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Popular science summary of the thesis (English)

Around one in five individuals suffers from a common mental disorder such as mild- to moderate depression, anxiety, and adjustment disorder. Individuals with common mental disorders are often employed, which is beneficial to their health and wellbeing. However, these individuals are more frequently absent from work and absent for longer periods of time than individuals suffering from other diagnoses.

To support these individuals to reduce their sickness absence, several interventions have been evaluated. A promising solution involves increasing patients' problem-solving abilities and involving their manager in the return-to-work process. In the current thesis, such an intervention is evaluated within primary health care. In a randomised trial, one group of employees received a problem-solving intervention with workplace involvement whilst another group received care as usual. The groups were compared in terms of days of sickness absence during an 18-month follow-up. Further evaluation of the intervention was undertaken through a process evaluation and through interviews with rehabilitation coordinators (delivering the intervention), employees (receiving the intervention) and the employees' managers, including questions regarding facilitating and hindering factors, and ethical challenges of the intervention.

The evaluation showed that, as compared to usual care, delivery of the intervention did not result in fewer days of sickness absence. The interviewed participants reported that the intervention was supportive, because it provided a structure for the return-to-work process, supported the employees by teaching them to identify problems and find solutions for returning to work and enabled a dialogue with the manager. However, the intervention was time consuming and ethical challenges such as different goals and values were identified in the collaboration between the workplace and the primary health care.

With our current knowledge, we cannot recommend using the intervention in primary health care in Sweden. A possible explanation for why we did not see an effect on sickness absence is that the intervention and control groups were too similar. It is also possible that the coordinators needed more time to deliver the intervention and that the training they received needs to be developed. Further research is needed to understand which individuals that need support from such an intervention and how much of the intervention that is needed to see results on return-to-work outcomes.

Popular science summary of the thesis (Swedish)

Ungefär var femte individ i arbetsför ålder lider av en vanlig psykisk diagnos såsom mild till måttlig depression, ångest eller anpassningsstörning. Individer som drabbas av dessa diagnoser är vanligtvis i arbete, vilket är fördelaktigt för deras hälsa och välbefinnande. Men dessa individer är oftare sjukrivna och när de är sjukskrivna är de borta från arbetet under längre perioder jämfört med individer som är sjukskrivna på grund av andra diagnoser.

För att stödja individer som är sjukskrivna på grund av vanliga psykiska diagnoser att återgå i arbete och minska sjukfrånvaro har flera interventioner utvärderats. En intervention som visat sig minska sjukskrivningslängd är problemlösningssamtal med involvering av individen/den anställdes arbetsplats. I föreliggande avhandling utvärderas en sådan intervention inom primärvården i Sverige. Genom en randomiserad studie gavs en grupp anställda den problemlösande interventionen och en grupp anställda vanlig vård. Gruppernas sjukfrånvaro jämfördes sedan under en 18 månaders uppföljning. Ytterligare utvärderingar av interventionen genomfördes genom intervjuer med rehabiliteringskoordinatorer som levererade interventionen, anställda som fick interventionen och deras chefer. Intervjuerna innehöll frågor om möjliggörande och hindrande faktorer samt etiska utmaningar.

Resultaten visade att anställda som fick problemlösningsintervention inte hade färre dagar med sjukfrånvaro jämfört med anställda som fick vanlig vård. De intervjuade deltagarna rapporterade att interventionen var stödjande eftersom den gav en struktur för att återgå till arbetet, stöttade de anställda genom att lära dem identifiera problem och lösningar för att återgå till arbetet samt att interventionen möjliggjorde en dialog med chefen. Interventionen var dock mer tidskrävande än vanlig vård och etiska utmaningar såsom mål- och värdekonflikter identifierades från samarbetet mellan arbetsplatsen och primärvården.

Med nuvarande kunskap kan vi inte rekommendera att använda interventionen inom primärvården i Sverige. En möjlig förklaring till att interventionen inte ledde till resultat på sjukskrivningsdagar kan vara en för liten skillnad mellan interventions och kontrollgruppen. Det är även möjligt att koordinatorerna behövde mer tid för att ge interventionen och att vi behöver utveckla koordinatorernas utbildning. Ytterligare forskning behövs för att förstå vilka individer som behöver interventionen och hur mycket av interventionen som de anställda behöver för att möjliggöra deras återgång.

Abstract

Purpose: Employees with common mental disorders (CMDs) which include depression, anxiety-, and adjustment disorder, are more often on sickness absence and have longer sickness absence episodes than employees with other diagnoses. To support these employees in their return-to-work process, problem-solving in combination with a work-directed intervention have previously been evaluated with positive results on earlier return-to-work and reduced sickness absence when provided in an occupational health service context. However, this combination has not been tested in primary health care in Sweden. A problem-solving intervention with workplace involvement (PSI-WPI) on top of care as usual (CAU) was provided in primary health care to employees on sickness absence due to common mental disorders with the aim of decreasing sickness absence. The overall aim of this thesis was to evaluate the effectiveness of the PSI-WPI on top of CAU for employees on sickness absence due to CMDs when compared to CAU alone, and to examine related contextual factors, ethical aspects, and process outcomes.

Methods: A cluster-randomised controlled trial was conducted including 19 coordinators (PSI-WPI=9 and CAU=10) working in the primary health care delivering the intervention and 197 employees (PSI-WPI=85 and CAU=112) receiving the intervention. Data were collected from the Swedish Social Insurance Agency register on sickness absence, semi-structured interviews with coordinators, employees, and managers, and questionnaires to coordinators and employees. To evaluate the effectiveness of the intervention, generalized estimating equations were used to estimate the difference in mean registered net sickness absence days per month between PSI-WPI and CAU during an 18-month follow-up. To explore experiences, content analysis was used to analyse interview data which was subsequently categorised according to the consolidated framework for implementation research. To explore ethical aspects, the theoretical framework for systematic identification of ethical aspects of health care technologies was used to build a coding scheme and thematic analysis was used to analyse interview data. Process evaluation outcomes evaluated were reach, dose delivered, dose received, fidelity and dose response.

Results: There was no statistically significant effect on sickness absence days for employees receiving the PSI-WPI compared to CAU during the 18-month follow-up. However, sickness absence days decreased in both groups over time.

Rehabilitation coordinators, employees, and managers reported that the structured process of the PSI-WPI was facilitating. As well, learning to identify problems and finding solutions, and early involvement of the manager in the return-to-work process was considered to be beneficial. Barriers to PSI-WPI included the time, and number of face-to-face meetings required as well as symptom severity. Ethical challenges of the PSI-WPI included workplace and health care differences in identified goals, values and norms. Further ethical challenges identified of the PSI-WPI were an increased sharing of information, unclear roles for coordinators and managers and juggling of the patient and employee roles. The process evaluation showed that rehabilitation coordinators delivering PSI-WPI agreed that their training and resources to deliver the PSI-WPI were sufficient. Out of 85 employees receiving PSI-WPI, 35 (41%) received the three sessions covering all five steps of the PSI-WPI.

Conclusions: In primary health care in Sweden, receiving the PSI-WPI on top of CAU did not result in a statistically significant effect on SA days compared to CAU alone. Even so, the PSI-WPI group received more sessions with the rehabilitation coordinators, three-part meetings and follow-up sessions compared to employees receiving CAU. Employees found it facilitating to learn about problems and solutions. The three-part meetings enabled a dialogue between the coordinator, employee and manager and a common view on how to move forward in the return-to-work process. Since time investment was reported as a barrier for the PSI-WPI it would be valuable to identify the employees that would benefit the most from the PSI-WPI. Ethical challenges were identified in the collaboration between the workplace and healthcare, and this collaboration in the Swedish setting needs further investigation. At this stage we cannot recommend the use of PSI-WPI in primary health care in Sweden. More research is needed on which employees require support from a PSI-WPI in returning to work and how much of the PSI-WPI that is needed to see effects on return-to-work outcomes.

List of scientific papers

I. Karlsson I, Frantz A, Axén I, Bergström G, Bültmann U, Finnes A, Holmgren K, Kwak L, Björk Brämberg E. Is a problem-solving intervention with workplace involvement for employees on sickness absence due to common mental disorders more effective, than care as usual, in reducing sickness absence days? Results of a cluster-randomised controlled trial in primary health care. [Revision submitted to Journal of Occupational Rehabilitation].

II. Karlsson I, Kwak L, Axén I, Bergström G, Bültmann U, Holmgren K, Björk Brämberg E. Experiences of participating in a problem-solving intervention with workplace involvement in Swedish primary health care: a qualitative study from rehabilitation coordinator's, employee's, and manager's perspectives. BMC Public Health. 2023;23(1):1135-.

III. Karlsson I, Sandman L, Axén I, Kwak L, Sernbo E, Björk Brämberg E. Ethical challenges from a problem-solving intervention with workplace involvement: a qualitative study among employees with common mental disorders, first-line managers, and rehabilitation coordinators. International Journal of Qualitative Studies on Health and Well-being. 2024;19(1):2308674.

IV. Karlsson I, Kwak L, Bültmann U, Bergström G, Axén I, Björk Brämberg E. Process evaluation of a problem-solving intervention with workplace involvement in primary health care in Sweden. [Manuscript].

Contents

List of abbreviations

CAU	Care as usual.
CBT	Cognitive behavioural therapy.
CFIR	Consolidated framework for implementation research.
CMD	Common mental disorder.
CONSORT	Consolidated Standards of Reporting Trials.
COREQ	Consolidated criteria for reporting qualitative research.
FORTE	Swedish Research Council for Health, Working life and Welfare.
ICD-10-SE	International Classification of Disease.
MiDAS	MicroData for the Analysis of Social insurance.
OHS	Occupational Health Service.
PROSA	Problem-solving in primary care.
PHC	Primary health care.
PSI-WPI	Problem-solving intervention with workplace involvement.
RC	Rehabilitation coordinator.
RCT	Randomised controlled trial.
RTW	Return-to-work.
SA	Sickness absence.

Introduction

Common mental disorders (CMDs) i.e., mild- to moderate depression, anxiety disorder and adjustment disorder affect around one in five individuals in the European Union (1). Most individuals with CMDs are employed and though the benefits of employment are recognised (2, 3) exposure to psychosocial stressors at work can increase the risk of a CMD (4). Individuals with CMDs are more often on sickness absence (SA) and absent for longer periods of time than individuals with other diagnoses (4, 5). To support employees with CMDs, combining a work-directed intervention (i.e., involvement of the manager or providing accommodated work tasks) and a clinical intervention (i.e., cognitive behavioural therapy (CBT) or a problem-solving intervention) has shown promising results on return-to-work (RTW) outcomes (6-8). However, RTW interventions have mostly been provided by occupational health service (OHS) providers but in Sweden, most individuals with CMDs are treated in primary health care (PHC) (9) and only approximately 60% of workers have access to the OHS (10).

To evaluate the effect from a combined intervention in PHC in Sweden, a problem-solving intervention with workplace involvement (PSI-WPI) was conducted. The target population consisted of employees with CMDs on SA for 2-12 weeks at inclusion. The intervention consisted of a five-step PSI-WPI on top of care-as-usual (CAU) provided by rehabilitation coordinators (RCs) in PHC. The control group received CAU. The primary outcome was number of registered SA days during an 18-month follow-up period. The current thesis evaluates the PSI-WPI through four studies. Study I was an effect evaluation conducted to learn if a PSI-WPI on top of CAU in PHC is more effective in reducing registered SA days compared to CAU. The following three studies were part of the process evaluation of the PSI-WPI. Study II explored experiences, facilitators, and barriers to participation in the PSI-WPI. Study III explored potential ethical challenges arising from the PSI-WPI. Study IV explored the process outcomes reach, dose delivered, dose received, fidelity and dose response of PSI-WPI sessions.

