Doctoral theses at NTNU, 2020:336

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Doctoral thesis

NTNU
Norwegian University of Science and Technology
Thesis for the Degree of
Philosophiae Doctor
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Department of Public Health and Nursing

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ISBN 978-82-326-5018-7 (printed ver.)
ISBN 978-82-326-5019-4 (electronic ver.)
ISSN 1503-8181

Doctoral theses at NTNU, 2020:336

Printed by NTNU Grafisk senter

For every ailment under the sun
There is a remedy, or there is none;
If there be one, try to find it;
If there be none, never mind it.

Mother Goose Rhyme (1695)

Avhandling er funnet verdig til å forsvares offentlig

for graden PhD i klinisk medisin

Disputas finner sted digitalt onsdag 4. november, kl. 12.15

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***Finansieringskilde*:**

Helse Midt-Norge / Hysnesprosjektet

Sammendrag (Summary in Norwegian)

Bakgrunn: Arbeidsrettede rehabiliteringsopphold har vært utbredt praksis i flere nordiske land, sannsynligvis med røtter tilbake til den europeiske kurbadtradisjonen og behandling av tuberkulosepasienter. Dagens arbeidsrettede rehabiliteringsinstitusjoner er fremdeles oftest plassert i geografisk isolerte og naturskjønne omgivelser. Som for tidligere tiders kurbad, er det god tilgang til natur, frisk luft og muligheter for fysisk aktivitet. Til tross for en lang klinisk tradisjon med ressurskrevende behandling har imidlertid kunnskap om effektene av denne typen arbeidsrettet rehabilitering manglet. Da Hysnes Helsefort ble opprettet i 2010, initierte Helse Midt-Norge et forskningsprosjekt for å undersøke effektene av arbeidsrettet rehabilitering på Hysnes Helsefort i et samarbeid mellom St. Olavs Hospital og NTNU.

Rehabiliteringstilnærmingen ved Hysnes Helsefort var tverrfaglig og multimodal med bruk av ulike elementer som fysisk aktivitet/trening, gruppebasert og individbasert undervisning/refleksjon, involvering av familie/nettverk og koordinering/utarbeiding av en plan for retur til arbeid. I tillegg ble ACT (Acceptance and Commitment Therapy), en ny type verdibasert kognitiv atferdsterapi, innlemmet i alle deler av rehabiliteringen. For å kunne måle effektene av intervensjonene med solide vitenskapelige metoder opprettet St. Olavs hospital også et 6 uker langt poliklinisk mestringstilbud (ACT i gruppe) for sammenligning. Deltakere ble fordelt tilfeldig (randomisert) til inneliggende rehabilitering på Hysnes eller poliklinisk ACT gruppe gjennomført ved klinikk for fysikalsk medisin og rehabilitering.

Metode: Denne avhandlingen er basert på resultatene fra to randomiserte studier gjennomført ved Hysnes Helsefort i perioden 2012-2014. Deltakerne ble invitert via NAV og var sykmeldte (>50%) med vanlige muskelskjelett- og/eller psykiske helseplager. Den ene studien undersøkte effektene av et kort opphold på Hysnes (4+4 dager, hvor deltakerne hadde to uker hjemme imellom). Den andre studien undersøkte effektene av et 3,5 ukers arbeidsrettet rehabiliteringsopphold, vanlig lengde for slik rehabilitering i Norge. NAVs registre ble brukt for å undersøke effektene på sykefravær. Helserelaterte utfallsmål ble målt med validerte spørreskjema. Siden ACT var en helt ny tilnærming innen arbeidsrettet rehabilitering ønsket vi også å undersøke om og hvordan deltakernes erfaringer reflekterte ACT prosessene. Jeg gjennomførte derfor 5 fokusgruppe-intervju med til sammen 22 deltakere på slutten av det 3,5 uker lange oppholdet.

Resultater: Deltakere i det lange oppholdet på Hysnes Helsefort hadde (i median) 32 færre utbetalte sykefraværsdager i løpet av et år sammenliknet med poliklinisk ACT-gruppe. Helsen bedret seg i begge grupper. Det var imidlertid ingen klinisk viktige forskjeller mellom gruppene (Paper I).

