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A randomized clinical trial

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Doctoral thesis

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Trondheim, March 2017

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Arbeidsrettet rehabilitering for sykmeldte med muskelskjelettplager og mentale lidelser: En randomisert, klinisk studie

For mange personer forlater arbeidslivet for tidlig på grunn av helseplager, og for få personer med helseplager er i stand til å forbli i arbeid. Mange ulike rehabiliteringstiltak har blitt etablert for å øke retur til arbeid og hindre varig utfall fra arbeidslivet. De fleste programmene beskrevet i den vitenskapelige litteraturen er laget for spesifikke diagnosegrupper, særlig for personer med korsryggsmerter, men også for vanlige psykiske lidelser. Denne diagnose-spesifikke tenkningen står i motsetning til den økende dokumentasjonen på at det er overlapp mellom muskel-skjelettlidelser og mentale helseplager. På arbeidsrettede rehabiliteringssenter i Norge har det vært vanlig å inkludere pasienter med ulike helseplager i samme program. Imidlertid er det ingen randomiserte, kontrollerte studier som har evaluert slike rehabiliteringsprogram for pasienter sykmeldt for somatiske eller psykiske lidelser i det samme programmet, så det eksisterte ikke kunnskap om *effektene* av slike tilbud. Vanligvis har senterbaserte rehabiliteringsopplegg hatt en varighet på ca. fire uker, og pasientene bor på senteret i denne perioden. Imidlertid er en slik varighet basert på erfaring og bekvemmelighet og ikke forskningsbasert kunnskap.

Denne avhandlingen undersøkte effekten av et døgnbasert arbeidsrettet rehabiliteringsprogram som varte 4+4 dager med et mindre omfattende poliklinisk behandlingstilbud for personer som var sykmeldt med muskelskjelettplager og lettere psykiske lidelser. Hovedformålet var å undersøke om det var forskjell i effekt på sykefravær (studie 1) og på fysisk og psykisk helse (studie 2). Et annet mål med avhandlingen var å vurdere anvendeligheten til spørreskjemaet «Klar for Arbeid skala», som er utviklet for å evaluere hvor den sykemeldte er i prosessen med å komme tilbake i arbeid (studie 3). «Klar for Arbeid skala» er basert på en modell hvor man ser på tilbakeføring til arbeid som en prosess som består av flere stadier. Jeg undersøkte sammenhengen mellom hva deltakerne fylte ut på de ulike stadiene og sannsynligheten for at de kom tilbake i arbeid.

Den første studien viste at det ikke var forskjell i sykefravær mellom de to programmene etter 12 måneder med oppfølging. Det var heller ikke forskjell mellom programmene i forhold til hvor hurtig og hvor mange av deltakerne som kom tilbake i jobb. Den andre studien viste at det ikke var noen forskjeller mellom programmene på fysisk eller psykisk helse. I den tredje studien ble det tydelig at det var store utfordringer med å bruke Klar for Arbeid spørreskjemaet for å si hvor

deltakerne var i prosessen med å komme tilbake i arbeid. Det var kun poengsummen på noen av stadiene som hadde sammenheng med om man kom tilbake i jobb. Det var også vanskelig å plassere deltakerne i et stadium da mange scoret like høyt på flere stadier. Det viste seg også at et enkelt-spørsmål om når deltakerne trodde de kom tilbake i jobb generelt var bedre til å si om deltakerne kom tilbake i jobb enn poengsummen på de ulike stadiene i spørreskjemaet.

Konklusjonen basert på resultatene fra studie 1 og 2 er at det ikke finnes støtte for at et 4+4 dager døgnbasert arbeidsrettet rehabiliteringsprogram er bedre enn et enklere poliklinisk program og at dette programmet derfor ikke bør implementeres i ordinær rehabilitering. Konklusjonen fra den tredje studien er at det bør gjøres mer forskning før «Klar for Arbeid skala» eventuelt kan tas i bruk som et verktøy i arbeidsrettet rehabilitering.

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Trondheim, November 2016

Lene Aasdahl

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   Effect of inpatient multicomponent occupational rehabilitation vs less comprehensive outpatient rehabilitation on sickness absence in persons with musculoskeletal- or mental health disorders: a randomized clinical trial

   Submitted to Journal of Occupational Rehabilitation

2. Lene Aasdahl, Kristine Pape, Ottar Vasseljen, Roar Johnsen, Sigmund Gismervik, Chris Jensen, Marius Steiro Fimland

   Effects of inpatient multicomponent occupational rehabilitation versus less comprehensive outpatient rehabilitation on somatic and mental health: secondary outcomes of a randomized clinical trial

   Journal of Occupational Rehabilitation 2016. Epub ahead of print.

3. Lene Aasdahl, Kristine Pape, Chris Jensen, Ottar Vasseljen, Tore Braathen, Roar Johnsen, Marius Steiro Fimland

   Associations between the Readiness for Return to Work scale and return to work: a prospective study

   Submitted to Journal of Occupational Rehabilitation

Abbreviations

ACT	Acceptance and Commitment Therapy
CI	Confidence interval
GEE	General estimating equations
HADS	Hospital Anxiety and Depression Scale
IPS	Individual Placement and Support
IQR	Interquartile range
RTW	Return to work
SD	Standard deviation

Summary

Background

Musculoskeletal complaints and mental health disorders are the two leading causes of sickness absence in Norway. Despite increasing documentation of overlap in symptoms between these diagnoses groups, most occupational rehabilitation programs described in the scientific literature are diagnosis-specific. In Norway, inpatient occupational rehabilitation programs including different diagnostic groups in the same groups has been done for decades, but such programs have never been evaluated with a rigorous study design.

Aims

The main aim of this thesis was to assess the effects of a 4+4 days multicomponent inpatient occupational rehabilitation program compared to a less comprehensive outpatient program on sickness absence and somatic and mental health in persons with musculoskeletal- or mental health disorders. A secondary aim was to explore the usefulness of the Readiness for Return to work scale, a questionnaire developed to evaluate where sick listed individuals are in their return to work (RTW) process, by assessing the association between the scale and RTW, and comparing the scale to a single question assessing participants` expectations about length of sick leave.

Methods

In a randomized trial with parallel groups, individuals on sick leave with musculoskeletal complaints or common mental health disorders were randomized to the inpatient program or the outpatient program. The inpatient program consisted of Acceptance and Commitment Therapy (ACT), physical training and work-related problem-solving including creating a RTW plan and a workplace visit if considered relevant. The outpatient program consisted primarily of ACT (6 sessions during 6 weeks). The primary outcome was cumulated number of sickness absence days at 6 and 12 months follow-up based on registry data. Secondary outcomes were time until sustainable RTW and different somatic and mental health outcomes measured by questionnaires up to 12 months follow-up (paper 1 and 2).

In a prospective cohort study with 9 months follow-up participants on sick leave with musculoskeletal complaints or common mental health disorders who took part in two randomized clinical trials were included. Associations between the Readiness for RTW scale and RTW was

analysed using linear and logistic regression. The Readiness for RTW scale was compared to a self-reported question assessing participants` expectations about length of sick leave using adjusted/pseudo R^2. Questionnaires were answered at the start and the end of rehabilitation programs and sick leave was measured using registry data (paper 3).

Results

168 individuals were randomized to the 4+4 days multicomponent inpatient program (n=92) or the outpatient program (n=76) (paper 1 and 2). There was no statistical difference between the programs in median number of sickness absence days at 6 and 12 months follow-up. The hazard ratio for sustainable RTW was 0.74 (95% CI 0.48-1.32, p=0.165), in favor of the outpatient program. There were no statistically significant differences between the programs in health outcomes, except for slightly more reduced pain after the outpatient program.

For participants not working at the end of rehabilitation (n=96), high scores on two dimensions (Prepared for action-self-evaluative and Prepared for action-behavioral) were associated with a higher probability of RTW and more working days (paper 3). For those working (n=121), high scores on the Uncertain maintenance dimension was associated with a lower probability of RTW and less working days. Stage allocation, allocating participants to the dimension with the highest score, was problematic due to several tied scores between (not necessarily adjacent) dimensions. Generally, models including the Readiness for RTW dimensions were not as good at explaining work outcomes as models including a single expectation question.

Conclusions

There was no difference between the inpatient program and the outpatient program on sick leave or sustainable RTW. There was no difference in self-reported health measures between the programs, except for slightly more reduced pain after the outpatient program. Therefore, this study presents no support that a 4+4 days inpatient multicomponent occupational rehabilitation program is superior to a less comprehensive outpatient program.

Three of the Readiness for RTW dimensions were associated with RTW, but only to a lesser or similar extent than a single expectation question. Furthermore, several weaknesses with the Readiness for RTW scale were established and particularly the stage allocation approach cannot be recommended for clinical use in its current form.

1 Introduction

Work disability (work incapacity) among working-age individuals is a vast challenge in most western countries and one in seven regards themselves as having a health problem that affects their daily life in the OECD countries [1]. In Norway 556 100 working years were lost due to poor health and disabilities in 2014 [2] and in 2010 five percent of the gross domestic product was spent on disability and sickness benefits [3], which amounts to about 65 billion NOK for sickness absence and 85 billion NOK for disability pensions [4].

In addition to societal costs, sickness absence causes individual suffering and affects the family and children of the person who is on sick leave. In societies where most people are working, work meets important psychosocial needs and is important for the individual`s identity, social role and social status [5]. Through work people can feel like they are useful and that they contribute to society, which may contribute to give life meaning and strengthen peoples` feeling of intrinsic value [5, 6]. Work also structures daily life, promotes activity and includes elements which can be therapeutic for individuals with health problems, especially common mental health disorders [5]. There are some instances where work can be bad for the worker`s health situation, but generally work is good for your health [5]. Long term sickness absence is associated with impaired wellbeing [7], self-image [7], career opportunities [8, 9] and financial situation [7, 9], as well as future disability pension [10, 11] and some studies even report that long term sickness absence and disability pension are associated with increased mortality [12, 13]. Therefore, the importance of preventing sickness absence and assisting sick listed people return to work (RTW) is recognized, and this was emphasized as the Research Council of Norway administered a Sickness absence, work and health program from 2007 to 2016.

2 Background

2.1 Factors associated with work disability

During the last decades there has been done considerable research on the determinants of work disability [14]. Much of this research has been done on low back pain, but it is increasingly accepted that factors associated with disability are similar across disorders [15, 16]. The causes of work disability are complex and include among others psychosocial factors, work factors, health care factors and societal factors. It is further complicated by the fact that, what leads to disease is not necessary what leads to sick leave [17]. Work disability comprises both sick leave and more long term benefits like disability pension, the main emphasis in the following sections will be on sick leave.

2.1.1 Personal factors

Traditional biomedical factors, like pain in patients with low back pain, are not good predictors for work disability, as the correlation between pain, disability and impairment is limited [18]. Similarly for mental health disorders, there is increasing documentation of the importance of non-medical factors for work disability [19]. Therefore, research has been directed more towards non-medical factors like socio-demographic variables and psychosocial factors.

Several studies show that women have a higher risk of sick leave than men, but the reason is largely unexplained [20]. There is limited support for the "double- burden" hypothesis (the combination of taking care of children and paid work) and also for women having more stressful or unhealthy occupations [21, 22]. However, studies suggest that differences in health and in how men and women respond to health problems are developed early in life, which could indicate that gender differences in sick leave is due to differences in biology or early socialization of boys and girls [21]. Older age is in many studies associated with longer duration of work disability [19, 23]. However, the mechanisms behind this is largely unknown [20].

There is an association between socioeconomic status and health, even in northern Europe [24], and several studies have found a negative association between socio-economic status and

sickness absence [20, 25, 26], which is even stronger for disability pension [27-29]. Socioeconomic status is a complex construct, where education, occupational social class and income are considered the main subdomains [30]. Factors suggested to be important in explaining the negative association between socioeconomic status and sickness absence is physical work environments [25] and educational level [31]. Lower education is in several studies associated with more sickness absence [31, 32]. Many occupations require educational qualifications, and education will therefore possibly determine future work, which is why part of the effect of education is mediated through occupation, another explanation is that knowledge about health leads to a healthier lifestyle [31]. Even though education is often used as an indicator of socioeconomic status, studies do suggests that low education independently is a strong determinant for both sick leave [31] and disability retirement [30].

Psychosocial factors have been shown to be important risk factors for prolonged disability [33]. Negative expectations about recovery is a factor that in several studies, and across different diagnoses, consistently is associated with prolonged work disability [19, 34, 35]. Other factors include individuals` beliefs about their health status [34], passive coping strategies [35] and fear avoidance beliefs [36, 37].

For people with depression, Lagerveld et al. [38] found an association between duration of the depressive episode and work disability. Similarly, Vlasveld et al. [39] found that moderate to severe depressive symptoms gave a longer duration to RTW independent of the diagnosis of the worker. However, Iles et al. [36] did not find this association for non-chronic low back pain.

There is some evidence that a history with previous sick leave is associated with increased duration of sickness absence [19, 38] and future disability pension [40]. However, Krause et al. [41] found that workers with subacute/chronic low back pain with previous sick leave had higher RTW rates than those who had their first sick leave episode.

2.1.2 Workplace factors

Shaw et al. [16] categorized workplace factors associated with disability in four main categories 1) physical job demands, 2) psychological job demands, 3) work organization and support and 4) worker beliefs and attitudes.

Several studies have found that occupational class is associated with sick leave, with more absence among manual workers and non-manual workers that are less skilled [25, 31, 42, 43]. Occupational class is part of what defines ones position in society and different type of occupations will lead to different exposures (physical and psychosocial) [31]. Studies have found that high physical work demands (self-reported) are associated with longer duration of sick leave [23, 39, 44] and future disability pension [45]. Possible explanations for this might be that; physical work demands can affect health directly [31, 46], workers with physical jobs might have greater concerns about reinjuries or exacerbation of their problems [16] and it might affect the possibilities for job modifications when you develop health complaints [16, 31].

The psychosocial working environment is often studied in the light of Karasek`s demand–control model [47], which describes the relationship between job demands and job control on work stress. In this model, high demands and low control increase the chance of low job satisfaction and poor health. Low job control has been associated with more sickness absence, while for high job demands the association is not so clear. Some studies find an association between high job demands and more sickness absence, while others do not find an association, and some have even found an association with lower absence [20, 32]. Social support was later added to the original demand-control model, as it was described to modify the impact of high demands on physical and mental health [48]. Studies have suggested that low workplace support is associated with increased risk of disability [49]. However, a study by Strømholm et al. [50] did not support the demand-control-support hypothesis. In a cohort study based on data from the Nord-Trøndelag Health Study they found that high demands in the workplace were associated with a higher risk of sickness absence, and that increasing job control and support were associated with a lower risk of sickness absence. But they only found weak evidence for an interaction between the factors [50].

Laisne et al. [35] found that lack of job accommodation predicted longer sick leave in workers with musculoskeletal disorders. Steenstra et al. [23] on the other hand found that modified work prolonged sick leave in patients with low back pain.

The importance of job satisfaction for sick leave is not conclusive. Hoogendoorn et al. [51] found low job satisfaction to be a risk factor for sick leave due to low back pain, and Labriola et al. [52] found an association between low job satisfaction and disability pension for women. While other studies suggest that job satisfaction is not predictive for work outcomes [36, 53].

2.1.3 Healthcare factors

There is considerable documentation on how the lack of clear communication between 1) health care providers and patients, 2) between healthcare providers and the work environment and 3) communication between health care providers themselves delays the RTW process [54]. Most health care providers are not trained for dealing with complex disability cases, as their training has a biomedical approach [14]. General practitioners are usually the first health care providers work disabled workers meet. Still, a study showed that in consultations between general practitioners and individuals with musculoskeletal complaints, work was only discussed in one third of the consultations [55]. It should be noted that the study took place in the Netherlands, where the primary health care is somewhat differently organized.

Winde et al. [56] compared general practitioners experiences` with sickness certification in Norway and Sweden based on survey data. They found that general practitioners in both countries found aspects of sickness certification, like assessing the degree of reduced functional capacity, problematic. They found some differences between the countries. In Sweden, for example, the general practitioners reported that it was difficult to discuss the pros and cons of being on sick leave, while in Norway situations where they did not agree with the patient on the need for sick leave was described as difficult [56].

In another study, Winde et al. [57] found no association between sick leave certification rate and general practitioners` age, gender or size of the patient list. The risk of sickness absence was

reduced if the list contained many people with higher education, older people and few on disability pension.

Evidence based guidelines have been developed for work disability prevention in several countries. However, guidelines are not always followed [58], which may lead to unnecessary diagnostic imaging test, overtreatments, more referrals and more work disability [59]. Studies have showed that workers with musculoskeletal complaints that visit medical specialists have delayed RTW, even when adjusting for severity of symptoms [60].

2.1.4 Societal factors

Sickness absence tends to be negatively correlated with the unemployment rate [20, 61]. One of the hypotheses that tries to explain this negative correlation is the disciplinary effect hypothesis, which says that workers are more "disciplined" when the unemployment rate and the risk of losing your job is high [61, 62]. This can both be due to reduction in unnecessarily long absences and more sickness presenteeism.

Interaction with the insurance system can in many cases be problematic due to the demand to prove causation [63]. Few studies have investigated this, but there seems to be moderate evidence that the sickness insurance system affects the level of sickness absence, but as Allebeck and Mastekaasa writes; it is highly unlikely that the design of the insurance system would not have some impact on sickness absence [20].

2.2 Work disability models

To understand work disability and what influences the RTW process we need a conceptual model describing the mechanism and variables involved and how they influence each other [64]. Historically, the biomedical model has been dominating since the 19th century. The principle of this model is that illness is due to identifiable pathology and that mind and body are separate [64, 65]. The biomedical model might work for uncomplicated injuries, but not for chronic and

complex disabilities. As it has been acknowledged that disability is a complex condition and affected by many other factors, it is also acknowledged that the biomedical model is incomplete in describing work disability [65].

Most models on work disability has been developed for musculoskeletal complaints [64]. However, researchers in other fields, like mental health disorders, are starting to use models developed for musculoskeletal complaints [15]. Despite considerable research on secondary and tertiary prevention and management of sickness absence related to musculoskeletal complaints, there is no single framework that is driving research or integrated into disability management and policy [65]. Below I have presented some of the models that are most frequently used today, and which were most influential for the design of the study described in this thesis.

2.2.1 The biopsychosocial model

Many of the shortcomings of the biomedical model are identified in the biopsychosocial model, originally proposed by Engel [66, 67]. It describes how illness can be understood as a combination of biology, behavioral factors and social conditions. The model has been applied to many different health related conditions. One model that is widely used is Waddell`s model for low back pain and disability, which describes the relationship between attitudes and beliefs about pain, psychological distress, illness behavior and social interactions [18, 68, 69]. Waddell describes how pain and disability have to be viewed in a social setting and how social influences affect illness behavior and disability. Among social influences he names among others; family, occupation, workers` compensation and social security [68]. So, in terms of the sick listed worker the model integrates interactions between the worker, employer, case manager, medical providers and social environment [65]. However, the biopsychosocial model have been critiqued for not clearly recognizing how other systems affect the individual in their decisions about work participation and how the workplace system is not specifically named in the model [64, 70].

2.2.2 The International Classification of Functioning, disability and health (ICF)

An influential model that reinforces the biopsychosocial model in rehabilitation is the ICF. It was developed by the World Health Organization (WHO) to facilitate communication about health and health related states, and as a framework for research [71]. The model consists of two parts: 1) Functioning and Disability, which consists of body functions and structures, and activities and participation; and 2) Contextual Factors which consists of environmental factors and personal factors [71]. Functioning and disability is explained as an interaction between the individual`s health condition and personal and environmental factors. Despite that the medical condition is in the core of this model, it emphasizes the social elements and how they are the context in which the limitations of the impairment become disabling [65]. The ICF does not disregard the biological component, but rather emphasizes the importance of both biological, psychological and social components [72].

The ICF model has been criticized for not saying much about its theoretical origins and not justifying choosing the biopsychosocial model as the underlying model [72]. Other shortcomings of the ICF that have been commented on are that the title disentangles health from functioning and disability and a lack of uniform coding conventions for Activity and Participation leading to problems in comparing data [73]. It has also been commented that use in occupational disability research and practice might be challenging due to its generic nature [65].

In an expanded version of the ICF, proposed by Heerkens et al. [74], the “external” (environmental) and ”personal” factors were expanded to describe work participation. Work related factors are described on macro level (e.g. legislation, labor market), meso level (company related) and micro level (the person`s specific job). Other not work related external factors are also described, like home environment and social support.

2.2.3 The case-management ecological model

As the importance of the different stakeholders in disability management has been acknowledged, the need for a shift towards interpersonal communication has been emphasized [75]. A model that

visually describes this multi-system relationship is The case-management ecological model by Loisel et al, [76]. This model describes how workers` disability is not only due to characteristics of the worker, but influenced by the action and attitudes of key stakeholders and the interaction between the stakeholders. The most important stakeholders are the workplace, the healthcare system, and the compensation system and these are all included with different organizational levels. The model also includes the personal system at the social, affective, cognitive and physical levels. It is suggested that the elements in the model should be considered as an organized way to avoid work disability. In an updated model, culture and politics were added as they address the more global and social context (figure 1) [77]. The principles of the model also has some empirical support, as an operational model based on the principles of the case-management ecological model, the Sherbrook model, has been evaluated in a population based randomized clinical trial (section 2.5.1) [78]. Although the case-management ecological model by Loisel et al. was developed originally for management of low back pain the model has been applied to other health conditions where the goal is to avoid work disability [15, 64]. The model captures the complexity of work disability as it includes all the influencing systems. But even though the worker is at the center of the model, the different systems dominate and the complexity of the model is both the models strength and limitation [65].

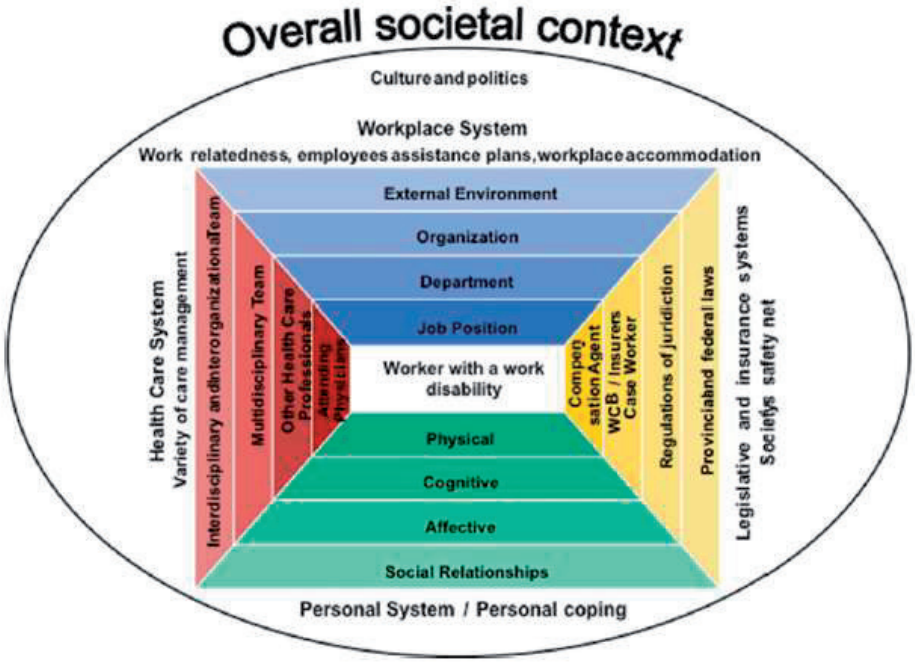

Figure 1 The arena in work disability prevention Loisel et al. Journal of Occupational Rehabilitation 15 (4). Copyright 2005 [77], with permission from Springer.

2.2.4 The Readiness for RTW model

Linton et al. [79] has underscored that work disability and the RTW process is not a static state, but rather dynamic and changing over time. These temporal aspects of the RTW process should be included in RTW models to allow the interactions between workers and stakeholders to change over time and also allow for the recurrent nature of many health complaints, like low back pain [65, 79]. One model that tries to incorporate this by describing the different stages of change during the RTW process is the Readiness for RTW model [80] which is based on the Readiness for change model [81] and the Phase model of disability [82].

The Phase model of disability takes into consideration the developmental character of disability and how interactions with the social environment changes over time [82]. The model consists of

eight phases where two phases are pre-disability (the occurrence of pain and the formal report of an injury) and the rest of the phases are distinguished by the duration of work disability.

The Readiness for change model describes how a person during a behavior change will be in one of five stages; from not thinking of changing, to starting to think about it, to making plans, to changing the behavior and to maintaining the change [81]. The model has been applied to different health behaviors, notably smoke cessation [81, 83, 84], but the Readiness for RTW model is the first model that applies it to the RTW process. Franche et al. [80] applied the stages from The Readiness for change model to the RTW process describing five stages: Precontemplation (not thinking about starting behavior with regards to RTW), Contemplation (considering RTW), Preparation for action (making plans for RTW), Action (RTW) and Maintenance (staying at work). Three dimensions of change mediates progression through the stages; the decisional balance (weighing of pros and cons for RTW), self-efficacy (confidence in engaging in RTW and maintaining it) and change processes [80]. Change processes can be both experiential (thoughts, feelings and attitudes) and behavioral. During the first stages, thoughts and feelings gradually increase about the need for change. In the later stages, actual change in behavior starts to happen, like contacting the employer. The impact of different stakeholders (like health care providers, the workplace and the insurer) on the sick listed worker can be shown through the impact on these three dimensions of change, while the sick listed worker is the primary agent of change.

2.3 Factors associated with RTW

There seems to be more research on factors associated with sickness absence than factors associated with RTW, and the two are not necessarily interchangeable. In the same way that negative expectations are associated with increased sick leave, positive expectations are associated with increased RTW, in both individuals who are on sick leave due to musculoskeletal complaints [35] and common mental health disorders [85]. In a qualitative study Young et al. [86] assessed what workers on sick leave with musculoskeletal disorders considered when forming their expectations about RTW. Among the themes they found were; wanting to go back

to normal, concerns about re-injury, concerns about employability (afraid of being replaced, limited work options), no job to go back to, feeling needed by the employer and their financial situation. Interestingly, pain was not among the major themes [86].

Higher education, socioeconomic status and self-efficacy have also been associated with positive RTW outcomes [87]. However, Labriola et al. [88] found that even though self-efficacy was lower in individuals on sick leave compared to the general working population, it was not associated with future sickness absence or RTW.

