = 6,064 \) (17.4%)
- No response: \( n = 28,842 \) (82.6%)

Score > cut off: \( n = 1,105 \) (18.2%)

- Score > cut off & no interest: \( n = 382 \) (6.3%)
- Score < cut off: \( n = 1,860 \) (30.7%)
- Excluded: \( n = 2,717 \) (44.8%)

Included and randomized: \( n = 120 \) (10.9%)

- Recovered, score < cut off: \( n = 55 \) (5.0%)
- Refused: \( n = 335 \) (30.3%)
- Excluded: \( n = 294 \) (26.6%)
- Other: \( n = 301 \) (27.3%)

**Stepped care**
\( n = 60 \) (50.0%) – baseline T0
- 55 (91.7%) non severe cases who started with guided self-help
- 5 (8.3%) severe cases who did not start with guided self-help

Dropout: \( n = 13 \) (21.7% of 60)

**T1 response**
- Non-severe cases, \( n = 38 \) (69.1% of 55)
- Severe cases, \( n = 4 \) (80.0% of 5)

**T1 analyzed**
- Non-severe cases, \( n = 55 \)

**Care as usual**
\( n = 60 \) (50.0%) – baseline T0
- 53 (88.3%) non severe cases
- 7 (11.7%) severe cases

Dropout: \( n = 14 \) (23.3% of 60)

**T1 response**
- Non-severe cases, \( n = 40 \) (75.5% of 53)
- Severe cases, \( n = 6 \) (85.7% of 7)

**T1 analyzed**
- Non-severe cases, \( n = 55 \)
Watchful Waiting

The four weeks between the first and second screener were considered as the watchful waiting period. Of the 1105 patients who scored positively on the first screener, 335 (30.3%) declined to participate further, 294 (26.6%) were excluded and 301 (27.3%) could not be reached or did not respond. One hundred and twenty patients (10.9%) were randomized to stepped care or care as usual. The remaining 55 patients (5%) had recovered and scored negatively on the second screener.

Randomization

We randomized patients at an individual level. They were randomized into two groups, stratified by care manager and we used blocks of 4 to prevent overburdening of the care managers. An independent researcher, not involved in the current project, used computer generated block randomization to produce sealed envelopes. After every inclusion the researcher opened a sealed envelope. We randomized 60 patients to the stepped care program and 60 patients to care as usual. GPs were informed which patients were randomized to the stepped care program to ensure that the patient received treatment from the GP and to ensure adherence to the stepped care protocol.

Intervention

Stepped Care

The stepped care program consists of four evidence-based interventions: (1) watchful waiting, (2) guided self-help, (3) Problem-solving Treatment and (4) pharmacotherapy and/or specialized mental health care. The patients were monitored after each step and depending on the outcome, the care manager decided whether or not the patient should ‘step-up’. GPs were asked to refrain from offering any treatment to patients who were included in the stepped care group (treatment group). Benzodiazepines were allowed in both study groups. Patients in the stepped care group were only allowed to receive antidepressants in later phase of the treatment protocol.

In the first step the patients received no treatment for four weeks (watchful waiting). After four weeks, the patients in the stepped care program commenced (guided) self-help, starting with one 30-minute face-to-face session with a psychiatric nurse. This session enabled the psychiatric nurse to check for exclusion criteria (e.g., severe psychopathology), to give psycho-education (e.g., advice on lifestyle) and to explain the self-help interventions.