Gjennom analyse av fokusgruppeintervjuene fant vi at deltakernes erfaringer i det lange oppholdet reflekterte alle relevante prosesser i ACT rettet mot å øke deltakernes psykologiske fleksibilitet. Det var imidlertid variasjon. Spesifikke ACT prosesser relatert til økt selvbevissthet var ikke tydelig gjenkjennbare i deltakernes erfaringer. Litt overraskende var det at ingen av deltakerne nevnte konkrete planer om retur til arbeidet. De snakket isteden om verdibaserte endringer hvor arbeid var nevnt som en del av en større endringsprosess som ville ta lang tid og kreve mye av dem (Paper II)

Reduksjon av fryktunngåelse, målt med FABQ (fear avoidance beliefs questionnaire score), er en annen mulig mekanisme for økt arbeidsdeltakelse. I min siste studie (Paper III) slo vi sammen data fra de to randomiserte studiene for bedre å kunne bedømme hvilken påvirkning intervensjonene hadde. Vi fant ingen effekt på endringer i FABQ ved sammenlikning av deltakerne i de to intervensjonsgruppene på Hysnes og deltakere som fikk poliklinisk ACT-gruppe. For alle deltakere var reduksjon i FABQ eller konstant lav FABQ gjennom rehabiliteringsperioden likevel assosiert med mindre sykefravær. Et interessant nytt funn var at assosiasjonen mellom lav FABQ og lite sykefravær var sterkest for deltakerne som var sykmeldt for psykiske helseplager.

Konklusjon: Forskningen jeg har presentert i denne avhandlingen gir støtte til dagens praksis med 3,5 ukes arbeidsrettet tverrfaglig inneliggende multikomponent rehabilitering for personer med vanlige muskel-skjelettplager og psykiske lidelser. Mekanismene for effekten av det lange oppholdet er imidlertid ikke klarlagt (det korte oppholdet hadde ingen effekt på sykefraværet). Deltakerne følges videre, i første omgang med en 2-års oppfølging hvor helse-økonomiske analyser vil inngå. Videre forskning basert på Hysnes-data vil bidra til å øke kunnskapsgrunnlaget, og vil derigjennom kunne gi bedre grunnlag for politiske prioriteringer.

Acknowledgements

The number of people who deserve recognition surmount the space available here. In addition to the many people who gave their professional contributions, I am indebted to just as many on a personal level for support and encouragement. My heartfelt gratitude to all those who have contributed directly to the research in this thesis and indirectly by sustaining my curiosity in research, in life itself and for raising me up. Thank you for simply being awesome people making it all worth-while. You know who you are. Suffice to say, I can only acknowledge a few of you by name here:

To my relentless group of supervisors: Marius Steiro Fimland, my main supervisor, thank you for always finding time for supervision when needed. The same goes for my co-supervisors Egil Fors, Marit By Rise and Ottar Vasseljen. Through their diverse competencies and unique personalities, each has contributed in ways that could not have been possible for any single person. Thank you for being available, for challenging me and intellectually stimulating me over so many years. Also, to emeritus Roar Johnsen, I will forever be grateful for our discussions. Through your vast experience and insights, you have ignited me to seek new perspectives and higher levels of enlightenment.

In addition to my formal supervisors, I have had many informal helpers. Many of them at the 5th floor of ISM: My dear colleague Lene Aasdahl, you have been of invaluable help regarding the statistical analysis' in addition to raising me up with your always kind and cheerful attitude. My dear colleague Karen Hara, through sharing office(s) as well as nearly everything else as my office cohabitant, I am forever indebted to you for your support in so many areas. To the rest of the people at the 5th floor of ISM, particularly Paul Jarle Mork, thank you for contributing to a work environment and culture of sharing wisdom and knowledge, always spiking my interest with intelligent discussions. For the same reasons I extend my gratitude to Solveig Osborg Ose who along with Gunn Hege Marchand and myself constitutes the Research and development unit for health and work in Central Norway. At NAV (the Norwegian national labour and welfare service), significant collaborators are too many to be mentioned by their individual names.

To Ulrich Schattel, Svein Øverland and Cecilie Parelius, thank you for numerous invaluable discussions and for your effort in establishing and running the outpatient ACT group. Your work was essential to conducting the randomized trials. To Bjørn Skogstad, the head of the department of physical medicine and rehabilitation, St. Olavs Hospital, and to Janne-Birgitte Børke, thank you for believing in me, letting me take my leave to do research and making sure that the outpatient clinic has always been running in my absence. Thank you to all the clinicians at the outpatient back-neck-shoulder pain clinic for constantly working so hard to improve the services we provide to the patients, despite being overloaded with work at times. A special note of gratitude to Magne Rø, without whom I doubt I would have entered research in the first place.

