General Discussion
The main goal of this dissertation was to evaluate stepped care treatment among patients with depressive and/or anxiety disorders in primary care. Studied topics are the stepped care model, the psychological treatment of anxiety in primary care and the influence of personality traits on the perceived need for care. In this final chapter, the main findings of these studies are summarized, the main limitations are discussed, their clinical implications are addressed, and suggestions for future research are given.

Main Findings and Prior Research

Depressive and anxiety disorders are common in general practice but unfortunately they are not always treated adequately. The stepped care model could provide a solution for this problem. Stepped care has been developed as a way of allocating scarce therapeutic resources to maintain effectiveness while increasing access to treatment. It starts with low-intensity, evidence-based interventions and continues, if necessary, with increased intensity treatments. Self-help is considered to be a suitable, low-intensity treatment as a first step. Its costs are relatively low and many patients can participate simultaneously, especially when offered through the Internet.

Effectiveness of Guided Self-Help for Depression and Anxiety Disorders in Primary Care

It has been demonstrated convincingly that guided self-help is effective for a number of mental health problems when offered to the general population. However, results from our study examining the effectiveness of (guided) self-help in primary care indicate that there is no difference in symptom improvement between the intervention group and care as usual. The self-help group reported slightly better outcomes than care as usual but these results were small and 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 pure anxiety, the anxiety symptoms decreased significantly compared to care as usual ($d = -0.68; 95\% \text{ CI} = 0.25$ to 4.77).

In previous research, the effectiveness of (online) self-help in primary care for anxiety and depression showed varying results: from no additional effect to significant improvements. However, it is difficult to compare the results of these studies. They differ in the level of offered guidance and they use different control groups (e.g. waiting list or care as usual), which probably has led to different effects. Computerized cognitive-behavioral therapy without guidance in primary care is not effective for depression. However, we did find a statistically significant decrease in the level of anxiety symptoms for self-help patients with an anxiety disorder without comorbid depression. This is in agreement with the findings of a review considering the effectiveness of guided self-help in anxiety disorders. Patients with pure anxiety might be more motivated than depressive patients to work on their assignments alone. The same review suggests to use guided self-help for anxiety disorders in a stepped care model for primary care. Guided self-help has been proven effective in prior research, but it remains unclear whether the deployment of guided self-help for depression and anxiety in primary care is beneficial compared to care as usual.
Stepped Care for Patients with Depressive and/or Anxiety Disorders in Primary Care

Stepped care models have been developed and proven effective for different health problems, for example eating disorders[7,8], alcohol related disorders[9,10] and smoking cessation.[11] Today, few data is available which clarify how the stepped care model has to be organized. Several aspects remain unclear in terms of implementation in health care[12], such as the number of optimal steps and what the most adequate decisions on ‘stepping up’ are. As far as we know, our trial is the first stepped care trial for treating depression and anxiety in primary care. Guidelines describe many available evidence-based treatments, but lack information about how these treatments should be offered. Stepped care is a model that seeks to balance the need to provide effective treatments, whilst remaining accessible and efficient in meeting the needs of the patients.

At present, stepped care is recommended for health care in several guidelines. For anxiety, depression and obsessive compulsive disorder in the NICE guidelines[13-15] and by the Ministry of Health in New Zealand in 2009.[16] However, symptoms of depression and anxiety decreased significantly over time for both stepped care and care as usual without any statistical significant difference between both groups (IDS: $P = 0.35$ and HADS: $P = 0.64$) [Chapter 5]. The largest, yet not significant, effect ($d = -0.21$) was found for anxiety symptoms on the last assessment. In both groups approximately 48% of the patients were recovered from their DSM-IV diagnosis at the final assessment (6 months). In summary, we could not demonstrate that stepped care for depression and anxiety in primary care was more effective than care as usual.

Psychological Treatment of Anxiety in Primary Care

Extensive research has been conducted on the psychological treatment of persons with depression in primary care[17], but less is known about the effectiveness of treating anxiety in primary care. In order to implement a care model in general practice, knowledge is needed on several aspects of treatment. For example, what type of treatment is most effective, who has to provide treatment, and how many treatment sessions are needed for optimal results. To obtain more information about determinants and the overall effectiveness, we conducted a meta-analysis [Chapter 6] of randomized trials on psychological treatment of anxiety disorders in primary care.