In a systematic review Cornelius et al. found that frequent communication between supervisors and workers with mental health disorders reduced the duration of work disability, however; it was suggested that this was only the case for individuals with low depression scores [19]. This is line with a study by Brouwer et al. that found that perceived social support was beneficial for workers with musculoskeletal complaints, but actually a barrier for RTW for workers with mental health complaints [89]. A possible explanation, suggested by Brouwer et al, was that for many workers who are sick listed with mental health problems, part of the background for their problems is too much work and exhaustion, and that how they perceive the support is more important than the actual support.

Brouwers et al. found that the severity of symptoms (somatization, anxiety and depression) were predictive of not achieving RTW in workers with common mental health disorders [85]. Lammerts et al., on the other side did not find an association for disorder-related factors when they assessed associations between biopsychosocial factors and long-term sustainable RTW (6 months) during 2 years follow-up for individuals sick listed with depression or anxiety. They found higher odds for sustainable RTW for individuals who were younger, had a higher household income level and were employed [90]. van Giezen et al. also found that disorder specific (physical) factors were less important than psychosocial aspects in predicting RTW for individuals sick listed due to low back pain [91]. They found that the most important RTW predictors were subjective evaluation of health status and job satisfaction. Cancelliere et al. on the other hand found no association between job satisfaction and RTW outcomes in a review including studies across different health conditions [87]. Other factors that are suggested to be

positively associated with RTW are work modification [35, 87, 92, 93] and stakeholder participation [87].

2.4 RTW interventions

RTW interventions are here defined as programs that aim to reduce work disability and increase work participation. As this includes a variety of approaches the main emphasis will be on occupational rehabilitation programs. Occupational rehabilitation may be described as "a multidisciplinary and multi-stakeholder process, which aims to reduce or eliminate the burden of work disability and facilitate work participation" [94].

In this section I will include studies on musculoskeletal- and mental health complaints, as they are the two largest diagnosis groups included in the study in this thesis. They are also the two main causes for years lived with disability globally [95], and in Norway they constitute about 60% of medically certified sick leave, with musculoskeletal complaints being the largest group amounting to about 40% of lost workdays in 2014 [96].

2.4.1 RTW interventions for musculoskeletal complaints

Disability has traditionally been seen as a consequence of illness, and hence the focus in treatment has been on improving physical and mental body functions which would then lead to improved function [64]. Treatment has often consisted of different components like physical exercise, patient education, ergonomic measures and behavioral treatments [97]. In a recent systematic review and meta-analysis of randomized controlled trials, Kamper et al. [98] found moderate effects of multidisciplinary biopsychosocial rehabilitation compared to physical treatment on work outcomes, disability and pain (short and medium term, not long term) for individuals with low back pain. However, compared to usual care they did not find an effect on work outcomes.

In another systematic review of randomized controlled trials and cohorts, Palmer et al. [99] included a broad range of different community- and workplace based interventions for sick listed people with musculoskeletal complaints. The comparative programs were mostly usual care. They found an effect on RTW and reduction in sickness absence, with larger effects in workers with shorter duration of sick leave at inclusion (<12 weeks). However, the treatment effect was smaller in large studies and high quality studies, suggesting a publication bias. Shorter interventions (<12 hours) seemed more effective than more intensive interventions (>32 hours).

Brief interventions usually refer to interventions that consist of patient education and a cognitive behavioral approach with a focus on removing fear of back pain and encouraging activity. In randomized controlled trials, brief intervention has been reported to reduce sickness absence compared to usual care, for individuals with low back pain [100, 101]. Jensen et al. [102] used a similar type of brief intervention as the comparative arm in a randomized clinical trial including a hospital based multidisciplinary treatment. They found no difference in RTW between the programs. Similarly, Brendbekken et al. [103] found no difference in time to full RTW when they compared a multidisciplinary intervention to brief intervention for individuals sick listed due to musculoskeletal pain. In a Norwegian multicenter-study Myhre, Marchand et al. [104] found no difference in RTW when they compared work-focused rehabilitation to either comprehensive multidisciplinary intervention or brief multidisciplinary intervention. Similar findings were reported by Reme et al. [105] who found no difference on sick leave at 12 months of follow-up when they compared brief intervention alone to a combination of brief intervention and CBT, brief intervention and seal oil or brief intervention and soy oil.

Research in the last decades, especially on low back pain, have suggested that disability is not merely due to the worker`s characteristics, but caused by interaction between several factors which should be included in treatment programs [76]. This change in how disability is viewed is referred to as the work disability paradigm. Important in this context is the Sherbrook model, a model for management of sub-acute back pain, developed and tested by Loisel et al. [78, 106]. This model focuses on early detection of new back pain cases at risk of chronicity, early clinical and ergonomic evaluations and early active treatment. Loisel et al. [106] tested this model in Canada in a population-based randomized clinical trial. Comparing a clinical intervention, an occupational intervention and a full intervention (combination of the two) with usual care, they

found that those receiving the full intervention were considerably more likely to RTW during follow-up as those receiving usual care. The effect was larger in the groups receiving the occupational intervention than in those who did not, emphasizing the effect of work place involvement. The study was later partly replicated in the Netherlands where workers sick listed with low back pain for 2-6 weeks were randomized to a workplace intervention or usual care, and if still sick listed at 8 weeks they were randomized to graded activity or usual care [107]. They found an effect on RTW for the workplace intervention, a negative effect for the graded activity intervention and no effect for the combined intervention. In another Dutch study, Lambeek et al. [108] found that an integrated program consisting of a workplace intervention, graded activity (based on cognitive behavioral principles) and integrated care management (coordinated communication with other healthcare professionals) substantially reduced disability, in the form of time to RTW and number of sickness absence days, compared to usual care for individuals with chronic low back pain.

A systematic review of controlled interventions and economic evaluations by Carroll et al. [109] found that interventions including the workplace seemed more effective on RTW than interventions that did not include the workplace, in workers with back pain, but only when structured communication with consensus between stakeholders and work modifications were included and not just a simple involvement of the workplace. They found the greatest results in trials with a quite short duration of sick leave (10-84 days); the results were more inconsistent in trials including workers with longer sick leave.

2.4.2 RTW interventions for common mental health disorders

Cognitive behavioral therapy (CBT) is often considered first- line treatment for common mental health disorders, like anxiety and depression [110]. Detecting and changing dysfunctional thought patterns into more functional ways of thinking is central in CBT [111, 112]. Gradual exposure is another princicple of CBT for depression and anxiety disorders. Graded activity which is often used in RTW interventions, can be considered a form of gradual exposure [113]. In a meta-analysis, van der Klink et al. [114] found that CBT was effective for reducing work-related psychological complaints compared to relaxation techniques and organization focused

interventions, but they did not find a difference between the programs on sick leave. However, few studies included that outcome. In a systematic review of randomized controlled trials including workers with adjustment disorders, Arends et al. [115] found similar RTW rates for CBT compared to no treatment. Problem-solving therapy reduced time to partial RTW, but not full RTW compared to usual care. However, the meta-analysis only included nine studies.

In a more recent review, Nieuwenhuijsen et al. [116] found that adding a work-directed intervention to a clinical intervention, e.g. modifying work tasks and working hours, reduced number of sick leave days compared to clinical interventions alone for individuals with depression. Two studies that suggested an effect of adding a work focus (addressing work issues) to CBT are Blonk et al. and Lagerveld et al. [113, 117]. Blonk et al. compared CBT to a combined intervention consisting of brief individual CBT and a workplace intervention with a focus on graded activity, and a no treatment control group for individuals with work-related psychological complaints such as anxiety and depression. They found a large effect on full RTW with a difference of almost 200 days between the combined intervention and the control groups. It should be noted that the number of participants was small (n=122) and that they were self-employed. They found no difference between the three groups for decrease in psychological complaints, suggesting that work resumption should not be based merely on reduction of symptoms [113]. Lagerveld et al. [117] also found an effect on time to RTW for work-focused CBT compared to CBT for workers sick listed with common mental health disorders, but no difference in reduction of mental health complaints. van Oostrom et al. [118], however, did not find an effect on lasting RTW when comparing a workplace intervention to usual care for people sick listed with distress. Reme et al. [119], on the other hand, found an effect on both work participation and psychological complaints when they compared a combination of work-focused CBT and individual job support to usual care in individuals with common mental health disorders. The job support was based on Individual Placement and Support (IPS), which was originally developed for individuals with severe mental health illnesses to assist them in obtaining and maintaining competitive employment [120]. Studies suggest it is effective [121, 122] and IPS is now being tested for other disorders.

2.4.3 RTW interventions for combined diagnoses

RTW interventions developed for diagnoses like musculoskeletal and mental health complaints contain many of the same elements. Additionally, there is increasing documentation of substantial overlap of symptoms in patients with musculoskeletal complaints and common mental health disorders [123-125]. Hence, it would seem natural to combine these diagnoses groups in the same rehabilitation programs. However, there are very few studies that have done this, especially randomized controlled trials. Poulsen et al. [126] included individuals on long term sick leave (>8 weeks) regardless of diagnoses. They compared a Danish RTW program consisting of a coordinated, tailored and multidisciplinary approach to usual care in three municipalities. They found an effect for the intervention on RTW in one of the municipalities, but there were large differences between the municipalities suggesting that contextual factors were important [126].

Pedersen et al. [127] found no effect of psychoeducation compared to standard case management on RTW during 6 months of follow-up, and at 3 months they actually found that the intervention group had a higher relative risk of not RTW. They included participants that were at risk of having a mental health disorder based on a questionnaire screening. When the participants were asked about the reason for their sick leave they responded both mental health complaints, musculoskeletal disorders and others, which could include cancer, lung disease etc. This was however the participants` judgement and not a medically confirmed diagnosis.

In another of the few trials that have included participants with different diagnoses, Braathen el al. [128] compared inpatient multidisciplinary rehabilitation to usual care. They found no difference on RTW at 4 months of follow-up. However, this trial was not randomized and the control group was recruited from the national sickness absence records.

A Swedish randomized pilot-study found that employees in the healthcare sector at risk of sick-leave with stress/pain who received a brief Acceptance and Commitment Therapy (ACT) intervention had fewer sick days than a group receiving usual care [129].

Some reviews have included studies with different diagnoses, although the single studies included are condition specific. Schandelmaier et al. [130] found that RTW coordination increased RTW compared to usual care in a systematic review and meta-analysis of randomized controlled trials. However, the effect was small and most of the included studies included participants with musculoskeletal complaints and only a few with mental health complaints. In another review, van Vilsteren et al. [131] included randomized controlled trials with workplace interventions for disabled workers. Most of their studies recruited individuals with musculoskeletal complaints as well (8 studies), five included individuals with mental health problems and one individuals with cancer. They found an effect on first RTW and length of sickness absence compared to usual care, but no effect on lasting RTW. In subgroup analyses they found an effect on time to RTW, pain and functional status for individuals with musculoskeletal complaints, but no considerable effects for individuals with mental health complaints or cancer. However, the quality of evidence for the last two groups were low [131].

To assess which generic interventions that are effective in enhancing work outcomes in people with chronic diseases, Vooijs et al. [132] did a systematic review of reviews on RTW interventions in populations with different chronic diseases. They argued that since interventions for different disorders are so similar, they may be applicable regardless of diagnoses. They found that the interventions that were effective mainly focused on changes at work, and they concluded that these interventions could be considered as a generic approach to enhance work participation for people with different chronic diseases [132]. However, about half the reviews were of low quality and many of the reviews did not include controlled studies. Hence, there is a need for more high quality controlled studies.

2.5 Norwegian social security schemes

The Norwegian Labor and Welfare Service administer medical benefits in Norway. All legal residents in Norway are included in the Norwegian public insurance system. Medically certified sick leave is compensated from day one and up to 12 months with 100% coverage, but not exceeding six times the national insurance base (about 550 000 NOK per year). The employer

covers the first 16 days, while the rest is covered by the Norwegian Labor and Welfare Administration. The medical certificate can, and is encouraged if possible, to be graded. It can be graded from 20% to 100%, independent of employment fraction. Within 4 weeks of sick leave, the sick listed worker and the employer must create a follow-up plan with aim of RTW. At 8 weeks an expanded medical certificate is needed if the sick listed individual has not started work-related activities, to document medical problems that are preventing work activities [133].

After 12 months of sick leave it is possible to apply for the more long-term medical benefits, work assessment allowance and disability pension, which both covers approximately 66% of the income. To be eligible for work assessment allowance and disability pension the person`s workability has to be impaired at least 50%. Work assessment allowance can be granted for up to four years (in special cases somewhat longer). Individuals receiving work assessment allowance are supposed to participate in modified work, but if this is not possible for medical reasons, the individual and the case manager develop a plan for later work resumption.

3 Aims of the thesis

The main aim of this thesis was to evaluate a 4+4 days multicomponent inpatient occupational rehabilitation program compared to a less comprehensive outpatient program. Despite that inpatient rehabilitation has been offered for over thirty years in Norway, the effect has not been evaluated with a rigorous study design. The two first hypotheses tested in this thesis regard the effect of the inpatient program. As the inpatient program was more comprehensive, included a RTW plan, physical exercise and a workplace visit if relevant, it was hypothesized that it would improve work participation and health outcomes more than the outpatient program. The third hypothesis regards the usefulness of a questionnaire developed to evaluate where sick listed individuals are in their process of RTW and what intervention they might need.

The following research questions were formulated:

1) Is the multicomponent inpatient program lasting 4+4 days more effective in reducing sickness absence than the comparative outpatient program consisting mainly of ACT? (paper 1)
2) Is the multicomponent inpatient program more effective than the less comprehensive outpatient program in improving pain, depression, anxiety and subjective health complaints, function and health-related quality of life? (paper 2)
3) What is the association between the Readiness for RTW scale and future work participation? (paper 3)

4 Method

4.1 Project context

The background for this project was the evaluation of a new occupational rehabilitation program, developed in a new rehabilitation center, Hysnes Helsefort (Hysnes Rehabilitation Center), which was established as a part of St. Olavs University Hospital in 2010. The center is located rurally outside Trondheim, about 90 minutes by car or 50 minutes by boat. The inpatient program evaluated in this thesis was provided at the rehabilitation center, while the comparative outpatient program was provided at the Department of Physical Medicine and Rehabilitation at St. Olavs University Hospital in Trondheim city.

4.2 Study design

The studies described in this thesis was part of a larger trial comparing a short (4+4 days) and a long (3.5 weeks) inpatient program to an outpatient program, as well as a treatment as usual control group only followed in sick leave registers (figure 2). The larger trial was comprised of two randomized trials; 1) where the short inpatient program was compared to the outpatient program (hereafter referred to as the short trial) and 2) where the long inpatient program was compared to the outpatient program (hereafter referred to as the long trial). The protocol for the whole trial has been published [134].

Paper 1 and 2 were based on a randomized clinical trial with parallel groups, comparing the short (4+4 days) inpatient multicomponent program with the single-component outpatient program (hereafter referred to as the inpatient- and outpatient program, respectively).

Paper 3 was a prospective cohort study with 9 months follow-up for individuals participating in one of two inpatient programs or the outpatient program.

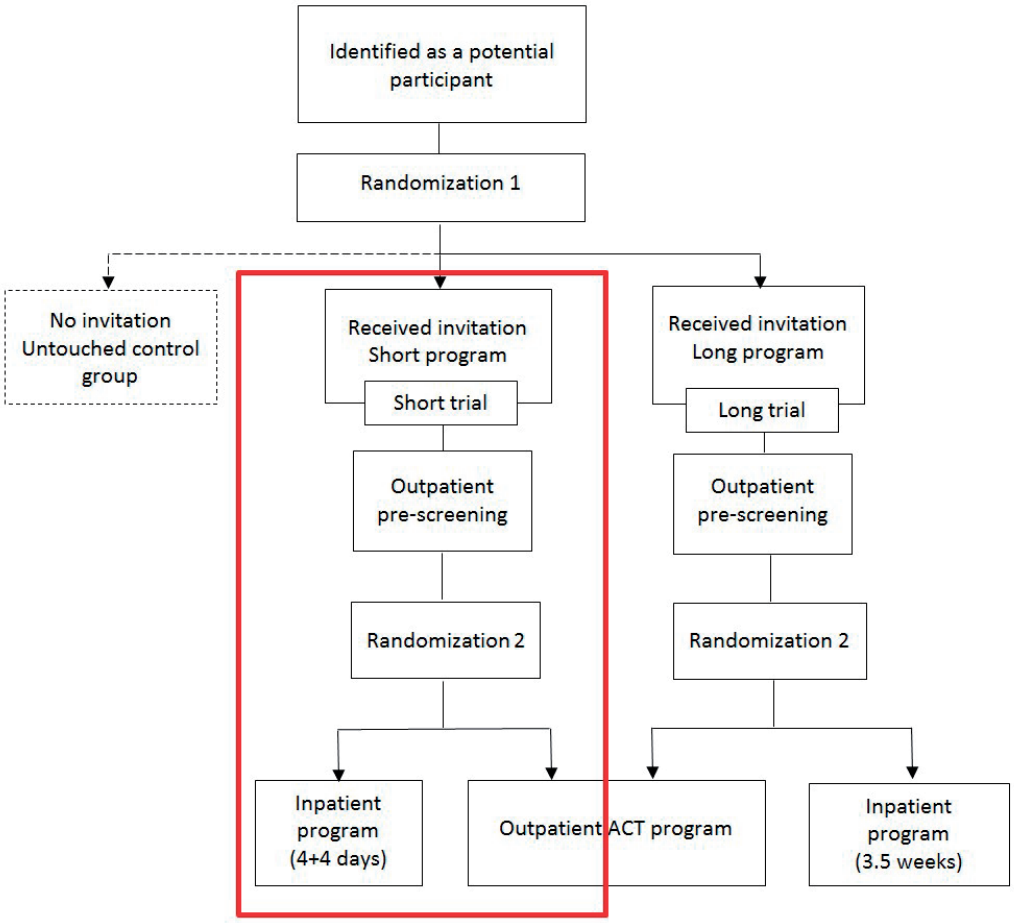

Figure 2 Design of the whole study. The red box indicates the short trial, which is assessed in this thesis.

4.3 Participants

4.3.1 Paper 1 and 2

Eligible participants were individuals who were 18 to 60 years of age and sick listed 2 to 12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the ICPC-2 (International Classification of Primary Care, Second edition). The current sick leave status had to be at least 50% off work. Exclusion criteria assessed by a questionnaire and an outpatient screening performed by a physician, physiotherapist and psychologist, were: 1) alcohol or drug abuse; 2) serious somatic (e.g. cancer, unstable heart disease) or psychological disorders (e.g. high suicidal risk, psychosis, ongoing manic episode); 3) specific disorders requiring specialized treatment; 4) pregnancy; 5) currently participating in another treatment or rehabilitation program; 6) insufficient oral or written Norwegian language skills to participate in group sessions and fill out questionnaires; 7) scheduled for surgery within the next 6 months; and 8) serious problems with functioning in a group setting.

In total, 3 318 persons identified in the National Social Security System Registry were randomized to receive an invitation to the short trial and 275 accepted. After screening 107 persons were excluded, withdrew or did not meet for their appointment. The remaining 168 persons were randomized to the inpatient program (n=92) or the outpatient program (n=76) (figure 3). More details about flow through the study and reasons for exclusion are described in the articles.

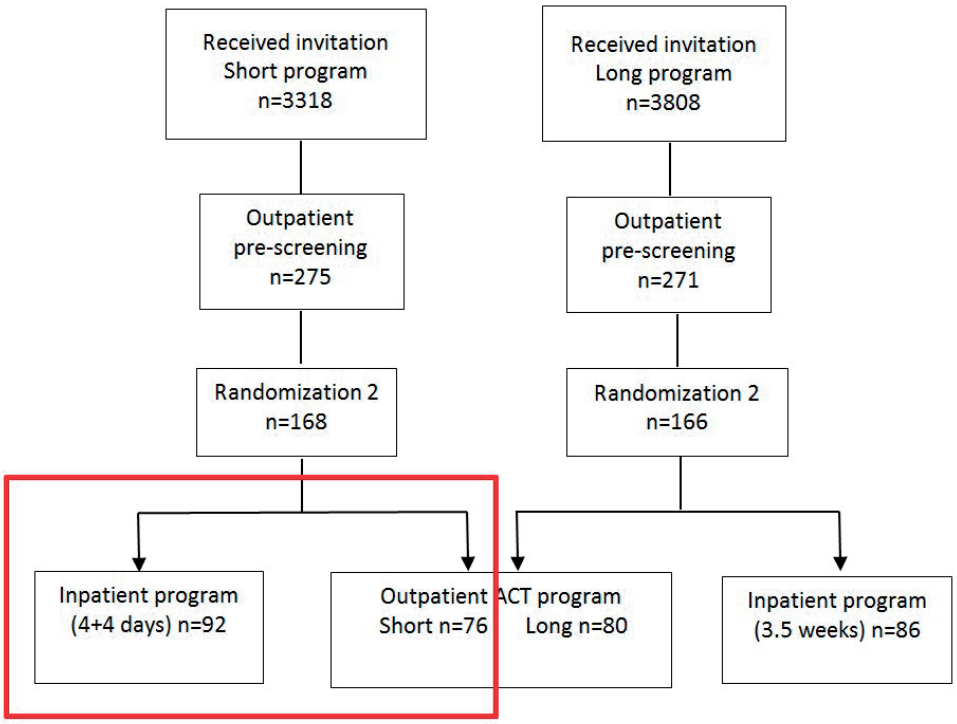

Figure 3 The red box indicates participants included in paper 1 and 2.

4.3.2 Paper 3

Eligible participants were individuals who had taken part in one of the two randomized trials and had filled out the Readiness for RTW scale at the end of the rehabilitation programs. Inclusion and exclusion criteria for participants to enter the long trial were the same as described above for the short trial in paper 1 and 2.

In total, 3 808 potential participants received an invitation for the long trial. Of these, 271 accepted the invitation, 105 were excluded and 166 were randomized to the long inpatient program (n=86) or the outpatient program (n=80). In total 334 participants took part in one of the

three programs, of these, 217 participants answered the Readiness for RTW scale questionnaire at the end of the rehabilitation program and were included in this study (figure 4).

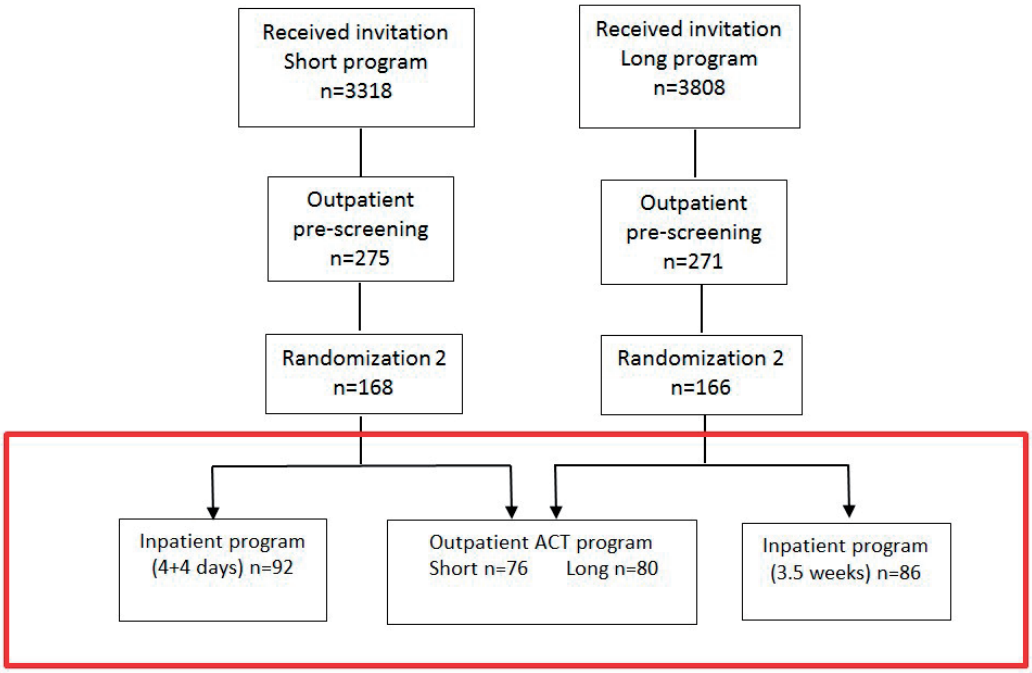

Figure 4 The red box indicates participants included in paper 3.

4.4 The interventions

All three programs included in the project were designed by clinicians at St Olavs University Hospital, with input from the research group.

4.4.1 Acceptance and Commitment Therapy

ACT, a new form of CBT, was the core component in both the inpatient programs and the outpatient program. In contrast to traditional CBT where the focus is on changing dysfunctional

thought patterns [112], ACT focuses on changing the relation to the thoughts and not their content [135, 136]. In ACT there is an emphasis on accepting both negative and positive experiences, while focusing on a person`s values to guide them towards their goals [135]. Through mindfulness techniques, values and committed action the aim is to increase psychological flexibility [135, 137]. ACT is taught through experiential exercises, mindfulness methods and metaphores [137]. ACT was chosen as the cognitive approach in the interventions, because of its transdiagnostic approach in dealing with the ubiquity of human suffering [136]. In specific diagnostic groups there has been an increasing number of studies on the effect of ACT [138]. There are some inconsistencies in the literature [138, 139], but studies suggest that ACT may have beneficial effects on chronic pain [140], anxiety [141, 142] and depression [141, 143].

4.4.2 The inpatient programs

The programs were designed to cover mental training, physical training and work-related problem solving. The mental training aimed to increase psychological flexibility, motivation and self-efficacy regarding RTW. The intervention manuals were based on ACT. The mental training consisted of individual- and group sessions, as well as mindfulness training and psychoeducation. Commitment, value-based actions and being mindful were intended to increase motivation and facilitate RTW [134]. In the short program there was psychoeducation on stress, in the long program there was in addition psychoeducation on pain and symptom interpretation, nutrition and sleep. The physical training aimed to target fear of movement and tension-related pain, increase physical strength and endurance capacity and promote physical activity. There were both individual and group sessions and the participants got an individualized exercise program. Work-related problem solving aimed to identify challenges and possibilities and increase readiness for RTW in both group and individual sessions, and a RTW plan was made for all participants.