Finally, I want to express my gratitude to the most important people in my life who make it all worthwhile – my friends and family! To my friends Ole Martin Hafsmo, Øystein Kjelling, Andrea Spranger, Sibylla Ramsay, Michaela Ledesma, Cecilie Løften Verkand, Will and Jenny Napier, Alexander Waage and Silas Spence, thanks for all the support. To my parents Anne and Svein Gismervik I want to express gratitude for your seemingly endless vitality, kindness and support. I am lucky to still have you so close in my everyday life. To my dear sister Kristine Gismervik, you finished your PhD way ahead of me, and you continue to inspire me by your stamina! To my five children Victor, Lykke, Oskar, Edgar, Iris, my daughter in law Sunniva and my granddaughter Ildri: I love you all and hope that we will spend even more time together in the time to come. Ultimate gratitude to you Gunnhild Breirem – you make my heart sing every day and help adjust my compass, so I find my way home every time. I would be lost without you.

This thesis probably does not answer ‘The Ultimate Question of Life, the Universe, and Everything” (the answer is still 42 by the way[1]). Such questions are probably best left to the arts. Nevertheless, thank you for reading this far and hopefully honoring my efforts by reading on. The rest of this thesis took me considerably more efforts to complete.

[1] https://en.wikipedia.org/wiki/Phrases_from_The_Hitchhiker%27s_Guide_to_the_Galaxy

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Inpatient multimodal occupational rehabilitation reduces sickness absence among individuals with musculoskeletal and common mental health disorders: a randomized clinical trial. Scandinavian Journal of Work, Environment & Health (Epub Date 05.01.2020).
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II. Sigmund Østgård Gismervik, Marius Steiro Fimland, Egil Andreas Fors, Roar Johnsen and Marit By Rise (2019).

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Changes in fear-avoidance beliefs and work participation after occupational rehabilitation for musculoskeletal- and common mental disorders: secondary outcomes of two randomized clinical trials. Journal of Rehabilitation Medicine 51(3): 175-182.
https://doi.org/10.2340/16501977-2520

Acronyms and abbreviations

ACT, Acceptance and commitment therapy.

AAQ-II, Acceptance and action questionnaire, second edition.

FABQ, Fear avoidance beliefs questionnaire.

I-MORE, Inpatient multimodal occupational rehabilitation program lasting 3.5 weeks.

NAV, Norwegian national labour and welfare service.

O-ACT, Outpatient acceptance and commitment therapy program.

OECD, Organisation for economic cooperation and development.

Short program, Inpatient rehabilitation during 4+4 days, separated by 2 weeks at home.

Summary

Background: Inpatient multimodal occupational rehabilitation programs are common in several parts of the world, probably rooted in a sanatorium tradition historically dating back to the era of tuberculosis and mental asylums. In Norway, sickness absent individuals are typically admitted to rurally located rehabilitation facilities for 3-4 weeks. However, hitherto, this practice lacks scientific support. Hence, when a new rural rehabilitation centre (Hysnes Helsefort) was established in 2010, several randomised trials commenced to scientifically investigate inpatient occupational interventions.

The 'Hysnes' rehabilitation centre accepted participants on sick-leave benefits due to musculoskeletal or common mental health disorders. All rehabilitation programs were group-based and included different diagnosis within the same intervention. To make this a workable strategy, all programs contained complex interventions, i.e. composed of multiple components such as physical exercise, creating a plan for return to work aiming to coordinate stakeholders and different sorts of therapy delivered by a multidisciplinary team. In addition, all programs integrated Acceptance and Commitment Therapy (ACT) as the main coping strategy. ACT is a new mindfulness-based approach stemming from the cognitive behavioural therapy tradition. In this thesis, I present results related to two randomised clinical trials assessing effects of different programs implemented at the above-mentioned 'Hysnes Helsefort'.

Methods: We conducted two randomised clinical trials with parallel groups. One assessed the effects of an inpatient rehabilitation program lasting 4+4 days separated by 2 weeks at home (The Short program). The other assessed the effects of 3.5 weeks of inpatient multimodal occupational rehabilitation (I-MORE) in line with the common practice in Norway. Both randomised trials were designed with outpatient group-based ACT (O-ACT) as the comparative arm.

Fully integrating ACT in inpatient occupational rehabilitation has never been done before. Hence, it was important to examine patient experiences. This could also help evaluate fidelity of the delivery of the ACT intervention. These qualitative research questions were explored within focus group interviews conducted with participants in I-MORE at the end of their stay.