We found that psychological treatment of anxiety is effective in primary care ($d = 0.57$) especially when patients receive cognitive behavioral therapy, when treatment is provided by psychologists, and when patients are referred to treatment instead of screened. The effectiveness of CBT for patients with anxiety disorders in general is well established.[18,19] Recently, Cape[20] demonstrated that brief CBT for anxiety (mostly generalized anxiety disorder and panic disorder) in primary care had a greater impact ($d = -1.06$) on clinical outcomes than brief CBT for depression or for mixed groups of patients. This effect-size is comparable to the one found in CBT provided in specialized mental health care.[21,22] These positive results offer the possibility of implementing CBT for anxiety disorders in primary care. Several guidelines already recommend (self-help) CBT for treating anxiety in primary care.[13,23]

When psychological therapy was provided by a (clinical) psychologist, effect-sizes were higher compared to other treatment providers (for example, GPs or trained students). Other studies on
treatment delivery show different results. One meta-analysis showed that paraprofessionals were equally effective than therapists\textsuperscript{[24]} and another meta-analysis\textsuperscript{[25]} showed that students as therapist were less effective than psychologists and other health professionals. Screening patients seems less effective than referral by a GP. This is in line with the results from previous studies.\textsuperscript{[17]} Referral appears to reflect a higher motivation to acknowledge symptoms and to change them.

**Perceived Need for Care**

In the recruitment phase of the stepped care study, a vast number of respondents showed substantial symptoms of depression and/or anxiety. Despite these symptoms they did not want to participate in our randomized controlled trial. Respondents gave multiple reasons for not wanting to participate or not wanting to receive any treatment of their symptoms. For example, patients had negative experience with health care. Patients might have good reasons for not seeking treatment themselves. It is also possible that patients do not experience mental health problems ("I don't need help, there is nothing wrong with me") or perceive no need for care. These patients might deviate from those who perceive a need for care in a number of ways, but these differences are as yet unknown. Therefore, we wanted to study the association between personality traits and perceived need for mental health care in general practice.

We found indications [Chapter 7] that personality traits, in particular neuroticism and openness to experience, have an impact on care needs independent of the severity of symptoms. Patients who perceived a need for care, irrespective whether this was met or not, had higher levels of neuroticism than patients who did not perceive a need for care. Patients who perceived a need for care also had higher levels of openness to experience. There were no differences between the perceived need for care on extraversion, agreeableness and conscientiousness. Patients with a perceived need might be more open to change their feelings, more willing to change their behavior and are able to value their emotions and ideas.

It is already known that neuroticism is highly related to having symptoms of depression and anxiety.\textsuperscript{[26]} Patients in need and patients who perceived no need for mental health care still scored higher on neuroticism after adjustment for symptom severity. Individuals with higher levels of neuroticism appear to be less capable of certain tasks such as solving problems or avoiding feelings of distress.\textsuperscript{[27]} A study of Tyssen\textsuperscript{[28]} demonstrated that patients who sought help had higher levels of emotional distress than those who did not. Neuroticism also predicts the use of primary care for mental health problems, even after adjustment for the influence of social support, education, functional impairments and emotional disorder.\textsuperscript{[29]} Patients with high levels of neuroticism are more likely to receive treatment in specialized mental health care as compared to others.\textsuperscript{[29]} This could explain why the economic costs of neuroticism are enormous and exceed those of common mental disorders. The 5\% highest scorers on neuroticism cost more than 1.5 times as much as a depressive disorder.\textsuperscript{[30]} This is mainly caused by absenteeism and productivity losses. The high health care utilization of neurotic patients could also lead to high economic costs.
Main Limitations

The previous chapters already discussed several limitations of the stepped care study. This paragraph addresses two important limitations.