The short program lasted four full workdays in week 1 and week 4 (eight days in total; 6-7 hours each day), separated by two weeks at home (week 2 and 3) (table 1). The two weeks at home included at least two contacts with the team coordinator (in person or by telephone) and a meeting with the employer if regarded relevant and the participant gave permission.

The long program lasted 3.5 weeks (17 days). It did not include the meeting with the employer that the short program could, but it did include a "network day" where the participant could bring whoever they wanted to the center for insight in the rehabilitation process and to enable support after the program ended. Most people brought family or friends, but it was also possible to bring their physician or employer. Midway and at the end of both programs, a summary letter was sent to the participant`s general practitioner in all cases, and to the social security office and the employer if relevant and consented by the participant.

The coordinators who mentored the participants were supervised by a certified ACT-instructor before and during (monthly) the intervention. The program took place at Hysnes rehabilitation center, established as part of St. Olavs Hospital.

4.4.3 The outpatient program

The program consisted primarily of group-based ACT. The sessions were held at the Department of Physical Medicine and Rehabilitation at St. Olavs Hospital once a week for six weeks, each session lasting 2.5 hours. The sessions were led by either one of two physicians (specialists in Physical Medicine and Rehabilitation) or a psychologist; all supervised by the same ACT instructor as the coordinators in the inpatient programs. The participants were given assignments to practice at home between sessions, including a daily 15 minutes audio-guided mindfulness practice. In addition, the participants were offered two individual sessions with a social worker experienced in occupational rehabilitation and trained in ACT to clarify personal values and work-related issues. The program also included a motivational group discussion with a physiotherapist on the benefits of physical training. An individual session with both the social worker and group leader present ended the program. In this session a summary letter was written to the participant's general practitioner with information about the intervention, the participants` experiences and future plans. Participants who were randomized to the outpatient program were included in the next available group, i.e. participants from the short and long trial were mixed in the same groups.

Table 1 Overview over the three rehabilitation programs

	Long multicomponent program	Short multicomponent program	ACT comparative arm
Setting	Inpatient rehabilitation center	Inpatient rehabilitation center	Outpatient Hospital clinic
Duration	3.5 weeks	4 + 4 days, separated by 2 weeks living at home	6 weeks
Contents and quantities	-group discussions (×8, total 16 h; ACT based)	-group discussions (×6, total 12 h; ACT based)	-ACT group discussions (×6, total 15 h)
	-psychoeducational sessions (×4, total 6.5 h)	-psychoeducational session on stress (×1, 2 h)	-group discussion on physical activity (×1, 1 h)
	-individual meetings with coordinator (×5, total 5 h)	-individual meetings with coordinator (×2, total 2 h)	-individual sessions with social worker (×2, total 2 h)
	-individual meeting with physician (×1, 0.5 h)	-individual meeting with physician (×1, 0.5 h)	-individual session with social worker and ACT group moderator (×1, 0.5 h)
	-mindfulness sessions (×7, total 3.5 h)	-mindfulness sessions (×4, total 2 h)	-home practice, including daily mindfulness
	-individual/group based supervised training sessions (×10, total 12 h)	-individual/group based supervised training sessions (×8, total 10.5 h)	
	-"walking to work" (×6, total 3 h)	-Create RTW-plan	
	-Create RTW-plan	In the 2 weeks between the stays at the rehab:	
	-outdoor activities day (×1, 5 h)	-Meeting with employer, if relevant and permitted	
	-"network day" with 2 group sessions (total 4 h)	-At least 2 contacts with team coordinator (telephone or personal)	

All references to time are average estimates, which may include short breaks in and between sessions. ACT: Acceptance and Commitment Therapy. RTW: Return-to-work.

From Fimland et al. 2014 [134] with permission.

4.5 Data sources

4.5.1 Sick leave registry data

Work outcomes were measured using data from the National Social Security System Registry, where all individuals receiving any form of benefits in Norway are registered by their social security number. The data consisted of registrations of medical benefits from four different sources; sick-leave payments, sick leave certificates, work assessment allowance and disability pension. As exact dates were not available for sick leave payments and the long-term benefits, monthly intervals (rather than exact dates) were used in order to be able to combine information from all relevant medical benefits.

For work assessment allowance it was observed that there could be a few months without payments before a larger supplementary pay was registered, especially in the transition from sick leave pay to work assessment allowance. When there were months without benefits before large

payments, excess pay (exceeding 100%) were transferred to the month before. Up to two months without pay during this transition period was considered as still receiving benefits as it would be highly unlikely that the participant had returned to work during this time period.

Days receiving sick-leave payment and work assessment allowance were adjusted for employment fraction, which was based on information from questionnaires answered by the participants at baseline and the employer registry. For participants receiving a graded disability pension at inclusion, days on benefits were reduced according to the percentage of disability, as their status at inclusion was defined as their baseline status. Any increase in disability pension during follow-up was counted as sick leave.

4.5.2 Questionnaires

Self-reported data on health and functioning were collected via internet-based questionnaires, which were filled out at six time-points: at screening before inclusion, at the start of the program, at the end of the program, and three, six and 12 months after the inpatient program ended (table 2). The participants received text messages on their mobile telephone when it was time to answer questionnaires and as reminders if they did not respond. If they had not responded after two text-message reminders a project co-worker made a final phone call to remind the participant.

Table 2 Time-points questionnaires were filled out

	Time-points					
	Outpatient screening	Start of program	End of program	3 months	6 months	12 months
HADS[a]	x	x	x	x		x
Pain	x	x	x	x		x
SHC[b]		x		x		x
15D		x		x	x	x
Coop/Wonca		x	x	x		x
Subjective health evaluation		x	x	x	x	x
Readiness for RTW		x	x			
Expectations about length of sick leave			x			

[a] Hospital Anxiety and Depression Scale
[b] The Subjective Health Complaints Inventory

4.5.2.1 Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS) was used to measure anxiety and depression symptoms [144]. It consists of 14 items, where seven items measure anxiety and seven measure depression symptoms. It is scored on a 4-point Likert scale according to intensity of symptoms the last week. The maximum score is 21 on each subscale. HADS is widely used and has been found to perform well in assessing severity and detecting anxiety and depression, with a cut-off of 8 giving an optimal balance between sensitivity and specificity [145].

4.5.2.2 Subjective Health complaints

Common somatic and mental health problems were recorded using The Subjective Health Complaints Inventory (SHC) [146], which registers complaints in five subscales: musculoskeletal

pain, pseudoneurology, gastrointestinal problems, allergy and flu. It consists of 29 questions regarding complaints experienced the last month - each scored on a 4-point Likert scale from 0 “not at all” to 3 “serious”. A severity score can be reported for each subscale or as a total score (score range 0-87) [146].

4.5.2.3 Pain

Two questions from the Brief Pain Inventory (BPI) were used to assess pain [147]. The participants were asked to grade the strongest and average pain during the last week on a 0 (no pain) to 10 (worst imaginable pain) numeric rating scale.

4.5.2.4 Health-related quality of life

15D was used to measure health-related quality of life [148]. It contains 15 dimensions covering physical, mental and social well-being and generates a total score ranging from 1 (no problem on any dimension) to 0 (being dead). It has been suggested that the generic minimal important change is ±0.015 and a large change is ±0.035 [149]. It should be noted that in the Alanne et al. study the cut-off for “slightly better” for persons with pain and depression were 0.036 and 0.051, respectively.

4.5.2.5 Function

Functioning were measured using COOP/WONKA [150]. It offers a self-reporting assessment of function in six domains. Four of the domains were used: physical fitness, feelings, daily activity and social activity. Each domain is scored on a 5-point Likert scale from 1 (no problems/not affected) to 5 (huge problems/considerably affected). Answers were analysed as a continuous score (range 1-5).

4.5.2.6 Subjective health evaluation

Participants were asked to evaluate their general health on a 4-point Likert scale from 1 “poor” to 4 “very good”. The variable was analysed both dichotomized (poor/not very good vs. good/very good) and as a continuous score (range 1-4).

4.5.2.7 The Readiness for RTW scale

The Readiness for RTW scale was developed by Franche et al., [151] based on the Readiness for RTW model (section 2.2.4). They psychometrically validated the scale in a Canadian cohort and identified four underlying factors for individuals not working and two for individuals working, corresponding to the stages in the Readiness for RTW model (table 3). The questionnaire (table 1 in Appendix) consists of two parts; part A which is answered by individuals who are 100% sick listed and part B which is answered by individuals who are working (includes graded sick leave). Part A consists of 22 items and part B of 12 items (not all included in the scoring, see table 1). Each item is answered on a 5-point scale from “strongly disagree” to “strongly agree”. The wording of two questions was changed from “pain” and “injury” in the original scale to “health complaints” in the Norwegian version to include participants with other complaints.

Table 3 Description of the different stages and items included in the Readiness for RTW scale

Stages	Description	Items included
Part A Individuals not working	Individuals who are 100% sick listed	
Precontemplation	The person is not thinking about starting behavior with regards to RTW	A1, A4, A22
Contemplation	The person has started to think about returning to work, but is still ambivalent and has no concrete plans	A15, A20, A21
Preparation for action-self-evaluative	The person seeks information about RTW and make concrete plans for RTW	A9, A12R, A13, A18
Preparation for action-behavioral	The RTW plans are set into action	A6, A10, A11
Part B Individuals working	Individuals who are partly or fully working (including graded sick leave)	
Uncertain maintenance	The person has returned to work, but is struggling to stay at work	B8, B9, B10, B11R, B12
Proactive maintenance	The person has found good strategies for staying at work	B2, B5, B6, B7

R= reversely scored

Franche et al. [151] described two approaches for scoring the questionnaire; 1) the multidimensional approach where a score is calculated for each dimension which was recommended for research, and 2) stage allocation where the individual is allocated to the stage corresponding to the dimension with the highest mean score and was recommended for clinical use. The dimension scores are calculated as the mean of the items it comprises (range 1-5). When

using the multidimensional approach the term dimension is used for the different stages, while the term stage is used for the stage allocation approach.

In a recent Norwegian validation study Braathen et al. [152] identified fewer factors, two for individuals not working; RTW inability (A1, A4, A10R, A22) and RTW uncertainty (A18, A20, A21), which corresponded to Precontemplation and Contemplation in the Canadian study, and Uncertain maintenance (B2R, B6R, B8, B10) and Proactive maintenance (B5, B7, B12R) for those working. The dimensions found in the Norwegian validation study are hereafter referred to as the Braathen dimensions, and the dimensions described by Franche et al. as the original dimensions.

4.5.2.8 Self-reported expectations about length of sick leave

Expectations about length of sick leave were recorded using the question "For how long do you believe you will be sick listed from today?" with 5 response options "not at all", "less than 1 month", "1-2 months", "2-4 months", "4-10 months" and "more than 10 months". Categories "not at all", "less than 1 month" and "1-2 months" were combined to one category "less than 2 months" in the analyses.

4.6 Main outcome variables

4.6.1 Paper 1

The primary outcome measure was cumulated number of sickness absence days, calculated at 6 and 12 months after inclusion. Information from the different medical benefits was combined to calculate days on medical benefits (according to a 5-day work week) for every month during follow-up. Time on graded sick leave was transformed to whole workdays. Days receiving sick-leave payment and work assessment allowance were adjusted for employment fraction, including a graded disability pension at inclusion. Any increase in disability pension during follow-up was counted as sick leave.

The secondary outcome measure was time until full sustainable RTW defined as one month without relapse, i.e. one monthly interval not receiving any medical benefits (except any graded disability the participant had when entering the study).

4.6.2 Paper 2

The outcome variables in this paper were the following health outcomes; anxiety, depression, pain, subjective health complaints, self-evaluated health, function and health-related quality of life. The variables were measured from three to six times during 12 months of follow-up.

4.6.3 Paper 3

Two different work outcome measures were constructed; 1) *Sustainable RTW*, which was defined as one month without receiving medical benefits during follow-up and 2) *Work participation days*, which was measured as number of days not receiving medical benefits during follow-up, adjusted for partial sick leave, employment fraction and calculated as a 5-day work week. Follow-up time was 9 months after the end of the rehabilitation program. Follow-up time was reduced from paper 1 and 2 as follow-up started from the end of the programs (and not at inclusion) and 9 months provided equal follow-up time for all included participants.

4.7 Randomization and blinding

Participants were randomized twice. Firstly, sick listed individuals identified in the National Social Security System were randomized to receive an invitation to either the long or the short trial. Invited participants completed a short questionnaire assessing initial eligibility. Those eligible were invited for an outpatient screening assessment. If the screening was passed (figure 1), the second randomization allocated the subjects to either the inpatient or the outpatient program. The first randomization was performed by a project co-worker. In the second allocation a flexibly weighted randomization procedure was provided by the Unit of Applied Clinical

Research (third-party) at the Norwegian University of Science and Technology (NTNU), to ensure that the rehabilitation center had enough participants to run monthly groups in periods of low recruitment. It was not possible to blind neither the participants nor the caregivers for treatment. The researchers were not blinded.

4.8 Ethical considerations

The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241), and the trial is registered in clinicaltrials.gov (No.: NCT01926574). The results are presented according to the CONSORT statement [153]. All participants that were enrolled in the study took part in a program offered by St. Olavs University Hospital.

4.9 Sample size

Three approaches were performed to determine sample size [134]:

1) Comparison of RTW with Kaplan Meier survival analysis with log rank test with a hazard ratio of 0.6 (alpha 0.05, beta 0.20) would require 63 in each group.
2) Comparison of number of days with sick leave at 6 months of follow-up (p=0.05; 90% power): An average of 60 days (SD 40) and 90 days (SD 60) of sick leave in the intervention and comparative group, respectively would require 61 persons for each group.
3) Comparing ratios of participants at work after 1 year of follow-up with the same statistical assumptions as point 2; and a difference of 60% versus 40% RTW, would require 63 people in each group.

With an estimated 20% loss to follow-up it was decided to include 80 persons in each arm.

4.10 Statistical analyses

For all three papers p-values (two-tailed) <0.05 were considered to be statistically significant. Precision was assessed using 95% confidence intervals. Analyses for paper 1 and 2 were performed using STATA 13.1 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP) and paper 3 STATA 14.1 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

4.10.1 Paper 1

Number of sickness absence days at 6 and 12 months follow-up after inclusion for the two groups were compared using the Mann-Whitney U (Wilcoxon rank sum) test, as sick leave days were not normally distributed. Time to sustainable RTW were analysed using survival analysis where time was calculated as number of months, and participants were censored at end of follow-up if they had not achieved sustainable RTW. Kaplan Meier curves were estimated and compared with the log rank test and hazard ratios for RTW were estimated using the Cox proportional hazard model with the Efron method for ties [154]. The main analyses were performed both without adjustment, and with adjustment for gender, age, level of education, main diagnosis for sick leave and length of sick leave at inclusion. The proportionality hazard assumption was checked using the Schoenfeld Residual test [155]. As length of sick leave did not fulfill the proportional hazard assumption it was included with an interaction term with time. All analyses were performed after the "intention to treat" principle, but in addition "per protocol" analyses were done by excluding participants that withdrew after randomization (before or during the programs) and/or attended less than 60% of the sessions of the outpatient program.

During analyses it was observed that several participants alternated between being on and off benefits. As the main analysis only recorded the first time the participant went one month without receiving medical benefits, it was decided to do a post-hoc analysis using information about whether the participant received benefits each month during follow-up. Therefore, a repeated events analysis was performed, allowing individuals to alternate between being on and off benefits every month of follow-up using general estimating equations (GEE). There were also

months without payment in between longer periods of payments. As this could be due to participants for some reason not receiving benefits during the holiday, an additional sensitivity analysis were performed on time until sustainable RTW where RTW was defined as two months without benefits, as the Norwegian holiday lasts 5 weeks.

4.10.2 Paper 2

Health outcomes over time for the inpatient and outpatient program were compared using linear (and logistic) mixed-effects models. To assess whether the effects of the two programs differed over time an interaction term was included between program and the six time-points in the analyses (in addition to the programs and time points). To take the repeated measures into account a random intercept (to allow the participants to start out at different levels) was included and a random slope for time (to allow an individual development over time). Estimates from the analyses (fixed effects) were used to predict health outcomes at the different time points for the two programs.

The main analyses were not adjusted for baseline characteristics, but this was done as a sensitivity analysis (gender, age, sick leave diagnosis, work status, education level and type of benefit) to assess the robustness of the results. The main analyses were performed after the "intention to treat" principle, but supplementary "per protocol" analyses were also performed as described for paper 1.

Due to quite a large loss to follow-up, baseline characteristics and sickness absence during follow-up were compared for participants who responded and participants who did not respond to the 12 months follow-up questionnaire. They were compared using χ^2 test, t-test or Mann Whitney-U test. Median numbers of sickness absence days were compared by the Mann-Whitney U test.

4.10.3 Paper 3

The main analyses were based on the original dimensions described by Franche et al., and separate analyses were performed according to work status (working/not working). Logistic regression was used to assess associations between scores on the Readiness for RTW scale dimensions (four dimensions for those not working and two for those working) and sustainable RTW. Linear regression was used for the association with work participation days. The analyses were performed with adjustment for age, gender and education. Education level was dichotomized as high (college/university) or low. The results from the regression analyses were used to estimate the predicted probability of RTW and number of work participation days using average adjusted predictions, that is, predictions were made with covariates constant at their means.

As the linearity assumption was not fully satisfied the analyses were repeated with categorized dimensions. For the results to be reproducible in other populations the dimensions were categorized from 1.0-1.9, 2.0-2.9, 3.0-3.9 and 4.0-5.0. The analyses were also performed using the stage allocation approach described in section 4.5.2.7. Differences between pre- and post-scores were compared using the Wilcoxon signed rank test, as they were not normally distributed. Associations between the single expectation question and work outcomes were assessed by logistic and linear regression, as in the main analyses. Adjusted R^2 and pseudo R^2 were used to compare the Readiness for RTW dimensions to the single expectation question. In addition, several sensitivity analyses were performed, which are described in the paper. Cronbach`s alpha coefficients were calculated for both the original dimension and the dimensions described by Braathen et al. [152]

5 Results

In this section the main results from the three papers are presented. More detailed results are presented in the respective papers. Analyses in paper 1 and 2 are based on the 168 participants who were included in the short trial and randomized to the short inpatient program and the outpatient program. Paper 1 is based on data from the National Social Security System Registry during 12 months of follow-up from inclusion, while paper 2 is based on questionnaires filled out at six time points during the same time period. Paper 3 is based on the 217 participants who were included in the short or long trial and participated in one of the three programs and answered the Readiness for RTW scale questionnaire at the end of the rehabilitation program. Analyses in paper 3 are based on sick leave registry data with 9 months follow-up after the end of the rehabilitation programs and on questionnaires answered at the start and the end of the programs. Table 4 shows baseline characteristics for the participants included in the three papers.

Table 4 Characteristics of the participants in the three papers

	Paper 1 and 2[a]		Paper 3[b]	
	Inpatient program (n=92)	**Outpatient program (n=76)**	**Not working[c] (n=96)**	**Working[d] (n=121)**
Age mean (SD)	45.0 (8.7)	45.1 (9.6)	47 (9.6)	47 (8.5)
Women n (%)	71 (77%)	62 (82%)	76 (79%)	102 (84%)
Higher education n (%)	45 (49%)	31 (41%)	37 (39%)	58 (48%)
Work status n (%)				
No work	15 (16%)	7 (9%)	20 (21%)	1 (1%)
Full time	57 (62%)	52 (68%)	51 (53%)	86 (71%)
Part time	15 (16%)	16 (21%)	17 (18%)	26 (21%)
Graded disability pension[c]	5 (5%)	1 (1%)	8 (8%)	8 (7 %)
Sick leave status at inclusion n (%)				
Full sick-leave	41 (45%)	35 (46%)	62 (65%)	23 (19%)
Partial sick-leave	45 (49%)	36 (47%)	24 (25%)	93 (77%)
Work assessment allowance	6 (7%)	5 (7%)	10 (10%)	5 (4%)
HADS mean (SD)				
Anxiety (0-21)	7.8 (4.4)	7.4 (4.3)	7.7 (4.4)	7.4 (3.9)
Depression (0-21)	6.7 (4.3)	6.0 (4.1)	6.1 (4.1)	6.0 (4.1)
Pain level mean (SD)				
Average pain (0-10)	4.7 (2.3)	4.6 (2.0)	4.1 (2.1)	4.1 (2.1)
Main diagnoses for sick-leave (ICPC-2) n (%)				
A - general and unspecified	9 (10%)	7 (9%)	8 (8%)	10 (8%)
L - musculoskeletal	48 (52%)	40 (53%)	48 (50%)	70 (58%)
P - psychological	35 (38%)	29 (38%)	40 (42%)	41 (34%)
Length of sick leave at Inclusion				
median days (IQR)[e]	224 (189-262)	229 (187-275)	232 (176-285)	215 (180-266)

[a] Characteristics recorded at the second randomization, except diagnosis which was recorded when the person was identified in the sick leave register as a potential participant

[b] Characteristics recorded at the end of the programs, except diagnosis which was recorded when the person was identified in the sick leave register as a potential participant, and work status, sick leave status and length of sick leave recorded at the second randomization

[c] 100% sick leave

[d] Graded sick leave/working

[e] Interquartile range

5.1 Paper 1

The objective of this study was to assess the effects of the short inpatient multicomponent rehabilitation program compared to the less comprehensive outpatient program on sickness absence and sustainable RTW.

There was no difference between the inpatient and outpatient program in the median number of sickness absence days at 6 months (58 days (interquartile range (IQR) 37-92) vs 51 days (IQR 32-85)) and 12 months (114 days (IQR 46-172) vs 96 days (IQR 35- 175)) after inclusion.

In total, 45 participants (49%) achieved sustainable RTW in the inpatient program and 43 participants (57%) in the outpatient program. The median time to sustainable RTW was 7 months for the outpatient program, while less than 50% of participants in the inpatient program achieved sustainable RTW. The difference between the programs was not statistically significant (log rank test, p=0.167). The unadjusted hazard ratio for sustainable RTW was 0.74 (95% CI 0.48-1.32, p=0.165) in favor of the outpatient program. When the analyses were repeated with adjustment for age, gender, education, main diagnosis for sick leave and length of sick leave at inclusion the results were similar (hazard ratio 0.71, 95% CI 0.46-1.09, p=0.119). Additional sensitivity analyses did not change the conclusions.

5.2 Paper 2

The objective of this study was to evaluate the effects of the short inpatient program compared to the outpatient program on somatic and mental health.

Only one of the health measures, strongest pain, showed a statistically significant difference between the programs from start to 12 months (1.1 points, 95% CI 0.1- 2.0, p=0.03). The result was in favor of the outpatient program. There was an increase in health-related quality of life for both programs, while the other health measures showed no or marginal changes. Per protocol analyses, sensitivity analyses and subgroup analyses gave similar results.

The number of people who answered the questionnaires decreased steadily through the study from practically 100% at the screening to less than 50% at 12 months. Comparison of baseline characteristics and sick leave for participants who responded and who did not respond at 12 months showed that the non–responders were somewhat younger (mean age 43.6 (SD 9.3) vs 46.7 (SD 8.6), p=0.023), but otherwise fairly similar.

5.3 Paper 3

The objective of this study was to assess the association between the Readiness for RTW scale and work outcomes.

Of the 217 participants in the cohort, 96 filled out the “not working” part of the questionnaire and 121 the “working” part. When using the multidimensional approach where the participant gets a score on each dimension, two of the four dimensions for those not working were associated with a higher probability of sustainable RTW and more work participation days (Prepared for action-self- evaluative and Prepared for action- behavioral). For persons working, high scores on the Uncertain maintenance dimension was associated with a lower probability of sustainable RTW and fewer work participation days.

Using the stage allocation approach where the participant is allocated to the dimension in which they have the highest mean score was problematic due to ties between dimensions. It was even more problematic that many of the ties were not on “adjacent” dimensions. When the Readiness for RTW scale was compared to a single expectation question concerning length of sick leave there was a slightly larger explained variance in models including the single expectation question compared to models including the different Readiness for RTW dimensions.

6 Discussion

The main result in this thesis was that there was no difference between a 4+4 days inpatient occupational rehabilitation program and a less comprehensive outpatient program on sick leave and health outcomes. Both groups improved health-related quality of life, while the other health measures showed no or marginal changes. Several weaknesses with the Readiness for RTW scale were discovered, especially for the stage allocation approach.

6.1 Interpretation of findings

6.1.1 Work outcomes

This is one of the first randomized trials evaluating effects of occupational rehabilitation including both musculoskeletal and mental health complaints. In one of the other few studies that have included participants with different diagnoses Poulsen et al. [126] evaluated a new a sickness management program consisting of a coordinated, tailored and multidisciplinary approach for sick listed workers regardless of diagnoses (both somatic and mental health problems) in three municipalities. They found an effect for the intervention on RTW compared to ordinary sickness benefit management in one of the municipalities, but there were large differences between the municipalities. As the intervention was more of a case management intervention it is not directly comparable to the intervention in the present study. In another study, Pedersen et al. [127] included participants at risk of having a mental health disorder, independent of the reason for their sickness absence, when they evaluated the effect of a psychoeducation program. They used a questionnaire to identify at risk individuals. They did not have information about diagnoses, but when asked about reasons for their sick leave 20% of the participants reported musculoskeletal complaints (they could report more than one reason). They found no effect of psychoeducation on RTW compared to standard case management; in fact they found a delayed RTW at 3 months.

The result of no difference between the programs on RTW and sickness absence days during follow-up in the present trial is in line with several studies evaluating diagnosis specific

interventions [102-104]. Still, the RTW rates in the present study (49% and 57%) were low compared to some of these studies. Jensen et al. [102] found a RTW rate of around 70% during 12 months of follow-up, when they compared a multidisciplinary intervention to a brief intervention for participants with low back pain. Myhre, Marchand et al. [104] found a RTW rate of 65-75% when they compared a work-focused intervention to a control intervention consisting of a multidisciplinary intervention or a brief intervention for individuals with low back pain. There are, however, other studies that have reported RTW rates in the same range as the present study [103, 105]. A possible explanation for the low RTW rates in the present study is the long duration of sick leave at inclusion (224 and 229 days), which is considerably longer than in most of the other studies. On the other hand, when Lambeek et al. [108] compared an integrated care program to usual care for sick listed people with chronic low back pain, length of sick leave at inclusion was comparable to the present study, but RTW rates for the intervention was much higher and they found a considerable effect of the integrated care program compared to usual care. However, it should be noted that they only counted recurrences of sick leave if caused by low back pain.