Results: My research show that I-MORE saved a median of 32 workdays and about halved the time to sustainable return to work among individuals with musculoskeletal or common mental disorders during one year of follow-up. Self-reported health outcomes largely improved over time (pain, distress and health-related quality of life) but did not differ between the groups.

In focus group interviews assessing experiences among I-MORE participants, the ACT specific processes of behavioural change were largely reflected in their experiences after I-MORE, indicating fidelity of delivery as intended. However, contrary to what we expected, there was little talk among participants about committed actions leading to imminent return to work.

Reduction of fear avoidance is another candidate mechanism for explaining reduction of sickness absence. By combining data from the two randomised trials to increase statistical power, we showed that a low FABQ (fear avoidance beliefs questionnaire) score at baseline and reduction of FABQ score during rehabilitation was associated with reduction in sickness absence. In addition, we found the FABQ scores to be more strongly associated with return to work for participants with common mental disorders than for participants with musculoskeletal disorders. However, neither I-MORE nor the Short program reduced FABQ scores more than O-ACT.

Conclusions: The research in this thesis contributes with evidence supporting the current practice of I-MORE lasting 3.5 weeks in Norway (no effect found for the Short program). Neither the qualitative nor the quantitative research presented in this thesis pinpointed any specific mechanisms explaining the superiority of I-MORE. Continued research on the Hysnes project data will further increase the knowledge base. Moreover, the I-MORE participants are still under follow-up and the upcoming analysis of 2-year data will feature a health economic analysis. This may aid the development of future evidence-based policies.

1 BACKGROUND

This thesis presents and discusses three studies that focused on i) the effect of a 3.5 weeks inpatient multimodal occupational rehabilitation program (I-MORE) on sickness absence, ii) the participant's experiences with the acceptance and commitment therapy (ACT) approach as implemented in I-MORE, and iii) the utility of the fear avoidance beliefs questionnaire (FABQ) in the context of occupational rehabilitation. The three studies included individuals sick-listed due to common musculoskeletal- and/or mental disorders. In the following, I will briefly account for the epidemiology of common musculoskeletal- and mental disorders in sickness absence including their societal costs. In addition, I will review the evidence on previous successful multimodal occupational rehabilitation interventions for individuals sick-listed with these diagnoses. Furthermore, I will provide a review of relevant theoretical perspectives as background for later discussion. I will put emphasis on the basic behavioural theory that led to development of the both the fear avoidance belief- and the ACT models. Finally, as contextual background relevant for interpretation of the research presented in this thesis, I will give an overview of the Norwegian social security system.

1.1 THE EPIDEMIOLOGY OF COMMON DISORDERS IN SICKNESS ABSENCE

Common musculoskeletal complaints (e.g. back- and neck pain) and mental health disorders (e.g. depression and anxiety) account for the most years lived with disability in the western world (Knudsen et al. 2012, Murray et al. 2013). With the addition of fatigue, these common diagnoses account for approximately 70% of all long-term sickness absence in Norway[a]. Moreover, the presence of a mental health disorder is strongly associated with socioeconomic deprivation and comorbid physical disorders, indicating a socioeconomic component of complex comorbidity (Barnett et al. 2012).

[a] www.nav.no

1.1.1 Comorbidity among individuals on sickness absence and recent trends

Comorbidity between musculoskeletal- and common mental health disorders is highly prevalent among individuals on sickness absence. Among individuals sick-listed with back pain undergoing the 'mini-international neuropsychiatric interview', ~30% fulfilled the criteria for a psychiatric disorder (Reme et al. 2011) and in a similar population of sick listed individuals with back pain, ~29% reported psychological stress above cut-off for depression and ~40% for anxiety (Marchand et al. 2015a). Among individuals with chronic widespread pain, comorbid major depressive disorder is reported in 65% of cases (Loge-Hagen et al. 2019). Among individuals referred by their general practitioner to a 3.5 weeks inpatient occupational rehabilitation program, 78% reported at least two overlapping symptoms of pain, fatigue or anxiety/depression and 40% reported having all of the above (Hara et al. 2017b). Finally, among individuals granted permanent disability pension in Norway, the officially registered diagnoses in the disability claim overlap 10-12% between musculoskeletal- and common mental disorders (Lindbol and Ellingsen 2018).