Implementation of Stepped Care

It was difficult to implement the stepped care model into daily practice. Some decisions had to be made regarding the implementation of research in general practice. We had to find a balance between performing a randomized controlled trial and maintaining daily practice as good as possible. Group supervision, for example, was very time-consuming for psychiatric nurses given the low number of patients per care manager. The decision to individualize supervision might have led to less involvement of the care managers in the study. Similar, the implementation of Internet-based guided self-help is also difficult despite its well-established effectiveness. Patients might perceive that self-help is not equivalent to regular treatment. Implementation could be improved by increasing the familiarity and experience with self-help, both among GPs and patients. Experts, for example care managers who have experience with self-help treatments could motivate colleagues to provide it in primary care.

Selection Bias

The recruitment method (screening) is probably a cause of including patients with chronic and recurrent anxiety and depression. Patients in both stepped care and care as usual had a, on average, mild to moderate symptom level. The small change over time and the high number of still existing diagnoses at the end of the study suggest that we may have included a chronic group of patients. The mean age of the sample is 50 years but the mean age of onset is 28, apparently suggesting an average 22-year chronicity. These patients might not have been motivated to work independently on a self-help treatment. The self-help offered in the stepped care program was with optional feedback: patients could ask for feedback on their own initiative. This implies that patients who did not ask for feedback also received less guidance, which may have gone at the expense of treatment compliance. It is well known that the effects of self-help without any guidance are much smaller than those with guidance.[5]

A similar stepped care prevention model has been studied in late life depression and anxiety. They concluded that stepped care prevention was effective in reducing the risk of onset of depressive and anxiety disorders.[31] They included patients with subthreshold symptoms which is an important difference with our, probably chronic, diagnosed sample. Furthermore, patients were visited by a psychiatric nurse who provided (information about) treatment. It is possible that providing treatment at home instead of in general practice increased adherence.

In total 38 (63.3%) of 60 patients dropped out of the stepped care model during our study. Most patients dropped out in the self-help step. It is likely that the stepped care treatment in was not suitable for the included patients. Stepped care might not be a suitable care model for treating depression and anxiety for all general practice patients.
Clinical Implications and Recommendations

With the current cost cutting of the government, the pressure on mental health care increases. The demand for mental health care is also increasing. In the Netherlands the demand for specialized mental health care increased on average 6.4% per year between 2000 and 2007.[32] The need for implementing brief and effective treatments in primary care is growing. To meet this demand stepped care is recommend in the revised Dutch multidisciplinary guidelines.[33] All psychological treatments recommended for stepped care models are evidence-based. The same could not be said for how these treatments should be offered in a stepped care model. There is very little evidence on stepped care models for treating common mental health disorders. As far as we know, our study is the first one on the effectiveness of a stepped care program in primary care. The guidelines give no blueprint for how a stepped care model exactly should be carried out. This could lead to different models in different practices leading to different results. They could for example differ on how patients are referred to the program or on decision making about patient-flow or ‘stepping up’. Problems could arise, for example patients that receive inappropriate low-intensity treatments because practices are not able to meet the demand on higher intensity treatments.

There appear to be three important elements regarding the implementation of a care model:

1. The level of offered treatment on a scale from stepped care to matched care;
2. The type of offered treatments;
3. Collaboration between professions.

The Level of Offered Treatment on a Scale from Stepped Care to Matched Care

Interventions can be offered in a stepped care sequence from low-intensity to high-intensity or they can be offered as matched care (or stratified care). In matched care, a suitable treatment is chosen after consideration of clinical characteristics, response to prior treatment and additional information about the patient. Stepped care and matched care can be seen as two extremes on a scale. This scale can be seen as a continuum. One can shift from stepped care towards matched care. For example when more clinical characteristics of a patient are known, a professional should provide the most suitable low-intensity treatment.

The design of our study of stepped care was probably too much on the stepped care side of the scale. Information about patients, such as clinical characteristics of patients’ preferences should be taken into account to offer appropriate treatment.