1 Literature review

1.1 Common mental disorders

Mental health is an essential part of life and suffering from a mental disorder (i.e., a clinically significant disruption in a person's cognition, emotional regulation, or behaviour, usually associated with impaired functioning) (11), can cause consequences on health and wellbeing, the individuals ability to work, as well as on relationships with family and friends (11). CMDs usually include the diagnoses: "mild- to moderate depression", "anxiety disorder" and "adjustment disorder" and these diagnoses will be referred to as CMDs throughout this thesis. To receive a diagnosis an individual must meet certain diagnostic criteria which are evaluated and diagnosed by a physician. In the European union, more than one in five individuals meets the criteria for a CMD (including substance use disorder) and the life-time prevalence reaches approximately 30% (1). The life-time prevalence of CMDs is higher in high income countries (~33%) than low-income countries (~23%) (1) and for women, who have a 28% higher incidence of CMDs compared to men (12). Approximately 5% of the working age population suffer from severe mental disorders such as severe depression, bipolar disorder, and psychotic disorders (13). Severe mental disorders and substance use disorders are not included in this thesis. Moreover, individuals with CMDs can face stigmatisation (i.e., being treated differently or unfairly due to for example a mental illness) from health care providers which can hinder access to care (14) or from managers and colleagues which can hinder RTW (15).

1.2 The role of employment and the connection to sickness absence

Most individuals with CMDs are employed. The benefits of employment on health have been widely recognised (2, 3). Employment provides structure, have a positive effect on health and wellbeing, a protective effect from depression and can decrease symptoms of anxiety, especially if workplace conditions are favourable and good supervision is available (2, 3). Being employed or entering

employment for >12 hours a week can increase health in general, self-esteem, physical health, and happiness (16). Being unemployed, on the other hand, can increase symptoms of depression and anxiety (2, 3). However, employment can also increase the risk of SA due to a CMD if a worker is exposed to psychosocial stressors at work such as low reward, high job strain (i.e., high demands combined with low control), or a negative effort-reward imbalance (17). Being exposed to such stressors increases the risk of SA (17), and employees with CMDs struggle with SA episodes more often (4, 5) and for longer periods than individuals on SA due to other diagnoses (4).

Even if employees with CMDs benefit from being employed, they are at risk of SA (13). Among individuals in the European Union with a diagnosed CMD, around 30% will experience a SA episode due to a CMD during their working life (13). Having had a SA episode due to a CMD is also a strong predictor of future SA (18). Re-occurring SA episodes are common when employees RTW after a SA episode due to a CMDs (4, 18, 19). One reason for this is that symptoms of CMDs often are present long after the employee returns to work (20). One study found that many still experience symptoms of anxiety, depression, and lower work functioning one year after a SA episode due to a CMDs, even when returned to work (20). One reason for this is that sometimes the employee returns to a workplace in which they are exposed to negative psychosocial work environment factors (17) or a toxic work environment (21).

In Sweden, workers are unequally at risk of SA depending on their work sector. Individuals employed in the public sector such as health care, education, and social services have an increased risk of SA due to a mental disorder, when compared with other occupations (12, 22). The increased risk of SA due to mental disorders in these occupations have been explained by psychosocial and organisational work-related factors such as low control over their worktime and emotional demands (23), but also due to demographic factors in which the peak of SA due to a mental disorder is in the age group of 30-39 years when many have young children, another risk factor for SA due to a mental disorder (12). In a study

from Finland, it was shown that employees with mental disorders benefit from receiving part-time SA, upholding the connection to the workplace, when compared to full-time SA (24).

1.3 Interventions supporting individuals with common mental disorders

Interventions aimed at supporting individuals on SA due to mental disorders have been evaluated in several reviews (6-8, 25-34). The interventions often involve a work-directed intervention, a clinical intervention, or a combination of these (6-8, 25-34). To understand the difference between these interventions, a definition by Nieuwenhuijsen et al. (7) has been adapted.

Work-directed interventions: The aims are mainly to improve conditions related to work. This can be achieved by supporting the worker through, for example, involving the manager in the RTW process, identifying barriers for RTW, arranging accommodations at work such as decreased work hours or change of work tasks, identifying and addressing causes of SA such as conflicts at the workplace, or teaching the employee how to cope with symptoms at the workplace.

Clinical interventions: The aims are mainly focusing on improvements of symptoms, often assuming that the symptoms are the barrier for returning to work. They can be administered through psychological interventions such as CBT or problem-solving interventions, psychiatric treatment such as problem-solving therapy, medical treatment, and increased care.

In Table 1, an overview of selected reviews of interventions engaging the workplace and their effects on SA and RTW have been summarised. These include multiple populations (employees on SA, at risk of SA or who have RTW after SA with mental health problems, mental illness, mental disorders, mental health conditions, CMDs or a specific mental disorder diagnosis) and there is variety of different interventions (see population and intervention description in Table 1).

As for work-directed interventions, our review showed positive effects on RTW in three reviews (29-31): Improved time until first RTW from workplace interventions delivered to employees with mental health problems (29), shorter time to RTW from interventions aimed at enhancing RTW delivered to employees on SA due to mental disorders (30), and earlier RTW from the combination of CBT and stress management delivered through the workplace to employees with depression and anxiety (31). The remaining reviews evaluating work-directed interventions reported no effects on RTW (8, 25, 27). Two reviews reported positive effects on SA days when CBT or problem-solving based interventions were administered through the OHS (8, 34). One reported reduced total number of SA days for employees on SA or who had RTW after a mental disorder (34). The second reported decreased number of days on SA and duration of SA for employees on SA or at risk of SA due to a CMD (8). Moreover, one review reported that work-directed interventions may increase the number of SA days and that they did not have an effect on decreasing symptoms for employees with depression (7). To conclude, interventions delivered through the workplace seem to have some effect on RTW outcomes (29-31) and SA (8, 34) but less effect on symptoms (7).

As for the clinical interventions, the reviews were based on CBT or problem-solving (6, 32, 33). The first reported reduced time to partial RTW when problem-solving therapy or CBT was provided to employees with adjustment disorders and compared to non-guideline based care (6). The second, reported inconclusive effects on RTW but an effect on reduced SA when compared to CAU for employees on SA due to CMDs that were provided with CBT. However, the effects on SA could not be identified when compared to other interventions (32). The third, reported effects on increased RTW (1.5 days earlier) and decreased SA (3.6 days) for employees on SA due to psychological reasons (33). To conclude, it seems problem-solving therapy and CBT may have an effect on RTW outcomes.

Combined interventions: Three reviews evaluated a combination of a work-directed intervention and a clinical intervention (7, 26, 28). Results showed that employees on SA due to CMDs receiving the combined interventions had 14 days

less sick-leave duration until RTW (28). Employees with depressive disorder had approximately 25 SA days less during the first year of follow up (7). Multi-domain interventions combining health, service coordination, and work modification significantly improved RTW rates (26).

The combined interventions have been designed thinking that work-directed interventions will support RTW while clinical interventions will support improvement of symptoms (7). However, it is still uncertain which combination yields repeatable results on RTW outcomes (25-27).

Table 1. Overview of reviews on interventions with a work-focus aimed at return to work or decreasing sickness absence

AUTHOR	POPULATION	INTERVENTION	CONTROL	RESULTS ON RTW	RESULTS ON SA	TYPE
VAN VILSTEREN, 2015 (29)	Employees with mental health problems	Workplace interventions	CAU or clinical intervention	Improved time until first RTW	Not analysed	Work-directed
MIKKELSEN, 2018 (30)	Employees on SA due to mental disorders	Interventions aimed at enhancing RTW	CAU	Shorter time to RTW	Not analysed	Work-directed
HOGG, 2021 (31)	Depression, anxiety and/or suicidal ideation/behaviour	Psychosocial interventions delivered through the workplace	CAU	Earlier full RTW from combined treatment (CBT and stress management)	Not analysed	Work-directed
DOKI, 2015 (34)	Employees on SA or who have returned from SA due to a mental disorder	CBT or Problem-solving treatment	CAU	Not analysed	Reduced total number of SA days, mean reduction ~6.6 days	Work-directed
HAMANN, 2022 (27)	Employees returning to work after a mental illness or a SA due to a mental illness	Interventions explicitly focusing on work issues or RTW	CAU	No effect on RTW	No effect on SA	Work-directed
DEWA, 2015 (25)	Employees on SA due to a mental disorder	RTW interventions including work-focused problem-solving skills	CAU	Inconclusive results on RTW	One out of 6 studies found an effect on decreased SA days	Work-directed
AXÉN, 2020 (8)	Employees at risk or diagnosed with a CMD	PST or CBT interventions among employees on SA due to CMDs	CAU	No effect on full time RTW	PST and CBT interventions decreased SA days and duration of SA	Work-directed
FINNES, 2019 (32)	Individuals on SA due to CMDs	CBT based interventions	CAU or other clinical intervention	Small positive effect on RTW	Effective in reducing SA when compared to CAU	Clinical
ARENDS, 2012 (6)	Sick-listed workers with adjustment disorder	Problem-solving therapy or CBT	Non guideline based care	Reduced time until partial RTW, mean decrease ~18 days at one year follow-up	Not analysed	Clinical
XU, 2024 (33)	Employees on SA due to psychological reasons	CBT based intervention often involving problem-solving	Non-CBT interventions	RTW 1,5 days earlier	Reduced SA days, mean reduction ~3,6 days	Clinical
NIGATU, 2016 (28)	Employees on SA due to CMDs	Workplace and clinical interventions aimed at enhancing RTW	CAU	No effect on RTW rates	Reduced the number of SA days, mean reduction ~13.4 days	Combined
NIEUWENHUIJSEN, 2020 (7)	Employees with depressive disorders	Work-directed intervention combined with a clinical intervention	CAU	Not analysed	Probably reduces SA days with up to 25 days during one year	Combined
NOWROUZI-KIA, 2023 (26)	Individuals with work-related mental health conditions	RTW interventions including health focused, service combination and/or work modification	CAU	A multidomain intervention led to 67% RTW full-time. A health-focused intervention led to 85% RTW full-time	Not analysed	Combined

Abbreviations: RTW, return to work; SA, sickness absence; CAU, care as usual; CBT, cognitive behavioural therapy; PST, problem-solving therapy; PSI, problem-solving intervention.

1.4 Problem-solving interventions

Problem-solving interventions have been developed from problem-solving therapy which is a cognitive approach that has been used since the 1970s, mostly for treating depression (35, 36). The therapy is aimed to increase the patients problem-solving skills which will enhance their ability to cope with life's stressors and increase self-efficacy (35, 36). Problem-solving integrates the patient's own ideas of what the problem and solutions can be as the core of the treatment, while being supported by a health care professional (36). The patient learns to identify and define problems, search for solutions, choose a solution(s), and evaluate the outcome. Problem-solving therapy has evolved into problem-solving approaches which can be provided in shorter sessions by a variety of health care professionals in the PHC and has shown effects on treatment outcomes of depression and anxiety (37).

1.5 Problem-solving combined with a work-directed intervention

Digging deeper into the different kinds of interventions, a combination of a clinical intervention focusing on problem-solving, and a work-directed intervention has shown promising results on RTW and SA (6-8, 25). One Cochrane systematic review recommended that interventions should be work-directed and based on problem-solving (6). However, a second systematic review that evaluated RTW interventions incorporating work-focused problem-solving skills, reported inconclusive results with some studies reporting significantly increased RTW rates and decreased SA duration, while others reported no effect (25). A third systematic review reported that interventions providing problem-solving skills in combination with a work-directed intervention such as involvement from the manager, decreased time until first RTW, but results on full RTW and CMDs symptoms were inconclusive (8).