This study used two different self-help interventions. The first is a generic intervention based on Problem-solving Treatment (PST), which is meant for patients with symptoms of depressive and/or anxiety disorders. The Dutch version is available as a book and via the Internet. It has proved to be effective for depression and anxiety. In this intervention, which takes five weeks to complete, participants are first asked to describe what really matters to them in life. Next they have to create a list of all their current worries and problems. Finally, they are offered a six-step procedure that assists them in solving their worries and problems. The aim of this intervention is to help people approach their problems in a more structured way so that they feel less overwhelmed by them. Participants could choose to follow this course via the Internet or by
using a book and they could opt to receive feedback on their assignments. If they applied for feedback, they were supported by email (the Internet group) or by telephone (the book group). The feedback was given by junior psychologists who were trained by the senior researcher (AvS). The feedback is not therapeutic in nature. It is primarily aimed at helping people to understand the techniques that are offered in the course. Furthermore, the feedback is used to motivate people to continue the course. The feedback is designed as being easy to learn by, for example, a care manager or psychiatric nurse. Participants received feedback within three working days of sending their assignments to their coach.

The second self-help intervention is aimed specifically at patients with phobias and is based on exposure therapy. In this course participants first have to make a list of all the situations that provoke anxiety and rank these in order of intensity. Next they make a plan to practice exposure to these situations based on this anxiety hierarchy. This course takes six weeks to complete and is only available as a book. Feedback is therefore provided by telephone. During the first session, the psychiatric nurse decides together with the patient, and based on the symptoms, which self-help course is most suitable.

In stepped care all patients start with the same treatment, however we pre-specified some exceptions. Even though there is no clear evidence that patients with more severe symptoms of anxiety or depression do not benefit from low intensity (self-help) interventions, we decided that patients with more severe disorders should be referred to specialized mental health care for face-to-face psychotherapy and/or pharmacotherapy directly. Thus they skipped the self-help intervention and PST completely. The severity of the disorders was based on questions about daily functioning on the Work and Social Adjustment Scale (WSAS). When the patient experienced extreme dysfunctioning (a score of 8 or higher) on at least three of the four domains (household tasks, work, social relations and social activities) he or she was directed to specialized mental health care.

Care as Usual

Patients randomized to care as usual were advised to see their GP if they wanted (mental health) care.

Assessments and Definition of Recovery

The patients were monitored after each step in the stepped care intervention. Monitoring after the (guided) self-help course was conducted after 8 weeks (T1). We measured symptoms of depression and anxiety and daily functioning. We considered a patient to have recovered when he or she scored less than 14 on the Inventory of Depressive Symptomatology (IDS), and scored less than 8 on the Hospital Anxiety and Depression Scale and scored less than 6 on the WSAS.

Instruments

Depressive Symptoms

We used the, self-report, Inventory of Depressive Symptomatology (IDS) to measure depressive symptoms. The IDS consists of 30 items and the total score varies between 0 and 79. Scores
below 14 indicate an absence of depressive symptoms. We used this cut-off score as an indication for recovery from depressive symptoms.\textsuperscript{[37,38]} Internal consistency is high for the IDS (Cronbach’s α: 0.92).\textsuperscript{[37]}

\textit{Anxiety Symptoms}

For identifying anxiety symptoms we used the Hospital Anxiety and Depression Scale (HADS)\textsuperscript{[31]} which is designed to identify anxiety disorders among patients in non-psychiatric settings. The HADS consists of 7 items. Item responses are on a 0 to 4 scale (0= "none" and higher ratings reflect greater degrees of symptom severity). Total scores range from 0 to 21. The HADS showed good homogeneity and reliability, with Cronbach’s α ranging from 0.81 to 0.84 in various clinical and non-clinical Dutch samples.\textsuperscript{[39]}

\textit{Dysfunction}

We measured daily functioning of the patient via four questions on the Work and Social Adjustment Scale (WSAS).\textsuperscript{[36]} Using this questionnaire, the patient gives an estimate, on a scale from 1 to 10, of the perceived dysfunction in his or her daily life. The questions contain four domains: household tasks, work, social relations and social activities.