There seems to be a slight decline in the societal impact of back pain in Europe (Lambeek et al. 2011) whereas mental health disorders are on the rise as an increasing attributed cause of work disability (OECD 2015). This has also been the trend in Norway. In 2001-2003, 36% of granted permanent disability benefits were registered due to musculoskeletal disorders and 24% due to mental disorders (Knudsen et al. 2012). However, since 2011, common mental disorders have surpassed musculoskeletal complaints as the primary cause of granted permanent disability pensions in Norway (Lindbol and Ellingsen 2018). Interestingly, a gender difference persists in the attributed causes of permanent work disability with mental health disorders most common in men (40%), and musculoskeletal disorders most common in women (34%) (Lindbol and Ellingsen 2018). However, among young individuals granted permanent disability pension, mental health disorders is the most common cause of disability in both genders (Lindbol and Ellingsen 2018).

1.1.2 Societal costs of disability and why return to work is advocated

Back pain and depression are two single diagnoses causing disability linked to a major economic burden on modern societies. A study assessing costs of back pain in the EU estimated that the yearly expenditure was €116-€209 per capita (Dagenais et al. 2008). Mental disorders has an estimated cost of 3-4% of the GDP in the EU (Wittchen et al. 2011)

and in UK alone, 45.6 million workdays are estimated lost each year (with another 32.4 million days estimated lost due to subthreshold symptoms of common mental disorders) (Rai et al. 2010). Considering that the current population of the EU is above 500 million people, even small reductions in work disability due to musculoskeletal- and common mental health disorders can amount to a large societal profit. In addition to the significant burden on society, musculoskeletal- and common mental health disorders constitute a significant burden for the individual as well as their families.

Short-term sickness absence can be a necessary measure to handle intercurrent disease that leads to reduced functioning. However, with longer lasting disability due to common musculoskeletal- or mental health disorders, the literature supports returning to work as the usually healthier option for the individual, that also reduces the risk of long-term disability (Waddell and Burton 2006, OECD 2015). OECD has therefore raised the concern that extensive income support systems such as in Norway, may worsen the prognosis in sick-listed individuals if allowing avoidant behaviour that result in permanent exclusion from the labour market (OECD 2013).

1.1.3 The timing of interventions in prolonged sickness absence

Among individuals sick-listed due to back pain, 70-80% return to work within 3 months (Frank et al. 1998). However, beyond 3 months duration of sickness absences, the probability of return to work is low both in individuals with musculoskeletal and common mental health disorders (Nossen and Brage 2016). Hence, sickness absence duration of approximately 3 months has been suggested as the 'golden hour' for initiating occupational rehabilitation interventions (Loisel et al. 2001). However, since multimodal occupational interventions has proven to be effective at different lengths of sickness absence durations the notion of this 'golden hour' is debatable (Aasdahl and Fimland 2019).

Since effective prevention strategies or specific cures for musculoskeletal and common mental health disorders is nowhere in sight, we need to further develop evidence-based interventions that take into consideration the comorbidity among the most common causes of long-term disability, i.e. musculoskeletal pain, common mental health-, and stress-related disorders.

1.2 EVIDENCE-BASED MULTIMODAL OCCUPATIONAL INTERVENTIONS

1.2.1 Components of return to work interventions in a clinical context

Most evidence-based clinical interventions on sickness absence have incorporated one or more components such as physical exercise (Schaafsma et al. 2013), brief education/fear-reducing techniques (Brox et al. 2008), psychotherapy (Finnes et al. 2019) or work place interventions (van Oostrom et al. 2009, Cullen et al. 2018).

Regular leisure-time physical activity has been associated with reduced risk of disability pension in large cohort studies (Fimland et al. 2015, Fimland et al. 2018). However, even though occupational rehabilitation may improve cardiovascular fitness (Nordstoga et al. 2018) and increased self-reported vigorous physical activity during rehabilitation has been associated with reduced sickness absence in registry data, it has been difficult to establish increased physical activity as an effect of inpatient multimodal occupational rehabilitation (Skagseth et al. 2019a). Psychoeducation is another commonly incorporated component in occupational rehabilitation (Pedersen et al. 2014). However, as a single component return to work intervention it has not proven effective (Pedersen et al. 2015). Moreover, a recent meta-analysis concluded that standalone psychological interventions (cognitive behavioural therapy) does not seem to be more effective compared to other active interventions (e.g. physical therapy) on return to work for individuals with musculoskeletal- or common mental health disorders, although psychotherapy is probably more effective than treatment as usual (Finnes et al. 2019).