The intervention in the Lambeek et al. study [108] consisted of, among other factors, a workplace intervention with stakeholder involvement. Findings from the Lambeek et al. study, as well as other studies suggesting an effect of involving the workplace [106, 107] was influential for the design of the present study. When the short inpatient program was designed, the workplace visit was an important element. However, it turned out that the workplace visit was only performed for 13% of the participants. The workplace visits were not performed in a structured way, but rather based on clinical judgement. Based on these findings a new randomized trial was designed to evaluate the effect of including a structured workplace intervention in the rehabilitation program. The results of this new trial are not available yet.

Based on the body of evidence suggesting the importance of workplace involvement in the RTW process and the results of the short trial it is interesting that preliminary unpublished results suggest an effect of the long inpatient program compared to the outpatient program, as the long inpatient program did not involve a workplace visit. Differences between the long and the short inpatient program, apart from being more extensive, were more psychoeducation sessions and a "network day" (table 1). Pedersen et al. [127] found no effect psychoeducation on RTW.

However, psychoeducation in their study was offered in open groups with continuous enrolment of participants, and contained more lectures than discussions, which might result in suboptimal group processes. When employees at Hysnes Rehabilitation Center were asked in qualitative interviews about experiences with the short inpatient programs, many said that they felt the program was too short (preliminary qualitative data). They also described that the processes intended in the ACT approach [137] take time, as the participants not simply need to understand ACT intellectually; they also need to experience it, implying a process of maturation. In addition, the employees emphasized that many of the participants needed a period of continuous time at the center to get a break from everyday life and being able to focus on themselves while starting on this process, and that the 4+4 days were too short. It might be this combination of a break from everyday life, the different components of the program and longer time to experience ACT that made the long inpatient program effective with regards to RTW, but not the short program. Comparison of results between the short and the long inpatient program should be done with caution as it was two different randomized trials and hence, two different samples. This is apparent when comparing participants in the outpatient program from the short and long trial. Despite receiving the same intervention, there are clear differences in sick leave days and RTW during follow-up (preliminary data).

The qualitative interviews with employees at the Rehabilitation Center also revealed that most of them were more comfortable with providing the long than the short program, and were more hopeful on behalf of the long program regarding potential outcome for the participants. There is some research on the effect of therapists` beliefs in the effect of treatments; much of this research is done in the field of psychiatry. However, it is reasonable to assume that the findings also apply more generally in patient treatment. There are several studies on psychotherapy suggesting that the effects of the therapist`s beliefs about the efficacy of the treatment they are giving can be quite substantial [156, 157]. The opposite is also suggested, that therapists` lack of belief in the treatment may unintentionally affect treatment outcomes negatively [158]. Participants` beliefs are of course also important, however, on questionnaires used in the clinic and in interviews with participants in the two different programs there was no clear difference in how satisfied the participants were with receiving the short versus the long program.

When the inpatient intervention included in this study was designed it was inspired by the case-management ecological model by Loisel et al. [76]. We considered workplace intervention to be an important component, as studies suggest it is important for effectiveness on RTW and it usually is not included in inpatient occupational rehabilitation programs in Norway. However, the workplace visit was only performed in 13% of the cases. It should also be noted that the geographical setting gave some limitations as to what was possible. The components of the inpatient programs are very similar to traditional multidisciplinary rehabilitation programs by including physical exercise, patient education and using a cognitive behavioral approach. One of the more work specific components in the program was the RTW plan created for all the participants. Focus group interviews with individuals participating in the related long program found that few had made concrete plans for RTW at the end of the program [159]. Disregarding the fact that the long program did have an effect on RTW, it is safe to say that the work emphasis was not extensive. However, to comply with the ACT model, work-focus could not be rigorously included. Comparing the programs to the case-management ecological model it is evident that both the work-place and the compensation system were not much involved in the programs. Based on these observations it might be argued that the programs were based on a more traditional biopsychosocial model, mainly including the sick listed worker and the healthcare system.

6.1.2 Health outcomes

There were no substantial differences in self-reported health outcomes between the two programs. Only one of the health outcomes showed a difference between the programs, strongest pain, however, the difference was not clinically significant and the results should be interpreted with caution due to the large number of statistical tests performed. Further, there was very little change in health outcomes at all during follow-up, except for an increase in health-related quality of life in both groups.

Several previous studies assessing RTW interventions have found little difference in symptoms [102, 160]. In the present study, it was striking that there was almost no change in health outcomes during follow-up. However, ACT emphasizes change in behavior and accepting

symptoms instead of trying to reduce them; meaning the goal of ACT is not to reduce pain or mood symptoms and therefore these type of outcomes may not be the best effect measures, instead measures of physical and social functioning would be better [161, 162]. The only measure of function included in this study was Coop/Wonca. This questionnaire was not originally developed for research, but as a method to screen function quickly in primary care [150]. The categories in the charts are quite coarse, for example on physical activity you only have to manage the described activity for 2 minutes, which in our sample meant that quite a large number of participants reported the highest score, hence this questionnaire did not work well for our sample. However, health-related quality of life was measured and it was one of the few measurements where both groups increased their scores. As there was no usual care group, it is not possible to know how much of the change that was due to the effect of time. But seen in light of the ACT mindset, and with the small changes observed on the other outcomes, it might be that the participants viewed their health differently as they started to accept their symptoms, which could lead to improved health-related quality of life.

The way ACT emphasizes behavior change rather than reduction of symptoms can be seen as compatible with the work disability paradigm. According to the work disability paradigm, work disability is not specific to a condition, but influenced by several factors/systems (like the healthcare system and the workplace) and these need to be included as well as the worker`s characteristics in aiding the individual's RTW-process [76]. This means helping the worker RTW despite residual complaints [76, 108] and the focus should be on increasing function and not reducing symptoms. This is similar to the core of ACT, which in addition underlines that the process has to be attuned to the workers values and goals [162]. There are several studies that support the work disability paradigm by showing effects on RTW despite little change in symptoms [107, 113, 163].

The inpatient program in our study had several similarities with traditional multidisciplinary rehabilitation. Therefore, it is relevant to compare the results with previous studies in that field. Most studies have recruited individuals with low back pain. Brox et al. [164] did a systematic review of randomized controlled trials on the effects of back schools, brief intervention and fear avoidance training for chronic low back pain. For back schools they found conflicting evidence on pain reduction and for brief intervention they found limited evidence on pain reduction

compared to back schools and exercises. For fear avoidance they only found one study, which showed limited evidence for pain reduction compared to usual care. In another systematic review on chronic low back pain Kamper et al. [98] found an effect of multidisciplinary biopsychosocial rehabilitation compared to usual care on pain, although the effect was small, and compared to physical treatment there was no long term effect. Generally, documentation on interventions with effect on pain is sparse for chronic low back pain.

6.1.3 Associations between the Readiness for RTW scale and work outcomes

The Readiness for RTW scale has been suggested to be a promising instrument for both research and clinical practice [33]. Franche et al. [151], who developed the scale, outlined several areas for use like deciding where the sick listed worker is in the RTW process to offer tailored intervention and evaluation of RTW interventions. These are important areas in RTW research and in the clinic. However, for the scale to be useful it has to be associated with work outcomes.

In research, the Readiness for RTW scale is recommended to be used with a multidimensional approach, which means that the participant gets a score on each of the dimensions. In our study associations with work outcomes were stronger for higher scores on the Prepared for action- self-evaluative dimension versus the action-behavioral dimension; which was surprising as the Prepared for action-behavioral dimension is closer to RTW according to the Readiness for RTW model. A possible explanation for this is the content of the questions making up the dimensions. The questions in the Prepared for action- self-evaluative dimension are quite precise as they ask about whether the sick listed worker has set a date for RTW and whether they feel ready to RTW. The questions in the Prepared for action-behavioral dimension (which according to the model is closer to RTW) are not that precise as they ask about whether the sick listed worker is doing things actively to get back to work and whether he/she are getting help from others. There is not much research done on the Readiness for RTW scale. However, in a Norwegian validation study Braathen et al. [152] found different dimensions than in the original study by Franche et al. [151]. In our sample the original dimensions gave higher Cronbach`s alphas than the Braathen dimensions. This was unexpected as the sample in our study should be considerably more similar

to the sample in the study by Braathen et al. than the Canadian study, as both were done in Norway, and participants had similar diagnoses and sick leave duration.

Another problem with the Readiness for RTW scale in our cohort was the stage allocation approach where the participant is allocated to the stage with the highest mean score. This could be very useful in the clinic for deciding where the patient is in their RTW process and thereby help tailor the most appropriate intervention. However, several participants had tied scores between stages, and even stages that were not adjacent. Most of the ties were between the two dimensions called Contemplation and Prepared for action-behavioral. The questions included in the Contemplation stage are quite generic: "I have been wondering if there is something I could do to return to work"; "I wish I had more ideas about how to get back to work", and "I would like to have some advice about how to get back to work", and are questions one would expect most people on long term sick leave are asking themselves, regardless of where they are in their RTW process. The practical issue that arises is how to choose which stage to allocate the person with a tie between dimensions, especially when the stages are not adjacent. But on a more profound level the questions do not seem to capture the different stages of the RTW process, which is crucial if the stage allocation approach is used to decide what intervention a sick listed worker should be offered. Knowledge about these challenges with the Readiness for RTW scale is highly important, as the scale is already in use at rehabilitation centers in Norway.

Randomized controlled trials with RTW and sickness absence as outcomes are time-consuming as they require long follow-up times to gain knowledge about long term effects, including relapses. Hence, the Readiness for RTW scale could be an intermediary measure of interest, as it could provide more rapid evaluations of occupational rehabilitation programs and also about the prognosis for RTW. However, this depends on the scale being responsive to change and that the change is associated with work outcomes. In our cohort only three of the dimensions changed during the interventions (Prepared for action- self-evaluative, Prepared for action-behavioral and Proactive maintenance). The change scores were not associated with work outcomes. This could partly be due to lack of statistical power, but also there seems to be a floor and ceiling problem for some of the dimensions. Another aspect is that rehabilitation takes time; it is a process that starts during the program and then hopefully continues afterwards. Hence, it may be that measuring change just at the end of the intervention was too short of a follow-up. The

questionnaire was filled out at 3 and 6 months as well, however, they were not included in the analyses as there was a substantial loss to follow-up. In addition some people changed which part of the questionnaire they answered (as they went back to work), and you will also no longer just be measuring change happening during the intervention, but also the experiences participants have afterwards.

When the Readiness for RTW dimensions were compared to a single question assessing the participants` expectations about length of sick leave, the models including the Readiness for RTW dimensions were generally not as good at explaining work outcomes as models including a single expectation question. This is not surprising as individuals expectations/predictions about length of sick leave and RTW repeatedly has been associated with RTW [35, 85, 165] and even predict length of sick leave better than officers (without medical competence) and experienced physicians at the Norwegian Labor and Welfare Service [166]. However, the dimensions provide much more information than the single expectation question and therefore the single expectation question cannot readily replace the Readiness for RTW scale, but rather complement it in clinical use. However, with all the challenges encountered with the Readiness for RTW scale in this study it cannot be recommended for clinical use in its current form.

Progression through the stages of the stages of change model is partly based on self-efficacy and a balance between pros and cons for behavior change [80, 84]. It could be that the RTW process after long term sickness absence is too complex for the stages of change model. The stages of change model has been critiqued for oversimplifying the complexities of behavioral change as individuals fluctuate as they try to change and the stages are not true stages, but rather artificial constructs [167]. Littell and Girvin [168] reviewed 87 studies on the stages of change across different problem behaviors (mostly smoking and substance abuse) and found little evidence for a sequential movement through discrete stages. They concluded that even though the model offers a heuristic perspective on change, there is a lack of evidence for the model and that the model should be applied with caution.

6.2 RTW outcomes

One of the most common outcomes in RTW research is time to RTW, often either defined as first day back at work or sustainable RTW, which often is defined as 4 weeks without relapse. First RTW defined as a short time back at work (e.g. one day) is problematic due to the large proportion of workers who experience recurrent absence [79]. For the same reasons using four weeks without relapse is problematic and the term sustainable is highly deceptive. People may choose to return too early, due to factors like fear of losing their job or financial strain, which may lead to new episodes of sick leave. A way to take this is into consideration is to measure the total number of sickness absence days during follow-up, as was done in this study. Another way to allow for recurrent episodes of absence which is recommended is to use repeated measures over considerable time periods [79]. Even though there were no statistical differences between the programs in our study, there were some indications that participants in the outpatient program had less sickness absence days and shorter time to sustainable RTW. However, when a post hoc analysis to assess the probability of receiving/not receiving monthly medical benefits throughout the one-year follow-up period was performed, it was possible to see how the probability of RTW developed through follow-up, which strengthened our belief in the conclusion of no difference between the programs.

Biering et al. [169] compared different methods for measuring RTW in individuals who had undergone treatment for coronary heart disease. Among the measures they included were proportions at work at 6 and 12 months and time to sustainable RTW (four weeks without receiving benefits), with or without including relapses during the 12 months follow-up. They found a good agreement between the measures; however, the agreement was lower for the time-to-event measure without considering relapses, meaning this is not necessarily a good measure of successful sustainable RTW.

Registry data on sick leave has the benefit of no missing data or recall bias, however, the registries contain information about benefits and it should be noted that cessation of benefits does not necessarily mean that the person has returned to work. Importantly, there is no reason to believe that this would affect the two groups differently.

6.3 Strengths and limitations

6.3.1 Internal validity

A general strength of this study was that a randomized design was chosen for the effect evaluation of the rehabilitation center (paper 1 and 2). By using this design the risk of confounding was minimized. In the second allocation a flexibly weighted randomization procedure was used to ensure that the rehabilitation center had enough participants to run monthly groups in periods of low recruitment. This affected the size of the two groups and made it quite obvious which group was the intervention group, and hence the researchers were not blinded. This was not optimal, but all participants were randomized and the randomization was provided by a third party (the Unit of Applied Clinical Research at the Norwegian University of Science and Technology). Blinding of the participants was not possible, but both groups received a treatment offered by the specialist health care system (St Olavs University Hospital) and the baseline questionnaires were completed before randomization. The main analyses were performed under the intention to treat principle. The analyses were also performed with adjustment for baseline characteristics to take consideration of possible imbalance in the randomization.

The main concern regarding internal validity in paper 1 and 2 was measurement error. The use of individual registry data for medical benefits ensured completeness without any recall bias in the ascertainment of the primary outcome.

A major limitation in paper 2 was loss to follow-up which steadily increased as time passed. From practically 100% answering the first questionnaire, less than 50% answered the questionnaire at 12 months follow-up. At the start and the end of the programs, more people answered the questionnaires in the inpatient program than in the outpatient program. A possible explanation was that the participants in the inpatient program answered the questionnaires at the rehabilitation center, while the outpatient participants did it at home. During follow-up, questionnaires were answered at home for both groups and the number of missing questionnaires was similar. It was therefore assumed that the structural differences in collecting questionnaire data account for the differences in responses between the two groups at the start and end of the intervention. At least 3 questionnaires were filled out by 72% of the participants. Linear mixed

models were used for analyses, which uses all available data and are less sensitive to missing values in outcome data. Still, these models rely on the assumption of "missing at random", and the possibility of bias due to loss to follow-up cannot be disregarded. However, the assumption about "missing at random" is strengthened by the sick leave data showing a similar number of sick leave days during 12 months of follow-up between participants who responded/not responded to the questionnaire at 12 months.

There were several sources of potential misclassification or measurement error. In the register data, sick leave certificates may be missing or there could be errors in the registration. This was taken into consideration by combining data from several sources (e.g. also including data on sick leave payments). There was no information available about whether participants had several jobs/employers. This would mainly be a problem if someone had two or more jobs and was just sick listed from one of them. Another limitation is that there was no information about type of work (e.g. blue collar, white collar) for the participants. However, due to the study design there is no reason to suspect that degree of errors or misclassification would differ between the groups.

Loss to follow-up was also to some degree a problem for paper 3 where 24% of the questionnaires were missing at the start of the rehabilitation programs and 35% at the end of the programs. However, in this paper the missing questionnaires would mainly be a problem if the responders and the non-responders had a different degree of association between their scores on the Readiness for RTW scale and work outcomes, which there is no reason to suspect. Hence, the missing questionnaires should not affect the results much besides the loss of statistical power in paper 3.

Another limitation in paper 3, and a problem with the Readiness for RTW scale, is the possible misclassification of participants. In Norway, graded sick leave is commonly used and the question; "are you currently back at work", that determined if the participants received the "not working" or "working" questionnaire could be misunderstood in regard to whether it means working at all or working as normal. Hence, the main problem would be people who are on graded sick leave filling out the part meant for those 100% sick listed. This part of the questionnaire is not validated for this group, and they might relate differently to the questions.

In paper 3 adjustments were done for possible confounders like anxiety and depression symptoms, length of sick leave, education and whether they had a job. However, these adjustments did not affect the results much.

The Readiness for RTW dimensions were included as continuous variables in the main analyses, even though some of them did not entirely meet the linearity assumption. The analyses were also performed with the dimensions categorized. The variables were categorized in such a way that the results could be reproducible in other populations. This did, however, give a low number of participants in some categories and hence less power. In addition, the use of the variables categorized restricted the possibility to adjust for possible confounders. Therefore, the dimensions were used as continuous variables in the main analyses, which mean the estimations should be interpreted with caution

6.3.2 Precision

The power calculations were adequate for the evaluation of the main outcome, sickness absence (paper 1). However, the number of participants was too small to do subgroup analyses, for example diagnosis for sick leave would have been relevant. As the power calculations were done for the main outcome the power might not have been sufficient for the analyses performed on secondary outcomes (paper 2). However, the changes observed for both groups during follow-up were small and the development for both groups over time gave little reason to doubt the conclusion of no difference between the groups.

In paper 3 the number of participants reduced the study`s ability to reach firm conclusions. This was mainly due to loss to follow-up and people answering either part A or B of the questionnaire. In addition few participants achieved sustainable RTW. When evaluating changes in scores between the start and the end of the rehabilitation program even more participants were lost, as they had to fill out the same questionnaire both times, i.e. those who only filled out one of the questionnaires and those who changed category (started to work) were lost. Also, 21% of the participants in the not working group did not have a job to return to and might relate differently

to the questions than people who have a job. There were not enough participants to do a subgroup analysis for this group.

6.3.3 External validity

In the short trial more than 3 300 invitations were sent out, and only 275 individuals accepted and almost 2 000 individuals did not answer the invitation at all, which was quite surprising as the invitation was sent from the Norwegian Welfare and Labour Administration. There was self-selection (paper 1 and 2) as to which individuals accepted the invitation to participate in the study. Accepting the invitation meant they had to be prepared to be away from family and friends for eight days in total during the program, if allocated to the inpatient program. Even though an inclusion criterion was sick leave for at least 8 weeks, the median length of sick leave at inclusion was more than 220 days for both programs. A reason might be that individuals with greater obstacles for RTW to a larger extent accepted the invitation. Similar response numbers was also seen in the long trial. With only about 8% accepting the invitation the generalizability of the results is a challenge. However, it should be noted that only a small portion of people on sick leave in Norway are referred to occupational rehabilitation centers. As welfare system differs considerably across countries, the results are also primarily generalizable to countries with similar welfare systems, primarily the Nordic countries.

6.3.4 General considerations

A limitation in paper 1 and 2 where the effect of the inpatient rehabilitation program was evaluated was the lack of a control group receiving usual care. Therefore, it is not possible to distinguish between the effects of rehabilitation and time. However, all the groups may be followed in register data with regards to sick leave, i.e. people who were invited and did not end up in the study, and also the untouched reference group who has never been contacted. The untouched group was meant to be randomized in the first randomization, but unfortunately this

was not done correctly during the whole inclusion period, and hence this will be a retrospectively identified control cohort.

7 Conclusions

There was no difference between the short inpatient program and the outpatient program on sick leave or sustainable RTW. There was a small difference between the programs on one pain variable, but the difference was too small to be of any clinical interest. Otherwise, there was no difference between the programs on somatic and mental health. Therefore, this study presents no support that a 4+4 days inpatient multicomponent occupational rehabilitation program is superior to a less comprehensive outpatient program (Paper 1 and 2).

Three dimensions in the Readiness for RTW scale were associated with work outcomes (Prepared for action- self-evaluative, Prepared for action- behavioral and Uncertain maintenance). Models including the Readiness for RTW dimensions were generally not as good at explaining work outcomes as models including a single expectation question. Furthermore, several weaknesses with the Readiness for RTW scale were established and therefore, more research and probably revision of the instrument is needed before the scale potentially can be used for evaluation of interventions and as a useful tool in clinical settings (Paper 3).

8 Implications and future research

This is the first randomized trial evaluating the effect of inpatient occupational rehabilitation in Norway. In this thesis the results of the short trial are presented. Inpatient rehabilitation programs in Norway are usually quite long, about 4 weeks, mainly based on tradition and convenience rather than scientific evidence. Hence, there was a need to investigate the effect of different durations. Evaluation of an inpatient program lasting 4+4 days showed no difference compared to a less comprehensive outpatient program, neither on sick leave nor health outcomes. Based on these results this short inpatient occupational rehabilitation program cannot be recommended for use in clinical settings.

Despite much research on the effects of occupational rehabilitation for sick listed workers in the last couple of decades, the results are inconsistent. One of the reasons for this might be the different welfare systems. This type of research must be viewed in light of the welfare system context. International research suggests that involvement of the workplace is crucial [106, 107, 109]. However, Norwegian geography and the organization of occupational health care services have made it difficult to include in trials in Norway. Still, there is a clear need for research evaluating the effect of including the workplace, which was also stressed in the evaluation-report of the Research Council of Norway`s Sickness absence, work and health program (2007-2016) [170]. Therefore, the new randomized trial carried out at Hysnes Rehabilitation Center evaluating the effect of a workplace visit is important.

Most of the research on occupational rehabilitation includes musculoskeletal complaints; however, there has been an increase in research on common mental health complaints the last couple of years. Despite increasing recognition of overlap in symptoms [123, 124], there is a lack of research on occupational rehabilitation programs including both individuals with somatic and mental health problems. There is also a lack of research comparing the effects of inpatient occupational rehabilitation to outpatient programs. In this trial the inpatient program was compared to a less comprehensive outpatient program to evaluate the effect of the inpatient program. However, there is also a need to compare comprehensive inpatient programs to comprehensive outpatient programs, as they tend to be less costly and let the sick listed worker live their daily life and more easily can incorporate the work place.

In this thesis The Readiness for RTW scale, a questionnaire developed to evaluate the sick listed worker`s degree of readiness for RTW was assessed. The model behind the scale is based on the stages of change model, which is much used and gives a good heuristic model for the RTW process as it incorporates the time aspect. However, several serious problems were found with the use of the scale in our study and the scale, particularly with the stage allocation approach, cannot be recommended for clinical use before more research is performed and revisions considered.

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Paper I

Effect of inpatient multicomponent occupational rehabilitation vs less comprehensive outpatient rehabilitation on sickness absence in persons with musculoskeletal- or mental health disorders: a randomized clinical trial

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Abstract

Purpose: To assess effects of an inpatient multicomponent rehabilitation program compared to less comprehensive outpatient rehabilitation on sickness absence in persons with musculoskeletal- or mental health disorders.

Methods: Randomized clinical trial with parallel groups. Participants were individuals 18-60 years old on sick-leave for 2-12 months with a sick-leave diagnosis within the musculoskeletal, psychological or general and unspecified chapters of ICPC-2, identified in a national register. The inpatient program (4+4 days) consisted of Acceptance and Commitment Therapy (ACT), physical training and work-related problem-solving including creating a return to work plan and a workplace visit if considered relevant. The outpatient program consisted primarily of ACT (6 sessions during 6 weeks). Both programs were group based. Primary outcome was cumulated number of sickness absence days at 6 and 12 months follow-up. Secondary outcome was time until sustainable return to work.

Results: 168 individuals were randomized to the inpatient program (n=92) or the outpatient program (n=76). We found no statistically significant difference between the programs in median number of sickness absence days at 6 and 12 months follow-up. In the outpatient program 57% of the participants achieved sustainable return to work (median time 7 months), in the inpatient program 49% (log rank, p=0.167). The hazard ratio for sustainable return to work was 0.74 (95% CI 0.48-1.32, p=0.165), in favor of the outpatient program.

Conclusions: This study provided no support that the more comprehensive 4+4 days inpatient multicomponent occupational rehabilitation program reduced sickness absence compared to the outpatient rehabilitation program.

Keywords: return to work, sick leave, Musculoskeletal Diseases, mental health, Cognitive Therapy

Introduction

Too many people leave the workforce prematurely due to health problems or disability, and too few workers with health problems are able to stay in work [1], particularly due to musculoskeletal and mental health disorders [2]. In addition to individual suffering this causes considerable costs for society. In Norway 5 % of the gross domestic product is spent on disability and sickness benefits [1].

Several treatment and rehabilitation programs to facilitate work participation have been investigated, notably for persons with low back pain, but also for common mental disorders [3-6]. This diagnosis-specific emphasis is somewhat in contrast to the increasing documentation of overlap between musculoskeletal complaints and mental health problems [7, 8], and the fact that return to work rehabilitation programs for low back pain also have been suggested to be useful for persons on sick leave with mental health disorders [9]. In line with this, occupational rehabilitation centers in Norway include different diagnostic groups in the same program [10]. However, we are not aware of studies evaluating return to work rehabilitation programs for both somatic and mental health disorders with a rigorous study design.

The inpatient occupational rehabilitation program investigated in this study included both individuals with musculoskeletal complaints, common mental health disorders and unspecific disorders in the same groups. The program consisted of Acceptance and Commitment Therapy (ACT) – a form of cognitive behavioral therapy [11], physical training, creating a return to work plan, and a workplace visit if considered relevant. ACT was the framework for all activity in the program. Physical activity provides substantial health benefits [12, 13] and is also inversely associated with disability pension [14] and sickness absence [15]. ACT emphasizes accepting both negative and positive experiences while using the individuals` values to guide them towards their goals [11]. Studies have suggested an effect of ACT on the main causes of sickness absence, namely chronic pain [16], anxiety [17] and depression [17, 18]. Furthermore, a randomized pilot study found fewer sick leave days for employees with stress/pain at risk of sick leave that received ACT compared to usual care [19].

