Introduction
The central aim of this thesis is to determine the effectiveness and cost-effectiveness of a nurse-led psychological intervention for patients with mental health problems who visit the general practitioner (GP). This first chapter briefly introduces the problems in mental health care for GPs and the history of the intervention, the aims and structure of this thesis, and objectives are stated. To clarify the situation of patients with mental health problems, we start with a case vignette.

Case vignette

Adrian is 42-years-old, married, and has two children (12 and 14 years-old). A year ago the family moved to a new town where he visited a new GP for the first time. Adrian is a youth worker experiencing serious problems at work; being unable to cope with pupils and colleagues and very afraid of making mistakes. At home, his marital relationship is also not good, and he feels that he does everything wrong. Adrian and his wife never do anything nice together, he cannot bring himself to enjoy other activities, and feels worried all of the time. When the GP asked him what the matter was, he said that he felt tired and down, had a pain in his back, and was unable to concentrate.

Primary mental health care

Patients with problems like Adrian’s are common in general practice. The estimated prevalence of psychological disorders varies, but it can be safely stated that patients with these kinds of problems visit their general practitioner frequently (1).

Therefore, mental health care is a core activity of primary care (2). The GP has become the gate-keeper for not just physical, but also psychological care, which frequently means a complicated and substantially expanded workload (3;4). Patients with mental health problems have significant social impairment, especially when they suffer from affective disorders (5). The GP uses guidelines for treatment of both the diagnosis anxiety and depression, which have been provided by the Dutch College of General
Practitioners (NHG, (6;7)). We will describe these guidelines for depression and anxiety shortly.

**Depression treatment guidelines for primary care**
After depression has been diagnosed, the first step in treating a patient is to explore the existence of potential co-morbid disorders and their treatment, provide psycho-education concerning depression, and advice regarding lifestyle. The GP and patient decide upon the best treatment option, either: by the GP, psychological treatment in primary care, or psychotherapy in an outpatient clinic. Treatment by the GP comprises one visit every two weeks where daily goals are created and pleasurable activities advised. Additional drug treatment is also an option, which fits well in daily practice, is acceptable to patients and is common (of all patients suffering of depression, only 4% are referred to a psychiatrist, psychologist or outpatient clinic) (3). If depression lasts for less than three months, no other specific interventions are advised in case of spontaneous recovery. In patients who show symptoms after three months, antidepressant drug treatment and/or short-term psychotherapy are advised.

**Anxiety treatment guidelines for primary care**
After an anxiety disorder is diagnosed, the first step in treating a patient is to make an inventory of possible psychosocial stressors and use of psychotropic substances related to anxiety. The GP and patient decide upon the best treatment option: treatment by the GP (with or without the use of sedatives), psychological treatment in primary care, or psychotherapy in an outpatient clinic. Cognitive behavioural therapy (CBT) is the evidence-based treatment for anxiety disorders. Treatment by the GP comprises one patient visit every two weeks where psycho-education is given on the role of catastrophic cognitions, and avoidance behaviour in the maintenance of anxiety symptoms. Drug prescription fits most easily in routine practice, but patients often prefer psychotherapy to antidepressants (8).

**Mental health problems in primary care**
Unfortunately, treatment tailored to patients with mental health problems is not available in general practice. The effectiveness of medication in primary
care has been found to have only limited success, with side-effects and non-compliance increasingly reported over time (9). Referral to a psychiatric outpatient clinic involves a waiting list and is not necessary for every mental health problem, while, for example, guided self-help could also be effective (10). For GPs to advise patients effectively on how to deal with mental health problems, better tools and support in daily practice is urgently required. Nurses already support some practices and carry out specific tasks. For example, diabetes nurses have become quite common in the Netherlands (11) unlike mental health nurses (12). When mental health nurses are present in general practice, they mostly assess the need for referral or provide short psychological treatment or counselling (13). This is in contrast with outpatient mental health care, where evidence-based therapies for depression and anxiety are widely applied (14).