Hence, it remains uncertain which exact mix of components is most effective in occupational rehabilitation. Nevertheless, among sick listed workers with musculoskeletal or common mental disorders, multidisciplinary interventions integrating several components and return to work coordination seems to be beneficial (Cancelliere et al. 2016). In addition, factors such as educational level, socio-economic status, level of self-efficacy/positive expectations, and severity of the disorder in question, affect return to work rates (Cancelliere et al. 2016). Clinical interventions can target some of these, e.g. expectations and the level of symptoms/disability caused by the health problem in question. Hence, a multimodal approach seems warranted for occupational rehabilitation interventions targeting musculoskeletal pain or common mental health disorders.

In Appendix 1, I provide a more detailed evidence table; summarising results from randomised trials published on the effects of different multimodal occupational interventions tested in different countries. This evidence table has been adapted and updated from Aasdahl and Fimland (2019) with permission from the authors. Below, I will give a brief account of the randomised studies that are most relevant to the topic of this thesis.

1.2.2 Interventions targeting musculoskeletal disorders

Most randomised trials reporting effect of multimodal interventions have focused on individuals with back pain (Lindstrom et al. 1992, Indahl et al. 1995, Loisel et al. 1997a, Hagen et al. 2000, Anema et al. 2007, Lambeek et al. 2010) or other musculoskeletal disorders (Bultmann et al. 2009). Moreover, most studies only included individuals on short-term sickness absence (<3 months). The study by Lambeek et al. (2010) is an exception where the median duration of sickness absence among the participants was 150 days at inclusion. This study reported impressive results with the median duration of sickness absence until sustainable return to work for the integrated care group was 88 days after randomisation, compared to 208 days in the usual care group (Lambeek et al. 2010). The integrated care intervention had a particularly strong emphasis on coordination between stakeholders in addition to integrating multimodal components in a coordinated multidisciplinary team approach. The study was conducted in the Netherlands where the liability of economic burden of sickness absence rests heavily on the employer. Conducting the study in a different context, e.g. a country like Norway where different legislation mostly leave the state economically responsible, may have led to a different outcome.

1.2.3 Interventions targeting common mental health disorders

For common mental disorders, fewer effective interventions have been reported on return to work outcomes than for musculoskeletal disorders. Two studies conducted in the Netherlands have reported effect of graded activity (gradual return to work) combined with a workplace intervention among individuals on short-term sickness absence due to adjustment disorder (van der Klink et al. 2003) and work-related psychological complaints (Blonk et al. 2006). Even though the latter study incorporated classical cognitive behavioural therapy in a successful multimodal approach they found no effect of cognitive behavioural therapy as a standalone intervention compared to the control group receiving two brief sessions with a general practitioner (Blonk et al. 2006). These two studies were conducted in the Netherlands

and both targeted short-term sickness absence (<3 months). A third study conducted in Norway, found its most profound effect for the subgroup of participants on long-term sickness absence. This study assessed the effect of an intervention combining individual job support with work-focused cognitive behavioural therapy for individuals with common mental disorders and treatment as usual was the comparison (Reme et al. 2015a). In addition, supported employment interventions such as Individual Placement and Support have proven to be an effective add-on to ordinary specialist care for moderate to severe mental illness (Reme et al. 2019).

1.2.4 Interventions targeting both musculoskeletal and mental health disorders

Since comorbidity between musculoskeletal and common mental health disorders is so common, the feasibility of interventions adopting approaches capable of handling both diagnostic groups are of interest (Hara et al. 2017b). However, to my knowledge only three randomised trials have recruited individuals with either musculoskeletal or common mental health disorders, provided them with the same occupational rehabilitation intervention and assessed the effect on sickness absence of such interventions (Lytsy et al. 2017, Aasdahl et al. 2018, Sveinsdottir et al. 2019). Two of these studies incorporated a similar approach based on ACT. One study assessed the effect of a short inpatient program (4+4 days of inpatient multidisciplinary rehabilitation) compared with a 6-week outpatient intervention (Aasdahl et al. 2018). Another study compared an outpatient multidisciplinary team assessment and individually tailored rehabilitation, a stand-alone individualized ACT intervention with usual care serving as a control group for both of these interventions (Lytsy et al. 2017). None of the studies found an effect on the number of reimbursed days of sickness absence or the return to work rate, using national insurance registry data as outcome. The third study recruited young adults that were not in employment, education or training and that received a medical social support benefit (work assessment allowance) due to various social or health-related problems. The participants were randomised to individual placement and support (a place and train approach where working with a job specialist aim to provide payed work) or traditional vocational training (featuring a train, then place approach where traineeship was first offered in a sheltered business and participants had to find competitive work later). Individual placement and support (place, then train) was superior to the traditional vocational (train, then place) approach during 12-months follow up on self-reported paid work (Sveinsdottir et al. 2019).