We designed a randomized study investigating effects on sick leave of an inpatient multicomponent occupational rehabilitation program compared to an outpatient program, consisting mainly of group based ACT. We hypothesized that the multicomponent inpatient program would reduce sickness absence more than the comparative outpatient program, as it in addition to ACT contained physical training, a return to work plan and a workplace visit when relevant.

Methods

Study design and participants

We conducted a randomized clinical trial with parallel groups, comparing an inpatient multicomponent program with a single-component outpatient program (hereafter referred to as the inpatient- and outpatient program, respectively) for individuals on sick-leave due to musculoskeletal-, unspecific-, or common mental health disorders. Details about the study design have been published in a protocol article [20]. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241), and the trial is registered in clinicaltrials.gov (No.: NCT01926574). The results are presented according to the CONSORT statement [21].

Eligible participants were 18 to 60 years of age sick listed 2 to 12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the ICPC-2 (International Classification of Primary Care, Second edition). The current sick leave status had to be at least 50% off work. Exclusion criteria, assessed by a comprehensive questionnaire and an outpatient screening performed by a physician, physiotherapist and psychologist, were: 1) alcohol or drug abuse; 2) serious somatic (e.g. cancer, unstable heart disease) or psychological disorders (e.g. high suicidal risk, psychosis, ongoing maniac episode); 3) specific disorders requiring specialized treatment; 4) pregnancy; 5) currently participating in another treatment or rehabilitation program; 6) insufficient oral or written Norwegian language skills to participate in group sessions and fill out questionnaires; 7) scheduled for surgery within the next 6 months; and 8) serious problems with functioning in a group setting.

Interventions

The inpatient program consisted of group-based ACT - where discussions were led by team coordinators, individual and group-based physical training, mindfulness, psychoeducation on stress and individual meetings with the coordinators for work-related problem-solving and creating a return to work plan. The intervention lasted four full workdays in week 1 and week 4 (eight days in total; 6-7 hours each day), separated by two weeks at home (week 2 and 3). The two weeks at home included at least two contacts with the team coordinator (in person or by telephone) and a meeting with the employer if regarded relevant and the participant gave permission. The coordinators who mentored the participants were supervised by a certified ACT-instructor before and during (monthly) the intervention. The program took place at Hysnes rehabilitation center, established as part of St. Olavs Hospital, in central Norway. A more detailed description of the program has been published elsewhere [20].

The outpatient program consisted primarily of group-based ACT. The sessions were held at the Department of Physical Medicine and Rehabilitation at St. Olavs Hospital once a week for six weeks, each session lasting 2.5 hours. The sessions were led by either one of two physicians (specialists in Physical Medicine and Rehabilitation) or a psychologist; all supervised by the same ACT instructor as the coordinators in the inpatient program. The participants were given assignments to practise at home between sessions, including a daily 15 minutes audio-guided mindfulness practice. In addition the participants were offered two individual sessions with a social worker experienced in occupational rehabilitation and trained in ACT to clarify personal values and work-related issues. The program also included a motivational group discussion with a physiotherapist on the benefits of physical training. An individual session with both the social worker and group leader present ended the program. In this session a summary letter was written to the participant's general practitioner. A more detailed description of the program has been published elsewhere [20].

Study context

All legal residents in Norway are included in the Norwegian public insurance system. Medically certified sick leave is compensated with 100% coverage for the first 12 months. The first 16 days are covered by the employer, the rest by the Norwegian Welfare and Labour Administration. After 12 months of sick leave it is possible to apply for the more long-term

medical benefits, work assessment allowance and disability pension, which both covers approximately 66% of the income. Individuals on work assessment allowance are supposed to work according to their workability.

Outcome measures

Participants were followed for 12 months after inclusion. During this period, sickness absence was registered in monthly intervals, both as number of days per month and as a dichotomous measure of whether or not the participant was registered on sick leave that month. Outcomes were measured using data from the National Social Security System Registry, where all individuals receiving any form of benefits in Norway are registered by their social security number. The data consisted of registrations of medical benefits from four different sources; sick-leave payments, sick leave certificates, work assessment allowance and disability pension. Monthly intervals (rather than exact dates) were used in order to include all relevant sick leave benefits in the same measure, as exact dates were not available for payments and the long-term benefits. Work assessment allowance was adjusted for delay in payments up to two months.

The primary outcome measure was cumulated number of sickness absence days, calculated at 6 and 12 months after inclusion. By combining information from the different medical benefits we calculated days on medical benefits (according to a 5-day work week) for every month during follow-up. Time on graded sick leave was transformed to whole workdays. Days receiving sick-leave payment and work assessment allowance were adjusted for employment fraction, including a graded disability pension at inclusion. Any increase in disability pension during follow-up was counted as sick leave.

The secondary outcome measure was time until full sustainable return to work defined as one month without relapse, i.e. one monthly interval not receiving any medical benefits (except any graded disability the participant had when entering the study).

Randomization

The present study was part of a larger trial comparing the current (4+4 days) and a longer (3.5 weeks) inpatient program to the outpatient program, as well as a treatment as usual control

group only followed in sick leave registers (see Figure 1). The current study reports on sick-leave in the 4+4 days inpatient program versus the outpatient program.

FIGURE 1 ABOUT HERE

Participants were randomized twice. Firstly, sick listed individuals identified in the National Social Security System were randomized to receive an invitation to either the long or the short program-evaluations. Invited participants completed a short questionnaire assessing initial eligibility. Those eligible were invited for an outpatient screening assessment. If the screening was passed (Figure 1), the second randomization allocated the subjects to either the inpatient or the outpatient program. The first randomization was performed by a project co-worker. In the second allocation a flexibly weighted randomization procedure was provided by the Unit of Applied Clinical Research (third-party) at the Norwegian University of Science and Technology (NTNU), to ensure that the rehabilitation center had enough participants to run monthly groups in periods of low recruitment. It was not possible to blind neither the participants nor the caregivers for treatment. The researchers were not blinded.

Sample size

Sample size was calculated based on number of sickness absence days and time to sustainable return to work, resulting in 80 persons in each arm [20].

Statistical analysis

Number of days of sick leave at 6 and 12 months after inclusion for the two programs were calculated and compared using the Mann-Whitney U (Wilcoxon rank sum) test. For time until sustainable return to work Kaplan Meier curves were estimated and compared with the log rank test. We estimated hazard ratios for return to work using Cox proportional hazard model with the Efron method for ties [22]. Time was calculated as number of months and participants were censored at "full sustainable return to work" or end of follow-up. We performed analyses without adjustment and with adjustment for gender, age, level of education, main diagnosis for sick leave and length of sick leave at inclusion. The proportionality hazard assumption was checked using the Schoenfeld Residual test [23]. All

analyses were performed after the "intention to treat" principle. Additional "per protocol" analyses were done by excluding participants that withdrew after randomization (before or during the programs) and/or attended less than 60% of the sessions of the outpatient program.

In addition to the main analyses, we performed several post hoc sensitivity analyses in order to account for characteristics of the sickness absence patterns and data structure which we observed in the course of the study. First, we observed that several participants alternated between being on and off benefits. We therefore performed a repeated events analysis allowing individuals to alternate between being on and off benefits every month of follow-up using general estimating equations (GEE). Secondly, we observed single months without payment in between longer periods of payments. As the Norwegian holiday lasts 5 weeks, we performed an additional sensitivity analysis on time until sustainable return to work where we defined return to work as two months without benefits.

We considered p-values (two-tailed) <0.05 to be statistically significant. Precision was assessed using 95% confidence intervals. All analyses were done using STATA 13.1 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Results

The flow of participants through the study is illustrated in Figure 1. Between October 2012 and November 2014, 12 007 potential participants from the regional area were identified in the National Social Security System Registry and 3 318 were randomized to receive an invitation to the short program. Of these 275 accepted the invitation. After screening 168 remained and were randomized to the inpatient program (n=92) or the outpatient program (n=76). The groups consisted of maximum 9 participants.

For the inpatient program, 14 people withdrew before they began the program and four quit during the program. For the outpatient program, five people withdrew before the program started and eight during the program. Those who started the outpatient program attended on

average 7.9 of the 10 meetings and 59 (83%) attended at least 60% of the sessions. For the inpatient program there is no data available regarding the number of sessions participants attended, but as it was an inpatient program the participants were assumed compliant if they did not withdraw. All participants were included in the analyses. A workplace visit was performed for 13% (n=10) of the participants who started the inpatient program.

Participants` characteristics

Most of the participants (65%) worked full time prior to their sick-leave, while 18% worked part time, 4% had a graded disability pension and 13% had no job. The median number of days on sick-leave the last 12 months before inclusion in the study (i.e. second randomization) was 226 calendar days (interquartile range (IQR) 189-271). A musculoskeletal diagnosis was most common (52%), followed by psychological (38%) and general and unspecific (10%) diagnoses. The mean age of participants was 45 years and the majority were women (79%). The baseline characteristics of the participants in the two programs were fairly similar (Table 1).

TABLE 1 ABOUT HERE

Sickness absence days

The median number of sickness absence days (work days) at 6 months after inclusion was 58 (IQR 37-92) for the inpatient program and 51 (IQR 32-85) for the outpatient program. The difference was not statistically significant (Mann-Whitney U test, p=0.284). For the 12 months follow-up, the median number of sickness absence days was 114 (IQR 46-172) for the inpatient program and 96 (IQR 35-175) for the outpatient program (Figure 2). The difference was not statistically significant (Mann-Whitney U test, p=0.403).

FIGURE 2 ABOUT HERE

Sustainable return to work

In total 88 participants achieved sustainable return to work (i.e. one month without benefits) during 12 months follow-up, 45 participants (49%) in the inpatient program and 43 participants (57%) in the outpatient program. Median time until sustainable return to work

was 7 months for the outpatient program (IQR 4-not reached). The inpatient program did not reach 50% return to work in the follow-up period (IQR 5- not reached). Figure 3 shows the Kaplan Meier plot. The difference between the programs was not statistically significant (log rank test: p=0.167). Cox regression analysis without adjustment gave a hazard ratio of 0.74 (95% CI 0.48-1.32, p=0.165) for sustainable return to work, in favor of the outpatient program. Adjustment for age, gender, education, main diagnosis for sick leave and length of sick leave at inclusion gave similar results (hazard ratio 0.71, 95% CI 0.46-1.09, p=0.119).

FIGURE 3 ABOUT HERE

Other sickness absence measures

Of the participants achieving sustainable return to work, 15 participants (33%) in the inpatient program and 20 (47%) participants in the outpatient program returned to medical benefits during the 12 months follow-up. At 12 months, 40 participants (43%) in the inpatient program and 30 (39%) in the outpatient program was not on medical benefits (excluding graded disability benefits). About half the participants received work assessment allowance in both groups (50% and 49% respectively) and 5% of the participants in the inpatient program and 12% in the outpatient program were on sick leave. One participant in the inpatient program received full disability pension.

Repeated events analyses for return to work showed no difference between the programs at any of the time points (months of follow-up) (Figure 4). The average odds ratio over time was 0.78 (95% CI 0.49-1.24, p=0.299) for return to work (i.e. one month without benefits) in favor of the outpatient program. Adjusting for aforementioned variables did not change the conclusion.

FIGURE 4 ABOUT HERE

When the analyses were performed using two months without medical benefits as event, the sustainable return to work rate dropped slightly to 45% and 53% for the inpatient and outpatient program respectively. Unadjusted and adjusted cox regression gave hazard ratios similar to the analyses performed with one month without benefits as the event.

Per protocol analyses comparing number of sickness absence days at 6 and 12 months and time to sustainable return to work showed only minor changes compared to the main analyses (results not shown).

Discussion

Among persons on sick leave with a musculoskeletal, psychological or unspecific diagnosis, this randomized trial showed no significant difference in number of sickness absence days and time to sustainable return to work following an inpatient multicomponent occupational rehabilitation program compared to a less comprehensive outpatient program.

Even though there were no statistical differences between the programs, there were some indications that participants in the outpatient program had less sickness absence days and shorter time to sustainable return to work. However, this group also had a higher fraction of recurring sickness episodes. Hence, we performed a post hoc analysis to assess the probability of receiving/not receiving monthly medical benefits throughout the one-year follow-up period. Assessing sickness absence in this way made the between-group differences smaller, strengthening the finding of no difference between the programs.

Return to work rates in this study were lower than in some previous return to work studies [3, 5, 4]. However, those studies only included participants with musculoskeletal complaints while this study also included common mental health disorders and unspecific complaints. The participants in this study also had longer current sickness episodes than some of the previous studies [5, 4], which might indicate more complex problems. They were also invited directly through the National Social Security System and not referred by a physician.

Nevertheless, the low return to work rate for the inpatient program could indicate that the program did not match their needs.

Studies have suggested that involving the workplace in return to work programs is effective for reducing sick leave for individuals on sick leave with low back pain [3, 24] and common mental health disorders [6]. The inpatient program in this study involved one workplace visit, but only when considered relevant by the participant and the rehabilitation team, and was only performed for 13% of the participants. The reasons for not performing the workplace visit were poorly registered. Focus group interviews with individuals participating in a similar but more long-lasting program at the same rehabilitation center found that few had made concrete plans for return to work at the end of the program [25]. That so few workplace visits were performed could possibly in part explain why there was no additional effect of the inpatient program compared to the outpatient program.

In a Norwegian context this was a relatively short inpatient occupational rehabilitation program (4+4 days), as traditional inpatient programs typically last about 4 weeks [10]. In that regard, lack of difference between the two programs could be due to the short length of the inpatient program. However, we are not aware of studies showing added effect of more intensive programs [26, 27]. In an upcoming study we will assess the effect of a 3 ½ week inpatient program compared to the same outpatient program [20].

The main strength of this randomized study was the use of registry data on medical benefits, ensuring that there were no biased assessments of end-points and no missing data. Furthermore, all participants were invited from the National Social Security System, meaning there was no referral bias. However, there was a self-selection bias as to which individuals accepted the invitation to participate in the study. Accepting the invitation meant they had to be prepared to be away from family and friends during the program if allocated to the inpatient program. From more than 3000 invitations sent, only 275 individuals accepted the invitation, which limits the generalizability of the results. Even though an inclusion criterion was sick leave for at least 8 weeks, the mean length of sick leave at inclusion was more than 220 days for both programs. It could be that individuals with greater obstacles for return to

work to a larger extent accepted the invitation. This assumption is strengthened by the fact that around 50% of the participants received work assessment allowance at 12 months follow-up. As this medical benefit provided after one year of sickness absence only reimburses 66% of the salary compared to 100% for sick leave pay, there is a considerable financial incentive for returning to work within one year. As there is no randomized usual care control group we do not know if the programs reduced sick leave and increased return to work compared to usual care. Qualitative studies of treatment protocol adherence among the team coordinators will be published.

Conclusion

Among persons on sick leave with a musculoskeletal, psychological or unspecific diagnosis, this study provides no support that the 4+4 days inpatient multicomponent occupational rehabilitation program reduces sickness absence compared to a less comprehensive outpatient program. Whether a more comprehensive inpatient program is more effective in reducing sickness absence will be investigated in an upcoming study.

Conflict of Interest: Marius Steiro Fimland has been employed at Hysnes Rehabilitation Center, St. Olavs Hospital. Sigmund Gismervik is employed at Department of Physical Medicine and Rehabilitation, St. Olavs Hospital. The other authors declare that they have no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study

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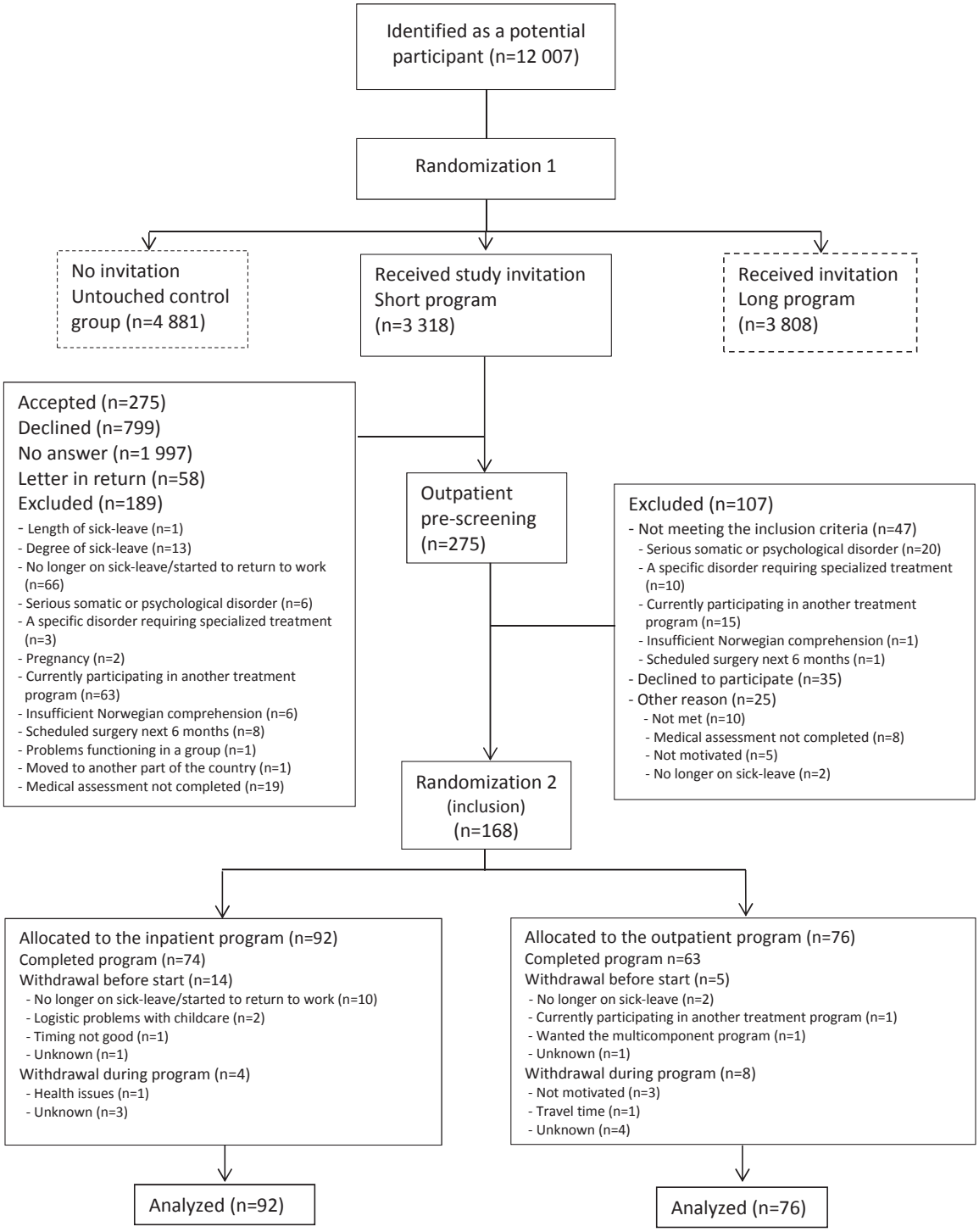

Figure 1 Participant flow through the study

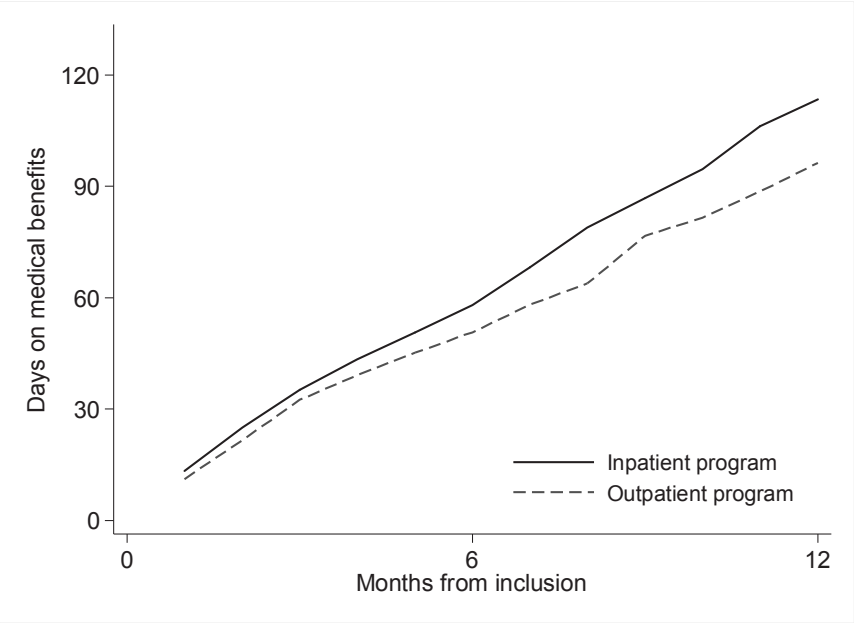

Figure 2 Cumulative number of days (median) on medical benefits for the two programs during 12 months of follow-up. Adjusted for employment fraction and transformed to whole workdays according to a 5-day work week.

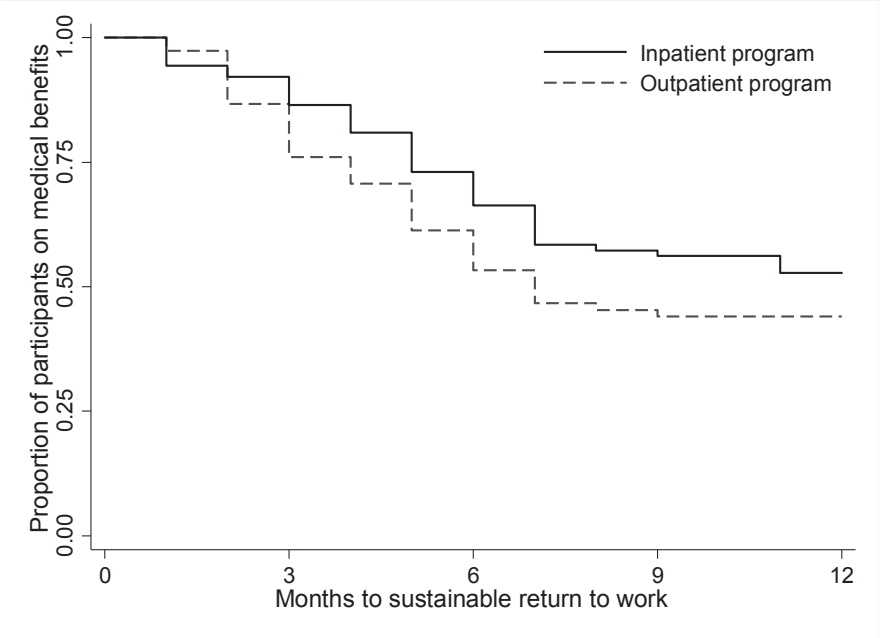

Figure 3 Survival curves from the Kaplan Meier analysis showing time to sustainable return to work for the inpatient- and the outpatient program.

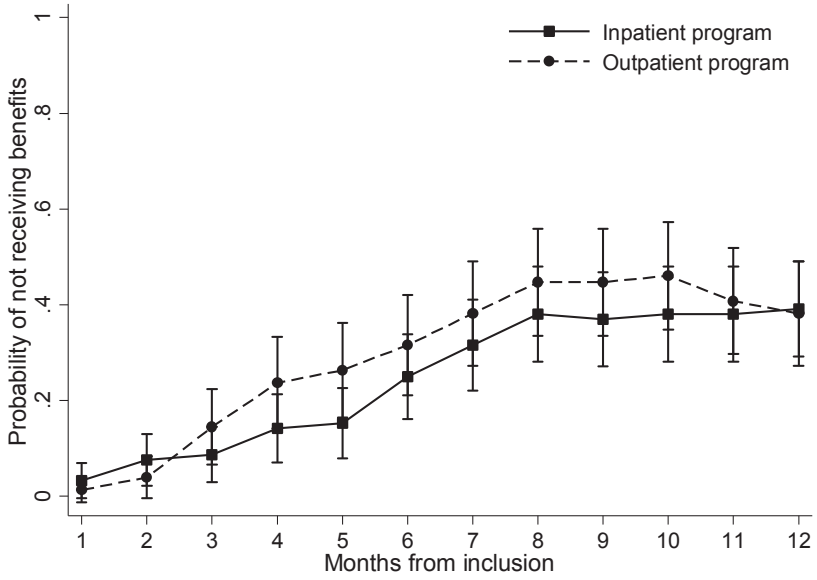

Figure 4 Estimated probabilities of not receiving benefits at each month during 12 months of follow-up. Results from a repeated events analysis using logistic General Estimating Equations (GEE).

Table 1 Baseline characteristics of participants

	Inpatient program (n=92)	**Outpatient program (n=76)**
Age mean (SD)	45.0 (8.7)	45.1 (9.6)
Women n (%)	71 (77%)	62 (82%)
Higher education[a, b] n (%)	45 (49%)	31 (41%)
Work status[b] n (%)		
No work	15 (16%)	7 (9%)
Full time	57 (62%)	52 (68%)
Part time	15 (16%)	16 (21%)
Graded disability pension[c]	5 (5%)	1 (1%)
Sick-leave status[d] n (%)		
Full sick-leave	41 (45%)	35 (46%)
Partial sick-leave	45 (49%)	36 (47%)
Work assessment allowance	6 (7%)	5 (7%)
HADS[b] mean (SD)		
Anxiety (0-21)	7.8 (4.4)	7.4 (4.3)
Depression (0-21)	6.7 (4.3)	6.0 (4.1)
Pain level[b] mean (SD)		
Average pain (0-10)	4.7 (2.3)	4.6 (2.0)
Main diagnoses for sick-leave (ICPC-2)[d] n (%)		
A - general and unspecified	9 (10%)	7 (9%)
L - musculoskeletal	48 (52%)	40 (53%)
P - psychological	35 (38%)	29 (38%)
Length of sick leave at inclusion[d, e]		
median days (IQR)	224 (189-262)	229 (187-275)

[a] Higher (tertiary) education: college or university
[b] At inclusion (second randomization)
[c] Individuals working part time that at inclusion also received a graded disability pension
[d] Based on data from the National Social Security System Registry
[e] Number of days on sick leave during the last 12 months prior to inclusion. Measured as calendar days, not adjusted for partial sick- leave

Paper II

J Occup Rehabil
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Effects of Inpatient Multicomponent Occupational Rehabilitation versus Less Comprehensive Outpatient Rehabilitation on Somatic and Mental Health: Secondary Outcomes of a Randomized Clinical Trial

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Abstract *Purpose* To evaluate effects on somatic and mental health of a multicomponent inpatient occupational rehabilitation program compared to a less comprehensive outpatient program in individuals on sick leave for musculoskeletal complaints or mental health disorders. *Methods* A randomized clinical trial with parallel groups. Participants were individuals on sick-leave for 2–12 months with a sick-leave diagnosis within the musculoskeletal, psychological or general and unspecified chapters of ICPC-2. Potential participants were identified in the Social Security System Registry. The multicomponent inpatient program (4 + 4 days) consisted of Acceptance and Commitment Therapy, physical training and work-related problem-solving including creating a return to work plan and a workplace visit if considered relevant. The comparative outpatient program consisted primarily of ACT (6 sessions during 6 weeks). Self-reported health-related quality of life, subjective health complaints, pain and anxiety and depression symptoms were assessed up to 12 months after the program. *Results* 168 individuals were randomized to the multicomponent inpatient program (n = 92) or the outpatient program (n = 76). Linear mixed models showed no statistically significant differences between the programs, except for slightly more reduced pain after the outpatient program. *Conclusions* This study presents no support that a 4 + 4 days multicomponent inpatient rehabilitation program is superior to a less comprehensive outpatient program, in improving health outcomes.