To understand more about specific problem-solving interventions, three randomised controlled trials (RCTs) with a problem-solving intervention similar to the intervention that will be evaluated in this thesis will be described in more detail (38-40). The three RCTs have evaluated the combination of a problem-solving intervention and a work-directed intervention for employees on SA due to mental disorders in the OHS in the Netherlands and Sweden (38-40). The first RCT, was conducted in the Netherlands and targeted a population on SA for distress. The intervention consisted of a participatory workplace intervention that involved the employees' manager and the creation of an action plan for RTW. The intervention was provided by RTW coordinators, the control population received CAU, and the primary outcome was lasting RTW i.e., working four consecutive weeks without SA (40). No overall effect on lasting RTW was found at the six-month follow-up. However, if the employees at baseline had the intention to RTW despite symptoms, an effect on lasting RTW was seen (40). The second RCT was also conducted in the Netherlands, targeting a population that had been on SA due to a CMD and returned-, or were assumed to RTW shortly. The intervention consisted of a five-step problem-solving intervention that involved the employees manager and the creation of an action plan. The intervention was provided by occupational physicians, the control group received CAU, and the primary outcome was recurrent SA i.e., having a new episode of SA due to CMDs after having had an episode of SA due to a CMD. Participants receiving the intervention had a lower incidence of recurrent SA at the three, six and 12-months follow-up and a longer time to recurrent SA compared to the control group (39). The third RCT was conducted in Sweden, targeting a population of individuals with CMDs or stress-related symptoms seeking support from the OHS while on SA or not on SA. The intervention consisted of a brief problem-solving intervention with manager involvement provided by OHS consultants; moreover, the control group received CAU, and the primary outcome was registered SA days during 12-months follow-up. Participants receiving the intervention had approximately 15 SA days less during the 12-month follow-up and returned to work earlier compared to individuals receiving CAU (38). Even if the interventions in the three RCTs were

similar, the populations were different, and the RCT conducted in Sweden had a population seeking support for a CMD in which around half of the participants had registered SA, and half did not (38).

1.6 Stakeholders roles during the return to work process

During the RTW process, it is recommended to involve a multistakeholder approach with the involvement of both the healthcare and the workplace (26, 41-43). This entails a complex interplay in which it has been reported that understanding the roles and actions of each stakeholder is important (41, 42, 44, 45). A recent Swedish study explored the effect of employer involvement in the collaboration between the PHC general practitioner, PHC RC, employer, and employee. The results showed that employer involvement increased the employees time to RTW when compared to CAU (46). The authors discussed that when a RTW plan is arranged during this collaboration, this may in fact prolong the SA, instead of reducing it (46).

For the employees, taking an active role during their RTW process is recommended by learning about their symptoms and seeking support when needed. This should be enabled by support from a RTW coordinator, their manager, and other involved stakeholders (21, 41). In addition, receiving work accommodations can increase the chance of a sustainable RTW i.e., working for four consecutive weeks without any full- or partial SA days (21). However, characteristics of the workplace and the employees work tasks can sometimes impede on the possibility to be provided with work accommodations (47). For the employers, their role has been described as a provider of support for the employee in terms of having a plan for regular communication with the employee on SA, providing encouragement (44), arranging accommodated work tasks, and information as well as ensuring a safe and trusting relationship with their employee (47). Trust is a factor mentioned both by employees and managers and if trust is lacking, this may impede on the employees ability to RTW (21). Likewise, it is

recommended that managers and colleagues provide recognition to the employee on SA, both during the SA period and upon RTW by maintaining contact, providing support, respecting if the returning employee has a different work-pace and potential limitations (48). For the RTW coordinators, their role during the RTW process has been described in terms of taking a coordinating role by involving necessary stakeholders and assessing the workers' situation regarding personal- and work-related factors, providing encouragement to the employee and monitoring the RTW process (41, 43). Furthermore, other stakeholders may be involved during the RTW process such as health care professionals, the Social Insurance Agency, the Employment Agency, etc. This makes RTW a complex interplay between multiple stakeholders, and understanding the roles and responsibilities of the stakeholders involved is crucial (41, 42, 44, 45).

1.7 Facilitators and barriers for return to work and coordination

There are several factors known to facilitate the RTW process, such as RTW coordination (42), manager involvement (49) and receiving a structure for the RTW procedure (50, 51). The use of a three-part meeting between the employee, RTW coordinator and manager can facilitate a dialogue between the stakeholders, but RTW coordination has also been described as dependent on the coordinators positive attitude, training, and competence (42). For RCs, it is facilitating for the RTW process to focus on the employees abilities in their professional role, instead of focusing on their inabilities (49). Moreover, for the employee, work accommodations, a RTW process with clear expectations and a supportive relationship with the manager and colleagues have been described as facilitators for RTW (51). The employee should try to ensure that the work tasks the employee returns to are meaningful (49). Moreover, employees experience of a positive, or a negative encounter with health care professionals can empower or disempower the rehabilitation process and consequently the employees ability to RTW (52, 53)

If the employee lack motivation to RTW, or do not want to RTW, this is a barrier for RTW (49). Moreover, for the employee, inadequate work accommodations, pressure of returning too quickly, lack of understanding from colleagues (51), and fear of negative reactions once returned have been reported as barriers for RTW (49). Reported barriers for coordinators are that the coordinator role lacks a detailed work description, if the coordinator lacks formal coordinator training (42), the employee lacking motivation to actively engage in their RTW process, and conflicts between the employee and manager (42, 49). Health care professional have also reported barriers for the employees RTW to be that employers does not want the employee to return, but this barrier, however, has not been reported in return by employers (49).

1.8 Ethical aspects of return-to-work interventions and coordination

The combination of stakeholders involved in the RTW process, and their collaboration may cause ethical challenges (54). RTW coordination from the perspective of the workplace may cause a conflict between supporting the employee with, for example, arranging work accommodations and supporting the company by optimising economic performance (55, 56). RTW coordination from the perspective of the individual can involve deciding whether to disclose information about a mental disorder to the manager and for some this may involve disclosure dilemmas, fear of stigma and fear of missing out on future opportunities at the workplace (15, 57, 58). A recent Dutch survey found that around one in four employees experiencing a mental health issue do not disclose information on their mental illness to their manager (57), which may cause missed opportunities for support when needed. Employees that do disclose information on their mental health to their manager most often report positive outcomes in the form of increased managerial support (57) as well as increased self-acceptance of their situation (15). While several studies have investigated the role of stigma and disclosure during the RTW process (15, 57), fewer have conducted ethical evaluations of RTW interventions (54, 59). A qualitative study exploring ethical

aspects of RTW coordination for employees on SA due to CMDs in Sweden (59) found that, while supporting the patient's autonomous decision making, there was a risk that the coordinator took over the patient's decision authority by recommending the way forward in contrast to supporting the patient into thinking about finding own solutions. While respecting the patient's privacy it was also necessary for the patient to be open about problems and needs in the contact with the workplace (59). Moreover, in the Swedish setting, the coordinator role was experienced as unclear due to the lack of a clear work description and the different professional values between working as a coordinator and working as a healthcare professional (59).

1.9 The problem-solving intervention with workplace involvement

Building on the literature (6-8, 25) (38-40), the problem-solving in primary care (PROSA) cluster RCT was conducted (60). In contrary to the earlier described trials which were conducted in OHS, the PROSA trial was conducted in Swedish PHC (38-40). The **study population** consisted of employees on SA for two to 12 weeks due to a CMD. **The intervention** was a five-step PSI-WPI on top of CAU. Employees in the **control group** received CAU alone from the PHC. The **primary outcome** was the number of registered SA days during the 18-month follow-up.

1.10 Programme theory of the PSI-WPI

A programme theory was created (post hoc) to help explain the logic behind the PSI-WPI and how it was evaluated (Table 2). Starting with *input*, this came from the results of a previous RCT in Swedish OHS (38): A licensed psychologists providing training in problem-solving and the structure of the intervention as well as RCs trained in problem-solving delivering the intervention to the participants. *Core intervention* activities consisted of the five step PSI-WPI. *Materials* consisted of a manual and worksheets provided to the RCs which described the work process.

Implementation strategies consisted of a two-day training of RCs delivering the PSI-WPI and booster sessions. *Mediators* were expected to be increased individual problem-solving skills, strengthened RTW self-efficacy and an increased dialogue between the coordinator, employee, and manager (although these are not evaluated as part of this thesis). *Outcomes*, the primary outcome was the number of registered SA days during the 18-month follow-up period and was evaluated through study I. *Process*, contextual factors were evaluated in study II, ethical aspects were evaluated in study III, and the process outcomes reach, dose delivered, dose received, fidelity, and dose response were evaluated in study IV. The five step PSI-WPI and specific studies will be described in detail under the method section.

Table 2. Programme theory of the problem-solving intervention with workplace involvement

Input	• Previous research results from Swedish OHS • Expert support from a licensed psychologist • Rehabilitation coordinators trained in PSI-WPI
Core intervention activities	• The five steps of the PSI-WPI
Materials	• Manual and worksheets
Strategies	• Training and booster sessions
Mediators	• Increased problem-solving skills • Strengthened return to work self-efficacy • Increased dialogue between the coordinator, employee, and manager
Outcome	• Registered sickness absence days (Study I)
Process	• Context (Study II) • Ethics (Study III) • Reach, dose delivered, dose received, fidelity, dose response (Study IV)

1.11 Evaluating complex interventions

An intervention is described as complex if it involves multiple properties such as number of components, and stakeholders involved, and if it targets, for example both behaviour and employment (61). When interventions are evaluated, the focus can shift depending on the stage the research is in and the outcome that is sought.

The stages of research have been described as a continuum, moving from theory - to efficacy - to effectiveness - to implementation (62). Using a theoretical foundation can help us establish if an intervention could work. Efficacy trials investigate if an intervention performs well under ideal and controlled conditions, and effectiveness trials investigate if an intervention is effective in a "real-world" setting (62). In parallel with an effectiveness evaluation, a process evaluation should be conducted to increase the understanding of why an intervention was successful or failed (61, 62). When evaluating the effectiveness of an intervention, studies conducted as RCTs have been described as the gold standard (63). Using a control group not exposed to the intervention allows for a comparison between the intervention and control groups. The randomisation of participants balances for example observed and unobserved characteristics between study groups and if blinding of study groups is used, this can minimise bias (63). A process evaluation is often conducted alongside an ongoing RCT and process outcomes should be stated beforehand to enable data collection of process outcomes during the trial (64). It has been acknowledged that process evaluations should be seen as an essential part of the evaluation of complex interventions as it can contribute to a better understanding of what was delivered and received, as well as if there is a relationship between key intervention components and the primary outcome (61, 64).

One part of a process evaluation also involves an exploration of the context in which the intervention was conducted, and if context had any influences on the outcome (61, 65). Describing context in sufficient detail is therefore important and allows for an increased understanding of the intervention, making it easier to replicate the study and test the study in a similar or different context (65). One part of analysing context is the identification of facilitators and barriers related to the intervention (66), which provides an opportunity to learn from the experiences of both deliverers and recipients of the intervention before a potential scale up.

Another aspect when evaluating new interventions is to explore if the intervention leads to ethical challenges, something that is especially important when delivering

trials within healthcare. When undertaking an ethical evaluation, it has been recommended to do a risk estimation, assessing if the intervention complies with ethical norms and values, and if the intervention impose ethical consequences (67).

1.12 Reporting guidelines

When reporting research findings, it can be difficult for researchers to summarise studies with only a few thousand words and still be able to inform the reader about what has been done, how it was done, and why it was done. To ensure that reporting is transparent, reliable, and complete, several reporting guidelines have been established and are being increasingly used (63, 68-70). The reporting guidelines describe items that should be reported and came in to use because the reporting of studies was deemed as insufficient (71). When reporting a RCT, it is recommended to follow the Consolidated Standards of Reporting Trials (CONSORT) checklist and flow-diagram (63). In addition, CONSORT have extensions for different kind of trials (63). One example is the extension for cluster randomised trials (68) which requires additional information in order for the reader to understand how clustering was taken into account. In addition, the Template for Intervention Description and Replication (TIDieR) (69) can be used to describe the intervention in sufficient detail. A checklist has also been developed for the reporting of qualitative studies to ensure the comprehensive reporting of necessary items, i.e., the consolidated criteria for reporting qualitative research (COREQ) (70).