Clinical characteristics (e.g., chronicity, severity and duration of the disorder and prior treatment) that influence treatment course are important to take into account. Depression severity, comorbid panic disorder, and other psychosocial vulnerabilities are associated with a decreased response to a collaborative care intervention.[34] The revised Dutch multidisciplinary guidelines[33] recommend categories of severity and duration of depression when applying treatment according to stepped care principles. We found indications of apparent chronicity in the study sample. Severity and duration of depression predict outcome in the short term treatment of depression[35], which means that patients with more severe or longer duration have a poor chance of recovery. Consequently, it is possible that the first, low-intensity, steps of
stepped care might not be the appropriate and most sufficient treatment for all patients. At present, Peter Bower of the National Primary Care Research and Development Centre of the University of Manchester is collecting all data of studies on Internet treatment of depression. His objective is to explore to what extent the severity of depression affects the effectiveness of Internet treatment. A stepped care approach seems acceptable and feasible in primary care, introducing different levels of care for different patient groups.[36]

Recently, the Netherlands Study of Depression and Anxiety (NESDA) presented the results of a two-year course of depressive and anxiety disorders. These results present 2-year diagnostic and symptom trajectory outcome of depressive and anxiety disorders. Course trajectory can be predicted with rather simple socio-demographic and clinical indicators, such as comorbid anxiety/depression and severity and duration of an episode. They give support for individualized care approaches in which the least intensive treatments are provided to those with low chronicity risk and providing more intensive treatment for those with high chronicity risk.[37] This deviates from the stepped care principle and needs some specific rules and decision making about 'stepping-up' and skipping some steps of the model. Treating numerous patients with inappropriate low-intensity treatments that are not beneficial is also costly in terms of money, time and probably quality of life of the patient. Future research should focus on how and where patients entry the model and on decision making regarding 'stepping-up' or skipping steps.

For increased adherence it is also recommended to take into account the patients’ preferences regarding psychological treatment. The majority of persons with mental problems in primary care prefer psychotherapy as a treatment.[38] A study on the need for care from the patients’ perspective[49] demonstrates that most patients with anxiety or depression expressed a need for counseling (psychotherapy, cognitive behavior therapy or counseling) or information. Medication, practical support, skills training and referral to specialized mental health care were less often perceived to be needed. Furthermore, patients who have a history of help-seeking behavior tend to have a clearer idea about what they expect from therapy.[40] Meeting the needs of patients should increase motivation for and adherence to treatment. A suggestion for clinical practice is to create higher adherence and to adjust the care model. This could be achieved, for example, by searching for other low-intensity treatments as a first step and, for example, to let the patient choose between two or more treatments. In the Phase IV field trial, described by Richards and Suckling[41], low-intensity stepped care psychological treatment is combined with a telephony-based collaborative care organizational system. This is a more flexible approach to stepped care. A suggestion to improve the model would be to offer the patient a choice in the first step between low-intensity treatments, for example: guided self-help, psycho-education in few group-sessions. It seems to be effective when patients can actually choose between interventions.[42] These adjustments result in a care model between stepped care and matched care.

The Type of Offered Treatments

Interventions differ in their nature, for example psychotherapy, pharmacotherapy and behavioral activation. These interventions can be offered in various intensities. For example, psychotherapy can be offered as Problem-solving Treatment (low-intensity), as Interpersonal
Therapy (moderate intensity) and as Cognitive Behavioral Analysis System of Psychotherapy (CBASP) (high-intensity). Low-intensity, first step, treatments are suitable for the use in primary care. Several studies suggest that problem solving therapy can be effectively provided by trained practice nurses. Another suitable low-intensity treatment is guided self-help. However, the advantage of this inexpensive treatment is that it can also be provided on other levels (or steps) of care. Patients might also benefit from self-help additionally to their long-term treatment. Furthermore, psycho-education and practical support should be provided in general practice. When patients suffer from severe and/or comorbid mental disorders they should be referred to specialized mental health care where the stepped care principle should continue to be applied.

Collaboration between Professions

In order to offer clinical effective and cost effective care, different professions have to work together. In the treatment of depression and anxiety it is important that primary care and specialized mental health care collaborate. Collaborative care has its origin in medical care. It is designed to schedule the care of a patient in an active way. Collaborative care is effective and feasible model for integrated care. A flexible collaboration between primary care and specialized mental health care has to be established.

