Prevention of recurrent sickness absence in workers with common mental disorders

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PREVENTION OF RECURRENT SICKNESS ABSENCE IN WORKERS WITH COMMON MENTAL DISORDERS

Iris Arends

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CONTENTS

1

General introduction

COMMON MENTAL DISORDERS AND WORK

Common mental disorders (CMDs), consisting of mild to moderate severe mental disorders such as depression, anxiety and adjustment disorders, are highly prevalent in working populations[1-4]. In many Western countries, CMDs are a frequent cause of work disability claims[5,6]. The WHO expects depression to be the leading cause of absenteeism in industrialized countries in 2020[7]. Furthermore, CMDs are more often related to long term sickness absence as compared to other health problems[8-11].

The negative consequences of sickness absence for the individual and society have been well established. For the individual, not being able to work because of a health problem is disturbing, not only because of loss of income but also because work constitutes an important part of social life. Work can give meaning to a person's life by contributing to society and developing social relationships with colleagues[12,13]. On a societal level, sickness absence and work disability are extremely costly due to lost productivity. For example, costs for sickness absence and work disability are estimated at €20 billion annually in the Netherlands[14,15]. The importance of preventing work disability and enabling workers with health problems to perform their job has been stressed repeatedly by international organisations, such as the World Health Organisation (WHO) and the Organisation for Economic Cooperation and Development (OECD)[5,16].

Considering the major impact of CMDs on sickness absence and associated personal and societal consequences, the management of sickness absence due to CMDs is high on the research agenda in the field of Occupational Safety and Health. The past two decades, the primary focus has been on enhancing return to work (RTW) of workers on sickness absence due to CMDs as long term sickness absence is related to an increased risk of permanent work disability[8-10].

Recently, the focus has shifted to how workers with CMDs function at work. Two main findings have contributed to this shift. Firstly, research has shown that workers with CMDs experience on-the-job productivity loss, meaning that workers with CMDs experience problems with functioning while at work. In the US, costs related to lost productivity at work are even more substantial than the costs related to sickness absence[17,18]. Secondly, recent studies have shown that 20% to 30% of the workers who have returned to work after sickness absence due to CMDs experience recurrent sickness absence[19,20]. The risk of sickness absence due to a CMD is higher in workers with previous sickness absence due to a CMD compared to the general working population. Furthermore, recurrent sickness absence after an initial sickness absence episode due to a CMD can be more serious and long-lasting[19,21]. These results stress the importance of providing interventions for workers who have been on sickness absence due to CMDs to prevent problems in work functioning and recurrent sickness

absence, and, thus, to enable sustainable RTW. Given the lack of interventions with this focus, the present thesis aims at evaluating an intervention to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

THE DUTCH SOCIAL SECURITY SYSTEM

As a country's social security system influences sickness absence, it is important to understand the context in which interventions focusing on sickness absence are developed and evaluated. In the Netherlands, at least 70% of the wage is covered by the employer during the first two years of sickness absence. No distinction is made between work-related or non-work related sickness absence, and the sick-listed worker cannot be fired. During these two years of sickness absence, both the employer and the worker are responsible for enabling RTW. The employer is obligated to hire an OP and has to pay for therapy or work accommodations if needed. The role of the OP is to give advice to the employer and worker during the RTW process. Thus, the OP plays a central role in the Dutch social security system. OP treatment guidelines are provided by the Netherlands Society of Occupational Medicine such as the guideline for managing mental health problems of workers[22]. Workers are obligated to visit the OP and have to collaborate with the OP and employer (often represented by the worker's supervisor) in developing and implementing an action plan to enable RTW. If RTW has not been realised within two years, a Social Security Officer (trained as an insurance physician) will evaluate if sufficient RTW efforts have been made by the employer and the worker and decides on the percentage of work disability for which the worker will be compensated by the Social Security Agency.

EXISTING LITERATURE ON INTERVENTIONS FOR WORKERS WITH COMMON MENTAL DISORDERS

So far, interventions for workers with CMDs have mainly focused on facilitating RTW for workers who are on sickness absence due to CMDs. Most of these interventions have taken a bio-psycho-social perspective, acknowledging the importance of focusing on other factors than biological factors like symptoms of CMDs[23-27]. Research has shown that returning to work does not automatically follow symptom recovery[28,29]. Thus, waiting for full symptom recovery before starting RTW, does not seem to be beneficial for successful RTW. Therefore, interventions to facilitate RTW among workers on sickness absence due to CMDs have integrated gradual RTW while symptom recovery is still taking place. These interventions focus on psychological factors (such as emotions and cognitions) and social factors (such as relationships with family, friends and especially supervisors and colleagues) which play an important role in enabling a

person to RTW. Several randomised controlled trials (RCTs) have been conducted to evaluate interventions to facilitate RTW in workers on sickness absence due to CMDs. Many of these RCTs were performed in the Netherlands, and, overall, it seems that the most successful interventions were conducted in proximity of the workplace. An example is the activating intervention developed by van der Klink et al. (2003) to facilitate RTW for workers on sickness absence due to adjustment disorders which has been influential in the Netherlands[23]. The intervention was conducted by OPs and focused on activating participants to regain control over their personal and working life and to follow a gradual RTW plan. The intervention was evaluated in a cluster-RCT and proved to be effective in reducing time to RTW. Presently, the intervention has been integrated in the guideline on "Management of mental health problems of workers by occupational physicians" of the Netherlands Society of Occupational Medicine[22]. Comparably, Blonk et al. (2006) found that a brief work-directed intervention consisting of stress management and advice on gradual RTW provided by trained labour experts was more effective in reducing time to RTW than a cognitive behavioural intervention provided by trained psychologists and a no-treatment control group[24]. Interventions that have been provided by health care providers who are less connected to the workplace did not find similar results. For example, Brouwers et al. (2006) used the same intervention protocol as developed by van der Klink et al. (2003) in a similar population (i.e. workers with minor mental disorders) but used social workers to conduct the intervention[30]. The study results did not show enhanced RTW for the intervention group compared to the control group. Also, Bakker et al. (2007) did not find that monitoring the problem solving process of a sick-listed worker with stress-related mental disorders by a general practitioner was effective in enhancing RTW compared to usual care[31].

Aside from research evaluating interventions to facilitate RTW of sick-listed workers with CMDs, there is a need to look beyond RTW. Regardless of any intervention, about 70% of the workers who are on sickness absence due to CMDs return to work within one year, but 20% to 30% of these workers experience recurrent sickness absence after RTW[9,19]. Therefore, research is needed that focuses on how to achieve sustainable RTW. The importance of providing guidance after RTW has also been stressed by workers themselves. In an interview study with workers who (partially) returned to work after sickness absence due to CMDs, Noordik et al. (2011) showed that difficulties were experienced with unsupportive communication within the working environment and with implementing solutions for work-related barriers[32]. To address the knowledge gap on sustainable RTW, the central theme of this thesis is the evaluation of an intervention to enhance sustainable RTW by preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

CONCEPTUAL MODEL OF THE PREVENTION OF RECURRENT SICKNESS ABSENCE

The conceptual model of the prevention of recurrent sickness absence builds upon the RTW process model for workers with CMDs developed by van der Klink et al. (2007)[23,33] and incorporated in the guideline on "Management of mental health problems of workers by occupational physicians" of the Netherlands Society of Occupational Medicine[22]. The conceptual model of the prevention of recurrent sickness absence is presented in Figure 1. The upper part of the figure shows the RTW process model, while the lower part is the extension of van der Klink's model, based on recent literature[32,34,35], incorporating an intervention to prevent recurrent sickness absence.

In the RTW process model, sickness absence due to CMDs is proposed to follow from not being able to cope successfully with daily (work) stressors which results in a feeling of loss of control and distress. When not addressed in time and when control cannot be regained in the work situation, the worker will often try to avoid the feeling of loss of control and distress by dismissal of the work role. According to the RTW process model, treatment by OPs should focus on helping the worker to regain control which is in line with patient empowerment theories that state that treatment should be aimed at helping patients to get a sense of control, self-determination and goal attainment[36]. The treatment to enable RTW consists of three phases and is based on stress inoculation training[37]. The first phase is focused on providing a rationale for why sickness absence occurred, educating about future prospects and structuring daily life. In the second phase, problems are addressed that caused sickness absence, and the worker is stimulated to generate solutions to enable RTW. In the final phase, gradual RTW is started and the solutions to problems are implemented.

As RTW is accompanied by new stressors such as setting boundaries, implementing solutions and communication with supervisors and colleagues[32], the RTW process model has been extended in this thesis with a structured intervention to prevent recurrent sickness absence in the post-RTW phase. After gradual RTW has started, the intervention should prevent a new failure to cope with stressors following RTW. The worker is again activated to go through the process of addressing problems and finding solutions but now specifically focused on problems that have occurred during RTW (step 1-3). Next to addressing problems, the worker can also focus on positive aspects such as opportunities within the work context that can further improve functioning at work. Discussions with the supervisor are stimulated to develop practical and applicable solutions that can be implemented in the work situation (step 4), as research has shown that the role of the supervisor is of paramount importance in the RTW process[32,35]. The final step in the extended model (step 5), is the evaluation of the problem solving process to enable workers to adopt this process as a common practice. It is hypothesized that the five-step process will prevent recurrent sickness

absence, improve work functioning and problem solving coping and decrease mental health complaints.

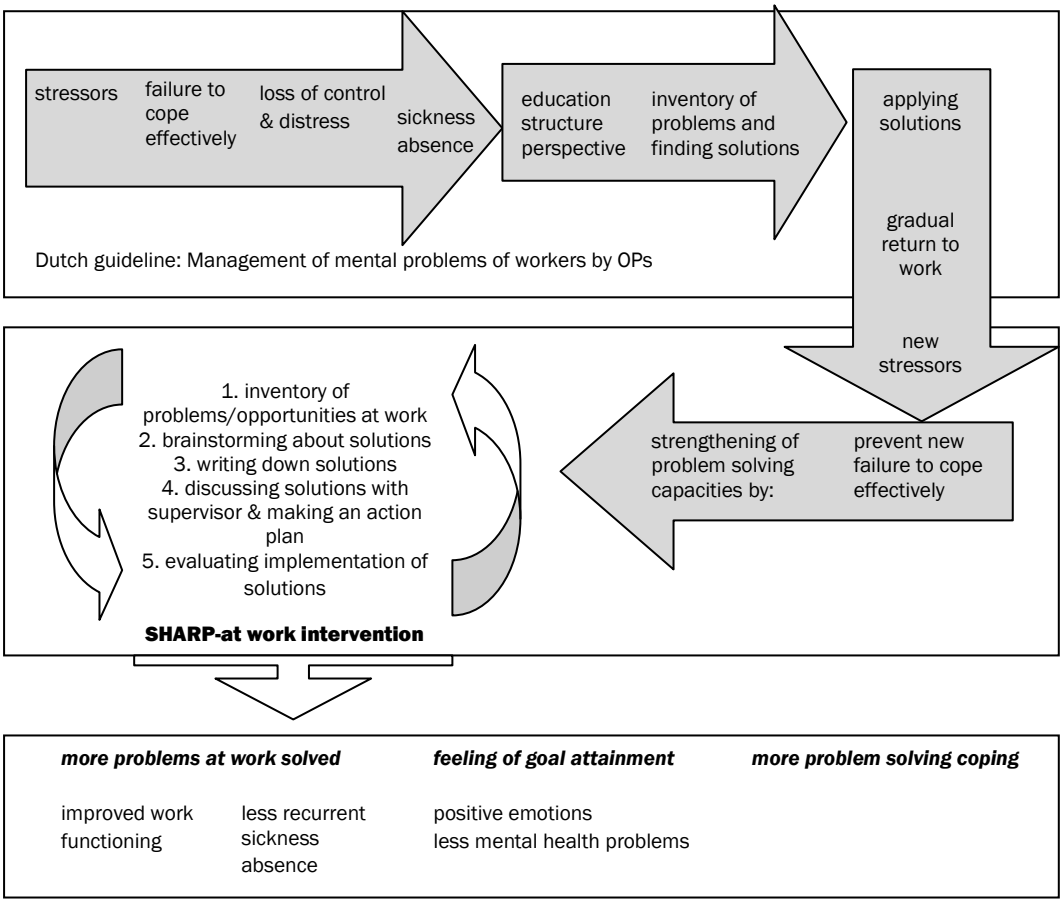

Figure 1. Conceptual model of the prevention of recurrent sickness absence in workers with CMDs.

THE SHARP-AT WORK INTERVENTION: PREVENTING RECURRENT SICKNESS ABSENCE IN WORKERS WITH COMMON MENTAL DISORDERS

In this thesis, an intervention to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs is evaluated. The SHARP (Stimulating Healthy participation And Relapse Prevention)-at work intervention is developed as an extension of the RTW process model[23,33]. The lower part of the model (see Figure 1) proposes the SHARP-at work intervention which consists of the five-step

process. The SHARP-at work intervention is provided by OPs to align with the Dutch OP guideline on the management of mental health problems of workers, and because OPs are closely connected to the work environment. OPs guide workers through the five-step problem solving process to find and implement solutions for problems/ opportunities experienced when back at work. OPs monitor that all steps are taken and activate and support the worker when needed. Furthermore, OPs empower the worker to define the problems and design solutions. Two to five consultations are recommended to the OPs, and assignments are available for each step of the intervention. The first assignment is the key element of the intervention. In this assignment, workers have to make an inventory of problems and opportunities at work and, subsequently, to define if help is needed to solve the problems or realise the opportunities.

THESIS OBJECTIVE AND RESEARCH QUESTIONS

The objective of this thesis is to generate knowledge on the prevention of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. The main focus is on the evaluation of the effectiveness of the SHARP-at work intervention in preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMD. Alongside this effect evaluation, a process evaluation and an economic evaluation are presented. The process evaluation is helpful in explaining the results of the effect evaluation and whether these results are attributable to the SHARP-at work intervention. As part of the process evaluation, an in-depth exploration of challenges with recruiting research participants by OPs is described. The economic evaluation provides information on the cost-effectiveness and cost-benefit of the intervention. Next to the evaluation of the SHARP-at work intervention, a systematic literature review is presented on interventions to facilitate return to work in adults with adjustment disorders. A specific focus on adjustment disorders as a subgroup of CMDs is chosen as this group has often been investigated in relation to RTW. Also, predictors for recurrent sickness absence among workers with CMDs are investigated. The following research questions form the basis of this thesis:

Research question 1: Which interventions are effective in facilitating return to work in workers with adjustment disorders?

Research question 2: Is the SHARP-at work intervention effective in preventing recurrent sickness absence and improving mental health, work functioning and problem solving coping in workers who returned to work after sickness absence due to CMDs compared to care as usual?

Research question 3: Is the SHARP-at work intervention conducted according to the protocol, does it differ from care as usual, and how are the key elements of the intervention related to the effect outcome (i.e. recurrent sickness absence)?

Research question 4: What are barriers and facilitators for participant recruitment by occupational physicians?

Research question 5: Is the SHARP-at work intervention cost-effective and cost-beneficial compared to care as usual?

Research question 6: Which factors predict recurrent sickness absence in workers who returned to work after sickness absence due to CMDs?

THESIS OUTLINE

This first chapter provides an overall introduction to the topic of the thesis to address the importance of the topic, explain the context and describe relevant constructs. In **Chapter 2**, the results of a systematic literature review are presented on the effectiveness of interventions to enhance return to work in workers with adjustment disorders. **Chapter 3** describes the study design of the cluster-RCT with an effect evaluation, process evaluation and economic evaluation of the SHARP-at work intervention compared to care as usual. **Chapter 4** presents the effect of the SHARP-at work intervention on preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Moreover, the effects on mental health complaints, work functioning and coping behaviour are evaluated. In **Chapter 5**, the process evaluation of the SHARP-at work intervention is described. The chapter focuses on: 1) evaluating whether the SHARP-at work intervention was conducted according to the protocol and differed from care as usual, and 2) investigating the relationship between the key elements of the intervention and the primary outcome of the effect evaluation (i.e. recurrent sickness absence). **Chapter 6** focuses on problems with participant recruitment by OPs. Barriers and facilitators for recruitment as experienced by OPs are reported, and the relationship between OP's personal and work characteristics and the recruitment of participants is evaluated. **Chapter 7** addresses the economic evaluation of the SHARP-at work intervention and presents the cost-effectiveness and cost-benefit evaluations. In **Chapter 8**, predictors for recurrent sickness absence in workers who returned to work after sickness absence due to CMDs are investigated. In **Chapter 9**, a general discussion is provided. The main research results are summarized and discussed, methodological considerations are addressed and the implications of this thesis for future research and practice are presented.

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2

Interventions to facilitate return to work in adults with adjustment disorders

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ABSTRACT

Background: Adjustment disorders are a frequent cause of sick leave and various interventions have been developed to expedite the return to work (RTW) of individuals on sick leave due to adjustment disorders.

Objectives: To assess the effects of interventions facilitating RTW for workers with acute or chronic adjustment disorders.

Search methods: We searched the Cochrane Depression, Anxiety and Neurosis Review Group's Specialised Register (CCDANCTR) to October 2011; the Cochrane Central Register of Controlled Trials (CENTRAL) to Issue 4, 2011; MEDLINE, EMBASE, PsycINFO and ISI Web of Science, all years to February 2011; the WHO trials portal (ICTRP) and ClinicalTrials.gov in March 2011. We also screened reference lists of included studies and relevant reviews.

Selection criteria: We selected randomised controlled trials (RCTs) evaluating the effectiveness of interventions to facilitate RTW of workers with adjustment disorders compared to no or other treatment. Eligible interventions were pharmacological interventions, psychological interventions (such as cognitive behavioural therapy (CBT) and problem solving therapy), relaxation techniques, exercise programmes, employee assistance programmes or combinations of these interventions. The primary outcomes were time to partial and time to full RTW, and secondary outcomes were severity of symptoms of adjustment disorder, work functioning, generic functional status (i.e. the overall functional capabilities of an individual, such as physical functioning, social function and general mental health) and quality of life.

Data collection and analysis: Two authors independently selected studies, assessed risk of bias and extracted data. We pooled studies that we deemed sufficiently clinically homogeneous in different comparison groups and assessed the overall quality of the evidence using the GRADE approach.

Results: We included nine studies reporting on 10 psychological interventions and one combined intervention. The studies included 1546 participants. No RCTs were found of pharmacological interventions, exercise programmes or employee assistance programmes. We assessed seven studies as having low risk of bias and the studies that were pooled together were comparable. For those who received no treatment, compared with CBT, the assumed time to partial and full RTW was 88 and 252 days respectively. Based on two studies with a total of 159 participants, moderate-quality evidence showed that CBT had similar results for time (measured in days) until partial RTW compared to no treatment at one-year follow-up (mean difference (MD) -8.78, 95% confidence interval (CI) -23.26 to 5.71). We found low-quality evidence of similar results for CBT and no treatment on the reduction of days until full RTW at one-year follow-up (MD -35.73, 95% CI -113.15 to 41.69) (one study with 105 participants

included in the analysis). Based on moderate-quality evidence, problem solving therapy (PST) significantly reduced time until partial RTW at one-year follow-up compared to non-guideline based care (MD -17.00, 95% CI -26.48 to -7.52) (one study with 192 participants clustered among 33 treatment providers included in the analysis), but we found moderate-quality evidence of no significant effect on reducing days until full RTW at one-year follow-up (MD -17.73, 95% CI -37.35 to 1.90) (two studies with 342 participants included in the analysis).

Authors' conclusions: We found moderate-quality evidence that CBT did not significantly reduce time until partial RTW and low-quality evidence that it did not significantly reduce time to full RTW compared with no treatment. Moderate-quality evidence showed that PST significantly enhanced partial RTW at one-year follow-up compared to non-guideline based care but did not significantly enhance time to full RTW at one-year follow-up. An important limitation was the small number of studies included in the meta-analyses and the small number of participants, which lowered the power of the analyses.

PLAIN LANGUAGE SUMMARY

Improving return to work in adults suffering from symptoms of distress

Adjustment disorders, characterised by distress symptoms and emotional disturbance as a reaction to a significant life change or stressful life event, are a frequent cause of sick leave among workers. Apart from the negative consequences for the worker, sick leave poses a heavy burden on society due to the loss of productivity of the worker and work disability claims. Different treatments have been developed to help such workers return to work. Our study assessed how effective these treatments are at enabling the sick-listed worker to return to partial or full-time work. We searched databases containing articles from different scientific journals and looked for studies that tested whether a certain type of treatment helped the worker to return to work when on sick leave because of an adjustment disorder. We found nine relevant studies. In total, 10 psychological treatments were evaluated and one combined treatment consisting of a psychological treatment and relaxation techniques. We found no studies on pharmacological interventions, exercise programmes or employee assistance programmes. The nine studies included in this review reported in total on 1546 participants. Of the 10 psychological treatments, five consisted of cognitive behavioural therapy and five of problem solving therapy, which are commonly used types of treatment for patients with mental health problems. Our results showed that workers on sick leave because of an adjustment disorder can be helped with making their first step back to work (i.e. partial return to work) by treating them with problem solving therapy. On average, workers who are offered problem solving therapy start 17 days earlier with partial return to work compared to workers who receive no treatment or the usual treatment from their occupational physician or general practitioner. However, we also found that cognitive behavioural therapy or problem solving therapy does not help the worker return to work with full-time hours any quicker than workers who receive no treatment or the usual treatment from their occupational physicians or general practitioners. These results are based on moderate-quality evidence, which implies that further research is likely to have an important impact on our confidence in the results and may change the results.

BACKGROUND

Description of the condition

In recent years, increasing attention has been paid to mental health problems and their consequences in terms of sick leave and work disability[1-4]. In many Western countries, mental health problems are the main cause of sick leave[5-7]. Sick leave has major consequences for the subjective well-being of an individual. Workers who are on sick leave can become isolated from family members and friends who are still working. Furthermore, they can become marginalised from their colleagues and the workplace[8,9]. Receiving compensation benefits is a possible source of stigma due to perceived laziness, leading to feelings of anger, shame and guilt in workers who are on sick leave[8,9]. Apart from the negative consequences for the individual worker, sick leave results in a heavy societal burden because of loss of productivity and work disability claims[10-13].

Adjustment disorders are a common mental health problem among workers[14]. The Bristol Stress and Health at Work Study found that more than 50% of the respondents reported being extremely, very or moderately stressed at work[15,16]. Furthermore, adjustment disorders are one of the most frequent causes of sick leave due to mental health problems[17,18]. In the Netherlands, work disability as a result of mental health problems accounts for 30% of all disability benefits[19,20]. Moreover, a majority (69% to 79%) of the employees suffer from common mental health problems such as adjustment disorders [21,22].

Adjustment disorders are defined in both the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)[23] and the International Statistical Classification of Diseases and Related Health Problems (ICD-10)[24]. DSM-IV has defined adjustment disorders as the occurrence of emotional and behavioural symptoms in response to an identifiable stressor occurring within three months after the onset of the stressor. Furthermore, the DSM-IV states that:

- The symptoms or behaviours are clinically significant as evidenced by either of the following:
  - marked distress that is in excess of what would be expected from exposure to the stressor;
  - significant impairment in social or occupational (academic) functioning.
- The stress-related disturbance does not meet the criteria for another specific Axis I disorder and is not merely an exacerbation of a pre-existing Axis I or Axis II disorder.
- The symptoms do not represent bereavement.
- Once the stressor (or its consequences) has terminated, the symptoms do not persist for more than an additional six months.

Adjustment disorders can be classified as acute if the disturbance lasts less than six months and as chronic if the disorder lasts longer than six months. The specification 'chronic' is only applicable when the disorder lasts longer than six months as a reaction to a chronic stressor or a stressor with lasting consequences.

The ICD, a detailed description of known diseases and injuries published by the World Health Organization, is revised periodically (last revision in 1992) and is currently in its 10th edition. The ICD-10 defines the following diagnostic criteria for adjustment disorders:

States of subjective distress and emotional disturbance, usually interfering with social functioning and performance, arising in the period of adaptation to a significant life change or a stressful life event. The stressor may have affected the integrity of an individual's social network (bereavement, separation experiences) or the wider system of social supports and values (migration, refugee status), or represented a major developmental transition or crisis (going to school, becoming a parent, failure to attain a cherished personal goal, retirement). Individual predisposition or vulnerability plays an important role in the risk of occurrence and the shaping of the manifestations of adjustment disorders, but it is nevertheless assumed that the condition would not have arisen without the stressor. The manifestations vary and include depressed mood, anxiety or worry (or mixture of these), a feeling of inability to cope, plan ahead, or continue in the present situation, as well as some degree of disability in the performance of daily routine.

Notwithstanding these clear definitions of adjustment disorder in the DSM-IV and the ICD-10, this diagnosis is not frequently used in the research literature. More often, mental health problems such as “sub-threshold symptoms of depression,” “stress-related mental disorder,” “burnout,” “emotional distress” or “distress” are investigated, which are not included in the DSM-IV or ICD-10[18,25,26]. However, the definitions of the DSM-IV and the ICD-10 show that distress or sub-threshold symptoms (e.g. depressed mood or anxiety), accompanied by a stressful life event, coincide with the diagnosis of adjustment disorder as long as no other mental disorders can be diagnosed according to the DSM-IV or ICD-10. Although adjustment disorders are considered mild compared to major psychiatric disorders, at least 20% of Dutch patients with such a disorder do not return to work (RTW) within a year[27]. In line with this, Nielsen et al. (2011) showed that 19% of a cohort of workers on sick leave because of stress and burnout complaints had not returned to work after 40 weeks of sick leave[28].

Description of the intervention

Interventions have been developed to facilitate RTW of workers on sick leave because of adjustment disorders. A broad range of interventions is available, such as pharmacotherapy, psychological interventions, relaxation therapy, exercise

programmes, employee assistance programmes or a combination of these. Interventions can be developed for the individual worker or for a group of workers. Commonly used interventions to address adjustment disorders and RTW are psychological interventions, such as cognitive behavioural therapy (CBT) or problem solving therapy (PST). Cognitive behavioural interventions focus on behavioural activation strategies (e.g. rehearsing activities before executing them, assertiveness or communication training), restructuring maladaptive thoughts, and identifying and challenging automatic thoughts[29]. For example, Stenlund et al. (2009) studied the effectiveness of cognitively oriented behavioural rehabilitation in combination with relaxation exercises on reducing sick leave[30]. Problem solving interventions are primarily focused on identifying problems, generating and selecting solutions, developing an action plan and evaluating the solution[31]. Other examples of psychological interventions are psychodynamic therapy, behavioural therapy, counselling and interpersonal therapy. Employee assistance programmes are offered by the employer and were originally developed from occupational alcohol programmes. Currently, employee assistance programmes are also designed to address other health problems that have a negative impact on workers' well-being or job performance[32]. Relaxation therapy can consist of any method to help relax a person and reduce levels of anxiety or stress (e.g. yoga), while exercise programmes are aimed at increasing physical activity.

How the intervention might work

Studies on prognostic factors for RTW of workers on sick leave because of mental health problems have shown that on-going mental health problems are a negative predictor for RTW[33,34]. We hypothesised that pharmacological interventions may improve RTW by the reduction of mental health complaints such as depressive and anxiety symptoms, related to the adjustment disorder, caused by the medication [35]. When the symptoms of the adjustment disorder are reduced, a worker on sick leave will be able to resume social roles, such as work[34]. The effect of psychological interventions, especially CBT and PST, on RTW is hypothesised to be established through one (or both) of two routes. Firstly, by addressing cognitions, behaviours and problems related to the adjustment disorder, psychological interventions may improve mental health. The improved mental health could then facilitate RTW[36,37]. Secondly, psychological interventions may specifically focus on cognitions, behaviours and problems that are work-related and may induce more adaptive cognitions and find solutions for the work-related problems to enhance RTW[38]. Also, when a graded activity approach for RTW is part of a psychological intervention, RTW could be facilitated by gradually building up exposure to the work environment and work tasks[39]. Relaxation techniques and exercise programmes may have an effect on RTW by introducing

enjoyable activities (i.e. relaxation or exercise) which create an understanding of the importance of a balance between work and leisure[40].

Why it is important to do this review

For those on sick leave from work due to adjustment disorders, various interventions for improving RTW have been developed; it is important to evaluate which types of interventions are effective and to quantify the effect size. To date, no systematic review has investigated the effectiveness of interventions aimed at improving RTW of workers on sick leave due to adjustment disorders. Therefore, this is the topic of the current review. Recently, three Cochrane reviews have been published in the same research area[41-43]. However, the review by Marine et al. (2006) was only performed for healthcare workers and focused on the reduction of symptoms of occupational stress, while the present review is focused on all workers on sick leave because of an adjustment disorder and has RTW as primary outcome measure[41]. The review by Nieuwenhuijsen et al. (2008) also focused on RTW (i.e. by looking at the reduction of sick leave), but within a working population suffering from depression, not adjustment disorders[42]. Finally, the review of van Oostrom et al. (2009) included all workers on sick leave and, therefore, also those on sick leave because of an adjustment disorder[43]. Nevertheless, the review included only workplace interventions whereas the present review describes a broader array of interventions.

OBJECTIVES

The objective of this review was to assess the effects of interventions facilitating RTW for workers with acute or chronic adjustment disorders.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs), including cluster RCTs, that evaluated an intervention to facilitate RTW of workers on sick leave due to adjustment disorders were considered.

Types of participants

Participant characteristics

Workers (18 to 65 years of age) with an adjustment disorder causing sick leave.

Sick leave status

When the study population consisted of a mix of workers who were working and who were on sick leave, studies were included if the distribution of workers on sick leave was comparable between study groups. Furthermore, we would only use the number of workers that were on sick leave in the analyses and thus "at risk" for the outcome (which was RTW). This was a post-hoc decision (i.e. made after the development of the review protocol).

Diagnosis - inclusion

Adjustment disorders were defined as acute significant emotional or behavioural problems in response to an identified stressor, as described in the DSM-IV[23] and ICD-10[24] criteria. Studies were included when participants had a main diagnosis of adjustment disorder based on the DSM-IV or ICD-10 criteria. Studies were also included when the authors stated that a diagnosis of adjustment disorder, burnout or neurasthenia was made by a qualified medical or psychological professional based on a classification system or by excluding other psychiatric disorders based on the DSM-IV or ICD-10. Moreover, studies were included when participants reported a distinct level of (di)stress-related symptoms or burnout-related symptoms assessed by a (di)stress or burnout scale of a validated self-report questionnaire such as the Four-Dimension Symptom Questionnaire (4DSQ)[44], the Depression, Anxiety and Stress Scales (DASS)[45] or the Maslach Burnout Inventory (MBI)[46,47].

Diagnosis - exclusion

Studies were excluded if it was clear that more than 30% of the participants (a) suffered from moderate to severe depression or anxiety disorder, (b) were diagnosed with other psychiatric disorders than adjustment disorder, or (c) were diagnosed with physical disorders. This criterion allowed us to include studies in which some participants (maximum 30%) were misclassified, in line with the misclassifications that sometimes occur in practice.

Types of studies

All interventions were included that aimed at facilitating RTW of workers on sick leave because of adjustment disorders, using individual or group approaches. We grouped interventions into the following categories:

1. Pharmacological interventions

Pharmacological interventions could consist of any psychotropic medication.

2. Psychological interventions

Psychological interventions could consist of any form of psychological therapy such as cognitive therapy, behaviour therapy, cognitive behavioural therapy (CBT), problem

solving therapy (PST), psychodynamic therapy or individual psychotherapy. However, we only found interventions that consisted of CBT or PST. Interventions were considered to be CBT when at least one of the components was cognitive restructuring[47]. Interventions were considered to be PST when at least one of the components was identifying problems and solutions by the patient/worker[31]. Treatment providers could be any type of healthcare professional trained in the therapy being investigated in the study.

3. Relaxation techniques

Relaxation techniques could consist of techniques to learn to relax muscles and breathing exercises to accomplish a state of calmness.

4. Exercise programs

Exercise programmes could consist of enhancing physical fitness by muscle training, endurance training, aerobics, etc.

5. Employee assistance programs

Employee assistance programmes could consist of programmes offered by the employer to help employees deal with problems that may have a negative impact on their work performance and health.

6. A combination of two or more of these interventions

We grouped interventions in different comparison groups when the type of control group differed. We grouped the following control groups together.

1. No treatment or waiting list condition
2. Care as usual
3. A similar alternative treatment

Types of outcome measures

Primary outcomes

The primary outcome was RTW and we considered the following measures of RTW for this review:

1. Time to partial RTW. Time to partial RTW was operationalized as (a) number of days of sick leave until partial RTW, (b) total number of days of partial sick leave during follow-up, or (c) rate of partial RTW at follow-up measurements.
2. Time to full RTW. Time to full RTW was operationalized as (a) number of days of sick leave until full RTW, (b) total number of days of full-time sick leave during follow-up, or (c) rate of full RTW at follow-up measurements.

When studies reported more than one measure of RTW including time to RTW, we only used time to RTW for data analysis because we considered this to be the most precise estimate of RTW.

Secondary outcomes

1. Symptoms related to an adjustment disorder as measured by a validated and reliable psychometric scale such as the distress scale of the Four-Dimensional Symptom Questionnaire (4DSQ)[44], the stress scale of the Depression, Anxiety and Stress Scales (DASS)[45] or the Maslach Burnout Inventory (MBI)[46]; or by structured diagnostic interviews like the Composite International Diagnostic Interview (CIDI)[48].
2. Work functioning, which we defined as productivity (economic impact of health problems on work) or performance (impact of health problems on the execution of a job) of workers[49]. Examples of validated work functioning measures are the Work Limitations Questionnaire (WLQ)[50] or the Stanford Presenteeism Scale (SPS)[51]. Only total scores on questionnaires were used in this review.
3. Generic functional status (the overall functional capabilities of an individual, such as physical functioning, social function, general mental health) and quality of life as measured by validated and reliable questionnaires such as the Short Form 36 Health Survey (SF-36)[52] and EuroQol[53]. Only total scores on questionnaires were used in this review.

When studies used different questionnaires to measure the same concept, only the results of one questionnaire were reported. The choice for one of the questionnaires was based on the best reflection of the concept being measured according to the opinion of the review authors. We grouped follow-up times into three categories that we considered to be sufficiently homogeneous; from zero to three months, from four to 12 months and from one to two years.

Search methods for identification of studies

Cochrane Depression, Anxiety and Neurosis Group (CCDAN) Specialised Register (CCDANCTR)

The Cochrane Depression, Anxiety and Neurosis Group (CCDAN) maintain two clinical trials registers at their editorial base in Bristol, UK; a references register and a studies-based register. The CCDANCTR-References Register contains over 29,000 reports of randomised controlled trials in depression, anxiety and neurosis. Approximately 65% of these references have been tagged to individual, coded trials. The coded trials are held in the CCDANCTR-Studies Register and records are linked between the two registers through the use of unique Study ID tags. Coding of trials is based on the EU-Psi coding manual. Please contact the CCDAN Trials Search Co-ordinator for further details.

Reports of trials for inclusion in the Group's registers are collated from routine (weekly), generic searches of MEDLINE (1950 -), EMBASE (1974 -) and PsycINFO

(1967-); quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. Reports of trials are also sourced from international trials registers c/o the World Health Organization's trials portal (ICTRP), drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCDAN's generic search strategies can be found on the Group's website.

Electronic searches

The CCDANCTR (Studies and References) was searched by the Group's Trials Search Co-ordinator (TSC), all years to 1 October 2011, using the following terms for POPULATION only (employees on sick leave):

Keywords = ("sick leave" or "medical leave" or absenteeism or (vocational and rehabilitation) or reemployment or "leave benefits")

OR Free-text = ((sick and (leave or list* or absen*)) or ((sick* or absen*) and (workplace or (work and related) or occupation* or job)) or "return to work")

We ran complementary searches on the following databases (see Appendix 1 for the search strategies):

- Cochrane Central Register of Controlled Trials (CENTRAL) (all years to Issue 4, 2011;
- MEDLINE (1950 to 21 February 2011) (search terms were based on those used by Gehanno et al. (2009)[54] in a study to identify RTW records in MEDLINE);
- EMBASE (1980 to 21 February 2011);
- PsycINFO (all years to 21 February 2011);
- ISI Web of Science (all years to 21 February 2011); and
- WHO trials portal (ICTRP) and the ClinicalTrials.gov (29 March 2011).

We applied no restriction on date or language. An update search was conducted in October 2011. At this stage we took the decision to rely on the CCDANCTR alone as no extra studies were found by our complementary searches.

Searching other sources

We checked the reference lists of all reports retrieved as full-text papers for other potentially relevant studies. We also screened systematic reviews and narrative literature reviews. We retrieved and assessed relevant articles for possible inclusion in the review.

Data collection and analysis

Selection of studies

We developed a standardised selection form to make a first selection of relevant studies, based on the following criteria: (1) study design is an RCT, (2) study population consists of a working population and (3) study population includes common mental disorders (adjustment disorders, depressive disorders, anxiety disorders). Two review authors (DB and DR, DB and IA, KN and IA, or UB and IA) screened all references on title, keywords and abstract independently by using the standardised form. Disagreements were resolved by consensus of opinion. If disagreements could not be resolved, a third review author (JV) was consulted. We documented a record of all rejected papers and the reasons for rejection. Subsequently, we retrieved the full papers of all remaining titles and abstracts. In addition, we retrieved all other potentially relevant articles identified by reference checking. Papers in all languages were included. The two authors who independently reviewed all articles, completed a form for each study and scored the eligibility of the study. The reasons for exclusion were documented. When the same study had more than one article written on the outcomes, we treated all articles as one study and presented the results only once. Disagreements were resolved as mentioned before.

Data extraction and management

Two authors (DB and IA and AN and IA) completed the extraction of data from the papers to a data extraction form to elicit the following information:

- **General:** published/unpublished, title, authors, source, contact address, country, language of publication, year of publication, duplicate publications
- **Methods:** design, country, setting, randomisation procedure, recruitment, inclusion period, follow-up, start/end dates, loss to follow-up
- **Participants:** number of participants, diagnosis, co-morbidity, inclusion/exclusion criteria, age, sex, days of sick leave at baseline, ethnicity, marital status, educational level, social economic status
- **Interventions per treatment group:** number of participants, treatment type/content, treatment provider, number of treatment providers, treatment frequency/duration, training/supervision of treatment providers
- **Outcomes:** length of follow-up, return to work, clinical outcomes, work functioning, generic functioning, quality of life and type of analysis for every outcome measured
- **Results:** absenteeism, clinical outcomes, work functioning, generic functioning and quality of life (effect measure, standard deviation, test statistic, confidence interval)

If there were any disagreements about the data extraction, consensus was achieved by discussion between the two review authors. If disagreements could not be resolved, a third author was consulted (JV).

Assessment of risk of bias in included studies

Two authors (IA and UB) assessed the risk of bias of the included studies. We assessed risk of bias with the use of an adapted version of The Cochrane Collaboration's tool for assessing risk of bias as described in the *Cochrane Handbook for Systematic Reviews of Interventions*, version 5.1.0.[55]. We assessed the following nine criteria.

- Random sequence generation
- Allocation concealment
- Blinding of participants
- Blinding of care providers
- Blinding of outcome assessment
- Co-interventions avoided or similar
- Treatment fidelity
- Incomplete outcome data
- Selective outcome reporting

We scored the criteria as “low risk of bias,“ “high risk of bias” or “unclear risk of bias.” When the two review authors disagreed about the risk of bias for one of the criteria, we tried to reach consensus. If disagreements could not be resolved by consensus of opinion, the judgement of a third review author (DB) was asked for. Where resolution was not possible, we contacted the study author to obtain more information and clarification. We pilot-tested the “Risk of bias” tool on two of the included studies in the review. When information to assess the risk of bias was lacking in a study article, we contacted the authors for additional information. If the authors did not reply, or if the information was no longer available, the criteria were judged as “unclear risk.”

Measures of treatment effect

<u>Dichotomous measures</u>

For studies that reported on dichotomous data, such as RTW rates, we used risk ratios as a measure of treatment effect.

Continuous measures

For studies that reported on continuous data, such as the number of days until full RTW, we used the mean difference (MD) because the same measurement scale was used. All estimates included a 95% confidence interval (CI).

Unit of analysis issues

Cross-over trials

We planned to include RCTs with a cross-over design, but no studies of this kind were found.

Multiple-armed trials

If studies had multiple treatment arms (e.g. two intervention arms and one control arm) and each treatment intervention could be used in the same meta-analysis, we chose to compare each treatment intervention with the comparison intervention and divided the number of participants in the comparison intervention over the number of treatment interventions. This was done to prevent double-counting of the participants in the comparison intervention. In case the number of participants in the comparison intervention could not be equally divided (e.g. there were 71 participants in the comparison intervention and there were two treatment interventions to make a comparison with), we chose to use the higher number of participants (36, following the example) for the comparison with the treatment intervention with the highest number of participants.

Cluster-randomised controlled trials

For the two studies[56,57] that employed a cluster-randomised design but did not account for the design effect, we made the following adjustments. In one study, the cluster-level results were reported for the primary outcome (days until partial and full RTW), which we used in the data-analysis[57]. For the other study, no intra-cluster correlation (ICC) was reported for the primary outcome (days until full RTW), but information was available on the intra-cluster correlation for the scores on the four scales of the 4DSQ (which was one of the secondary outcome measures in this study). Therefore, to calculate the design effect for the primary outcome, we used the mean of the intra-cluster correlations of the four 4DSQ scales[56]. We assumed that differences between treatment providers would be comparable for the reduction of distress symptoms and the facilitation of return to work. Furthermore, ICCs for the level of treatment providers are generally low and do not have a big impact on the outcome data (i.e. the effect of individual differences between treatment providers on the outcome is often low). We used the intra-cluster correlation reported by Bakker et al. (2007) for the distress scale of the 4DSQ to calculate the design effect for this secondary outcome measure for both

the studies of Bakker et al. (2007) and van der Klink et al. (2003)[56,57]. For the calculation of the design effect, we used the method described in the *Cochrane Handbook* in chapter 16.3.4[55].

Dealing with missing data

We contacted the authors of all nine studies to obtain data missing from their study report which we needed for the risk of bias assessment and/or input for the meta-analysis. We received a response from all authors, except for Stenlund et al. (2009)[30]. For the studies of van der Klink et al. (2003)[57] and Willert et al. (2011) [67], we calculated the standard deviations (SDs) for the primary outcome measure based on the 95% CI using the calculation tool provided by RevMan 5.1[58]. For calculating the SD, only one of the two sides of the 95% CI needs to be entered in the calculation tool (next to the group mean and the group N). Therefore, we chose to enter the left side of the 95% CI since this results in a more conservative (i.e. larger) SD.

Assessment of heterogeneity

For judging clinical similarity between studies, we followed the algorithm provided by Verbeek et al. (2012)[59]. We deemed interventions similar if the mechanism by which they were believed to achieve RTW was similar, such as a cognitive behavioural or a problem solving mechanism. For RTW outcomes, we considered both number of days until RTW and number of days on sick leave during follow-up as sufficiently similar. Studies with study populations consisting of working age participants were deemed similar enough because studies generally include a broad range of participants. Thus, we expected characteristics such as age, gender and job type to be heterogeneous in all studies alike.

For judging statistical heterogeneity, we inspected graphical representations of the data. In addition, we quantified statistical heterogeneity with the I^2 statistic. We judged statistical heterogeneity as not important when the I^2 was less than 40%, moderate if it was between 30% and 60%, substantial if between 50% and 90%, and considerable if between 75% and 90%[55].

Assessment of reporting biases

We intended to assess publication bias with funnel plots, if 10 or more studies had been available for each of the seven data analyses. If there had been an indication of publication bias we would have used Egger's test to assess this[60].

Data synthesis

We pooled studies into different comparisons with RevMan 5.1 software when they were judged to be clinical homogeneous and had sufficient and adequate data. The

data allowed us to make comparisons according to the interventions mentioned under the heading “Types of interventions.” We expected that possible observed differences between study results might not be solely due to chance, because of differences in bias or treatment provider. Therefore, we used random-effects models. If small studies were included in a comparison group, we compared the random-effects model with the fixed-effect meta-analysis to see whether the small studies increased the estimate of the beneficial effect of the intervention in the random-effects model. If small studies significantly increased the estimate of the effect of the intervention (i.e. from a non-significant effect in a fixed-effect meta-analysis to a significant effect in a random-effects analysis), we chose to present the results of the fixed-effect meta-analysis.

For studies with continuous outcomes, we used the mean number of days until RTW/on sick leave and the SD of each study group to calculate the mean difference (MD). For studies with a dichotomous outcome measure (rate of RTW), we used risk ratios (RR) and combined them in the meta-analysis.

We combined continuous measures, such as number of days until RTW, using the mean difference as implemented in the RevMan 5.1 software. For dichotomous outcomes such as rate of RTW we used the Mantel-Haenzel method to combine the risk ratios.

We assessed the overall quality of the evidence for each outcome using the GRADE approach as recommended by the *Cochrane Handbook*[55]. The quality of the evidence on a specific outcome was based on the following five domains: limitations of the study design, inconsistency of results, indirectness of results, imprecision of results and publication bias across all studies that measured that particular outcome. At the start of the GRADE assessment process we assumed high quality for all studies and we downgraded the quality of the evidence for each comparison by one to three levels depending on the seriousness of the violations of each domain. For limitations in study design, we considered a majority of studies with high risk of bias as a serious limitation leading to downgrading of the quality. For consistency, we considered an I^2 value of 30% to 60% as moderate inconsistency, 50% to 90% as substantial inconsistency and of 75% to 90% as considerable inconsistency, which would lead to downgrading quality. For imprecision of results, we judged serious imprecision leading to downgrading at a number of less than 400 participants or, for a non-significant effect, a confidence interval that included an effect size (ES) of 0.5. We judged publication bias with funnel plots when enough studies were available. If not, we looked at the characteristics (e.g. only studies with a positive result) of the studies that were available, to get an indication of possible publication bias. The interpretation of the quality level of evidence that resulted from these judgements was as follows:

- High: further research is very unlikely to change our confidence in the estimate of effect.
- Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- Very low: any estimate of effect is very uncertain.

Subgroup analysis and investigation of heterogeneity

We intended to carry out subgroup analyses on: (1) organisational setting, (2) type/level of job undertaken, (3) group versus individual therapy and (4) the setting of treatment providers. It could be possible that the effects of interventions are altered by these study features. For example, bigger organisations might be better able to create an infrastructure for executing an intervention, workers with a higher job level might have better cognitive abilities to understand intervention assignments and treatment providers that are more closely related to the workplace (e.g. occupational physicians) might have more influence on the RTW process. Furthermore, differences in effectiveness between individual and group therapy are not frequently investigated for adjustment disorders but it is interesting for practice since group therapy can be more cost-effective[61,62]. However, we did not find enough studies for these analyses. One study did make a direct comparison between an individual and a group intervention[63], and we decided to compare both interventions in a separate data-analysis.