Keywords Return to work · Sick leave · Musculoskeletal diseases · Absenteeism · Cognitive therapy

Introduction

Musculoskeletal and mental health disorders are the two leading causes of sickness absence in Norway [1]. Five percent of the gross domestic product is spent on disability and sickness benefits, and this is by far the highest level in the OECD countries [2].

Most occupational rehabilitation programs described in the scientific literature are directed towards specific diagnostic groups, mainly musculoskeletal disorders [3, 4]. Effects reported in the literature are ambiguous. For example, Jensen et al. [5] did not find added effects on return to work or pain reduction of multidisciplinary occupational rehabilitation compared to a brief intervention program for subjects with low back pain. In contrast, Lambeek et al. [6] and Loisel et al. [7] reported that multidisciplinary occupational rehabilitation led to

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increased return to work and reduced disability, but with little effect on pain. Others have found increased return to work rates, but no effect on functional status [8]. Studies on the effect of return to work programs for individuals with mental health disorders have also showed increased return to work, but no added reduction in symptoms [9, 10]. However, a recent study showed that work-focused cognitive behavioral therapy for individuals on sick leave with common mental disorders was more effective than usual care in reducing depression and anxiety symptoms, increasing health-related quality of life, as well as increasing or maintaining work participation [11].

In Norway, the occupational rehabilitation services offer both inpatient and outpatient programs to increase work participation and improve health outcomes for patients on sick-leave, and the inclusion of different diagnostic groups in the same rehabilitation programs has been common practice for several years [12]. However, effects of such programs have never been evaluated with a rigorous study design. Recently, we participated in developing a multicomponent occupational rehabilitation program [13]. The program consisted of cognitive behavioral therapy, physical training, creating a return to work plan, and a workplace visit if considered relevant by the participant and rehabilitation team. Physical exercise has been shown to reduce depression [14], seems to reduce pain [15] and is recommended as an adjunctive treatment for anxiety disorders [16]. Different diagnostic groups were included in the program. All activity at the center was framed within a cognitive behavioral therapy approach in the form of Acceptance and Commitment Therapy (ACT) [17]. The ACT model emphasizes accepting both negative and positive experiences, while focusing on a person‘s values to guide them towards their goals [17]. In specific diagnostic groups there has been an increasing number of studies on the effect of ACT [18]. Although there are some inconsistencies in the literature [18, 19], studies suggest that ACT may have beneficial effects on chronic pain [20], anxiety [21, 22] and depression [21, 23].

We evaluated the effects of the multicomponent program delivered at the inpatient occupational rehabilitation center by comparing it to a less comprehensive outpatient program consisting mainly of ACT. In a recent study with 12 months of follow-up we found no difference between the programs on number of sickness absence days and return to work (under review). Here, we present results of secondary outcomes related to health as the programs also aimed to improve the participants‘ health status and health perception.

We hypothesized that the inpatient program, to a greater extent than the outpatient program, would reduce pain, depression, anxiety and subjective health complaints and increase function and health-related quality of life.

Methods

Study Design and Participants

We conducted a randomized clinical trial with parallel groups, comparing an inpatient multicomponent program (4 + 4 days) with a single-component program (6 sessions during 6 weeks) (hereafter referred to as the inpatient- and outpatient program, respectively) for individuals on sick-leave due to musculoskeletal-, unspecific-, or common mental health disorders. Details about the study design have been published elsewhere [13]. The primary outcome in the main study was sickness absence (under review). The current study assesses effects on somatic and mental health in the inpatient program versus the outpatient program through 12 months follow-up. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241), and the trial is registered in clinicaltrials.gov (No.: NCT01926574). The results are presented according to the CONSORT statement [24].

Eligible participants were individuals aged 18 to 60 years sick listed 2–12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of ICPC-2 (International Classification of Primary Care, Second edition). Sick leave status at inclusion had to be at least 50 % off work. Exclusion criteria, assessed by a questionnaire and an outpatient screening performed by a physician, a physiotherapist and a psychologist, were: (1) alcohol or drug abuse; (2) serious somatic (e.g. cancer, unstable heart disease) or psychiatric disorders (e.g. high suicidal risk, psychosis, ongoing manic episode); (3) specific disorders requiring specialized treatment; (4) pregnancy; (5) currently participating in another treatment or rehabilitation program; (6) insufficient oral or written Norwegian language skills to participate in group sessions and fill out questionnaires; (7) scheduled for surgery within the next 6 months; and (8) serious problems with functioning in a group setting.

Data was obtained by questionnaires and filled out at six time-points: at screening before inclusion, at the start of the program, at the end of the program, and three, six and 12 months after the inpatient program ended.

Programs

The Inpatient Program

Consisted of group discussions (ACT based) led by team coordinators, individual and group based physical training, mindfulness, psychoeducation on stress and individual meetings with coordinator for work-related problem-

solving and creating a return to work plan. The intervention lasted four full workdays in week 1 and week 4 (8 days in total; 6–7 h each day), separated by 2 weeks at home (week 2 and 3). The two weeks at home included at least two contacts with the team coordinator (in person or by telephone) and a meeting with the employer if regarded relevant and the participant gave permission. A certified ACT instructor supervised the coordinators who mentored the participants before and during (monthly) the intervention. The program took place at Hysnes rehabilitation center, established as a part of St. Olavs Hospital, in central Norway. A more detailed description of the program has been published elsewhere [13].

The Outpatient Program

Consisted of group based ACT. The sessions were held at the Department of Physical Medicine and Rehabilitation at St. Olavs Hospital once a week for six weeks, each session lasting 2.5 h. One of two physicians (specialists in Physical Medicine and Rehabilitation) or a psychologist, all three educated in ACT, led the sessions. The participants were encouraged to practise at home between sessions, including a daily 15 min audio-guided mindfulness practice. In addition the participants were offered two individual sessions with a social worker experienced in occupational rehabilitation and trained in ACT to clarify personal values and work-related issues. The intervention also included a motivational group discussion with a physiotherapist on the benefits of physical training. An individual session with both the social worker and ACT therapist present ended the intervention. In this session a summary letter was written to the participant's general practitioner. A more detailed description of the program has been published elsewhere [13].

Outcome Measures

Self-reported data on health and functioning were collected via internet-based questionnaires. The participants received text messages on their mobile telephone when it was time to answer questionnaires and as reminders if they did not respond. If they had not responded after two text-message reminders a project co-worker made a final phone call to remind the participant.

Anxiety and depression were recorded using The Hospital Anxiety and Depression Scale (HADS) [25]. It consists of 14 items, where seven items measure anxiety and seven measure depression symptoms. It is scored on a 4-point Likert scale according to intensity of symptoms the last week. The maximum score is 21 on each subscale. HADS is widely used and has been found to perform well in assessing severity and detecting anxiety and depression, with a cut-off of 8 giving an optimal balance between sensitivity and specificity [26]. HADS was answered at all time-points, except at six months.

Common somatic and mental health problems were recorded using The Subjective Health Complaints Inventory (SHC) [27], which registers complaints in five subscales: musculoskeletal pain, pseudoneurology, gastrointestinal problems, allergy and flu. It consists of 29 questions regarding complaints experienced the last month—each scored on a 4-point Likert scale from 0 "not at all" to 3 "serious". A severity score can be reported for each subscale or as a total score (score range 0–87) [27]. The questionnaire was answered at the start of the program, and three and 12 months after the program.

To assess pain we used two questions from the Brief Pain Inventory (BPI) [28]. The participants were asked to grade the strongest and average pain during the last week on a 0 (no pain) to 10 (worst imaginable pain) numeric rating scale. The pain questions were answered at all time-points, except at 6 months.

Health-related quality of life was recorded using 15D [29]. It contains 15 dimensions covering physical, mental and social well-being and generates a total score ranging from 1 (no problem on any dimension) to 0 (being dead). It has been suggested that the generic minimal important change is ± 0.015 and a large change is ± 0.035 [30]. It should be noted that in the Alanne et al. study the cut-off for "slightly better" for pain and depression alone were 0.036 and 0.051, respectively. 15 D was answered at all time-points, except at screening and the end of the program.

Functioning was recorded using COOP/WONKA [31]. It offers a self-reporting assessment of function in six domains. We used four of the domains: physical fitness, feelings, daily activity and social activity. Each domain is scored on a 5-point Likert scale from 1 (no problems/not affected) to 5 (huge problems/considerably affected). Answers were used as a continuous score (range 1–5). It was included at all time-points, except at screening and six months.

Participants were asked to evaluate their general health on a 4-point Likert scale from 1 "poor" to 4 "very good". The variable was analysed both dichotomized (poor/not very good vs. good/very good) and as a continuous score (range 1–4). The question was answered at all time-points, except at screening.

Randomization and Blinding

The present study was part of a larger trial comparing the current ($4 + 4$ days) and a longer (3.5 weeks) inpatient program, an outpatient program, as well as a treatment as usual control group only followed in sick leave registers

(see Fig. 1). The current study reports on health outcomes in the 4 + 4 days inpatient program and the comparative outpatient program.

Participants were randomized twice. Firstly, sick listed individuals identified in the Social Security System were randomized to receive an invitation to either the long or short program. Invited participants randomized to the short program completed a short initial questionnaire assessing eligibility. Those eligible were invited for an outpatient screening assessment. If the screening was passed (Fig. 1), the second randomization allocated the subjects to either the inpatient or the outpatient program. The first

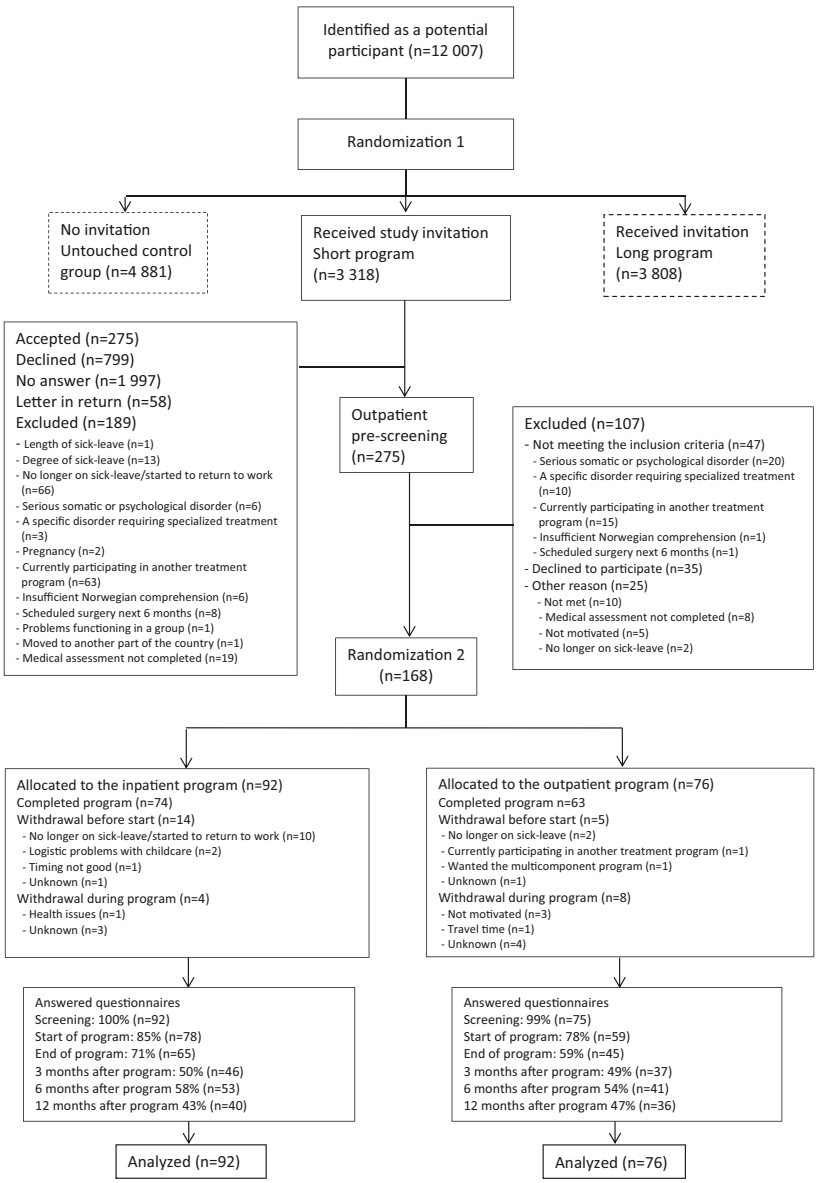

Fig. 1 Participant flow through the study

randomization was performed by a project co-worker. In the second allocation a flexibly weighted randomization procedure was provided by the Unit of Applied Clinical Research (third-party) at the Norwegian University of Science and Technology (NTNU), to ensure that the rehabilitation center had enough participants to run monthly groups in periods of low recruitment.

It was not possible to blind neither the participants nor the caregivers for treatment. Outcomes were measured using web-based questionnaires that the participants filled out independently on their own. The researchers were not blinded.

Statistics

Sample size was calculated based on the primary outcome, i.e. number of sickness absence days (under review), resulting in 80 persons in each arm. Details about the estimations are published elsewhere [13].

Under the intention to treat principle we used linear (and logistic) mixed-effects models to compare outcome measures of health and function over time for the two rehabilitation programs. In addition to program and time (time points 1–6) we included an interaction term between program and the six time-points in the analyses to assess whether the effects of the programs differed over time. Repeated measurements (at the different time-points) were handled by including a random intercept for person in the models (thereby allowing the participants to start out at different levels) and a random slope for time (allowing individual development over time). The estimates from the analyses (fixed effects) were used to predict health outcomes at different time points for the two programs. We considered p values (two-tailed) <0.05 to be statistically significant. Precision was assessed using 95 % confidence intervals.

In the main analyses we did not adjust for baseline characteristics, but this was done in sensitivity analyses (gender, age, sick leave diagnosis, work status, education level and type of benefit) to assess the robustness of the results. Supplementary "per protocol" analyses were done by excluding participants that withdrew after randomization (before or during the programs) and/or attended less than 60 % of the sessions of the outpatient program.

Baseline characteristics for responders and non-responders to the 12 month follow-up questionnaire were compared using χ^2 test, t test or Mann–Whitney U test. Median numbers of sickness absence days were compared by Mann–Whitney U test.

All analyses were done using STATA 13.1 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Results

In brief, 12 007 potential participants from the regional area were identified in the National Social Security System Registry. Of these, 3 318 were randomized to receive an invitation to the short program and 275 accepted. After screening 107 persons were excluded, withdrew or did not meet for their appointment. The remaining 168 persons were randomized to the inpatient program (n = 92) or the outpatient program (n = 76). The groups consisted of maximum 9 participants. The flow of participants through the study is illustrated in Fig. 1.

For the inpatient program, 14 people withdrew before they began the program and four quit during the program. For the outpatient program, five people withdrew before the program started and eight during the program. Those who started the outpatient program attended on average 7.9 of the 10 meetings and 59 (83 %) attended at least 60 % of the sessions. For the inpatient program there is no data for number of sessions participants attended, but as it was an inpatient program the participants were assumed compliant if they did not withdraw. All randomized participants were included in the analyses.

The number of people who answered the questionnaires decreased steadily through the study. For the inpatient program 100 % of the participants answered the questionnaire before the screening, 85 % at the start of program, 71 % at the end of the program, 50 % at three months, 58 % at six months and 43 % at 12 months after the program. For the outpatient program the numbers were 99, 78, 59, 49, 54 and 47 %, respectively. One participant in the outpatient program answered none of the questionnaires. At least 3 questionnaires were filled out by 72 % of the participants. A workplace visit was performed for 13 % of the participants randomized to the inpatient program.

Participant Characteristics

The participants were mainly women (79 %), and their mean age was 45 years (SD 9.1) (Table 1). The majority (65 %) of the participants worked full-time prior to their sick leave, 18 % worked part time, 4 % had a graded disability pension and 13 % had no job. About half were on full sick-leave (45 %) and half on graded sick-leave (48 %). A smaller part (7 %) received work assessment allowance, which can be applied for in Norway after being on sick leave for a year. The latter group consisted of individuals who were invited to the study just before their benefit was changed from sick-leave to work assessment allowance. The median number of days on sick-leave the last 12 months before inclusion in the study (i.e. second randomization) was 226 days (interquartile range (IQR) 189–271). Sick-leave diagnoses within the

Table 1 Baseline characteristics of participants[a]

	Inpatient program (n = 92)	Outpatient program (n = 76)
Age mean (SD)	45.0 (8.7)	45.1 (9.6)
Women n (%)	71 (77 %)	62 (82 %)
Higher education[b] n (%)	45 (49 %)	31 (41 %)
Work status n (%)		
No work	15 (16 %)	7 (9 %)
Full time	57 (62 %)	52 (68 %)
Part time	15 (16 %)	16 (21 %)
Graded disability pension	5 (5 %)	1 (1 %)
Sick-leave status[c] n (%)		
Full sick-leave	41 (45 %)	35 (46 %)
Partial sick-leave	45 (49 %)	36 (47 %)
Work assessment allowance	6 (7 %)	5 (7 %)
Main diagnoses for sick-leave (ICPC-2)[c] n (%)		
A-general and unspecified	9 (10 %)	7 (9 %)
L-musculoskeletal	48 (52 %)	40 (53 %)
P-psychological	35 (38 %)	29 (38 %)
Length of sick leave at inclusion[c,d]		
Median days (IQR)	224 (189–262)	229 (187–275)
HADS mean (SD)		
Anxiety (0–21)	7.8 (4.4)	7.4 (4.3)
Depression (0–21)	6.7 (4.3)	6.0 (4.1)
Pain level mean (SD)		
Average pain (0–10)	4.7 (2.3)	4.6 (2.0)
Strongest pain (0–10)	5.4 (2.5)	5.9 (2.0)
Quality of life 15D (0–1)		
Mean (SD)	0.79 (0.10)	0.79 (0.09)
Subjective health evaluation n (%)		
Poor	7 (8 %)	10 (13 %)
Not so good	55 (60 %)	39 (51 %)
Good	15 (16 %)	10 (13 %)
Very good	1 (1 %)	0
No response	14 (15 %)	17 (22 %)

[a] Work status, sick-leave status, diagnosis and length of sick leave recorded at inclusion. Education, HADS and pain recorded at screening. Quality of life and subjective health evaluation recorded at start of program

[b] Higher (tertiary) education (College or university)

[c] Based on data in the medical certificate from the National Social Security System Registry

[d] Number of days on sick leave during the last 12 months prior to inclusion. Measured as calendar days, not adjusted for graded sick- leave or part time job

musculoskeletal chapter in ICPC-2 were most common (52 %), followed by psychological (38 %) and general and unspecified (10 %). The baseline characteristics of the participants in the two programs were fairly similar (Table 1).

Outcome Measures

Comparison of Intervention Groups

Only one of the health measures, strongest pain, showed a statistically significant difference between the programs (Fig. 2 and Table 2). The estimated mean difference in strongest pain from start of the program to 12 months was 1.1 (95 % CI 0.1–2.0, $p = 0.03$) in favor of the outpatient program.

Development of Health Outcomes Over Time

Both programs showed increased health-related quality of life from start of the programs to 12 months (Table 2). The other health measures showed no or marginal changes (Table 2 and online supplementary Table 1).

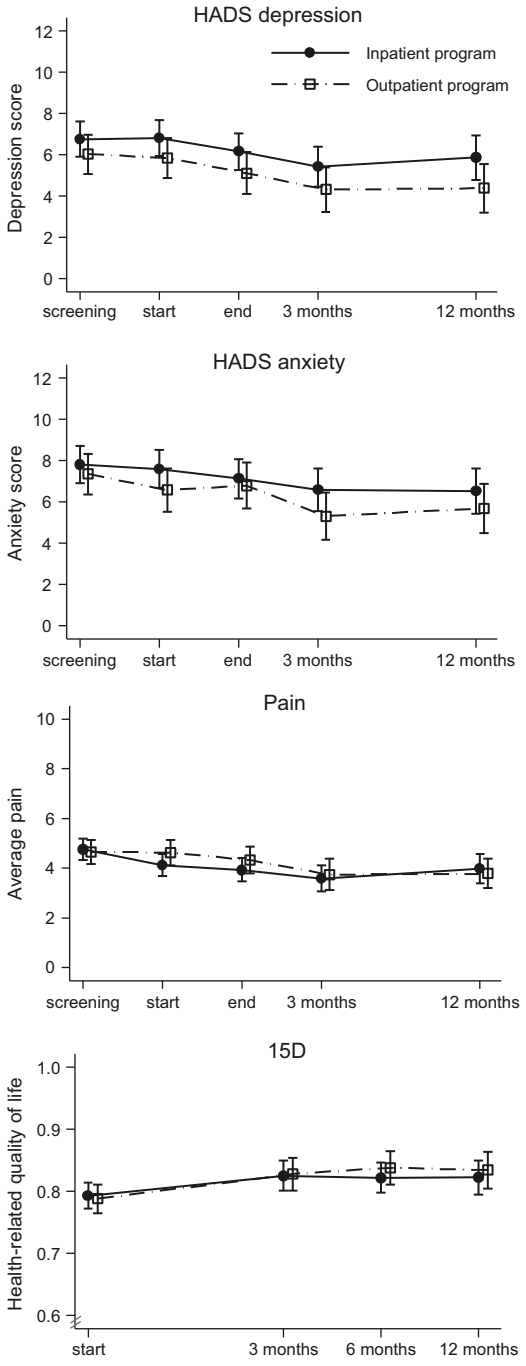

Fig. 2 The Hospital Anxiety and Depression Scale (HADS), average pain and 15D. Data are estimated means with 95 % confidence intervals

Per Protocol, Sensitivity and Post Hoc Subgroup Analyses

The "per protocol" analyses provided only minor changes in the estimates. The estimated difference between the programs was statistically significant for average and strongest pain, in favour of the outpatient program. The main analyses were repeated adjusting for gender, age, diagnosis, education level, work status and type of benefit received. There were only small changes in the estimates and the adjusted analyses did not change any conclusions about the programs.

We performed subgroup analyses for HADS and average pain according to the two main diagnostic groups (see online supplementary Tables 2 and 3). For the HADS depression subscale there was a somewhat larger reduction in symptoms for participants with a psychological diagnosis. The same was observed for the HADS anxiety subscale for the inpatient program, while for the outpatient program there were only minor differences between the diagnostic groups. For average pain there was little difference between participants with a musculoskeletal- and psychological diagnosis for both programs. When performing the analyses for participants having the highest baseline scores on anxiety, depression and pain the results were similar to the main analyses. The differences between the two programs from start of the programs to 12 months were not statistically significant in any of the subgroup analyses.

Non-Responders

The participants not answering the questionnaire at 12 months were younger than the responders (mean age 43.6 (SD 9.3) vs. 46.7 (SD 8.6), $p = 0.023$). The other baseline values were fairly similar. The median number of sickness absence days during 12 months of follow-up were 87 (IQR 39–146) for the responders and 112 (IQR 44–185) for the non-responders ($p = 0.252$).

Discussion

This randomized clinical trial showed no differences in self-reported health measures between a 4 + 4 days inpatient multicomponent occupational rehabilitation program and a less comprehensive outpatient program consisting mainly of group-based ACT, except for slightly more reduced pain after the outpatient program.