1.2.5 Effects on subgroups, potential for timing of interventions and stratified care

Several randomised trials have failed to show effect on sickness absence of different multimodal approaches for musculoskeletal disorders (Haldorsen et al. 2002, Jensen et al. 2011, Vermeulen et al. 2011, Myhre et al. 2014, Reme et al. 2016, Brendbekken et al. 2017, Gross et al. 2017a, Moll et al. 2018) and common mental disorders (van Oostrom et al. 2010, Vlasveld et al. 2013a, Lammerts et al. 2016b, Dalgaard et al. 2017, Finnes et al. 2017, Salomonsson et al. 2017b).

However, individuals with the most complex problems in a stratified care intervention for musculoskeletal disorders (Haldorsen et al. 2002) and female (but not male) participants with widespread pain (Skouen et al. 2006), returned to work faster when provided with extensive outpatient rehabilitation. Moreover, in the study by Reme et al. (2015a), combining work-focused cognitive behavioural therapy with individual job placement and support for common mental disorders, the largest and most sustained effect at 4 years follow-up was found among the sub-group of individuals receiving work assessment allowance (Overland et al. 2018). Receiving work assessment allowance in Norway imply more complex cases of sickness absence lasting more than one year. Moreover, these individuals often lack an employer. Hence, an individual job placement and support modality could potentially have a larger effect in this subgroup.

There are several possible reasons for a lack of effect on sickness absence in intervention studies, e.g. wrong timing of the intervention, a heterogeneous group of participants where interventions efficient for a subgroup may not be able to show a significant effect on the group level. In addition, different cultural and contextual factors could influence the effects of interventions (e.g. through legislations and national insurance systems differing between countries). Based on the abovementioned studies and those summarized in Appendix 1, workplace interventions seem to be best documented for short-term sickness absence and show good results in the context of the insurance systems of Canada and the Netherlands. Extensive multimodal occupational rehabilitation interventions may be most warranted for subgroups of individuals with longer lasting problems and problems that are more complex, but more research is needed.

A recent discussion of the literature by Aasdahl and Fimland (2019) raises the question of ‘what to offer when’. I feel tempted to add the question ‘what to offer to whom’ to this

discussion. However, the available literature provides very limited answers to these questions. The inherent complexities of understanding and predicting human behaviour may partially explain this lack of literature, as quickly becomes apparent when appraising theoretical models relevant to the field of occupational rehabilitation.

1.3 THEORY AND MODELS RELEVANT TO OCCUPATIONAL REHABILITATION

According to the online etymology dictionary[a], from late 15th century the word 'theory' came to mean "principles or methods of science or art (rather than its practise)", whereas the word 'model' came to mean "a standard for imitation or comparison…. that serves or may serve as a pattern or type". Although interrelated concepts, the term 'model' differ from the term 'theory' in several ways. Nevertheless, both 'models' and 'theories' provide a conceptual framework specifying variables and relationships important for explaining the phenomena in question (Costa-Black et al. 2013).

A 'model' in this context often consist of a visual presentation combining concepts from empirical evidence, experiences of practitioners' sometimes pragmatically including some theoretical elements, hence not necessarily creating a theoretical set of "principles or methods of science". For models, a further distinction is often made between conceptual- and operationalized models (Costa-Black et al. 2013). Whereas 'conceptual models', possibly drawing on several theories, most often provide visualisations of mechanisms and variables that may explain a phenomenon, 'operationalized models' tend to define theoretical mechanisms and variables into measurable (and testable) factors. The latter often aim at prediction, decision-making or optimization of interventions (Costa-Black et al. 2013). Hence, an 'operationalized model' may take the form of a statistical model allowing mathematical calculations, predictions and simulation. To my knowledge, there is a paucity of mathematically 'operationalized models' within the field of occupational rehabilitation.