1.13 Outcome measures for return-to-work interventions

In addition to improving the reporting of trials, there has been an ongoing debate about which outcome measures to use when evaluating interventions aimed at improving RTW or reducing SA among individuals with mental disorders (74). In

1998, a literature review on how to measure SA was published which recommended measuring frequency, length, incidence rate, cumulative incidence, and duration of SA (72). Since then, several reviews have reported the number of registered SA days (7, 8, 25, 28) when evaluating RTW interventions. However, SA data are complex in several ways as they are often truncated, zero-inflated, over-dispersed or seasonal which makes the choice of statistical analysis method challenging (73). Other commonly used outcome measures involve RTW: time to RTW either full or partial (6, 8, 27, 29-31) and RTW rates i.e., the percentage of workers that have RTW compared to a control group (26). But as mentioned earlier, reviews on RTW interventions shows that these include several outcome measures, which is one reason that makes it difficult to synthesise evidence of effects (74). Considering this discussion, a recent study proposed a core outcome that should be reported when evaluating interventions including individuals that are absent from work. The study recommended including the proportion of workers that RTW after being absent, and time to RTW (74). Perhaps such recommendation can strengthen the evidence of which RTW interventions provide the best effect and support researchers in replicating studies and their results.

1.14 Theoretical frameworks

Theoretical frameworks provide a foundation based on theory which can be used to build a structure for collecting and analysing data (75). Using a framework can increase the studies credibility (i.e., confidence that the analysis captured the outcome of focus), transferability (i.e., the degree to which the results can be transferred to another setting) and dependability (i.e., the consistency and reliability of interpretations) of qualitative findings (75, 76). For quantitative findings a theoretical framework can increase the internal validity (i.e., how well the study is designed and accuracy of results), external validity (i.e., if study findings are generalisable), objectivity (i.e., without bias) and reliability (i.e., if research results can be repeated) (75). When conducting research, the above-mentioned

factors should be considered, and using a theoretical framework supports the planning of the study based on previous research, which in turn supports the choice of outcomes and methods of analysis (75, 76). In this thesis, four frameworks have been used for study II, study III, and study IV and these will be briefly described.

The Consolidated framework for implementation research (CFIR) (66, 77) provides a structure for evaluating the implementation of complex interventions. It also enables a systematic assessment of facilitators and barriers that may influence implementation (66, 78). Five domains are included in CFIR: Intervention characteristics, inner setting, outer setting, characteristics of the individual and process of implementation. Each domain contains key constructs related to the respective domain and an explanation of how the evaluation should be undertaken (66, 77). The framework for systematic identification of ethical aspects of healthcare technologies (67) can be applied to evaluate ethical aspects of using new interventions. The framework contains four domains: the assumed effect on health, accordance with ethical norms, structural factors that may cause ethical challenges, and long-term ethical challenges (67). There are two commonly referenced frameworks for process evaluations. One is proposed by Linnan and Steckler (64), which defines key components to evaluate in order to understand more about reach, dose delivered, dose received, fidelity, and recruitment. Analysing these components provides further understanding to why an intervention is, or is not effective, if it is effective for a certain patient group, or if it is effective under certain conditions (64). The second framework is proposed by the Medical Research Council (61) and suggests the core process evaluations elements as context, theory, engaging participants, identifying uncertainties, exploring if the intervention need refinement, and if there are economic considerations.

1.15 The Swedish system and sickness absence

In Sweden, all citizens have access to PHC. PHC is the first line psychiatry for individuals seeking support for mental disorders and is where most individuals with these disorders are treated (9, 79). In addition to providing medical care and treatment, PHC is also where most individuals receive their SA certificates which can be assigned by a PHC physician (79). It has been reported that it is difficult for PHC physicians to have the time to focus on work related factors in addition to treating the mental disorder (80). During the past decade, the Swedish government has had a goal of working towards reducing SA. To achieve this goal, PHC units across the Swedish regions (as well as other actors) have employed RCs to provide coordination services (81). Coordination services are not regulated in the Health and Medical Care Act (82) although healthcare services usually are: instead, coordination services are regulated by the Act on Coordination Services (81). According to the Act, the county councils should offer coordination services to patients that are sick-listed including individual support and coordination of other actors involved such as the Social Insurance Agency and the Employment Agency (81). Despite a "Swedish manual for coordination" (83), the RC's role has been described as lacking specific working models and evidence-based methods for RTW coordination which has led coordinators to finding their own work models (42, 84).

Evaluations of coordination services for mental disorders have found little or no effect on time to RTW at six and 12-months follow-up (85), and receiving support from a RTW coordinator may delay RTW (86). However, a delayed RTW may result in a more sustainable RTW and could thus be beneficial (86). Moreover, RTW coordination has received positive feed-back from its receivers regarding eased communication with involved stakeholders (87). However, a recent systematic review exploring the effects of RTW coordinators for all health conditions found that face-to-face contact can decrease the duration of SA and increase RTW rates (88). In addition, developing a RTW plan and identifying facilitators and barriers for RTW can decrease the duration of SA (88).

1.15.1 Occupational health services

In regard to the OHS, there are central recommendations from the World Health Organisation and European Union for countries to offer and organise OHSs for all working individuals (89). The OHS should ensure workers safety, well-being, and health as well as offer support to workers at risk of, or on SA and in need of support (89, 90). In Sweden, the OHS is regulated by law and should be available for employees, if the working conditions require it (91). The OHSs are specialised in occupational health, most often employing physicians, nurses, and other health care professionals with a specialisation in occupational health and this is also where most RTW interventions have been provided (8). However, a recent survey from the Swedish Work Environment Agency showed that only approximately 60% of Swedish employees have access to the OHS (10). Thus, the incentive to focus on RTW and provide RTW interventions in PHC is needed.

1.16 Sickness absence regulations and recommendations

In Sweden, all individuals that are employed or studying are entitled to paid SA. The employer is responsible for the SA compensation during the first two weeks, and if a longer period is needed, the reimbursement is paid by the Social Insurance Agency, which is tax funded. SA of seven consecutive days or less does not require a medical certificate (if not otherwise stated) but if a longer duration is needed, the employee is obligated to send a medical certificate to the employer, and after day 14, the Social Insurance Agency (92). To receive reimbursement from the Social Insurance Agency, the employee must obtain a SA certificate from a physician, and in the next step the Social Insurance Agency must approve the certificate. The SA certificate can contain up to three diagnoses. One of them needs to be stated as the primary diagnosis. Moreover, the SA certificate includes written information about the patient's inability to work and the symptoms that may have caused it (92). It is not the diagnosis per se that gives the right to sickness benefits, it is the circumstances due to the diagnosis that decreases the employee's ability to work. The primary diagnosis on the certificate guides the

length of the SA period, and the degree which can be 25%, 50%, 75% or full time (92). The National Board of Health and Welfare provides recommendations for the length and degree of SA (92). These recommendations consider all diagnoses included in the International Classification of Disease (ICD-10-SE) and are used as reference by physicians and by the Social Insurance Agency when they approve or deny a SA application (93).

Due to high SA rates in Sweden, the rehabilitation chain was implemented in 2008 (94). The rehabilitation chain evaluates the individual's work ability in relation their work role at several timepoints during a SA episode to decide on their right to SA compensation (94). Regarding the first 90 days of SA, the individual's work ability is assessed against their current work role. After day 90, the individual's work ability is assessed against any work role at the individual's workplace. After day 180, the individuals work ability is assessed against any work role in the labour market (94). It has been argued that these recommendations provide a financial incentive for employees to RTW as they otherwise may need to start a new work role or workplace. Another area of debate concern recommendations of the length of SA based on diagnosis. The recommendations are based on the severity of diagnosis usually including mild, moderate or severe and if the SA should be partial- or full time (92). However, mental disorders are difficult to diagnose, and patients with these disorders tend to shift between diagnosis. A recent Swedish study showed low correspondence between the diagnosis on the SA certificate and diagnoses established from a structured psychiatric interview (95).

1.17 Laws and regulations in the Swedish setting

All residents and individuals working or studying in Sweden are entitled to social insurance and social welfare (94). To protect the interest of individuals receiving support from health care, all health care professionals work by the Health and Medical Care Act (SFS 2017:30), which states that healthcare should be available for all (82) and the Patient Act (SFS 2014:821), which states that healthcare should

clarify and strengthen the patients' position and support their participation, integrity, and autonomy (96). Further, employers are obliged to provide a healthy work environment and to work with the prevention of work-related accidents; this is regulated by the Work Environment Act (SOFS 1977:1160) (90). Moreover, employers must work according to the Swedish Work Environment Authority`s regulations (AFS 2015:4), which regulates for example workload, working hours and discrimination (97). The laws and regulations are in place to guide and protect the patient/worker and the involved stakeholders as well as to define their responsibilities.

1.18 Research gap

Previous research has shown that combining work-directed interventions with problem-solving interventions by involving the employer in the RTW process yields promising results for RTW outcomes (6-8). In Sweden, a decrease of up to 15 SA days during the first year has been demonstrated when a PSI-WPI was conducted in the OHS (38). However, the effect from such interventions in PHC in Sweden have not been established, and the effect on a decrease in SA beyond 12 months is inconclusive (8, 25). Moreover, the PHC in Sweden does not have a history of providing work-directed interventions, and involving the manager in the RTW process is fairly new. Therefore, research on the effects, the process, and potential ethical challenges arising from this way of working is needed. Moreover, process evaluations of similar studies are scarce (98-100), and these are needed to understand more about potential contextual factors that may impact the effects from such studies.

2 Research aims

The overall aim of the thesis was to evaluate the effectiveness of the PSI-WPI on top of CAU for employees on SA due to CMDs when compared to CAU alone, and to examine related contextual factors, ethical aspects, and process outcomes.

Study I: The aim was to evaluate the effectiveness of a PSI-WPI added to CAU in reducing SA days among employees with CMDs compared to CAU alone in Swedish PHC on a monthly basis over 18-months follow-up.

Study II: This study had a twofold aim: 1) to explore the experiences of participating in a PSI-WPI aimed at reducing SA in employees with CMDs, delivered in Swedish PHC, and 2) to identify facilitators of and barriers to participate in the intervention. Both aims targeted RCs, employees on SA, and first-line managers.

Study III: The aim was to explore ethical challenges potentially arising from a PSI-WPI in PHC (with first-line manager involvement) for employees on SA due to CMDs.

Study IV: The aim was to examine reach, dose delivered, and dose received for PSI-WPI and CAU, and the interventions fidelity, and dose response for PSI-WPI.

3 Materials and methods

3.1 Setting

The studies in this thesis were funded by the Swedish Council for Working Life and Social Research (FORTE) under Grant numbers 2016-07415 and 2018-01252. The promising results from problem-solving interventions in combination with a work-directed intervention have been reported by the OHS in Sweden (38) and in the Netherlands (39, 40) and through this study the goal was to investigate if similar results could be replicated in a PHC setting (60). The PROSA RCT was conducted in PHC in the Region of Västra Götaland, Sweden which has around 1,7 million inhabitants and approximately 200 publicly funded PHC units.

3.2 Sample size calculation

The sample size calculation was based on the primary outcome, SA days during the 18-month follow-up. The calculation was estimated to 80% power to detect a difference of at least 20% registered net sickness absence days during the 18-months after baseline between for the intervention and control groups (101, 102). To achieve this power, it was estimated that 10 clusters with approximately 11 employees per cluster were needed in the intervention and control groups, respectively. Resulting in a total sample of 220 participating employees, approximately 110 in each group. An intra-cluster correlation of 0.01 was estimated and the alpha level was set to 0.05%.

3.3 Study design, participants and methods of analysis

The studies included in the thesis used quantitative methods (study I and IV) and qualitative methods (study II and III). In addition, multiple data collection methods were involved such as register data, questionnaires, medical records, and interviews. All the data used for the studies comes from the PROSA study and

participants. The PROSA study was registered at ClinicalTrials.gov, identifier: NCT03346395 on January 12th, 2018.

For study I, all employees in the PROSA study were included and general estimating equations were used to analyse the monthly mean difference in registered SA days between the PSI-WPI and CAU groups.

For study II, a sample of RCs, employees and managers were included. Content analysis (76) was used to analyse interviews and the CFIR was used to group the data according to four of the contextual domains in the framework: characteristics of the intervention, outer setting, inner setting and characteristics of the individual (66).

For study III, the sample of interviewed RCs, employees and managers were the same as in study II, except for two RCs unable to participate. Reflexive thematic analysis (103) was used to analyse interviews and the framework for systematic identification of ethical aspects of healthcare technologies (67) was used to organise the data.

For study IV, a framework for process evaluations by Steckler and Linnan was used (64) to evaluate the PSI-WPI and CAU groups in regard to process outcomes.

3.4 Inclusion and exclusion criteria

3.4.1 Rehabilitation coordinators

The RCs could be included in the study if they worked at a PHC unit in Västra Götaland, agreed with their manager that they could participate and were not expected to go on leave of absence or maternity leave.

3.4.2 Employees

The inclusion criteria were employment; age between 18-59 years old; on SA due to a diagnosis of mild- to moderate depression, anxiety, or adjustment disorder between two to twelve weeks at inclusion, diagnosed by a physician at one of the participating PHC units; accepting the involvement of the employer in the rehabilitation process; as well as the ability to understand written and spoken Swedish. The exclusion criteria were a diagnosis of severe depression, acute stress reaction, post-traumatic stress, or any other severe mental disorder such as psychotic- or bipolar disorder, having been referred to a psychiatrist, pregnancy, somatic complaints, or any other disorder(s) that could affect work ability.

3.5 Recruitment, randomisation and blinding

Approximately 80 PHC units were informed about the study. Out of these, 19 RCs agreed to participate, covering 24 PHC units (one RC covered three and three RCs covered two). Randomisation was conducted at the RC level using a random number allocator created by an independent statistician. The participating RCs were divided into two groups. The first contained RCs responsible for one PHC unit and the second contained RCs responsible for two to three PHC units. The RCs in the two groups were ranked in order of the care-need-index of their PHC unit(s). The care-need-index includes socio-economic variables that can be used to identify risk of ill health in the community (104). A random number generator was used to decide if the first RC in the list should be allocated to the PSI-WPI or CAU group. The included RCs were lined up in the order of the care-need-index of their PHC unit and every other RC was randomised to the PSI-WPI or CAU group to ensure a spread of the care-need-index need in both groups.

During the recruitment period, a PHC assistant blinded to allocation screened medical records for the employees inclusion and exclusion criteria. Eligible participants were sent information and an invitation to participate by post; the information provided was the same for all employees to ensure blinding. If

consenting to participation, the employee signed a written informed consent and sent it back to the PHC in a prepaid envelope. When the PHC had received the written consent, the principal investigator was informed of the patient's name and phone number, and provided this information to the RC who in turn contacted the participant for a first meeting. Thus, employees followed the randomisation of the RC at their respective PHC unit and were blinded to allocation.

3.6 The problem-solving intervention with workplace involvement

The RCs in the intervention group delivered a five step PSI-WPI on top of CAU. A licensed psychologist provided a two-day training to the RCs in the PSI-WPI group on the PSI-WPI, the steps of the intervention and how to actively deliver problem-solving. If needed, booster sessions were offered, but this was not requested from any of the RCs. In addition, the RCs were provided with a manual and worksheets containing a detailed description of the problem-solving process and a set of questions that could be used in the sessions with the employee, if the employee needed support with, for example, concretising problems. The content of the steps of the intervention can be found in Table 3.

Table 3. The five-step problem-solving intervention with workplace involvement

Steps	*Focus*	*Content*
Step 1	Inventory of problems in relation to return to work	The RC conducts an inventory of the employees' personal and work-related problems related to returning to work. After the inventory, the RC should call the employees manager to conduct a problem-inventory, schedule a time for the three-part meeting and ask what rehabilitative measures have been taken by the workplace.
Step 2	Brainstorming about solutions	The RC and employee brainstorm solutions and prepare topics to discuss during the three-part meeting.
Step 3	Formulation of an action plan	The RC and employee write down the solutions in an action plan, assess their applicability, and discuss if there is a need for support to implement the planned solutions.
Step 4	Three-part meeting	A three-part meeting guided by the RC between the RC, employee, and manager. The meeting involved discussing problems and solutions, agreeing on the action plan and a discussion around the potential need for work accommodations.
Step 5	Implementation, evaluation, and follow-up	The employee implements the action plan and evaluates the process together with the RC. The manager could but did not have to be involved in the evaluation. If necessary, all steps of the intervention could be repeated.

3.7 Care as usual

The RCs in the control group delivered CAU which is usually based on recommended treatment for the CMD. For anxiety and depression, treatment guidelines from the National Board of Health and Welfare (105) recommend CBT and pharmacological treatment (on their own or in combination), but there are no similar guidelines for adjustment disorder. CAU can also contain involvement of the workplace if this was part of routine care at the PHC unit. RCs delivering CAU received a four-hour workshop about RTW and rehabilitation from a licensed psychologist.

3.8 Materials

Register data on SA days during the 18-month follow-up and 24-months prior to inclusion were obtained from the MicroData for the Analysis of Social insurance (MiDAS) register (106) which is provided by the Swedish Social Insurance Agency.

The register contains SA days that exceed the 14th day and comes with a diagnosis of the SA episode, a start and end date. The register holds SA days that are full time (100%) and part time (75%, 50% or 25%).

Baseline questionnaire: A web-based questionnaire was distributed to all employees at baseline. The baseline questionnaire included questions about psychological symptoms, measured by the Hospital Anxiety and Depression Scale (HAD) (107) and the Self-reported Exhaustion Disorder Scale (s-ED) (108). Sleep quality was measured by four items from the Karolinska Sleep Questionnaire (109), self-reported health was measured by the Euro-QoL health state questionnaire (EQ-5D) (110). Intention to RTW was measured by the question: "Do you intend to RTW even if you continue to have symptoms of stress, exhaustion, depression, or anxiety?" (111).

Medical records: The RCs from the PSI-WPI and CAU groups were instructed to document the sessions delivered to the study participants in the PHC's medical journal. These records were made available to the research group through agreements with the PHC's management.

Process questionnaire: A web-based questionnaire was distributed to RCs in the PSI-WPI and CAU groups. The questionnaire included retrospective estimations about how often the RCs delivered face-to-face sessions, telephone sessions, three-part meetings, and workplace visits. For RCs delivering the PSI-WPI additional questions were asked about if they followed the structure of the PSI-WPI.

Semi-structured interviews: Interviews were conducted with employees, RCs, and first-line managers from the PSI-WPI group. The interview guides were divided into two parts. The first contained questions on experiences, facilitators of and barriers to participate in the PSI-WPI (the interview guide is available in the published article, study II). The second part contained questions on ethical challenges associated with PSI-WPI (the interview guide is available in the published article, study III).

3.9 Outcome measures

For study I, the primary outcome was registered net sickness absence days over the 18-month follow-up period.

For study IV, several process outcomes were evaluated: Reach, i.e., the proportion of eligible participants and those not accepting/not responding to participate and dose delivered, i.e., the number of sessions the RCs delivered by estimating the frequency of face-to-face sessions, telephone sessions, three-part meetings, and workplace visits. Data were collected from the RCs process evaluation questionnaire. Dose received, i.e., how many sessions the employees received was categorised as: No session, one session, two sessions, three or more sessions. Fidelity, i.e., whether the intervention was delivered as planned was evaluated by RCs estimating overall adherence to the worksheets. Finally, dose response, i.e., the relationship between number of PSI-WPI sessions received and number of registered net SA days over the 18-month follow-up period was evaluated.

Contextual factors and ethical challenges were also evaluated. For study II, the contextual factors experiences, facilitators, and barriers to participate in the PSI-WPI were evaluated. For study III, ethical challenges associated with the PSI-WPI were evaluated.

3.10 Ethical considerations

The studies followed the principles of the World Medical Association Declaration of Helsinki (112). The Swedish Ethical Review Authority approved of the studies included in the thesis on June 21st, 2017, reference numbers 496-17, T039-18.

Participants that were eligible received written information and had the opportunity to ask questions regarding the study. Participants received information that their participation was voluntary and that they at any time could withdraw from the study without stating a reason. Participants agreeing to participate signed a written informed consent.

To be eligible, the employees had to consent to employer involvement during their RTW process. This may, for some, have been considered difficult, especially if there was a lack of trust or an ongoing conflict. We do not know if employees saying yes would be employees with a positive relationship with their manager or a negative one. The inclusion of employees was based on pre-decided inclusion criteria and conducted by a PHC assistant. Using a PHC assistant not involved in the trial decreases the risk of selection bias because all employees received the same information, and RCs did not choose which individual could participate. The RCs delivering the PSI-WPI and CAU volunteered to participate which increases their incentive to adapt to the structure of PSI-WPI. Further, the trial involved three stakeholders in the RTW process, the RC representing the health care, the employee representing the individual, and the employer representing the workplace. During discussions before the studies took place, it was considered that these stakeholders would work from different perspectives which might collide. In order to understand more about potential ethical challenges that may be associated with the PSI-WPI, a study exploring ethical challenges was planned (study III in this thesis).

The control group in the PROSA RCT received CAU which is the standard care according to the current best practice guidelines available for CMDs and RTW coordination. Despite the PSI-WPI showing positive effects on RTW and SA in the OHS, we cannot assume that the same effects will be found in PHC. Therefore, the employees receiving CAU are not withheld from "better" treatment.

3.10.1.1 Data management

Sensitive data were collected that included names and personal identification numbers. The sensitive data were collected to enable the research group to use data from the PHC medical journals and registry data on SA from the Social Insurance Agency. Only researchers within the project had access to the sensitive data, which are password protected. Work files were created in which the sensitive data were de-identified by creating record IDs. The interview records

and transcripts were also de-identified by removing the name of the participant and other potential personal information.

3.11 Data analysis

3.11.1 Statistical analysis

Study I applied generalized estimating equations (GEE) analysis to estimate the difference in mean registered net SA days per month during the 18-month follow-up for the PSI-WPI and CAU groups. The GEE analysis contained mean registered net SA days per month (dependent variable) and group i.e., PSI-WPI and CAU (independent variable). Group x time was estimated for months 1-18. The cluster variable was not included in the analysis because one cluster only had one employee, instead robust standard errors and within-subject correlation was used accounting for differences in individual employee SA days each month. Differences in mean SA days between the PSI-WPI and CAU group were reported as a ratio with estimated confidence intervals. Analysis was performed with the statistical program RStudio 2023 (R version 4.2.3) (2023-03-15) (113) and with support from a statistician. For full details on the analysis, please see the attached manuscript.

Study IV used a Kruskall-Wallis test applying the Bonferroni correction for multiple tests to analyse if there was a differences in SA days depending on how many PSI-WPI sessions the employees received. In addition, a one-way Anova applying the Bonferroni correction for multiple tests was used to analyse differences in employee characteristics depending on how many PSI-WPI sessions the employees received. The analyses for study I and IV were conducted with the statistical program IBM SPSS statistics, version 28.01.1 (114). Significance level was $p<0.05$ for all analyses.

3.11.2 Qualitative analysis

Study II applied content analysis following the recommendations for a content analysis process (76, 115). Interview transcripts were explored by a latent analysis looking at the deep structure of the text and meaning units related to the aim were collected by inductive open coding. Meaning units were then given a code related to the latent content and codes with similar content were combined into sub-themes. After this, a deductive approach of the analysis was taken. The CFIR domains received a description of its content and which stakeholder was involved. All sub-themes were then categorised into these domains. All the steps of the analysis have been described in detail in manuscript number II.