We are not aware of studies comparing inpatient and outpatient return to work programs. No substantial difference on somatic and mental health outcomes between the two rehabilitation programs is in line with some earlier studies on individuals with musculoskeletal complaints

Table 2 Comparison of estimated health scores between the inpatient and the outpatient program

	Inpatient program		Outpatient program		Estimated difference between programs[b]		
	Mean	95 % CI	Mean	95 % CI	Mean	95 % CI	*p* value
HADS anxiety (0–21)							
Screening	7.8	6.9–8.7	7.3	6.3–8.3			
Start of program	7.6	6.7–8.5	6.6	5.5–7.6			
End of program	7.1	6.2–8.1	6.8	5.7–7.9			
3 months	6.6	5.5–7.6	5.3	4.2–6.5			
12 months	6.5	5.4–7.6	5.7	4.5–6.9	0.2	−1.2 to 1.5	0.78
HADS depression (0–21)							
Screening	6.7	5.9–7.6	6.0	5.1–7.0			
Start of program	6.8	5.9–7.7	5.8	4.9–6.8			
End of program	6.2	5.3–7.0	5.1	4.1–6.1			
3 months	5.4	4.5–6.4	4.3	3.2–5.4			
12 months	5.9	4.8–7.0	4.4	3.2–5.6	−0.5	−2.0 to 1.0	0.49
Average pain (0–10)							
Screening	4.8	4.3–5.2	4.6	4.2–5.1			
Start of program	4.1	3.7–4.6	4.6	4.1–5.1			
End of program	3.9	3.5–4.4	4.3	3.8–4.9			
3 months	3.6	3.1–4.1	3.8	3.2–4.4			
12 months	4.0	3.4–4.6	3.7	3.1–4.3	−0.8	−1.5 to 0.0	0.06
Strongest pain (0–10)							
Screening	5.4	4.9–5.9	6.0	5.5–6.5			
Start of program	5.0	4.5–5.5	6.0	5.5–6.6			
End of program	4.9	4.4–5.4	5.5	4.8–6.1			
3 months	4.7	4.1–5.3	4.9	4.2–5.5			
12 months	5.1	4.4–5.8	5.1	4.3–5.8	−1.1	−2.0 to −0.1	0.03
Health-related quality of life (0–1)							
Start of program	0.79	0.77–0.81	0.79	0.76–0.81			
3 months	0.82	0.80–0.85	0.83	0.80–0.85			
6 months	0.82	0.80–0.85	0.84	0.81–0.86			
12 months	0.82	0.80–0.85	0.83	0.80–0.86	−0.02	−0.05 to 0.02	0.41
SHC total[a] (0–87)							
Start of program	15.2	13.4–16.9	15.9	13.9–17.9			
3 months	13.3	11.3–15.3	13.8	11.6–16.1			
12 months	14.3	12.2–16.5	13.9	11.6–16.2	−1.2	−3.8 to 1.5	0.39
SHC musculoskeletal pain[a] (0–24)							
Start of program	6.0	5.2–6.8	6.7	5.7–7.6			
3 months	5.2	4.3–6.2	6.0	4.9–7.1			
12 months	5.7	4.7–6.7	5.5	4.4–6.6	−0.9	−2.1 to 0.4	0.17
SHC pseudoneurology (0–21)							
Start of program	5.0	4.3–5.7	5.1	4.3–5.9			
3 months	4.4	3.6–5.2	4.0	3.2–4.9			
12 months	4.4	3.6–5.2	4.8	4.0–5.6	0.3	−0.8 to 1.4	0.58
SHC gastrointestinal problems (0–21)							
Start of program	2.1	1.6–2.6	2.2	1.7–2.8			
3 months	1.8	1.2–2.3	2.1	1.4–2.7			

Table 2 continued

	Inpatient program		Outpatient program		Estimated difference between programs[b]		
	Mean	95 % CI	Mean	95 % CI	Mean	95 % CI	*p* value
12 months	2.3	1.7–3.0	2.3	1.6–3.0	−0.3	−1.1 to 0.6	0.56

Means and mean differences with 95 % confidence intervals (95 % CI) were estimated using linear mixed models (unadjusted model)

[a] Estimates presented are from models without random slope due to lack of convergence

[b] Estimated from start of program to 12 months after the program; inpatient minus outpatient program

[5, 32] and mental health disorders [9]. The key element of both the inpatient and outpatient program in the present study was ACT. Differences between the two programs, in addition to the inpatient versus outpatient setting, were that the inpatient program was more extensive and included physical training, creation of a return to work plan and a workplace visit in 13 % of the cases. However, these additional components did not induce additional benefits.

Most occupational rehabilitation programs described in the scientific literature use some sort of cognitive behavioral therapy approach [6, 11]. In ACT the participants are encouraged to accept pain rather than try to control it. It has therefore been argued that pain might not be the best outcome measure for acceptance-based therapies [33]. This also applies to several of the other outcomes in this study like anxiety and depression, as ACT emphasize behavior change and not symptom reduction [34]. This is line with our findings of modest changes for these outcomes. The outpatient program was slightly more effective in reducing one pain variable, but the difference was not clinically significant and due to the number of statistical tests performed this result should be interpreted with caution.

We found an increase in health related quality of life in both groups measured by 15D, estimated to be 0.03 (95 % 0.01–0.06) for the inpatient program and 0.05 (95 % CI 0.02–0.07) for the outpatient program. The clinical importance of this change is uncertain, but it is in the area of cut-off suggested as a minimum important change [30]. When this is compared to the rather small changes observed on the other measures this might suggest that the focus of ACT on values and acceptance of negative experiences in life might have changed how the participants perceive their quality of life despite little change in health symptoms.

Few randomized studies have included participants with different diagnoses in the same return to work programs. As we included individuals on sick leave due to musculoskeletal, mental or general/unspecific disorders, some had pain and others not, which was also the case for anxiety and depression symptoms. This would likely reduce the statistical power to detect between group effects. However, we performed subgroup analyses according to the participants' main sick-leave diagnosis. Participants with a psychological diagnosis had a somewhat larger reduction in depression symptoms than participants with a musculoskeletal diagnosis. However, there was no difference between participants with musculoskeletal and psychological diagnoses in reductions of average pain. As a substantial degree of overlap in symptoms is common in these patients [35, 36] and the diagnostic labelling by the general practitioner may be somewhat arbitrary [37], we performed subgroup analyses for highest baseline scores on anxiety and depression symptoms and average pain. The estimates were fairly similar to the main analyses. It should be noted that the post hoc subgroup analyses were not planned a priori.

The main strength of this randomized study was that all participants were invited from the Social Security System Registry, meaning there was no referral bias. Return to work rehabilitation centers have existed for about 30 years in Norway, but this is the first randomized controlled study investigating effects on somatic or mental health of such programs. The programs were not diagnosis specific and add important knowledge to a field where previous research has focused on diagnosis specific interventions. Also, the study included a broad range of validated health-related measures.

Some limitations should be addressed. Firstly, the response rate for the questionnaires were low at 3, 6 and 12 months. At the start and the end of the programs, more people answered the questionnaires in the inpatient program than in the outpatient program. The participants in the inpatient program answered the questionnaire at the rehabilitation center, while the outpatient participants did it at home. During follow-up, questionnaires were answered at home for both groups and the numbers of missing questionnaires were similar. We therefore assume that the structural differences in collecting questionnaire data account for the differences in responses between the two groups at the start and end of the intervention. For analyses we used linear mixed models which are less sensitive to missing values in outcome data. Still, these models rely on the assumption of "missing at random", and we cannot disregard the possibility of bias due to loss to follow-up.

However, we consider it unlikely that such bias should influence the two groups differentially and thereby the main results of the study. This assumption is strengthened by register-based sick leave data showing a similar number of sick leave days during 12 months of follow-up between participants responding/not responding to the questionnaire at 12 months.

In the current study there was no usual care control group. Therefore, we cannot distinguish between the effects of rehabilitation and time. It should also be noted that the power calculation for the study was done with regard to the primary outcome (sickness absence) and not the secondary outcomes presented in this article.

With regards to external validity it should be noted that from the over 3000 invitations sent, only 275 individuals accepted the invitation. A possible explanation might be that they had to be prepared to be away from their family for 2 weeks if randomized to the inpatient program. With only about 8 % of the invited accepting the invitation the generalizability of the results is a challenge. However, it should be noted that only a small portion of people on sick leave in Norway are referred to occupational rehabilitation centers. By inviting participants this broadly we were able to reach all individuals on sick-leave with these diagnoses without referral bias induced by the general practitioner.

Conclusions

There was no substantial difference between the programs on somatic and mental health; hence, this study presents no support that a 4 + 4 days inpatient multicomponent rehabilitation program is superior to a less comprehensive outpatient program. Whether a longer lasting inpatient program will have greater effects on somatic and mental health will be investigated in an upcoming study.

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Compliance with Ethical Standards

Conflict of interest Marius Steiro Fimland has been employed at Hysnes Rehabilitation Center, St. Olavs Hospital. Sigmund Gismervik is employed at Department of Physical Medicine and Rehabilitation, St. Olavs Hospital. The other authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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Online appendix

Table 1: Comparison of estimated scores between the inpatient and the outpatient program on self-rated health and function (Coop-Wonca). Means and mean differences with 95% confidence intervals (95% CI) were estimated using linear mixed models (unadjusted model).

		Inpatient program		Outpatient program		Estimated difference between programs [b]		
		mean	95% CI	mean	95% CI	mean	95% CI	p-value
Self-rated health (1-4)	Start of program	2.1	2.0- 2.3	2.0	1.8- 2.2			
	End of program	2.3	2.1- 2.4	2.4	2.2- 2.6			
	3 months	2.4	2.3- 2.6	2.4	2.2- 2.6			
	6 months	2.4	2.2- 2-6	2.4	2.2- 2.6			
	12 months	2.3	2.1- 2.6	2.5	2.2- 2.7	-0.3	-0.6- 0.1	0.14
Coop-Wonca physical fitness (1-5)	Start of program	2.2	2.0- 2.5	2.3	2.0- 2.5			
	End of program	2.5	2.2- 2.7	2.5	2.2- 2.7			
	3 months	2.2	1.9- 2.5	2.0	1.7- 2.3			
	12 months	2.3	2.0- 2.5	2.0	1.7- 2.3	-0.3	-0.7-0.1	0.21
Coop-Wonca feelings (1-5)	Start of program	2.5	2.2- 2.8	2.5	2.2- 2.8			
	End of program	2.4	2.1- 2.7	2.4	2.1- 2.8			
	3 months	2.2	1.9- 2.5	2.2	1.9- 2.6			
	12 months	2.4	2.1- 2.7	2.5	2.1- 2.8	0.1	-0.3-0.5	0.70
Coop-Wonca daily activity [a] (1-5)	Start of program	2.6	2.4- 2.8	2.7	2.4- 2.9			
	End of program	2.6	2.3- 2.8	2.5	2.2- 2.8			
	3 months	2.3	2.0- 2.6	2.2	1.9- 2.5			
	12 months	2.1	1.8- 2.4	2.1	1.8- 2.4	-0.1	-0.5- 0.3	0.63
Coop-Wonca social activity (1-5)	Start of program	2.4	2.2- 2.7	2.4	2.1- 2.7			
	End of program	2.2	2.0- 2.5	2.2	1.9- 2.5			
	3 months	2.1	1.8- 2.4	2.1	1.8- 2.5			
	12 months	2.4	2.0- 2.7	1.9	1.5- 2.2	-0.4	-0.9- 0.1	0.08

[a] Estimates presented are from models without random slope due to lack of convergence

[b] Estimated from start of program to 12 months after the program; inpatient minus outpatient program

Table 2: Comparison of estimated scores between the inpatient and the outpatient program for HADS anxiety and depression according to sick-leave diagnosis and baseline score. Means and mean differences with 95% confidence intervals (95% CI) were estimated using linear mixed models (unadjusted model).

		Inpatient program		Outpatient program		Estimated difference between programs [b]		
		mean	95% CI	mean	95% CI	mean	95% CI	p-value
HADS depression (0-21) Psychiatric diagnosis (P)	Screening	8.8	7.4- 10.2	7.3	5.8- 8.9			
	Start of program	9.2	7.8- 10.6	7.3	5.8- 8.9			
	End of program	8.1	6.7- 9.6	5.7	4.1- 7.3			
	3 months	7.2	5.7- 8.8	5.3	3.6- 6.9			
	12 months	7.1	5.2- 9.0	5.2	3.2- 7.2	-0.1	-2.9- 2.7	0.95
HADS depression (0-21) Musculoskeletal diagnosis (L)	Screening	5.5	4.4- 6.5	5.1	3.9- 6.3			
	Start of program	5.4	4.3-6.5	4.7	3.5- 5.9			
	End of program	5.1	3.9- 6.2	4.6	3.3- 5.9			
	3 months	4.4	3.2- 5.6	3.7	2.3- 5.1			
	12 months	5.0	3.7- 6.4	3.8	2.3- 5.3	-0.5	-2.3- 1.2	0.55
HADS depression (0-21) Baseline score ≥ 8	Screening	10.7	9.9-11.6	10.8	9.6-11.9			
	Start of program	10.3	9.3-11.2	8.8	7.5-10.1			
	End of program	9.2	8.0-10.3	7.5	5.8- 9.1			
	3 months	7.9	6.5- 9.3	6.0	4.2- 7.9			
	12 months	8.7	6.8- 10.6	7.3	5.1- 9.5	0.0	-2.7- 2.8	0.99
HADS anxiety (0-21) Psychiatric diagnosis (P)	Screening	10.1	8.8-11.3	9.3	7.9- 10.7			
	Start of program	10.4	9.0- 11.7	8.0	6.4- 9.5			
	End of program	9.7	8.2- 11.2	7.9	6.2- 9.5			
	3 months	8.9	7.3- 10.6	6.3	4.6- 8.1			
	12 months	8.2	6.2- 10.1	7.2	5.2- 9.3	1.5	-1.0- 3.9	0.24
HADS anxiety (0-21) Musculoskeletal diagnosis (L)	Screening	6.4	5.2- 7.6	6.1	4.8- 7.4			
	Start of program	6.0	4.8- 7.2	5.5	4.2- 6.8			
	End of program	5.5	4.3- 6.8	6.1	4.6- 7.5			
	3 months	4.9	3.6- 6.2	4.8	3.3- 6.4			
	12 months	5.8	4.4- 7.2	4.6	3.1- 6.2	-0.7	-2.5 1.1	0.45
HADS anxiety[a] (0-21) Baseline score ≥ 8	Screening	11.5	10.5- 12.4	11.3	10.2- 12.4			
	Start of program	10.5	9.5- 11.5	9.6	8.4-10.8			
	End of program	10.0	8.9-11.1	9.4	8.1-10.8			
	3 months	9.2	7.9-10.4	8.3	6.9- 9.8			
	12 months	9.1	7.9- 10.4	8.9	7.4- 10.3	0.6	-1.4-2.6	0.55

[a] Estimates presented are from models without random slope due to lack of convergence
[b] Estimated from start of program to 12 months after the program; inpatient minus outpatient program

Table 3: Comparison of estimated scores between the inpatient and the outpatient program for pain according to sick-leave diagnosis and baseline score. Means and mean differences with 95% confidence intervals (95% CI) were estimated using linear mixed models (unadjusted model).

		Inpatient program		Outpatient program		Estimated difference between programs [a]		
		mean	mean	95% CI	mean	95% CI	mean	p-value
Average Pain (0-10) Psychiatric diagnosis (P)	Screening	3.4	2.8- 4.1	3.7	2.9- 4.4			
	Start of program	3.2	2.6- 3.9	3.8	3.1- 4.6			
	End of program	2.8	2.1- 3.5	2.9	2.1- 3.6			
	3 months	2.6	1.8- 3.3	3.1	2.3- 3.9			
	12 months	2.9	1.9- 3.8	2.9	1.9- 3.8	-0.6	-1.8- 0.7	0.38
Average Pain (0-10) Musculoskeletal diagnosis (L)	Screening	5.7	5.2- 6.2	5.5	4.9- 6.1			
	Start of program	4.9	4.4- 5.5	5.4	4.8- 6.0			
	End of program	4.9	4.4- 5.5	5.7	5.0- 6.4			
	3 months	4.2	3.6- 4.9	4.5	3.7- 5.3			
	12 months	4.9	4.1- 5.7	4.6	3.7- 5.4	-0.8	-1.9- 0.3	0.14
Average Pain (0-10) Baseline score ≥ 4	Screening	5.9	5.6-6.3	5.7	5.3-6.1			
	Start of program	4.9	4.5-5.3	5.4	5.0-5.9			
	End of program	4.8	4.3-5.3	5.0	4.4- 5.6			
	3 months	4.5	3.9- 5.1	4.5	3.8-5.2			
	12 months	4.9	4.1- 5.6	4.4	3.6- 5.2	-1.0	-2.0-0.0	0.61

[a] Estimated from start of program to 12 months after the program; inpatient minus outpatient program

Paper III

Associations between the Readiness for Return to Work scale and return to work: a prospective study

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Abstract

Purpose: To explore the usefulness of the Readiness for Return to Work scale in individuals participating in occupational rehabilitation, by assessing the association between the scale and return to work (RTW), and comparing the scale to a single question assessing individuals expectations about length of sick leave.

Methods: Prospective cohort study with 9 months follow-up. Participants took part in one of two randomized clinical trials. Associations between the Readiness for RTW scale and RTW was analyzed using linear and logistic regression, with adjustment for age, gender and education. The Readiness for RTW scale was compared to a self-reported question assessing participants` expectations about length of sick leave using adjusted/pseudo R^2.

Results: For participants not working (n=96), high scores on two dimensions (Prepared for action-self-evaluative and Prepared for action-behavioral) were associated with a higher probability of RTW and more working days. For those working (n=121), high scores on the Uncertain maintenance dimension was associated with a lower probability of RTW and less working days. Generally, models including the Readiness for RTW dimensions were not as good at explaining work outcomes as models including a single expectation question. Stage allocation, allocating participants to the dimension with the highest score, was problematic due to several tied scores between (not necessarily adjacent) dimensions.

Conclusions: Three of the Readiness for RTW dimensions were associated with RTW. However, several weaknesses with the Readiness for RTW scale were established and we particularly do not recommend the stage allocation approach for clinical use in its current form.

Keywords: Rehabilitation, Sick leave, Occupational health, Mental health, Musculoskeletal Diseases

Introduction

Return to work (RTW) after long-term sick leave is a complex and dynamic process described in several conceptual models [1-3]. One such model is The Readiness for RTW model [4], which is based on the stages of change model [5] and the phase model of occupational disability [6]. The Readiness for RTW model suggests that RTW is a process where the person on sick leave progresses through different dimensions or stages of change towards RTW. These stages are precontemplation (not intending to RTW), contemplation (considering RTW), preparation (making plans to RTW), action (RTW), and maintenance (staying at work). Three dimensions of change have been suggested to mediate the progression through the stages: self-efficacy, the individual`s decisional balance and change processes concerning RTW [4]. Change processes can be both mental (thoughts, feelings and attitudes) and behavioral. During the first stages, thoughts and feelings are gradually oriented towards the need for change, then in the later stages actual change in behavior manifests, like contacting the employer [4].

It is important to have instruments which can capture the dynamic nature of the RTW process [3], but currently no such instruments have solid empirical support. Based on the Readiness for RTW model, Franche et al. [7] developed and psychometrically validated the Readiness for RTW scale in a Canadian cohort. They identified four underlying factors for individuals not working and two for individuals working, corresponding to the stages in the Readiness for RTW model (table 1). More recently; however, a validation study in persons referred to occupational rehabilitation in Norway found fewer factors; two for people not working, and two for people working [8]. Two of these four factors were later found to be associated with future work participation in the only published longitudinal investigation of the Readiness for RTW scale [9].

TABLE 1 ABOUT HERE

Franche et al. [7] suggested that the Readiness for RTW scale could be used for evaluation of interventions and also clinically in tailoring stage-specific interventions. This is tested in an ongoing Danish study where the individual`s rehabilitation program is tailored based on the allocated Readiness for RTW stage [10]. The Readiness for RTW model is considered promising as it captures the dynamics of the RTW process [3]. However, limited research has been

performed on the Readiness for RTW model and the Readiness for RTW scale [7-9], and more research is needed on this instrument before it can be applied clinically [3, 11].

In two randomized clinical trials evaluating different occupational rehabilitation programs [12, 13], all participants were asked to answer the Readiness for RTW scale before and after the rehabilitation program. In the current study we assessed the association between the Readiness for RTW scale dimensions and future RTW in persons with musculoskeletal or mental health disorders participating in occupational rehabilitation. We also assessed whether a model including the Readiness for RTW dimensions or a model including a self-reported question assessing the participants` expectations about length of sick leave best described work outcomes, as a single expectation question has been associated with RTW in previous studies [14-17].

Methods

Study design and participants

We conducted a prospective cohort study with 9 months follow-up in individuals participating in one of two randomized clinical trials including three different rehabilitation programs. Details about the randomized trials have been published in a protocol article [12]. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241), and the trial is registered in clinicaltrials.gov (No.: NCT01926574).

Eligible participants were 18 to 60 years of age, sick listed 2 to 12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the ICPC-2 (International Classification of Primary Care, Second edition). The current sick leave status at inclusion had to be at least 50% off work. Exclusion criteria were: 1) alcohol or drug abuse; 2) serious somatic (e.g. cancer, unstable heart disease) or psychological disorders (e.g. high suicidal risk, psychosis, ongoing manic episode); 3) specific disorders requiring specialized treatment; 4) pregnancy; 5) currently participating in another treatment or rehabilitation program; 6) insufficient oral or written Norwegian language skills to participate in group sessions and fill out

questionnaires; 7) scheduled for surgery within the next 6 months; or 8) serious problems with functioning in a group settings.

The rehabilitation programs

The inpatient programs consisted of group-based Acceptance and Commitment therapy (ACT) [18], individual and group-based physical training, mindfulness and individual meetings with the coordinators in work-related problem-solving sessions and creating a RTW plan. One program lasted 3.5 weeks and the other 4+4 days (with two weeks at home in-between). Both programs lasted 6-7 hours each day. The programs took place at Hysnes rehabilitation center, established as part of St. Olavs Hospital, in central Norway. *The outpatient program* consisted mainly of group-based ACT. The sessions were held at the Department of Physical Medicine and Rehabilitation at St. Olavs Hospital once a week for six weeks, each session lasting 2.5 hours. A more detailed description of the programs has been published elsewhere [12].

Questionnaires

Self-reported data on the Readiness for RTW scale and other questionnaires were collected via internet-based questionnaires at the start and end of the rehabilitation programs.

The Readiness for RTW scale [7] consists of two parts; part A is answered by individuals who are 100% sick listed and part B is answered by individuals who are working (includes graded sick leave). Part A consists of 22 items and part B of 12 items (online resource 1). Each item is answered on a 5-point scale from "strongly disagree" to "strongly agree". The wording of two questions was changed from "pain" and "injury" in the original scale to "health complaints" in the Norwegian version to include participants with other complaints. In the study by Franche et al. the items reflected four dimensions (hereafter referred to as the original dimensions) for individuals not working; precontemplation (items A1, A4, A22), Contemplation (A15, A20, A21), Prepared for action- self-evaluative (A9, A12R (reversed item scale), A13, A18) and Prepared for action- behavioral (A6, A10, A11). For individuals working there were two

dimensions; Uncertain maintenance (B8, B9, B10, B11R, B12) and Proactive maintenance (B2, B5, B6, B7). Franche et al. [7] described two approaches for scoring the questionnaire; 1) the multidimensional approach where a score is calculated for each dimension which was recommended for research, and 2) stage allocation where the individual is allocated to the stage corresponding to the dimension with the highest mean score and was recommended for clinical use. The dimension scores are calculated as the mean of the items it comprises (range 1-5). When using the multidimensional approach the term dimension is used for the different stages, while the term stage is used for the stage allocation approach. The dimensions found in the Norwegian validation study [8] (hereafter referred to as the Braathen dimensions) were RTW inability (A1, A4, A10R, A22) and RTW uncertainty (A18, A20, A21) for individuals not working, corresponding to the Precontemplation and Contemplation dimensions in the original scale. For individuals working they found Uncertain work maintenance (B2R, B6R, B8, B10) and Proactive work maintenance (B5, B7, B12R).

Expectations about length of sick leave were recorded using the question "For how long do you believe you will be sick listed from today?" with 6 response options "not at all", "less than 1 month", "1-2 months", "2-4 months, "4-10 months" and "more than 10 months". Categories "not at all", "less than 1 month" and "1-2 months" were combined to one category "less than 2 months" in the analyses.

Data on possible confounders such as age, gender, anxiety and depression symptoms (measured using The Hospital Anxiety and depression scale (HADS) [19]), length of sick leave, education and job status (having employment or not) were recorded at baseline.

Sick leave register data

Sick leave was measured using data from the National Social Security System Registry, where all individuals receiving any form of benefits in Norway are registered by their social security number. Medically certified sick leave is compensated with 100% coverage for the first 12 months. The first 16 days are covered by the employer, the rest by the Norwegian Welfare and Labour Administration. After 12 months of sick leave more long-term benefits may be offered in

the form of work assessment allowance and disability pension, which both covers approximately 66% of the income. Individuals on work assessment allowance are supposed to participate in modified work, but if this is not possible for medical reasons, the individual and the case manager develop a plan for later work resumption.

The data consisted of registrations of benefits from four different sources; sick-leave payments, sick leave certificates, work assessment allowance and disability pension. Participants were followed for 9 months after they ended the rehabilitation programs.

Two different measures of RTW were constructed; 1) *Sustainable RTW* was defined as one month without receiving medical benefits during follow-up and 2) *Work participation days* was measured as number of days not receiving medical benefits during follow-up, adjusted for graded sick leave, employment fraction and calculated as a 5-day work week.

Statistical analysis

The main analyses were based on the original dimensions by Franche et al. [7], and separate analyses were conducted according to work status (working/not working) at the end of rehabilitation. We used linear and logistic regression to assess associations between scores on the Readiness for RTW scale dimensions (four dimensions for those not working and two for those working) and the two RTW measures. The main analyses were adjusted for age, gender and education. Education level was dichotomized as high (college/university) or low. We used the results from the adjusted regression analyses to estimate the predicted probability of RTW and work participation days using average adjusted predictions (i.e. predictions were made with covariates constant at their means).

As the linearity assumption was not fully satisfied the analyses were repeated with the dimension scores categorized into 1.0-1.9, 2.0-2.9, 3.0-3.9 and 4.0-5.0. The analyses were also performed using the stage allocation approach described above. Changes in the dimension scores from before to after rehabilitation were compared using the Wilcoxon signed rank test, as they were

not normally distributed. Associations between the single expectation question and RTW were assessed by logistic and linear regression, as in the main analyses.

We compared how the Readiness for RTW dimensions and the single expectation question explained work outcomes using adjusted R^2/pseudo R^2. First we compared models including the different dimensions, both as continuous and categorical variables, but also with interactions between the dimensions. Secondly we compared models including the different dimensions with a model including the single expectation question.

We performed the following sensitivity analyses: 1) adjustment for type of rehabilitation program in addition to age, gender and education, 2) adjustment for length of sick leave at inclusion, total HADS score and whether the participant had a job (for those not working) in addition to the variables in the main analyses, and 3) we repeated the main analyses without participants who failed to answer the questionnaire within 30 days after rehabilitation. Cronbach`s alpha coefficients were calculated for both the original and the Braathen dimensions to assess the average covariance between items in the associated dimension construct.

We considered p-values (two-tailed) <0.05 to be statistically significant. Precision was assessed using 95% confidence intervals. All analyses were done using STATA 14.1 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

Results

In total, 217 participants answered the Readiness for RTW scale questionnaire at the end of the rehabilitation program and were included in this study (of the 334 participants who participated in the randomized clinical trials). Of these, 96 participants filled out the “not working” part of the questionnaire and 121 filled out the “working” part. Table 2 shows baseline characteristics of the two groups. Of the participants not working, 28 (29%) achieved sustainable RTW during 9 months follow-up and the median number of work participation days was 80 (interquartile range (IQR) 27-139). Of those working, 78 (64%) participants achieved sustainable RTW and the median number of work participation days was 165 (IQR 111-189).