Sensitivity analysis

Methodological heterogeneity can lead to differences between the results of individual studies. Therefore, we intended to undertake sensitivity analyses on the results by looking at the possible contribution of differences in methodological quality, for example by excluding studies with a high or unclear risk of bias for allocation concealment or acceptable compliance. However, the number of studies in each analysis was insufficient to perform these sensitivity analyses. We did perform sensitivity analyses on the diagnosis of adjustment disorder, by excluding studies from comparisons that did not diagnose an adjustment disorder based on the DSM-IV or ICD-10.

RESULTS

Results of the search

Figure 1 presents a flow diagram of included and excluded studies. The initial search in the electronic databases identified 3546 references; 121 in the CCDANCTR, 299 in

CENTRAL, 488 in EMBASE, 590 in MEDLINE, 264 in PsycINFO and 1784 in ISI Web of Science. After removing duplicate references, 1454 references remained. Based on title and abstract, we identified 59 eligible references and retrieved the full text of the references. Checking the references of all articles that were retrieved as full papers and two systematic reviews[43,64] did not result in any additional studies. Following this, we screened the 59 full-text articles with the help of the study eligibility form.

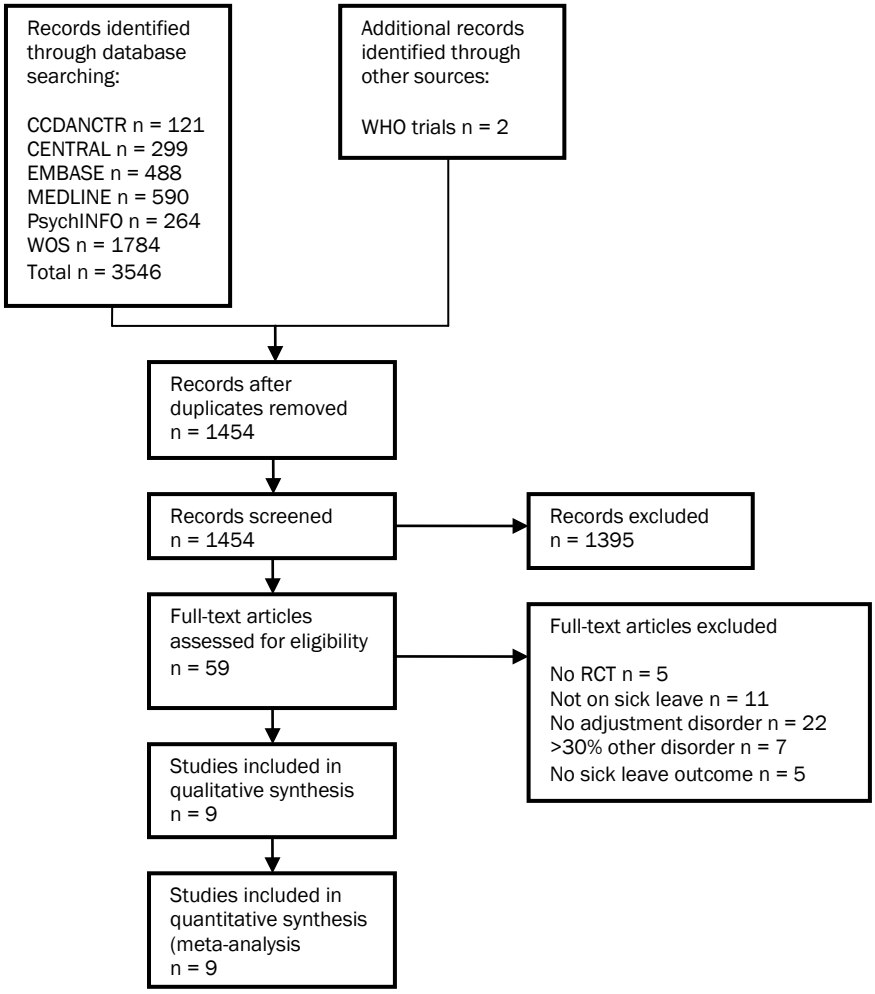

Figure 1. Study flow diagram.

Eight studies met the inclusion criteria and were included in the review[30,39,56,57,63,65-67]. A study by Rebergen et al. (2009) met all the inclusion criteria, except one: 32% of the study population had symptoms related to an anxiety or depressive disorder. The other 68% of the study population had symptoms related to adjustment disorders. Therefore, we contacted the author for outcome data on the subgroup of participants with adjustment disorders. The author was willing to provide these data, and because the distribution of participants with symptoms of adjustment disorders was equal for both study groups (86 participants in the trial and comparison intervention), the study was also included in the review[68]. In the study of Willert et al. (2011), some of the participants were not on sick leave at baseline[67]. Therefore, we contacted the author and asked him to provide separate data including only the participants that were on sick leave at baseline. The author was willing to provide the data and the distribution of the participants on sick leave at baseline was comparable between the trial and comparison intervention (29 and 31 respectively). Thus, this study was also included. Two study protocols were found for studies that are still ongoing[69,70]. With the additional search in the WHO trials portal, we found two other studies that are also still on-going[71,72].

Included studies

Characteristics of studies and participants

The main characteristics of the nine included studies are summarised in Table 1. Seven of the nine studies were performed in the Netherlands, one in Denmark and one in Sweden. Overall, 1546 participants were included. The average age of the participants ranged between 39 and 49 years; the percentage of female participants ranged between 19% and 71%. All studies recruited participants with disorders that were compatible with our definition of adjustment disorders. Two studies used the DSM-IV or ICD-10 diagnostic criteria for adjustment disorder to select participants[39,57]. Two studies[56,66] used a validated distress screener to select participants, based on three questions of the Four-Dimension Symptom Questionnaire developed by Terluin et al. (2006)[44,73,74]. Two studies used the Composite International Diagnostic Interview (CIDI)[48] to exclude participants with other mental disorders than adjustment disorders and used a diagnosis of minor mental disorders according to the general practitioner (GP)[65] or symptoms of neurasthenia diagnosed in a semi-structured interview by a clinical psychologist[63] as inclusion criterion. In one study, a Stress Clinic was responsible for psychological examinations to confirm the diagnosis of burnout. Furthermore, participants had to score above a cut-off score on the Shirom–Melamed Burnout Questionnaire (SMBQ)[75]. In the study of Rebergen et al. (2009)[68], the Depression, Anxiety and Stress Scales (DASS)[45] were used, after diagnosis of a mental health problem by the OP, to define subgroups of participants with anxiety or

depression and a subgroup of participants with stress symptoms related to adjustment disorders. Finally, one study used a semi-structured assessment interview by a clinical psychologist to diagnose persistent symptoms of work-related stress and to exclude severe psychiatric conditions or a history of repeated psychiatric conditions in participants[67].

In all but one of the nine studies[67], participants were on sick leave at the start of the study. In the study of Willert et al. (2011)[67], 57% of the participants were on sick leave. The maximum duration of sick leave at baseline differed between studies. In two studies, participants were only included if they were on sick leave for no longer than half a year[63,67]; two other studies chose a maximum period of sick leave of three months[56,65]. The study by Stenlund et al. (2009)[30] allowed for a longer sick leave period, namely between three and 12 months. Compared to this, the study by van Oostrom et al. (2010)[66] only included participants with two to eight weeks of sick leave. In the study by Rebergen et al. (2009)[68], workers were immediately contacted in their first week of sick leave. Two studies had no criterion defined on the minimum or maximum length of sick leave[39,57].

Table 1. Study characteristics.

Study	Number	Follow-up	Diagnosis	Treatment type	CBT or PST	Treatment provider	Treatment frequency	Comparison type	Work outcome
Bakker 2007; Nether-lands	227 versus 206	12 mnths	Stress-related mental disorders measured by means of self-reported levels of distress with a validated question-naire	Individual sessions on: information on the importance of the patient's active role with regard to successful RTW; advice on the content of functional rehabilitation; monitoring of the patient's efforts to translate the (work) situation into a problem that could be solved; referral to specialised care in case of no progressions	PST: translate the (work) situation into a problem that could be solved; information on successful RTW; the work situation is translated into a problem that could be solved	24 primary care physicians trained in the intervention (2 session of 3.5 hours and 2 follow-up sessions of 2 hours)	3 consultations within 3 months	Care as usual by primary care physician	Duration of sick leave in calendar days from the first day of sick leave until full RTW, lasting for a period of at least 4 weeks without partial or full relapse into sick leave (self-report)
Blonk 2006; Nether-lands	40 versus 21	12 mnths	Adjustment disorders diagnosed with the CIDI	Individual sessions on cognitive restructuring; registration of symptoms and situations; sessions on time-management, work resumption, workplace interventions, conflict handling and fatigue; assignments related to the work situation	CBT: sessions on cognitive restructuring	Psychologists who followed a highly structured protocol	11 sessions of 45 minutes (2 sessions a week)	No treatment	The length of time until partial RTW and the length of time until full RTW (register-based)
Blonk work 2006; Nether-lands	40 versus 21	12 mnths	Adjustment disorders diagnosed with the CIDI	Individual sessions on: psycho education on work stress; registration of symptoms and situations; relaxation; self-help books on rational emotive behaviour therapy; time-management; writing assignments; advice on work processes (setting priorities, planning, conflict management, reducing work demands, delegating tasks, organisation of work); stimulating work resumption	CBT: self-help books on rational emotive behaviour therapy; advice on work processes	6 labour experts trained in brief CBT-based stress management	5 to 6 1-hour sessions (2 sessions a week)	No treatment	The length of time until partial RTW and the length of time until full RTW (register-based)

Table 1. (continued)

Study	Number	Follow-up	Diagnosis	Treatment type	CBT or PST	Treatment provider	Treatment frequency	Comparison type	Work outcome
Brouwers 2006; Nether-lands	98 versus 96	18 mnths	Emotional distress or minor mental disorders according to GPs and self-report	Individual sessions on: acknowledging the problem and accepting responsibility for its resolution; developing and implementing problem solving strategies, with a special focus on solving work-related problems and promoting early work resumption; making a daily activity schedule	PST: developing and implementing problem solving strategies; focus on work-related problems and promoting early work resumption	11 social workers trained in the intervention (3-day training course with 2 follow-up sessions)	5 individual 50-minute sessions over 10 weeks	Care as usual by the GP	Sick leave duration (in days), defined as the period between the first day of absenteeism and the first day of partial and full work resumption (self-report)
de Vente group 2008; Nether-lands	28 versus 13	10 mnths	Symptoms of neuras-thenia based on a screening interview	Group sessions and homework assignments on: psycho education; self-assessment of stressors and complaints; life style; relaxation techniques; cognitive restructuring; time-management; goal setting; assertiveness skills; evaluation and relapse prevention	CBT: cognitive restructuring	12 clinical psychologists trained in the intervention (4 x 1-hour sessions)	12 x 1-hour sessions	Care as usual by the OP and GP	Number of days absent and number of weeks until complete work resumption (self-report)
de Vente individual 2008; Nether-lands	28 versus 13	10 mnths	Symptoms of neuras-thenia based on a screening interview	Individual sessions and homework assignments on: psycho education; self-assessment of stressors and complaints; life style; relaxation techniques; cognitive restructuring; time-management; goal setting; assertiveness skills; evaluation and relapse prevention	CBT: cognitive restructuring	12 clinical psychologists trained in the intervention (4 x 1-hour sessions)	12 x 2-hour sessions	Care as usual by the OP and GP	Number of days absent and number of weeks until complete work resumption (self-report)

Table 1. (continued)

Study	Number	Follow-up	Diagnosis	Treatment type	CBT or PST	Treatment provider	Treatment frequency	Comparison type	Work outcome
Rebergen 2009; Nether-lands	125 versus 115	12 mnths	Symptoms of adjustment disorders based on the DASS (based on unpublish-ed data from author)	Individuals sessions on: information about the origin and cause of loss of control; structuring daily activities developing and implementing problem solving skills and strategies for the causes of stress; gradual RTW	PST: developing and implementing problem solving skills	5 OPs trained in the interven-tion (3-day training course)	Mean number of consultations with OP was 3.4	Minimal involvement of the OP (same OPs as intervention group) and access to treatment by a psychologist	Duration of sick leave due to mental health problems in calendar days from the moment of inclusion to first (partial or full) and full RTW, respectively, in own or equal earnings; duration of sick leave days until full RTW added with number of days of recurrences on sick leave in the 1-year follow-up
Stenlund 2009; Sweden	67 versus 69	2 years	Burnout based on psycholo-gical examina-tions at the Stress Clinic	Group session on: education on stress reactions, medication and rest; awareness of reactions and self-talk; development of cognitive/behavioural/ emotional skills; spiritual issues and life values; preparation for RTW; physical relaxation and mindfulness meditation	CBT: awareness of reactions and self-talk	1 group leader trained in CBR; 1 physio-therapist	CBR: 30 x 3-hour sessions over 1 year with short follow-up meetings 3, 6 and 12 months after the treat-ment year; Qigong: a 1-hour session every week during 1 year	Physical relaxation and mindfulness meditation	Sick leave rate: 100, 75, 50, 25 or 0% (register-based)
Van der Klink 2003; Nether-lands	109 versus 83	12 mnths	Adjustment disorders diagnosed with a checklist based on the DSM-IV criteria for adjustment disorder	Individual sessions on: information on the origin and cause of loss of control; structuring daily activities; development and implementation of problem solving strategies for the causes of stress; gradual RTW	PST: development and implementa-tion of problem solving strategies	17 occupatio-nal physicians trained in the interven-tion (3-day training course)	4 to 5 sessions (with a total length over all sessions of at least 90 minutes) in the first 6 weeks of sickness leave and 1 session after work resumption	Care as usual by OPs	Time (days) to partial and full RTW; duration (days) of sick leave; partial and full RTW rate at 3 and 12 months follow-up; inci-dence of recurrent sick leave in the year following full RTW; time to first recurrent sick leave in the year following full RTW

Table 1. (continued)

Study	Number	Follow-up	Diagnosis	Treatment type	CBT or PST	Treatment provider	Treatment frequency	Comparison type	Work outcome
van Oostrom 2010; Nether-lands	73 versus 72	12 mnths	Distress based on a validated screening question-naire	Consultations with the worker and supervisor to (1) identify obstacles and solutions for RTW, (2) formulate a plan for implementation of the solutions and (3) to evaluate the actual implementation of solutions	PST: identifying obstacles (problems) for RTW and finding/ implementing solutions	9 RTW co-ordinators (company social worker or a labour expert) trained in the intervene-tion	3 sessions at 1 day and a follow-up meeting after 1 month	Care as usual by OPs	Days until full and lasting RTW; total number of days of sick leave in the 12-month follow-up (register-based)
Willert 2011; Denmark	51 versus 51	48 weeks	Persistent symptoms of work-related stress based on a semi-structured assess-ment interview	Group sessions and homework on: introduction to CBT; psycho education on stress; identifying dysfunctional thinking; modifying dysfunctional thinking; communication and stress; communication skills training; implementing strategies at work (e.g. cope with stressful situations at work); review of techniques	CBT: identifying and modifying dysfunctional thinking	2 licensed clinical psycholo-gists, with > 5 years of clinical experience and a 1-year advanced training course in CBT	8 x 3-hour sessions over a period of 3 months	Waiting list control group; after 3 months on the waiting list, the participants also received the intervention	Sick leave days 3-month in retrospect (self-report); weeks registered with part- or full-time sick leave (register-based)

CBT = cognitive behavioural therapy; PST = problem solving therapy; CIDI = Composite International Diagnostic Interview; RTW = return to work; GP = general practitioner; OP = occupational physician; DASS = Depression Anxiety and Stress Scales; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders IV.

Interventions

Eight studies reported on the effect of 10 psychological interventions and one study on the effect of a combined intervention consisting of a psychological intervention and relaxation techniques. For the other intervention types (e.g. pharmacological intervention, exercise programme) no studies were found. Of the 10 psychological interventions, five were based on CBT[39,63,67] and the other five were based on PST[56,57,65,66,68]. Two of the interventions were performed in groups of (seven to nine) participants[63,67]; the other eight interventions were all performed with the individual participant. Eight interventions[39,56,57,65-68] had a strong focus on the work environment by incorporating consultations/assignments aimed at identifying work-related problems to facilitate early work resumption. The other two psychological interventions were performed according to strict CBT protocols (one in a group format and one in an individual format) which focused on giving psycho-education, cognitive restructuring, relaxation, conflict management and time management[63]. These protocols were tailored to general life problems and had a less specific focus on work-related problems. The study by Willert et al. (2011)[67] also used a CBT protocol with the aim of enabling participants to cope with stressful situations at their workplace and strengthen their ability to be active at work. The main components of this intervention were psycho-education, cognitive restructuring, communication skills training and implementing strategies at work. The study of Blonk et al. (2006)[39] had two intervention arms; in one arm, participants received CBT according to a highly structured and commonly used protocol (in the Netherlands) which consisted mainly of cognitive restructuring but also focused on work resumption, time management, workplace interventions, conflict handling and fatigue. The other intervention arm consisted of a shorter CBT programme combined with advice on work processes (e.g. setting priorities, planning and conflict management) by labour experts.

The interventions tested by Brouwers et al. (2006)[65] and Rebergen et al. (2009)[68] used the same intervention as developed and evaluated by van der Klink et al. (2003)[57]. These studies used an intervention protocol based on PST. The main components were to (1) give information about the origin and cause of loss of control, (2) develop and implement problem solving strategies and (3) apply gradual RTW. However, in the study by Brouwers et al the treatment providers were different (social workers instead of OPs) and the intervention protocol was adjusted to fit this group of treatment providers. Likewise, Bakker et al. (2007)[56] used a problem solving intervention which was conducted by primary care physicians (i.e. GPs). The intervention focused on giving information about the active role of the worker in his RTW process, advising about functional rehabilitation and monitoring the problem solving strategies of the worker. Finally, the study by van Oostrom et al. (2010)[66] also used a problem solving intervention. However, the intervention in this study

differentiates from the other PST-based interventions because of a participatory approach in which the worker and supervisor work together in the development of problem solving strategies. Specifically, the intervention consisted of a stepwise communication process between the worker and his supervisor, guided by a RTW co-ordinator, to identify and solve obstacles for RTW. Three meetings were planned; one with the worker and the RTW co-ordinator, one with the supervisor and the RTW co-ordinator and one with all three parties. Obstacles for RTW were identified from the perspective of the worker and the supervisor. Following this, solutions were discussed during the third meeting and a plan (based on consensus) was made for implementing the solutions. If needed, the RTW co-ordinator visited the workplace of the worker to give advice or instructions. One month after the meetings, the RTW co-ordinator planned an evaluation meeting with the worker and supervisor.

The combined intervention evaluated by Stenlund et al. (2009)[30] consisted of Cognitive Behavioural Rehabilitation (CBR) in groups of six to nine participants and Qigong in groups of 12 to 16 participants. The CBR programme had five key components: education; awareness of reactions and self-talk (a form of cognitive restructuring); development of behavioural, cognitive and emotional skills; spiritual issues and life values; and preparation for RTW. Qigong is a form of relaxation techniques consisting of warm-up movements; basic movements to affect body awareness, balance and co-ordination, breathing and muscular tension; and relaxation and mindfulness meditation. Although participants had to perform some bodily exercises, we did not regard this as an exercise programme because the focus was on relaxation. CBR included 30 three-hour sessions over one year and Qigong included weekly one-hour sessions for one year.

Treatment providers were comparable for some studies. In three studies, (clinical) psychologists trained in CBT provided the intervention[39,63,67]. OPs were the treatment providers in the studies of Rebergen et al. (2009)[68] and van der Klink et al. (2003)[57] and received a three-day training in the intervention. Labour experts and social workers conducted the intervention in the study of van Oostrom et al. (2010)[66]. Labour experts were also the treatment providers in one trial arm of the study by Blonk et al. (2006)[39], and social workers delivered the intervention in the study by Brouwers et al. (2006)[65]. In all cases, the labour experts and social workers received training in the intervention. In Bakker et al. (2007)[56], primary care physicians were the treatment providers, and they had received seven hours of training in the intervention. Finally, Stenlund et al. (2009)[30] did not specify the professional background of the treatment providers providing CBR but did mention that the group leaders had received training in CBR. The Qigong intervention in this study was delivered by a physiotherapist trained in Qigong.

Three psychological interventions were compared to a waiting list control group[39,67]. Five psychological interventions were compared to non-guideline based care (defined

as "care as usual" in the studies) by a GP[56,65] or OP[57,63]. One psychological intervention was compared to minimal intervention by the OP and treatment by psychologists working according to cognitive behavioural principles[68]. The combined intervention was compared to Qigong[30], and the participatory problem solving intervention was compared to treatment by the OP according to a problem solving guideline[66].

Study design and setting

Seven studies were randomised controlled trials with randomisation at the level of the participant[30,39,63,65-68] and two studies were cluster-randomised controlled trials with randomisation at the level of the GP [56] or OP[57]. Two studies had three treatment arms[39,63]. In the study by Blonk et al. (2006)[39], the first trial intervention (named "Blonk labour expert 2006" in the analyses) consisted of CBT-based stress management intervention with a focus on graded RTW. The second trial intervention (named "Blonk psychologist 2006" in the analyses) consisted of highly structured CBT according to a commonly used protocol. Both trial interventions were compared to a waiting list control group. In the study by de Vente et al. (2008)[63], the first trial intervention (named "de Vente individual 2008" in the analyses) was individual stress-management training (SMT) according to a strict protocol based on cognitive behavioural techniques. The second trial intervention (named "de Vente group 2008" in the analyses) was group SMT according to the same protocol as the individual SMT. Both trial interventions were compared to care as usual by the OP and GP.

Four studies were performed in an occupational health care setting; in three studies participants were treated by an Occupational Health Care Service of a company[57,66,68], and in one study participants were treated by labour experts[39]. Two studies were performed in a primary care setting where participants were treated by their general physicians[56] or by social workers[65]. Finally, three studies were performed in a clinical setting with treatment by a clinical psychologist [63,67] or treatment in a Stress Clinic[30].

Outcomes

Time to partial or full RTW, measured as number of days or weeks between the start of sick leave until partial or full work resumption or the number of days on sick leave during follow-up, was measured in eight of the nine included studies[39,56,57,63,65-68]. The follow-up time ranged from four to 18 months. One study reported on the rate of sick leave at different time measurements[30]. Clinical status of adjustment disorder was measured with a validated psychometric instrument in seven studies: four studies used the Four-Dimension Symptom Questionnaire[56,57,65,66]; two studies used the Depression, Anxiety and Stress Scales[39,63]; and one study used the Shirom–Melamed Burnout Questionnaire[30]. All studies had multiple follow-up measurements between two months and two years after baseline. One study measured generic functional status with the

SF-36, but only reported scores on subscales and no total scores[65]. None of the studies measured quality of life or work functioning.

Excluded studies

Of the 59 full-text retrieved studies, 50 studies were excluded from the review because the study was not a randomised controlled trial (N = 5), the study population was not on sick leave (N = 11), participants did not have an adjustment disorder according to the definition of this review (N = 22), more than 30% of the participants were diagnosed with physical disorders or other mental disorders than adjustment disorders (N = 7) or because sick leave was not measured (N = 5).

Risk of bias in included studies

The results are summarised in the Risk of bias graph which presents the authors' judgement about each "Risk of bias" item presented as percentages across all included studies (Figure 2). The results for each risk of bias item for each individual study are presented in the Risk of bias summary (Figure 3). Of the nine included studies, we assessed seven as having a low risk of bias[39,56,57,63,66-68]. We assessed the other two studies as having high risk of bias[30,65].

Allocation (selection bias)

In all studies, an adequate system for random sequence generation was reported, as well as adequate allocation concealment. Overall, computer-generated random numbers or dice were used for randomisation. To conceal allocation, the results of the randomisation were hidden in opaque envelopes or an independent research assistant performed the randomisation.

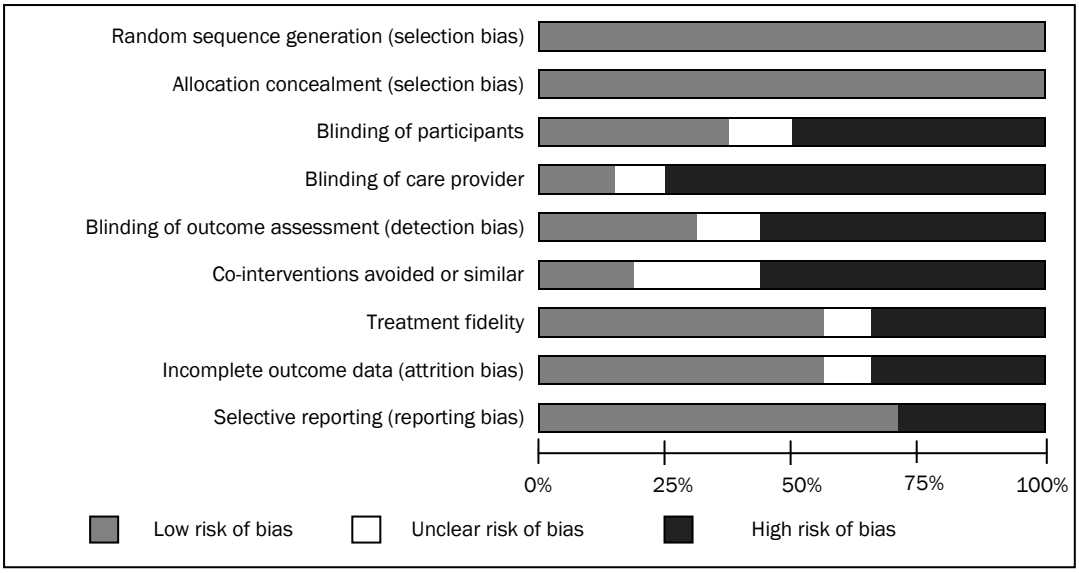

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Wilert 2011	van Oostrom 2010	van der Klink 2003	Stenlund 2009	Rebergen 2009	de vente 2008	Brouwers 2006	Blonk 2006	Bakker 2007	= High risk of bias = Low risk of bias ? = Unclear risk of bias
✸	✸	✸	✸	✸	✸	✸	✸	✸	Random sequence generation
✸	✸	✸	✸	✸	✸	✸	✸	✸	Allocation concealment
☼	☼	✸	?	☼	☼	✸	✸	✸	Blinding of participants
✸	☼	☼	?	☼	☼	☼	☼	✸	Blinding of care provider
☼	✸	?	?	✸	☼	☼	☼	✸	Blinding of outcome assessment
☼	☼	☼	☼	☼	✸	☼	?	?	Co-interventions avoided or similar
✸	☼	✸	?	☼	✸	☼	✸	☼	Treatment fidelity
☼	✸	✸	☼	✸	☼	?	✸	✸	Incomplete outcome data
☼	☼	✸	✸	✸	✸	✸	✸	☼	Selective reporting

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Blinding (performance bias and detection bias)

Blinding of participants was realised in three studies[39,56,57]. We judged blinding of the care provider as having low risk of bias for two studies[56,67]. In the study of Bakker et al. (2007)[56], the care providers were randomised to the intervention or control group and treated all their patients according to their protocol, but they were unaware of which patients participated in the study. In the study of Willert et al. (2011)[67], two care providers treated participants from both the intervention and waiting list control group according to the intervention protocol and did not know whether their participants belonged to the intervention or waiting list control group. In the study of van der Klink et al. (2003)[57], participants received a global overview of both treatment strategies which were presented as equally effective and of which the participants were not able to notice the difference. Blonk et al. (2006)[39] blinded the participants in their study by only giving general information about the goal of the study (based on personal communication with the author). Bakker et al. (2007)[56] used a cluster-randomised controlled trial by which the allocation of participants was already pre-defined by the allocation of their care provider (in this study, their treating GP). Therefore, the participants were not informed about the two different study groups and were only told that the study was about stress and sick leave. The care providers were blinded because they had to treat all their patients according to the intervention treatment or comparison treatment (depending on their randomisation) and were unaware of which patients were included. In the study of Willert et al. (2011)[67], the group leaders of the stress management intervention (i.e. the care providers) led the different groups of participants without knowledge of the participants' randomisation. The first two groups consisted of those randomised to the intervention arm of the trial. Groups three to 10 consisted of participants mixed from the intervention and waiting list control arms. Group 11 and 12 consisted of participants randomised to the waiting list control arm (based on unpublished information from the author). Blinding of outcome assessors was reported in three studies[56,66,68]. In these studies, the researchers responsible for collecting outcome data as well as the researchers responsible for analysing the data were kept blind to treatment allocation.

Incomplete outcome data (attrition bias)

All studies reported on drop-outs, but in four studies the reasons for drop-out were not comparable for all study groups[30,57,63,67]. Furthermore, for one study, no information was available about the reasons for drop-out, and this study was therefore judged as "unclear risk of bias"[65]. In all studies, except one[39], an intention-to-treat analysis was conducted.

Selective reporting (reporting bias)

All but three studies[56,66,67] were free from selective reporting. In the study of Bakker et al. (2007)[56] and van Oostrom et al. (2010)[66], analyses of secondary outcome measures that were planned in the study protocol were omitted from the papers in which the study results were reported. Willert et al. (2011)[67] presented supplementary analyses that were not described in the methods section.

Other potential sources of bias

Two authors were not able to provide information on the use of co-interventions by the different groups in their study[39,56]. In the other six studies, co-interventions were not avoided and not similar for the different study groups. In four studies, treatment fidelity was rated as acceptable[39,57,63,67]. In these studies, fidelity was ensured by checking with questionnaires or feedback moments if care providers followed the study protocols. Acceptable attendance rates were reported by de Vente et al. (2008)[63], and from Willert et al. (2011)[67] unpublished information was received on acceptable attendance rates. We included studies with smaller (N = 82[63]) and larger (N = 431[56]) sample sizes, and studies with positive (e.g. Blonk et al. 2006[39] and van der Klink et al. 2003[57]) as well as non-significant results (e.g. Bakker et al. 2007[56] and van Oostrom et al. 2010[66]) were included. However, we were not able to further analyse publication bias because of an insufficient number of studies.

Effects of interventions

No studies were found that evaluated pharmacological interventions, relaxation techniques, exercise programmes or employee assistance programmes. The nine included studies reported on 10 psychological interventions and one combined intervention, consisting of a psychological intervention and relaxation techniques. A complete overview of the effects of the interventions is presented in the "Data and analyses" section of this review.

Psychological interventions

1. Cognitive behavioural therapy (CBT) versus no treatment

1.1 Partial return to work (RTW), follow-up one year

Two studies[39,67], one of which had two treatment arms[39], compared three CBT interventions to a no treatment control group. The results of these two studies showed that there is moderate-quality evidence (Appendix 2) that days until partial RTW are similar for the CBT intervention groups and the no treatment control groups (mean difference (MD) -8.78, 95% confidence interval (CI) -23.26 to 5.71) (Figure 4).

1.2 Full RTW, follow-up one year

Blonk et al. (2006)[39] also evaluated the effect of the two CBT interventions on time until full RTW compared to no treatment. The results indicated that there is low-quality evidence (Appendix 2) of no significant difference between the CBT interventions and no treatment for this outcome measure (MD -35.73, 95% CI -113.15 to 41.69) (Figure 5).

1.3 Depression, Anxiety and Stress Scales (DASS) distress score, follow-up one year

Concerning the secondary outcome of clinical status of adjustment disorder, Blonk et al. (2006)[39] evaluated the effect of CBT interventions on the stress scale of the DASS. The results showed that there is moderate-quality evidence (Appendix 2) of a similar outcome for the CBT interventions and no treatment for mean score on the DASS stress scale at one-year follow-up (MD 0.06, 95% CI -3.91 to 4.02).

2. CBT versus non-guideline based care

2.1 Full RTW, follow-up one year

One study[63], consisting of two treatment arms, assessed the effects of a group-based CBT intervention and an individual-based CBT intervention on time to full RTW after one year of follow-up. The interventions were compared to non-guideline based care by the occupational physician (OP) and general practitioner (GP), which was defined as "care as usual" in the study paper. The pooled analysis showed that the CBT interventions were slightly less effective in reducing time to full RTW compared to non-guideline based care, but this effect was not significant (MD 35.50, 95% CI -30.84 to 101.84), with low-quality evidence (Appendix 2).

2.2 DASS distress score, follow-up three months

De Vente et al. (2008)[63] also investigated the effect of the two CBT interventions on mean score on the DASS stress scale at three months follow-up. The results indicated that there is low-quality evidence (Appendix 2) of a similar outcome for the CBT interventions and non-guideline based care for the mean score on the DASS stress scale at three months follow-up (MD 0.66, 95% CI -2.78 to 4.11).

2.3 DASS distress score, follow-up one year

Also, based on one study[63], no significant difference was found between CBT interventions and non-guideline based care for the DASS stress scale at one-year follow-up (MD -0.67, 95% CI -6.06 to 4.73), with low-quality evidence (Appendix 2).

3. Problem solving therapy (PST) versus non-guideline based care

3.1 Partial RTW, follow-up one year

One study investigated the effect of a PST-based intervention on time to partial RTW after one year of follow-up, compared to non-guideline based care by the OP[57]. The results showed that there is moderate-quality evidence (Appendix 2) that the PST-based intervention significantly reduced time to partial RTW with 17 days compared to non-guideline based care (MD -17.00, 95% CI -26.48 to -7.52) (Figure 6).

3.2 Full RTW, follow-up one year

Based on two studies[56,57], meta-analysis showed that there is moderate-quality evidence (Appendix 2) that PST-based interventions did not result in a significant reduction of time until full RTW compared to non-guideline based care by the OP or GP (MD -17.73, 95% CI -37.35 to 1.90). The confidence interval still included a potential relevant effect (Figure 7).

3.3 Full RTW, follow-up one to two years

In line with the findings for full RTW with a follow-up of one year, a PST-based intervention had a similar reduction of days until full RTW compared to non-guideline based care by the GP at one to two years follow-up (MD -4.00, 95% CI -41.61 to 33.61), based on low-quality evidence (Appendix 2).

3.4 Four-Dimension Symptom Questionnaire (4DSQ) distress score, follow-up three months

Three studies[56,57,65] investigated the effect of PST-based interventions on the score on the distress scale of the 4DSQ, compared to non-guideline based care by the OP or GP. The results indicated moderate-quality evidence (Appendix 2) of a significant reduction in the distress score in favour of the PST-based interventions (MD -1.69, 95% CI -3.11 to -0.27).

3.5 4DSQ distress score, follow-up four to 12 months

The significant reduction in the distress score by the PST-based interventions was not found for the follow-up period of three to 12 months (MD -0.36, 95% CI -1.76 to 1.04), based on moderate-quality evidence (Appendix 2).

3.6 4DSQ distress score, follow-up one to two years

Also, at one to two years follow-up, the results showed that there is low-quality evidence (Appendix 2) of no significant difference between a PST-based intervention and non-guideline based care (MD -2.03, 95% CI -4.25 to 0.19).

4. PST versus CBT

4.1 Partial RTW, follow-up one year

Rebergen et al. (2009)[68] investigated the effect of a PST-based intervention compared to a CBT intervention on partial RTW after one year of follow-up. Based on moderate-quality evidence (Appendix 2), no difference was found between these treatments in the effect on time to partial RTW (MD -6.28, 95% CI -29.36 to 16.80).

4.2 Full RTW, follow-up one year

For days until full RTW after one year of follow-up, a non-significant reduction of sick leave was found between the PST-based intervention compared to the CBT intervention (MD -6.74, 95% CI -37.43 to 23.95), with moderate-quality evidence (Appendix 2).

5. Participatory PST versus PST

5.1 Full RTW, follow-up one year

One study[66] investigated the effect of a participatory PST-based intervention compared to a PST-based intervention on full RTW after one year of follow-up. The results showed that there is moderate-quality evidence (Appendix 2) that there is no difference in effectiveness between the two treatments (MD -1.00, 95% CI -36.32 to 34.32).

5.2 4DSQ distress score, follow-up three months

Van Oostrom et al. (2010)[66] also investigated the effect of the participatory PST-based intervention on distress score, based on the distress scale of the 4DSQ, measured at three months follow-up. The data analysis showed moderate-quality evidence (Appendix 2) of no difference in distress score compared to a PST-based intervention (MD -0.40, 95% CI -3.27 to 2.47).

5.3 4DSQ distress score, follow-up four to 12 months

There was also no effect of the participatory PST-based intervention compared to the PST-based intervention on distress score at three to 12 months follow-up (MD 0.63, 95% CI -2.05 to 3.31), based on moderate-quality evidence (Appendix 2).

Combination of interventions

1. CBT and physical relaxation versus physical relaxation

1.1 Rate of partial RTW, follow-up one year

One study[30] reported on the effectiveness of a CBT intervention and physical relaxation compared to physical relaxation alone on rate of partial RTW at one-year follow-up. The results indicate that there is low-quality evidence (Appendix 2) of a similar outcome for the two study groups on this outcome measure (risk ratio [RR] 1.04, 95% CI 0.58 to 1.89).

1.2 Rate of partial RTW, follow-up one to two years

For rate of partial RTW with a follow-up of one to two years, no significant difference was found between the CBT intervention and physical relaxation versus physical relaxation alone (RR 0.82, 95% CI 0.50 to 1.34). This result was based on low-quality evidence (Appendix 2).

1.3 Rate of full RTW, follow-up one year

In the same study by Stenlund et al. (2009)[30], the combined intervention was also compared to physical relaxation for the effect on rate of full RTW after one year of follow-up. The analysis showed low-quality evidence (Appendix 2) of a similar outcome for the two study groups (RR 0.72, 95% CI 0.23 to 2.20).

1.4. Rate of full RTW, follow-up one to two years

For rate of full RTW after one to two years follow-up, the results showed no significant difference between the combined intervention and physical relaxation (RR 1.25, 95% CI 0.64 to 2.43), based on low-quality evidence (Appendix 2).

1.5 Shirom–Melamed Burnout Questionnaire (SMBQ) score, follow-up one year

Stenlund et al. (2009)[30] also investigated if the CBT intervention and physical relaxation had an effect on the SMBQ score at one-year follow-up compared to physical relaxation alone. The results indicated that there is low-quality evidence (Appendix 2) of a significant reduction in the SMBQ score in favour of the combined intervention (RR -0.50, 95% CI -0.97 to -0.03).

1.6 SMBQ score, follow-up one to two years

There was no significant difference in mean SMBQ score at one to two years follow-up between the combined intervention and physical relaxation alone (RR -0.40, 95% CI -0.92 to 0.12), based on low-quality evidence (Appendix 2).

Subgroup analyses

1. Individual CBT versus group CBT

1.1 Full RTW, follow-up one year

A direct comparison between individual-based CBT and group-based CBT on time until full RTW, based on the data from the study by de Vente et al. (2008)[63], indicated that there is low-quality evidence (Appendix 2) that there is no significant difference between individual-based and group-based CBT on time to full RTW (MD 2.94, 95% CI -12.07 to 17.95).

1.2 DASS distress score, follow-up three months

The study by de Vente et al. (2008)[63] also evaluated the effect of individual-based CBT versus group-based CBT on distress score at three months follow-up based on the DASS. The results showed that there is low-quality evidence (Appendix 2) of no significant difference between the two study groups (MD -1.80, 95% CI -6.21 to 2.61).

1.3 DASS distress score, follow-up four to 12 months

For the distress score at three to 12 months follow-up, the results also showed no significant difference between individual-based CBT and group-based CBT (MD -0.86, 95% CI -5.84 to 4.12), based on moderate-quality evidence (Appendix 2).

Sensitivity analyses

1. CBT versus no treatment, full adjustment disorder diagnosis

1.1 Partial RTW, follow-up one year

A sensitivity analysis was conducted for the comparison of CBT versus no treatment excluding the study of Willert et al. (2011)[67] because adjustment disorder was not diagnosed according to the DSM-IV or ICD-10 in this study. The analysis showed that there is moderate-quality evidence (Appendix 2) that there is no significant difference between CBT and no treatment on time to partial RTW (MD -24.92, 95% CI -80.58 to 30.74).

2. PST versus non-guideline based care, full adjustment disorder diagnosis

2.1 Full RTW, follow-up one year

When excluding the study by Bakker et al. (2007)[56], based on no diagnosis of adjustment disorder according to the DSM-IV or ICD-10, the results showed that there is moderate-quality evidence (Appendix 2) of a significant difference between PST and non-guideline based care for full RTW after one year of follow-up (MD -24.00, 95% CI -47.58 to -0.42) (Figure 8).

2.2 4DSQ distress score, follow-up three months

Results for the distress score at three months follow-up based on studies including a diagnosis of adjustment disorder according to the DSM-IV or ICD-10 criteria showed that there is moderate-quality evidence (Appendix 2) of no significant difference between PST and non-guideline based care (MD -1.90, 95% CI -4.69 to 0.89).

2.3 4DSQ distress score, follow-up four to 12 months

Similarly, there was no significant difference between PST and non-guideline based care for the distress score at four to 12 months follow-up (MD -1.06, 95% CI -3.86 to 1.74), based on moderate-quality evidence (Appendix 2).

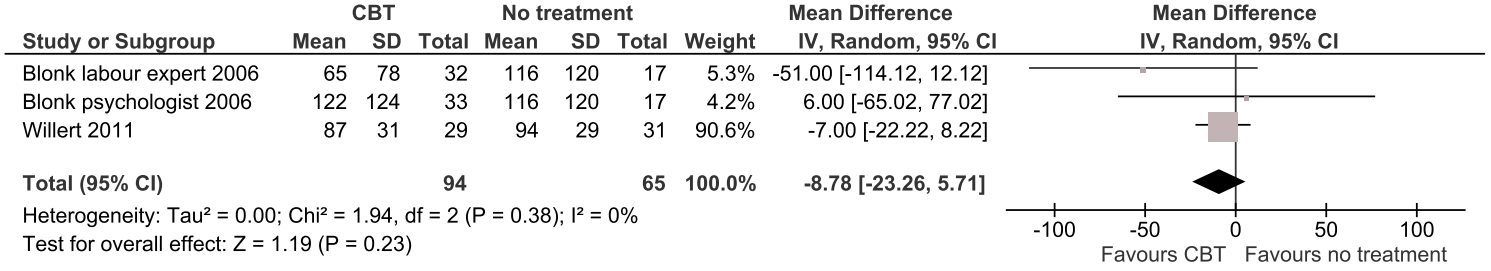

Figure 4. Forest plot for partial RTW with one year follow-up (CBT vs. no treatment).

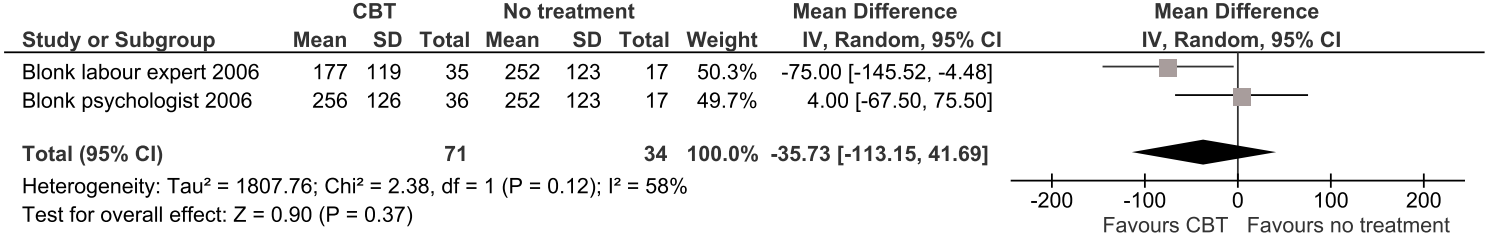

Figure 5. Forest plot for full RTW with one year follow-up (CBT vs. no treatment).

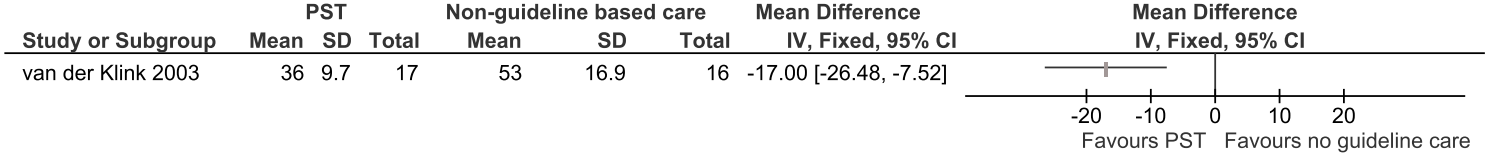

Figure 6. Forest plot for partial RTW with one year follow-up (PST vs. non-guideline based care).

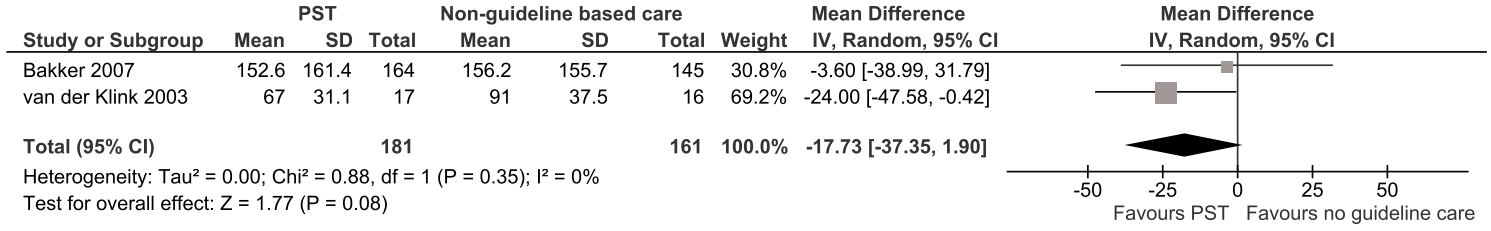

Figure 7. Forest plot for full RTW with one year follow-up (PST vs. non-guideline based care).

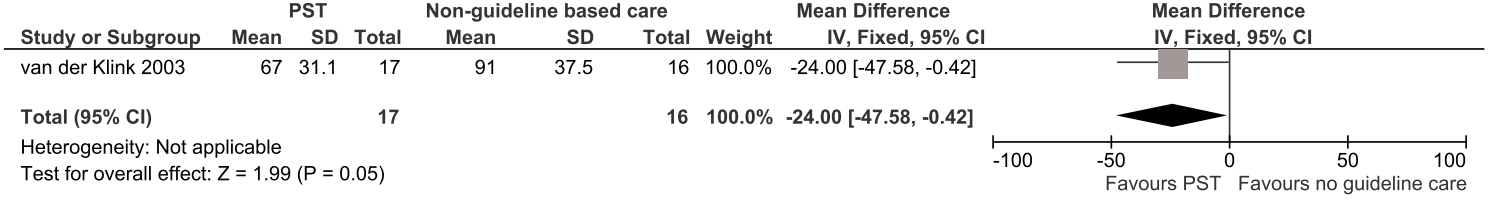

Figure 8. Forest plot for full RTW with one year follow-up, full adjustment disorder diagnosis (PST vs. non-guideline based care).

DISCUSSION

Summary of main results

We found nine RCTs reporting on ten psychological interventions and one intervention that combined a psychological intervention with physical relaxation. We did not find RCTs of pharmacological interventions, exercise programmes or employee assistance programmes. Of the ten psychological interventions, five consisted of CBT and five of PST. Our results showed moderate-quality evidence that time until partial return to work (RTW) was similar for workers receiving CBT or no treatment (mean difference (MD) -8.78, 95% confidence interval (CI) -23.6 to 5.71) at one-year follow-up. A sensitivity analysis, including studies in which adjustment disorder was diagnosed according to the DSM-IV and ICD-10, confirmed this result (MD -24.92, 95% CI -80.58 to 30.74). For full RTW, we found low-quality evidence that CBT did not significantly reduce days until full RTW at one-year follow-up compared to no treatment. There was also moderate-quality evidence that CBT did not significantly reduce distress complaints at one-year follow-up compared to no treatment.

PST significantly reduced time until partial RTW by 17 days (MD -17.00, 95% CI -26.48 to -7.52) after one year of follow-up compared to non-guideline based care, but no significant differences were found for full RTW and distress complaints at one-year follow-up. However, a sensitivity analysis, only including studies with a diagnosis of adjustment disorder according to the DSM-IV or ICD-10, showed a significant difference between PST and non-guideline based care for full RTW after one year follow-up (MD -24.00, 95% CI -47.58 to -0.42).

Moderate-quality evidence showed that PST led to similar effects on partial and full RTW as CBT. Participatory PST led to similar results as PST. The rate of partial and full RTW was similar after a combined intervention consisting of CBT and physical relaxation compared to physical relaxation alone at one and two years follow-up. Finally, we found moderate-quality evidence that individual CBT and group CBT led to a similar time to full RTW.

Overall completeness and applicability of evidence

We have performed an extensive literature search for this study to find all relevant RCTs. By searching the WHO trials portal and ClinicalTrials.gov, we also found studies that are still being conducted and which can be followed until they are finished and ready to be assessed for inclusion in this review. Furthermore, the review authors are all experts in the field of occupational health care and work disability prevention and are knowledgeable about the studies that have been performed in this field. This ensures that most available studies have been found for this review. Considering the variability in the interventions that are included in this review and because we have not

searched the grey literature, there remains a possibility that some studies have not been found.

Regarding the overall completeness of the review, it should be noted that we only found studies on psychological interventions and a combined intervention which consisted of a psychological intervention and physical relaxation. Thus, studies on the effect of other types of interventions, such as pharmacological interventions or exercise programmes, on RTW are lacking. Furthermore, not enough studies were included to perform subgroup analyses for organisational setting, treatment setting and type of job, which impedes generalisation of the results. Also, we could not assess publication bias because of the small number of studies included in the review. We have to acknowledge that the review might have been affected by publication bias. On the other hand, there were a wide range of participants included in the studies. The mean age of participants ranged between 39 and 49 years, and the percentage of females ranged from 19% to 71%. The percentage of participants with a high educational level ranged from 4% to 52%. This indicates that the current review consists of a rather heterogeneous group of participants. Some studies did not provide information on job type, but the studies that did so, indicated that participants worked, for example, for a postal company, the police department, a university, a hospital and a steel company. Although this shows a relative mixture of job types, it may be interesting to conduct more research on workers in job types that are known to be related to high sick leave rates because of adjustment disorders, such as in health care and education[76,77]. Furthermore, the results that we found in this review for partial RTW were based on studies which mainly consisted of men[39,57]. It could be that this is a gender-specific effect and it should be studied more among women.

Applicability of the findings of this review may be restricted to the Dutch context, since seven of the nine included studies were performed in the Netherlands. In particular, the term adjustment disorder, which is commonly used in the Netherlands to refer to the group of patients suffering from distress-related complaints, is not frequently used in other countries. Terminology such as burnout, distress, minor mental disorders or (occupational or work) stress is more common[78-80]. Furthermore, the term “common mental disorders” is becoming more popular in research articles, where distress-related complaints are defined as being a subgroup of common mental disorders[26,68,81,82]. This made it challenging to operationalize the diagnosis of adjustment disorder for this review. Our aim was to only include participants with burnout-related or distress-related complaints and, therefore, we excluded participants suffering from more debilitating disorders, such as anxiety and depressive disorders. For future research, it would be helpful to come to a shared definition for the group of patients that suffer from adjustment disorders and to validated assessment tools to enhance comparability between studies.

Although the majority of the included studies was performed in the Netherlands, the problem of sick leave related to adjustment disorders is encountered in many other countries[6,83]. It could be that the interventions evaluated in this review are more effective in other countries than the Netherlands because the comparison interventions may have included effective interventions. Occupational physicians (OPs) in the Netherlands have a guideline for managing sick leave because of mental health problems since 2000[84,85]. Furthermore, with the Gatekeeper Improvement Act, that has been effective in the Netherlands since 2002, more investments have been made in RTW by employers, employees and occupational health care services. Six of the Dutch studies included in this review were performed after these dates. Thus, participants in the comparison interventions of these studies were obliged to see the OP to be supported in RTW and will have received support from their employers to enhance RTW. This may have led to small contrasts between study groups in some of the Dutch studies, such as the studies of van Oostrom et al. (2010)[66] and Rebergen et al. (2009)[68]. However, when comparing the mean days until partial or full RTW for the comparison interventions of the Dutch studies performed before 2002 and after 2002, no clear difference in time to RTW can be seen. When looking at the two studies included in this review that were performed in other countries (Denmark and Sweden), one study showed a significant difference in sick leave days between the experimental (CBT) and comparison (no treatment) group[67]. The other study, comparing CBT and physical relaxation versus physical relaxation alone, did not detect a significant difference in rate of sick leave[30]. Thus, our hypothesis that the interventions included in this review might be more effective in other countries than the Netherlands needs to be evaluated in future research to be confirmed.

Finally, the follow-up time in most studies was one year. Only two studies had a follow-up time of 18 months[65] and two years[30]. However, we believe that a follow-up time of one year is sufficient when evaluating the effect of an intervention on RTW, because most workers on sick leave because of adjustment disorders return to work within one year.

Quality of the evidence

We were able to include nine RCTs. We considered this a fair number, since it is not easy to perform randomised studies in a healthcare setting. Furthermore, we used a clear definition of adjustment disorders, also including studies that did not use a strict DSM-IV or ICD-10 diagnosis but did focus on a study population with comparable complaints. Since only two studies used a strict DSM-IV and ICD-10 diagnosis, our broadened definition of adjustment disorders allowed us to give a good overview of the research done on study populations with more mild mental health complaints. The drawback of the broadened definition is that the different studies did not consist of

homogeneous populations. We dealt with this by performing sensitivity analyses on the studies that did use the diagnostic criteria of the DSM-IV or ICD-10 to assess whether participants had an adjustment disorder. In future research, a strict diagnosis of adjustment disorder, based on the DSM-IV or ICD-10, should be used to enhance comparability between studies.

The studies mainly included small numbers of participants with a mean number of 156 participants. The outcome measure of mean days until partial or full RTW had a large standard deviation (SD) with approximately the same magnitude as the mean. Given these large SDs, the power to detect relevant differences in these studies may have been insufficient. Moreover, most comparisons were based on one study and only a few comparisons consisted of two or three studies. In light of this, results have to be interpreted carefully. The extent to which the findings are applicable to other study settings and future trials may be limited. Future researchers investigating interventions to facilitate RTW of workers with adjustment disorders should try to recruit double the amount of participants and will need to find ways to overcome recruitment problems.

A potential threat to the quality of the evidence could be the way we incorporated multiple trial arms in the meta-analyses. We chose to include each trial arm in the comparison and divide the control group in two. This method can influence the estimation of between-study variance, especially because of the small number of studies in the meta-analyses. Thus, these estimates are imprecise and should be interpreted cautiously.

Some studies used the median when reporting days until partial or full RTW because sick leave data are known to be skewed. Although the mean number of days until partial and full RTW was used in this review, our results are comparable to the results of the individual studies. For example, van Oostrom et al. (2010)[66] reported on the median days until full RTW and found a non-significant hazard ratio (HR) of 0.99, which is comparable to the mean difference of one day found in this review. In general, it is known that the t-test is fairly robust for data being skewed to one side[86].

All studies had acceptable randomisation and treatment allocation procedures. However, only one study succeeded in keeping co-interventions comparable between the treatment and control group[63]. The fact that the other studies did not succeed in preventing co-interventions or keeping them similar for all study groups, makes it difficult to draw strong conclusions on the effectiveness or ineffectiveness of the interventions in this review. If control groups had easy access to psychiatrists, psychologists and psychotropic medication, the contrast with the intervention groups, and thus the chance of finding an effect of the intervention, will have been diminished. Furthermore, compliance to the treatment was not acceptable in four of the nine studies[56,65,66,68]. This could explain our finding that most of the interventions had no significant effect. Thus, researchers need to become more aware of avoiding or

keeping co-interventions similar for all study groups and ensuring compliance to the study protocol by care providers.

Another problem encountered in the studies in this review was the lack of blinding of participants and care providers. Only three studies succeeded in blinding participants[39,56,57] and two in blinding care providers[56,67]. This problem often arises in studies that are designed as pragmatic trials, such as the studies in this review. Pragmatic trials investigate the effectiveness of an intervention in everyday practice. Often, it is difficult to blind participants and care givers for the treatment intervention, because it is clearly different from normal practice[87]. A possible solution to this problem is to design a cluster-randomised controlled trial or to pre-randomise participants[88]. In a pre-randomised design, randomisation takes place before detailed information is given about the study, and participants allocated to one study group are kept blind to the randomisation procedure and to the existence of the other study group.

We also planned to analyse, as a secondary outcome measure, outcomes related to work functioning or work productivity, but the studies in this review only used time until RTW as a work-related outcome measure. It would be interesting to know more about workers after they have returned to work. It could be that workers are less productive or not functioning well after their RTW. Therefore, it would be helpful to include other work-related outcomes in addition to sick leave measures to gain insight into the process after RTW in future studies.

Potential biases in the review process

In this review, we did not restrict the languages in which studies were published. This prevented bias in the selection of studies only published in the English language. However, it should be mentioned that two of the review authors were the study authors of one of the included studies[68]. To prevent biased assessment, these authors were not involved in the selection, risk of bias assessment and data extraction for this study. Moreover, all these steps of the review process were always independently performed by two review authors. To prevent reporting bias, we reported on individual studies, not on individual articles. For every RCT, we traced all articles that were related to the same study and used these articles for data extraction for that single study.

Potential bias might have occurred in defining the different interventions included in the review. Instead of using the names that the authors gave to their intervention, we first predefined which components should be part of an intervention to frame it as CBT or PST. Following this, we checked the components of every intervention and, based on this, we classified it as being CBT or PST. We feel that this approach is more systematic than using the names that were given to the interventions by the authors, and we believe that it has not biased our results.

We combined studies that evaluated the same intervention, but in which the intervention was provided by different health care professionals. In some studies, these professionals were specialised psychologists and in other studies they were OPs or GPs with little experience in providing CBT or PST. This could increase heterogeneity in two ways. First of all, because of a higher-intensity treatment and better effect with more professional treatment. Secondly, the relationship of the health care professional with the employer and the focus on work differs between professionals and could have an effect on how a treatment is delivered. However, we were not able to evaluate these hypotheses because of an insufficient number of studies.

Finally, bias might have been introduced by using the intra-cluster correlation (ICC) of the distress score, which was given in the study of Bakker et al. (2007)[56], to calculate the ICC for RTW in Bakker et al. (2007)[56] and the ICC for distress in the study of van der Klink et al. (2003)[57]. This could have inflated the variance for both outcomes and misrepresented the true degree of variation of the study population for the outcomes concerned.

Agreements and disagreements with other studies or reviews

There are other reviews that have also focused on interventions to facilitate RTW but for different study populations. For example, Schaafsma et al. (2010)[89] investigated the effect of physical conditioning programmes for improving work outcomes in workers with back pain. In this systematic review, the authors could not find an effect of light or intensive physical conditioning programmes on the reduction of sick leave, compared to usual care or other exercise programmes. These results are in line with the results of this review, which mainly showed no significant effects of the interventions on time to full RTW at one-year follow-up, although CBT and PST did show a significant effect for time to partial RTW. Nieuwenhuijsen et al. (2008)[42] investigated the effect of interventions aimed at improving occupational health in depressed people and did not find clear evidence of an effect of medication, enhanced primary care, psychological interventions or a combination of these interventions with medication on sick leave in depressed workers. A systematic review evaluating the effect of workplace interventions on sick leave for all types of disorders only found a significant effect of a workplace intervention on the reduction of sick leave among workers with musculoskeletal disorders, compared to usual care. No effect was found of workplace interventions for back pain, upper-extremity disorders or mental health problems[66]. Finally, de Boer et al. (2011)[90] recently published a systematic review on interventions to enhance RTW for cancer patients. This review showed that physical training was not effective in reducing time to RTW compared to usual care. Furthermore, medical interventions with a functioning conservative approach were not more effective in increasing RTW rates than more radical treatments. There was only a positive effect of

multidisciplinary interventions (consisting of physical, psychological and vocational components) on RTW rates compared to care as usual.

When combining the results of this review and the reviews mentioned above, we can conclude that there are already quite a number of studies performed on the effects of different types of intervention on reducing sick leave or time to RTW for different study populations. Overall, none of the reviews showed high-quality evidence that any type of intervention was effective in reducing sick leave or time to RTW.

AUTHORS' CONCLUSIONS

Implications for practice

We found moderate-quality evidence that time until partial return to work (RTW) at one-year follow-up was similar for workers receiving cognitive behavioural therapy (CBT) or no treatment. Results from low-quality evidence indicate that CBT was not significantly effective in reducing time to full RTW at one-year follow-up compared to no treatment. Moderate-quality evidence showed that problem solving therapy (PST) significantly enhanced partial RTW at one-year follow-up compared to non-guideline based care but did not significantly enhance time to full RTW at one-year follow-up. A PST intervention could readily be implemented in a work context by occupational health care professionals to enable participants to take the first steps towards RTW. This might also reduce the costs related to sick leave. However, there was insufficient evidence that PST or CBT are effective in restoring individuals back to their full duties.

Implications for research

International consensus should be reached on the terminology used to address the group of workers with adjustment disorders and assessment tools need to be developed and validated for diagnosing adjustment disorders. Almost every study in this review used different terms for describing complaints related to adjustment disorders, such as distress, stress, burnout and minor mental disorders, which impedes making comparisons.

Future studies should include more women and should focus research on participants with certain job types that are prone to adjustment disorders (e.g. distress complaints and burnout), such as nurses and teachers. Because of the large standard deviations related to mean days until RTW, which led to a loss of power, studies need to recruit at least 300 or more participants.

Researchers may consider exploring other possible interventions, in addition to CBT and PST interventions, to try to affect full RTW. Moreover, in future studies more attention should be paid to proper blinding of participants, care providers and data analysts, and to controlling of co-interventions and compliance with the treatment

protocol by care providers. Comparison conditions such as “usual care” should be better defined and described. Otherwise, it is hard to compare the effects of different studies. Finally, different types of work-related outcome measures, such as work functioning and work productivity, should be used besides sick leave days and time until RTW to better understand how workers are performing following RTW.

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APPENDIX 1: SEARCH STRATEGIES

CENTRAL search terms

#1 MeSH descriptor ADJUSTMENT DISORDERS, this term only; #2 MeSH descriptor BURNOUT, PROFESSIONAL, this term only; #3 MeSH descriptor NEURASTHENIA, this term only; #4 (mental NEXT disorder*):ti,ab; #5 (adjustment NEXT disorder*):ti,ab,kw; #6 (burnout):ti,ab,kw; #7 (reactive NEXT disorder*):ti,ab,kw; #8 (reactive NEXT depression):ti,ab,kw; #9 (psychologic* or mental health or depress* or anxi* or somat* or distress or stress[TSC2]):ti,ab,kw; #10 ((sick* NEAR/3 leave) or (sick NEAR/3 list*) or (sick NEAR/3 absen*)):ti,ab,kw; #11 (workplace or (work NEAR/3 related) or occupation* or job):ti,ab,kw; #12 (#9 and (#10 or #11)); #13 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #12); #14 MeSH descriptor SICK LEAVE, this term only; #15 MeSH descriptor ABSENTEEISM, this term only; #16 MeSH descriptor REHABILITATION, VOCATIONAL, this term only; #17 ((sick* NEAR/3 leave) or (sick NEAR/3 list*) or (sick NEAR/3 absen*)):ti,ab,kw; #18 (return* NEAR/3 work*):ti,ab,kw; #19 ((sick* or absen*) AND (workplace or (work NEAR/2 related) or occupation* or job)):ti,ab,kw; #20 (#14 or #15 or #16 or #17 or #18 or #19); #21 (#13 and #20)

OVID MEDLINE search terms

1. randomized controlled trial.pt.; 2. controlled clinical trial.pt.; 3. randomi#ed.ti,ab.; 4. randomly.ab.; 5. placebo.ab.'6. drug therapy.fs.; 7. trial.ab.; 8. groups.ab.; 9. (control$ adj3 (trial or study)).ab,ti.; 10. ((singl$ or doubl$ or tripl$ or trebl$) adj3 (blind$ or mask$ or dummy)).mp.; 11. or/1-10; 12. ADJUSTMENT DISORDERS/; 13. BURNOUT, PROFESSIONAL/; 14. *MENTAL DISORDERS/
15. NEURASTHENIA/; 16. adjustment disorder*.tw.; 17. burnout.tw.; 18. reactive disorder*.tw.; 19. reactive depression.tw.; 20. (psychologic* or mental health or mental disorder* or depress* or anxi* or somat* or distress or stress).tw.; 21. ((sick* adj3 (leave or list* or absen*)) or (workplace or (work adj2 related)) or occupation* or job).tw.; 22. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or (20 and 21); 23. SICK LEAVE/; 24. ABSENTEEISM/; 25. REHABILITATION, VOCATIONAL/; 26. (sick adj3 (leave or list* or absen*)).tw.; 27. (return* adj3 work*).tw.; 28. ((sick* or absen*) adj5 (workplace or (work adj2 related) or occupation* or job)).tw.; 29. or/23-28; 30. 11 and 22 and 29

OVID EMBASE search terms

1. randomized controlled trial.de.; 2. randomization.de.; 3. placebo.de.; 4. placebo$.ti,ab.; 5. randomi#ed.ti,ab.; 6. randomly.ab.; 7. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$ or dummy)).mp.; 8. factorial$.ti,ab.; 9. allocat$.ti,ab.; 10. assign$.ti,ab.; 11. volunteer$.ti,ab.; 12. crossover procedure.de.; 13. (crossover$ or cross over$).ti,ab.; 14. (quasi adj (experimental or random$)).mp.; 15. (control$ adj3 (trial$ or study or studies or group$)).ti,ab.; 16. ((animal or nonhuman) not (human and (animal or nonhuman))).de.; 17. or/1-15; 18. 17 not 16; 19. adjustment disorder/; 20. neurasthenia/; 21. burnout/; 22. job stress/; 23. *mental disease/; 24. reactive depression/; 25. adjustment disorder*.tw.; 26. burnout.tw.; 27. reactive disorder*.tw.; 28. reactive depression.tw.; 29. (psychologic* or mental health or mental disorder* or depress* or anxi* or somat* or distress or stress).tw.; 30. ((sick* adj3 (leave or list* or absen*)) or (workplace or (work adj2 related)) or occupation* or job).tw.; 31. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or (29 and 30); 32. medical leave/; 33. absenteeism/; 34. vocational rehabilitation/; 35. (sick adj3 (leave or list* or absen*)).tw.; 36. (return* adj3 work*).tw.; 37. ((sick* or absen*) adj5 (workplace or (work adj2 related) or occupation* or job)).tw.; 38. or/32-37; 39. 18 and 31 and 38

OVID PsycInfo search terms

1. treatment effectiveness evaluation.sh.; 2. clinical trials.sh.; 3. mental health program evaluation.sh.; 4. placebo.sh.; 5. placebo$.ti,ab.; 6. randomly.ab.; 7. randomi#ed.ti,ab.; 8. trial.ti,ab.; 9. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$ or dummy)).mp.; 10. (control$ adj3 (trial$ or study or studies or group$)).ti,ab.; 11. factorial$.ti,ab.; 12. allocat$.ti,ab.; 13. assign$.ti,ab.; 14. volunteer$.ti,ab.; 15. (crossover$ or cross over$).ti,ab.; 16. (quasi adj (experimental or random$)).mp.; 17. "2000".md.; 18. or/1-17; 19. Adjustment Disorders/; 20. asthenia/ or myasthenia/ or neurasthenia/; 21. occupational stress/ or work related illnesses/; 22. *mental disorders/; 23. Reactive Depression/; 24. adjustment disorder*.tw.; 25. burnout.tw.; 26. reactive disorder*.tw.; 27. reactive depression.tw.; 28. (psychologic* or mental health or mental disorder* or depress* or anxi* or somat* or distress or stress).tw.; 29. ((sick* adj3 (leave or list* or absen*)) or (workplace or (work adj2 related)) or occupation* or job).tw.; 30. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or (28 and 29); 31. employee leave benefits/; 32. employee absenteeism/; 33.

reemployment/; 34. exp vocational rehabilitation/; 35. (sick adj3 (leave or list* or absen*)).tw.; 36. (return* adj3 work*).tw.; 37. ((sick* or absen*) adj5 (workplace or (work adj2 related) or occupation* or job)).tw.; 38. or/31-37; 39. 18 and 30 and 38

Web of Science search terms

1. Topic=(randomized controlled trial); 2. Topic=(randomi*ed); 3. Topic=(placebo); 4. Title=(trial); 5. Topic=(groups); 6. Topic=((singl* OR doubl* OR tripl* or trebl*) SAME (blind* OR mask* OR dummy)); 7. Topic=(control* SAME (trial* or study or studies or group*)); 8. Topic=(factorial* OR allocat* OR assign* OR volunteer* OR crossover* OR cross-over*); 9. Topic=(quasi SAME (experimental or random*)); 10. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9; 11. Topic=("adjustment disorder*"); 12. Topic=(burnout); 13. Topic=(reactive SAME disorder*); 14. Topic=(reactive SAME depression); 15. Topic=(psychologic* OR mental health OR depress* OR anxi* OR somat* OR distress OR stress*); 16. Topic=((sick SAME (leave OR list* OR absen*)) OR (workplace OR (work SAME related) OR occupation* OR job)); 17. 15 AND 16; 18. 11 OR 12 OR 13 OR 14 OR 17; 19. Topic=(absentee*); 20. Topic=(rehabilitat* SAME (vocation* or workplace)); 21. Topic=((sick* SAME leave) OR (sick* SAME list*) OR (sick* SAME absen*)); 22. Topic=(return* SAME work*); 23. Topic=((sick* OR absen*) AND (workplace OR (work SAME related) OR occupation* OR job)); 24. 19 OR 20 OR 21 OR 22 OR 23; 25. 10 AND 18 AND 24

International trial registers (ICTRP, clinicaltrials.gov) search terms

The WHO Trials Portal (ICTRP) and ClinicalTrials.gov was searched by entering individual keywords and phrases related to return to work: "return to work"; "sick leave"; "absenteeism"; "vocational rehabilitation"; "sickness absence"; "workplace"

APPENDIX 2: QUALITY OF EVIDENCE (GRADE)

Comparison/outcome	Studies in comparison	Risk of bias in studies	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence
CBT versus no treatment/partial RTW follow-up 1 year	Blonk psychologist 2006; Willert 2011	No: the majority of studies have low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
CBT versus no treatment/full RTW follow-up 1 year	Blonk psychologist 2006	No: the study has low risk of bias	Inconsistent: $I^2 > 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT versus no treatment/distress follow-up 1 year	Blonk psychologist 2006	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
CBT versus non-guideline based care/full RTW follow-up 1 year	de Vente individual 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT versus non-guideline based care/distress follow-up 3 months	de Vente individual 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT versus non-guideline based care/distress follow-up 1 year	de Vente individual 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus non-guideline based care/partial RTW follow-up 1 year	van der Klink 2003	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus non-guideline based care/full RTW follow-up 1 year	Bakker 2007; van der Klink 2003	No: the studies have low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus non-guideline based care/full RTW follow-up 1 to 2 years	Brouwers 2006	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
PST versus non-guideline based care/distress follow-up 3 months	Bakker 2007; Brouwers 2006; van der Klink 2003	No: the majority of studies have low risk of bias	Consistent: $I^2 < 50\%$	Direct	Precise: > 400 participants	Undetected	High quality
PST versus non-guideline based care/distress follow-up 3 to 12 months	Bakker 2007; Brouwers 2006; van der Klink 2003	No: the majority of studies have low risk of bias	Consistent: $I^2 < 50\%$	Direct	Precise: > 400 participants	Undetected	High quality

Appendix 2. (continued)

Comparison/outcome	Studies in comparison	Risk of bias in studies	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence
PST versus non-guideline based care/distress follow-up 1 to 2 years	Brouwers 2006	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
PST work versus CBT work/partial RTW follow-up 1 year	Rebergen 2009	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST work versus CBT work/full RTW follow-up 1 year	Rebergen 2009	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
Participatory PST work versus PST work/full RTW follow-up 1 year	van Oostrom 2010	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
Participatory PST work versus PST work/distress follow-up 3 months	van Oostrom 2010	No: the study has low risk of bias	No: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
Participatory PST work versus PST work/distress follow-up 3 to 12 months	van Oostrom 2010	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
CBT and physical relaxation versus Physical relaxation/rate of partial RTW follow-up 1 year	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT and physical relaxation versus physical relaxation/rate of partial RTW follow-up 1 to 2 years	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT and physical relaxation versus physical relaxation/rate of full RTW follow-up 1 year	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality

Appendix 2. (continued)

Comparison/outcome	Studies in comparison	Risk of bias in studies	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence
CBT and physical relaxation versus physical relaxation/rate of full RTW follow-up 1 to 2 years	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT and physical relaxation versus physical relaxation/SMBQ score follow-up 1 year	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT and physical relaxation versus physical relaxation/SMBQ score follow-up 1 to 2 years	Stenlund 2009	Serious limitation: the study has high risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
Individual CBT versus group CBT/full RTW follow-up 1 year	de Vente individual 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
Individual CBT versus group CBT/distress follow-up 3 months	de Vente individual 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
Individual CBT versus group CBT/distress follow-up 3 to 12 months	de Vente group 2008	Yes: the study has high risk of attrition bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Low quality
CBT versus no treatment full AD/partial RTW follow-up 1 year	Blonk psychologist 2006	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus Non-guideline based care full AD/full RTW follow-up 1 year	van der Klink 2003	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus non-guideline based care full AD/distress follow-up 3 months	van der Klink 2003	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality
PST versus non-guideline based care full AD/distress follow-up 4 to 12 months	van der Klink 2003	No: the study has low risk of bias	Consistent: $I^2 < 50\%$	Direct	Imprecise: < 400 participants	Undetected	Moderate quality

3

Prevention of recurrent sickness absence among employees with common mental disorders: Design of a cluster-randomised controlled trial with cost-benefit and effectiveness evaluation

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BMC Public Health 2010, 10: 132.

ABSTRACT

Background: Common mental disorders, such as depression, anxiety disorder, and adjustment disorder, have emerged as a major public and occupational health problem in many countries. These disorders can have severe consequences such as absenteeism and work disability. Different interventions have been developed to improve the return to work of employees with common mental disorders, but still a large proportion of employees experiences health and work problems after their return to work. For this reason, the SHARP-at work intervention is developed to prevent a relapse of sickness absence among employees who have returned to work after a period of sickness absence because of common mental disorders. We aim to evaluate the effectiveness, cost-benefit and process of the intervention compared to care as usual.

Methods/Design: The study is designed as a cluster-randomised controlled trial with randomisation at the level of the occupational physician. Employees who have returned to work after a period of sickness absence because of a common mental disorder are included in the study. Employees in the intervention group will receive the SHARP-at work intervention. The intervention focuses on active guidance of employees by occupational physicians during the first weeks of work after sickness absence. Employees in the control group will receive care as usual. Outcomes will be assessed at baseline and at 3, 6, and 12 months follow-up. The primary outcome is cumulative recurrent sickness absence days. Secondary outcome measures are mental health, work functioning and coping. Adherence to the protocol, communication between stakeholders and satisfaction with the treatment are the process measures assessed in both study groups. Cost-benefit is calculated from a societal perspective. Finally, prognostic factors for a relapse of sickness absence are investigated.

Discussion: This study goes beyond return to work by focussing on the prevention of recurrent sickness absence. The study incorporates not only outcomes on sickness absence and mental health but also on health-related work functioning. The results of this study can contribute to a further development of practice guidelines and the promotion of sustainable work participation.

Trial registration: NTR1963.

BACKGROUND

Common mental disorders (CMDs), such as depression, anxiety disorder and adjustment disorder, have emerged as a major public and occupational health problem in many countries[1]. Several studies have found a relationship between CMDs and long term sickness absence and work disability[2-7]. In the Netherlands, about one in every three new work disability benefit recipients is disabled for work because of mental health problems[8,9]. The increase in sickness absence and work disability because of CMDs has serious negative economic consequences calling for preventive action[3,5,7,10,11].

Recently, attention is also given to the at-work decrements in performance because of CMDs which seem to be even more costly than absenteeism[1,6,12-15]. In their review, Lerner and Henke show that depression is significantly associated with a reduction in job performance and productivity; it was demonstrated that employees with a significant improvement in depression still have more trouble with performing well compared to their healthy colleagues[6]. These findings emphasize the importance of interventions aiming at employees with CMDs who are at work. Yet, most interventions for employees with mental health problems are curative and focus on reintegration[16-20]. No interventions exist which aim at providing support after return to work although it is known that employees who return to work often are not fully recovered from their initial complaints[16-20]. Moreover, research in the Netherlands showed that one out of five employees who have returned to work after a sickness absence period because of a CMD experiences a relapse of sickness absence due to CMDs (Koopmans et al., submitted for publication). For these reasons, we have developed an intervention aiming at the prevention of a relapse of sickness absence among employees who have (partially/fully) returned to work after a period of sickness absence because of a CMD.

The intervention is called “SHARP-at work.” SHARP is an acronym for Stimulating Healthy participation And Relapse Prevention. The intervention is based on the guideline “Management of mental health problems of workers by occupational physicians” of the Netherlands Society of Occupational Medicine. This evidence-based guideline, developed in 2000 and revised in 2007, is introduced to facilitate the return to work of employees on sickness absence because of mental health problems[21,22]. The goal of the guideline is to activate the employee when stagnation occurs in the process of problem identification, problem solving and implementation of solutions regarding issues that caused sickness absence and factors that hinder return to work. By this, employees learn to control their own recovery. The guideline has shown to be effective in reducing the number of employees who are on long-term sickness absence because of CMDs[18,23,24].

The SHARP-at work intervention is developed to improve problem solving strategies regarding problems or opportunities at work for employees who have returned to work. Successful implementation of solutions is stimulated by guiding employees in involving their line manager (i.e. the supervisor). This intervention will be implemented by the occupational physicians (OPs) of the employees. The goal of the intervention is the prevention of a relapse of sickness absence and improving mental health and work functioning.

Given the serious consequences of CMDs for the individual employee and the high social and economic costs for the workplace, the employer, the health system and society, the promotion of sustainable work participation among employees with CMDs is very important. Therefore, the primary aim of this study is to evaluate the effectiveness of the SHARP-at work intervention compared to care as usual (CAU) in preventing a relapse of sickness absence among employees who have returned to work after a period of sickness absence because of a CMD. We hypothesise that employees who return to work, after sickness absence because of a CMD, and undergo the SHARP-at work intervention will have less recurrent sickness absence days compared to employees who receive CAU. Secondary aims are to improve mental health and work functioning and to stimulate better coping mechanisms. In addition, the cost-benefit of the intervention will be examined. Along with these evaluations, we will conduct a process evaluation among employees, OPs and line managers. Finally, prognostic factors for a relapse of sickness absence will be investigated. To our knowledge, this is the first study focussing on guiding employees at work after they have returned to work because of a period of sickness absence due to CMDs.

METHODS/DESIGN

The CONSORT statement and the extension for cluster-randomised trials is used to describe the design of the study[25,26].

Study context

In the Netherlands, both the employer and the employee are responsible for return to work. According to the Dutch Gate Keeper Act, the employer has a two-year obligation to pay an employee on sickness absence. After this period, the employee can apply for work disability benefit. During the first two years of sickness absence, the employer and the employee have to make all efforts possible to realise a return to work for the employee. For this reason, the employer is obliged to contract an occupational physician (OP). The employee has to visit the OP when being on sickness absence. OPs treat employees according to guidelines. For CMDs, the evidence-based guideline of the Netherlands Society of Occupational Medicine is used to support employees on

sickness absence because of mental health problems[21,22]. The OP and the employee should be meeting each other regularly as long as the employee has not fully returned to work. After full return to work, at least one meeting should take place to focus on relapse prevention. In practice, OPs do not seem to act upon this last step of the guideline (Rebergen et al., submitted for publication).

Study design

The study is designed as a two-armed cluster-randomised controlled trial for the prevention of a relapse of sickness absence by the SHARP-at work intervention compared to CAU (Figure 1). The study is conducted among employees who have returned to work after a period of sickness absence because of a CMD. Randomisation occurs at the level of the OP because employees cannot be randomly assigned to OPs and OPs cannot be expected to provide both guidance according to the SHARP-at work intervention and CAU. OPs, who have given their consent for participation, are randomised in the intervention or control group. OPs in the intervention group receive training in the SHARP-at work intervention. OPs in the control condition do not receive this training until the end of the study period and provide CAU.

Employees will be included from December 2009 to December 2010. OPs will invite an employee to participate in the study if the employee is diagnosed with a CMD at the start of the sickness absence period and ready to return to work. Employees treated by an OP trained in the intervention will receive the intervention. Employees who are treated by an OP in the control group will receive CAU. Regardless of the treatment group, employees still have the possibility to be treated simultaneously by other health care workers.

The Medical Ethical Board of the University Medical Center Groningen has given approval for the study design, the research protocol, questionnaires, information letters and the informed consent. Employees can participate voluntarily in this study. They are informed that they can leave the study at any time without consequences. All employees sign an informed consent. If an employee drops out, care will be continued.

Recruitment of occupational physicians

Recruitment of OPs takes place in collaboration with ArboNed, one of the largest Occupational Health Services (OHS) in the Netherlands. OPs participating in this study are employed at this OHS and are affiliated with companies of different sizes, in different sectors and in different parts of the Netherlands. Company size ranges from less than five employees up to more than a 1000 employees in different sectors, for instance industry, education, health care and customer services. All regions in the Netherlands, except the south, are participating in the study. OPs are excluded when

they: 1. have an upcoming retirement, resignation, sabbatical, or pregnancy leave, or 2. are unable to use the internet and/or email.

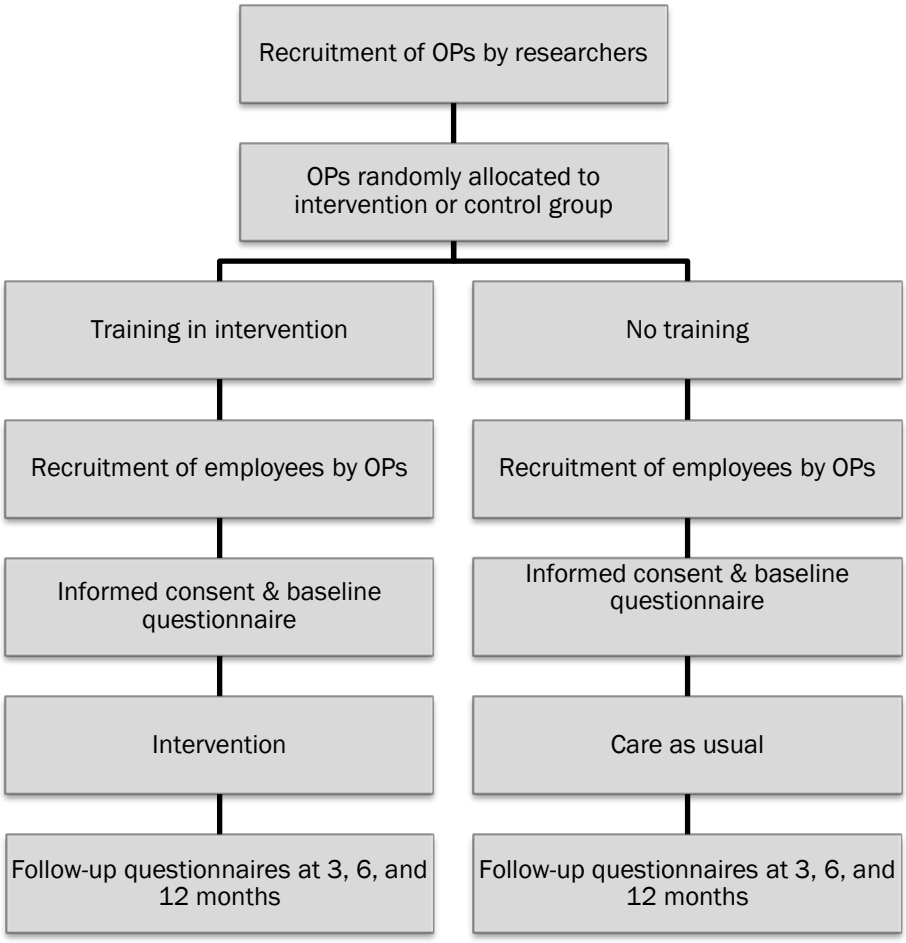

Figure 1. Study design.

Recruitment of participants

Inclusion criteria

Employees participating in the study are between 18 and 63 years old and employed in a paid job. Furthermore, they have: 1. a diagnosis of a CMD given by their OP at the start of the sickness absence period, 2. a period of sickness absence due to a CMD of at least two weeks, and 3. a planned return to work within two weeks.

Exclusion criteria

Employees are excluded when: 1. the present sickness absence spell has been longer than 12 months, 2. they have had a period of sickness absence due to a CMD three months prior to the present sickness absence spell, 3. they have severe mental disorders, like psychotic disorders, bipolar disorder or post-traumatic stress disorder, 4. they have somatic complaints or disorders that have a predominant influence on work disability, 5. they are pregnant or have an upcoming retirement, resignation or layoff, and 6. they are unable to speak, read, write or understand the Dutch language.

Procedure

Employees are recruited by the OPs participating in the study. The OP checks all inclusion and exclusion criteria. The diagnosis of a CMD has been made by the OP at the start of the sickness absence period. OPs are trained in diagnosing mental disorders and use a nationwide coding system, Classification of Diseases (in Dutch: CAS)[27], based on the International Classification of Diseases[28].

If the employee is interested in participating in the study, the OP asks whether contact information of the employee can be given to the researcher (IA) and hands over an information folder about the study. After the employee has received the information and has given approval for the researcher to make contact, the OP gives the contact information to the researcher. The researcher contacts the employee and asks if the employee would like to participate in the study. If the employee is willing to participate, informed consent and the baseline questionnaire (electronic or paper version) are send to the employee with a postage paid envelope.

When the informed consent and the baseline questionnaire are filled in and returned to the researcher, OPs in the intervention group are informed that the intervention can be started. OPs in the control group keep on treating their employees according to CAU. Follow-up questionnaires are send to the employee at 3, 6 and 12 months. At these points in time, administrative data on cumulative sickness absence days are also collected by means of the registry system of the OHS.

Intervention

Training of occupational physicians in the intervention group

OPs receive a two-day training in the SHARP-at work intervention. Training is provided by experienced trainers in occupational health interventions.

Treatment of participants in the intervention group

The intervention consists of five steps the employee has to undertake when return to work is started. The OP monitors that the employee follows these steps and uses

interventions to activate the employee when needed. The five steps are delineated below.

1. Make an inventory of problems and/or opportunities encountered at work
2. Brainstorm on solutions
3. Write down the solutions and the support needed and assess the applicability
4. Discuss the solutions with the line manager and make an action plan
5. Evaluate the action plan and the implementation of solutions

The OP can use assignments for the employee to write down and structure the process. In general, the OP will counsel on the process level. (S)he does not discuss the content of problems and solutions but challenges the employee to reflect on the relative seriousness of problems and the feasibility of solutions. This can be done by asking questions that stimulate the employee to think about possible perspectives. This form of guidance is related to Socratic questioning. The intervention differs from the guideline of the Netherlands Society of Occupational Medicine by the emphasis on problems and possibilities encountered *at work* when an employee has already returned to work.

Care as usual

Training of occupational physicians in the control group

All OPs participating in the study are trained in the guideline of the Netherlands Society of Occupational Medicine. There is no additional training of OPs in the control group as part of this study. At the end of the study period these OPs will be trained in the SHARP-at work intervention if it proves to be effective.

Treatment of participants in the control group

CAU is delivered according to the evidence-based guideline of the Netherlands Society of Occupational Medicine[21,22]. CAU comprises guidance in regaining control and activating problem solving when the employee is still on sickness absence and at least one consultation session after return to work, addressing relapse prevention.

Sample size

For the power calculation, recurrent sickness absence days are considered the primary outcome measure. To calculate the sample size, administrative data from the sickness absence registry of the OHS was used. From 2001 to 2007, recurrent sickness absence days among employees, who returned to work after a period of sickness absence because of CMDs, were registered. For the power calculation, only recurrent sickness absence days of the first recurrence episode until 1 year later were used to

approximate the 1 year follow-up of the present study (N=4443). The variance in recurrent sickness absence days at the level of the OP was taken into account.

During the above-mentioned period, the mean days of recurrent sickness absence was 68.5 (standard deviation is 119.6). The target of the present study is to reduce the recurrent sickness absence days with 20%, i.e. an average of 12.7 recurrent sickness absence days per employee per year. The OPs in this OHS's dataset were randomly divided into two groups. One group was called "the intervention group" from which 20% of the recurrent sickness absence days was subtracted to create the difference between the intervention and control group and to calculate an effect size.

For a decrease of 12.7 recurrent sickness absence days per employee during 1 year at alpha = 0.05 and ICC = 0.05, 50 OPs, each providing five employees, need to be included in each group (the intervention and control group)[29]. The five employees must be viewed as the average number per OP. For this multilevel power calculation, an effect size of 0.18 was taken into account. This effect size was calculated by using a log-transformation on the data to create a normal distribution and subsequently by dividing the difference in mean days of recurrent sickness absence between the intervention and control group (difference is 0.25) by the standard deviation (standard deviation of difference is 1.4). To include the effect size in the multilevel power calculation, it had to be transformed to a correlation coefficient, which resulted in a correlation of 0.09[30].

The collaborating OHS serves approximately one million insured employees. A total of 350 OPs is working for this OHS and each OP serves around 2500 to 3000 employees. Of these employees it is estimated that 1.3% (30% of the national sickness absence rate among Dutch employees of 4.3%) will be on sickness absence because of a CMD during a 1 year period[31]. Therefore, an OP will see around 32 to 39 employees per year who are absent because of CMDs. Following this, the source population of the OHS is large enough to recruit the required number of OPs and employees according to the sample size calculation.

Randomisation and treatment allocation

Employees cannot be randomly assigned to OPs trained in the intervention or OPs not trained in the intervention because the OPs and employees are bound to each other by the company. It is also impossible to train all OPs and to let them randomly apply the intervention or CAU to employees because of the risk of contamination. Therefore, randomisation occurs at the level of the OP. OPs who have given their consent to participate in the study are randomly assigned to the intervention group or the control group. To ensure a good contrast between these two groups, OPs in the intervention group are specifically asked not to talk about the intervention with OPs in the control

group. Additionally, the OPs in the intervention group have two feedback meetings to discuss the application of the intervention with each other.

A computerised random allocation sequence for randomising the OPs is developed by an independent researcher. When all OPs are recruited, the independent researcher, who is blind to the identity of the OPs, uses the allocation sequence to randomise the OPs. After this, the allocation of the OPs cannot be changed and the independent researcher informs the researchers about the allocation of the OPs. The allocation of employees follows the allocation of their OP. Employees with an OP in the intervention group are automatically allocated to the intervention group and employees with an OP in the control group are automatically allocated to the control group.

Blinding

Validity can be threatened if employees in the intervention and control group would know about the other group. Because this study is a pre-randomised trial, in which the employees are already randomised before informed consent is given, different information about the study can be provided to the intervention and control group[32]. To ensure that employees are not aware and stay unaware of the two study conditions, the OPs are requested not to talk about this with the employees. Whereas employees are blinded for treatment allocation, blinding of allocation for OPs is not possible because they will know if they are trained in the intervention or not.

Primary outcome

The primary outcome measure is a relapse of sickness absence, measured as cumulative recurrent sickness absence days. A relapse is defined as a 30% decrease in working days per week or a decrease of at least one day per week because of sickness absence. Recurrent sickness absence days are operationalized as days of sickness absence among employees who have worked a steady amount of days during the first two weeks after they have returned to work. This information will be obtained by record linkages with the sickness absence registry of the OHS and by the employee questionnaires.

Secondary outcomes

Mental health problems

The Four-Dimensional Symptom Questionnaire (4DSQ) is used to measure symptoms of distress, depression, anxiety and somatisation. The 4DSQ is a self-report questionnaire of 50 items and measures distress, depression, anxiety and somatisation. The 4DSQ has been validated in a primary care and working population[33,34].

The HADS is a 14-item self-report questionnaire used to measure depression (7 items) and anxiety (7 items)[35]. The questionnaire can be used in somatic, psychiatric

and primary care patients, as well as in the general population[36] and in working populations[37]. The HADS has been validated in different groups of Dutch subjects[38].

Work functioning

Work functioning is measured by the Work Role Functioning Questionnaire (WRFQ)[39,40]. The questionnaire has been cross-culturally adapted and translated into Dutch and pre-tested in a working population (Abma et al., submitted for publication). Results of the pre-test showed that the cross-cultural adaptation was successful. The WRFQ measures the perceived difficulties in meeting work demands among employees given their physical health or emotional problems. The WRFQ consists of 27 items divided into five subdomains: 1. work scheduling demands, 2. output demands, 3. physical demands, 4. mental demands, and 5. social demands.

Coping behaviour

Coping behaviour is measured by the 19-item version of the Utrecht Coping List (UCL) which assesses coping styles[41]. The questionnaire consists of the following five (coping style) scales: 1. active problem-focussing, 2. seeking social support, 3. palliative reaction pattern, 4. avoidance behaviour, and 5. expression of emotions.

Economic evaluation measures

Along with the sickness absence data from the OHS's registry system, administrative data of the OHS on consultations of the employee with the OP and company welfare workers is collected. Furthermore, the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (Tic-P), a validated Dutch questionnaire, is used to measure medical consumption and at-work decrements in performance[42]. Finally, an extra item on out-of-pocket costs is added to the Tic-P to calculate medical expenses that are not covered by health insurance.

Process evaluation measures

A process evaluation is conducted to examine a) the appraisals, attitudes and activities of OPs, employees and line managers in the intervention and control group during the treatment period and b) whether OPs adhere to their protocol. OPs who are trained in the intervention receive a questionnaire before and after the training to examine the quality of the training and the skills and attitudes of the OPs. For the intervention group, a questionnaire is developed for the OP and the employee at baseline. These questionnaires contain items on readiness for change concerning the intervention. At 3-months follow-up, the employees and the OPs in both the intervention and control group receive a questionnaire about the process of treatment during the first three months of return to work. The questions elaborate on what was discussed during the

consultations, whether assignments were given, which assignments were made, satisfaction with the treatment and communication between the employee, OP and line manager. For the intervention group, a questionnaire is also developed for the line manager. The line manager receives a questionnaire on readiness for change before a meeting takes place with the employee as part of the intervention. At 3-months follow-up, the line manager receives a second questionnaire with the same questions as the questionnaires at 3 months for the employee and the OP.

Prognostic measures

Research on prognostic variables for a relapse of sickness absence has only been conducted in a few studies. For this reason, a range of variables is included in this study to investigate prognostic factors for a relapse of sickness absence. At baseline, the following variables are measured: personal characteristics (e.g. age, gender, marital status, educational level and physical health), job characteristics (e.g. tenure, size of the company, sector, profession, contract type, number of contract hours before and after sickness absence and work accommodations after return to work) and psychosocial work characteristics (job demands, decision latitude, social support[43,44], job insecurity, conflicts, emotional load[45], work engagement[46] and expectancy to stay-at-work).

Statistical analyses

Due to the multilevel design of the study (i.e. employees are nested in OPs), multilevel regression analyses will be performed according to the intention-to-treat principle. Per protocol analyses will be conducted to explore if deviations from the protocol have caused bias. Descriptive statistics will be used to measure differences in baseline characteristics between the intervention and control group. In case of significant differences, these will be controlled for in the effect evaluations.

Effect evaluation

The primary outcome variable “cumulative recurrent sickness absence days during follow-up” will be compared between the intervention and control group in the multilevel regression analyses. Time until a relapse of sickness absence will be examined by using Cox proportional hazard analysis to estimate hazard ratio’s for a relapse and the 95% confidence interval. In case no software is available to conduct these analyses in a multilevel structure, cluster level survival analyses will be conducted with means for each cluster. In these analyses, cluster size will be introduced as a weighting factor. To investigate differences between the intervention and control group in changes (improvement) on all secondary outcomes, multilevel longitudinal analysis will be used. Pre-planned subgroup analyses on type of CMD, line

manager participation in the study, size of the company, perceived decision latitude, type of work and expectancy to stay-at-work will be conducted.

Economic evaluation

The economic evaluation will be performed as a cost-benefit analysis from a societal perspective. For this evaluation, the primary outcome measure, i.e. the number of recurrent sickness absence days after return to work, will be expressed in monetary terms. The time window will be from return to work until 1 year follow-up. Discounting will not be applied. Both direct and indirect costs will be measured and valued. Costs of the intervention will be calculated by using the hourly wages of OPs. All contacts between the OP and the employee will be registered. The costs of health care consumption outside the intervention will be calculated by using tariffs of Dutch Guideline prices[47] based on information collected by the Tic-P questionnaire[42]. Out-of-pocket costs made by the employees in relation to their condition will also be included. The indirect costs of production losses due to sickness absence and presenteeism will be calculated by using the Friction costs method[48,49] according to the Dutch guidelines for economic evaluation[47].

DISCUSSION

This study is designed to investigate if employees, who have returned to work after a period of sickness absence because of a CMD, benefit from extra support during their first weeks of return to work. Effectiveness analyses will be performed to examine if the SHARP-at work intervention is successful in reducing recurrent sickness absence days compared to CAU. A cost-benefit analysis will be conducted to evaluate if the intervention is efficient, e.g. if better results are not at the expense of higher costs. Furthermore, the process of the intervention will be evaluated by inquiring employees, OPs and line managers on adherence to the protocol and satisfaction with the treatment. Finally, prognostic factors for a relapse of sickness absence will be investigated.

Methodological considerations

This study design has important strengths. First of all, the cluster-randomisation diminishes the risk of contamination of employees participating in the study. OPs are randomised in the intervention or control group, i.e. they will only treat employees, participating in the study, according to the SHARP-at work intervention or CAU. Furthermore, OPs in the intervention and control group work for different companies or for different departments of big companies. Hence, it is unlikely that employees in the intervention group will get in contact with employees in the control group. Additionally,

the pre-randomisation in the cluster design makes it possible to blind employees for the study condition. Another strength of this study is the combination of objective and subjective data. Recurrent sickness absence days are not only measured by asking the employees on days of sickness absence after their return to work, but also by the OHS's sickness absence registry system. Finally, the study covers a large geographical area in the Netherlands and companies of different sizes and sectors are included. This will make it possible to generalise the results to a relatively large working population.

A limitation of the study is the inclusion of participants by the OPs. The possibility exists that OPs in both study groups select those employees who have, in their view, good potential for fast recovery and small chances for a relapse of sickness absence. Although it has been stressed to all OPs to invite all employees eligible for the study, we cannot exclude the possibility of bias. Questions to investigate if participating employees were thought to be more suitable for the study are included in the process evaluation for OPs. Another possibility for bias to occur is the selection of employees who have a good relationship with their OP. Unfortunately, we cannot exclude this bias, but we ask questions in the process evaluation on the relationship between the OP and the employee. Finally, recruiting 500 employees for the study is a challenge. Most studies in this field have problems with recruiting participants. We have tried to minimise these problems by embedding this study in one large OHS. All participating OPs work for the same OHS and are stimulated to contribute to the study by this OHS. Moreover, we expect fewer refusals to participate because OPs invite employees to participate in the study. The OP has already built a relationship with the employee which will contribute to a safe environment to make the choice to participate in the study.

Relevance/impact of results

This study goes beyond return to work by focussing on sustainable work participation after return to work. It incorporates not only outcomes on sickness absence and mental health but also on health-related work functioning. The study has a high societal relevance because costs for sickness absence could be lowered and a sustainable working life could be facilitated. Furthermore, OPs and other occupational health professionals may benefit from the intervention as it could serve as an extension of the already existing guideline of the Netherlands Society of Occupational Medicine. Results of the study will become available in 2012.

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Prevention of recurrent sickness absence in workers with common mental disorders: Results of a cluster-randomised controlled trial

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ABSTRACT

Objectives: Workers with common mental disorders (CMDs) frequently experience recurrent sickness absence but interventions to prevent this are lacking. The goal of this study was to evaluate the effectiveness of the SHARP-at work intervention in preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

Methods: We performed a cluster-randomised controlled trial with 3, 6 and 12 months follow-up. Treatment providers were randomised to either a 2-day training in the SHARP-at work intervention, a problem solving intervention, or usual care. Primary outcome measures were the incidence of recurrent sickness absence and time to recurrent sickness absence. Secondary outcome measures were mental health complaints, work functioning and coping behaviour.

Results: 80 participants were randomised in the intervention group and 78 in the control group. The adjusted odds ratio for the incidence of recurrent sickness absence was 0.40 (95% confidence interval (CI) 0.20 to 0.81) and the adjusted hazard ratio for time to recurrent sickness absence was 0.53 (95% CI 0.33 to 0.86) for the intervention group compared to CAU.

Conclusions: This study demonstrates the 12-month effectiveness of a problem solving intervention for reducing recurrent sickness absence in workers with CMDs and emphasizes the importance of continuous attention for workers who have been on sickness absence due to CMDs.

Trial registration number: NTR1963.

INTRODUCTION

Common mental disorders (CMDs), such as depressive, anxiety and adjustment disorders, are an important contributor to the global burden of disease[1-4]. Besides the detrimental effects on the individual, CMDs have an enormous impact on society in terms of medical care consumption, work disability and associated costs[3,5-14]. Moreover, reduced job performance persists after clinical improvements in mental health complaints[15,16], and workers with CMDs frequently experience recurrent sickness absence. Recent findings from the Netherlands and Finland have shown that 20% to 30% of the workers who returned to work after sickness absence due to CMDs experience recurrent sickness absence. Moreover, the risk of sickness absence due to a CMD is higher in workers with previous sickness absence due to a CMD compared to a general worker population[17-19]. In several studies, cognitive behavioural and problem solving interventions have been evaluated for effectiveness in facilitating return to work (RTW) of workers on sickness absence due to CMDs[20-25]. These studies have used RTW as main outcome measure, but little attention has been given to preventing recurrent sickness absence. Recurrent sickness absence, however, has a major health impact because frequent sickness absence episodes are related to an increased risk of work disability in later years[19,26]. Furthermore, recurrent sickness absence after an initial sickness absence episode due to a CMD is often more serious and long-lasting[17]. Hence, interventions that focus on the treatment of workers with CMDs after RTW to prevent recurrent sickness absence are of paramount importance.

To our knowledge, no interventions have been developed and evaluated that focus on the prevention of recurrent sickness absence after RTW. This study aims to evaluate the effect of the Stimulating Healthy participation And Relapse Prevention at work (SHARP-at work) intervention, developed to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. The intervention was based on the guideline "Management of mental health problems of workers by occupational physicians" of the Netherlands Society of Occupational Medicine. This evidence-based guideline, developed in 2000 and revised in 2007, aims to facilitate RTW of workers on sickness absence due to mental health problems by OPs[28]. The guideline is effective in improving RTW in workers on sickness absence due to CMDs[20,29]. According to the guideline, one relapse prevention consultation has to take place after RTW, but this is rarely done by OPs[30]. The SHARP-at work intervention was developed to prevent recurrent sickness absence by structuring OP treatment after RTW. We hypothesize that compared to care as usual the SHARP-at work intervention (1) prevents recurrent sickness absence, (2) reduces mental health complaints and (3) enhances work functioning and problem solving coping.

METHODS

Study setting and participants

The study was designed as a cluster-randomised controlled parallel-group trial (cluster-RCT). Occupational physicians (OPs), responsible for conducting the intervention, were recruited through 365/ArboNed, one of the largest Occupational Health Services (OHS) in the Netherlands. Research participants were recruited by participating OPs. Inclusion criteria were: age 18 to 63 years; employed in a paid job; a diagnosis of a CMD given by the OP (based on ICD-10 codes) at the start of the sickness absence period; an episode of sickness absence of at least two weeks; a planned RTW within two weeks (so the intervention could start directly when a worker started RTW). Exclusion criteria were: a sickness absence episode >12 months; a prior sickness absence episode due to a CMD in the past three months; severe mental disorders, such as psychotic disorder or bipolar disorder; somatic complaints/disorders that would affect RTW; pregnancy, an upcoming retirement/resignation/lay-off; not able to read, write and understand Dutch. More detailed information on the study design can be found elsewhere[27]. The Medical Ethical Board of the University Medical Center Groningen provided approval for the study design, the research protocol, questionnaires, information letters, and the informed consent. Participants participated voluntarily in this study and signed an informed consent.

Interventions

SHARP-at work intervention

The intervention guides the workers through a five-step problem solving process to find and implement solutions for problems experienced when back at work. Consultations between the worker and supervisor are included in this process as research showed that the importance of the supervisor in the RTW process is stressed by workers and health care professionals[31,32]. The following five-step problem solving process had to be followed by the worker when RTW was started:

- Make an inventory of problems and/or opportunities encountered at work after RTW
- Brainstorm about solutions
- Write down solutions and the support needed and assess the applicability of these solutions
- Discuss solutions and make an action plan with the supervisor
- Evaluate the action plan/implementation of solutions

The OP started the intervention when the workers were in their first two weeks of RTW, monitored that all steps were taken and activated and supported the worker when needed. The role of the OP was to counsel the worker on the process level; not to comment on the content of the problems or solutions of the worker. The OP empowered the worker to define his own problems and design his own solutions. Two to five consultations were recommended to the OPs within three months after RTW started depending on what was necessary for the individual worker, but two consultations were set as a minimum to be able to conduct the intervention. In the Netherlands, OPs have about 30 minutes for a consultation, thus this was the length of the consultations in the intervention group. The first of five assignments (i.e. making an inventory of problems and opportunities and assessing the help needed to solve them) instigated the problem solving process and was therefore a key element. More detailed information on the intervention's content and process evaluation is described elsewhere (Arends et al., submitted).

OPs received a two-day training in the intervention, provided by experienced trainers in occupational health interventions. Three feedback moments of two hours were organised to jointly discuss problems and successes with conducting the intervention.

Care as usual

OPs of the OHS delivered care as usual (CAU) according to the guideline on "Management of mental health problems of workers by occupational physicians"[28]. No additional training of OPs in the control group was provided as part of the study.

Primary outcome measure

Recurrent sickness absence

Based on administrative data of the OHS, we measured recurrent sickness absence days and recurrent sickness absence incidence due to all causes at three, six and 12 months follow-up and time to first episode of recurrent sickness absence (measured in calendar days). Recurrent sickness absence was defined as ≥ 30% decrease in working days per week due to sickness absence, regardless of partial or full RTW. No limits were set on a minimum or maximum time period for which the ≥ 30% decrease should hold. When a worker returned to <30% decrease in working days per week, this was recorded as the end of the recurrent sickness absence episode. In the Netherlands, RTW is gradually built up, and, therefore, recurrent sickness absence could also occur during RTW and not only after full-time RTW. Recurrent sickness absence days were corrected for part-time sickness absence by dividing the sickness absence days by 1/RTW percentage.

Secondary outcome measures

Mental health complaints

The Hospital Anxiety and Depression Scale (HADS) was used to assess depression and anxiety (each 7 items). The questionnaire has been validated for working populations[33] and for the Dutch population[34]. Each item is scored on a 4-point Likert scale indicating the extent to which an item was experienced in the past week. The Four-Dimensional Symptom Questionnaire (4DSQ) was used to assess symptoms of distress, depression, anxiety and somatisation. The 4DSQ has been validated in a primary care and working population[35,36]. It consists of 50 items in four subscales (somatisation, distress, anxiety and depression) and is scored on a 5-point Likert scale ranging from 1 = no to 5 = very often or continuous. Lower scores indicate lower symptom levels.

Work functioning

Work functioning was assessed with the Work Role Functioning Questionnaire, which has been cross-culturally adapted to the Dutch language and is validated in the working population [37,38]. The WRFQ assesses the perceived difficulties in meeting work demands given physical or emotional problems. It contains 27 items, scored on a 5-point Likert scale from 100% (all of the time) to 0% (none of the time), with an option to score "not applicable." Scores are converted to 0 and 100, with higher scores indicating better work functioning.

Coping behaviour

Coping behaviour was assessed with the 14-item version of the Utrecht Coping List (UCL)[39]. The questionnaire consists of three (coping style) scales: (1) active problem focused coping, (2) emotional coping and (3) looking for distraction and decreasing tension. Each item is scored on a 4-point Likert scale ranging from 1 = seldom or never to 4 = very often. Lower scores indicate low usage of a certain coping style.

Sample size

The sample size calculation was based on the outcome of recurrent sickness absence days. Recurrent sickness absence days of a first recurrent episode (after full RTW) within one year were extracted from the OHS sickness absence registry, including 4443 workers. The variance in recurrent sickness absence days at OP level was taken into account. The mean number of days of recurrent sickness absence was 68.5 (SD=119.6). The target of the present study was to reduce recurrent sickness absence days with 20% (i.e. 12.7 days). We calculated that 25 OPs per group were needed, each providing five participants, in order to have 80% power to find a mean difference in decreased recurrent sickness absence days during 1 year follow-up of 12.7 days, assuming an alpha of 0.05 and an intraclass correlation coefficient of 0.05[40].

Randomisation

Randomisation took place at OP level because participants could not be randomly assigned to OPs. A computerised random allocation sequence was developed by an independent statistician to randomise the OPs over the SHARP and the CAU group. When all OPs were recruited, the independent researcher, who was blinded to the identity of the OPs, used the allocation sequence to randomise the OPs. After randomisation, the allocation of the OPs could not be changed and the statistician informed the researchers about OP allocation.

Blinding

In this pre-randomised trial, the allocation of the participants was already decided based on the allocation of their OPs. Therefore, we were able to provide different information about the study to the intervention and control group[41]. Participants were blinded for study design and group comparison. Blinding OPs for allocation was not possible. An independent researcher at the OHS, blinded for study group, collected the administrative data on recurrent sickness absence days.

Statistical analyses

Baseline characteristics of the participants were compared to assess the success of randomisation. Per follow-up measurement, the number of workers with a recurrence and the median number of recurrent sickness absence days were calculated per study group. We predefined the following potential confounders based on previous research[42-45]: age, sex, educational level, mental health complaints and days of sickness absence at baseline. All outcome measures were assessed at baseline and at three, six and 12 months follow-up.

Primary outcome measures

Differences in number of recurrent sickness absence days between the two treatment groups were not analysed because of the skewed distribution; at each follow-up measurement, more than 50% of the study population had no recurrent sickness absence days. We examined the difference in incidence of recurrent sickness absence between the two treatment groups during follow-up with multilevel longitudinal regression analyses to account for the three-level design. In addition, we included interaction terms of treatment X time to assess whether he difference between the two groups changed between the three follow-up measurements. Crude analyses were followed by analyses adjusted for the predefined confounders. Kaplan-Meier survival analyses were conducted to compare time to first recurrent sickness absence episode in the two treatment groups. Participants were censored when lost to follow-up or when recurrent sickness absence had not occurred at the end of the 12 months follow-up

period. The cox proportional hazard model was used to estimate hazard ratios (HR). The proportional hazard assumption was tested[46]. A separate model was run to adjust for the predefined confounders. No clustering effect was found in the multilevel logistic regression analyses, i.e. we did not adjust for clustering in the cox model.

Secondary outcome measures

To assess differences between the two treatment groups on mental health complaints, work functioning and coping behaviour, linear mixed models with unstructured covariance matrices were used.

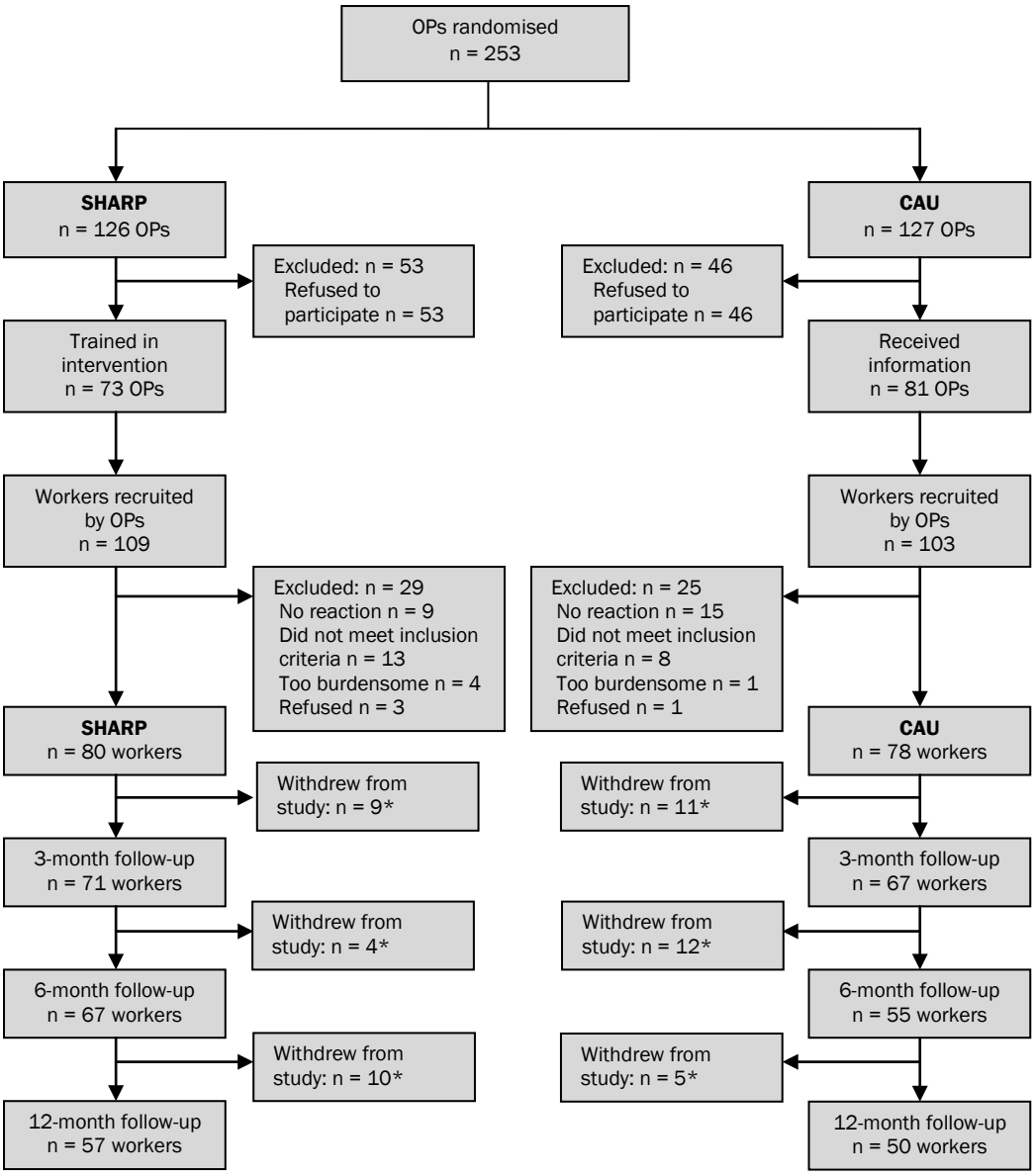
Effect modification

We analysed modification of the group effects by size of company, decision latitude and readiness to stay at work. Company size was assessed with one single question and dichotomised to <100 workers versus >100 workers. Decision latitude was assessed with the Job Content Questionnaire[47,48]. Items were scored on a 4-point Likert scale ranging from 1 = totally disagree to 4 = totally agree. Scores were divided into the following tertiles: 34-64, 65-72 and 73-92). Readiness to stay at work was assessed with the Readiness to Stay at Work Scale[49]. Scores were divided at the 50% percentile to form two groups (scores 10-20 and scores 21-29). Subgroups were too small to conduct subgroup analyses on ICD-10 diagnosis, supervisor participation in the RTW process and type of occupation.

All analyses were performed according to the intention-to-treat principle. We used MLwiN, version 2.23 and SPSS, version 20.0, for the analyses.

RESULTS

Between January 2010 and June 2011, OPs recruited 212 workers. Of these workers, 158 agreed to participate in the study. Recruitment fell short according to the sample size calculation and reasons for the recruitment problems have been described extensively elsewhere (Arends et al., submitted for publication). Workers who did not want to participate did not significantly differ from those who agreed to participate with regard to gender and age. The participant flow and reasons for non-participation are presented in Figure 1. Of the 158 included participants, 80 participants were randomised to the SHARP group and 78 participants to the CAU group. Table 1 shows the baseline characteristics of the participants in both groups. Follow-up measurements ended in June 2012.



SHARP = intervention group; CAU = care as usual group; OP = occupational physician.
*Reasons for withdrawal from the study for the intervention group were: health problems (n = 1), research too burdensome (n = 2), a new OP (n = 1), pregnancy (n = 1), no time (n = 2), job loss (n = 2) or unknown (n = 14). Reasons for the control group were: health problems (n = 1), research too burdensome (n = 1), job loss (n = 2), refused (n = 2), no time (n = 2) or unknown (n = 20). Numbers pertain to the secondary outcome measures.

Figure 1. Flowchart of participant recruitment, allocation and outcome assessment.

Table 1. Worker characteristics per study group.

Characteristics		SHARP (n = 80) M / n	SD / %	CAU (n = 78) M / n	SD / %
Socio-demographic characteristics					
Age (years)		41.3	9.4	43.3	9.8
Gender (male)		27	33.8	38	48.7
Marital status (married or living together)		67	83.8	60	76.9
Breadwinner (yes)		40	50.0	49	62.8
Education level					
Low		6	7.5	13	16.7
Intermediate		36	45.0	40	51.3
High		38	47.5	23	29.5
Clinical characteristics					
ICD diagnosis by OP					
F32.9 Depressive episode, unspecified		4	5.0	12	15.4
F41.9 Anxiety disorder, unspecified		0	0.0	2	2.6
F43.2 Adjustment disorders		58	72.5	39	50.0
F43.9 Reaction to severe stress, unspecified		1	1.25	0	0.0
R45 Symptoms and signs involving emotional state		7	8.75	14	17.9
Z73.0 Burn-out		2	2.5	7	9.0
Other		8	10.0	4	5.1
Work-related characteristics					
Type of occupation					
Commercial service providers		23	28.8	11	14.1
Management		11	13.8	15	19.2
Administrative staff		19	23.8	12	15.4
ICT staff		4	5.0	4	5.1
Sales staff		2	2.5	5	6.4
Health care providers		12	15.0	12	15.4
Hotel and catering staff		3	3.8	0	0.0
Stock and/or transport staff		1	1.3	11	14.1
Designers/planners		3	3.8	2	2.6
Mechanics/repairmen		2	2.5	5	6.4
Employment (hours per week)		32.6	7.0	32.9	7.3
Irregular work (e.g. shift work)		6	7.5	10	12.8
Executive/manager responsibilities		23	28.8	21	26.9
WRFQ-Total score		66.9	15.5	61.0	20.0
RTW %		48.7	32.2	43.1	27.2
Duration of sickness absence		130.9	94.2	99.3	66.1
Health-related characteristics					
4DSQ	Distress	13.8	7.5	15.5	7.5
	Depression	1.5	2.1	2.0	2.4
	Anxiety	3.1	3.3	3.6	3.5
	Somatisation	7.9	5.3	7.9	5.5
HADS	Depression	7.0	4.5	7.3	4.4
	Anxiety	7.2	3.9	7.8	3.4

SHARP = intervention group; CAU = care as usual group; OP = occupational physician; WRFQ = Work Role Functioning Questionnaire; 4DSQ = Four-Dimensional Symptom Questionnaire; HADS = Hospital Anxiety and Depression Scales; M = mean; SD = standard differentiation.

Loss to follow-up

Administrative data on recurrent sickness absence at three, six and 12 months follow-up and time to recurrent sickness absence were available for 147 participants (N=72

for the SHARP group and N=75 for the CAU group). For six participants, administrative data could not be retrieved. Furthermore, one participant who became pregnant and experienced pregnancy-related complaints and four participants who left their company during follow-up were censored. For the self-reported outcomes, 20 participants did not respond at three months follow-up, 36 participants at six months follow-up and 51 participants at 12 months follow-up. Reasons for non-response per study group are reported in Figure 1. No significant differences were found between respondents and non-respondents for age, sex, educational level, mental health complaints and duration of sickness absence at baseline.

Non-compliance

At three months follow-up, 67 participants of the SHARP group completed a questionnaire on received intervention components. Of this group, 43 (64%) participants reported that they had two or more consultations with the OP and had made the first intervention assignment.

Co-interventions

In the intervention group, two participants (2.5%) reported that they visited a psychiatrist, 34 (42.5%) a psychologist (mean number of visits in a 4-week period was 1.6) and one (1.3%) a social worker. Seven participants (9%) reported that they used psychopharmacologic medication. In the control group, nine participants (12%) reported that they visited a psychiatrist, 21 (27%) a psychologist (mean number of visits in a 4-week period was 1.7) and three (3.8%) a social worker. Psychopharmacologic medication was used by 15 participants (19%).

Recurrent sickness absence

Compared to CAU, the SHARP group had a lower incidence of recurrent sickness absence. In both groups, the median number of recurrent sickness absence days was 0 at all follow-up measurements, but there were some differences between the 75th percentiles of the two groups (Table 2). The multilevel logistic regression analyses showed that, when adjusted for confounders, the OR for recurrent sickness absence of the SHARP group compared to CAU was 0.40 (95% CI 0.20 to 0.81). Analysis of the interaction between group and time showed that the effect of the SHARP-at work intervention on recurrent sickness absence did not significantly differ at the different time points (Table 3). None of the subgroup analyses on company size, decision latitude and readiness to stay at work showed a significant interaction with treatment group on the incidence of recurrent sickness absence.

Table 2. Number of workers with a recurrent sickness absence episode and the duration of recurrence in the SHARP and CAU group

	SHARP			CAU		
Outcome	T1	T2	T3	T1	T2	T3
Recurrence, n (%)	8 (11)	15 (21)	24 (34)	17 (22)	29 (39)	35 (47)
Recurrent sickness absence days, median (IQR)	0 (0-0)	0 (0-0)	0 (0-5)	0 (0-0)	0 (0-4)	0 (0-8)

SHARP = intervention group; CAU = care as usual group; IQR = interquartile range 25th – 75th percentile; T1 = 3 months, T2 = 6 months, T3 = 12 months.

Time to recurrent sickness absence

Figure 2 shows the cumulative survival curves of time to first recurrent sickness absence episode for the SHARP and CAU group. Because the event was defined as first recurrent sickness absence, longer survival indicated a favourable outcome. The SHARP group had a median of 365 days (inter quartile range (IQR) 174 to 365) to recurrent sickness absence and the CAU group had a median of 253 days (IQR 117 to 365) (Log Rank test; p = 0.003). When adjusted for confounders, time to recurrent sickness absence was significantly longer in the SHARP group compared to the CAU group (adjusted HR = 0.53, 95% CI 0.33 to 0.86). No violation was found of the proportional hazards assumption based on three analyses of interactions between treatment group and dichotomised time variables. The three time variables were constructed using three different cut-off points based on time points in the survival plot that seemed to indicate a change in survival between the two groups (at 100, 150 and 200 days).

Mental health complaints, work functioning and coping behaviour

The effect of the intervention on mental health complaints, work functioning and coping behaviour are presented in Table 3. Both treatment groups improved on mental health complaints and work functioning. No clear differences were found between the two groups on mental health complaints at the follow-up measurements. The SHARP group had a better score on work functioning at 12-month follow-up and slightly higher usage of all three coping behaviours at all follow-up measurements. No significant group X time interaction was found for mental health complaints, work functioning and coping behaviour.

Table 3. Multilevel regression analyses of differences in incidence of recurrent sickness absence, mental health complaints, work functioning and coping behaviour between the SHARP-at work intervention and CAU

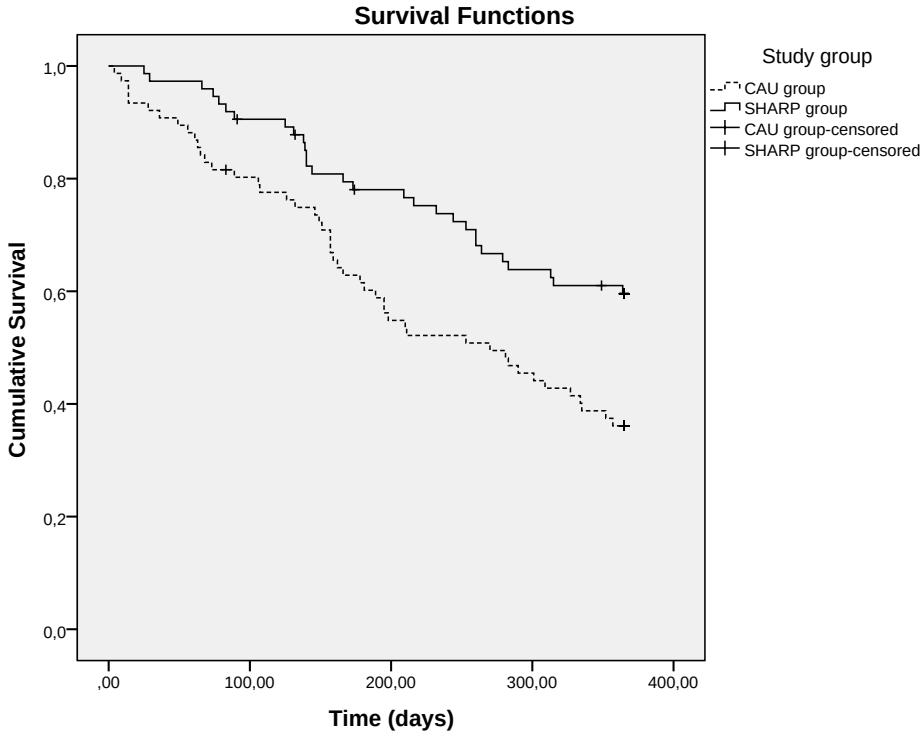
	T1 (3 months)			T2 (6 months)			T3 (12 months)		
Primary outcome[1]	OR	95% CI Lower	Upper	OR	95% CI Lower	Upper	OR	95% CI Lower	Upper
Incidence of recurrent sickness absence	0.32	0.06	1.83	0.28‡	0.09	0.85	0.45	0.17	1.23
Secondary outcomes[2]	B	95% CI Lower	Upper	B	95% CI Lower	Upper	B	95% CI Lower	Upper
4DSQ-Somatisation	0.69	-1.44	2.83	1.43	-0.80	3.66	1.71	-0.64	4.05
4DSQ-Distress	0.97	-2.00	3.94	1.69	-1.45	4.82	0.95	-2.38	4.27
4DSQ-Anxiety	0.66	-0.45	1.76	1.16	-0.01	2.33	0.64	-0.59	1.87
4DSQ- Depression	-0.03	-0.76	0.70	1.08*	0.30	1.86	0.59	-0.25	1.42
HADS-Anxiety	0.59	-0.33	1.51	1.06*	0.08	2.04	0.61	-0.43	1.65
HADS-Depression	-0.79	-1.87	0.29	0.48	-0.67	1.62	0.85	-0.36	2.06
WRFQ-Total score	-3.62	-9.01	1.76	1.08	-4.69	6.85	3.56	-2.64	9.75
UCL-Problem focused	0.14	-0.70	0.98	-0.39	-1.28	0.51	0.59	-0.35	1.53
UCL-Emotional	-0.37	-1.05	0.31	0.37	-0.35	1.09	0.05	-0.71	0.81
UCL-Distraction	0.78*	0.07	1.49	0.38	-0.38	1.14	0.42	-0.39	1.23

4DSQ = Four-Dimensional Symptom Questionnaire; HADS = Hospital Anxiety and Depression Scales; WRFQ = Work Role Functioning Questionnaire; UCL = Utrecht Coping List, OR = odds ratio; B = mean difference between SHARP and CAU.

[1]Analyses were corrected for age, gender, educational level, mental health complaints and sickness absence days at baseline.

[2]Analyses were corrected for baseline values, age, gender, educational level and sickness absence days at baseline.

*P < 0.05.



CAU = care as usual (n = 76); SHARP = intervention group (n = 74).

Figure 2. Cumulative probability of recurrent sickness absence from baseline measurement to 12 months follow-up per study group.

DISCUSSION

Our primary aim was to evaluate if the SHARP-at work intervention was effective in preventing recurrent sickness absence compared to CAU. At each follow-up measurement, the incidence of recurrent sickness absence was lower in the SHARP group compared to the CAU group. The adjusted OR for the incidence of recurrent sickness absence was 0.40 (95% CI 0.20 to 0.81) in favour of the SHARP group. At six months follow-up, i.e. three months after the intervention was finished, the biggest difference was found between the SHARP and CAU group in incidence of recurrent sickness absence. However, no significant interaction was found between group and time indicating that the effect of the SHARP-at work intervention did not significantly differ between three, six and 12 months follow-up. Time to first recurrent sickness absence episode was significantly longer in the SHARP group compared to the CAU

group (median number of 112 days longer for the SHARP group). The expected effects on improved work functioning and problem solving coping and reduced mental health complaints were not observed.

Currently, no other studies have been published on the effects of an intervention to prevent recurrent sickness absence in workers with CMDs. Van der Klink et al. (2003), evaluated an intervention that was primarily aimed at enhancing RTW in workers with adjustment disorders, but also the effect on recurrent sickness absence was analysed. The authors found no significant differences between the intervention and control group on incidence of recurrent sickness absence and time to recurrent sickness absence[20]. Although the SHARP-at work intervention is comparable to the intervention of van der Klink et al., the different results might be explained by the different timing of the interventions. Whereas the intervention of van der Klink et al. took place at the start of and during the sickness absence period and focused on helping the worker to RTW, the SHARP-at work intervention is offered when a worker has started RTW and focuses on the prevention of recurrent sickness absence and helping the worker to stay at work. The process evaluation, which was conducted alongside the effect evaluation, showed that the intervention was conducted as planned. Compared to the CAU group, participants in the SHARP group had significantly more often ≥2 consultations with the OP and ≥1 consultation with the supervisor and made significantly more assignments (Arends et al., submitted for publication). Therefore, we conclude that the observed effect on recurrent sickness absence is due to the intervention. The SHARP-at work intervention could be used as an extension of the intervention of van der Klink et al. (which has become a guideline for OPs in the Netherlands), reinforcing the problem solving process at the moment workers are back at work and preventing recurrent sickness absence. Our finding that the SHARP-at work intervention did not cause significant reductions in mental health complaints compared to CAU, is corroborated by findings of several other studies on the effectiveness of different types of interventions (e.g. cognitive behavioural treatment, problem solving treatment and occupational therapy) to enhance RTW in workers with mental health problems[20-23]. Thus, the effect on recurrent sickness absence cannot be explained through a mediating effect of better mental health. In the literature, explanations for the lack of effect on mental health complaints vary. It has been suggested that usual care is of such quality that a difference in symptom level is hard to achieve or that natural recovery may hinder the detection of treatment effects[21]. Another explanation could be that the interventions are primarily aimed at improving social functioning and not the reduction of mental health complaints[21], as is the SHARP-at work intervention. Finally, participants might already have a higher level of mental health complaints before they develop a mental disorder (trait effect)[50].

Strengths and limitations

A strength of this study is the cluster-randomised design which allowed participant blinding. Participants knew the study was aimed at investigating the treatment process after the start of RTW but were unaware that groups were compared. Because participants were recruited by OPs that worked for companies of different sizes, in different sectors and in different parts of the Netherlands, our study population was quite diverse regarding type of occupation, company size and geographical location. This enhances the generalizability of our results. A problem of the study is that we could not recruit the number of participants according to the sample size calculation. Furthermore, the sample size calculation was based on the outcome of recurrent sickness absence days which we were not able to analyse due to a very skewed distribution. However, we were able to detect relevant differences between the SHARP and CAU group for the incidence of recurrent sickness absence and time to recurrent sickness absence. The distribution of baseline characteristics between the SHARP and CAU group showed that there were some differences between the two groups regarding gender, educational level and sickness absence days. For the variable "educational level," this was probably due to selection bias by OPs in the SHARP group. During feedback moments, OPs mentioned that it was easier to conduct the intervention with more highly educated workers, and as the baseline data show, participants in the SHARP group were more highly educated. All analyses were adjusted for baseline differences in educational level, sickness absence, gender, age and mental health complaints. However, the results might not be generalisable to workers with a low educational level. Finally, we could not distinguish between different causes of recurrent sickness absence because the reasons for the recurrences were not consistently registered in the administrative database.

Future research

Although the incidence of recurrent sickness absence was significantly lower in the SHARP group compared to the CAU group, the SHARP group had a considerable amount of recurrent sickness absence episodes at six and 12 months follow-up (21% and 34% respectively). Because the SHARP-at work intervention took place during the first three months following return to work, future research should investigate whether follow-up "booster" treatment after six months might help to further reduce recurrent sickness absence and enhance mental health and work functioning. It would be interesting to investigate the long-term effects of the intervention. Furthermore, an in-depth investigation of the specific characteristics of the group of workers that experience recurrent sickness absence, persistent mental health complaints and work functioning problems can help to focus the intervention on the needs of the most vulnerable group. Although both the SHARP and CAU group showed a reduction in

mental health complaints, both groups still had relatively high scores on some of the mental health scales at 12 months follow-up. In addition, both treatment groups showed improvements in work functioning over time, but after 12 months follow-up the mean score on work functioning was still lower compared to a healthy working population[38]. Possibly, not being fully recovered from mental health complaints impedes optimal work functioning, which would explain why both study groups still had sub-optimal work functioning scores. For example, in a recent study, Lerner et al. (2012) found that a work-focused intervention for workers with depression, who were not on sickness absence, decreased depression symptom severity and increased at-work performance[51]. Future research needs to focus on how reductions in mental health complaints and improvements in work functioning can be accomplished for workers who have returned to work after sickness absence due to CMDs. Furthermore, research would benefit from including outcome measures related to social functioning, such as colleague/supervisor support.

Implications

For workers who returned to work after sickness absence due to CMDs, the SHARP-at work intervention is effective in reducing the incidence of recurrent sickness absence. Our study demonstrates that continuous attention is needed for workers who have been on sickness absence due to CMDs. Before implementation of this intervention in practice, the economic benefit of the intervention also needs to be demonstrated.

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5

Process evaluation of a problem solving intervention to prevent recurrent sickness absence in workers with common mental disorders

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ABSTRACT

Common mental disorders (CMDs) are a major cause of sickness absence. Twenty to 30% of the workers who returned to work after sickness absence due to CMDs experience recurrent sickness absence. We developed the SHARP-at work intervention, a problem solving intervention delivered by occupational physicians (OPs), to prevent recurrent sickness absence in this worker population. A process evaluation was conducted alongside a cluster-randomised controlled trial to (1) evaluate whether the SHARP-at work intervention was implemented according to the protocol and differed from treatment in the control group, and (2) to investigate the relationship between the key elements of the intervention and the effect outcome (i.e. recurrent sickness absence). We collected process data for the intervention and control group on recruitment, reach, dose delivered, dose received, fidelity, context and satisfaction. Data on recurrent sickness absence was collected through the registry system of the collaborating occupational health service. The study was performed in the Netherlands. Between 2010 and 2012, 154 OPs and 158 participants participated. Compared to the control group, participants in the intervention group more frequently had two or more consultations with the OP (odds ratio [OR] = 3.2, 95% confidence interval [CI] = 1.2 to 8.8) and completed more assignments (OR = 33.8, 95% CI = 10.4 to 109.5) as recommended in the intervention protocol. OPs and participants were satisfied with the intervention and rated it as applicable. Several individual intervention components were linked to the effect outcome. The process evaluation showed that the SHARP-at work intervention was conducted according to the protocol for the majority of the participants and well-received by OPs and participants. Furthermore, the intervention differed from treatment in the control group. Overall, the results provide support for implementing the intervention in practice.

INTRODUCTION

In many Western countries, common mental disorders (CMDs), such as depression, anxiety and adjustment disorders, are highly prevalent in the labour force[1-3]. CMDs do not only cause sickness absence and work disability[1,4-8], but are also related to on-the-job productivity loss because of reduced work functioning[9-11]. To reduce the individual and societal burden of sickness absence due to CMDs, interventions have been developed to facilitate return to work (RTW)[12-18]. The primary goal of these interventions is to get the worker back to work, though research has shown that 20% to 30% of the workers who return to work after sickness absence due to CMDs experience recurrent sickness absence[19,20].

To prevent recurrent sickness absence in workers who have been on sickness absence due to CMDs, the "Stimulating Healthy participation And Relapse Prevention (SHARP)-at work" intervention was developed[21]. The intervention is provided by occupational physicians (OPs) and aims to guide workers through a problem solving process, to solve new arising problems and realise improvements when back at work. Furthermore, the supervisor is involved to enable practical solutions that can be implemented. The intervention was evaluated in a cluster-randomised controlled trial (cluster-RCT), and the effect evaluation showed that the intervention group had a significantly lower incidence of recurrent sickness absence compared to the control group (Arends et al., submitted for publication).

Although an effect evaluation is often the primary goal of intervention research, it does not provide insight into why and how an intervention was successful or failed. This impedes the generalisability and implementation of intervention results[22-24]. A process evaluation can be conducted to collect data about how interventions were planned and implemented. A properly conducted process evaluation can help explain the success or failure of finding a relationship between the intervention and the outcome(s) of interest. Kristensen (2005) emphasised the importance of distinguishing between theory and program failure[25]. When an intervention is delivered and received as planned but no effect of the intervention is found, theory failure is plausible. However, when an intervention is poorly executed (i.e. not delivered or received according to the protocol), this indicates program failure and no conclusions should be drawn about the effectiveness of the intervention. [22,25]. The process evaluation framework of Steckler and Linnan (2002) can be related to the theoretical model of Kristensen because in this framework the different elements are specified that need to be evaluated to understand whether program failure occurred. Steckler and Linnan summarised the elements of a process evaluation into seven components: fidelity (quality), recruitment, reach (participation rate), dose delivered (completeness), dose received (exposure), implementation and context[26].

Previous research on process evaluations of occupational intervention studies has been fragmented and unstructured[23,27]. Especially, the linkage of process variables (e.g. reach, dose received) to effect outcomes to investigate which elements of an intervention are related to the effects is often missing. Murta et al. (2007) performed a systematic review of process evaluations conducted for occupational stress management programs and found that only 46% of the 84 included studies made an explicit link between process evaluation variables and the outcome[23].

This study reports on a theoretically founded and structured process evaluation of the SHARP-at work intervention. The framework of Steckler and Linnan was used to develop, plan and guide the process evaluation[23,24,26]. The aims of the study were: 1) to evaluate whether the SHARP-at work intervention was conducted according to the protocol and differed from care as usual, and 2) to investigate the relationship between the key elements of the intervention and the effect outcome of the trial (i.e. recurrent sickness absence).

METHODS

Design

The process evaluation was part of a cluster-RCT in which the effectiveness of the SHARP-at work intervention was evaluated on the prevention of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. The trial was conducted in the Netherlands. OPs were randomised into intervention and control groups. Workers were recruited by the OPs and their allocation followed the allocation of their OP. For more detailed information on the design of the cluster-RCT, see Arends et al. (2010)[21].

Participants

OPs were recruited from one of the largest occupational health services (OHS) in the Netherlands. All OPs were eligible except those with an upcoming retirement, resignation, sabbatical or pregnancy leave. After the recruitment and training of OPs, workers between 18 and 63 years were invited by their OP to participate in the study. Participants had to be diagnosed by their OP with a CMD at the start of their sickness absence period (of at least two weeks) and had to have planned RTW within two weeks. Detailed information on exclusion criteria can be found elsewhere[21].

Procedure

The Medical Ethical Board of the University Medical Center Groningen approved the study design, research protocol, questionnaires, information letters, and the informed consent. After workers were recruited by their OP and consented to participate in the

study, they received the baseline questionnaire. Following this, the OPs in the intervention group initiated the intervention. OPs in the control group continued with treatment according to care as usual. Three months post baseline, questionnaires were sent to participants and OPs including questions about the treatment process.

Intervention

OPs received a two-day training in the SHARP-at work intervention which was provided by experienced trainers in occupational health care interventions and guideline training. Three feedback moments (approximately 6, 12 and 18 months after the intervention training) were organised to discuss problems and successes with conducting the intervention.

The SHARP-at work intervention expands on the guideline of the Netherlands Society of Occupational Medicine on "Management of mental health problems of workers by occupational physicians"[28,29]. This is an evidence-based guideline directed at structuring OP's treatment to help sick-listed workers with mental health problems to RTW. The goal of the guideline is to help workers regain control by activating them to go through a problem solving process to find and implement solutions for problems that caused sickness absence and hinder RTW. This is in line with patient empowerment theories which state that treatment should be aimed at helping patients to get a sense of control, self-determination and goal attainment[30,31]. Though relapse prevention is part of the guideline (one consultation has to take place after RTW to address relapse prevention), limited attention is given to a structured follow-up by OPs after RTW has been accomplished. The SHARP-at work intervention was developed to focus on the prevention of recurrent sickness absence by structuring OP's guidance after RTW. The intervention was started by OPs when participants on sickness absence due to CMDs were ready to RTW and consisted of five steps which had to be followed by the participant when RTW was started. The OP monitored that all steps were taken and activated the participant when needed. The five steps comprised: (1) making an inventory of problems and/or opportunities encountered at work after RTW, (2) brainstorming about solutions, (3) writing down solutions and the support needed and assessing the applicability of these solutions, (4) discussing solutions and making an action plan with the supervisor, and (5) evaluating the action plan/implementation of solutions.

For each step of the intervention, the OP could give assignments to stimulate the participant to write down and structure the problem solving process. The first assignment was the key assignment and focused on making an inventory of problems and opportunities at the workplace. A separate component of the assignment was to decide whether help was needed to solve/realise problems/opportunities (options: A. the participant could do it him-/herself; B. help of someone else was needed; C. it was

unsolvable at the moment). This first assignment was meant to activate the participant to reflect on his/her work situation when back at work. The other four assignments were: writing down solutions, preparing a consultation with the supervisor, making an action plan and evaluating the problem-solving process. The role of the OP was to guide the participant on the process level. The content of problems and solutions was not discussed by the OP. Rather, the OP empowered the participant to define the problems and to design solutions. Furthermore, the OP had to stimulate the participant to reflect on the significance of problems and the feasibility of solutions. When the participant was ready to discuss problems, opportunities and solutions with the supervisor, the OP could join this conversation as a neutral third party if requested by the participant. Two to five consultations within three months were recommended to the OPs for conducting the intervention.

Care as usual

All participating OPs have been trained in the evidence-based guideline of the Netherlands Society of Occupational Medicine "Management of mental health problems of workers by occupational physicians"[29] which has been described above. No additional training of OPs in the control group was part of the study and they were not familiar with the SHARP-at work intervention.

The process evaluation

The process evaluation was based on Steckler and Linnan's framework and included the components: recruitment, reach, dose delivered, dose received, fidelity and context. Additionally, as recent research and debates on process evaluation have suggested that Steckler and Linnan's framework needs to be extended with other concepts, such as stakeholders' beliefs and attitudes[23,32], we added a component on OPs' and participants' satisfaction with the intervention.

Data collection

Administrative data on the trial's primary outcome, incidence of recurrent sickness absence (yes/no), were collected during the 12-month follow-up period from the OHS' registry. At 3-months follow-up, the components of the process evaluation were assessed with questionnaires. Data on the components were collected on OP and participant level in the intervention and control group. Fidelity was not assessed in the control group as this component relates to the extent to which the intervention was delivered as planned which is not applicable for the control group. The different components of the process evaluation were operationalised as follows:

Recruitment

OP level

The number of OPs that agreed to participate in the study. OPs were recruited through a large OHS. The OHS' research coordinator randomly selected several group practices (i.e. clinical units in which OPs are organised) and invited all OPs in these group practices to participate in the study.

Participant level

The number of participants that agreed to participate in the study by filling out the baseline questionnaire. Participants were recruited by OPs.

Reach

OP level

The number of OPs randomised into the intervention group who completed the intervention training and the number of OPs randomised in the control group who participated in the information session on the study's procedure.

Participant level

The number of consultations between (1) the participant and the OP, (2) the participant and the supervisor and (3) the participant, the OP and the supervisor. The number of consultations between the participant and the OP was categorised into <2 consultations or ≥2 consultations as a minimum of two consultations was advised to the OPs in the intervention group. For the other two components of reach, the number of consultations was categorised into <1 consultation or ≥1 consultation.

Dose delivered

OP level

Dose delivered was assessed at the OP level by questioning OPs and participants about the number and type of assignments given to the participant by the OP. Furthermore, participants were asked two questions on whether the OP stimulated them to be actively involved in the consultations and to make their own decisions. Both aspects were stressed during the training in the intervention for the OPs. The questions were scored on a five-point Likert scale from 1 = *totally disagree* to 5 = *totally agree*, with the option to choose *not applicable*.

Dose received

Participant level

Dose received was assessed at the participant level by questioning OPs and participants about the number and type of assignments completed by the participant.

Additionally, participants were questioned about the number and type of topics discussed between the OP and the participant (a selection of seven topics related to the five intervention steps was given, with the option of an open answer).

Fidelity

OP level

The number of participants to whom the two key elements of the intervention was delivered by the OP: i.e. two consultations with the OP and the first intervention assignment.

Participant level

The number of participants who had two consultations with the OP and completed the first intervention assignment.

Context

Participant level

Factors related to the private and work environment of the participant that could have influenced the treatment or the trial outcome (i.e. recurrent sickness absence). The incidence of a major life event in private life was measured with one question at baseline: "Did you experience any stressful life events in the past year, such as a serious illness, an accident, death, a divorce?" (yes/no). The influence of the work environment was measured with six statements for both participant and OP. One question focused on organisational changes during RTW that influenced the participant (yes/no) and a second question asked how these changes were experienced (positive, negative, neither positive nor negative). Furthermore, four statements were formulated regarding contextual factors at work that might have influenced the intervention or the trial outcome (see Appendix 1). The statements were scored on a five-point Likert scale (1 = *totally disagree* and 5 = *totally agree*, with the option to choose *not applicable*).

Satisfaction

OP and participant level

First, satisfaction was assessed by seven statements about the process of the treatment (see Appendix 1) and were rated on a five-point Likert scale (1 = *totally disagree* and 5 = *totally agree*, with the option to choose *not applicable*). Second, the OP and the participant were asked to indicate what was most helpful for the participant during the post-RTW phase. The following options could be selected: consultations with the OP; consultations with the supervisor; consultations with both the OP and supervisor; the assignments; and something else (with open space to respond).

Data analysis

Descriptive statistics were generated on the components of the process evaluation for the intervention and control group. Multilevel logistic regression analyses (with 2nd order penalised quasi-likelihood as estimation method) and multilevel linear regression analyses were performed to investigate whether differences between the two groups on reach, dose delivered, dose received, context and satisfaction were significant. We used multilevel analysis to control for dependency of participants within OP's.

To investigate the relationship of the different intervention components with recurrent sickness absence, multilevel logistic regression analyses were performed with recurrent sickness absence at three, six and 12 months follow-up as the dependent variable and the components of the intervention as independent variables. The responses of the participants were used for these analyses, as the participants were blinded for their allocation status, as opposed to the OPs who were not blinded. The intervention components that constituted the key elements of the intervention were added in a multivariable multilevel logistic regression analysis. The following components were considered to constitute the core of the intervention: (a) number of consultations between the OP and the participant (2≤ consultations or ≥2 consultations); (b) number of consultations between the supervisor and the participant (1≤ consultations or ≥1 consultations); (c) having completed the problem inventory assignment (yes/no) and (d) the inventory on whether help is needed with solving problems or realising opportunities (yes/no) (these inventories together constitute the first intervention assignment); (e) having discussed with the OP problems at work (yes/no); (f) having discussed with the OP possible opportunities at work (yes/no); (g) having discussed with the OP solutions for the problems (yes/no); (h) having discussed with the OP how to realise opportunities (yes/no). Additionally, the relationship between the sum score of the total number of components received (0-8) and the incidence of recurrent sickness absence was investigated to assess whether having received more intervention components was related to a lower risk of recurrent sickness absence. We used an alpha of <0.05 to indicate statistical significance. We did not control for potential confounders because the small sample size did not allow many variables in the regression model. Furthermore, potential confounders (i.e. sex, age, educational level, baseline symptom severity and number of sickness absence days) did not significantly correlate with the outcome recurrent sickness absence. Analyses were performed with SPSS (20.0) and MLwiN (2.23).

RESULTS

Tables 1 and 2 present the baseline characteristics of the OPs and participants for the intervention and control group. Tables 3 and Table 4 present the responses of the

participants and OPs on the components reach, dose delivered, dose received, fidelity, context and satisfaction. Below, the results of each process evaluation component are summarised.

Table 1. OP characteristics per study group.

	SHARP (n = 73)		**CAU (n = 81)**	
Characteristics of OPs	M / n	SD / %	M / n	SD / %
Age (years)	49.9	7.6	50.5	6.9
Gender (male)	42	58.0	52	64
Years working for OHS	10.0	4.9	11.1	8.4
Working area in the Netherlands				
North	6	8	8	10
East	9	12	12	15
West	38	52	40	49
South	9	12	17	21
Sector				
Small/medium sized businesses	41	56	47	58
Large businesses	29	40	32	40

Note. SHARP = intervention group; CAU = care as usual group; OP = occupational physician; OHS = occupational health service.

Recruitment

OP and participant level

Figure 1 provides a detailed overview of the recruitment process of OPs and participants.

Reach

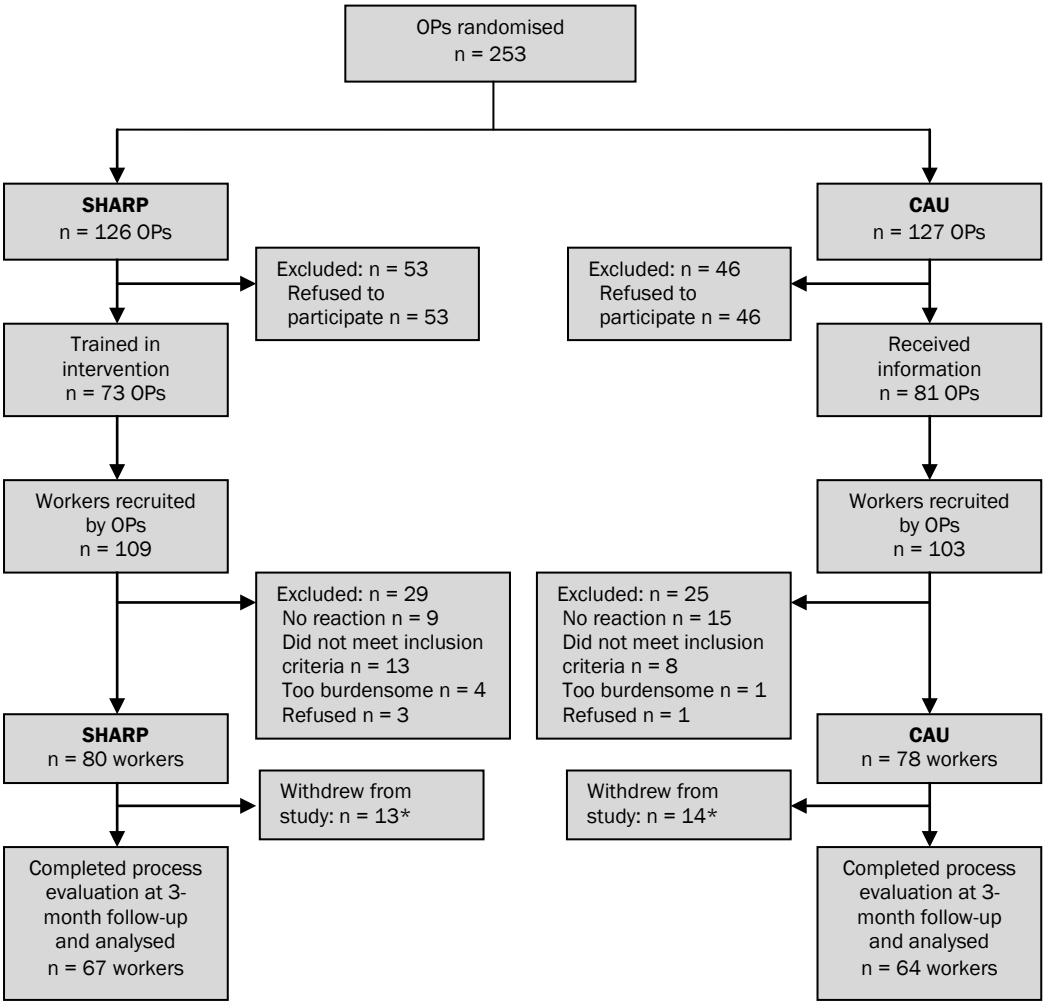
OP level

As shown in Figure 1, 73 (58%) of the 126 OPs randomised in the intervention group participated in the intervention training, and 81 (64%) of the 127 OPs randomised in the control group participated in the information session on the study procedure. The main reasons for non-participation were having been delegated new and extra duties due to a reorganisation of the OHS or an overall busy work schedule.

Table 2. Participant characteristics per study group.

Characteristics		SHARP (n = 80) M / n	SD / %	CAU (n = 78) M / n	SD / %
Socio-demographic characteristics					
Age (years)		41.3	9.4	43.3	9.8
Gender (male)		27	33.8	38	48.7
Marital status (married or living together)		67	83.8	60	76.9
Breadwinner (yes)		40	50.0	49	62.8
Education level					
Low		6	7.5	13	16.7
Intermediate		36	45.0	40	51.3
High		38	47.5	23	29.5
Clinical characteristics					
ICD diagnosis by OP					
F32.9 Depressive episode, unspecified		4	5.0	12	15.4
F41.9 Anxiety disorder, unspecified		0	0.0	2	2.6
F43.2 Adjustment disorders		58	72.5	39	50.0
F43.9 Reaction to severe stress, unspecified		1	1.25	0	0.0
R45 Symptoms and signs involving emotional state		7	8.75	14	17.9
Z73.0 Burn-out		2	2.5	7	9.0
Other		8	10.0	4	5.1
Work-related characteristics					
Type of occupation					
Commercial service providers		23	28.8	11	14.1
Management		11	13.8	15	19.2
Administrative staff		19	23.8	12	15.4
ICT staff		4	5.0	4	5.1
Sales staff		2	2.5	5	6.4
Health care providers		12	15.0	12	15.4
Hotel and catering staff		3	3.8	0	0.0
Stock and/or transport staff		1	1.3	11	14.1
Designers/planners		3	3.8	2	2.6
Mechanics/repairmen		2	2.5	5	6.4
Employment (hours per week)		32.6	7.0	32.9	7.3
Irregular work (e.g. shift work)		6	7.5	10	12.8
Executive/manager responsibilities		23	28.8	21	26.9
Duration of sickness absence		130.9	94.2	99.3	66.1
WRFQ-Total score		66.9	15.5	61.0	20.0
Health-related characteristics					
4DSQ	Distress	13.8	7.5	15.5	7.5
	Depression	1.5	2.1	2.0	2.4
	Anxiety	3.1	3.3	3.6	3.5
	Somatization	7.9	5.3	7.9	5.5
HADS	Depression	7.0	4.5	7.3	4.4
	Anxiety	7.2	3.9	7.8	3.4
Incidence of recurrent sickness absence					
3 months[1]		8	11	17	22
6 months[2]		15	21	29	39
12 months[3]		24	34	35	47

Note. SHARP = intervention group; CAU = care as usual group; OP = occupational physician; 4DSQ = Four-Dimensional Symptom Questionnaire; HADS = Hospital Anxiety and Depression Scales.
[1]n = 76 in intervention group.
[2]n = 72 in intervention group; n = 74 in control group.
[3]n = 71 in intervention group; n = 74 in control group.



SHARP = intervention group; CAU = care as usual group; OP = occupational physician.
For the intervention group, reasons for withdrawal were: health problems (*n* = 1), research too burdensome (*n* = 1), a new OP (*n* =1), or unknown (*n* = 10). For the control group, reasons for withdrawal were: health problems (*n* = 1), research too burdensome (*n* = 1), job loss (*n* = 2), not in the mood (*n* = 1), no time (*n* = 1), or unknown (*n* = 8).

Figure 1. Flowchart of participant recruitment, allocation and outcome assessment.

Participant level

Compared to the control group, participants in the intervention group more frequently had ≥2 consultations with the OP (OR = 3.2, 95% CI = 1.2 to 8.8) and ≥1 consultation with the supervisor (OR = 3.6, 95% CI = 1.1 to 12.0), as recommended in the SHARP-at

work intervention protocol. There was no significant difference between the two groups in the number of consultations between the supervisor, the participant and the OP.

Dose delivered

OP level

All OPs in the intervention group reported that they had given assignments to the participant. Of the participants in the intervention group, 73% confirmed they had received assignments from the OP. For the control group, these responses were significantly lower; 29% of the OPs and 8% of the participants reported that assignments had been given. OPs and participants from the intervention group indicated which of the five assignments of the SHARP-at work intervention were provided. Regarding the first and most important assignment of the intervention (making an inventory of problems and possibilities for improvement at work), 66% of the participants reported that they had received the first assignment, while 98% of the OPs reported they had given the first assignment to the participant. For the other assignments, 54% of the participants replied they had received the assignment on writing down solutions, 48% had received the assignment on making an action plan and preparing a consultation with the supervisor and 36% had received the assignment on evaluating the problem-solving process (not presented in table). Finally, 64% of the participants agreed that the OP had stimulated them to be actively involved in consultations and to make their own decisions (not presented in table).

Dose received

Participant level

Comparable to the results for dose delivered, participants in the intervention group more often completed assignments that were provided by the OP compared to the control group (OR = 33.8, 95% CI = 10.4 to 109.5). Of the participants in the intervention group that completed assignments, 88% made the first assignment, 65% the second assignment, 57% the third assignment, 55% the fourth assignment and 37% the fifth assignment (not presented in table). Participants indicated which of the seven topics, related to the RTW process, were discussed during consultations with the OP. In the intervention group, the most common topics that were discussed were problems at work (84%), possible solutions for the problems (58%), and who could help with solving the problems (55%). Significantly less participants in the control group reported that these topics were discussed with the OP.

Fidelity

OP level

In the intervention group, 63% of the participants reported that they had ≥2 consultations with the OP and they received the first assignment from the OP. Almost all OPs (96%) reported that they had acted according to the intervention (i.e. ≥2 consultations with participant and first assignment distributed to participant).

Participant level

In the intervention group, 64% of the participants reported that they had ≥2 consultations with the OP and that they completed the first assignment (one participant who reported that the OP did not provide the first assignment did report that he/she made the first assignment, explaining the difference with the 63% reported above). Of the OPs, 79% reported that they had ≥2 consultations with the participant and that the participant completed the first assignment.

Context

Participant level

For the participants in the intervention group, the context in which the treatment took place was characterised by good communication with the OP and the supervisor. Participants in the control group also responded that in general communication with the OP and the supervisor was good. In the intervention group, 51% had to deal with an organisational change during the first three months of RTW compared to 39% in the control group; this difference was not statistically significant.

Satisfaction

OP level

OPs in the intervention and control group were both positive about the treatment they had provided. OPs in the intervention group indicated that the intervention was applicable. With respect to aspects that helped in the post-RTW phase, OPs (36% in both the intervention and control group) reported that support and treatment from other health care professionals (mainly psychologists and social workers) were helpful.

Participant level

Overall, participants in the intervention and control group were both positive about the treatment by the OP. With respect to aspects that helped in the post-RTW phase, participants (39% in the intervention group and 33% in the control group) frequently mentioned that support from colleagues and friends was helpful for RTW.

Table 3. Components of the process evaluation as reported by the participants.

Components[1]	SHARP (*n* = 67)	CAU (*n* = 64)	OR or MD (95% CI)
Reach			
0-1 consultations with OP	11 (16)	24 (38)	reference
≥2 consultations with OP	56 (84)	39 (61)	3.2 (1.2 – 8.8)
0 consultations with supervisor	4 (6)	12 (19)	reference
≥1 consultations with supervisor	63 (94)	52 (81)	3.6 (1.1 – 12.0)
0 consultations with OP and supervisor	47 (70)	49 (77)	reference
≥1 consultations with OP and supervisor	20 (30)	15 (23)	1.4 (0.6 – 3.0)
Dose delivered			
Assignments received from OP	49 (73)	5 (8)	58.6 (14.7 – 228.6)
OP stimulated being involved, mean (SD)	3.9 (1.2)	3.5 (1.4)	0.6 (0.1 – 1.2)
OP stimulated making own decisions, mean (SD)	3.8 (1.1)	3.6 (1.3)	0.2 (-0.3 – 0.6)
Dose received			
Assignments completed	47 (70)	5 (8)	33.8 (10.4 – 109.5)
Topics discussed related to RTW			
Problems at work	56 (84)	40 (63)	2.9 (1.3 – 6.6)
Possible opportunities at work	33 (49)	17 (27)	3.1 (1.1 – 9.2)
Solutions for problems	39 (58)	22 (34)	2.6 (1.2 – 5.4)
How to realise opportunities	30 (45)	23 (36)	1.4 (0.6 – 3.0)
Who can help	37 (55)	14 (22)	4.3 (2.0 – 9.5)
How to make an action plan	17 (25)	16 (25)	1.0 (0.5 – 2.2)
Evaluation of RTW process	31 (46)	35 (55)	0.63 (0.3 – 1.4)
Fidelity OP			
≥2 consultations with OP and first assignment delivered by OP	42(63)	-	-
Fidelity participant			
≥2 consultations with OP and first assignment completed by participant	43 (64)	-	-
Context			
Good communication with OP in general (1-5), mean (SD)	4.4 (0.7)	3.8 (1.0)	0.2 (-0.2 – 0.6)
Good communication with supervisor in general (1-5), mean (SD)	3.6 (1.1)	3.8 (1.1)	-0.6 (-1.1 – -0.1)
Supervisor helped with RTW (1-5), mean (SD)	3.3 (1.1)	3.7 (1.0)	-0.7 (-1.3 – -0.1)
Supervisor positive about treatment OP (1-5), mean (SD)	3.6 (0.9)	3.9 (0.8)	-0.3 (-0.8 – 0.1)
Major life event in the year before baseline	33 (49)	28 (44)	1.1 (0.5 – 2.4)
Organisational change during RTW	34 (51)	25 (39)	1.6 (0.7 – 3.5)
Impact of organisational change[2]			
Positive	12 (35)	14 (56)	-
Negative	9 (26)	7 (28)	-
Positive nor negative	13 (38)	4 (16)	-
Satisfaction			
Treatment helped with RTW (1-5), mean (SD)	4.0 (1.0)	3.4 (1.2)	0.5 (-0.0 – 1.1)
Treatment appreciated (1-5) , mean (SD)	4.0 (0.9)	3.6 (1.1)	0.4 (-0.2 – 0.9)
Treatment overall positive (1-5), mean (SD)	4.2 (1.0)	3.7 (1.1)	0.03 (-0.4 – 0.5)
Enough consultations with OP (1-5), mean (SD)	4.1 (0.8)	3.6 (1.2)	0.5 (-0.1 – 1.1)
Treatment had good structure (1-5) , mean (SD)	3.9 (1.0)	3.3 (1.2)	0.5 (-0.1 – 1.0)
Good communication with OP during consultations (1-5), mean (SD)	4.3 (0.8)	3.8 (1.0)	0.3 (-0.2 – 0.8)
Implemented solutions positive (1-5), mean (SD)	3.6 (1.0)	3.6 (1.0)	-0.02 (-0.6 – 0.6)

Table 3. (continued)

Components[1]	SHARP (*n* = 67)	CAU (*n* = 64)	OR or MD (95% CI)
What helped with RTW			
Consultations OP	35 (52)	16 (25)	3.3 (1.5 – 7.3)
Consultations supervisor	21 (31)	24 (38)	0.7 (0.4 – 1.5)
Consultations supervisor + OP	14 (21)	18 (28)	0.7 (0.3 – 1.5)
Assignments	11 (16)	2 (3)	6.0 (1.3 – 28.2)
Something else	23 (34)	33 (52)	0.5 (0.2 – 0.9)

SHARP = intervention group; CAU = care as usual; OP = occupational physician; RTW = return to work; OR = odds ratio; MD = mean difference; CI = confidence interval.
[1]N (%) reported unless indicated otherwise.
[2]No significance tests due to small sample that reported organisational changes.

Table 4. Components of the process evaluation as reported by the OPs.

Components[1]	SHARP (*n* = 48)	CAU (*n* = 52)	OR or MD (95% CI)
Reach participant			
0-1 consultations with participant	2 (4)	17 (33)	reference
≥2 more consultations with participant	46 (96)	35 (67)	15.5 (1.7 – 141.9)
0 consultations with participant and supervisor	38 (79)	43 (83)	reference
≥1 consultations with participant and supervisor	9 (19)	9 (17)	0.1 (0.0 – 0.3)
Dose delivered			
Assignments given to participant	48 (100)	15 (29)	N.E.
Stimulated participant to be involved	4.2 (0.6)	3.9 (1.0)	0.4 (-0.1 – 1.0)
Stimulated participant to make own decisions	4.3 (0.6)	4.2 (0.8)	0.0 (-0.3 – 0.4)
Dose received			
Assignments completed by participant	43 (90)	11 (21)	28.8 (6.7 – 124.5)[2]
Fidelity OP			
≥2 consultations with OP and first assignment delivered by OP	46 (96)	-	-
Fidelity participant			
≥2 consultations with OP and first assignment completed by participant	38 (79)	-	-
Context			
Good communication with participant in general (1-5), mean (SD)	4.2 (0.6)	4.2 (0.7)	-0.2 (-0.5 – 0.1)
Good communication with supervisor in general (1-5), mean (SD)	4.0 (0.9)	3.9 (0.8)	0.0 (-0.6 – 0.6)
Supervisor helped with RTW (1-5), mean (SD)	3.9 (0.8)	4.0 (0.8)	0.25 (-0.2 – 0.7)
Supervisor positive about treatment OP (1-5), mean (SD)	3.9 (0.8)	3.9 (0.7)	0.0 (-0.5 – 0.5)
Organisational change during RTW	24 (50)	24 (46)	1.3 (0.4 – 4.3)
Impact of organisational change[3]			
Positive	11 (46)	11 (46)	-
Negative	5 (21)	5 (21)	-
Positive nor negative	8 (33)	8 (33)	-

Table 4. (continued)

Components[1]	SHARP (*n* = 48)	CAU (*n* = 52)	OR or MD (95% CI)
Satisfaction			
Treatment helped with RTW (1-5), mean (SD)	3.8 (0.8)	4.1 (0.9)	-0.4 (-0.9 - -0.0)
Treatment applicable (1-5), mean (SD)	3.8 (1.0)	n.a.	
Treatment overall positive (1-5), mean (SD)	3.8 (0.8)	4.3 (0.6)	-0.5 (-1.0 - -0.1)
Enough consultations with worker (1-5), mean (SD)	4.3 (0.8)	4.1 (0.7)	0.0 (-0.5 – 0.5)
Treatment had good structure (1-5), mean (SD)	4.0 (0.7)	4.0 (0.6)	-0.2 (-0.5 – 0.2)
Good communication with participant during consultations (1-5), mean (SD)	4.3 (0.5)	4.3 (0.6)	-0.2 (-0.5 – 0.2)
Implemented solutions positive (1-5), mean (SD)	3.9 (0.9)	4.0 (0.8)	-0.3 (-0.9 – 0.3)
What helped with RTW			
Consultations OP	24 (50)	18 (35)	1.8 (0.6 – 6.1)
Consultations supervisor	18 (38)	10 (19)	2.4 (0.6 – 9.3)
Consultations supervisor + OP	12 (25)	19 (37)	0.5 (0.2 – 1.4)
Assignments	29 (60)	4 (8)	138.4 (5.3 – 3838.4)
Something else	14 (29)	30 (58)	0.2 (0.1 – 0.6)

SHARP = intervention group; CAU = care as usual; OP = occupational physician; RTW = return to work; OR = odds ratio; MD = mean difference; CI = confidence interval; N.E. = not estimable.
[1]N (%) reported unless indicated otherwise.
[2]1st order maximised quasi-likelihood used as estimation method.
[3]No significance tests due to small sample that reported organisational changes.

Relationship between intervention components and the incidence of recurrent sickness absence

Three intervention components were significantly related to recurrent sickness absence at three, six and 12 months follow-up (Table 5). These components were: the inventory of problems/opportunities (OR = 15.3, 95% CI = 1.78 to 132.4), the inventory on whether help is needed with solving problems or realising opportunities (OR = .10, 95% CI = .02 to .69]), and the discussion with the OP on how to realise opportunities at work (OR = 0.17, 95% CI = .04 to .73]). Participants that made the inventory on whether help is needed and had discussed with the OP how opportunities could be realised at work, had a significantly lower risk of recurrent sickness absence. In contrast, participants that made the problem inventory had a significantly higher risk of recurrent sickness absence. Participants who received more intervention components did not have a reduced risk of recurrent sickness absence compared to participants who received fewer components.

Table 5. Multivariable multilevel logistic regression model showing the relationship between the key intervention components and the incidence of recurrent sickness absence.

				95% CI		
Components	**B**	**SE**	**OR**	**LL**	**UL**	**P-value**
Consultations with OP (reference = <2 consultations)	2.16	1.14	8.67	0.93	81.00	0.058
Consultations with supervisor (reference = <1 consultations)	-0.81	1.19	0.44	0.04	4.58	0.498
Inventory of problems/opportunities (reference = not made)	2.73	1.10	15.3	1.78	132.4	0.013
Inventory of help needed (reference = not made)	-2.27	0.97	0.10	0.02	0.69	0.019
Problems at work discussed with OP (reference = no)	-1.73	1.14	0.18	0.02	1.66	0.129
Opportunities at work discussed with OP (reference = no)	0.61	0.69	1.84	0.48	7.11	0.377
Solutions for problems discussed with OP (reference = no)	1.24	0.81	3.46	0.71	16.90	0.126
How to realise opportunities discussed with OP (reference = no)	-1.78	0.75	0.17	0.04	0.73	0.018
Total number of components received (0-8)	0.01	0.16	1.00	0.74	1.38	0.956

OP = occupational physician; CI = confidence interval; LL = lower limit, UL = upper limit.

DISCUSSION

We conducted a process evaluation, analysing for both the intervention and control group: recruitment, reach, dose delivered, dose received, fidelity, contextual factors and satisfaction with the treatment. Furthermore, we analysed the relationship between intervention components and the primary outcome, i.e. incidence of recurrent sickness absence. The results showed that the majority of the participants in the intervention group received the key components of the SHARP-at work intervention. The intervention reached the participants through the OP consultations. The majority of the intervention group made the first assignment, which was one of the key elements of the intervention. When comparing the results on reach, dose delivered and dose received for the intervention group with the control group, fewer activities took place in the control group. Less often consultations with the OP took place, and assignments were rarely provided to participants by OPs. Furthermore, important topics related to the intervention were more often discussed between participants and the OPs in the intervention group compared to the control group. There were no major differences between the intervention and control group for satisfaction with the treatment and for contextual factors that might have influenced the treatment or the study outcomes. Overall, participants and OPs in the intervention group were satisfied with the intervention, considered it helpful for RTW and applicable. We conclude that the

intervention accounted for the lower risk of recurrent sickness absence that was found in the effect evaluation for the intervention group compared to the control group because the intervention was properly conducted for the majority of the participants in the intervention group and the control group received only few activities. The results provide support for implementing the intervention in practice.

The analysis of the relationship between the key components of the intervention and the incidence of recurrent sickness absence showed that participants that made the inventory of problems or opportunities at work had a significantly higher risk of experiencing recurrent sickness absence. Participants had a significantly lower risk of recurrent sickness absence when they made the inventory of whether help was needed to solve a problem or realise an opportunity at work, and when they talked with the OP about how opportunities could be realised. A possible explanation for these results could be that making an inventory of problems/opportunities at work by itself is not beneficial. It may be necessary that a worker also thinks about whether help is needed to solve/realise problems/opportunities and talks about concrete improvements that can be implemented at work, as has been suggested in solution focused theories[33,34]. The results need to be interpreted carefully due to the small sample size. The incidence of recurrent sickness absence was rather low for the intervention group at three months follow-up. Furthermore, for some intervention components, the majority of the participants had received the component, and thus, no clear contrast could be made between participants receiving and not receiving the components. Nonetheless, reporting these results is important. Within occupational health care, multicomponent interventions have proven to be more effective than single component interventions[35,36]. However, without evaluating the relationship between separate intervention components and study outcomes, we have no clear understanding of why multicomponent interventions are more effective and what the strength of these interventions is. Thus, future research needs to focus more on how multicomponent interventions work. To do this, larger sample sizes are essential in order to detect robust associations within the intervention group.

To the best of our knowledge, no studies have been published that evaluate the effect and process of an intervention for the prevention of recurrent sickness absence in workers with CMDs. Our study showed that a process evaluation helps to explain the results of the effect evaluation. Furthermore, the investigation of the relationship between intervention components and the primary outcome provided insight into which components are important to achieve a reduced risk of recurrent sickness absence. This analysis also showed that the total amount of received intervention components did not affect the risk of recurrent sickness absence.

When comparing our study with other process evaluations of interventions within the occupational health care field, it is striking that these studies often do not have a

theoretical framework for the process evaluation. Researchers have frequently focused on investigating whether the intervention was conducted according to the protocol and feasible, but they have not connected the process evaluation to the results of the effect evaluation. An important goal of a process evaluation is to investigate whether the intervention can account for the results on the primary outcome. Thus, linking process and effect outcomes is essential[32]. Also, some researchers concluded in the process evaluation that the intervention was conducted according to the protocol and feasible, while the effect evaluation showed no relevant differences between intervention and control groups. However, these contradicting findings were not further explained[37-40]. This impedes decision making on using the intervention in practice.

Strengths and limitations

The present study provides rich information. We did not only examine whether the intervention was conducted according to the protocol and feasible, we also investigated whether the intervention explained the results of the effect evaluation. One of the main strengths of this study is the thorough process evaluation based on a theoretical framework. Furthermore, we were able to link different intervention components to the study outcome to explore the working mechanism of the intervention. The use of similar questionnaires for participants and OPs enabled us to compare perceptions of both groups and to report on a more complete picture of how the intervention was conducted. Including multiple perspectives in a process evaluation can overcome one-sided and biased information[41-43]. Furthermore, information from multiple stakeholders may provide an understanding of the level at which problems can be expected when implementing the intervention in practice[22,42]. We found that the perspectives of participants and OPs regarding the implementation of the intervention (i.e. reach, dose delivered, etc.) were in the same direction. A final strength of the study is that we investigated the differences and similarities between the treatment in the intervention and control group. Often, process evaluations only evaluate the treatment process of the intervention group[37,38,44]. The disadvantage of such an evaluation is that it does not provide insight into why an intervention, conducted as planned, has no effect when participants in the control group received (unintentionally) similar or more intensive care. Based on our process evaluation, we were able to conclude that treatment in the control group was different from and less intensive than treatment in the intervention group, as expected.

Our study has several limitations. One limitation is that not all included participants and OPs responded to the process evaluation questionnaires. It is possible that participants or OPs not satisfied with the intervention or care as usual refrained from completing the process questionnaire which could have biased the results. Furthermore, the OPs were not blinded for the study design, which might have

influenced their responses. When comparing the responses of the participants (who were blinded) and the OPs, it can be concluded that the OPs gave somewhat more positive answers regarding the treatment provided, which could be due to social desirability. A third limitation is that we had to develop our own process evaluation questionnaires. No generic tools are available to analyse process components because interventions often vary in content and are context-dependent. However, by developing similar questionnaires for the participants and the OPs, we were able to compare the answers of both groups. The fact that participants and OPs gave comparable answers to the questions strengthens the reliability of the data. Moreover, although the context of our process evaluation was specific, the method of evaluation can be transferred to other interventions in a different context. Another problem was the small sample size that impeded a robust analysis of the relationship between the key intervention components and the incidence of recurrent sickness absence. We could not draw firm conclusions about which key components were significantly related to recurrent sickness absence and why. However, because earlier studies in the occupational health care field have not related intervention components to the primary outcome of a study and because this information can be very valuable in getting insight into why an intervention is effective, we did report these results as to explore the relationships but also to provide an example for future research. Finally, considering the generalisability of the results, we have to acknowledge that the SHARP-at work intervention was developed in a Dutch context. OPs have an important role in the Dutch social security system and, therefore, were a suitable group of treatment providers for delivering the intervention. For countries where OPs play a less significant role in the RTW process, or where sickness absence due to CMDs is not compensated, the SHARP-at work intervention might not be applicable in its current form.

Conclusion

An important contribution of the process evaluation is that it helped explain the results of the effect evaluation. The process evaluation showed that the SHARP-at work intervention was conducted according to the protocol for the majority of the participants. Also, the intervention differed from care as usual by the OP. Based on this, we conclude that the intervention accounted for the reduced risk of recurrent sickness absence that was found in the effect evaluation for the intervention group compared to the control group. Furthermore, the intervention was well-received by OPs and participants. Overall, the results provide support for implementing the intervention in practice.

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APPENDIX 1

Statements on context and treatment satisfaction for workers

Context	
1	In general, communication with the OP goes well
2	The supervisor had a positive attitude regarding the guidance
3	In general, communication with the supervisor goes well
3	My supervisor helped to accomplish a smooth return to work
Satisfaction	
1	The guidance of the OP helped me to start working again
2	I appreciated the guidance of the OP during my return to work
3	In general, I am positive about the guidance of the OP
4	I have had enough consultations with the OP
5	The guidance of the OP had a good structure
6	During a consultation, I can have a good conversation with the OP
7	I experience the solutions that were realised during my return to work as positive

OP = occupational physician.

Statements on context and treatment satisfaction for occupational physicians

Context	
1	In general, communication with the worker goes well
2	The supervisor had a positive attitude regarding the guidance
3	In general, communication with the supervisor goes well
4	The supervisor helped to accomplish a smooth return to work
Satisfaction	
1	My guidance helped the worker to start working again
2	My guidance was applicable to the situation of the worker *(only intervention group)*
3	In general, I am positive about my guidance
4	I have had enough consultations with the worker
5	My guidance had a good structure
6	During a consultation, I can have a good conversation with the worker
7	I experience the solutions that were realised for the worker because of the guidance as positive

6

How to engage occupational physicians in recruitment of research participants: A mixed-methods study of challenges and opportunities

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ABSTRACT

Purpose: To investigate barriers and facilitators for research participant recruitment by occupational physicians.

Methods: A mixed-methods approach was used. Focus groups and interviews were conducted with OPs to explore perceived barriers and facilitators for recruitment. Based on data of a cluster-randomised controlled trial (cluster-RCT), univariate and multivariate analyses were conducted to investigate associations between OPs' personal and work characteristics and the number of recruited participants for the cluster-RCT per OP.

Results: Perceived barriers and facilitators for recruitment were categorised into: study characteristics (e.g. concise inclusion criteria); study population characteristics; OP's attention; OP's workload; context (e.g. working at different locations); and OP's characteristics (e.g. motivated to help). Important facilitators were encouragement by colleagues and reminders by information technology tools. Multivariate analyses showed that the number of OPs within the clinical unit who recruited participants was positively associated with the number of recruited participants per OP (rate ratio = 1.43, 95% confidence interval = 1.24-1.64).

Conclusion: When mobilising OPs for participant recruitment, researchers need to engage entire clinical units rather than approach OPs on an individual basis. OPs consider regular communication, especially face-to-face contact and information technology tools serving as reminders, as helpful.

INTRODUCTION

Recruiting a sufficient number of participants into randomised controlled trials (RCTs) is a challenge. Recruitment difficulties can reduce the statistical power for detecting differences between treatment groups[1]. Bower et al. (2007) investigated recruitment delays in UK primary care trials and found that only 29% of 70 trials recruited according to their timetable. Thirty-five per cent of the trials needed 50% more time for recruitment than planned, and 35% of the trials required even more than 50% additional time[2]. Similar numbers were found in a survey among researchers in Dutch primary care research; in more than 50% of 78 studies, the fieldwork period was extended to recruit sufficient participants[3]. The problem of participant recruitment has been described by clinical pharmacologist Louis Lasagna in what is called "Lasagna's Law," which implies that researchers tend to overestimate the number of eligible participants available in the population they want to recruit from[4].

Recruitment problems are even more pronounced when non-researcher clinicians are solicited to recruit participants from their normal patient caseload[2,3]. Bower et al. found that when general practitioners (GPs) recruited participants, only 12.5% of the trials recruited in time compared to 61.5% when others were responsible for recruitment[2]. Previous systematic reviews have reported on clinician barriers to participant recruitment, effective strategies to improve recruitment and clinicians' attitudes towards recruiting for RCTs[5,6]. However, these reviews are solely based on hospital and primary care studies. Few studies have reported details of participant recruitment challenges in the occupational health care (OHC) setting.

In OHC research, interventions are often conducted by clinicians, such as occupational physicians (OPs) or occupational therapists, who can also be responsible for participant recruitment[7-9]. Recruitment problems for OHC providers might be different from hospital and primary care settings. OHC providers have a dual role being advocates of workers and employers. They might have difficulties with recruiting participants when employers are not keen on participating in research. Furthermore, patients might be unsure how participation in research affects their jobs when recruited by OHC providers[10,11]. Although problems with participant recruitment by clinicians are experienced in OHC research, only one study is available on clinician participation in research and recruitment. This is a Dutch short report solely based on researchers' experiences[12]. Research is needed on how OHC providers experience participant recruitment. Furthermore, (also in hospital and primary care research) studies are lacking that analyse which clinician characteristics are associated with successful participant recruitment. Currently, only one study has analysed which family physician characteristics were related to recruitment[13]. Knowing which characteristics

of OHC providers relate to participant recruitment can be helpful when approaching OHC providers for participation in recruitment.

The overall aim of this study was to provide insight into the barriers and facilitators for participant recruitment by OPs enrolled in a cluster-randomised controlled trial (cluster-RCT) to reduce recurrent sickness absence for mental health conditions. In this cluster-RCT, 500 participants had to be recruited by OPs according to the power calculation. At the end of the trial, 212 participants were recruited (Arends et al., submitted for publication). Several OPs were successful in recruiting participants but many did not recruit any participant. Therefore, we investigated the following research questions: 1) "Which barriers and facilitators were experienced by OPs during participant recruitment?" and 2) "Which OP personal and work characteristics are associated with participant recruitment?"

METHODS

The STROBE statement[14], developed to improve the reporting of observational studies, and the COREQ guideline[15], developed to improve the reporting of qualitative studies, were used for reporting on the quantitative and qualitative parts of the study, respectively. More detailed information on the design of the cluster-RCT has been reported elsewhere[16]. A mixed-methods approach was employed because we wanted to examine relationships between OP characteristics and successful recruitment (based on survey data of a cluster-RCT) and explore OPs' perspectives on participant recruitment (based on focus groups and interviews).

Cluster-randomised controlled trial

The cluster-RCT was designed to evaluate the effectiveness of a problem solving intervention on the prevention of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs, compared to care as usual. OPs were randomised to an intervention group (and received training in the intervention and treated participants according to the intervention) or a control group (where OPs treated participants according to care as usual. OPs recruited participants. Allocation of participants followed the allocation of their OPs. More detailed information on the design of the cluster-RCT has been reported elsewhere[16].

Recruitment of OPs

OPs were recruited by collaborating with a large occupational health service (OHS) in the Netherlands. Within the OHS, OPs were organised in clinical units, called "group practices." All OPs of the OHS were eligible to participate, unless they were already participating in other research projects. The OHS' research coordinator randomly

selected clinical units in different regions of the Netherlands because participation of only 100 OPs was needed for the cluster-RCT. In September 2009, a first wave of 134 OPs (n=67 in both intervention and control group) was invited to participate in the cluster-RCT. Because of an insufficient number of recruited participants, a second wave of 122 OPs (n=60 in the intervention group and n=62 on the control group) was invited to participate in September 2010. A total of 87 OPs of the first wave (response rate 65%; n=43 in intervention and n=44 in the control group) and 67 OPs of the second wave (response rate 53%; n=30 in intervention and n=37 in control group) agreed to participate. Main reasons for non-participation were pregnancy, upcoming retirement or a busy work schedule.

Recruitment of participants

To recruit participants, OPs had to screen their patients for eligibility based on a list of 10 inclusion and exclusion criteria (see Arends et al.[16] for the criteria). If a patient was eligible, OPs could introduce the research shortly and hand over an information leaflet. After this, contact information of the patient was given to the researchers who took over the recruitment procedure. Based on data from the OHS, the OPs would see 32 to 39 eligible patients per year and we asked each OP to approach 8 eligible patients[16].

Data collection

Data on the number of recruited workers (for the cluster-RCT) per OP were collected at the end of the recruitment period (June 30th, 2011). Information on OP's personal and work characteristics was obtained from administrative data provided by the OHS and from a process evaluation questionnaire developed for the cluster-RCT. This questionnaire was distributed to OPs in the intervention group before they started their intervention training and contained questions on readiness for change (two items) and attitudes towards the intervention (three items). The items were scored on a 5-point Likert scale from totally disagree to totally agree. Participation in feedback sessions, on working according to the intervention protocol, (yes/no) was documented for each intervention OP. From the OHS, administrative data were obtained on: sex, age, OHS tenure, clinical unit, size of clinical unit, percentage of OPs in the same clinical unit that participated in the cluster-RCT (including the index person), sector (companies >500 workers yes/no), geographical working area, number of companies the OP works for, number of clients (i.e. the workers), number of OPs within the clinical unit who recruited participants and productivity in 2011 (% of hours worked according to the work contract; e.g. <100% = less hours worked in 2011 than contracted for).

Focus groups and interviews

Recruitment of OPs

For the focus groups, all OPs from the intervention group were invited by e-mail to participate in a discussion of experiences with participant recruitment and conducting the intervention. Based on convenience sampling, to focus groups were organised at the end of the inclusion period, in June 2011, including six OPs in each focus group following recommendations for optimal group dynamics[17]. Additionally, telephone interviews were organised from November 2011 until March 2012 to complement the information from the two focus groups. For the individual telephone interviews, OPs were invited by email to talk with the first author about their experiences with participant recruitment. Purposive sampling was used reflecting different demographic backgrounds and different levels of recruitment success. OPs who had not participated in the focus groups were grouped based on sex (male/female), study group (intervention group/control group) and having recruited participants (yes/no). From each group, one OP was randomly selected by the use of a computer program. If an OP declined participation, another OP from the same group was randomly selected. Because six OPs did not reply to the emails, two OPs were recruited based on convenience sampling to reach data saturation. After six interviews, the researchers felt that the point of data saturation had been reached and no more interviews were planned.

Data collection

The focus groups took place in a conference room of the OHS and lasted 1.5 hours. Two authors (IA, psychologist, and JK, occupational physician and psychologist) acted as focus group moderators. Both moderators knew the participating OPs because of previous training and feedback sessions. The telephone interviews were performed by IA to ensure continuity in the interview process. The interviews lasted approximately 15 minutes. The same semi-structured, open-ended interview protocol was used for both focus groups and interviews to collect data on experienced barriers and facilitators for participant recruitment. The following questions were asked:

1. How did you manage to recruit participants for the research?
2. What made it difficult for you to recruit participants?
    - Which environmental factors played a role?
    - Which patient-related factors played a role?
    - Which personal factors played a role?
3. What would have made it easier for you to recruit participants (e.g. what could the researchers have done differently)?

Ethics

The Medical Ethical Board of the University Medical Center Groningen, the Netherlands, approved of the cluster-RCT and judged that no ethical approval was necessary for conducting focus groups, individual interviews and for using administrative data on the OPs, provided by the collaborating occupational health service (OHS). The administrative data were anonymised for the researchers by deleting OPs' names and ascribing random numbers to the OPs. Before the start of the focus groups, OPs had to read and sign an informed consent form. The form provided information about the purpose of the focus group and the assurance of confidentiality. For the telephone interviews, OPs were asked to give oral consent. Audiotapes of the focus groups and interviews were destroyed after transcription, and names by which the OPs could be identified were omitted from the transcripts.

Data analysis

Qualitative data analysis

The focus group discussions and telephone interviews were audio taped and transcribed verbatim. During focus groups and interviews, one author (IA) took detailed notes. These data were analysed based on the qualitative description method, as described by Sandelowski[18,19]. Qualitative content analysis was used to summarise the manifest content of the focus group texts[20]. Three authors (IA, UB and JK) read the focus group and interview transcripts several times and independently grouped words related to the same central topic into meaning units. Subsequently, the meaning units were condensed and given a code. The three authors discussed the abstracted meaning units and codes and differences were solved based on consensus. Then, the three authors grouped codes related to each other into categories. The iterative process of coding and categorising was manually performed, and the meaning units and corresponding codes and categories were documented in tables. These tables were used for discussions with all authors to reach agreement on how the data were labelled and categorised. The final list of categories was presented to the participating OPs. The OPs could comment on the document to improve credibility of the data analysis process.

Quantitative data analysis

Multilevel Poisson regression analysis was used because the number of recruited participants per OP (dependent variable) had a skewed distribution and the clustering of OPs in different clinical units had to be taken into account. We investigated the relationship between OP's characteristics (independent variables) and the number of recruited participants per OP, with control for over-dispersion. Five OPs (3%) were excluded from the multilevel analyses, because of missing data on the clinical unit.

First, univariable analyses were performed and variables with a p-value of <0.20 were included in the multivariable model[21]. In a backward, stepwise selection procedure, the variable with the highest p-value was manually deleted from the model until the model only contained variables with p-values of <0.05[21]. The variables "readiness for change," "attitudes towards the intervention" and "participation in feedback moments" were only available for intervention OPs and, therefore, not included in the multivariate analyses. We used SPSS, version 20.0, for the descriptive analyses and MLwiN, version 2.23, for the regression analyses.

RESULTS

OP characteristics

Cluster-randomised controlled trial

Of the 256 OPs invited to participate in the cluster-RCT, 154 agreed to participate. When comparing the participating and non-participating OPs on sex, working area (North, East, South or West of the Netherlands) and study group (intervention or control group), they significantly differed on working area with more non-participating OPs in the Eastern part of the Netherlands. Five OPs (3%) were excluded from the multilevel analyses, because of missing data on the clinical unit. A total of 149 OPs working in 40 different clinical units were included in the analyses. OPs were 50.2 ± 7.2 years of age and 63.1% (n=94) were male. The mean number of years worked for the OHS was 10.6 ± 7.1 and 52.3% (n=78) worked in Western regions of the Netherlands. The mean number of recruited workers per OP was 1.3 ± 2.3. More details of the study population are presented in Table 1.

Focus groups and interviews

A total of 18 OPs participated in the focus groups (two groups of n=6) and interviews (n=6). Their mean age was 51.4 ± 6.3 years and 72% (n=13) was male. Five OPs (28%) belonged to the control group of the cluster-RCT. Thirteen OPs (72.2%) worked in Western regions of the Netherlands. The mean number of workers recruited by each OP was 2.8 ± 3.3, with a minimum of zero workers (by 4 OPs) and a maximum of 11 workers (by 2 OPs).

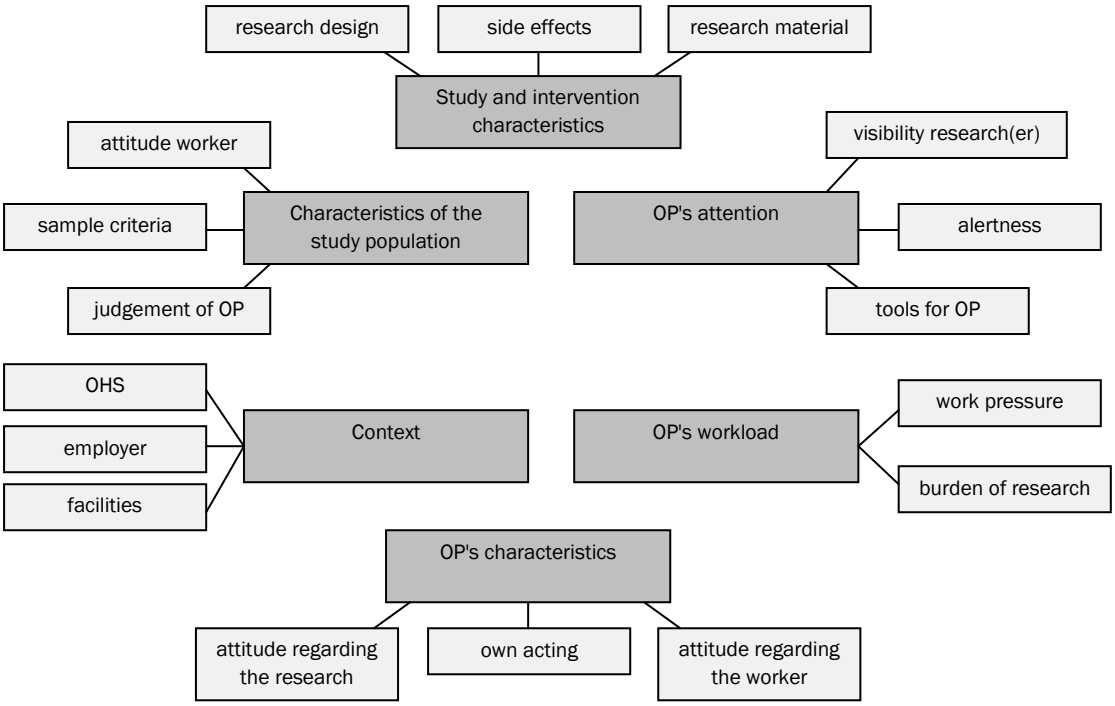
Table 1. Characteristics of study population for the quantitative analyses (N=149).

Variable	n	Mean (SD) / Median (IQR)	Frequency (%)
Demographic factors			
Age in years	147	50.2 (7.2)	
Gender			
Male	94		94 (63.1)
Female	55		55 (36.9)
OHS tenure in years	138	10.6 (7.1)	
Workload factors			
Number of clients	116	2159.2 (1143.5)	
Number of companies	116	28.6 (40.7)	
Productivity (% of contracted hours)	143	105.3 (24.8)	
Work environment factors			
Working area	139		
North of Netherlands			14 (9.4)
East of Netherlands			21 (14.1)
West of Netherlands			78 (52.3)
South of Netherlands			26 (17.4)
Sector	149		
Small/medium sized companies			88 (59.1)
Large companies			61 (40.9)
Number of OPs within clinical unit	149	11.6 (9.4)	
Percentage of OPs within clinical unit participating in the cluster-RCT	149	51.1 (20.1)	
Mean number of recruited workers in clinical unit	149	1.3 (1.1)	
Study factors			
Study group	149		
Control group			79 (53.0)
Intervention group			70 (47.0)
Start inclusion period	149		
January 2010			85 (57.0)
January 2011			64 (43.0)
Attitude towards intervention[1] (range 3-15)	64	11. 6 (1.6)	
Readiness for change[1] (range 2-10)	63	8.7 (1.0)	
Participation in feedback moments[1]	70		
Yes			35 (50.0)
No			35 (50.0)
Dependent variable			
Number of recruited workers	149	1.3 (2.3) / 0 (0 -2)	

[1]Only measured in the intervention group (n = 70).

Barriers and facilitators for participant recruitment according to OPs

After individually creating codes for each piece of distinctive information and discussing these codes, the authors agreed upon 136 unique codes. The codes were grouped into six different categories: (1) study and intervention characteristics, (2) characteristics of the study population, (3) OP's attention, (4) OP's workload, (5) context and (6) OP's characteristics. Each category was divided into two or more subcategories. Of the 18 participating OPs, three responded that they agreed with the categorisation. The other 15 OPs did not respond. The final categories and subcategories are presented in Figure 1 and quotes related to the categories are presented in Table 2.



OP = occupational physician; OHS = occupational health service.

Figure 1. Extracted categories and subcategories related to facilitators and barriers for participant recruitment.

Table 2. Quotes related to barriers and facilitators for participant recruitment.

Category	Quote
Study and intervention characteristics	*"I… I think that… as few as possible of those criteria. I think that… it is probably simpler if you just say that everyone who experiences distress, eh… they can just participate in the research. Just eh… then I don't need to think as much anymore… I would only be triggered by distress."* (OP 4, interview, intervention group)
	"Because it takes… well… if you want to do it correctly, it takes you 45 minutes for the first consultation. To motivate people, to explain, et cetera." (OP 12, focus group, intervention group)
Characteristics of the study population	*"Some people… cannot always understand what is written. You have… how do you say it… a type of category of low educated people. If you want… to present this to them… it costs a lot of time. That could be a barrier."* (OP 8, focus group, intervention group)
OP's attention	*"Yes, how I succeeded [in participant recruitment]… In any case of course the moments that we had a meeting with you. Then you have a more face-to-face reminder, and you are better able to start with it. So, that is very important, I think, that after such a meeting or story from you, that you have more of a drive, to call it that way. That is something that diminishes after a vast amount of time."* (OP 6, interview, intervention group)
OP's workload	*"There are so many things that need to be done during a consultation that you just forget about it"* (OP 13, focus group, intervention group).
	"It is difficult that you have to ask permission of the people [before sending their contact information to the researchers], so you have to be alert during the consultation" (OP 5, interview, control group).
Context	*"Some internal person [of the OHS]… who once a week passes every door to remind everyone about the research. … One coordinator per group practice."* (OP 11, focus group, control group).
	"They [the employer] decide when someone can come [for a consultation]. And if you ask, I would like to see that person within two weeks, then it could just as well be that they plan a new consultation after two months." (OP 12, focus group, intervention group)
OP's characteristics	*"Personally, I was very driven to help because I have been in the same position when I was writing my master thesis."* (OP 2, interview, control group)

OP = occupational physician; OHS = occupational health service.

Study and intervention characteristics

Facilitators for participant recruitment were clear inclusion criteria and research material, such as workbooks or a checklist with criteria. One OP explained that concise or simple inclusion criteria were important for recruitment. As a positive "side effect" of the intervention, one OP stated that participating in research was an impulse for the

OHS and that the intervention could contribute to the development of new services. This stimulated the OP to participate and recruit participants. However, study characteristics could also act as barriers for participant recruitment. OPs experienced problems with recruitment because they could only include workers at a specific point in time (i.e. when workers were ready to return to work) and not directly when they saw the worker during the first consultation. Furthermore, the intervention had negative "side effects," i.e. it took extra time for the OPs to conduct the intervention and this prevented some OPs from recruiting participants.

Characteristics of the study population

OPs mentioned that they were more eager to recruit workers who had an optimistic and enthusiastic attitude in general, and they rather recruited workers that were able to participate in the study without being overstrained. OPs from the intervention group pointed out that they thought that workers had to have some level of basic intelligence to be able to participate in the intervention, and thus, they felt they could not include lower educated workers. Other barriers for recruitment were, for example, being restricted by exclusion criteria (e.g. pregnancy, English-speaking), a worker who started return to work without waiting for the OP's advice (workers had to be recruited before return to work started) or the inclusion criterion of common mental disorders (CMDs). For some OPs, guiding workers with CMDs took much consultation time, and this made it difficult to invest additional time to explain and discuss study participation.

OP's attention

An important problem pointed out by all OPs was focusing their attention on participant recruitment. OPs mentioned that they often forgot to approach eligible patients because they were more focused on their regular tasks and did not have enough time left at the end of their consultation to discuss recruitment. However, OPs also described facilitators that could help focusing attention on recruitment. One frequently mentioned facilitator was regular face-to-face contact sessions with the researcher. Other facilitators were having the research material at hand to enhance visibility and receiving reminders and weekly newsletters by email, although some OPs thought this would not help as much as actual face-to-face contact. For the future improvement of recruitment, a facilitator mentioned by several OPs was use of ICT tools as a reminder, such as a pop-up screen reminding the OP of the research after entering CMD as a diagnosis.

OP's workload

Another aspect affecting participant recruitment was OP's workload. Workload consisted of OPs' perceived burden of work (i.e. OPs felt they were very busy and did not have time to introduce the research project) and burden of the research project (i.e. being focused on recruitment during a consultation, keeping track of all eligibility criteria, time spent on explaining the study).

Context

Regarding OP's own work context, many OPs reported that recruitment could have been encouraged to a higher extent in the clinical units. For example, an OP mentioned that it would have been helpful if one OP had functioned as an ambassador of the research and done a weekly check on colleagues asking about how recruitment was going. In line with this, several OPs said that it was helpful when colleagues reminded them of the study and the recruitment that had to be done. One reported barrier was the reorganisation at the time the cluster-RCT was conducted. OPs referred to this period as a hectic time with a lot of commotion and changes. OPs' colleagues were also overloaded, which made the OPs reluctant to invest time in participant recruitment. Also, OPs experienced problems with recruitment when they worked at different location and did not have the recruitment folders available at all locations. For some OPs, another contextual barrier was the employer they had to deal with. In particular, when the employer controlled the timing and number of consultations between the OP and the worker this could be problematic for recruitment. When the OP was not able to see the worker on time, participation was no longer possible. As a solution to this problem, some OPs mentioned that involving the worker's employer in the research was helpful (e.g. by giving information about the study).

OP's characteristics

Key barriers to recruitment were related to the OP's own acting; OPs felt they could stay passive without major consequences and they prioritised other matters. OPs differed substantially with regard to their commitment to research in general. Some considered themselves treatment and guidance-oriented and less focused on research. Others had research experience, could empathise with the researchers and were driven to help with recruitment.

Factors associated with recruitment of workers

Univariable associations of survey and administrative data to recruitment success are presented in Table 3. The univariable analyses showed that OHS tenure, working area, number of OPs within the clinical unit who recruited participants, start of inclusion period and productivity had significant positive relationships with successful

recruitment. OPs from the intervention group who participated in at least one feedback moment recruited significantly more workers than OPs who did not participate in feedback moments. Multivariable analyses showed that, after deleting the variables with the highest p-values, only the number of OPs within the clinical unit who recruited participants remained significant in the multivariable analysis (rate ratio = 1.43, 95% confidence interval = 1.24-1.64) (Table 4).

Table 3. Univariable associations between variables and number of workers recruited per OP.

	Workers recruited by OP	
Variables	Rate ratio[1] (95% CI)[2]	**P-value**
Demographic factors		
Age	1.0 (0.97-1.04)	0.51
Gender		
Male (reference)	1.00	
Female	1.10 (0.63-1.93)	0.78
OHS tenure in years	0.97 (0.92-1.02)	0.16
Workload factors		
Number of clients	1.00 (1.00-1.00)	0.47
Number of companies	1.00 (0.99-1.00)	0.55
Productivity (% of contracted hours)	1.01 (0.99-1.02)	0.18
Work environment factors		
Working area		
North of Netherlands (reference)	1.00	
East of Netherlands	0.64 (0.24-1.71)	0.41
West of Netherlands	0.26 (0.20-1.34)	0.24
South of Netherlands	0.19 (0.05-0.70)	0.01
Sector		
Small/medium sized companies (reference)	1.00	
Large companies	1.11 (0.57-2.18)	0.92
Number of OPs within clinical unit	0.99 (0.94-1.04)	0.63
Percentage of OPs within clinical unit participating in the cluster-RCT	2.50 (0.36-17.47)	0.82
Number of OPs within clinical unit who recruited participants	1.43 (1.24-1.64)	0.00
Study factors		
Study group		
Control group (reference)	1.00	
Intervention group	1.27 (0.73-2.21)	0.39
Start inclusion period		
January 2010 (reference)	1.00	
January 2011	0.42 (0.22-0.81)	0.01
Attitude towards intervention[2]	1.25 (0.81-1.92)	0.33
Readiness for change[2]	1.01 (0.77-1.31)	0.73
Participation in feedback moments[2]		
No (reference)	1.00	
Yes	2.42 (1.09-5.35)	0.03

OHS = occupational health service; OP = occupational physician; RCT = randomised controlled trial.
[1]A rate ratio of >1 indicates more recruited workers by the OP.
[2]Only measured in intervention group (n=70).

Table 4. Multivariable associations between variables and number of workers recruited per OP.

Variables	**Step 1** Rate ratio (95% CI)	***P***	**Step 2** Rate ratio (95% CI)	***P***	**Step 3** Rate ratio (95% CI)	***P***	**Step 4** Rate ratio (95% CI)	***P***	**Step 5** Rate ratio (95% CI)	***P***
OHS tenure	0.97 (0.92-1.02)	0.20	0.97 (0.92-1.02)	0.20	-		-		-	
Working area										
North of Netherland (reference)	1.00		1.00		1.00				-	
East of Netherlands	0.91 (0.36-2.29)	0.84	0.89 (0.36-2.21)	0.79	0.99 (0.40-2.45)	0.97	0.89 (0.37-2.17)	0.81		
West of Netherlands	0.65 (0.31-1.39)	0.27	0.70 (0.34-1.42)	0.32	0.76 (0.37-1.54)	0.45	0.77 (0.38-1.56)	0.47		
South of Netherlands	0.31 (0.07-1.31)	0.11	0.37 (0.10-1.36)	0.16	0.43 (0.08-2.31)	0.20	0.42 (0.12-1.51)	0.18		
Number of OPs within clinical unit who recruited participants	1.36 (1.14-1.63)	0.00	1.33 (1.13-1.57)	0.00	1.37 (1.17-1.60)	0.00	1.37 (1.17-1.60)	0.00	1.43 (1.24-1.64)	0.00
Start inclusion period										
January 2010 (reference)	1.00		-		-		-		-	
January 2011	1.30 (0.55-3.05)	0.55	1.15 (0.58-2.29)							
Productivity	1.01 (0.99-1.02)	0.13	1.01 (0.99-1.02)	0.13	1.01 (0.99-1.02)	0.24	-		-	

OHS = occupational health service; CI = confidence interval.

DISCUSSION

To investigate recruitment problems in the OHC setting, the present study explored barriers and facilitators related to participant recruitment by OPs using different data sources in a mixed-methods study. The focus group and interview study provided six main categories of barriers and facilitators for participant recruitment by OPs. These categories can be addressed by researchers when developing future studies in which participant recruitment is (mainly) relying on OPs. Three categories were related to the OPs themselves, like OP's workload, and three categories were related to external factors, such as the organisational context. Although not all categories can be influenced by researchers, the categorisation can be helpful in determining the suitability of a recruitment strategy. It may be advisable to explore if some factors in the categorisation act as barriers and consider these when developing the recruitment strategy. Fortunately, many (sub)categories can be modified by researchers. For example, inclusion criteria can be formulated in a concise and not too exclusive way. Frequent visits to talk face-to-face to OHC providers responsible for recruitment are recommended, as well as providing clear research material and using reminder tools.

The main finding, based on the multivariable analysis, is that the number of OPs within the clinical unit who recruited participants is significantly associated with the number of recruited participants by the OP. Thus, OPs who work in clinical units where colleague OPs recruit participants are more likely to recruit participants themselves compared to OPs who work in clinical units where colleagues do not recruit. The finding that the number of OPs in the clinical unit who participated in the cluster-RCT was not related to recruitment shows that is not about how many colleague OPs agree to participate in the study but about how many colleague OPs really do something (i.e. recruit participants). Thus, researchers should not only motivate individual OPs to recruit participants for a study but also OPs' entire clinical unit. This finding was supported by the qualitative data where OPs stressed the importance of support by colleagues of the clinical units and the OHS for recruitment. The results of the univariable analyses may be valuable for future trials where OHC providers are not organised in clinical units. Based on the univariable analyses, OPs working in the South of the Netherlands recruited fewer participants than OPs working in the North of the Netherlands. An explanation for this finding could be that the OPs in the Southern clinical units started recruitment one year later than the OPs in the other regions, but the recruitment duration was included in the multivariate analyses and did not remain significant. Another factor seems to have influenced recruitment in the Southern clinical units. Possibly, patients in the South were less willing to participate. During the cluster-RCT, information was collected from OPs on if they had been unable to include eligible patients and why. OPs from the North as well as the South often mentioned

that they forgot about recruitment or that the patient declined participation. However, the frequency of patients declining did not differ between OPs from the North and South. The fact that the researchers were located in the North of the Netherlands, and were thus at greater distance from the Southern regions, might have played a role. It is advisable for researchers to think about possible regional differences that could affect participant recruitment by OHC providers. Other important aspects to consider when involving OHC providers in participant recruitment are the time OHC providers are given to recruit and the organisation of feedback moments during the intervention trial.

When comparing the present study with other research, only one Dutch publication is available on OP participation in RCTs. Steenstra et al. discussed OP participation from the viewpoint of researchers and the main problems mentioned were research that does not fit the OPs' practice, high work pressure and unfamiliarity with RCTs[12]. Our study adds to this knowledge by (1) presenting the problems that are experienced from the viewpoint of OPs which supports some findings (e.g. work pressure) but also differs on some points (e.g. unfamiliarity with RCTs was not mentioned in our study) and (2) presenting new findings (e.g. use of ICT-tools, research is experienced as an impulse for the services of the OHS). There are several studies that have investigated barriers to participation in research for other types of clinicians and found comparable results. Based on a survey among 78 studies in Dutch primary care research, van der Wouden et al. (2007) concluded that a software module linked to the electronic medical record may be helpful in reminding GPs about eligible patients, which is in agreement with our current findings[3]. Ross et al. reviewed barriers to clinician participation in RCTs and identified 78 papers describing problems related to clinician and participant recruitment in hospital and primary care settings[5]. The main barriers to clinician participation (i.e. as a treatment provider and recruiter of participants) were lack of time, not being prepared for a research role, alteration of the doctor-patient relationship, loss of clinical autonomy and burden of the research for the clinician and the participant. Some of these barriers were also pointed out by the OPs in this study, such as work pressure (i.e. lack of time), burden of the research and being more focused on patient care than on research (i.e. not prepared for a research role). Taking the similarities between our findings and those from other research areas into account, our results may have a broader applicability than the OHC setting of this study.

Our study contributes to the current knowledge on recruitment problems, as this is first study that quantitatively and qualitatively investigated recruitment problems in the OHC context. Furthermore, this is the first study that has found that participant recruitment by an OP is positively related to the number of OPs within the clinical unit who recruit participants. This finding might be specific to the Dutch OHC context where OPs are actively cooperating in clinical units but can be very relevant for other research contexts as well. Often, practitioners are approached individually to participate in

research, while most are part of some kind of practitioner group, such as peer coaching and feedback groups. Our research shows that it might be worthwhile to investigate in what kind of group practitioners are organised and to approach these groups instead of various individual practitioners. Also, the univariate analyses revealed potential relevant factors in participant recruitment that have not been found in recruitment studies within clinical and primary care contexts. Finally, compared to a recent qualitative meta-analysis on improving recruitment for RCTs, which included studies from hospital and primary care settings[6], we found several major themes that were not found in the meta-analysis, such as "OP's attention," "OP's characteristics" and "context." Thus, research on recruitment problems in the OHC setting is necessary as several factors seem to specifically influence participant recruitment in the OHC context.

Strengths and limitations

A strength of this study was the use of different data sources and a mixed-methods approach to investigate barriers and facilitators for participant recruitment by OPs. The results from the quantitative and qualitative analyses did not only complement each other but also confirmed each other on some parts. For the quantitative analyses, data of most OPs, involved in participant recruitment for the cluster-RCT, could be used. Another strength is the combination of focus groups and, additionally, telephone interviews as input for the qualitative analyses. In the focus group setting, OPs were able to react to each other's ideas and came up with new insights based on what they heard from others, while in the interview setting, OPs were not influenced by possible group dynamics. Finally, we collected data from OPs that were very successful in recruiting participants which enabled us to not only report on barriers but also on facilitators for participant recruitment.

A limitation of the focus group and interview study is that the coordinating researcher (IA) of the cluster-RCT acted as interviewer and moderator, implicating that OPs might not have spoken speak freely about problems with participant recruitment. However, the results showed that OPs were open in mentioning problems related to the study design and protocol. Further, the list of categories and subcategories extracted from the focus groups and interviews was only confirmed by three of the 18 OPs that participated; the other OPs did not respond. We do believe that the categorisation reflects the perspective of the OPs based on conversations with different OPs during feedback moments and visits to the clinical units where often similar barriers and facilitators were mentioned as presented in the categorisation. Another limitation is the cross-sectional analysis of the quantitative data, which makes it impossible to draw causal inferences between OP characteristics and participant recruitment. The independent variable "number of OPs within the clinical unit who recruited

participants" included the participation of the OP of interest, and this might have influenced the results because of its relationship with the outcome variable "number of workers recruited per OP." Furthermore, the qualitative data showed that work pressure was an important barrier to recruitment, but we were not able to include in the quantitative analysis as there were no quantitative data available on work pressure. Finally, as three variables ("readiness for change," "attitudes towards the intervention" and "participation in feedback moments") were only measured for the intervention group it would have been interesting to make a separate multivariate regression model for the intervention group, but this was not feasible due to the small sample size.

Conclusion

Barriers to research participant recruitment in the OHC setting are comparable to hospital and primary care settings. However, an important difference seems to be the influence of the OP's organisational context on recruitment, such as support from the OHS and patients' employers. Recruitment in the OHC setting can be facilitated when researchers not only motivate individual OPs but entire clinical units. OPs consider continuous attention on recruitment strategies, especially face-to-face contact and ICT tools as reminders, as helpful for improving participant recruitment.

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7

Economic evaluation of a problem solving intervention to prevent recurrent sickness absence in workers with common mental disorders

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ABSTRACT

Objectives: Workers with common mental disorders (CMDs) frequently experience recurrent sickness absence but scientifically evaluated interventions to prevent recurrences are lacking. The objectives of this study are to evaluate the cost-effectiveness and cost-benefit of a problem solving intervention aimed at preventing recurrent sickness absence in workers with CMDs compared to care as usual care as usual.

Methods: An economic evaluation was conducted alongside a cluster-randomised controlled trial with 12 months follow-up. Treatment providers were randomised to either a 2-day training in the SHARP-at work intervention, i.e. a problem solving intervention, or care as usual. Effect outcomes were the incidence of recurrent sickness absence and time to recurrent sickness absence. Self-reported health care utilisation was measured by questionnaires. A cost-effectiveness analysis (CEA) from the societal perspective and a cost-benefit analysis (CBA) from the employer's perspective were conducted.

Results: The CEA showed that the intervention was more effective but also more expensive than care as usual. The CBA revealed that employer's occupational health care costs were significantly higher in the intervention group compared to care as usual. Overall, the SHARP-at work intervention showed no economic benefit compared to care as usual.

Conclusions: As implementation of the SHARP-at work intervention might require additional investments, health care policy makers need to decide if these investments are worthwhile considering the results that can be accomplished in reducing recurrent sickness absence.

Trial registration number: NTR1963.

INTRODUCTION

The costs of mental disorders to society are substantial in terms of medical care consumption, but even more because of productivity loss due to sickness absence, work disability and at-the-job productivity loss[1-7]. Common mental disorders (CMDs, i.e. depressive, anxiety and adjustment disorders), as opposed to severe mental disorders, account for the majority of costs related to mental ill-health[7]. However, evidence for work-related interventions is much more established for severe mental disorders, such as supported employment programs[8]. In the last decade, several studies have focused on workers suffering from CMDs and have evaluated interventions to enhance return to work (RTW)[9-12]. In these studies, RTW has been defined as endpoint while recent research has shown that 20% to 30% of the workers who returned to work after sickness absence due to CMDs experience recurrent sickness absence[13,14]. Moreover, recurrent sickness absence is often more serious and long-lasting than the initial sickness episode due to CMDs[13]. Thus, more attention is needed for enhancing sustainable RTW of workers with CMDs by preventing recurrent sickness absence.

The SHARP-at work intervention is developed to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs[15]. The intervention consists of problem-solving treatment provided by occupational physicians (OPs). OPs guide workers through a problem-solving process focused on establishing solutions for problems and opportunities encountered when back at work. Furthermore, consultations between the worker and the supervisor are stimulated by the OP to achieve solutions that can be readily implemented. The intervention was compared to care as usual (CAU) in a cluster-randomised controlled trial (cluster-RCT) and has shown to be effective in reducing recurrent sickness absence (Arends et al., submitted).

Before implementing the SHARP-at work intervention in the occupational health care practice, insight is needed in the relationship between intervention costs and benefits compared to CAU[16]. Therefore, the objective of this study was to perform an economic evaluation of the SHARP-at work intervention compared to CAU. Cost-effectiveness was evaluated from the societal perspective and cost-benefit from the societal and employer perspective.

METHODS

Study design

An economic evaluation was conducted alongside a cluster-RCT. OPs, who conducted the intervention, were recruited through 365/ArboNed, one of the largest Occupational Health Services in the Netherlands. The Medical Ethical Board of the University Medical Center Groningen provided approval for the study design, the research protocol,

questionnaires, information letters and the informed consent. More detailed information on the study design and procedure of the cluster-RCT has been presented elsewhere[15].

Study setting

In the Netherlands, the employer pays sickness absence benefits to the sick-listed worker for two years. During these two years, both the employer and sick-listed worker are responsible for RTW. The employer is obliged to contract an OP to help guiding the RTW process. If RTW has not been accomplished after two years, the Social Security Agency (SSA) evaluates if sufficient RTW efforts have been made by the employer and worker and decides on the percentage of work disability for which the worker will be compensated by the SSA. Costs for treatment and work accommodations are the responsibility of the employer, but compensation can be requested from the SSA for work accommodations.

Study population

Participants were recruited by OPs between January 2010 and June 2011. Eligible participants were workers between 18 and 63 years, had to be diagnosed with a CMD by their OP at the start of sickness absence and had to be ready to (partially) RTW. A detailed overview of all inclusion and exclusion criteria has been presented elsewhere[15].

Randomisation and blinding

OPs were randomised to the intervention or control group based on a computer-generated random allocation sequence because workers could not be randomly allocated to OPs as OPs are bound to companies. Since a worker's allocation was predefined based on the OP's allocation, we only provided information on the treatment the worker would receive and blinded the worker for study design and comparison group. OPs were not blinded for study design and allocation.

Interventions

SHARP-at work intervention

A detailed description of the intervention has been provided elsewhere (Arends et al., submitted for publication). In brief, the SHARP-at work intervention was developed to prevent recurrent sickness absence by structured OP guidance after RTW. The intervention was started by OPs when participants on sickness absence due to CMDs were ready to RTW. Five steps had to be followed by the participant when RTW was started. The OP monitored that all steps were taken and activated the participant when needed. For each step, facilitating assignments for the worker were at the OP's

disposal. The five steps comprised: (1) making an inventory of problems and/or opportunities encountered at work after RTW, (2) brainstorming about solutions/realisations, (3) writing down solutions/realisations and the support needed and assessing the applicability of these solutions, (4) discussing solutions/realisations and making an action plan with the supervisor, and (5) evaluating the action plan/implementation of solutions. Two to five consultations, of 30 minutes each, were recommended to OPs. The first of five assignments (i.e. making an inventory of problems and opportunities and assessing the help needed to solve them) instigated the problem solving process and was therefore a key element. OPs received a two-day training in the SHARP-at work intervention and had three feedback moments to discuss their experiences with conducting the intervention.

Care as usual

All participating OPs were already trained in the evidence-based guideline of the Netherlands Society of Occupational Medicine "The treatment of workers with mental health problems by the OP"[17,18]. The guideline is primarily directed at structuring OP's treatment to help sick-listed workers with mental health problems to RTW. Though one consultation has to take place after RTW to address relapse prevention, limited attention is given to a structured follow-up of OP's treatment after RTW has been accomplished.

Economic evaluation

An economic evaluation was performed from the societal and employer perspective. The evaluation from the societal perspective consisted of a cost-effectiveness analysis (CEA) with the difference in incidence of recurrent sickness absence and time to recurrent sickness absence between the two study groups as the outcomes. Costs associated with health care utilisation and the intervention or CAU costs were included in the CEA. From the employer perspective, a cost-benefit analysis (CBA) was performed comparing the two study groups regarding costs associated with health care utilisation and the intervention or CAU costs and the monetary value of differences in productivity.

Effects

The effect measures were the incidence of recurrent sickness absence over 12 months follow-up and time to recurrent sickness absence. Recurrent sickness absence was defined as ≥ 30% decrease in working days per week due to sickness absence. Recurrent sickness absence days were corrected for partial RTW by dividing the sickness absence days by 1/RTW percentage.

Health care costs

Data were collected using the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P) with a 4-week recall period at baseline and at 3, 6 and 12 months follow-up. The data were linearly interpolated over 12 months. The unit prices used for valuing resource utilisation are presented in Table 1. The study's index year was 2009. The Dutch Manual for Costing was used for calculating standard prices [19]. Costs for alternative care were based on real costs reported by the participants. Medication costs were valued with cost prices of the Royal Dutch Society for Pharmacy[20]. Two questions on number of consultations with the OP and company social worker were added to the Tic-P to collect data on use of occupational health services. For the calculation of costs from the societal perspective, the OP consultations were valued using the cost level for general practitioners, and consultations with the company social worker were valued using the cost level for social workers. For the calculation of costs from the employer perspective real employer prices for OPs and company social workers were used which were provided by the Occupational Health Service.

Productivity loss

Costs associated with productivity loss were estimated from an employer perspective. Productivity loss was operationalized as costs resulting from sickness absence and at-work productivity loss (i.e. presenteeism). To measure sickness absence costs, administrative data were collected on cumulative number of days of sickness absence over a period of 12 months. Calendar days of sickness absence were corrected for part-time sickness absence and converted to number of working hours based on participants'' work contract. For the calculation of productivity loss costs, we assumed that participants were 100% productive during the hours of work resumption. At-work productivity loss was assessed with one question of the TiC-P stating: "How many extra hours would you have to work to catch up on tasks you were unable to complete in normal working hours due to health problems over the past two weeks?" Sickness absence costs and costs for at-work productivity loss were calculated by multiplying the number of sickness absence hours by the estimated cost of production loss for a worker per hour of absence, differentiating between costs for men and women. We used the Human Capital Approach (HCA) and the Friction Cost Approach (FCA) to calculate the total costs of production loss. A friction period of 154 days and an elasticity of 0.8 were applied in the FCA[19,21].

Table 1. Unit prices used and mean (SD) total costs per study group.

		Mean costs (SD)	
Type of costs	**Unit prices**	**SHARP**	**CAU**
Health care costs for society			
General practitioner	29[1]	59 (63)	61 (70)
Regional Institute for Community Mental Health Care	70[1]	69 (140)	96 (194)
Psychiatrist	107[1]	22 (74)	67 (212)
Psychologist	83[1]	212 (228)	209 (205)
Occupational physician	29	81 (48)	60 (46)
Company social worker	68	34 (80)	16 (48)
Medical specialist	75[1]	103 (239)	91 (208)
Physiotherapist	37[1]	61 (138)	68 (118)
Social worker	68[1]	15 (52)	15 (80)
Alternative health care	31 - 64[2]	66 (137)	91 (189)
Psychiatric part-time or day program	200[1]	48 (347)	27 (186)
Hospitalisation	452-597[1]	164 (1000)	42 (163)
Prescribed medication	Variable[3]	43 (83)	38 (65)
Self-purchased medication	Variable[2]	33 (105)	80 (158)
Out-of-pocket costs	Variable[2]	29 (109)	38 (159)
SHARP-at work intervention	661	661	0
Total health care costs		4167 (9407)	2403 (2360)
Costs of occupational health services for employer			
Occupational physician	154	420 (250)	314 (240)
Company social worker	121	248 (239)	178 (125)
SHARP-at work intervention	661	661	0
Total costs of occupational health services		1143 (342)	343 (254)
Costs of productivity loss			
Productivity loss net HCA			
Only sickness absence		37265 (26227)	32019 (22442)
Combined[4]		36072 (20015)	31342 (24039)
Productivity loss net FCA			
Only sickness absence		27789 (17185)	24594 (15993)
Combined[4]		28194 (14529)	24264 (18069)

All costs are given in euros. SHARP = intervention group; CAU = care as usual; HCA = human capital approach; FCA = friction cost approach.
[1]Price according to Dutch guidelines for costing studies.
[2]Price according to self-report of participants.
[3]Price according to the Royal Dutch Society for Pharmacy.
[4]Productivity loss costs are a combination of sickness absence costs and costs due to lost productivity at work.

Data analysis

The economic evaluation was performed according to the intention-to-treat principle. Discounting of costs was not applied because the follow-up was limited to one year. Sickness absence data were collected for 145 (92%) participants and a complete follow-up on self-reported data was available for 99 (63%) participants.

For the CEA, the incremental cost-effectiveness ratio (ICER) was calculated by dividing the incremental costs by the incremental effects. The incremental costs consisted of the difference in all health care utilisation costs (including the intervention costs) between the intervention and control group. Two incremental effect measures were calculated: (1) the difference in incidence of recurrent sickness absence and (2) the difference in time (measured in days) to recurrent sickness absence between the

intervention and control group. The ICER represents the additional investments needed to prevent one case of recurrent sickness absence or to prevent one day of recurrent sickness absence. For the CBA from the employer's perspective, the net monetary benefit (NMB) was calculated by subtracting the difference in costs for occupational health services (including the intervention costs) between the intervention and control group from the difference in costs of productivity loss between the two groups. Total costs of productivity loss was calculated with and without costs due lost productivity at work, next to costs of sickness absence, as data on lost productivity at work were only available for 51% of the study sample. The CBA was performed using both the HCA and FCA. The mean difference in costs and benefits between the intervention and control group and the 95% confidence intervals (CI) were calculated with multilevel regression analysis to account for the study's multilevel design.

The 95% CI's for the incremental costs were estimated using a bias corrected and accelerated bootstrapping procedure with 5000 replications[22]. Bootstrapped cost-effect pairs were plotted on a cost-effectiveness plane. Cost-effectiveness acceptability curves were generated if the ICER was located in the north-east quadrant [23]. Sensitivity analysis for the CEA was conducted to assess the effect of one extreme outlier. Sensitivity analyses for the CEA and CBA were conducted to assess the effect of reducing the intervention costs to €30 per participant. This reduction in costs was calculated under the assumption that, in practice, OPs will treat more workers according to the intervention than the 80 workers that were included in the intervention group of the present study. In this way, the training costs of the intervention could be divided over more workers causing a reduction in intervention costs per worker. Based on the OHS's data, every OP treats 2500 to 3000 workers of which 32 to 39 experience sickness absence due to CMDs within one year[15]. Taking the conservative assumption that OPs can treat 24 of the 32 to 39 workers according to the intervention per year, the intervention training costs for the 73 OPs that participated in the study can be divided over 1752 (73 x 24) workers, leading to a total amount of €30 per worker instead of €661 (see also Table 2). Data processing was performed in SPSS 20.0. Calculation of CIs and CEA analyses were conducted in R[24].

Table 2. Costs of the SHARP-at work intervention.

Resources	Description	Aggregated costs in euros	
Costs for training OPs in the intervention			
Trainer costs[1]	Preparation of training: 2 trainers, 2-10 hours, €100 per hour	1200	
	Training sessions: 2 trainers, 12-108 hours, €100 per hour	12000	
	Follow-up meetings: 1 trainer, 6 hours, €100 per hour	600	
OP attendance costs[2]	Training of OPs: 73 OPs, 12 hours, €40 per hour	35040	
	Follow-up meetings: 40 OPs, 1,5 hours, €40 per hour	2400	
Additional training costs	Rent for training location, refreshments and study materials	1660	
Total training costs	Sum of trainer costs, OP attendance costs and additional training costs		52900
Training costs per worker	Total training costs divided by 80 workers		661
Training costs per worker sensitivity analysis	Total training costs divided by 1740 workers		30

OP = occupational physician.
[1]Based on price requested by trainer.
[2]Based on OP's mean wage paid by the Occupational Health Service that was responsible for training the OPs.

RESULTS

Participants

OPs recruited 212 workers of whom 158 agreed to participate. Eighty participants were treated by OPs in the intervention group and received the SHARP-at work intervention, and 78 participants were treated by OPs in the control group and received CAU. Baseline characteristics of the study population are presented in Table 3.

Effects on recurrent sickness absence

The incidence of recurrent sickness absence during 12 months follow-up was 39% for the SHARP group and 62% for the CAU group. The mean effect difference between the SHARP and CAU group was 24% (95% CI 3% to 45%) in favour of the SHARP group, i.e. there was 24% less recurrent sickness absence in the SHARP group (Table 4). The median number of days to recurrent sickness absence was 365 (inter quartile range (IQR) 174 to 365) in the SHARP group and 253 (IQR 117 to 365) in the CAU group. The mean effect difference between the SHARP and CAU group was 55 (95% CI 2.85 to 106.09) days in favour of the SHARP group, i.e. the SHARP group experienced recurrent sickness absence 55 days later than the CAU group (Table 4).

Table 3. Baseline characteristics of the study population.

Characteristics		SHARP (n = 80) M / n	SD / %	CAU (n = 78) M / n	SD / %
Socio-demographic characteristics					
Age (years)		41.3	9.4	43.3	9.8
Gender (male)		27	33.8	38	48.7
Marital status (married or living together)		67	83.8	60	76.9
Breadwinner (yes)		40	50.0	49	62.8
Education level					
Low		6	7.5	13	16.7
Intermediate		36	45.0	40	51.3
High		38	47.5	23	29.5
Clinical characteristics					
ICD diagnosis by OP					
F32.9 Depressive episode, unspecified		4	5.0	12	15.4
F41.9 Anxiety disorder, unspecified		0	0.0	2	2.6
F43.2 Adjustment disorders		58	72.5	39	50.0
F43.9 Reaction to severe stress, unspecified		1	1.25	0	0.0
R45 Symptoms and signs involving emotional state		7	8.75	14	17.9
Z73.0 Burn-out		2	2.5	7	9.0
Other		8	10.0	4	5.1
Work-related characteristics					
Type of occupation					
Commercial service providers		23	28.8	11	14.1
Management		11	13.8	15	19.2
Administrative staff		19	23.8	12	15.4
ICT staff		4	5.0	4	5.1
Sales staff		2	2.5	5	6.4
Health care providers		12	15.0	12	15.4
Hotel and catering staff		3	3.8	0	0.0
Stock and/or transport staff		1	1.3	11	14.1
Designers/planners		3	3.8	2	2.6
Mechanics/repairmen		2	2.5	5	6.4
Employment (hours per week)		32.6	7.0	32.9	7.3
Irregular work (e.g. shift work)		6	7.5	10	12.8
Executive/manager responsibilities		23	28.8	21	26.9
Duration of sickness absence		130.9	94.2	99.3	66.1
WRFQ-Total score		66.9	15.5	61.0	20.0
Health-related characteristics					
4DSQ	Distress	13.8	7.5	15.5	7.5
	Depression	1.5	2.1	2.0	2.4
	Anxiety	3.1	3.3	3.6	3.5
	Somatisation	7.9	5.3	7.9	5.5
HADS	Depression	7.0	4.5	7.3	4.4
	Anxiety	7.2	3.9	7.8	3.4

SHARP = intervention group; CAU = care as usual group; OP = occupational physician; WRFQ = Work Role Functioning Questionnaire; 4DSQ = Four-Dimensional Symptom Questionnaire; HADS = Hospital Anxiety and Depression Scales; M = mean; SD = standard differentiation.

Health care and productivity loss costs

The mean costs of health care utilisation are presented in Table 1. An important cost driver was care by the psychologist. There were small differences between the SHARP and CAU group regarding non-occupational health care use. The SHARP group more frequently visited the OP and company social worker. Following this, total occupational health care costs for the employer were significantly higher in the SHARP group (Table 4). The costs of the SHARP-at work intervention were €661 per worker. We also calculated the intervention costs based on the assumption that, in practice, every OP could treat at least 24 workers according to the intervention lowering intervention costs per worker to €30 (Table 2). The difference in mean total health care costs between the two study groups was mainly due to one outlier in the SHARP group whose total health care costs were more than nine times higher than the upper limit of the 95% CI of the total health care costs of the SHARP group. The high costs for this outlier were mainly due to hospitalisation in a psychiatric ward.

No significant differences were found between the SHARP and CAU group regarding cost of productivity loss (Table 4). For both groups, cost of productivity loss represented 87% to 93% of the total costs, depending on how it was measured (HCA or FCA).

Table 4. Mean cost and effect differences between the SHARP and CAU group.

Analysis[1]	**ΔC (95% CI)** euros	**ΔE (95% CI)** percentage/days/euros[4]	**ICER**	**NMB**[5]
Total group				
CEA-incidence of RSA	1932 (-318 to 5350)	0.24 (0.03 to 0.45)	10605	
CEA-time to RSA	1358 (-945 to 4886)	55 (2.85 to 106.09)	2183	
CBA HCA only sickness absence	800 (678 to 922)	5246 (-2701 to 13192)		6046
CBA FCA only sickness absence	800 (678 to 922)	3195 (-2214 to 8604)		3995
CBA HCA combined[2]	800 (678 to 922)	4730 (-5699 to 15158)		5530
CBA FCA combined[2]	800 (678 to 922)	3929 (-3764 to 11623)		4729
Excluding outlier[3]				
CEA-incidence of RSA	-133 (-1155 to 914)	0.25 (0.03 to 0.46)	-533	
CEA-time to RSA	-129 (-1266 to 964)	59 (5.95 to 111.15)	-2	

CEA = cost-effectiveness analysis; RSA = recurrent sickness absence; CBA = cost-benefit analysis; ΔC = mean cost difference; ΔE = mean effect difference; HCA = human capital approach; FCA = friction cost approach; ICER = incremental cost effect ration; NMB = net monetary benefit.

[1]In the CEA, ΔC is the mean difference in total health care costs and ΔE is the mean difference in percentage of workers that experienced recurrent sickness absence; in the CBA, ΔC is the mean difference in total occupational health care costs, including the intervention, for the employer and ΔE is the mean difference in sickness absence costs estimated by the HCA or FCA.

[2]Productivity loss costs are a combination of sickness absence costs and costs due to lost productivity at work.

[3]Sensitivity analysis excluding one extreme outlier.

[4]Differences in CEA effects are presented in (1) percentage of workers that experienced recurrent sickness absence, (2) number of days to recurrent sickness absence; differences in CBA benefits are presented as costs in euros.

[5]Negative values of the NMB imply lower costs for the intervention group compared to the control group.

Cost-effectiveness analysis

The CEA with incidence of recurrent sickness absence as effect measure showed an ICER of €10.605 per percent of prevented recurrent sickness absence episode, i.e. an additional €10.605 were needed in the SHARP group to have 1% less recurrent sickness absence compared to the CAU group (Table 4). The cost-effectiveness plane showed that 92% of the bootstrap cost-effectiveness pairs were in the north-east quadrant (Figure 1A). The cost-effectiveness acceptability curve showed that if one is willing to invest €20.000 for 1% less recurrent sickness absence, there is a 0.84 probability that the intervention is cost-effective compared to CAU (Figure 1A). The CEA with time to recurrent sickness absence as effect measure showed an ICER of €2813 per one day of prevented recurrent sickness absence, meaning that an additional €2813 was needed in the SHARP group to prevent one day of recurrent sickness absence. The cost-effectiveness plane showed that 77% of the bootstrap cost-effectiveness pairs were in the north-east quadrant (Figure 1B). The cost-effectiveness acceptability curve showed that if one is willing to invest €70 to prevent one day of recurrent sickness absence, there is a 0.85 probability that the intervention is cost-effective compared to CAU (Figure 1B). Thus, the SHARP-at work intervention was more effective but also more costly compared to CAU.

The sensitivity analysis excluding the outlier showed an ICER of €-533 for the incidence of recurrent sickness absence, indicating that the intervention was cost-effective: 1% less recurrent sickness absence saved €533. In the cost-effectiveness plane 60% of the bootstrap cost-effectiveness pairs were in the south-east quadrant (Figure 2). The cost-effectiveness acceptability curve showed a 0.98 probability that the intervention is cost-effective compared to CAU if one is willing to invest €15.000 for 1% less recurrent sickness absence (Figure 2). Similarly, the sensitivity analysis excluding the outlier changed the direction of the primary results regarding time to recurrent sickness absence. An ICER of €-2 was found, indicating that the intervention was cost-effective compared to care as usual: the prevention of one day of recurrent sickness absence saved €2. The cost-effectiveness plane showed that 58% of the bootstrap cost-effectiveness pairs are in the south-east quadrant (Figure 2). The cost-effectiveness acceptability curve showed a 0.98 probability that the intervention is cost-effective compared to CAU if one is willing to invest €70 to prevent one day of recurrent sickness absence (Figure 2).

Sensitivity analyses with reduced intervention costs did not change the direction of the primary analyses.

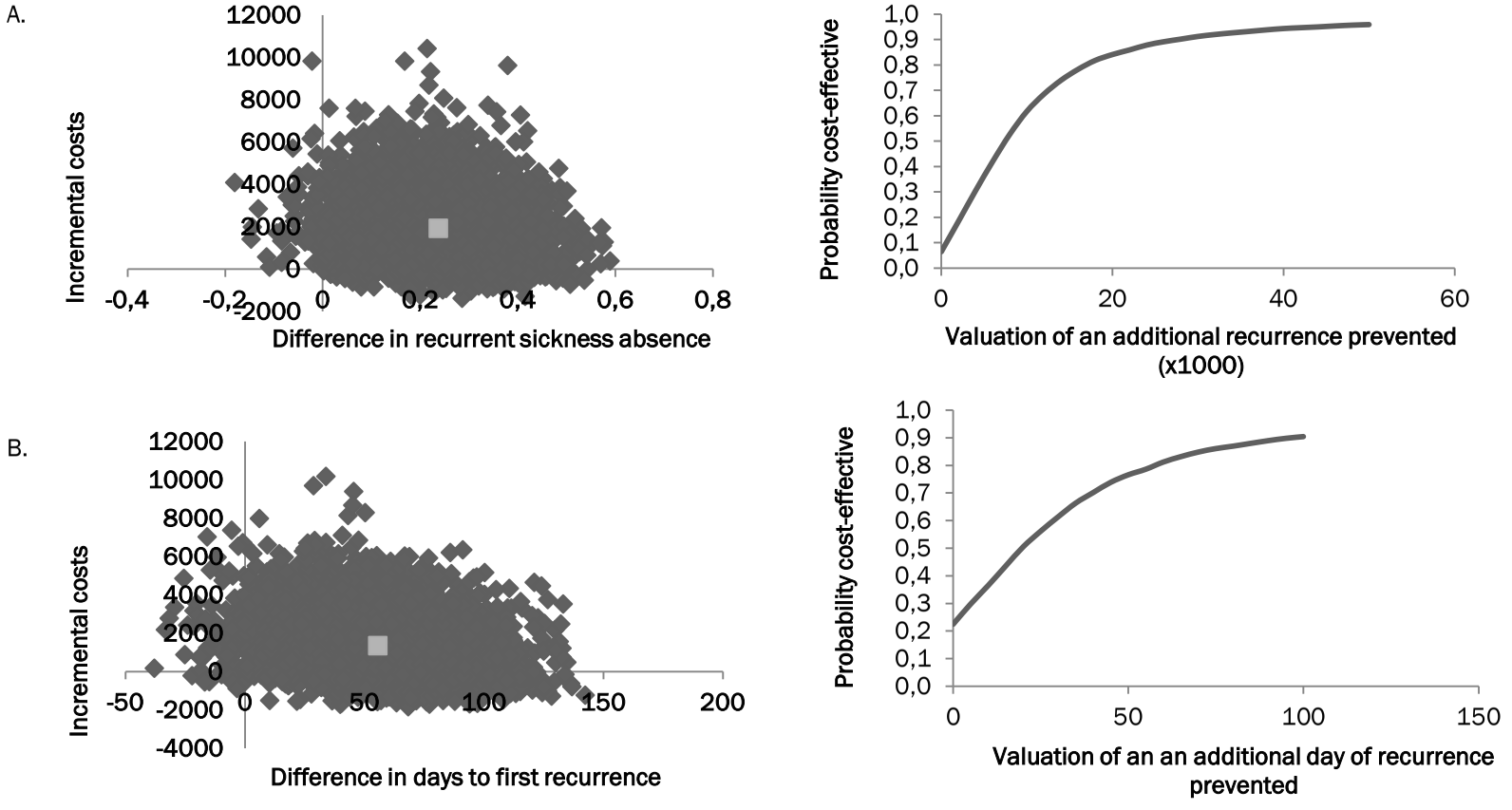
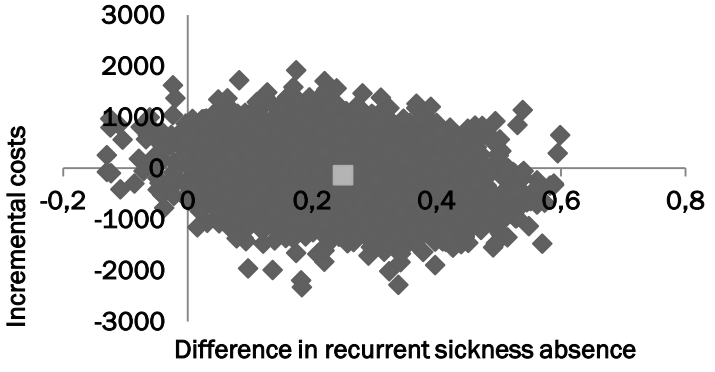
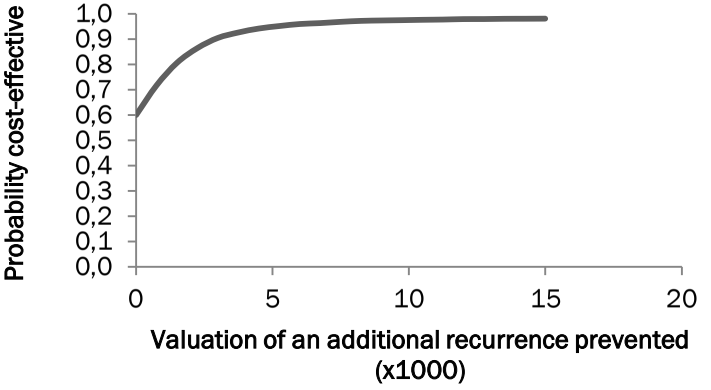
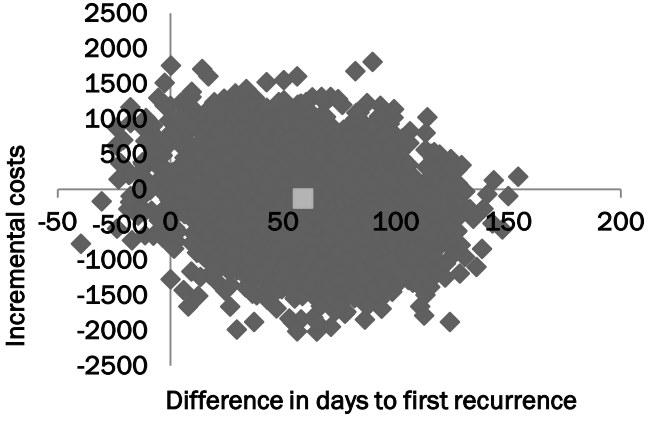


Figure 1. Cost-effectiveness planes and acceptability curves for the difference in incidence of recurrent sickness absence (A) and time to recurrent sickness absence (B).







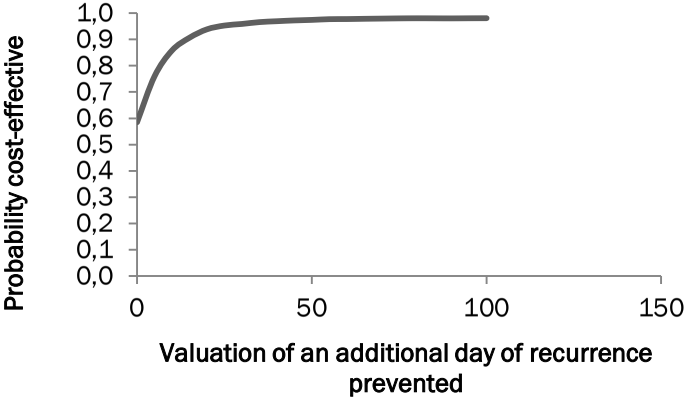


Figure 2. Cost-effectiveness planes and acceptability curves excluding one outlier for (A) the difference in incidence of recurrent sickness absence and (B) time to recurrent sickness absence.

Cost-benefit analysis

The CBA from the employer's perspective showed that the mean cost difference for occupational health services was in favour of the CAU group. The mean costs were €800 (95% CI 678 to 922) higher in the SHARP group compared to the CAU group. The mean cost difference for productivity loss was also in favour of the CAU group. According to the HCA, only including sickness absence costs, the mean costs for productivity loss were €5246 (95% CI -2701 to 13192) higher in the SHARP group. Following the FCA, only including sickness absence costs, the mean costs for productivity loss were €3195 (95% CI -2214 to 8604) higher in the SHARP group. Thus, no net monetary benefit was achieved with the SHARP-at work intervention compared to CAU. The sensitivity analyses with reduced intervention costs did not change these results.

DISCUSSION

The SHARP- at work intervention had a superior effect on the incidence of and time to recurrent sickness absence but had no economic benefit compared to care as usual. From a societal perspective, there were no significant differences in health care costs between the SHARP group and CAU group. Employer costs for occupational health care were significantly higher in the SHARP group compared to CAU. Costs due to lost productivity did not significantly differ between the two study groups. Thus, to realise the effect on recurrent sickness absence, additional monetary investments in the SHARP-at work intervention were needed. Even though an economic benefit of the intervention was not found, a societal benefit may be realised when the reduction in recurrent sickness absence results in more stable work participation. Sensitivity analyses for the CEA excluding one major outlier changed the direction of the primary CEA results. Excluding the outlier, the SHARP-at work intervention was cost-effective in preventing the incidence of recurrent sickness absence and increasing time to recurrent sickness absence.

Although the SHARP-at work intervention was effective in reducing the incidence of recurrent sickness absence and increased the time to recurrent sickness absence, the CBA showed no effect on reduced costs of productivity loss. This result might be counterintuitive as a reduced incidence of recurrent sickness absence would be expected to result in reduced sickness absence days and, thus, reduced costs due to productivity loss. However, costs due to productivity loss were found to be somewhat higher for the SHARP group, meaning that the SHARP group had more sickness absence days. This result may be partly explained by the fact that the CAU group had a shorter duration of sickness absence and a higher RTW percentage at baseline,

resulting in less sickness absence days. Possibly, the study's one-year follow-up timeframe was too short to pick up long-term effects on sickness absence.

No previous studies have been published on an economic evaluation of an intervention to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Recently, several economic evaluations of RTW interventions for workers with mental health problems were published[25-28]. Comparing our study results with these RTW studies is complicated as the study populations and the effect measures differ. The participants in the RTW studies were still off work and the interventions aimed to facilitate RTW. Effect measures in the economic evaluations of these RTW studies are focused on days to first or full RTW. Most of the RTW studies showed no economic benefit of the RTW intervention under investigation[25,27,28].

Strengths and limitations

The strengths of this study are the pragmatic design, data collection on productivity loss and the use of a societal and employer perspective for the economic evaluation. Firstly, the pragmatic study design enabled an economic evaluation of the SHARP-at work intervention in a real life situation and in a heterogeneous study population. Participants lived in different parts of the Netherlands, worked for small and large companies in different branches and occupied various job positions. This increased the external validity of the study results. Secondly, data on productivity loss included costs due to self-reported lost productivity at work, i.e. presenteeism, next to costs due to sickness absence. Even though information on productivity loss at work was only collected for 51% of the study sample, the CBA including this information gives a clear indication of the underestimation of productivity loss costs when only using sickness absence data and assuming that participants are 100% productive when at work. As presenteeism seems to be an important contributor to productivity loss among workers with mental health problems, this is an important variable to include in economic evaluations[6,29,30]. However, previous studies on the economic benefit of occupational health care interventions for workers with mental health problems often missed information on presenteeism[26-28]. Lastly, the cost-effectiveness evaluation from the broad societal perspective increased the generalisability of the results, while the cost-benefit analysis from the employer perspective provided a realistic perspective on the distribution of costs and benefits of the SHARP-at work intervention within the Dutch social security context.

Some methodological limitations need to be considered. Data on health care utilisation were collected based on retrospective, self-reported questionnaires which may have biased the results. Although participants received diaries to keep track of health care utilisation to improve the reliability of the self-reported questionnaires, these diaries were sent for participants' own convenience and not recollected. Thus, we

were not able to check whether the diaries were used. Furthermore, data on health care utilisation during the past month were only collected at four measurement points and were linearly interpolated to 12 months, assuming a linear time trend in health care utilisation. Health care costs may have been overestimated or underestimated if health care utilisation between two time measurements was not linear over time. However, this probably will not have affected the direction of our results, as the health care costs only presented a small proportion of the total costs and data were linearly interpolated for both study groups. Another limitation is the missing data due to loss to follow-up: 62% of the participants had complete cost data. By using a bootstrap procedure with 5000 replications for the CEA, the problem of missing data was partly averted. Furthermore, we chose to conduct complete case analysis because we assumed that the data were missing completely at random: no significant differences were found between participants who were lost to follow-up and those who completed the study (Arends et al. submitted for publication). One exception might have been the data collected on productivity loss at work. Many participants responded to this question with a question mark, indicating that participants had trouble understanding this item. Therefore, we decided to also conduct the CBA excluding the information on lost productivity at work. As 62% of the data could be used for the CEA and CBA and no power calculation was conducted for the economic evaluation, it could be possible that the study was underpowered. For example, sensitivity analyses excluding one major outlier in the intervention group showed that the CEA results were strongly influenced by this outlier as the direction of the results changed after excluding the outlier. Finally, no information was collected on the costs of workplace adaptations that possibly resulted from the SHARP-at work intervention. This might have caused an underestimation of the intervention costs. However, costs due to possible workplace adaptations would be difficult to measure in a population of workers with CMDs. These workers do not so much require adaptations in workplace equipment or design but are more in need of, for example, frequent/longer breaks, lower work pace or other job content[31] of which the costs are hard to estimate. Comparable workplace adaptations could also have been introduced in the CAU group, as participants in this group also had consultations with their OPs. Thus, differences in total health care costs between the two study groups would probably not drastically increase by including costs related to workplace adaptations.

Conclusion

The SHARP-at work intervention is effective in reducing recurrent sickness absence and in increasing time to recurrent sickness absence but is associated with higher costs compared to CAU. Bearing in mind the study's limitations, future research needs to confirm that the SHARP-at work intervention is not cost-effective and cost-beneficial. As

implementation of the SHARP-at work intervention might require additional investments, health care policy makers need to decide if these investments are worthwhile considering the results that can be accomplished in reducing recurrent sickness absence.

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8

Predictors of recurrent sickness absence in workers with common mental disorders

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ABSTRACT

Objective: To investigate whether socio-demographic, disease-related, personal, and work-related factors, measured at baseline, are predictors of recurrent sickness absence at 6 and 12 months follow-up in workers who returned to work after sickness absence due to common mental disorders (CMDs).

Methods: A prospective study based on a cluster-randomized controlled trial with 6 and 12 months follow-up conducted in an occupational health care setting. Occupational physicians included 158 participants, aged 18-63 years and diagnosed with a CMD, who had returned to work. The outcome was the incidence of recurrent sickness absence at 6 and 12 months follow-up.

Results: At 6 and 12 months follow-up, 32% and 37% of the participants experienced recurrent sickness absence, respectively. Longitudinal logistic regression analysis with backward elimination showed that company size >100 (odds ratio [OR] = 2.59, 95% confidence interval [CI] 1.40 to 4.80) and conflicts with the supervisor (OR = 2.21, 95% CI 1.21 to 4.04) were predictive of recurrent sickness absence. Having one or more chronic diseases decreased the risk of recurrent sickness absence (OR = 0.54, 95% CI 0.30 to 0.96).

Conclusions: Work-related factors rather than disease-related factors predicted the incidence of recurrent sickness absence in workers with CMDs. Health care providers can use the findings to detect and help workers who returned to work and are at higher risk for recurrent sickness absence. Furthermore, future interventions to prevent recurrent sickness absence may focus on supervisor conflicts.

INTRODUCTION

Common mental disorders (CMDs, i.e. depressive, anxiety, and adjustment disorders) are a frequent cause of sickness absence, work disability, and reduced on-the-job productivity[1-6]. Several studies investigated predictors of first sickness absence and return to work (RTW) in workers with CMDs[7-11], but limited evidence is available about factors predicting recurrent sickness absence in workers who have returned to work after sickness absence due to CMDs. Recent studies have shown that recurrent sickness absence is a frequent problem in this worker population; 20% to 30% of the workers who returned to work after sickness absence due to a CMD experiences a recurrence of sickness absence[12,13]. Furthermore, studies have demonstrated that workers on sickness absence due to mental disorders have an increased risk of another sickness absence episode[14,15]. Recurrent sickness absence has a significant health impact. Recurrent sickness absence due to CMDs is often more serious and long-lasting than the first sickness absence episode[12]. Additionally, frequent sickness absence episodes are related to an increased risk of work disability in later years[15,16], and.

Few studies have investigated predictors for recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Based on a Dutch register study and a large Swedish cohort study, age <45 years and being married for women, age 44 to 55 years for men, and low socio-economic position for men and women were related to recurrent sickness absence[12,13]. However, these two studies did not investigate other potential predictors. Several studies have identified predictors of first sickness absence and RTW in workers with CMDs, such as disease-related factors (e.g. severity of mental health problems, problem duration, sickness absence) and work-related factors (e.g. decision authority, skill discretion, work motivation)[7,8,10,11,17-19]. Predictors of recurrent sickness absence could be different because workers might have had treatment or guidance during the previous sickness absence period and work accommodations might have been installed to enable RTW. Therefore, the goal of this prospective study was to investigate whether socio-demographic, disease-related, personal, and work-related factors predict recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

METHODS

Procedure

Data of a cluster-randomized controlled trial (cluster-RCT) were used in which problem solving treatment by occupational physicians (OPs) was compared to care as usual (CAU) by OPs on effectiveness in preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Participants were recruited from

January 2010 to June 2011 by OPs working for a large Dutch Occupational Health Service (OHS). OPs worked in different regions of the Netherlands, for companies of different sizes, and in different sectors. Inclusion criteria were: aged 18 to 63 years; employed in a paid job; diagnosed with a CMD by the OP (based on ICD-10 codes) at the start of the sickness absence episode; sickness absence for at least two weeks; RTW within two weeks. Exclusion criteria were: sickness absence episode > 12 months; prior sickness absence episode due to CMDs in past three months; severe mental disorders, such as psychotic disorder or bipolar disorder; somatic complaints/disorders that affect RTW; pregnancy, upcoming retirement/resignation/lay-off; not able to read, write, and understand Dutch. Participants received the baseline questionnaire when they had resumed work (mostly partial RTW) for two to four weeks. More detailed information on study design and setting can be found elsewhere (reference withheld to ensure anonymity). The Medical Ethical Board of the University Medical Center Groningen provided approval for the study.

Predictors

Based on previous research[8,11,12,18,20], the following potential predictors were examined:

Socio-demographic factors

Sex, age, educational level (low/medium/high) and cohabiting (yes/no).

Disease-related factors

The 14-item self-report Hospital Anxiety and Depression Scale (HADS) was used to assess depression (7 items) and anxiety (7 items). Item scores range from 0 to 3 with higher scores indicating more symptoms[21,22]. Distress symptoms were assessed with the 16-item distress scale of the Four-Dimensional Symptom Questionnaire (4DSQ) with scores ranging from *0 = no* to *2 = frequently, often or very often*[23,24]. All mental health measures were dichotomized at the cut-off score for clinical relevance (8 for the HADS en 20 for the distress scale[25,26]). Data on psychopharmacologic medication use (yes/no) was collected with the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (Tic-P)[27]. Sickness absence duration (in days) at baseline was obtained from the OHS registry and divided into tertiles because of the skewed data. General health was assessed with one question of the 36-item Short-Form Heath Survey (SF-36): "In general, how would you rate your health?'' The response categories were dichotomized to *very good*, *good*, or *fair* versus *poor* or *very poor*. Participants were also asked if they had one or more physical and/or mental chronic diseases (yes/no).

Personal factor

Coping behavior was assessed with the 14-item Utrecht Coping List[28]. The questionnaire consists of three scales: (1) active problem focused coping, (2) emotional coping, and (3) avoidance coping. Item scores range from *1 = seldom or never* to *4 = very often* with lower scores indicating infrequent use of a certain coping behavior.

Work-related factors

Work status was assessed by questionnaire data on tenure (0-5 years, >5 years), contract type (temporary/permanent), company size (<100, ≥100), supervisor (yes/no), monthly income in euro's, work accommodations for RTW (yes, no), and consultations with OP in the past month (0, 1, >1). Based on administrative data from the OHS' registry, we collected data on RTW percentage at the start of RTW and at baseline (two to four weeks after RTW started).

Work functioning was assessed with the 27-item Work Role Functioning Questionnaire [29,30]. Response categories ranged from *100% (all of the time)* to *0% (none of the time)*, with an option to score "not applicable." Scores were converted to a total score between 0 and 100, with higher scores indicating better work functioning.
Work engagement was assessed with the 9-item Utrecht Work Engagement Scale (UWES). Item scores range from *0 = never* to *6 = always* with higher scores indicating more work engagement[31,32].

Readiness to stay at work (RSAW) was assessed with the Stay At Work subscale (6 items) of the Readiness to Return to Work Scale[33]. Item scores range from *0 = totally disagree* to *4 = totally agree* with higher scores indicating more readiness to stay at work.

Work-related psychosocial factors, i.e. decision latitude, psychological job demands, supervisor social support, and co-worker social support, were measured with the Job Content Questionnaire [34-36]. Scores were divided into tertiles. Conflicts with colleagues and supervisors were both measured with one question from the Dutch Questionnaire on Perception and Judgment of Work[37] and dichotomized to *never* versus *sometimes, often or always*. Job insecurity was assesses with one question: "Are you afraid to lose your job within the near future?" (yes/no).

Outcome

Recurrent sickness absence (yes/no) was examined at 6 and 12 months follow-up. Recurrent sickness absence was defined as a 30% decrease in working days per week due to all-cause sickness absence, regardless of partial or full RTW. For example, a participant who had partially returned to work for 50% of the contract hours and went

back to 20% of the contract hours was registered as having recurrent sickness absence.

Statistical analysis

To identify predictors of recurrent sickness absence at 6 and 12 months follow-up, univariable and multivariable logistic Generalized Estimating Equations (GEE) analyses with exchangeable correlation matrices were conducted. Random effects at the OP level were examined in a mixed model but these did not improve model fit and were not included in the analyses. Intervention and control group were combined in the analyses. To investigate whether the intervention modified the relation between the predictor and the outcome variable, treatment type x predictor interactions were analyzed[38]. We first identified predictors with a p-value ≤ 0.20 in univariable analyses for inclusion in a multivariable model[39]. Subsequently, we tested interactions between each of these predictors and treatment type (problem solving treatment or CAU) in univariable models. Interaction terms with a p-value ≤ 0.20 were also included in the multivariable model. In the multivariable model, a backward selection procedure was used until the model only contained variables with p-values of <0.05[39]. Dummy variables were included when at least one of the dummies had a p-value <0.05 and when the model fit did not decrease due to the dummy variable. Treatment type was included as a covariate. For the final multivariable model, interactions with time were tested to examine whether the strength of associations between predictors and recurrent sickness absence differed at 6 and 12 months follow-up. In a sensitivity analysis, a multivariable model with a p-value <0.10 was analyzed. All analyses were performed in SPSS version 20.0.

RESULTS

Sample characteristics

Between January 2010 and June 2011, 212 participants were recruited by OPs of which 54 (25%) declined participation. Workers who declined participation did not significantly differ from those who agreed to participate regarding gender and age.The total study sample consisted of 158 participants (80 participants in the intervention group and 78 in the control group). For 146 participants administrative data were collected on recurrent sickness absence at 6 months follow-up and for 145 participants at 12 months follow-up (92%). One participant was excluded because of missing data on all variables. Baseline values for potential predictors are presented in Table 1. Recurrent sickness absence was experienced by 51 participants between baseline and 6 months follow-up (cumulative 6-month incidence 32%) and by 59 participants between 6 and 12 months follow-up (cumulative 6-month incidence 37%).

Predictors of recurrent sickness absence

In the univariable GEE analyses, 11 potential predictors showed a p-value of ≤0.20 (Table 2). Significant interactions with treatment group were shown for psychopharmacologic medication use and supervisor social support. Thus, 11 potential predictors and two interactions were entered into the multivariable GEE model. After backward elimination, the final multivariable model contained one disease-related predictor and two work-related predictors (Table 2). Company size >100 workers (OR = 2.59, 95% CI 1.40 to 5.80) and conflicts with supervisor (OR = 2.21, 95% CI 1.21 to 4.04) increased the risk of recurrent sickness absence. Reporting one or more chronic diseases (OR = 0.54, 95% CI 0.30 to 0.96) decreased the risk of recurrent sickness absence. None of these predictors had significant interactions with treatment group or time.

Sensitivity analysis with a p-value of ≤0.10 for the multivariable model resulted in two extra work-related predictors, i.e. job tenure and supervisor social support (Table 2). Longer job tenure increased the risk of recurrent sickness absence (OR = 1.89, 95% CI 0.99 to 3.61). Supervisor social support showed a significant interaction with treatment type. For workers in the control group, those in the highest tertile of supervisor social support scores were at lower risk of recurrent sickness absence compared to workers in the lowest tertile (OR = 0.28, 95% CI 0.07 to 1.14), while for the intervention group there was no statistically significant effect of supervisor social support.

Table 1. Baseline characteristics of study population.

Factors	Total (n = 158)
Socio-demographic factors	
Gender, male (N, %)	65 (41)
Age (mean, SD)	42.3 (9.6)
Educational level (N, %)	
Low	19 (12)
Medium	76 (48)
High	61 (39)
Cohabiting, yes	126 (80)
Disease-related factors	
General health, poor or very poor (N, %)	45 (29)
One or more chronic diseases, yes (N, %)	82 (52)
HADS anxiety score (mean, SD) (0-21)	7.5 (3.7)
HADS depression score (mean, SD) (0-21)	7.1 (4.4)
4DSQ distress score (mean, SD) (0-32)	14.7 (7.5)
Psychopharmacologic medication use (N, %)	39 (25)
Sickness absence duration (median, interquartile range [IQR])	101.8 (59.3-145.1)
Personal factor	
UCL subscale scores (mean, SD)	
Active problem focused coping (5-20)	13.2 (3.1)
Emotional coping (5-20)	10.4 (2.7)
Avoidance coping (4-16)	8.7 (1.9)
Work-related factors	
Tenure, 0-5 years (N, %)	69 (44)
Contract type, permanent (N, %)	
Company size, <100 (N, %)	62 (39)
Supervisor (N, %)	44 (28)
Monthly income in euros (median, IQR)	1750 (1300-2100)
Work accommodation for RTW	109 (69)
Consultation with OP	
0 consultations	20 (13)
1 consultation	91 (58)
>1 consultation	43 (27)
RTW percentage at start of RTW (median, IQR)	40.0 (22.0-63.0)
RTW percentage at baseline (median, IQR)	25.0 (0.0-50.0)
WRFQ total score (mean, SD) (0-100)	63.6 (18.4)
Work engagement, mean total score (mean, SD) (0-6)	3.3 (1.3)
RSAW total score (mean, SD) (0-24)	20.4 (3.7)
JCQ subscale scores (mean, SD)	
Decision latitude	67.58 (10.4)
Psychological job demands	33.9 (6.6)
Supervisor social support	10.6 (2.5)
Colleague social support	12.0 (1.6)
Conflicts with colleagues, never (N, %)	76 (48)
Conflicts with supervisor, never (N, %)	75 (48)
Job insecurity, yes (N, %)	20 (13)

HADS = Hospital Anxiety and Depression SCALE; 4DSQ = Four-Dimensional Symptom Questionnaire; RTW = return to work; WRFQ = Work Role Functioning Questionnaire; RSAW = Readiness to Stay at Work.

Table 2. Predictors of recurrent sickness absence at 6 and 12 months.

	Univariable analyses			Multiple regression model p<0.05[1]			Multiple regression model p<0.10[2]		
Predictor	OR	95% CI	*P*	OR	95% CI	*P*	OR	95% CI	*P*
Socio-demographic factors									
Cohabiting									
yes	1.00								
no	1.69	0.88-3.23	0.11						
Disease-related factors									
Duration of sickness absence									
0-64 days	1.00								
65-127 days	0.69	0.35-1.34	0.27						
>127 days	0.63	0.32-1.25	0.19						
Psychopharmacologic medication use									
no	1.00								
yes	1.87	1.00-3.49	0.05						
One or more chronic diseases									
no	1.00								
yes	0.62	0.35-1.09	0.09	0.54	0.30-0.96	0.04	0.51	0.28-0.94	0.03
Work-related factors									
Tenure									
0-5 years	1.00								
>5 years	1.46	0.82-2.59	0.20				1.89	0.99-3.61	0.05
Company size									
<100	1.00								
≥100	1.90	1.06-3.41	0.03	2.59	1.40-4.80	0.00	2.57	1.35-4.93	0.00
RTW percentage at baseline									
0-12	1.00								
13-49	1.60	0.78-3.29	0.20						
>49	2.19	1.11-4.32	0.02						
Supervisor social support[b]									
0-9	1.00						0.00		
10-12	0.54	0.28-1.03	0.06				0.71	0.30-1.67	0.43
>12	0.52	0.20-1.33	0.17				0.28	0.07-1.14	0.08
Colleague social support									
0-11	1.00								
12	0.53	0.27-1.02	0.06						
>12	0.56	0.25-1.25	0.16						

Table 2. (continued)

	Univariable analyses			Multiple regression model p<0.05[1]			Multiple regression model p<0.10[2]		
Predictor	OR	95% CI	*P*	OR	95% CI	*P*	OR	95% CI	*P*
Conflicts with supervisor									
never	1.00								
sometimes, often or always	1.71	0.98-3.01	0.06	2.21	1.21-4.04	0.01	2.50	1.32-4.75	0.01
Job insecurity									
no	1.00								
yes	1.77	0.76-4.09	0.19						

RTW = return to work.

[1]The final multiple regression model is adjusted for treatment group.

[2]For this variable, only data of the control group are presented in the multivariable model due to significant predictor x treatment type interaction. Relations were not statistically significant for the intervention group.

DISCUSSION

The goal of this study was to identify predictors of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. The multivariable analyses revealed three main predictors for recurrent sickness absence at 6 and 12 months follow-up: company size >100 workers and conflicts with supervisor increased the odds of recurrent sickness absence, while one or more chronic diseases decreased the odds. The finding that more than 30% of the study population experienced recurrent sickness absence is comparable to previous research, and supports the recommendation of Koopmans et al. (2011) to monitor workers who returned to work after sickness absence due to CMDs [12,13]. Although a predictor such as company size cannot be modified, health care providers can use our results to identify and follow workers at greater risk of recurrent sickness absence. Conflicts with supervisor are more amendable to change as health care providers can help the worker to adequately deal with supervisor conflicts. In the future design of interventions to prevent recurrent sickness absence, a treatment component might be incorporated focusing on how to deal with supervisor conflicts. We also found that having one or more chronic diseases was predictive of reduced incident recurrent sickness absence. A possible explanation might be that workers that have succeeded in returning to work despite chronic diseases have acquired more experience in dealing with health-related problems that hinder work functioning and are better equipped to prevent recurrent sickness absence (e.g. more knowledgeable and competent in asking help to overcome work-related problems). Finally, we found that working in a small company was protective for the incidence of recurrent sickness absence. This might be counterintuitive as larger companies have more resources to accommodate workers that have health-related work functioning problems. However, work accommodations were also included in the analyses but not found to be predictive of recurrent sickness absence. A possible explanation for the protective effect of small companies might be that workers in small companies experience more commitment and responsibility towards colleagues and the employer, more supervisor support is provided, and the impact of the worker's behavior on others (e.g. sickness absence) is more visible. In the present study, no information on organizational commitment was included. Future studies should include this variable when analyzing recurrent sickness absence.

Two previous studies have investigated predictors of recurrent sickness absence in workers with CMDs[12,13]. Comparisons with these studies, however, are constrained because the studies were based on register data and did not include a great variety of predictors. Koopmans et al. (2010) examined the effect of sex and age on recurrent sickness absence and did not find differences between men and women which is comparable to our results[40]. The authors did find an age effect for women and showed

that women aged <35 years and between 35-44 years were at greater risk of recurrent sickness absence. Due to the small sample size of our study, we were not able to conduct gender-specified analyses. Virtanen et al. (2011) primarily investigated the effect of socio-economic position on recurrent sickness absence and found that manual occupations had a significantly higher risk of recurrent sickness absence compared to higher, non-manual occupations[13]. In the present study, no data on type of occupations were available. Educational level and income were included as proxy measures, but both measures were not significantly associated with recurrent sickness absence. When comparing our results with studies that have investigated predictors of sickness absence duration in workers on sickness absence due to CMDs, some differences can be observed. From several studies it is known that older age and also severity of the mental health problems (e.g. depression severity, comorbidity, duration of the problems) predict longer sickness absence[9,11,19,20,41]. Our results showed that both age and symptom severity did not predict recurrent sickness absence. The present study showed for the first time that conflicts with supervisor is a predictor of recurrent sickness absence. This factor has not been frequently investigated in prognostic studies on duration of sickness absence although the role of the supervisor in the RTW process has been stressed by OPs, psychologists, and workers[42,43].

Strengths and limitations

Strengths of this study are its prospective design and the inclusion of participants based on OP diagnoses instead of self-report. An additional strength is the use of registry data to measure the incidence of recurrent sickness absence at different time points which allowed us to examine phase-specificity of predictors. Furthermore, the study is the first examining a wide variety of factors in different domains for the prediction of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

A limitation is the relatively small sample size which has limited the power to detect relevant predictors. The sensitivity analysis showed that when increasing the power of the study by applying a p-value <0.10, two extra predictors were included in the final multivariable model. As this sensitivity analysis increased the chances of a Type-I error, future studies should include more participants. The small sample size also forced us to dichotomize several categorical variables, thereby loosing important information. This might have led to underestimations of the associations under study. The generalizability of the findings to other populations may be limited as participants were selected for a cluster-RCT based on specific eligibility criteria. Finally, even though a broad range of factors was included in this study, there might be some unmeasured

constructs, such as previous sickness absence episodes[44], which impact recurrent sickness absence.

Conclusion

This study found that company size >100 workers and conflicts with supervisor increased the odds of recurrent sickness absence at 6 and 12 months follow-up, while one or more chronic diseases decreased the odds in workers returned to work after sickness absence due to CMDs. Factors related to symptom severity did not predict recurrent sickness absence. As this is the first study that has investigated a broad range of predictors for recurrent sickness absence in workers with CMDs, future research, consisting of larger study populations, needs to further investigate predictors of recurrent sickness absence in this worker population to corroborate our findings.

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9

General discussion

The objective of this thesis is to generate knowledge on the prevention of recurrent sickness absence in workers who returned to work after sickness absence due to common mental disorders (CMDs). Therefore, a systematic review has been conducted to evaluate the effectiveness of interventions to facilitate return to work (RTW) in workers with adjustment disorders; the effectiveness, process and economic benefit have been evaluated of the SHARP-at work intervention which was developed to prevent recurrent sickness absence in workers with CMDs; and finally, predictors of incident recurrent sickness absence in workers with CMDs were investigated. In this chapter, the main findings of the thesis are summarised, methodological considerations are discussed, a reflection on the main findings is provided and implications for research and practice are presented.

MAIN FINDINGS

Effectiveness of interventions to facilitate return to work in workers with adjustment disorders

In a Cochrane systematic literature review, interventions to facilitate RTW in workers with adjustment disorders were evaluated. Nine randomised controlled trials were included, reporting on eleven interventions consisting of cognitive behavioural therapy (CBT) or problem solving therapy (PST). The interventions were compared to either no treatment or usual care which was mostly treatment by a general practitioner (GP) or occupational physician (OP). Meta-analysis showed that CBT did not reduce time to partial RTW and time to full RTW compared to no treatment. PST did reduce time to partial RTW but not full RTW compared to non-guideline based treatment by the GP or OP. To conclude, there is insufficient evidence that CBT or PST is effective in restoring workers with adjustment disorders back to their full duties.

The effectiveness of the SHARP-at work intervention in preventing recurrent sickness absence in workers with common mental disorders

The SHARP-at work intervention consists of problem solving guidance by OPs in a five-step process. OPs activate workers to: (1) make an inventory of problems and/or opportunities at work, (2) brainstorm on solutions/realisations, (3) write down solutions/realisations and prepare themselves for a consultation with the supervisor, (4) discuss the problems/opportunities and solutions/realisations with the supervisor and develop an action plan and (5) evaluate the implementation of solutions. For each step of the intervention, OPs can provide workers with a facilitating assignment. A key component of the intervention is the first assignment in which workers are asked to write down concrete problems/opportunities experienced when they are back at work. Additionally, workers are asked to rate for each problem or opportunity whether it (A)

could be solved/realised by themselves, (B) could be solved/realised with the help of others or (C) is unsolvable/unrealisable for the moment.

In a cluster-randomised controlled trial with 12 months follow-up, the effectiveness of the SHARP-at work intervention in preventing recurrent sickness absence in workers who returned to work after sickness absence due to CMDs was evaluated. OPs were randomised to either the intervention or control group. OPs in the intervention group received a two-day training in the SHARP-at work intervention, and OPs in the control group provided care as usual. Eligible participants were recruited by the OPs when ready to start RTW.

Multilevel longitudinal analyses showed that workers in the intervention group had a statistically significant 60% reduced likelihood of experiencing recurrent sickness absence compared to the control group. Additionally, time to recurrent sickness absence was significantly longer for the intervention group compared to the control group. This resulted in a median number of days to recurrent sickness absence of 253 days for the control group and 365 days for the intervention group (participants with no recurrent sickness absence were censored after 12 months follow-up). Both the intervention and control group reported reduced mental health complaints and improved work functioning during the 12 months follow-up but did not report changes in coping behaviour. No significant differences were found between the intervention and control group regarding changes in mental health complaints, work functioning and coping behaviour.

Process evaluation of the SHARP-at work intervention: compliance, accountability for study outcome, feasibility and relationship between intervention components and study outcome

A process evaluation was conducted to: (1) evaluate whether the SHARP-at work intervention was conducted according to the protocol and accounted for the study outcome (i.e. lower incidence of recurrent sickness absence for participants in the intervention group compared to the control group), (2) evaluate whether the intervention was feasible, and (3) investigate the relationship between the key elements of the intervention and the effect outcome. Results based on 67 participants of the intervention group showed that 82% had 2 or more consultations with the OP and 70% made one or more intervention assignments as recommended in the intervention protocol. Thus, compliance to the intervention protocol by OPs was high. In the control group, consultations with the OP took also place but less frequently (60% of 64 workers reported that they had 2 or more OP consultations). Furthermore, assignments were rarely provided to participants (7% made assignments). Following that (1) the intervention was conducted according to the protocol for the majority of the participants, (2) few activities took place in the control group and (3) no important

contextual differences were found between the intervention and control group, it was concluded that the SHARP- at work intervention accounted for the lower incidence of recurrent sickness absence in the intervention group.

Both participants and OPs reported that they were satisfied with the SHARP-at work intervention. Overall, OPs judged the intervention as well-structured, applicable and helpful during the worker's RTW-process. These results indicate that the SHARP-at work intervention may be feasible for application in daily practice.

Analysis of the relationship between key intervention components and the study outcome (recurrent sickness absence) was difficult due to the small sample size, and the results need to be interpreted with caution. Participants who made the inventory of problems/opportunities at work had a significantly higher risk of experiencing recurrent sickness absence. However, participants who made the assignment in which they evaluated if help was needed to solve a problem/opportunity had a significantly lower risk of recurrent sickness absence. Also, when participants talked with the OP about how opportunities could be realised the risk of recurrent sickness absence was significantly reduced.

Barriers and facilitators for participant recruitment by occupational physicians

Recruitment of research participants for the intervention study was difficult. Recruitment was conducted by OPs of which some were successful but many did not recruit any participant. To understand the reason of the recruitment problems and to prevent future recruitment problems, barriers and facilitators experienced by OPs during recruitment were investigated. Additionally, the relationship between OP personal and work characteristics and the number of recruited participants was investigated. Results showed that barriers and facilitators for participant recruitment as experienced by OPs could be divided into six categories: study characteristics (e.g. concise inclusion criteria); study population characteristics (e.g. educational level); OP's attention (e.g. having face-to-face contact with the researcher); OP's workload (e.g. busy consultations); context (e.g. working at different locations); and OP's characteristics (e.g. motivated to help). Analysis of the relationship between OP personal and work characteristics and the number of recruited participants showed that OPs recruited significantly more participants when colleagues in the same clinical unit recruited more participants. Based on the results, it is recommended to engage entire clinical units instead of approaching individual OPs when recruiting participants. Furthermore, frequent communication between the researchers and OPs, especially by face-to-face contact, and the use of ICT reminder tools are experienced as helpful by OPs.

Cost-effectiveness and cost-benefit of the SHARP-at work intervention

An economic evaluation of the SHARP-at work intervention was conducted alongside the cluster-randomised controlled trial to investigate the cost-effectiveness and cost-benefit of the intervention compared to care as usual. For the cost-effectiveness analysis (CEA) from the societal perspective, differences between the intervention and control group in health care utilisation costs were compared to differences between the two study groups in incidence of recurrent sickness absence and time to recurrent sickness absence. For the cost-benefit analysis (CBA) from the employer perspective, differences between the two study groups in health care utilisations costs for the employer were compared to differences between the two groups in costs of productivity loss. The results of the economic evaluation showed no economic benefit of the SHARP-at work intervention compared to care as usual.

Predictors of recurrent sickness absence in workers who returned to work after sickness absence due to common mental disorders

Data of the cluster-randomised controlled trial were used to investigate predictors of recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Baseline data on socio-demographic, disease-related, personal and work-related factors were related to recurrent sickness absence at six and 12 months follow-up. The results showed that a company size of over 100 employees and conflicts with the supervisor were predictive of incident recurrent sickness absence. Having one or more chronic diseases reduced the risk of recurrent sickness absence.

METHODOLOGICAL CONSIDERATIONS

Evaluation of the SHARP-at work intervention

An important strength of this thesis is the comprehensive evaluation of the SHARP-at work intervention consisting of an effect, process and economic evaluation. Often, interventions are only evaluated for their effectiveness and no process evaluation takes place to investigate whether the intervention has truly been conducted according to protocol and whether the intervention is feasible[1,2]. A process evaluation can help interpret the findings of an effect evaluation. When no effect is found, a process evaluation can help evaluate if program failure or theory failure has occurred. Program failure refers to the possibility that an intervention has not been conducted as planned, while theory failure encompasses that the hypothesized working mechanisms of an intervention are incorrect[3]. A process evaluation is also valuable when the intervention has shown to be effective. In case of the SHARP-at work intervention, the process evaluation confirmed that the intervention was conducted according to the protocol and that treatment in the control group differed. Furthermore, no contextual factors

were found to have influenced the results. The process evaluation also provided information on the feasibility of the SHARP-at work intervention and on specific intervention components that were linked to the study outcome. Economic evaluations add to the knowledge on the effectiveness of an intervention by analysing the cost-effectiveness and/or cost-benefit of the intervention. This information provides valuable input for the decision to implement an intervention or not[4]. Thus, the data that have become available with the effect, process and economic evaluation of the SHARP-at work intervention allow health care providers and policy makers to come to a more balanced decision about whether or not the intervention should be implemented, compared to having only information available about the effectiveness of the intervention.

Efficacy versus effectiveness

The SHARP-at work intervention was evaluated in an effectiveness trial, also referred to as a pragmatic trial. The goal of an effectiveness trial is to investigate the effectiveness of an intervention in a "real life" context. Effectiveness trials are often contrasted with efficacy trials (or explanatory trials). Efficacy trials aim to determine whether an intervention works in a highly selected participant population and in tightly controlled study conditions[5-8]. The choice for evaluating an intervention in an efficacy or effectiveness trial depends on several aspects (e.g. is there already evidence supporting the intervention, can study conditions be controlled), but there is always a trade-off between advantages and disadvantages for either option.

Evaluating the SHARP-at work intervention in an effectiveness trial provided the opportunity to analyse the intervention in the complex environment of the actual occupational health care practice. A fairly broad range of participants (e.g. with different mental health problems and sickness absence periods varying in time, and from various geographical locations, companies and occupations) was included in the study, and OPs conducted the intervention during their daily routine. The study conditions closely reflected the real-life context in which the intervention would be implemented in practice, supporting the intervention's external validity.

A drawback of an effectiveness trial is the large number of participants that needs to be recruited to detect an effect in a heterogeneous study population. In the SHARP-at work study, recruitment was entirely embedded in the practice of OPs and could not be supported by researchers as they were not allowed to scan medical files for eligible participants with a CMD diagnosis. Recruiting research participants proved to be difficult for OPs and this caused recruitment to seriously lag behind the sample size calculation. Additionally, evaluating the SHARP-at work intervention in a real-life context resulted in having limited control over what the OPs did. For example, OPs were sometimes selective in participant recruitment. During feedback moments with OPs in

the intervention group, a frequent comment was that it was difficult to conduct the intervention with participants with a low educational level. This may have influenced baseline differences between the intervention and control group in educational level: the intervention group contained almost 20% more participants with a high educational level and 10% less participants with a low educational level. Having no control over the actions of the OPs also resulted in suboptimal treatment adherence, even though over 80% of the participants in the intervention group had two or more consultations with the OP and one consultation with the supervisor, and over 70% received assignments from the OP as recommended in the intervention protocol. Finally, by evaluating the SHARP-at work intervention in a real-life context, the effect of contextual factors on recurrent sickness absence cannot be ruled out. Although important contextual factors were explored in the process evaluation (e.g. major life events, organisational changes) some unmeasured factors could have had an impact on the results of the effectiveness trial.

Taking these considerations into account, the question arises whether the SHARP-at work intervention should have been evaluated in an efficacy study. Despite the drawbacks, the choice to evaluate the SHARP-at work intervention in an effectiveness trial was supported by the conceptual framework of the intervention and the Dutch occupational health care context. Based on the conceptual framework, the intervention is developed to be conducted after workers have returned to work. The intervention is not focused on treatment of the CMD but on how to manage to stay at work, as all workers will have recovered to some extent when ready to RTW. This supported the inclusion of a broad range of participants who suffered from different CMDs. Furthermore, the Dutch occupational health care context provided the opportunity to conduct the intervention on a broad scale as OPs already have a guideline for treating workers with mental health problems. The intervention is based on and developed as an extension of this guideline and consists of treatment procedures that are familiar to the OPs. Thus, evaluating the SHARP-at work intervention in an effectiveness trial was a right decision, but the execution of the effectiveness trial could have been improved. For example, in future studies, the recruitment procedure could be organised differently with more responsibility for researchers. A possible recruitment strategy could be to send all workers on sickness absence a letter about the study and to ask them to contact the researchers if interested in participation.

REFLECTION ON MAIN FINDINGS

The effectiveness of the SHARP-at work intervention

Compared to care as usual, the SHARP-at work intervention was effective in preventing recurrent sickness absence among workers who returned to work after sickness

absence due to CMDs. The risk of recurrent sickness absence was significantly lower and time to recurrent sickness absence was significantly longer in the intervention group during 12 months follow-up compared to care as usual. Results of the process evaluation showed that it is likely that these effects were truly a consequence of the SHARP-at work intervention. Although these results are positive, an important question remains unanswered: "What is the duration of the recurrent sickness absence episodes and what happens after the recurrence?" An exploration of descriptive data on recurrence duration indicated that workers in the intervention group had somewhat longer recurrence episodes. However, due to the small sample size of the intervention study, it was not possible to statistically analyse the differences in duration of the recurrences between the intervention and control group. Furthermore, a limitation is that the diagnoses related to the recurrences were not consistently available in the occupational health service registry system. It would be valuable to know which diagnoses were related to recurrent sickness absence. For example, it is possible that the diagnoses related to recurrent sickness absence differed between the two study groups. Also, it would be interesting to know whether type of diagnosis influenced the duration of recurrent sickness absence. The RTW trajectory after a recurrence is also of great interest. Research has shown that the risk of sickness absence and permanent disability increases when workers have experienced previous sickness absence episodes[9,10]. It has not been investigated whether the SHARP-at work intervention prevented a RTW trajectory consisting of more than one recurrent sickness absence episode. The time window of one year follow-up should be extended in future studies to two or three years follow-up to properly investigate RTW trajectories after the SHARP-at work intervention. To conclude, the results of the SHARP-at work intervention on preventing recurrent sickness absence are encouraging but show only one part of a bigger picture.

The economic evaluation provided additional information on the effectiveness of the intervention and the RTW process of study participants. Somewhat surprisingly, the SHARP-at work intervention was not cost-beneficial. Although occupational health care costs were expected to be higher in the intervention group due to extra consultations with the OP, the effect on the incidence of recurrent sickness absence was expected to result in lower sickness absence costs. However, sickness absence costs were higher in the intervention group. This result may, at least partially, be explained by the fact that participants in the control group already started with higher RTW percentages at baseline. Whereas the intervention group had a mean RTW percentage of 24% at baseline, the control group had a mean RTW percentage of 42%. Although time to full RTW was not investigated, a closer look at the sickness absence data indicated that participants in the intervention group more frequently had a gradual RTW process taking them longer to full RTW compared to participants in the control group. An

explanation for the higher sickness absence costs in the intervention group could also (partly) be due to the longer duration of the recurrent sickness absence episodes in this group.

Predictors of recurrent sickness absence

Having conflicts with the supervisor was strongly predictive of incident recurrent sickness absence and confirmed the importance of incorporating consultations between the worker and supervisor in the SHARP-at work intervention. No previous research has investigated the effect of conflicts with the supervisor on recurrent sickness absence in workers with CMDs, but conflicts with the supervisor have been stressed as an important factor in qualitative RTW studies with OPs, psychologists and sick-listed workers[11,12]. Surprisingly, sensitivity analyses (in which the power of the study was slightly increased) showed that low supervisor social support was only predictive of recurrent sickness absence for the control group. A possible explanation for this result could be that the SHARP-at work intervention led to improved communication with the supervisor for participants in the intervention group with low supervisor support at baseline. However, the intervention did not specifically consist of a component that focused on dealing with conflicts with the supervisor.

IMPLICATIONS FOR RESEARCH

Defining and operationalizing common mental disorders

There is no universal agreement on the group of mental disorders that constitute CMDs. Various studies have investigated different types of disorders under the umbrella term of CMDs. Some researchers define CMDs as consisting of anxiety and depressive disorders[13], others also include somatoform disorders[14,15] or adjustment disorders[16,17] or go even broader by also including substance abuse disorders, post-traumatic stress disorders and manic episodes[18]. The systematic review on interventions to facilitate RTW in workers with adjustment disorders showed that there is also no consensus on how to define this subcategory of CMDs. Terms such as “minor mental disorders,” “stress-related disorders” and “distress” have been used to describe study populations with symptoms that resemble the symptoms associated with adjustment disorders.

The operationalization of CMDs might be even more divergent. Most studies use questionnaires, but often different questionnaires, to screen for workers with symptoms related to CMDs such as the Hospital Anxiety and Depression Scale (HADS), the Depression, Anxiety and Distress Scale (DASS), the Four-Dimension Symptom Questionnaire (4DSQ), the Symptom Checklist-90. In other studies CMDs have been diagnosed by a trained health care provider, but rarely do researchers use a diagnostic

interview with participants (e.g. the Composite International Diagnostic Interview) while this is a good method to derive at a specific diagnosis and to cover the whole range of mental disorders of the ICD-10 and DSM-IV [19]. This diversity in defining and operationalizing CMDs is problematic because it complicates direct comparison of studies. A different operationalization of CMDs can lead to studies consisting of different study populations of which it may be questionable that an intervention works in a comparable way. Furthermore, combining the results of participants with varying CMDs is not desirable when it cannot be presumed that an intervention works similar for every participant regardless of the type of CMD. In the SHARP-at work study, workers with adjustment disorders, depressive disorders and anxiety disorders were included based on OPs' diagnoses. As explained above, it was hypothesized that the intervention would equally work for workers with varying CMDs. However, future research would benefit from distinguishing intervention effects for the different types of CMDs. Such analyses require bigger sample sizes to be able to conduct subgroup analyses on types of CMD. Still, a shared understanding is needed of how to operationalize CMDs and which diagnostic/measurement tools are valid and reliable.

Improving the SHARP-at work intervention

The analysis of predictors of recurrent sickness absence in workers with CMDs showed that conflicts with the supervisor increase the risk of incident recurrent sickness absence for the control group as well as the intervention group. Furthermore, research has shown that positive supervisor behaviour facilitates RTW[20,21]. Based on these results, it would be advisable to further investigate whether a stronger focus on worker-supervisor communication should be integrated in the SHARP-at work intervention. An additional intervention component could be developed focusing on how to deal with supervisor conflicts. Moreover, focus groups with OPs and psychologists and interviews with supervisors have shown that supervisors experience difficulties in communicating with workers who suffer(ed) from mental health problems[12,22]. Thus, the responsibility of the supervisor in the worker's RTW process could be even more acknowledged in the SHARP-at work intervention by adding a training program for supervisors on how to communicate about work processes with workers who have returned to work.

Selection of outcome measures

Primarily, the effect of the SHARP-at work intervention on preventing recurrent sickness absence was investigated in this thesis. A study by Hees et al. (2012) has shown that different stakeholders (OPs, supervisors and workers) perceive this outcome as an important aspect of successful RTW. However, other outcomes were also regarded as a prerequisite of successful RTW, such as work functioning[23]. Until now, work functioning has rarely been investigated in workers with CMDs and validated measurement tools to

assess work functioning in CMD populations are lacking[24]. In the SHARP-at work study, work functioning was assessed with the Work-Role Functioning Questionnaire (WRFQ)[25,26] as a secondary outcome measure. Although there was no difference between the WRFQ-scores between the two study groups, the results of the WRFQ did show that the workers improved in work functioning during 12 months follow-up after RTW. Some aspects of work functioning that were deemed important by the stakeholders in the study of Hees et al. (2012) are not evaluated in existing work functioning tools, e.g. whether the worker fulfils the tasks agreed upon with the employer. Future research should include additional information that is important for stakeholders in work functioning tools and these tools need to be validated for workers with CMDs.

In the SHARP-at work study, symptoms of mental health problems were measured as a secondary outcome. The question rises whether this outcome should be included in future research on the effectiveness of interventions to prevent recurrent sickness absence in workers with CMDs. The results of the intervention study showed that no difference was found between the intervention and control group for improved mental health. This result has also repeatedly been found in intervention studies aimed at facilitating RTW of workers with CMDs[15,27-29]. When focussing on preventing recurrent sickness absence among workers who returned to work and have (partly) recovered from their mental health problems, it might be less important to focus on further improvement in mental health. Although it might be important to assess whether an intervention aimed at improving sustainable RTW at least does not deteriorate mental health. The study of Hees et al. (2012) showed that stakeholders did not ascribe great importance to a worker having limited psychological symptoms when returned to work. It was found more important that a worker has the insight and skills to deal with his psychological vulnerability[23]. Future studies on workers with CMDs should look beyond traditional outcome measures, such as sickness absence days and time to RTW, to outcome measures that are relevant to stakeholders such as the worker, OP and supervisor.

The SHARP-at work intervention in other contexts

The development and evaluation of the SHARP-at work intervention is connected to the Dutch occupational health care context. Therefore, generalising the results to other contexts is difficult. Although it might be interesting to investigate whether the intervention's five-step problem solving process would also help to prevent recurrent sickness absence in other countries, it will be difficult to translate the intervention and study protocol one-on-one. The responsibility of employers to invest in RTW and the central role of the OP in the RTW process which follow from the Dutch social security legislation created a context in which stakeholders are willing to invest in interventions

such as the SHARP-at work intervention. In countries where (a) sickness absence is only compensated when caused by an occupational injury, (b) compensation benefits are paid by the government and (c) OPs do not have a role in guiding workers in the RTW process, conducting the SHARP-at work intervention in its current form would not be possible[30]. However, future research might investigate how the SHARP-at work intervention could be adapted to align with the socio-political context of other countries so that it can be evaluated in different contexts.

IMPLICATIONS FOR PRACTICE

Use of the SHARP-at work intervention in practice

Although it is not the role of the researcher to decide whether an intervention should be implemented in practice, a judgement on whether the SHARP-at work intervention could be implemented in practice can be formed based on the study results. Especially the results of the process evaluation are helpful as these results showed that workers and OPs were satisfied with the content of the intervention, that the intervention helped in the process beyond RTW and that it was applicable. As the intervention was also effective in preventing recurrent sickness absence, implementation of the SHARP-at work intervention seems possible. However, feedback moments organised with the OPs at the end of the study provided additional information that showed that a broad implementation would require additional actions. Most importantly, OPs indicated that employer contracts with the occupational health service should be extended to incorporate the additional consultations that are needed to conduct the intervention. Thus, an important prerequisite for implementing the intervention in practice is getting the employers aboard.

The growing research area on implementation science emphasizes that barriers to implementing interventions may arise at different health care system levels such as the patient level, the provider level, the organisational level and the policy level [31]. Even effective interventions rarely get implemented in practice. The Consolidated Framework for Implementation Research (CIFR) offers a comprehensive theoretical framework to analyse whether an intervention could be implemented in a specific context and what actions/adaptations are needed to foster successful implementation. The CIFR consists of five main dimensions: the intervention, the inner and outer setting, the individuals involved and the process by which implementation is accomplished[31]. To implement the SHARP-at work intervention, different stakeholders, such as workers, supervisors, employers, OPs, occupational health services and policy makers, need to collaborate to investigate the possible barriers and facilitators to implementation within the five dimensions of the CIFR. For example, are OPs who were not involved in the SHARP-at work study open to the intervention (*individuals involved*)? Would

governmental policy makers be willing/able to provide financial incentives to organisations to implement the intervention (*outer setting*)? Does the organisation have the facilities to implement the intervention; does the intervention align with the norms and values of the organisational culture (*inner setting*)? How can people be involved or motivated to implement the intervention (*process by which implementation is accomplished*)? An evaluation of whether the intervention costs are outweighed by the monetary, societal, personal or organisational benefits would also be part of the implementation assessment. To conclude, a thorough analysis of the context in which the intervention would be implemented and an implementation plan to overcome possible barriers is of paramount importance when any stakeholder considers implementing the SHARP-at work intervention.

Are occupational physicians the appropriate treatment provider?

The SHARP-at work intervention was conducted by OPs to align with the current Dutch occupational health care practice, in which OPs monitor the RTW process of workers with CMDs, and because OPs are closest to the work context compared to other health care providers. It can be questioned, however, whether OPs are the most appropriate treatment providers for conducting the intervention. During the intervention training and feedback moments, several OPs mentioned that they would rather approach the company social worker (CSW) to conduct the intervention and be only responsible for monitoring the RTW process. In the Netherlands, the CSW works for an occupational health service like most OPs. OPs can refer workers to the CSW to help address psychosocial problems. For example, CSWs help workers to deal with problems due to reorganisations, (sexual) intimidation, sickness absence, conflicts with colleagues or the supervisor. The CSW has also contact with the supervisor or a human resource manager when needed. Thus, on the one hand, the CSW does indeed have the competencies and the connections with the work context that are important for conducting the SHARP-at work intervention. On the other hand, the CSW is not involved in a worker's RTW process from beginning to end which could hamper the implementation of the intervention. Furthermore, CSWs are not present in every occupational health service and, therefore, not available for every company.

Continuity in the treatment provider who guides a worker with a CMD through the RTW process and after RTW would be desirable. This way the treatment provider knows what has happened at every stage of the RTW process and how this could influence the future course. One treatment provider can establish a strong relationship with the worker which provides clarity to the worker about who can be contacted when having problems during and after the RTW process. Currently, most OPs might not be sufficiently educated to guide and treat workers with CMDs as the treatment of CMDs gets limited attention in their standard education. Moreover, OPs who participated in

the intervention study frequently mentioned that it was difficult to conduct the intervention within their 30-minute consultations and that they struggled with a high work load. This work load will probably continue to rise in the future as there is a growing need for new OPs because few medical students choose this specialisation. Considering these difficulties and the fact that CMDs take up a large proportion of OP's consultations, there is a need to look for alternative solutions such as other treatment providers that could take over the OP's role in guiding workers with CMDs within the occupational health care context. This treatment provider should have close contact with the work environment to know how situations are at work. Furthermore, keeping close contact with other health care professionals that are treating the worker with a CMD (e.g. the general practitioner, psychologist) would be essential as, currently, coordination between different health care professionals is minimal [32]. A possible option for a treatment provider that could be responsible for guiding workers with CMDs within the work context is the occupational psychologist. The organisational psychologist is educated in workplace factors that contribute to a healthy working life and could take over the coordinating role of the OP and the treatment role of the CSW for workers that suffer from CMDs. A possible difficulty could be that an occupational psychologist works stigmatising for a worker. Additionally, contrary to OPs, occupational psychologists are not institutionalised within the Dutch occupational health care context. Another possible solution might be found in better attuning the actions of the various treatment providers that are involved in the treatment of workers with CMDs. A first initiative is the recently developed multidisciplinary guideline for the treatment of adjustment disorders by primary care providers[32]. The guideline describes the role/tasks of the general practitioner, the psychologist and the OP and how these treatment providers can coordinate their roles in the benefit of the worker. For either option, i.e. the institutionalisation of the occupational psychologist or attuning the actions of the treatment providers involved in the RTW process and the post-RTW phase, research and practice need to work together to evaluate whether it is truly beneficial for the worker, the organisation and society.

GENERAL CONCLUSION

This thesis is the first to focus on the post-RTW phase of workers who have been on sickness absence due to CMDs and adds to the knowledge on the prevention of recurrent sickness absence in this worker population. The thoroughly conducted effect and process evaluation of the SHARP-at work intervention showed that the intervention was effective in preventing recurrent sickness absence compared to care as usual, conducted according to the protocol, well-received by OPs and workers and feasible. The economic evaluation showed that although the SHARP-at work intervention is

effective, it is also more costly. The evaluation of predictors of recurrent sickness absence in workers with CMDs showed that the risk of recurrent sickness absence was increased when workers had conflicts with their supervisor. Occupational health care providers can use the information generated by this thesis to provide guidance to workers with CMDs, and future researchers can build upon the results of the SHARP-at work intervention to evaluate the intervention in different contexts and with different outcome measures.

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Summary

The objective of this thesis is to generate knowledge on the prevention of recurrent sickness absence in workers who returned to work after sickness absence due to common mental disorders (CMDs).

In **Chapter 1**, an overall introduction is provided to address the importance of the topic of the thesis, to explain the context and to describe relevant constructs. CMDs, such as depression, anxiety and adjustment disorder, are highly prevalent in the working population and a major cause of sickness absence. Considering the impact of CMDs on sickness absence and the associated negative consequences for the individual (not being able to work) and society (high sickness absence costs), interventions have been developed to facilitate return to work (RTW) in this worker population. However, in occupational health care research and practice, the focus is shifting from facilitating RTW to improving functioning at work of workers with CMDs. This is due to research that has shown that workers with CMDs frequently experience: 1) at-work productivity loss, and 2) recurrent sickness absence. Thus, there is a need to look beyond RTW and develop interventions to realise a sustainable RTW. Therefore, this thesis describes the evaluation of the SHARP (Stimulating Healthy participation And Relapse Prevention)-at work intervention which is developed to prevent recurrent sickness absence in workers who returned to work after sickness absence due to CMDs.

Chapter 2 presents a systematic literature review in which the effectiveness of interventions to facilitate RTW in workers with adjustment disorders is investigated. Studies with a randomised controlled trial design were included in the review, leading to nine included studies all evaluating psychological interventions. Studies that were considered clinically homogeneous (e.g. comparable intervention and control groups, comparable outcome measures) were grouped into comparison groups to conduct meta-analyses. The results of the meta-analyses showed moderate quality evidence of no significant difference in time to partial RTW between workers receiving cognitive-behavioural therapy (CBT) or no treatment at one-year follow-up. For time to full RTW, it was also found that CBT did not significantly reduce days to full RTW compared to no treatment at one-year follow-up, based on low quality evidence. Problem solving therapy (PST) significantly reduced time to partial RTW compared to non-guideline based care with (-)17 days (95% CI -26.48 to -7.52) at one year follow-up. No significant differences between PST and non-guideline based care were found for time to full RTW. Because most studies included relatively few participants, it was concluded that studies are needed with >300 participants to increase the power of the meta-analyses and thus the reliability of the results found in the review. Furthermore, to be able to make good comparisons between studies, international consensus should be reached on terminology and assessment tools to diagnose adjustment disorders.

Chapter 3 describes the content of the SHARP-at work intervention and the study design for evaluating the effectiveness of the intervention. The SHARP-at work intervention is a problem solving intervention developed to prevent recurrent sickness absence in workers with CMDs. The intervention is delivered by the occupational physician (OP) when a worker has started RTW and consists of five problem solving steps: 1) make an inventory of problems and/or opportunities encountered at work after RTW, 2) brainstorm about solutions, 3) write down solutions and the support needed to realise them and assess the applicability of the solutions, 4) discuss solutions and make an action plan with the supervisor, and 5) evaluate the implementation of solutions. OPs monitor that all steps are taken and activate the worker when needed. OPs can use assignments to stimulate the worker to write down and structure the process. Two to five consultations are recommended to the OPs to conduct the intervention.

A cluster-randomised controlled trial (cluster-RCT) was developed to evaluate the effectiveness of the SHARP-at work intervention. OPs were randomised to the intervention or control group. OPs in the intervention group received a two-day training in the intervention and delivered care according to the intervention. OPs in the control group received no training and provided care as usual which is based on the guideline of the Netherlands Society of Occupational Medicine on "Management of mental health problems of workers by the OP." The primary outcome was recurrent sickness absence, defined as a 30% decrease in working days per week due to all-cause sickness absence, regardless of partial or full RTW. Secondary outcomes were mental health complaints, work functioning and coping. All outcomes were measured at baseline and at 3, 6, and 12 months follow-up.

The results of the cluster-RCT are presented in **Chapter 4**. In total, 158 participants were included in the study; 80 participants were treated by OPs from the intervention group and 78 participants were treated by OPs from the control group. The majority of the participants in both treatment groups were diagnosed with an adjustment disorder by the OP. Effectiveness analyses showed that the risk of recurrent sickness absence was significantly lower in the intervention group compared to the control group (adjusted odds ratio [OR] = 0.40, 95% confidence interval [CI] 0.20 to 0.81). Furthermore, time to first recurrent sickness absence episode was significantly longer for the intervention group compared to the control group (adjusted hazard ratio = 0.53, 95% CI 0.33 to 0.86). Regarding the secondary outcome measures, mental health complaints, work functioning and coping behaviour, no significant group differences were found. It was concluded that for workers who returned to work after sickness absence due to CMDs, the SHARP-at work intervention in effective in reducing the risk of recurrent sickness absence.

Chapter 5 focuses on the process evaluation of the SHARP-at work intervention. The aims of this study were: 1) to evaluate whether the SHARP-at work intervention was conducted according to the protocol and differed from care as usual, and 2) to investigate the relationship between the key elements of the intervention and the primary outcome of the effect evaluation (i.e. recurrent sickness absence). The process evaluation revealed that, compared to the control group, the participants in the intervention group more frequently had ≥2 consultations with the OP (OR = 3.2, 95% CI 1.2 to 8.8) and ≥1 consultation with the supervisor (OR = 3.6, 95% CI 1.1 to 12.0), as recommended in the SHARP-at work intervention protocol. Furthermore, participants in the intervention group more often received (73%) and completed (70%) assignments from the OP compared to participants in the control group (only 8% received and completed assignments). Thus, the SHARP-at work intervention was conducted according to the protocol for the majority of the participants and significantly differed from care as usual. Therefore, it was concluded that the intervention accounted for the lower risk of recurrent sickness absence that was found in the effect evaluation for the intervention group compared to the control group.

The analysis of the relationship between the key components of the intervention and the risk of recurrent sickness absence showed the following results. Receiving more intervention components was not associated with a lower risk of recurrent sickness absence. Participants who made an inventory of whether help is needed to solve problems/realise opportunities at work and who had discussed with the OP how opportunities could be realised at work, had a significantly lower risk of recurrent sickness absence. In contrast, participants that made an inventory of problems at work had a significantly higher risk of recurrent sickness absence. A possible explanation for this result could be that making an inventory of problems by itself is not beneficial. It may be necessary that a worker also thinks about whether help is needed to solve problems and talks about concrete improvements that can be implemented at work. These results need to be interpreted carefully due to the small sample size that was available for the analyses.

Chapter 6 provides an in-depth exploration of the barriers and facilitators for recruiting research participants by OPs. This study was conducted because fewer participants were recruited for the cluster-RCT by OPs than anticipated. Recruiting a sufficient number of research participants is important to improve the statistical power for detecting differences between treatment groups. The following research questions were investigated: 1) Which barriers and facilitators were experienced by OPs during participant recruitment; and 2) Which OP personal and work characteristics are associated with participant recruitment? Based on focus groups and interviews with OPs, six main categories of barriers and facilitators for participant recruitment were

extracted: 1) study and intervention characteristics, 2) characteristics of the study population, 3) context, 4) OP's attention, 5) OP's workload, and 6) OP's characteristics. These categories (and the underlying elements) can be addressed by researchers when developing future studies in which participant recruitment relies on OPs.

The analysis of the relationship between OP personal and work characteristics and the number of recruited participants, showed that the number of OPs within the OP's clinical unit (i.e. group practice) who actively recruited participants was significantly associated with the number of recruited participants by the OP (rate ratio = 1.93, 95% CI 1.61 to 2.32). Thus, when mobilising OPs for participant recruitment, researchers need to engage entire clinical units rather than approach OPs on an individual basis.

In **Chapter 7**, an economic evaluation of the SHARP-at work is presented. From a societal perspective, a cost-effectiveness analysis (CEA) was conducted. Differences between the intervention and control group in costs associated with health care utilisation and the intervention/care as usual costs were calculated. Also, differences between the two groups for the following two effect measures were calculated: 1) the incidence of recurrent sickness absence, and 2) time to first recurrent sickness absence episode. The CEA results with incidence of recurrent sickness absence as effect measure showed an Incremental Cost-Effectiveness Ratio (ICER) of €10.605 per percent of prevented recurrent sickness absence episode. This means that an additional €10.605 was needed in the intervention group to have 1% less recurrent sickness absence. The CEA with time to first recurrent sickness absence episode as effect measure showed an ICER of €2813 per one day of prevented recurrent sickness absence. Sensitivity analyses excluding one major outlier in the intervention group (due to psychiatric hospitalisation) showed an ICER of €-533 for the incidence of recurrent sickness absence. This indicated that the SHARP-at work intervention was cost-effective compared to care as usual; the prevention of 1% recurrent sickness absence saved €533. Comparably, sensitivity analyses for time to first recurrent sickness absence episode showed an ICER of €-2 also indicating that the intervention was cost-effective compared to care as usual.

From an employer's perspective, a cost-benefit analysis (CBA) was conducted. Differences between the intervention and control group in costs associated with occupational health care costs (in the Netherlands paid by the employer) and the intervention/care as usual costs were calculated. Furthermore, differences between the two study groups in costs association with productivity loss were calculated. Productivity loss was operationalised as costs resulting from sickness absence (also paid by the employer in the Netherlands). The CBA results showed that there was no net monetary benefit achieved with the SHARP-at work intervention compared to care as usual.

Chapter 8 examines factors that predict recurrent sickness absence in workers who returned to work after sickness absence due to CMDs. Based on previous research, potential predictors were assessed for all participants at baseline and categorised into the following domains: 1) socio-demographic factors (e.g. age and sex), 2) disease-related factors (e.g. distress symptoms, chronic diseases), 3) personal factors (e.g. coping behaviour), and 4) work-related factors (e.g. tenure, company size). The incidence of recurrent sickness absence at 6 and 12 months follow-up was the outcome measure. Multivariabe logistic Generalised Estimating Equations (GEE) with backward elimination ($p<0.05$) revealed three main predictors: company size >100 workers (OR = 2.59, 95% CI 1.40 to 5.80) and conflicts with supervisor (OR = 2.21, 95% CI 1.21 to 4.04) increased the risk of recurrent sickness absence, while one or more chronic diseases decreased this risk (OR = 0.54, 95% CI 0.30 to 0.96). Factors related to symptom severity did not predict the incidence of recurrent sickness absence.

Chapter 9 presents a general discussion of the thesis, focusing on the main findings of the thesis, methodological consideration, reflection on the main findings and implications for research and practice. It is concluded that the SHARP-at work intervention is effective in reducing the risk of recurrent sickness absence compared to care as usual. Furthermore, the intervention was conducted according to the protocol for the majority of the participants, and the intervention was well-received by OPs and participants. The thesis' results demonstrate that continuous attention is needed for workers who have been on sickness absence due to CMDs.

Future research needs to evaluate whether the effects of the SHARP-at work intervention also hold in different contexts. Furthermore, the effect of the SHARP-at work intervention should be evaluated for other outcome measures, next to recurrent sickness absence, relevant for important stakeholders (i.e. workers, supervisors, employers) such as fulfilling tasks agreed upon and worker's job satisfaction.

An important implication when implementing the SHARP-at work intervention in the OPs' practice is that employer contracts need to be extended to incorporate the additional consultations necessary to conduct the intervention. Moreover, to ensure smooth implementation of the SHARP-at work intervention, different stakeholders (e.g. workers, supervisors, employers, OPs, occupational health services, policy makers and researchers) need to collaborate to investigate the possible barriers and facilitators to implementation.

Samenvatting

Het doel van dit proefschrift is het genereren van kennis over hoe terugval naar verzuim voorkomen kan worden bij werknemers die teruggekeerd zijn naar het werk na verzuim wegens psychische problemen.

Hoofdstuk 1 biedt een algemene introductie in het onderwerp van het proefschrift met als doel het belang van het onderwerp te schetsen, de context toe te lichten en relevante constructen te introduceren. Psychische problemen, zoals depressie, angst en aanpassingsstoornissen, komen veel voor in de beroepsbevolking en vormen een belangrijke oorzaak van ziekteverzuim. Gezien de impact van psychische problemen op ziekteverzuim en de hiermee gepaard gaande negatieve consequenties voor het individu (niet meer kunnen werken) en de maatschappij (hoge verzuimkosten), zijn de afgelopen jaren interventies ontwikkeld om een terugkeer naar werk te faciliteren. In de wetenschap en praktijk van de bedrijfsgezondheidszorg verschuift de focus echter van het faciliteren van terugkeer naar werk naar het verbeteren van het functioneren in werk bij werknemers met psychische klachten. Aanleiding hiervoor is onderzoek dat heeft aangetoond dat werknemers met psychische problemen ten eerste regelmatig minder productief kunnen zijn op het werk en ten tweede vaak een terugval naar verzuim ervaren. Het is dus van groot belang om verder te kijken dan alleen het bewerkstelligen van een terugkeer naar werk en interventies te ontwikkelen die het mogelijk maken dat werknemers duurzaam terugkeren. Om deze reden wordt in dit proefschrift de evaluatie beschreven van de SHARP (Stimulating Healthy participation And Relapse Prevention)-at work interventie die ontwikkeld is om terugval naar verzuim te voorkomen bij werknemers die teruggekeerd zijn naar het werk na verzuim wegens psychische problemen.

Hoofdstuk 2 presenteert een systematische literatuurstudie waarin de effectiviteit van interventies werd onderzocht die gericht zijn op het faciliteren van terugkeer naar werk bij werknemers met aanpassingsstoornissen. Studies met een gerandomiseerde en gecontroleerde studieopzet werden geïncludeerd in de literatuurstudie, wat resulteerde in de inclusie van negen studies die psychologische interventies evalueerden. Klinisch homogene studies (bv. gelijksoortige interventies, gelijksoortige uitkomstmaten) werden gecombineerd in een vergelijkingsgroep om zo meta-analyses uit te kunnen voeren. De resultaten van de meta-analyses lieten zien dat het aantal dagen tot gedeeltelijke terugkeer naar werk gelijk was voor werknemers die cognitieve gedragstherapie (CGT) of geen behandeling ontvingen over een periode van één jaar. Wat betreft het aantal dagen tot volledige terugkeer naar werk was er eveneens geen significant verschil tussen CGT en geen behandeling over een periode van één jaar. Probleemoplossingsgerichte therapie (PT) reduceerde het aantal dagen tot gedeeltelijke terugkeer naar werk significant ten opzichte van gebruikelijke zorg door

de bedrijfsarts of huisarts met (-)17 dagen (95% BI -26.48 tot -7.52) over een periode van één jaar. Geen significante verschillen werden gevonden tussen PT en gebruikelijke zorg met betrekking tot aantal dagen tot volledige terugkeer naar werk. In de conclusie werd onderstreept dat studies met meer dan 300 deelnemers nodig zijn om de power van de meta-analyses, en dus de betrouwbaarheid van de resultaten van de literatuurstudie, te vergroten. Daarnaast is het, om een goede vergelijkingen tussen studies te realiseren, belangrijk om internationale consensus te bereiken met betrekking tot de terminologie en de meetinstrumenten om aanpassingsstoornissen te diagnosticeren.

Hoofdstuk 3 beschrijft de inhoud van de SHARP-at work interventie en de studieopzet om de effectiviteit van de interventie te evalueren. De SHARP-at work interventie is een probleemoplossingsgerichte interventie ontwikkeld om terugval naar verzuim te voorkomen bij werknemers met psychische problemen. De interventie wordt door bedrijfsartsen ingezet wanneer een werknemer begonnen is met de terugkeer naar werk en bestaat uit vijf probleemoplossingsgerichte stappen: 1) inventariseren van problemen en/of kansen op het werk na terugkeer, 2) brainstormen over oplossingen, 3) opschrijven van oplossingen en in kaart brengen van ondersteuning die daarvoor nodig is en inschatten van de toepasbaarheid van de oplossingen, 4) bespreken van oplossingen en maken van een actieplan met de leidinggevende, en 5) evalueren van de implementatie van oplossingen. De bedrijfsarts houdt in de gaten dat alle stappen genomen worden en activeert de werknemer wanneer nodig. De bedrijfsarts kan opdrachten inzetten om de werknemer te stimuleren om het proces op te schrijven en te structureren. Twee tot vijf consultaties worden aanbevolen aan de bedrijfsarts om de interventie uit te voeren.

Er werd een cluster gerandomiseerde onderzoeksopzet ontwikkeld om de effectiviteit van de SHARP-at work interventie te evalueren. Bedrijfsartsen werden op basis van toeval aan de interventie of controle groep toegewezen. Bedrijfsartsen in de interventiegroep ontvingen een tweedaagse training in de interventie en leverden zorg volgens de interventie. Bedrijfsartsen in de controle groep ontvingen geen training en leverden de gebruikelijke zorg welke gebaseerd is op de richtlijn "Behandeling van werknemers met psychische problemen door de bedrijfsarts" van de Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde. De primaire uitkomstmaat was terugval naar verzuim gedefinieerd als een 30% vermindering in het aantal werkdagen per week door verzuim ongeacht gedeeltelijke of volledige terugkeer naar werk. Secundaire uitkomstmaten waren psychische klachten, functioneren in werk en coping. Alle uitkomsten werden gemeten op baseline en 3, 6 en 12 maanden follow-up.

De resultaten van de effectstudie worden gepresenteerd in **Hoofdstuk 4**. In totaal werden 158 deelnemers geïncludeerd in de studie; 80 deelnemers werden behandeld door bedrijfsartsen uit de interventie groep en 78 deelnemers werden behandeld door bedrijfsartsen uit de controlegroep. De meerderheid van de deelnemers in beide groepen had een aanpassingsstoornis volgens de diagnose van de bedrijfsarts. In de interventiegroep was de gemiddelde verzuimduur op baseline 30 dagen langer ten opzichte van de controlegroep. De effectevaluatie toonde aan dat op 3, 6 en 12 maanden follow-up het risico op terugval naar verzuim voor de interventiegroep 60% lager was dan voor de controlegroep, wat een significant resultaat was. Daarnaast was de duur tot een eerste terugval significant langer voor de interventiegroep in vergelijking met de controlegroep (ten opzichte van de controlegroep was de mediane duur tot terugval 112 dagen later voor de interventiegroep). Wat betreft de secundaire uitkomstmaten psychische klachten, functioneren in werk en coping, werden er geen significante groepsverschillen gevonden. Concluderend werd gesteld dat de SHARP-at work interventie effectief is in het verlagen van het risico op terugval naar verzuim voor werknemers die teruggekeerd zijn naar het werk na verzuim wegens psychische problemen.

Hoofdstuk 5 richt zich op de procesevaluatie van de SHARP-at work interventie. De doelen van deze studie waren: 1) evalueren of de SHARP-at work interventie uitgevoerd was volgens het interventieprotocol en verschilde van de gebruikelijke zorg, en 2) de relatie onderzoeken tussen de belangrijkste interventiecomponenten en de primaire uitkomst van de effectevaluatie (d.i. terugval naar verzuim). De procesevaluatie liet zien dat, vergeleken met de controlegroep, deelnemers in de interventiegroep vaker ≥2 consultaties met de bedrijfsarts en ≥1 gesprek met de leidinggevende hadden, zoals aanbevolen in het SHARP-at work interventieprotocol. Daarnaast ontvingen deelnemers in de interventiegroep vaker een opdracht van de bedrijfsarts (73%) en maakten ze deze opdracht ook (70%) ten opzichte van deelnemers in de controle groep (slechts 8% ontving en maakte opdrachten). De SHARP-at work interventie is dus uitgevoerd volgens het interventieprotocol voor de meerderheid van de deelnemers en verschilde significant van de gebruikelijke zorg. Om deze redenen werd geconcludeerd dat het in de effectevaluatie gevonden lagere risico op terugval naar verzuim voor de interventiegroep ten opzichte van de controlegroep daadwerkelijk aan de interventie toegeschreven kon worden.

De analyse van de relatie tussen de belangrijkste interventiecomponenten en het risico op terugval naar verzuim, leidde tot de volgende resultaten. Het ontvangen van meerdere interventiecomponenten was niet gerelateerd aan een hoger of lager risico op terugval naar verzuim. Deelnemers die inventariseerden of ondersteuning nodig was om problemen op te lossen/kansen te realiseren op het werk en die met de

bedrijfsarts besproken hadden hoe kansen gerealiseerd zouden kunnen worden op het werk, hadden een significant lager risico op terugval naar verzuim. Echter, deelnemers die problemen op het werk geïnventariseerd hadden, hadden een significant hogere kans op terugval naar verzuim. Een mogelijke verklaring voor dit resultaat zou kunnen zijn dat het maken van een probleeminventarisatie op zichzelf niet helpend is. Wellicht is het juist essentieel dat een werknemer nadenkt over of hulp nodig is voor het oplossen van een probleem en over concrete oplossingen praat die op het werk geïmplementeerd kunnen worden. Deze resultaten moeten voorzichtig geïnterpreteerd worden omdat maar een klein aantal deelnemers beschikbaar was voor de analyses wat de onzekerheid van de resultaten vergroot.

Hoofdstuk 6 biedt een overzicht van belemmerende en faciliterende factoren voor het rekruteren van onderzoeksdeelnemers via bedrijfsartsen. Deze studie is uitgevoerd omdat minder deelnemers door de bedrijfsartsen werden gerekruteerd voor de effectstudie dan geanticipeerd. Het rekruteren van genoeg onderzoeks-deelnemers is belangrijk om voldoende statistische power te hebben om verschillen tussen studiegroepen te detecteren. De volgende onderzoeksvragen werden onderzocht: 1) Welke belemmerende en faciliterende factoren werden door bedrijfsartsen ervaren tijdens het rekruteren van deelnemers, en 2) Welke persoonlijke en werkgerelateerde karakteristieken van de bedrijfsarts zijn geassocieerd met de rekrutering van onderzoeksdeelnemers? Op basis van focusgroepen en interviews met bedrijfsartsen werden zes categorieën van belemmerende en faciliterende factoren voor de rekrutering van onderzoeksdeelnemers geëxtraheerd: 1) karakteristieken van de studie en interventie, 2) karakteristieken van de onderzoekspopulatie, 3) context, 4) aandacht van de bedrijfsarts, 5) werkdruk van de bedrijfsarts, en 6) karakteristieken van de bedrijfsarts. Deze categorieën (en de onderliggende elementen) kunnen in overweging genomen worden door onderzoekers bij het ontwikkelen van toekomstig onderzoek waarbij rekrutering van deelnemers afhankelijk is van bedrijfsartsen.

De analyse van de relatie tussen persoonlijke en werkgerelateerde karakteristieken van de bedrijfsarts en het aantal gerekruteerd deelnemers, liet zien dat het aantal bedrijfsartsen in de groepspraktijk van de bedrijfsarts die actief deelnemers rekruteerden significant geassocieerd was met het aantal gerekruteerde deelnemers door de bedrijfsarts zelf. Oftewel, bij het mobiliseren van bedrijfsartsen voor het rekruteren van onderzoeksdeelnemers kunnen onderzoekers zich beter richten op het betrekken van hele groepspraktijken in plaats van bedrijfsartsen individueel te benaderen.

In **Hoofdstuk 7** wordt een economische evaluatie van de SHARP-at work interventie gepresenteerd. Vanuit een maatschappelijk perspectief werd een

kosteneffectiviteitsanalyse (KEA) uitgevoerd. Verschillen tussen de interventie- en controlegroep in kosten gerelateerd aan gezondheidszorg en de inzet van de interventie/gebruikelijke zorg werden berekend. Daarnaast werden verschillen tussen de twee groepen berekend voor de volgende twee effectmaten: 1) incidentie van terugval naar verzuim, en 2) duur (in dagen) tot aan (de eerste) terugval naar verzuim. De KEA met incidentie van terugval naar verzuim als effectmaat liet zien dat €10.605 in de interventiegroep nodig was om 1% minder terugval naar verzuim te realiseren ten opzichte van de controlegroep. De KEA met duur tot terugval naar verzuim als effectmaat liet zien dat €2813 in de interventiegroep nodig was om één dag terugval naar verzuim te voorkomen. Een sensitiviteitsanalyse waarbij één extreme outlier in de interventiegroep (vanwege psychiatrische ziekenhuisopnames) geëxcludeerd werd, liet zien dat de SHARP-at work interventie kosteneffectief was ten opzichte van de gebruikelijke zorg; het voorkómen van 1% terugval naar verzuim leidde tot een besparing van €533. Een vergelijkbaar resultaat werd gevonden op basis van de sensitiviteitsanalyse voor duur tot aan terugval naar verzuim; het voorkómen van één dag terugval naar verzuim leidde tot een besparing van €2. Ook in dit geval was de interventie dus kosteneffectief ten opzichte van gebruikelijke zorg.

Vanuit een werkgeversperspectief werd een kosten-batenanalyse (KBA) uitgevoerd. Verschillen tussen de interventie- en controlegroep in kosten gerelateerd aan bedrijfsgezondheidszorg (in Nederland betaald door de werkgever) en de interventie/gebruikelijke zorg werden berekend. Daarnaast werden verschillen tussen de twee groepen berekend in kosten gerelateerd aan productiviteitsverlies. Productiviteitsverlies was geoperationaliseerd als kosten voor ziekteverzuim (in Nederland ook betaald door de werkgever). De KBA liet zien dat er geen netto monetair voordeel behaald werd met de interventie in vergelijking tot gebruikelijke zorg.

In **Hoofdstuk 8** worden factoren onderzocht die een terugval naar verzuim kunnen voorspellen bij werknemers die teruggekeerd zijn naar het werk na verzuim wegens psychische problemen. Gebaseerd op eerder onderzoek werden potentiële voorspellers bij alle deelnemers gemeten op baseline en gecategoriseerd in de volgende groepen: 1) socio-demografische factoren (bv. leeftijd, geslacht), 2) ziektegerelateerde factoren (bv. psychische klachten, chronische ziekten), 3) persoonlijke factoren (bv. coping gedrag), en 4) werkgerelateerde factoren (bv. aanstellingsduur, bedrijfsgrootte, functioneren in werk). Het risico op terugval naar verzuim op 6 en 12 maanden follow-up was de uitkomstmaat. Op basis van de analyses werden drie voorspellers gevonden: een bedrijfsgrootte van meer dan 100 werknemers en conflicten met de leidinggevende verhoogden het risico op terugval naar verzuim, terwijl het hebben van één of meerdere chronische ziekten dit risico verkleinde. Factoren gerelateerd aan de

ernst van (psychische) symptomen waren niet voorspellend voor het risico op terugval naar verzuim.

In **Hoofdstuk 9** wordt het proefschrift bediscussieerd waarbij de focus ligt op de belangrijkste bevindingen, methodologische overwegingen, een reflectie op de bevindingen en implicaties voor onderzoek en de praktijk. De conclusie wordt getrokken dat de SHARP-at work interventie effectief is in het verminderen van het risico op terugval naar verzuim ten opzichte van de gebruikelijke zorg. Bovendien is de interventie volgens het protocol uitgevoerd voor de meerderheid van de deelnemers en is de interventie goed ontvangen door de bedrijfsartsen en de deelnemers. De resultaten van het proefschrift demonstreren dat continue aandacht nodig is voor werknemers die teruggekeerd zijn naar het werk na verzuim wegens psychische problemen om een duurzame terugkeer te realiseren.

Toekomstig onderzoek moet evalueren of de effecten van de SHARP-at work interventie ook gevonden worden in andere contexten. Daarnaast moet het effect van de interventie geëvalueerd worden voor andere uitkomstmaten dan terugval naar verzuim, die relevant zijn voor betrokken partijen (werknemers, leidinggevende, werkgevers) zoals het uitvoeren van de taken waarover men afspraken heeft gemaakt en de werktevredenheid van de werknemer.

Een belangrijke implicatie voor de praktijk van de bedrijfsartsen is dat als de SHARP-at work interventie geïmplementeerd wordt, contracten met werkgevers uitgebreid moeten worden met de extra consultaties die nodig zijn om de interventie uit te voeren. Voor een goede implementatie van de interventie in de praktijk is het eveneens belangrijk dat verschillende partijen (bv. werknemers, leidinggevenden, werkgevers, bedrijfsartsen, arbodiensten, beleidsmakers en onderzoekers) samenwerken om de mogelijke barrières en faciliterende factoren voor implementatie in kaart te brengen.

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Ute, in mijn ogen ben je een vooraanstaand epidemioloog met een tomeloze passie voor wetenschap. Dat maakt dat jij voor mij een bron van kennis bent en tevens een rolmodel. Al ruim vijf jaar lang hebben wij ons wekelijkse overleg op dinsdag 9.00 en altijd kijk ik er naar uit. Zo'n overleg betekent vooruitgang; wanneer ik jouw deur uitloop ben ik altijd weer een stukje wijzer.

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Now I have to switch to English, as I would like to pay some words of gratitude to my two international co-authors. Karina Nielsen, I feel that the knowledge I have gained by working with you on the process evaluation has contributed greatly to my development as a researcher. It has changed my view on intervention research and made me a better researcher. Bill Shaw, you were the instigator for trying to make something positive out of the somewhat depressing recruitment problems I was experiencing during the intervention study. I have very much enjoyed working with you. You have been more than a co-author; you have been a supportive and encouraging mentor.

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C

Curriculum Vitae

Iris Arends was born on October 14, 1984 in Nijmegen, the Netherlands. She received her high school degree (Atheneum) in 2002 and went to study Psychology at the University of Utrecht. After her first year, she received a 1-year Erasmus scholarship to study at the Catholic University Leuven, in Leuven, Belgium. After completing this year, she decided to finish her studies in Leuven. In 2007, she received her Master in Psychology, with a specialisation in Labour and Organisational Psychology. Iris started her PhD in 2008 at the Department of Health Sciences, Community and Occupational Medicine, of the University Medical Center Groningen / University of Groningen, in Groningen, the Netherlands. She developed and evaluated an intervention to prevent recurrent sickness absence in workers who returned to work after sickness absence due to common mental disorders. During her PhD, Iris was actively involved in the PhD council and Education Committee of the Research Institute for Health Research (SHARE) of the Graduate School of Medical Sciences. She also co-organised the 2nd international ICOH conference on Work Disability Prevention and Integration, which took place in Groningen, in 2012. In 2010, Iris received a 3-year scholarship for the Work Disability Prevention Strategic Training Program (a part-time training program) at the University of Toronto, Toronto, Canada. Iris is currently continuing her research work at the Department of Health Sciences of the University Medical Center Groningen and is applying for a post-doctoral fellowship abroad.

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