\textit{Composite International Diagnostic Interview (CIDI)}

The CIDI (version 2.1), a structured interview developed by the World Health Organization\textsuperscript{[33]}, enables trained interviewers to assess psychiatric diagnosis defined in the DSM-IV.\textsuperscript{[30]} The assessment typically lasts 30 to 75 minutes, depending on the mental state of the respondents.\textsuperscript{[40]} In this study, current mental status (last six months) is taken into consideration. The CIDI is a well-known and reliable instrument that can be used by anyone who received training. Our interviewers were master psychology students who received a full day of training and practiced on several patients before the first interview.

\textit{Quality of Life}

Quality of life was measured through the MOS Short-Form general health survey (SF-20) that identifies health related quality of life.\textsuperscript{[41]} This self-report questionnaire (20 items) consists of six scales covering mental health, perceived health (mental and physical), social functioning, role functioning, physical functioning and pain. A high score on the SF-20 indicates a high level of functioning, except for the subscale physical pain where a higher score indicates greater pain. The α of the scale varies between 0.80 and 0.91.\textsuperscript{[41,42]}

\textit{Analyses}

All analyses were conducted according to the intention-to-treat principle. All respondents were randomized and were included in the analyses. Missing \textit{items} on questionnaires were imputed using a Two-Way Imputation of Missing Test Data.\textsuperscript{[43]} This method first calculates the overall mean of all the observed item scores of all respondents on the scale items. Next, for each person the average score for the observed items is calculated; for each item an average is calculated over all complete responses as well. These two estimates are used to add a person effect and an item effect to the overall mean. For example, the score of a subject who scores high on the
observed item score, on an item for which most respondents have high values, will result in a high-predicted item score. To this best guess a random error is added, which is drawn from a normal distribution; this error is needed to compensate for the low variance that results from mean imputations. This method has its origin in the two-way layout, used in ANOVA, by imputing a row-effect (person effect), plus a column-effect (item effect), minus an overall effect. Respondents should not miss more than 60% if items on a questionnaire to be eligible for imputation. Two respondents missed more than 60% of their scores on HADS and IDS and were treated as missing scores on questionnaires. Missing total scores on questionnaires (because respondents did not return the questionnaire) were imputed using regression imputation. We calculated a regression model with the mean baseline scores on the IDS and HADS and the sex of the respondents. We replaced the missing values with the predicted values from the regression model.

We compared the baseline characteristics of the intervention and control group with independent t-tests. Where the cells had a count of less than five we used Fisher’s exact test. For the main outcome effectiveness of guided self-help we used independent samples t-tests to examine the difference in mean between the stepped care group and the care as usual group. We used Cohen’s $d^{[44]}$ to measure the size of the effect. Cohen’s $d$ is calculated as the difference between the post-test mean score of the intervention group and the control group divided by the pooled standard deviation. A Cohen’s $d$ of 0.5 thus indicates that the mean of the intervention group is half a standard deviation larger than the mean of the control group. Values of $d$ from 0.56 to 1.20 can be assumed to be large, 0.33 to 0.55 are moderate, and 0 to 0.32 are small.$^{[45]}$ The within group effect sizes, baseline versus post-test were compared with a paired t-test. The difference in percentage of recovery was calculated by using a χ²-Square analysis. SPSS (SPSS Science, Chicago, IL, USA) 17.0 was used for the analysis.

Results

Baseline Characteristics

Twelve (10.0%) of the 120 randomized participants reported severe dysfunctioning on the WSAS (Table 1). As indicated in our stepped care protocol, these 12 patients were referred to the last step of our stepped care model (psychotherapy or pharmacotherapy) and did not start with self-help. Therefore, those patients are excluded from the current analysis. Only 8 patients (7.4%) suffered from a depressive disorder only (depression single episode mild/moderate/severe, depression recurrent mild/moderate/severe, dysthymic disorder). Another 47 patients (43.5%) suffered from anxiety disorders only (generalized anxiety disorder, social phobia, panic disorder without agoraphobia, panic disorder with agoraphobia, agoraphobia without panic disorder in the past and minor anxiety). The remaining 53 patients (49.1%) had both depressive and anxiety disorders. Most patients ($n = 100; 92.6\%$) fulfilled the criteria for a DSM-diagnosis, except for eight patients, who suffered from a minor anxiety only. In the stepped care condition, the mean age is 51.3 (SD 9.7) years and in the care as usual group the mean age is 49.9 (SD 12.6). For stepped care the age of onset of the DSM-diagnosis is 29.1 (SD 15.1) years and for care as usual the age of onset is 29.1 (SD 16.2). More than half of the participants were women (66.7%) and the mean age was 50.6 (SD 11.2) years. At baseline, the mean IDS score was 30.0 (SD 10.7) and the mean HADS score was 9.7 (SD 4.0). There were no
significant differences between the stepped care and control group on the demographic or clinical variables [Table 1].

Table 1. Patient social-demographic and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Stepped Care</th>
<th>Care as usual</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>108 (100%)</td>
<td>55 (100%)</td>
<td>53 (100%)</td>
<td></td>
</tr>
<tr>
<td>Mean age, years (SD)</td>
<td>50.6 (11.2%)</td>
<td>51.3 (9.7%)</td>
<td>49.9 (12.6%)</td>
<td>0.51</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>72 (66.7%)</td>
<td>39 (70.9%)</td>
<td>33 (62.3%)</td>
<td>0.34</td>
</tr>
<tr>
<td>With a paid job</td>
<td>62 (57.4%)</td>
<td>31 (50.0%)</td>
<td>31 (50.0%)</td>
<td>0.58</td>
</tr>
<tr>
<td>Born in the Netherlands</td>
<td>88 (81.5%)</td>
<td>42 (82.4%)</td>
<td>46 (83.6%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Married</td>
<td>37 (36.3%)</td>
<td>21 (41.2%)</td>
<td>16 (31.4%)</td>
<td>0.24</td>
</tr>
<tr>
<td><strong>Clinical status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression (IDS, mean (SD))</td>
<td>30.7 (10.8%)</td>
<td>29.5 (11.3%)</td>
<td>31.8 (10.3%)</td>
<td>0.18</td>
</tr>
<tr>
<td>Anxiety (HADS, mean (SD))&lt;sup&gt;a&lt;/sup&gt;</td>
<td>9.7 (4.0%)</td>
<td>9.7 (4.1%)</td>
<td>9.8 (4.0%)</td>
<td>0.69</td>
</tr>
<tr>
<td><strong>DSM IV Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>100 (92.6%)</td>
<td>52 (94.5%)</td>
<td>48 (90.6%)</td>
<td>0.43</td>
</tr>
<tr>
<td>Only anxiety disorder</td>
<td>47 (43.5%)</td>
<td>28 (50.9%)</td>
<td>19 (35.9%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Depression</td>
<td>61 (56.5%)</td>
<td>27 (49.1%)</td>
<td>34 (64.2%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Only depressive disorder</td>
<td>8 (7.4%)</td>
<td>3 (5.5%)</td>
<td>5 (9.4%)</td>
<td>0.43</td>
</tr>
<tr>
<td>Comorbid depressive and anxiety disorder</td>
<td>53 (49.1%)</td>
<td>24 (43.6%)</td>
<td>29 (54.7%)</td>
<td>0.25</td>
</tr>
<tr>
<td>Mean age of Onset DSM-IV Diagnosis (SD)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>29.1 (15.6)</td>
<td>29.1 (15.1)</td>
<td>29.1 (16.2)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

HADS = Hospital Anxiety and Depression Scale, IDS = Inventory of Depressive Symptomatology, <sup>a</sup>n = 107 (one missing HADS). <sup>b</sup>n = 100 (eight patients with unofficial DSM-diagnosis)

Response on Questionnaires after 8 Weeks

There was no significant difference in the response rate at T1 between guided self-help (69.1%; <i>n = 38</i>) and care as usual (75.5%; <i>n = 40</i>; <i>P = 0.46</i>). There were no significant differences in gender (<i>P = 0.17</i>), depressive symptoms (<i>P = 0.22</i>) and anxiety symptoms (<i>P = 0.55</i>) between responders and non-responders. Responders and non-responders did differ in age: non-responders were significantly younger than responders (<i>P = 0.03</i>) [Table 2]. Patients in the care as usual who responded (<i>n = 38</i>) received the following care: 21 (55%) went to their GP, 10 (26%) received mental health care (psychiatric nurse, specialized mental health care, a psychiatrist or a psychotherapist), 2 (5%) went to a medical specialist, 1 (3%) went to a social worker and 4 (11%) went to some form of complementary and alternative medicine. Nine patients (24%) received benzodiazepines but none of them received antidepressants.
Table 2. Demographic and clinical differences between responders and non-responders

<table>
<thead>
<tr>
<th></th>
<th>Responders (n = 78)</th>
<th>Non-responders (n = 30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (% F, n)</td>
<td>70.5 (55)</td>
<td>56.7 (17)</td>
<td>0.17</td>
</tr>
<tr>
<td>Age (M, SD)</td>
<td>52.2 (10.4)</td>
<td>46.6 (12.4)</td>
<td>0.03*</td>
</tr>
<tr>
<td>Depression (IDS) at baseline (M, SD)</td>
<td>30.8 (10.8)</td>
<td>28.0 (10.3)</td>
<td>0.22</td>
</tr>
<tr>
<td>Anxiety (HADS) at baseline (M, SD)</td>
<td>9.9 (4.1)</td>
<td>9.3 (3.8)</td>
<td>0.55</td>
</tr>
</tbody>
</table>

IDS = Inventory of Depressive Symptomatology, HADS = Hospital Anxiety and Depression Scale, *Significant at 0.05

Treatment and Treatment Adherence

Of the 55 self-help patients, 35 (61.8%) received the PST self-help intervention (Internet or book) and 9 (16.4%) received the book on phobias. Of those patients who received PST, about half preferred the book (n = 18) while the other half (n = 17) preferred the Internet version [Table 3].

None of the patients who received a self-help intervention via book (PST or Phobias) contacted the coach for feedback. The 16 patients who performed the PST online completed 1.13 (SD = 1.4) out of 6 lessons on average. It is however not possible to draw any conclusions from this number because all patients with a book or Internet and who did not fill in their homework online are not included.

Table 3. Received treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-help (PST) via Internet</td>
<td>17</td>
<td>30.9</td>
</tr>
<tr>
<td>Self-help (PST) via book</td>
<td>18</td>
<td>32.7</td>
</tr>
<tr>
<td>Self-help for phobias (exposure)</td>
<td>9</td>
<td>16.4</td>
</tr>
<tr>
<td>Referred to fourth step</td>
<td>9</td>
<td>16.4</td>
</tr>
<tr>
<td>Refused</td>
<td>6</td>
<td>11.9</td>
</tr>
</tbody>
</table>

There were 7 (12.7%) patients who left the stepped care program (3 were physical ill and 4 could not be reached when the psychiatric nurse tried to make an appointment). We also referred 4 (7.3%) patients without severe dysfunction to specialized mental health care based on the judgment of the psychiatric nurse. For these analyses we choose to handle according to the protocol in both stepped care and care as usual. Therefore, these patients did not receive a self-help course because they were referred, but they are analyzed as being in the self-help group.

Effect of Guided Self-Help Treatment on Symptoms of Depression and Anxiety

Symptom Severity of Depression

The IDS symptom level improved significantly for patients in the stepped care treatment group (mean difference 4.24; 95% CI = 2.20 to 6.28, P < 0.001), but also for patients in the care as usual group (mean difference 4.49; 95% CI = 2.41 to 6.57, P < 0.001). The patients in the intervention group reported less symptoms of depression than the patients in the care as usual group (d = -0.18) but this difference did not reach statistical significance (95% CI = -2.29 to 7.31) [Table 4].
Symptom Severity of Anxiety

The HADS symptom level improved significantly for patients in the stepped care treatment group (mean difference 1.04; 95% CI = 0.32 to 1.76, P < 0.001), but not for patients in the care as usual group (mean difference 0.54; 95% CI = -0.25 to 1.33, P = 0.17). The patients in the intervention group reported less symptoms of anxiety than the patients in the care as usual group (d = -0.20) but this difference did not reach statistical significance (95% CI = -0.74 to 2.29; P = 0.31) [Table 4].

**Table 4.** Effects of guided self-help on symptoms of anxiety and depression

<table>
<thead>
<tr>
<th></th>
<th>Stepped care mean (SD)</th>
<th>Care as usual mean (SD)</th>
<th>P</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-test</td>
<td>Post-test</td>
<td>Pre-test</td>
<td>Post-test</td>
</tr>
<tr>
<td>Anxiety (HADS)</td>
<td>9.6 (4.1)</td>
<td>8.5 (4.2)</td>
<td>9.9 (3.9)*</td>
<td>9.3 (3.8)</td>
</tr>
<tr>
<td>Depression (IDS)</td>
<td>28.7 (11.1)</td>
<td>24.4 (11.9)</td>
<td>31.4 (10.2)</td>
<td>26.9 (13.2)</td>
</tr>
<tr>
<td>Anxiety disorders (n = 46)</td>
<td>(\text{HADS})</td>
<td>9.2 (3.9)</td>
<td>8.0 (4.0)</td>
<td>10.8 (4.4)</td>
</tr>
<tr>
<td></td>
<td>(\text{IDS})</td>
<td>26.8 (11.3)</td>
<td>21.8 (10.6)</td>
<td>30.5 (12.0)</td>
</tr>
<tr>
<td>Depressive disorders (n = 8)</td>
<td>(\text{HADS})</td>
<td>8.7 (0.6)</td>
<td>8.5 (2.2)</td>
<td>8.6 (2.7)</td>
</tr>
<tr>
<td></td>
<td>(\text{IDS})</td>
<td>30.0 (3.5)</td>
<td>23.0 (8.2)</td>
<td>28.4 (7.3)</td>
</tr>
<tr>
<td>Comorbid disorders (n = 53)</td>
<td>(\text{HADS})</td>
<td>10.1 (4.6)</td>
<td>9.2 (4.5)</td>
<td>9.5 (3.7)</td>
</tr>
<tr>
<td></td>
<td>(\text{IDS})</td>
<td>30.7 (11.3)</td>
<td>27.7 (13.3)</td>
<td>32.6 (9.4)</td>
</tr>
</tbody>
</table>

\*\(n = 52\) for HADS in CAU on pre-test, IDS - Inventory of Depressive Symptomatology, HADS - Hospital Anxiety and Depression Scale

Effect of Guided Self-Help Treatment on Quality of Life

On the domains physical and social functioning, mental health and health perception, the intervention group reported better outcomes than the care as usual group. However, the differences were small (d ranges between 0.02 and 0.20) and not statistically significant [Table 5].