TABLE 2 ABOUT HERE

Cronbach`s alphas for the original dimensions were; Precontemplation 0.78, Contemplation 0.72, Prepared for action- self-evaluative 0.64, Prepared for action-behavioral 0.59, Uncertain maintenance 0.65 and Proactive maintenance 0.70. Cronbach`s alphas for the Braathen dimensions were: RTW inability 0.64, RTW uncertainty 0.66, Uncertain work maintenance 0.41 and Proactive work maintenance 0.55. The original dimensions were therefore used in the subsequent analyses.

Associations between the Readiness for RTW scale and work outcomes: Multidimensional approach

For individuals not working two of the four dimensions were associated with a higher probability of sustainable RTW and more work participation days (figure 1, 2 and online resource 2); Prepared for action-self-evaluative ($p<0.001$) and Prepared for action-behavioral ($p=0.01$- 0.02). For persons working, high scores on the Uncertain maintenance dimension was associated with a lower probability of sustainable RTW ($p<0.001$) and fewer work participation days ($p<0.001$). None of the sensitivity analyses changed the conclusions. However, the associations were less clear when the main analyses were performed with the dimensions as categorical variables, but for the Prepared for action-self-evaluative and Uncertain maintenance dimensions some of the categories were still statistically significant (results not shown).

FIGURE 1 AND FIGURE 2 ABOUT HERE

Associations between the Readiness for RTW scale and work outcomes: Stage allocation approach

When using the stage allocation approach in the not working group 16 participants obtained the same score on two dimensions, in which 12 had the same score on two dimensions that were not adjacent regarding progression towards work (Contemplation and Prepared for action-

behavioral). One participant had equal scores on three dimensions. Excluding participants with ties gave 2 participants with the highest score in the Precontemplation stage, 40 in Contemplation, 4 in Prepared for action-self-evaluative, 31 in Prepared for action-behavioral, 91 in Uncertain maintenance and 25 in Proactive maintenance. When excluding the Precontemplation and Prepared for action-self-evaluative stages due to low numbers of persons, those in the Prepared for action-behavioral stage had a higher probability of sustainable RTW than those in the Contemplation stage and more work participation days in the follow-up period (online resource 3). Persons in the Uncertain maintenance stage had a higher probability for sustainable RTW and more work participation days than those in the proactive maintenance stage.

Changes during rehabilitation

Comparing scores at the start and the end of the rehabilitation programs showed a statistically significant increase in scores for three of the dimensions; Prepared for action- self-evaluative, Prepared for action-behavioral and Proactive maintenance (online resource 4). The change scores for Uncertain maintenance ($p=0.08$) and Prepared for action- self-evaluative ($p=0.05$) tended to be associated with work participation days during follow-up, and Uncertain maintenance also for sustainable RTW ($p=0.07$). However, none of the change scores were statistically significantly associated with sustainable RTW or work participation days during follow-up (results not shown).

The Readiness for RTW scale versus a single expectation question

The single question assessing the participants` expectations about length of sick leave was associated with both sustainable RTW and work participation days (table 3). For those working, there was a graded association between expected length of sick leave and work participation. For those not working there was not a clear association, but a noticeable difference between the less than 2 months category and the others. Although small, there was a larger explained variance in

models including the single expectation question compared to models including the different Readiness for RTW dimensions (online resource 5). Combining the different Readiness for RTW dimensions in the same model (according to work status), somewhat increased the explained variance, but still not more than the single expectation question.

TABLE 3 ABOUT HERE

Discussion

Three of the Readiness for RTW dimensions were associated with work outcomes. For participants not working, high scores on the Prepared for action-self-evaluative and Prepared for action-behavioral scale were associated with a higher probability of sustainable RTW and more work participation days. For those working, high scores on Uncertain maintenance was associated with a lower probability of sustainable RTW and less work participation days. Allocating participants to the dimension with the highest score was problematic due to several tied scores between (not necessarily adjacent) dimensions. Models including the Readiness for RTW dimensions were generally not as good at explaining work outcomes as models including a single expectation question.

The association between the Readiness for RTW scale and work outcomes has only been investigated in one previous study [9]. In that study Braathen and co-workers, based on fewer dimensions, reported an association between two of the dimensions and RTW; RTW inability (corresponds to precontemplation) and Proactive maintenance. In the present study the original dimensions gave higher Cronbach`s alphas than the Braathen dimensions. This was unexpected as the sample in our study should be considerably more similar to the sample in the study by Braathen et al. than the Canadian study, as both were done in Norway, and participants had similar diagnoses and sick leave duration. It should also be noted that the Cronbach`s alphas were not high for the three dimensions associated with work outcomes (between 0.59 and 0.65),

indicating that the items making up these dimensions do not measure the same construct very well.

The associations with work outcomes were stronger for higher scores on the Prepared for action-self-evaluative dimension than the action-behavioral dimension. This was somewhat surprising as the Prepared for action-behavioral dimension is closer to RTW according to the Readiness for RTW model. A possible explanation is the wording of the items constituting the dimensions. The items in the Prepared for action-self -evaluative dimension can be viewed as more precise in describing a RTW plan than the items in the Prepared for action-behavioral dimension, as it includes items like "you have a date for your first day back at work" and "you are not ready to go back to work" (reversely scored). The Prepared for action-behavioral items on the other hand are less precise. For example: "you are actively doing things to get back to work" and "you are getting help from others to return to work". This could explain the low Cronbach`s alpha (0.59) for the Prepared for action-behavioral dimension, which indicates that this dimension was not well captured by the items used, at least in this sample.

The stage allocation method, categorizing participants to the dimension where they reported the highest score, was problematic in this sample as several participants tied between different dimensions. Franche et al. [7] solved this by placing participants with ties in the least advanced dimension towards RTW. In our study, however; 13% of the participants in the not working group had their highest score on two dimensions that were not adjacent. Most of these were between Contemplation and Prepared for action-behavioral. The items included in the Contemplation dimension are quite generic: "I have been wondering if there is something I could do to return to work"; "I wish I had more ideas about how to get back to work", and "I would like to have some advice about how to get back to work". These are questions most people on long term sick leave would ask themselves, regardless of where they are in their RTW process. This was supported by the fact that about 50% of the participants scored 4 or higher on this item both at the start and the end of the program, with no statistically significant change. Hence, we suggest that the items in the Contemplation dimension should be revised. After excluding participants with ties between dimensions, participants were poorly distributed across the stages. This is in line with the previous studies; Braathen et al. [8] had to exclude two stages from the analyses due to low number of participants and Franche et al. [7] excluded one stage. In addition, for

individuals working, there was a higher probability of sustainable RTW for those allocated to the Uncertain maintenance stage than the Proactive maintenance stage, which is contradictory to the Readiness for RTW model.

The problems related to the stage allocation approach in this study might indicate that the Readiness for RTW scale in its present form does not satisfactory capture the stages of the RTW process. Another possibility is that the RTW process cannot be based on the same theories that describe other health behavior changes like smoking cessation. Obviously, motivational factors do play a role in any behavioral change, also when deciding to RTW after sick leave. However, the major difference between the RTW process and other health behavior changes may be the importance of contextual factors. Workplace factors like work demands, supervisor support and possibilities for work modifications and temporary flexible part-time work may be just as important for the RTW decision, as the readiness of the employee.

In line with previous studies for both musculoskeletal complaints [15] and common mental health disorders [16, 20], the single question assessing the participants` expectations about length of sick leave was associated with work outcomes. Models including the single expectation question were better than models including the Readiness for RTW dimensions for work outcomes. Therefore, if the goal is to just predict RTW, our results indicate that the single expectation question should be preferred over the Readiness for RTW questionnaire. However, the Readiness for RTW scale was also developed to assess the individual's stage of readiness for RTW and not merely predict RTW. However, the results of the present study suggest that more research is needed before it can be considered for clinical use.

Another application of the Readiness for RTW scale proposed by Franche et al. [7] is evaluation of RTW interventions. In this study we found that three of the dimensions changed during the interventions; Prepared for action- self-evaluative, Prepared for action-behavioral and Proactive maintenance, but their change scores were not associated with work outcomes. This could partly be due to lack of statistical power or effect of the rehabilitation programs, but there seems to be a floor and ceiling problem for some of the dimensions. The observed changes in scores were small, and there are currently no established values for clinically significant changes.

Due to the low number of participants achieving sustainable RTW we were not able to calculate areas under the receiver operating characteristic (ROC) curve, which would have been useful when comparing the dimensions in the Readiness for RTW scale with the single expectation question. Another limitation in this study, and a problem with the Readiness for RTW scale, is the possible misclassification of participants. In Norway, graded sick leave is commonly used and the question; "are you currently back at work", that determined if the participants received the "not working" or "working" questionnaire could be misunderstood in regard to whether it means working at all or working as normal. Also, 21% of the participants in the not working group did not have a job to return to and might relate differently to the questions than people who have a job. We did not have enough participants to do a subgroup analysis for this group. Another limitation was the number of missing questionnaires, 24% at the start of the rehabilitation programs and 35% at the end of the programs. However, we do not expect that the non-responders differ in the association between the Readiness for RTW scale and RTW compared to the responders. Hence, the missing questionnaires should not significantly affect the results besides the loss of statistical power. A third methodological consideration was the use of the dimensions as continuous variables. Some of them did not entirely meet the linearity assumption. The way we chose to categorize the variables gave a low number of participants in some categories, and therefore some categories had to be excluded from the analyses. Furthermore, using categorized variables also restricted the possibility to adjust for possible confounders. Therefore, we chose to report the dimensions as continuous variables in the main analyses, which mean that estimations should be interpreted with caution. A major strength of this study was the use of registry data on sick leave, which ensured no missing data or recall bias.

Conclusion

Three dimensions of the Readiness for RTW scale were associated with RTW outcomes; Prepared for action- self-evaluative, Prepared for action- behavioral and Uncertain maintenance. However, several weaknesses with the Readiness for RTW scale were established; high scores on the most advanced dimension towards RTW was not the one that predicted work outcomes best and stage allocation was problematic due to several ties between not necessarily adjacent

dimensions in the RTW-process. Models including the Readiness for RTW dimensions were generally not as good at explaining work outcomes as models including a single expectation question. Therefore, more research and probably revision of the instrument is needed if the Readiness for RTW scale is to be used for evaluation of interventions and as a useful tool in clinical settings.

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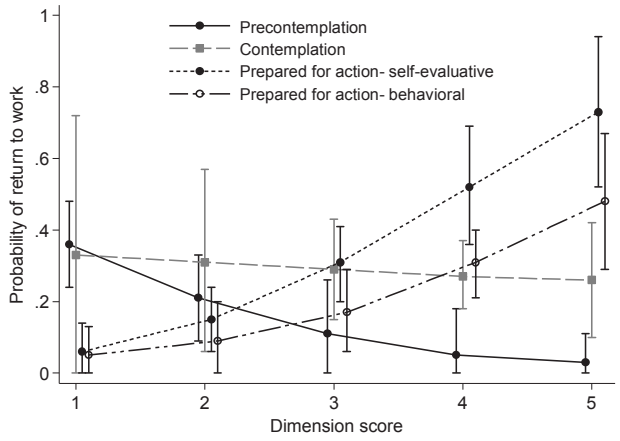
a)



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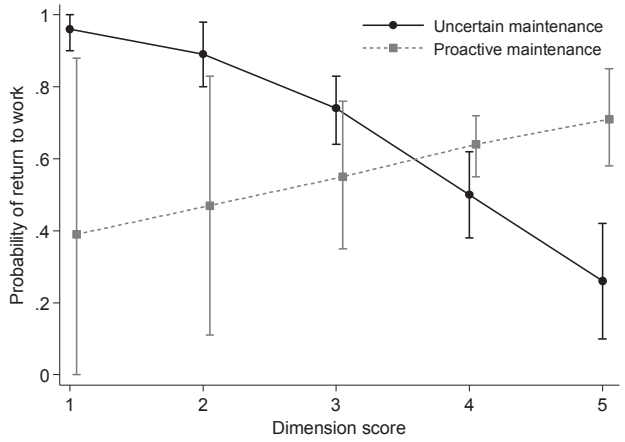
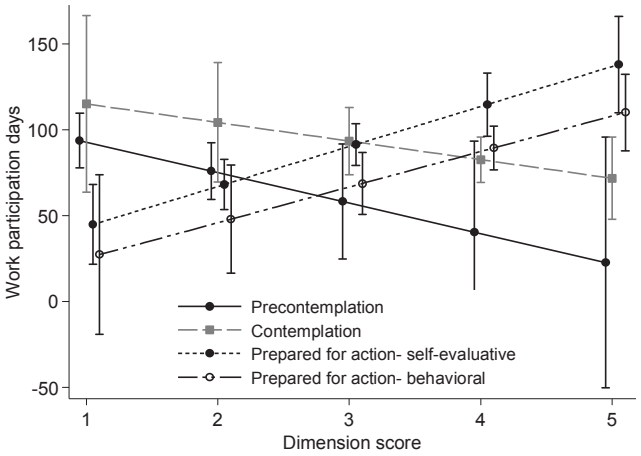


Figure 1 Estimated probabilities (with 95% confidence intervals) for sustainable return to work during 9 months of follow- up for the different dimensions (scale scores 1-5) in the (a) not working sample and (b) working sample. Analyses performed with logistic regression, adjustment for age, gender and education. For both samples N varied somewhat according to the number of missing information on each variable. Dimension scores measured at the end of rehabilitation.

a)



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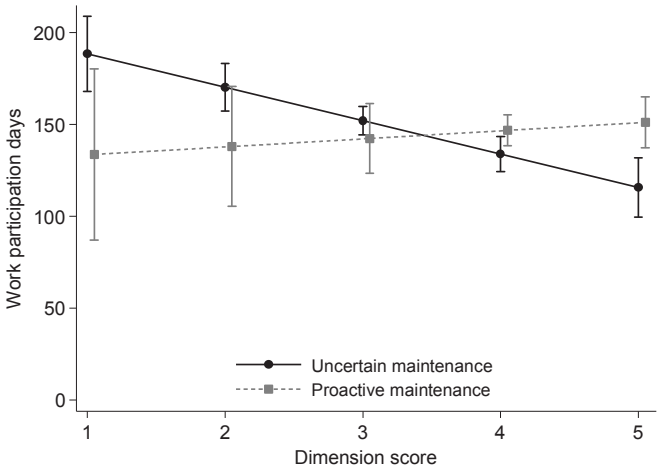

Figure 2 Estimated number of work participation days (with 95% confidence intervals) during 9 months follow- up for the different dimensions (scale 1-5) in the (a) not working sample and (b) working sample. Analyses performed with linear regression, adjustment for age, gender and education. For both samples N varied somewhat according to the number of missing information on each variable. Dimension scores measured at the end of rehabilitation.

Table 1 Description of the different stages in the Readiness for RTW scale

Stage	Description
Individuals not working	Individuals who are 100% sick listed
Precontemplation	The person is not thinking about starting behavior change with regards to RTW
Contemplation	The person has started to think about returning to work, but is still ambivalent and has no concrete plans
Prepared for action-self-evaluative	The person seeks information about RTW and make concrete plans for RTW
Prepared for action-behavioral	The RTW plans are set into action
Individuals working	Individuals who are partly or fully working (including graded sick leave)
Uncertain maintenance	The person has returned to work, but is struggling to stay at work
Proactive maintenance	The person has found good strategies for staying at work

Table 2 Participants` characteristics at the end of the rehabilitation programs (baseline in the main analyses)

	Not working[a] (n=96)	**Working[b] (n=121)**
Age[c] mean (SD)	47 (9.6)	47 (8.5)
Women n (%)	76 (79%)	102 (84%)
Higher education[c,d] n (%)	37 (39%)	58 (48%)
Employment fraction before inclusion[c] n (%)		
No work	20 (21%)	1 (1%)
Full time	51 (53%)	86 (71%)
Part time	17 (18%)	26 (21%)
Graded disability pension	8 (8%)	8 (7 %)
HADS mean (SD)		
Anxiety (0-21)	7.7 (4.4)	7.4 (3.9)
Depression (0-21)	6.1 (4.1)	6.0 (4.1)
Pain level mean (SD)		
Average pain (0-10)	4.1 (2.1)	4.1 (2.1)
Expectations about length of sick leave n %		
<2 months	24 (25%)	31 (26%)
2-4 months	29 (30%)	29 (24%)
4-10 months	21 (22%)	22 (18%)
>10 months	11 (11%)	14 (12%)
missing	11 (11%)	25 (21%)
Main diagnosis for sick-leave (ICPC-2)[e] n (%)		
A - general and unspecified	8 (8%)	10 (8%)
L - musculoskeletal	48 (50%)	70 (58%)
P - psychological	40 (42%)	41 (34%)
Length of sick leave at inclusion[e,f]		
median days (IQR)	232 (176-285)	215 (180-266)
Readiness for Return to Work median (IQR)		
Precontemplation (1-5)	1.0 (1.0-1.7)	
Contemplation (1-5)	4.0 (3.3-4.3)	
Prepared for action- self-evaluative (1-5)	2.5 (2.0-3.5)	
Prepared for action- behavioral (1-5)	4.0 (3.3-4.7)	
Uncertain maintenance (1-5)		3.4 (2.6- 4.0)
Proactive maintenance (1-5)		4.3 (3.9- 4.5)

[a] 100% sick leave
[b] Graded sick leave/working
[c] Measured at inclusion in the randomized trials
[d] Higher (tertiary) education: college or university
[e] Based on data from the National Social Security System Registry
[f] Number of days on sick leave during the last 12 months prior to inclusion. Measured as calendar days, not adjusted for graded sick- leave

Table 3 Associations between a single question assessing participants` expectations about length of sick leave answered at the end of rehabilitation and work outcomes during 9 months follow-up

	Estimated work participation days[a] (95% CI)	**Probability of sustainable return to work**[b] (95% CI)
Expectations about length of sick leave for participants not working (n=85)		
<2 months	127 (104- 150)	0.65 (0.47- 0.84)
2-4 months	72 (51- 94)	0.14 (0.01- 0.27)
4-10 months	61 (36- 86)	0.18 (0.02- 0.34)
>10 months	62 (28- 97)	0.08 (0.00- 0.22)
Expectation about length of sick leave for participants working (n=96)		
<2 months	167 (153- 181)	0.87 (0.75- 0.99)
2-4 months	138 (123- 152)	0.57 (0.39- 0.74)
4-10 months	122 (105- 139)	0.39 (0.19- 0.59)
>10 months	96 (74- 117)	0.15 (0.00- 0.33)

[a] Estimated from linear regression analyses with adjustment for gender, age and education (set at their mean)
[b] Estimated from logistic regression analyses with adjustment for gender, age and education (set at their mean)

Online resource 1 The Readiness for Return to Work questionnaire

Not working sample

Precontemplation dimension items

- I don`t think I will ever be able to go back to work (A1)
- As far as I`m concerned, there is no point in thinking about returning to work (A4)
- As far as I`m concerned, I don`t need to go back to work ever (A22)

Contemplation dimension items

- I have been wondering if there is something I could do to return to work (A15)
- I wish I had more ideas about how to get back to work (A20)
- I would like to have some advice about how to get back to work (A21)

Prepared for action – self evaluative dimension items

- Physically, I am starting to feel ready to go back to work (A9)
- I am not ready to go back to work (R) (A12)
- I have found strategies to make my work manageable so I can return to work (A13)
- I have a date for my first day back at work (A18)

Prepared for action – behavioral dimension items

- I am doing things actively now to get back to work (A6)
- I have been increasing my activities at home in order to build up my strength to go back to work (A10)
- I am getting help from others to return to work (A11)

Working sample

Uncertain maintenance dimension items

- I am back at work but not sure I can keep up the effort (B8)
- I worry about having to stop working again due to my health complaints* (B9)
- I still find myself struggling to stay at work due to my health complaints* (B10)
- I am back at work and it is going well (R) (B11)
- I feel I may need help in order to stay at work (B12)

Proactive maintenance dimension items

- I am doing everything I can to stay at work (B2)
- I have learnt different ways to cope with my health complaints so that I can stay at work* (B5)
- I am taking steps to prevent having to go off work due to my health complaints* (B6)
- I have found strategies to make my work manageable so I can stay at work (B7)

R: Item scale reversed

* “health complaints” was “injury” or “pain” in the original questionnaire.

Online resource 2 Associations between the Readiness for RTW dimensions and work outcomes (sustainable RTW and work participation days) during 9 months follow-up as scores increase one unit.

	Odds ratio for return to work (95% CI)[a]	Work participation days (95% CI)[b]
Not working		
Precontemplation (1-5)	0.46 (0.18-1.15)	-17.78 (-38.22- 2.66)
Contemplation (1-5)	0.91 (0.49- 1.68)	-10.83 (-28.30- 6.64)
Prepared for action- self evaluative (1-5)	2.54 (1.52- 4.22)	23.28 (11.92- 34.65)
Prepared for action- behavioral (1-5)	2.11 (1.13- 3.95)	20.71 (4.90- 36.51)
Working		
Uncertain maintenance (1-5)	0.33 (0.19- 0.58)	-18.17 (-26.49- -9.84)
Proactive maintenance (1-5)	1.44 (0.72- 2.87)	4.38 (-9.94- 18.70)

For both samples N varied somewhat according to the number of missing information on each variable. Dimension scores measured at the end of rehabilitation.

[a] Logistic regression adjusted for age, gender and education.

[b] Linear regression adjusted for age, gender and education.

Online resource 3 Associations between the Readiness for Return to Work stages (stage allocation) and work outcomes during 9 months of follow-up

	Estimated work participation days[a] (95% CI)	**Probability of sustainable return to work**[b] (95% CI)
Not working	**n=71**	**n=71**
Precontemplation[c]	-	-
Contemplation	63.7 (44.2- 83.3)	0.17 (0.06- 0.29)
Prepared for action-self evaluative[c]	-	-
Prepared for action-behavioural	100.9 (78.6-123.1)	0.42 (0.25- 0.60)
Working	**n=116**	**n=116**
Uncertain maintenance	151.3 (142.2-160.3)	0.70 (0.61- 0.79)
Proactive maintenance	133.5 (116.2- 150.8)	0.45 (0.27- 0.64)

Stage allocation based on scores on the Readiness for RTW scale at the end of rehabilitation.
[a] Linear regression, adjustment for gender, age and education
[b] Logistic regression, adjustment for gender, age and education
[c] Excluded due to low number of participants

Online resource 4 Scores on the Readiness for return to work dimensions at the beginning and at the end of rehabilitation.

	Pre-scores (before the start of the program) median (IQR)	**Post-scores (at the end of the program)** median (IQR)	**Median change** (IQR)	**Pre- vs post-scores p-value**[a]
Not working				
Precontemplation	1.3 (1.0-1.7)	1.3 (1.0-1.7)	0 (-0.3- 0)	0.333
Contemplation	4.0 (3.7-4.3)	4.0 (3.7-4.3)	0 (-0.3- 0.3)	0.355
Prepared for action-self evaluative	2.5 (2.0-3.0)	2.5 (2.0-3.5)	0.3 (-0.3- 1)	0.006
Prepared for action-behavioral	3.7 (3.3-4.0)	4.0 (3.3-4.7)	0.3 (-0.3- 0.7)	0.014
Working				
Uncertain maintenance	3.6 (3.0-4.0)	3.4 (2.7- 4.0)	0 (-0.4- 0.2)	0.220
Proactive maintenance	4.0 (3.5-4.3)	4.3 (4.0- 4.5)	0.3 (0- 0.8)	<0.001

For both samples N varied somewhat according to the number of missing information on each variable.
[a] Pre- and post-scores compared with Wilcoxon signed rank test

Online resource 5 Measures of explained variance (adjusted R^2 and pseudo R^2) from the regression models for each of the outcomes used in the article - including separate models for each of the Readiness for RTW dimension scores, models with all the dimension scores included and models with the single expectation question.

	Outcome measures	
	Work participation days[a]	**Probability of sustainable RTW**[b]
	Adjusted R^2	Pseudo R^2
Not working		
Precontemplation	0	0.02
Contemplation	0	0.01
Prepared for action-self-evaluative	0.10	0.10
Prepared for action-behavioral	0.08	0.09
All four dimensions[c]	0.13	0.13
Expectations about length of sick leave	0.14	0.19
Working		
Uncertain maintenance	0.17	0.18
Proactive maintenance	0.03	0.05
Both dimensions[d]	0.16	0.18
Expectations about length of sick leave	0.24	0.23

[a] Linear regression adjusted for age, gender and education.
[b] Logistic regression adjusted for age, gender and education.
[c] All four dimensions for participants not working included in the same model
[d] Both dimensions for participants working included in the same model

Appendix

Appendix

Table 1 The Readiness for Return to Work questionnaire

Not working sample

Precontemplation dimension items
- I don`t think I will ever be able to go back to work (A1)
- As far as I`m concerned, there is no point in thinking about returning to work (A4)
- As far as I`m concerned, I don`t need to go back to work ever (A22)

Contemplation dimension items
- I have been wondering if there is something I could do to return to work (A15)
- I wish I had more ideas about how to get back to work (A20)
- I would like to have some advice about how to get back to work (A21)

Prepared for action – self evaluative dimension items
- Physically, I am starting to feel ready to go back to work (A9)
- I am not ready to go back to work (R) (A12)
- I have found strategies to make my work manageable so I can return to work (A13)
- I have a date for my first day back at work (A18)

Prepared for action – behavioral dimension items
- I am doing things actively now to get back to work (A6)
- I have been increasing my activities at home in order to build up my strength to go back to work (A10)
- I am getting help from others to return to work (A11)

Working sample

Uncertain maintenance dimension items
- I am back at work but not sure I can keep up the effort (B8)
- I worry about having to stop working again due to my health complaints* (B9)
- I still find myself struggling to stay at work due to my health complaints* (B10)
- I am back at work and it is going well (R) (B11)
- I feel I may need help in order to stay at work (B12)

Proactive maintenance dimension items
- I am doing everything I can to stay at work (B2)
- I have learnt different ways to cope with my health complaints so that I can stay at work* (B5)
- I am taking steps to prevent having to go off work due to my health complaints* (B6)
- I have found strategies to make my work manageable so I can stay at work (B7)

R: Item scale reversed, * “health complaints” was “injury” or “pain” in the original questionnaire.