In our study, the collaboration between primary care and specialized mental health care was not optimal. Some tasks, e.g. monitoring and decision making about ‘stepping-up’, were performed by research assistants. We recommend that the collaboration between mental health specialist (for example a psychiatry nurse) and general practitioners should be improved. Today, an increasing number of general practices work with a practice nurse. This should be a common collaboration and needs further expansion. It should be easier to refer patients with severe mental problems to specialized mental health care. And this should also work in the opposite direction: referral from specialized mental health care to primary care. For example, when a treatment-resistant patient needs practical support that can be provided in primary care. Furthermore, if a psychiatric nurse treats a patient in primary care and needs the expertise of a psychiatrist during a brief crisis or emergency, this should be settled quickly. This can be achieved by implementing a collaborative care model in primary care and specialized mental health care. The psychiatric nurse creates a treatment plan while the general practitioner remains responsible. Furthermore a psychiatrist (or psychologist) provides supervision, can advice in the decision-making about stepping up to a higher intensity treatment, and can respond easily if there is crisis. Furthermore, the practice nurse can consult the general practitioner and/or the patient about most the suitable low-intensity treatment (for example, a choice between two types of low-intensity treatment in the first step).

These three main elements have to be integrated into a care model. This should lead to better-structured and organized mental health care. Furthermore, the treatment of mental disorders in primary care should lead to a smaller, more specialized mental health care without waiting lists for patients with severe and complex disorders.

Future Research

Based on the results of this randomized trial, some advice and adjustments for future research can be given. First of all, recruitment of patients in future research should be via referral by their
GP instead of screening patients via a general practice population. Second, to create better adherence it is recommended to provide active guidance or coaching with bibliotherapy or self-help via Internet. Furthermore, case management, monitoring and collaboration with specialized mental health care should be improved and centrally organized (e.g. performed by the case manager).

More studies should be carried out to demonstrate effectiveness or ineffectiveness of care models. Future research can create an evidence-based blueprint on how the offering of care should be carried out, i.e. which aspects are crucial determinants of effectiveness. Furthermore, research is needed on how care models should be implemented for primary care. Systematic reviews and meta-analyses are also recommended to explore the active elements of care models.[45] For example, a recent systematic review of models in the delivery of depression care identified several key elements that were associated with improved depression outcomes. Components that predict improvement were the provision of a case manager who provided feedback and delivered an psychological therapy, and an intervention that incorporated patient preferences into care.[46]

Another recommendation is that the patients' need for care requires attention. It is important to identify patients who perceive that they need care, but do not or only partially receive care. It is also important to identify possible barriers these patients experience in order to receive care. Research is needed on the undertreatment of the needs of these patients and the possible perceived barriers. Patients that perceive no need for care are less neurotic than patients that do perceive need for care. It is important to explore the justification of the perceived need because several questions remain unanswered. For instance, whether people with high levels of neuroticism really need more care than patients with lower levels of neuroticism, or if it is a burden on the care system that these patients receive unnecessary treatment. However, if patients receive a DSM-IV diagnosis this is, from a professional perspective, an indication that mental health care is needed. This ethical issue on which patients should be treated when should be addressed before any practical and clinical implications can be described.

Finally, cost-effectiveness of the stepped care program has to be calculated. Stepped care does not outperform care as usual in clinical aspects, but it might be more cost-effective. In The United Kingdom, the government has set up the Increasing Access to Psychological Therapies (IAPT)[47] program for depression and anxiety disorders. IAPT offers evidence-based psychological treatments that are recommended by the NICE guidelines. Clinical services were offered in a stepped care model. Stepped care was not more effective than care as usual, but care as usual was more expensive than stepped care.

**Summary and Conclusion**

We did not find significant differences between stepped care and care as usual. However, the objective of starting with low-intensity interventions and continue, if necessary, with increased intensity treatments seems very suitable for primary care. To increase adherence and effectiveness it seems necessary to take into account several aspects, for example the chronicity and duration of the symptoms, the patients' perception regarding the need of care and the decision-making about the patient flow. This can be achieved by shifting from stepped care towards matched care. In other words, by seeking a balance between stepped and matched care.
Subsequently, this level of offered treatments should be implemented in a collaborative care model. Today, specific rules for how a care model should be offered are lacking. Future research can offer a possibility to create an evidence-based blueprint for its implementation. Furthermore, it can identify the active elements in care models. A care model should benefit the patient, but also the GP, the care manager, and unburden specialized mental health care.
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