**Table 5.** Effects of guided self-help on quality of life

<table>
<thead>
<tr>
<th></th>
<th>Stepped care (n)</th>
<th>Pre-test</th>
<th>Post-test</th>
<th>Care as usual (n)</th>
<th>Pre-test</th>
<th>Post-test</th>
<th>P</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>55/52</td>
<td>67.0 (29.5)</td>
<td>62.2 (29.5)</td>
<td>62.8 (33.4)</td>
<td>57.4 (33.9)</td>
<td>0.43</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>Role functioning</td>
<td>55/53</td>
<td>63.7 (45.6)</td>
<td>62.3 (39.1)</td>
<td>62.3 (46.9)</td>
<td>68.0 (41.9)</td>
<td>0.46</td>
<td>-0.14</td>
<td></td>
</tr>
<tr>
<td>Social functioning</td>
<td>55/53</td>
<td>63.3 (26.9)</td>
<td>68.9 (20.4)</td>
<td>64.5 (25.9)</td>
<td>64.8 (21.9)</td>
<td>0.33</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Mental health</td>
<td>54/53</td>
<td>49.3 (14.2)</td>
<td>54.2 (15.4)</td>
<td>48.2 (12.8)</td>
<td>51.3 (16.0)</td>
<td>0.35</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Health perception</td>
<td>52/50</td>
<td>44.4 (26.0)</td>
<td>50.7 (21.4)</td>
<td>50.7 (23.0)</td>
<td>46.4 (22.3)</td>
<td>0.30</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>55/53</td>
<td>55.0 (29.0)</td>
<td>53.4 (24.4)</td>
<td>61.3 (29.7)</td>
<td>54.0 (27.3)</td>
<td>0.91</td>
<td>-0.02</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER 4

Treatment Effects According to Diagnosis

We compared the effect differences between guided self-help and care as usual for patients with anxiety disorders only \((n = 46)\), depressive disorders only \((n = 8)\) and comorbid depressive and anxiety disorders \((n = 53)\) (Table 4).

Symptom Severity of Depression

Patients in the intervention group with an anxiety disorder only reported less symptoms of depression than the patients in the care as usual group \((d = -0.35)\) but this difference did not reach statistical significance \((95\% \ CI = -3.36 \text{ to } 12.24, P = 0.26)\). Both depressive disorders only and comorbid disorders showed no improvement in depressive symptoms compared with care as usual.

Symptom Severity of Anxiety

The patients in the intervention group with an anxiety disorder only reported significantly \((95\% \ CI = 0.25 \text{ to } 4.77, P = 0.03)\) less symptoms of anxiety than the patients in the care as usual group \((d = -0.68)\). The HADS symptoms level did not improve for depressive disorders \((P = 0.67)\) or comorbid depressive and anxiety \((P = 0.77)\).

Recovery

In the stepped care condition 8 patients \((14.6\%)\) had recovered after the self-help intervention and in the care as usual condition 6 patients \((11.3\%)\). The difference was not statistically significant \((P = 0.62)\).

Discussion

This trial, performed in daily general practice, shows that guided self-help in patients with mild to moderate anxiety and/or depressive disorders was not significantly more effective than care as usual on symptoms of depression, anxiety and quality of life. The only statistically significant result indicated that self-help improved symptoms of anxiety, in contrast to care as usual, in patients with an anxiety disorder only.

We found a significant decrease in anxiety symptoms for guided self-help patients with an anxiety disorder without comorbid depression. This is in agreement with the findings of a review\(^{[46]}\) considering the effectiveness of guided self-help in anxiety disorders. They suggest guided self-help for anxiety disorders in a stepped care model for primary care. A study that compared a guided self-help intervention with a waiting list control group\(^{[25]}\) did not find any significant results on neither anxiety nor depressive symptoms. Griffiths\(^{[47]}\) found in a study large effect sizes for Internet self-help for patients with anxiety disorders. Also for social anxiety there is some evidence that self-help is effective.\(^{[48]}\) A possible explanation for this could be that patients with anxiety disorders tend to avoid social interactions with other people and therefore might experience difficulties in face-to-face therapy. For patients with anxiety disorders, working at home might feel more secure and therefore might be more suitable for these patients. Another explanation could be the motivation of patients. Maybe patients with
depression are less motivated and have less discipline to work through assignments on their own. Apparently more research is needed to clarify these varying results.