Specialized and integrated assistance by mental health nurses could solve this problem. Nurses could specialize in short and effective treatment for common mental health problems to prevent or stimulate a referral to secondary care for patients with complaints, which cannot be treated in primary care. This would also stimulate better tailored collaborative forms of care and reduce the number of complaints (15). Such treatment has been available as a multipurpose stand-alone psychological intervention since 1996, developed for particular use in primary care and is called Problem Solving Treatment.

**Problem Solving Treatment**

In 1971 D’Zurilla and Goldfried published a theory in which problem-solving was defined as a cyclic process in five stages: problem orientation; problem definition; generation of alternative solutions; decision making, and solution implementation – collectively called *problem solving therapy* (16). This therapy is strictly protocolized and based on the principles of CBT.

Problem solving *therapy* has been applied to a wide range of psychological disorders in many areas. For example, the outcome of a meta-analysis showed such therapy to be suitable for deliberate self-harm patients (17). Therapy has also proven itself in: long-term weight reduction for people suffering from obesity (18); in reducing rates of depression, hopelessness and suicidal ideation...
in patients after a suicide-attempt (19); strengthen problem-solving abilities and assertiveness in mildly mentally retarded people (20), palliative care (20); diabetes care (21), and elderly people suffering from depression (22).

In 1995 Gath and Mynors-Wallis conducted an experiment using a basic form of problem solving called Problem Solving Treatment (PST), developed primarily for use in busy and time-constrained primary care settings. It has also been developed so that non-mental health specialists (such as nurses) in primary care settings can be trained to administer treatment. PST is brief when compared to psychotherapy; a maximum of six sessions is advised (totalling 3.5 hours).

PST begins by establishing the link between the symptoms and the practical problems that patients experience. The theoretical assumption is that mental health problems are often caused by practical problems people experience in their everyday lives. Treatment is focused on the ‘here and now’ and setting goals for the future (it does not dwell on past relationships and mistakes). PST is collaborative, with the patient playing an active part in the recovery process. Each session contains seven problem-solving stages applied systematically towards problem resolution (Figure 1). Therapy also aims to train patients to use problem-solving techniques to overcome their problems themselves, and therefore helps them regain a sense of control of their lives (23).

**What do we know about PST?**

The following six trials, conducted since 1995, emphasise what was known about the effectiveness of PST towards several diagnoses, prior to this trial.

**Major depression**

In 1995 a PST trial on patients suffering from major depression, consisted of three groups. In one group patients received PST from the GP or psychiatrist, in another patients received usual care (UC) with amitriptyline (an antidepressant), while the third group received a drug placebo. The results showed that PST given by the GP or psychiatrist was as effective as amitriptyline, in contrast to the drug placebo (24). In this study GPs referred patients into the trial, which means patients could be judged as patients who
may benefit of the PST by the GP. Although this could be a resemblance of daily care, patient selection could not be excluded. While the results show an optimistic outcome for PST, the sample size is small; only (around) 30 patients per group. Therefore, conclusions should be drawn carefully.

In 2000, a second trial for primary care patients suffering from major depression was conducted. The patients were recruited from lists of GPs so the risk of patient selection is smaller than when referral is done by a GP. It was a randomised clinical trial (RCT) with four groups: paroxetine (an antidepressant) provided by the GP; PST provided by the GP; PST provided by a nurse, and patients who received PST from a nurse and paroxetine provided by the GP. No differences in outcomes were found between the groups, and the anti-depressant was found to be as effective as PST. Paroxetine combined with PST showed no difference with paroxetine or PST alone. Although 116 patients completed the full course of treatment, the groups were small again (around 30) (25). This trial also showed nurses can effectively provide PST.

**Minor depression and dysthymia**

The third trial discussed here was conducted in 2001 and carried out by psychiatrists and PhD psychologists for patients suffering from minor depression or dysthymia – randomised in a PST (PhD psychologist), paroxetine or placebo condition (psychiatrist). A research psychiatrist judged diagnoses for all settings. Patients were recruited from two primary care settings (in different countries) for this study, as a part of a larger study for comparing results for patients of 60 years and older were four other settings were involved.

For dysthymia, paroxetine followed by PST improved remission when compared to placebo plus non clinical management. For minor depression, the interventions were equally effective; this means for minor depression watchful waiting is an appropriate treatment option. PST also proved a good option when the severity of symptoms increases (26). In this trial, the groups of patients who completed the trial were between 60 to 70 patients.
**Mental health problems**

The fourth study was concerned with patients with mental health problems including: anxiety; tension; depressed moods; irritability, and sleep disturbance and carried out in 1991. One group of patients was randomised in a PST condition, the second group received UC. After 28 weeks the PST group showed significantly better results than the UC group, in contrast to the post-treatment findings, where no significant differences were found (27). In this study, the GPs selected the potentially suitable patients but gave them treatment for four weeks, and after these four weeks, patients were assessed for participation in the trial. Referrals were made by 26 GPs from different practices, 113 patients entered the study, 47 were allocated to PST or control condition and 44 patients completed it. The distribution of the patients is not clear and the power of this study was not calculated. More research is needed to establish this outcome.

The following study was carried out in 1997 and also with patients suffering from emotional disorders. The GPs referred the patients to the trial and patients were randomly allocated into the separate conditions. Nurses carried out PST and the GP provided UC. No differences were found between the groups, except for reduced sickness-related days for patients who received PST. Seventy patients were allocated, 58 patients completed the trial (28). In this study there are small sample sizes (22 PST vs. 36 UC); caution is needed to draw any conclusions.

The final trial discussed here is from 2001 and involved three groups. In 62 practices, 98 GPs referred 247 patients. The patients were randomly allocated into the three arms. In one group PST was carried out by psychiatric nurses, in another psychiatric nurses delivered UC, while in the third patients received UC by the GP. No differences in outcomes were found between the groups, although PST patients were more satisfied with the treatment. 173 patients completed this trial. The dropout rate was a bit higher in the GP group. (29).
Overall, it can safely be stated that PST given by nurses, psychiatrists or GPs is as good as UC provided by the GP, or in cases of depression, just as good as antidepressants.

**PST provided by nurses**

Patients with mental health problems need more time than is available in general practice. The usual 10-minute consultation with a GP is generally too short to explain and explore such problems. Mental disorders are often interwoven with physical issues such as fatigue and sleeplessness; and so recognising and diagnosing a mental health problem can be difficult. Furthermore, patients are often ambiguous when presenting symptoms (30). These facts, together with the high prevalence of psychological problems in primary care, make it clear that such care needs assistance in treating mental health problems. Nurses who are skilled in working with psychiatric patients could become indispensable in primary care (13).

Previous research has shown that nurses can successfully provide effective treatment for primary care patients (31). PST is also suitable for non-mental health workers, and can also be provided by nurse practitioners or other primary care workers. At present, there are still very few nurses working in Dutch general practice, and although preliminary experiments are taking place to enhance and define the role of nurses in primary care, PST could be a welcome innovation in their work profiles.

**Aim and outline of this thesis**

The central aim of this study is to investigate whether PST for mental health problems provided by nurses in primary care is effective and cost-effective in potentially providing GPs and patients with tailored care.

A randomised clinical trial (RCT) was conducted and analysed over nine months. Subsequently, predictors of outcome in the research population were studied. Furthermore, the sensitivity of change of two of the questionnaires used for primary and secondary outcome analysis was measured.
The thesis is structured as follows:

In Chapter 2 the protocol of this study is extensively described, including all measurements, the design, power calculation and randomisation. Chapters 3 and 4 present the effectiveness of PST compared to UC at post-treatment (six months) and follow-up (nine-months). In Chapter 4 the predictors of improvement of mental health are also described and the analysis and outcome of this analysis is presented and discussed. Chapter 5 is concerned with how well the questionnaires measured the sensitivity of change in the trial. We compared an expert-derived questionnaire with a patient-generated measurement by comparing effect-sizes and classify the problems into a widely used classification system. Chapter 6 reports on cost-effectiveness of PST compared to usual care. In Chapter 7 the main findings are summarized, strengths and limitations discussed. Recommendations for future research and for general practice are presented. This thesis will be concluded with a summary in English and Dutch. Translated questionnaires are included in the APPENDIX.
Chapter 1

References


Introduction