[a] Etymonline.com (accessed on the 3rd of May 2020)

Turning to existing theories and models relevant to occupational health and sickness absence, it is important to distinguish conceptually between phenomena such as 'presenteeism' (continuing to work while illness/disease is causing disability), 'sickness absence' (staying away from work attributed to illness/disease), 'return to work' (the process of returning to work after a period of often prolonged sickness absence). As these phenomena differ in many ways, they may require different models. However, most relevant models and theories used in this field highlight general rather than narrowly specified processes and perspectives. Most theories presented below are therefore relevant to several, if not all the phenomena above. One example of such a general theory that many other builds upon is 'The biopsychosocial model'.

The biopsychosocial model has since the seventies expanded on the narrower biomedical perspective by emphasizing the complex interplay between biomedical, cultural, social and psychological factors relevant to any models of human illness and disease (Engel 1977). Since Engel advocated its clinical application (Engel 1980), the biopsychosocial model has become one of the most clinically influential theoretical perspectives in modern medicine and this perspective is especially relevant to musculoskeletal pain and mental health disorders.

A biopsychosocial multimodal perspective underlies most conceptual models and theories relevant to the current field of occupational rehabilitation. Besides the medical sciences, several relevant models have been conceptualized within different theoretical frameworks of such different disciplines as sociology, psychology and economics (Allebeck and Mastekaasa 2004).

Falsifiability was claimed by Popper to be one of the hallmarks of scientific theories (Popper 1963). He argued that theoretical models should be required to produce predictions, not just produce explanations of known facts. However, no single model from any of these disciplines seem to be superiorly backed by empirical evidence (Allebeck and Mastekaasa 2004, Schultz et al. 2007, Costa-Black et al. 2013). Theories and models within physics have advanced more in this sense than theories and models of fields involving human sciences and the medical tradition (Bird and Ladyman 2013).

The social sciences and medicine face several challenges when aiming to form unified scientific theoretical models that can provide scope across different contexts while retaining

utility for prediction and control in specific real life situation (Bird and Ladyman 2013). Human sciences, i.e. including fields such as philosophy, religion, history, sociology, psychology etc., often pose research questions on intentionality, e.g. "to study individual actions based on intentions" as Dilthey (1833-1911) put it. The German sociologist and economist Max Weber (1864-1920) supported this view on human research, arguing that knowledge depended on “verstehen”, which meant that the concept of meaning only could be understood in the context of values and culture (Allsop and Saks 2013). These epistemological controversies, often called ‘the positivism’ dispute, have to a certain degree continued throughout the 20th century (Albert and Mele 2015). Moreover, these controversies have been linked to a qualitative-quantitative divide in research methodology due to different epistemology (Yilmaz 2013). A quantitative research approach endorses the view that a phenomenon has an objective reality that is independent of the subjects being studied and the purpose of a quantitative deductive approach is to measure outcomes, to obtain generalizability, prediction and causal explanations (Yilmaz 2013). A qualitative research approach on the other hand incorporate studies of human activity, people, cases, phenomena, social situations and processes in an inductive, interpretive and naturalistic manner (Yilmaz 2013). The purpose of the latter approach is most often to identify and describe the meaning of peoples’ experiences.

In addition to challenging epistemological and static complexity, feedback loops is another mechanism adding complexity that halt development of theoretical models for human activities. Feedback loops, which are inherent in all real life biological mechanisms (e.g. homeostasis) and in social systems, may generate dynamic complexity that appear chaotic or random even if generated by underlying simple, non-random processes (Rickles et al. 2007). Most theoretical models relevant to the field of occupational rehabilitation treat this aspect vaguely or not at all, maybe in fear of rendering models too complex and therefore useless or unpopular for use in common practice. However, a version of the biopsychosocial model based on negative feedback and control has been suggested (Carey et al. 2014). This might represent a step forward in this regard. In addition, a recently published research framework for the development and implementation of interventions for work-related musculoskeletal disorders also advocated a feedback loop combining pragmatic and theoretical aspects from different disciplines (van der Beek et al. 2017).

However, a source of infinite complexity that no theory in this field has considered is the potentially hierarchical complexity of feedback loops between levels of a system. In the concepts of complexity theory; *"…complexity is in the dynamical evolution (the way the system changes over time driven by numerous iterations of some very simple rule), rather than the system itself.*" (Rickles et al. 2007). As a hypothetical example, if a perfect model enabled detailed prediction of return to work at the level of the individual (level 1), the simple existence of such a model (let alone its implementation) would affect political, macroeconomic and societal processes at the societal level (level 2). If changes on level 2 through feedback on level 1 changes the original conditions that the model was built upon this would influence the reliability of predictions made by a model accounting only for changes on level 1 (a non-hierarchical model). