



Effectiveness of guided self-help for depression and anxiety disorders in primary care: A pragmatic randomized controlled trial

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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 mood and/or anxiety disorder. The study population consists of 120 (screened) primary care patients aged 18–65 years with at least one mood 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.

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1. Introduction

Depressive and anxiety disorders are both highly prevalent (Bijl et al., 1997). Anxiety and depression can cause serious functional impairment and reduced quality of life (Wells et al., 1989; von Korff et al., 1992). 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 (Kessler et al., 2003). Because of this high comorbidity our study is aimed at individuals with depressive disorder, anxiety disorders as well those with comorbid 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 (Bijl and Ravelli, 2000; Andrews et al., 2001). Those that do seek help usually go to their general practice first (Bijl and Ravelli, 2000; Wang et al., 2007). 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 (Ustun and Von Korff, 1995). And those patients whose mental health problems are recognized do not always receive evidence-based treatments. Andrews et al. (2004) estimate that this might be true for half of the patients in primary care. According to several studies (Schulberg et al., 1995; Schulberg et al., 1997; Cardol et al., 2004) 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 (Simon et al., 1993). It is also important to note that the majority of primary care patients prefer psychotherapy as a treatment (van Schaik et al., 2004). 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 (Marrs, 1995). Most self-help interventions are based on cognitive-behavioural therapy (CBT) (Cuijpers and Schuurmans, 2007) but nowadays other types of treatment (i.e. problem solving treatment (PST), interpersonal therapy (IPT)) have become available as (guided) self-help interventions as well. Self-help interventions are available via books

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(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 (Hirai and Clum, 2006; Morgan and Jorm, 2008).

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 their symptoms are monitored by a care manager. 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 (Katon et al., 2002; Neumeyer-Gromen et al., 2004; Bower and Gilbody, 2005) 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 (Bower and Gilbody, 2005). 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 (van Straten et al., 2008; Warmerdam et al., 2008), 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 (Warrilow and Beech, 2009). 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 (Mead et al., 2005). Another study found no differences between three groups: computerized cognitive-behavioural 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 (de Graaf et al., 2009). Another randomized trial found that treating general practice patients suffering from anxiety and/or depression with a computerized cognitive-behavioural therapy program led to significant improvement on all response variables measured. For example, depression and anxiety decreased, and work and social adjustment improved. (Proudfoot et al., 2004).

We performed a stepped care randomized controlled trial (RCT) for patients with minor and major mood 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.

2. Methods

2.1. 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 (Seekles et al., 2009). 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 (Zwarenstein and Treweek, 2009). 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 comorbidity) and that the therapists

(psychiatric nurses or psychologists) have average qualifications (instead of top level therapists from an academic centre). 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.

2.2. 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) (APA, 2001): 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 (Zigmond and Snaith, 1983) 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) (Babor et al., 1989), indicated having no motivation for treatment or had insufficient knowledge of the Dutch language.

2.3. Recruitment

2.3.1. Recruitment of GPs

In the stepped care study we collaborated with two mental health centres in Amsterdam (GGZ inGeest and Mentrum). Both of these mental health centres 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.

2.3.2. 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) (World Health Organization, 1990) 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. Based on a power of 0.80 in a two-tailed test and an alpha 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 (Fig. 1).

2.4. 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.

2.5. 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.

2.6. Intervention

2.6.1. 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) Medication and/or specialized mental health care (Seekles et al., 2009). The patients were monitored after each step and depending on the outcome, the care manager decided whether or not the

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