Study III applied a theoretically driven reflexive thematic analysis (103, 116). The process started with a theoretical base (67) which was used to build a coding scheme including several ethical values. Data were coded deductively, and codes were then categorised according to the ethical values in the coding scheme. An inductive approach was taken to generate the themes, by interpreting the latent content of the data and formulating preliminary themes. Going back and forth between the data, and the preliminary codes and themes, a process of discussion and reflection was used by the researchers to create the final themes. All the steps of the analysis have been described in detail in manuscript number III.

For study II and III, the software program Nvivo; version 12 was used to sort and categorise the data (117).

4 Results

4.1 Participants included in the PROSA trial

In Figure 1, a flow-diagram over the randomisation of RCs and allocation of employees is reported. Around 80 PHC managers and RCs were informed about the trial. Out of these, 19 RCs agreed to participate, covering 24 PHC units (three RCs covered two PHC units and one RC covered three PHC units). Nine RCs were randomised to the intervention and ten RCs were randomised to control. During recruitment of employees (February 2018 to February 2020), 1506 employees met the inclusion criteria and received information about the trial. Out of these, 199 agreed to participate. Two employees were excluded (one because of unemployment and one withdrew without reason). The final sample consisted of 197 employees. The nine clusters in the PSI-WPI group had a median number of 9 (range 1-19) employees per cluster and the ten clusters in the CAU group had a median number of 11 (range 5-28) employees per cluster. The employees that were informed about the study but did not respond to the invitation had a mean age of 40 years in the intervention group (74% were females), whereas in the control group the mean age was 43 years and 74% were females.

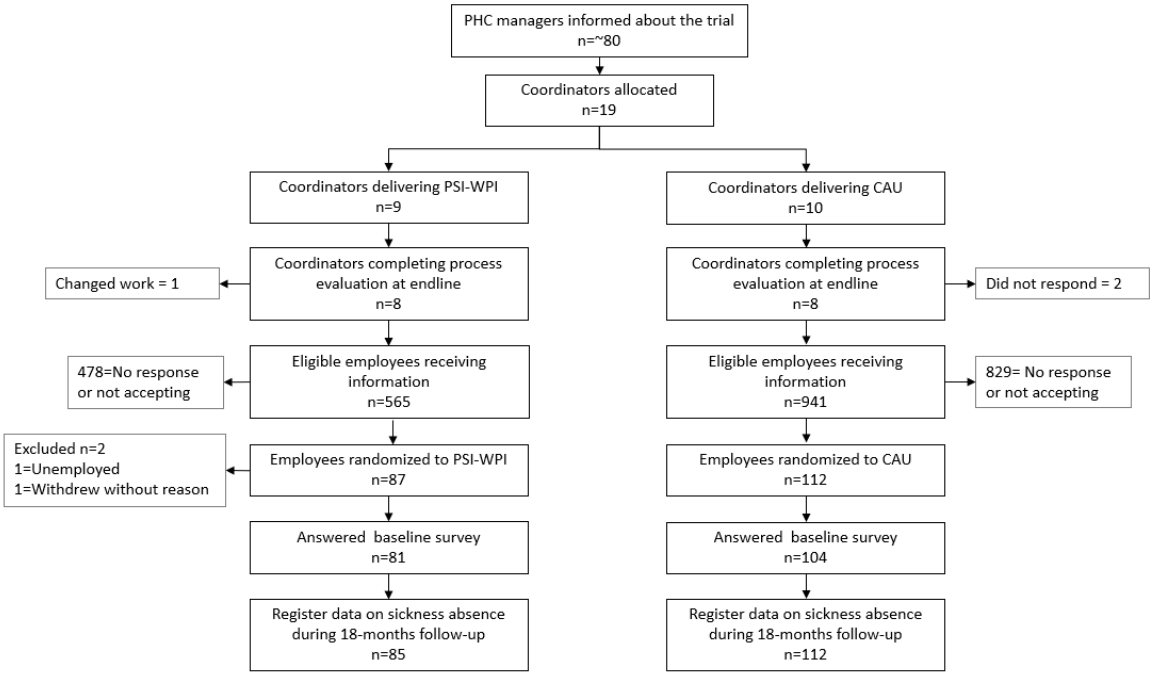

Figure 1. PROSA trial flow diagram[1]

4.2 Participant characteristics

4.2.1 Employees

The characteristics of the employees in the PSI-WPI and CAU groups were similar in most variables. The median age of employees in the PSI-WPI and CAU group was 42 years; in addition, both groups consisted of 85% females. Differences between the groups were found concerning diagnosis at baseline in which a higher proportion of employees in the intervention group were diagnosed with adjustment disorder (60% versus 46%) and a higher proportion of employees in the control group were diagnosed with depression (32% versus 14%). Additionally, a higher proportion of employees in the intervention group had a managerial position (20% versus 8%) (see Table 4).

[1] Adapted figure. Original figure obtained from Karlsson et al. Submitted manuscript (Study I)

Table 4. Employee characteristics at baseline for PSI-WPI and CAU[2]

Characteristic	*PSI-WPI (n=85)*	*CAU (n=112)*
Age, mean (SD)	42 (11)	42 (10)
Gender, n (%)	85	112
Female	72 (85)	95 (85)
Sickness absence diagnosis at baseline, n (%)	85	112
Mild- to moderate depression	12 (14)	36 (32)
Anxiety disorder	22 (26)	24 (22)
Adjustment disorder	51 (60)	52 (46)
Children <16 living at home, n (%)	79	103
Yes	44 (66)	59 (57)
Immigrant status, n (%)	79	103
Yes	4 (6)	9 (9)
Education, n (%)	80	102
Primary	3 (4)	4 (4)
Secondary education	42 (42)	52 (51)
University/Higher education	35 (44)	46 (45)
Work sector, n (%)	79	103
Public	40 (50)	52 (51)
Private	32 (41)	33 (32)
State	5 (6)	10 (10)
Other	2 (3)	8 (7)
Employment terms, n (%)	79	103
Permanent employment	71 (90)	99 (96)
Temporary employment	8 (10)	4 (4)
Years at workplace, n (%)	79	103
Less than 1 year	17 (22)	13 (13)
1-2 years	11 (14)	30 (29)
3-5 years	19 (24)	24 (23)
>5 years	32 (40)	36 (35)
Managerial position, n (%)	79	103
Yes	16 (20)	8 (8)
Intention to return to work[1], n (%)	61	84
1. Not at all	9 (15)	14 (17)
2	9 (15)	14 (17)
3	20 (33)	22 (26)
4	7 (11)	12 (14)
5. Absolutely	16 (26)	22 (26)
Self-reported depression[2], n (%) *No depression (0-6 points)* *Mild depression (7-10 points)* *Depression (>10 points)*	79 25 (32) 22 (28) 32 (40)	102 29 (28) 32 (31) 41 (40)

[2] Table obtained and adapted from Karlsson et al. Submitted manuscript (Study I)

Self-reported anxiety[2], n (%)	79	102
No anxiety (0-6 points)	14 (18)	23 (23)
Mild to moderate anxiety (7-10 points)	17 (21)	24 (23)
Anxiety (>10 points)	48 (61)	55 (54)
Self-reported exhaustion[3], n (%)	79	100
No exhaustion	11 (14)	12 (12)
Light/moderate exhaustion	11 (14)	16 (16)
Pronounced exhaustion	57 (72)	72 (72)
Self-rated health[4], mean (SD)	61	82
	43 (20)	48 (20)
Sleep quality[5], mean (SD)	76	101
	3,5 (1.1)	3,3 (1.4)

*[1]Measured by the question: Do you intend to return to work even if you continue to have symptoms of stress, exhaustion, depression, or anxiety? [2]Measured with HAD depression and anxiety scale. [3]Measuered with the self-report instrument s-ED. [4]Measured with EQ-5D visual analog*ue *scale which records the self-rated health status on a scale of 0-100. [5]Measured with Karolinska sleep questionnaire.*

4.2.2 Rehabilitation coordinators

A comparison of characteristics of RCs delivering PSI-WPI and CAU was explored descriptively. A higher proportion of RCs delivering CAU had full-time employment as a RC, had worked as a RC for more than three years, and had taken a coordinator course compared to RCs delivering PSI-WPI (see Table 5).

Table 5. Rehabilitation coordinator characteristic (Data from the 16 RCs that answered the survey)[3]

Variable	PSI-WPI n=8	CAU n=8
Age, mean (min-max)	57 (39-68)	52 (33-64)
Gender (Female), n (%)	8 (100)	6 (75)
Employed as Rehab coordinator, full time, n (%) [1]Employed as Unit manager, nurse, physiotherapist, counsellor, and RC part time, n (%)	3 (37.5) 5 (62.5)	5 (62.5) 3 (37.5)
Worked as RC >3 years, n (%)	5 (62.5)	7 (87.5)
[2]Did a coordinator course (yes), n (%)	6 (75)	7 (87.5)
Number of employees per coordinator, median (min-max)	9 (1-19)	11 (5-28)
[1]Specific numbers not reported due to the small sample size. [2]Have taken the course: Rehab coordinator – coordination of the rehabilitation process (7,5 hp).		

[3] Table obtained from Karlsson et al. Unpublished manuscript (Study IV)

4.3 Study II and III: Participant characteristics

For study II and III, a sample of employees (n=13), first-line managers (n=8) and RCs (n=8 in study II and n=6 in study III) were interviewed. The employee characteristics were as follows: a diagnosis of mild- to moderate depression, anxiety- or adjustment disorder, all were female; mean age was 44 years (range 22-60); and ten had returned to work at the 12-month follow-up. The employees did not differ significantly in regard to education, age, exhaustion, and self-reported symptoms of depression or anxiety compared to PROSA study participants that had responded to the baseline questionnaire by June 10th (n=172). First-line managers had a mean age of 46 years (range 34-61), half were female, most had university education, half worked in the public sector and six had manager responsibility for more than ten employees. The RCs had a mean age of 59 years (range 39-68), all were female, and their basic profession was nurse, occupational therapist, or physiotherapist.

4.4 Study I: Effectiveness of the PSI-WPI on sickness absence days

The primary outcome of the PROSA trial was registered net SA days during the 18-month follow-up period. As an intention-to-treat analysis, the outcome was analysed for all participating employees, 85 in the PSI-WPI and 112 in the CAU group. The GEE analysis showed no statistically significant effect on SA days during the 18-month follow-up between PSI-WPI and CAU, p=0.384. In Figure 2, the GEE estimated mean of registered SA days are reported. Both the PSI-WPI and CAU group decreased in SA days over time, but the PSI-WPI group had on average 0.9 – 3.6 additional SA days per month during the follow-up period. The difference between the groups monthly SA days were most prominent at month five (Ratio 1.64, 95% CI 1.11 – 2.43), month six (Ratio 1.59, 95% CI 1.07 – 2.36) and month eight (Ratio 1.68, 95% CI 1.06 – 2.67), and all were in favour of the CAU group (Table 6).