One reason for the lack of effectiveness in this study is that there could be a bias in the general practices selected for the research. We included GPs who already worked with a psychiatric nurse in their practice. It is possible that the care as usual of these GPs is better than otherwise because they pay more attention to common mental health disorders. It has been demonstrated that depressed patients are more often recognized and more often adequately treated in practices with a nurse case-manager, than in a general practices without. However, in contrast with this evidence, in our study most of the care of usual patients did not seem to have received adequate treatment. Almost half of the patients in the care as usual group saw their GP. Unfortunately, it is unknown for what reason and it is unknown whether or not any form of counseling took place. None of the patients received antidepressants and only a quarter received any form of mental health care. The remaining patients did not receive any treatment at all. All this indicates that the lack of significant results in this study is probably not caused by a high quality of care in the control group.

Another reason for the lack of effectiveness is the recruitment of the patients. We screened patients from the GP-population for depressive and anxiety disorders. A recent meta-analysis of psychological treatment of depression in primary care found no evidence that psychological treatment is effective if patients are recruited through systematic screening in primary care. This meta-analysis suggests some explanations that might be true for this study. For example, patients who do not actively seek treatment might have good reasons for not seeking treatment themselves. Another important suggestion that might apply to this study is the fact that GPs play a role in informing and motivating patients regarding treatment of their depression and/or anxiety. Thus, when patients are recruited by screeners and receive a ‘computer-generated’ treatment recommendation they might be less convinced of the necessity for treatment. We need a new stepped care trial to examine the differences in effect when patients are referred by their GP.

A third reason for lack of effectiveness is that we have insufficient knowledge about treatment compliance. We wanted to simulate the real-life setting as much as possible. Therefore we used two different interventions and patients could choose whether they wanted feedback on their assignments or not. Patients in this study did not ask for feedback even though they could. A randomized controlled trial testing the clinical effectiveness of online computerized cognitive-behavioral therapy without support for depression in primary care shows no difference in effect. In this study we find that the addition of the option to receive feedback also shows no effect. This also means that those not receiving feedback also received less guidance, which may have been at the expense of treatment compliance. This is true for the Internet group as well as for the book group. It is not possible to require patients who work through a self-help book to contact a person in order to receive feedback. We did not actively contact the patients ourselves because our experiences in earlier studies with this were not very positive. The patients who performed the self-help through a website could also, just as with a book, read all the lessons and carry out the ‘homework’ without sending it in order to receive feedback. Currently, we changed our websites so that patients have to send their homework before they can continue to the next lesson. For those without PCs, who still use a book, this problem will remain.
Unfortunately, due to this lack of knowledge, we cannot make any statements about treatment adherence; this could be an important explanation why the guided self-help group did not outperform care as usual.

A fourth possible reason for the lack of effect is that the study was underpowered. We included 120 patients in this study instead of the 200 needed according to the power analysis. Because of the low effect-sizes we do not feel that these results would change to a medium effect size if 60 more patients were added to the study. That this study is underpowered is a limitation but it is unlikely that it has direct effect on the reported results. We used an regression analysis for the intention-to-treat, this might have been a conservative method, but similar as the previous point, we feel that it is unlikely that this has a direct effect on the reported results because current effect-sizes do not approach medium effect-sizes.

We wanted to create a setting to maximize the external validity to offer a complete package of self-help treatment in primary care. Thus two different types of self-help and the option to ask for feedback were offered. This might have gone on the expense of internal validity. We know that both courses have high internal validity of their own, and therefore we feel that it is unlikely that we would have found very different effects if we, for example, only had used one of the offered courses.

Finally we should note that although the CIDI is a reliable instrument, and all the interviewers were trained, we did not collect any data on the interrater reliability.

**Conclusion**

This pragmatic randomized trial shows that both the intervention group and the care as usual group improve on symptoms of depression while stepped care patients also improve on anxiety symptoms. When compared to care as usual, there is no significant difference in symptom reduction or quality of life. However, this study shows a decrease in anxiety symptoms for patients with one or more anxiety disorder(s) only. This guided self-help intervention is part of a stepped care model that could mean that this single step shows no clear results as such. Nonetheless, it could influence the general outcome of the full stepped care model and the results of these analyses will follow in the near future.

**Acknowledgements**

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References