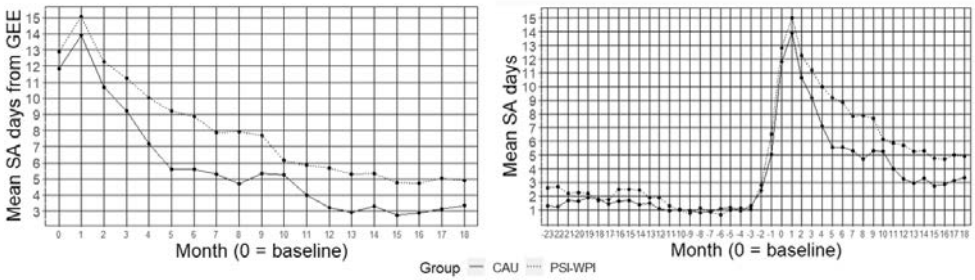

Figure 2. On the left, mean net sickness absence days per month estimated from GEE analysis. On the right, empirical mean net sickness absence days per month before and after baseline[4]

Table 6. GEE analysis. Mean sickness absence days per month, mean difference estimated and an estimated ratio with 95% confidence intervals[5]

Month	BL	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Data from GEE																			
Mean days (CAU)	*11,8*	*13,9*	*10,7*	*9,2*	*7,2*	*5,6*	*5,6*	*5,3*	*4,7*	*5,3*	*5,2*	*4,0*	*3,2*	*2,9*	*3,3*	*2,7*	*2,9*	*3,1*	*3,4*
Mean days (PSI-WPI)	*12,9*	*15,1*	*12,3*	*11,2*	*10,0*	*9,2*	*8,9*	*7,9*	*7,9*	*7,7*	*6,2*	*5,9*	*5,7*	*5,3*	*5,3*	*4,8*	*4,7*	*5,0*	*4,9*
**Mean difference*	*1,0*	*1,2*	*1,6*	*2,0*	*2,8*	*3,6*	*3,3*	*2,5*	*3,2*	*2,4*	*0,9*	*1,9*	*2,5*	*2,4*	*2,0*	*2,0*	*1,9*	*1,9*	*1,6*
***Ratio*	*1,09*	*1,08*	*1,15*	*1,22*	*1,40*	***1,64***	***1,59***	*1,48*	***1,68***	*1,45*	*1,18*	*1,46*	*1,76*	*1,81*	*1,60*	*1,74*	*1,65*	*1,60*	*1,46*
95% CI lower	*0,90*	*0,90*	*0,89*	*0,91*	*0,99*	***1,11***	***1,07***	*0,96*	***1,06***	*0,93*	*0,72*	*0,84*	*0,95*	*0,95*	*0,87*	*0,88*	*0,84*	*0,83*	*0,77*
95% CI upper	*1,31*	*1,31*	*1,49*	*1,63*	*1,96*	***2,43***	***2,36***	*2,27*	***2,67***	*2,27*	*1,93*	*2,55*	*3,27*	*3,45*	*2,96*	*3,46*	*3,26*	*3,08*	*2,79*

**Mean difference; mean days, PSI-WPI - CAU. **Ratio; exponentiate of the GEE log odds ratio with CAU as reference group.*

4.5 Study II: Experiences, facilitators and barriers to the PSI-WPI

RCs, employees, and managers reported that the PSI-WPI provided a structure for returning to work, but time investment was high. The PSI-WPI enabled a dialogue between the RC, employee and manager and helped create a bridge between the workplace and healthcare. Moreover, RCs reported that the structured work method and a unified vision on how to work with RTW at the PHC helped them in establishing the RC role.

[4] Figure obtained from Karlsson et al. Submitted manuscript (Study I)

[5] Table obtained from Karlsson et al. Submitted manuscript (Study I)

RCs reported that facilitating factors were the manual and worksheets, good relationships between stakeholders and a shared vision at the PHC on how to work with decreasing SA. Barriers were the time needed to invest in each employee (which was considered more than CAU), the extensiveness of the manual, conflicts between employees and managers and the severity of symptoms for the employee. Moreover, split roles i.e., working as a RC and nurse/physiotherapist/occupational therapist on different days of the week, and sometimes seeing the same patient/employee in both their roles led to role unclarities, both for the coordinator and for the employee.

For the employees, facilitating factors were the structured work process which supported them with actively participating in their RTW. Moreover, learning to identify problems and implement solutions, receiving trust and feeling validated in the discussion surrounding reasons for the SA episode were facilitating. Identified barriers were the number of in-person meetings at the PHC, symptom severity and disagreements with the manager.

For the managers, facilitating factors were the structured process of the intervention, early involvement in the employees RTW process and support from the RC regarding knowledge of CMDs. Barriers reported were time investment when compared to usual RTW activities, disagreements with the employee surrounding, for example, the reason for the SA episode or the RTW plan and that characteristics of the workplace could make it difficult to offer work accommodations.

4.6 Study III: Ethical challenges of the PSI-WPI

The reflexive thematic analysis of ethical challenges potentially arising from using the PSI-WPI identified that the workplace and healthcare held different organisational value logics regarding the content of goals, values, and norms (see Figure 3[6]).

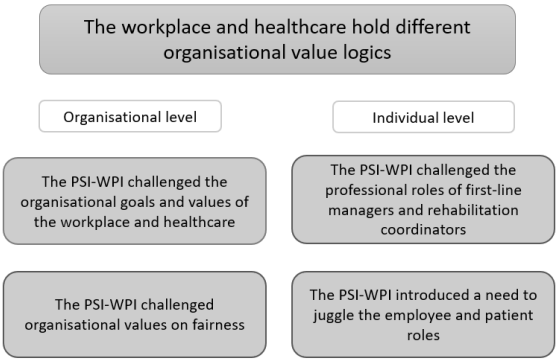

Figure 3. An overview of the main theme and four sub-themes[6]

On the organisational level, the PSI-WPI introduced a collaboration that required the workplace and healthcare to go beyond their organisational goals and values. Effects on third parties were identified because the first-line manager was exposed to conflicting goals when catering to the employees' need of work accommodations while also upholding the workplace goal of productivity. Differences in the workplace and healthcare value logics could impact what was thought of as a fair distribution of resources. For the workplace, this could mean decreased productivity and increased workload on colleagues. For the healthcare, the PSI-WPI caused a shift from providing resources to those most in need to providing resources to a patient group with (perhaps) higher work ability.

PSI-WPI expanded the first-line managers role because they were expected to take part in a problem-inventory with their employee as well as participate in a three-part meeting at the PHC. Offering work accommodations is regulated by law but the possibility to offer work accommodations can still depend on the characteristics of the workplace. RCs were instructed to act in a neutral way during the meetings with the employee and manager, but several RCs described that the norm was to be the patient's advocate. Moreover, the PSI-WPI challenged

[6] Figure obtained from Karlsson et al (2024)

the employee's privacy due to an increased sharing of information between the health care and workplace. It was recommended that the RC and employee discuss which information they wanted to share with their manager before the three-part meeting, but some employees feared stigma when revealing their mental illness and problems and needed to balance the potential benefit of sharing information against potential negative ones. Moreover, the employees needed to juggle between their employee (displaying a soon to be capable employee) and patient role (displaying symptoms and need of support).

4.7 Study IV: Process evaluation of the PSI-WPI

Reach: Out of 80 PHC managers and RCs informed about the study, 24 (30%) participated (one RC could cover one to three PHC units). Of the RCs that accepted participation (N=19), all participated in the training, either the two-day training for PSI-WPI (n=9) or two-hour workshop for CAU (n=10). Out of 1506 eligible employees receiving information about the study, 197 (13%) participated.

Dose delivered: The RCs delivering PSI-WPI estimated that they delivered face-to-face sessions, meetings with the employees manager and workplace visits slightly more often than RCs delivering CAU. RCs delivering CAU estimated that they delivered telephone sessions more often compared to RCs delivering PSI-WPI.

Dose received: 13 (15%) employees in PSI-WPI and 64 (57%) employees in CAU did not receive a first session with the RC. A first session with the RC was received by 37 (44%) employees in PSI-WPI and 37 (33%) employees in CAU. A first session, a three-part meeting and one or more follow-up sessions was received by 35 (41%) employees in PSI-WPI and 10 (9%) employees in CAU. The number of sessions were counted for both PSI-WPI and CAU but the content of the CAU sessions did not follow the structure of PSI-WPI.

Fidelity: four out of eight RCs delivering PSI-WPI estimated that they delivered three sessions to all their patients and if a session was not conducted, it was the three-part meeting. On a scale of 1 (completely disagree) to 7 (completely agree), RCs rated their training and resources as a score of 6. On a scale of 1 (never) to 7 (always), the structure in the workbook was followed most often for a first session with the employee score of 5.9, a phone call with the manager score of 5.4 and a three-part meeting score of 4.5.

Dose response: Employees were divided into receiving no PSI-WPI session, one PSI-WPI session, or three or more PSI-WPI sessions. There were differences in number of registered SA days between the three groups (see Table 7). There was a significant difference in SA days depending on number of PSI-WPI sessions received, p=0,007. The only significant difference in characteristics was between the no PSI-WPI session and three or more sessions group. The three or more sessions group had a significantly higher proportion of self-reported SA days during the four weeks before answering the baseline questionnaire.

Table 7. Net sickness absence days retrieved from the MiDAS register over 18-month follow-up categorised according to number of PSI-WPI sessions[7]

Number of PSI-WPI sessions	*Registered sickness absence days Median (range)*	*n (%)*
No PSI-WPI session	10 (0-248)	13 (15)
One PSI-WPI session	44 (0-540)	37 (44)
Three or more PSI-WPI sessions	129 (0-540)	35 (41)

[7] Table obtained from Karlsson et al. Unpublished (study IV).

5 Discussion

5.1 Main findings

The overall aim of the thesis was to evaluate the effectiveness of the PSI-WPI on top of CAU for employees on SA due to CMDs when compared to CAU alone, and to examine related contextual factors, ethical aspects, and process outcomes. The results showed that there was no statistically significant effect on SA days for employees receiving a PSI-WPI compared to employees receiving CAU, during the 18-month follow-up period. However, SA days decreased for both groups. The results suggest that PSI-WPI and CAU were equally effective in decreasing SA-days among employees with CMDs during the 18-month follow-up period.

Facilitating factors of the PSI-WPI included the structure of the PSI-WPI, the problem-solving procedure and that PSI-WPI facilitated an increased dialogue between the RC, employee, and manager, supporting a common view on the RTW process. A barrier to PSI-WPI was that it required more time investment for all stakeholders compared to CAU. Moreover, employees reported difficulties collaborating with the manager and RC if there was a lack of trust, and if there were disagreements about the cause of SA. The ethical evaluation identified challenges on the organisational level, in terms of differences in goals and values between the healthcare and the workplace. Ethical challenges were also identified on the individual level, with increased collaboration between the RC, employee and manager leading to disclosure dilemmas and fear of stigmatisation for the employee and unclear roles for RCs and managers.

The process evaluation showed that more employees in PSI-WPI had a diagnosis of adjustment disorder at baseline. Otherwise, there were no differences in characteristics of employees receiving PSI-WPI and CAU. Compared to those delivering PSI-WPI, RCs delivering CAU had longer experience in their RC role and more commonly worked as a RC full-time. The employees receiving PSI-WPI received more sessions with the RC, three-part meetings, and follow-up sessions than those receiving CAU.

5.2 Points of discussion

In Sweden, PHC is the first-line psychiatry provider for persons with CMDs. During the last decade, PHC has started to provide work-directed interventions, for example by RTW-coordinators. Previously, these interventions have more commonly been delivered by the OHS, at least in the Swedish setting. A stronger focus on work-directed interventions in the PHC has been recommended (9, 118), but barriers have been identified, such as lack of knowledge among PHC professionals on how work impacts symptoms (80), and lack of familiarity with workplace interventions, as well as lack of guidelines on how to support patients with their RTW process (118). The PSI-WPI was expected to overcome these barriers by providing a structured approach to PHCs' RTW practice. It seems, however, that the PHC context needs further consideration in order to understand if a contextual adaptation from the OHS to PHC is feasible.

All employees in the current RCT had been on SA due to a CMD for two to 12 weeks at inclusion. Systematic reviews reporting effectiveness of combined interventions (i.e., clinical and work-directed) on RTW outcomes, have sometimes included employees at risk of SA (8) and employees with less than 12 weeks of SA (7). Moreover, the RCT in OHS in Sweden reporting effects from a PSI-WPI on reduced SA days, included employees at risk of occupational stress or a CMD, in which approximately half of the study participants at baseline had no registered SA (38). This could indicate that the population in the current trial had a larger need for support.

RCs delivering PSI-WPI received a two-day training on the content and structure of the PSI-WPI. One could argue that this training was insufficient compared to the competence of OHS RTW coordinators and occupational physicians, specialised in occupational medicine (6, 8, 25). This difference in competence may be one reason for why the current trial showed no effectiveness on SA compared to CAU. Moreover, the current trial lasted for two years, weeks or months might pass between the PSI-WPI related sessions delivered by RCs. RCs delivering PSI-WPI

may have benefited from a more consistent flow of participants to increase their experience and develop their competence to provide the PSI-WPI.

Although, RCs in the CAU group delivered fewer sessions to their employees than RCs delivering PSI-WPI, the SA days followed a similar reduction in both groups. This could indicate that the RCs providing CAU were successful in supporting their patients' RTW. However, it could also indicate an impact from the Swedish Social Insurance system or reflect that the decrease in SA days followed a natural course. Additionally, the lack of contrast between PSI-WPI and CAU can be due the fact that only 35 (41%) employees in the PSI-WPI group received a three-part meeting, which represents the workplace's involvement in the PSI-WPI. We do not know why 50 (59%) employees did not receive a three-part meeting, but it seems as though some did not need support to RTW since 13 (15%) did not receive a meeting with the RC, and some employees may not have wanted to involve the manager. Moreover, the RCs may have had time constraints or problems reaching the manager, or managers may have refused to participate. This should be investigated in future studies. Identifying the employees that do not need support in their RTW could ensure that the resources from the PHC are used on those individuals in most need.

The PSI-WPI (if fully completed) involved five steps being delivered over the course of two to five sessions, in which one session included the manager. The problem-solving interventions combined with work involvement that have been evaluated in systematic reviews differ in terms of the content and number of sessions delivered to the employees (25), but there is no consensus on how many sessions are actually needed. More research is also needed on the optimal amount of problem-solving. One way of evaluating this could be by measuring problem-solving skills as a mediator of the outcome, as recommended in previous research (25).

The PSI-WPI facilitated the structure for delivering and receiving RTW coordination for both RCs, employees and managers. This is in line with previous research in which a structured approach has been reported to increase the

employees' understanding of what is expected of them (50, 119, 120). The collaboration between the RC, employee and manager has been identified both as a facilitator, and a barrier (42, 43, 51). The PSI-WPI supported collaboration and dialogue between the RC, employee and manager by supporting them in reaching a consensus around the cause of the SA and the way forward, in line with previous studies (43). However, RCs reported difficulties supporting individuals in conflict with their manager and may therefor also benefit from training in conflict management.

From the PSI-WPI, disclosure dilemmas were reported as an ethical challenge, in line with previous research (15, 59). The collaboration between the healthcare and workplace involved some employees fearing stigmatisation and risk of losing future opportunities at the workplace, which is also in line with previous research (51). It has, however, been reported that despite the stress and anxiety that may come with disclosure, most employees report beneficial outcomes after having done so (15). To decrease the risk of disclosure dilemmas and to create a safe and trusting environment during the RTW collaboration, the RC should define and explain their own role and expectations as well as the expectations upon the employee and the manager. These recommendations are also in line with previous research (41, 59).

To understand more about potential ethical challenges of implementing the PSI-WPI in PHC, an analysis was undertaken using a framework for systematic identification of ethical aspects of healthcare technologies (67). This framework has long been used to evaluate new healthcare technology but has less commonly been used to evaluate RTW interventions (59). We recommend using country specific ethical frameworks as part of the evaluation of complex RTW interventions. This could provide a broader understanding of potential ethical aspects that may come from the collaboration between multiple stakeholders and organisations.

5.3 Transferring knowledge to practice

At this stage, we cannot suggest that the PSI-WPI should be provided in PHC in Sweden because it appears to be the case that CAU provides similar effects on SA with less effort. We need more information about the degree to which the RCs followed the steps of the PSI-WPI and if the training that the RCs received was sufficient.

The results from the qualitative studies can be used by researchers and health care professionals to understand more about contextual factors that have been identified as facilitators and barriers. One contextual factor that should be considered is that the RCs, employees, and managers in the PSI-WPI group were facilitated from receiving a structure for the RTW process. Some RCs explained that they had lacked a structured work method before participating in the trial, which would indicate that a structured work method is lacking for CAU. This has been reported in previous studies (42, 84) and warrants further exploration.

The PSI-WPI led to ethical challenges on the organisational level, in terms of differences between the goals and values of health care and workplace, and on the individual level, in terms of disclosure dilemmas and unclear roles. We recommend that RCs are made aware of these challenges to be able to support employees and managers during the RTW process.

5.4 Strengths and limitations

The methodological strengths of the PROSA RCT included the design of the trial. A RCT is often referred to as the gold standard for evaluating effectiveness under real world conditions. For the primary outcome, registry data was used which provides an objective measure without loss to follow-up. Recruitment bias was avoided by having an independent PHC assistant recruiting participants from the PHC medical journals based on pre-decided inclusion criteria. All potential participants were provided with the same information about the trial and thus blinded to allocation. A process evaluation was undertaken to further understand

the results from the RCT (61). In line with other studies evaluating SA days over time (38), in the current trial, the decision was made to include all cause SA for the follow-up of SA. This is considered a strength because the diagnoses included in CMDs often goes hand in hand and may fluctuate between each other over time (22). The randomization of participants resulted in two groups with similar demographics and self-reported symptoms. We do not know the reason behind why a large proportion of individuals (n=1307) receiving information about the trial did not respond or declined participation, but their demographics were similar to the group that accepted participation in terms of median age and proportion of females (85% in PSI-WPI and CAU versus 74% in the non-responding group). The high proportion of females, half of whom worked in the public sector and had children living at home indicated that we reached the most common group suffering from CMD. This means that the results are most likely generalisable to individuals seeking support during their SA due to CMDs.

There are also limitations of the RCT. The planned sample size of 220 individuals was not reached, increasing the risk of type II error i.e., not finding an effect despite there being one (121). It may also be that the employees that accepted to participate in the trial (199 out of 1506), had less severe symptoms and most likely less serious conflicts with their manager, potentially resulting in a selective sample of more healthy individuals.

The PROSA trial was a cluster RCT. It is recommended that clustered trials are evaluated on the cluster level (122), but the clusters in our trial differed in number of participants (one cluster only had one employee) and clustering was therefore not accounted for in the analysis. In our estimation, not analysing on cluster most likely did not influence our results because the intra-cluster correlation was estimated to be small (0.010), there was a geographic distribution of clusters, and the level of the care-need-index was distributed between the PSI-WPI and CAU clusters.

This thesis is based within the field of intervention research. One could argue that it is an effectiveness implementation hybrid type 1 design, as the project's focus

is on understanding the effectiveness of an intervention in parallel to understanding the implementation process and identifying contextual factors (123, 124). A limitation of this study is that we did not explore more factors related to the implementation of the PSI-WPI such as how the RCs worked with problem-solving during their sessions with the employees and the employees acquisition of problem-solving skills, as recommended in previous studies (25).

The COVID-19 outbreak, with its high risk of transmission was announced by the Swedish government in March 2020 (125). Inclusion of participants in the PROSA trial ended in February 2020 and out of the sample, only 1 (1%) employee in PSI-WPI and 6 (5%) employees in CAU were included during January to February 2020. It may be that these employees had sessions during the outbreak and that they may have faced obstacles such as that the PHC needed to prioritise the care they provided or that the employees were less prone to visit the PHC. Also, the follow-up period of the PSI-WPI was ongoing for more than 12-months during the outbreak for 28 (33%) employees in PSI-WPI and 45 (40%) employees in CAU. This may have had an effect on short term SA but no COVID-19 diagnosis was reported for the registered SA. To further explore if COVID-19 had an effect on our outcome, a dummy variable was created. When included in the GEE analysis, this variable did not have an effect on the primary outcome which leads us to the assumption that the COVID-19 outbreak did not largely affect our trial.

A strength of the qualitative studies is that the interviews included three stakeholders (RCs, employees, and managers) which provides an understanding of the perspectives of both deliverers and receivers of the PSI-WPI. Study II and study III used frameworks to support the data analysis which increases the credibility of the results (66, 67, 76). The results of study II are transferrable to RTW interventions involving multiple stakeholders. Although, the results from study III should be transferrable to interventions including health care and the workplace, the Swedish context, in terms of laws and regulations, needs to be considered. With regards to limitations, it was difficult to recruit employees and managers to participate in the interviews. We could therefore not use a strategic

sampling procedure. As a result, the employees and managers that agreed to participate in an interview may be a selective group, possibly having more positive experiences of participating in the PSI-WPI. However, the interviewed employees did not differ in terms of symptoms at baseline when compared to the whole PROSA sample.

For study II and study III, the semi-structured interviews with employees and managers were conducted as one coherent interview. The interview guide was divided in two parts, with the first part containing questions on the process (study II) and the second part containing questions on ethical aspects (study III). To make this division clear to the interviewed participants, the interviewer informed the study participant of this division at the beginning of the interview and told the study participant when the second part of the interview started. Despite this division, there was sometimes an overlap between the two parts in which a barrier could later be described as an ethical challenge. When an overlap was evident, such as the importance of a good collaboration between the stakeholders, this was discussed in the research group. It is possible that a barrier to the PSI-WPI also qualified as an ethical challenge.

6 Conclusions

Delivering a PSI-WPI to employees on SA due to CMDs did not have an additional effect on SA days when compared to CAU. SA days in both the PSI-WPI and CAU groups decreased over time. Employees receiving the PSI-WPI received more sessions with the RC, more three-part meetings, and more follow-up sessions than employees receiving CAU. Despite this, there was no statistically significant effect on SA days for employees receiving PSI-WPI compared to CAU, during the 18-month follow-up period. The non-significant results may be due to a lack of contrast between the PSI-WPI and CAU which may be explained by an inconsistent flow of employees for RCs delivering the PSI-WPI, leading to low exposure. Moreover, 50 (59%) employees from the PSI-WPI group did not have a three-part meeting i.e., workplace involvement during their RTW process, possibly making PSI-WPI and CAU more similar. Furthermore, the similar way in which SA days decreased for employees in PSI-WPI and CAU may be due to the Swedish rehabilitation chain which assesses the individuals' work ability at different time points.

RCs, employees, and managers described the structured process and learning of problems and solutions in relation to RTW as facilitating factors. Barriers for the successful implementation of PSI-WPI were that PSI-WPI took more time than CAU, conflicts between employees and managers, and workplace characteristics that hinder the possibility of receiving work accommodations. Moreover, ethical challenges such as disclosure dilemmas and unclear roles for the RCs, managers, and employees were identified.

With current knowledge the use of a PSI-WPI in PHC in Sweden cannot be recommended. More research is needed to understand if the process of implementing a PSI-WPI is suitable in the PHC context. The reason why so many employees in the PSI-WPI group did not have a three-part meeting also needs further exploration. Furthermore, it would be beneficial to understand which employees are in need of support from a PSI-WPI, and how much of the PSI-WPI the employees require to show results on RTW outcomes.

7 Points of perspective

The research field of RTW interventions is wide and the research is often conducted through a collaboration between the healthcare and the workplace. Further knowledge is needed on which combination of interventions are effective on RTW outcomes in PHC and on how to ensure a good collaboration between the PHC and the workplace.

Future research should explore implementation strategies that can increase compliance to the PSI-WPI and help us understand why there were so many employees that did not receive the three-part meeting. A better understanding of the content of the five-step problem-solving intervention would be beneficial to understand if certain steps are more important for RTW outcomes. One part of this could be to explore the amount of problem-solving skills needed to support the employees in their RTW process (25). Also, we need to explore the reason why such a high proportion of employees did not receive a three-part meeting. Finally, a better understanding of which group of employees that needs support to return to their work would assist the PHC in distributing their resources to those that need them the most.

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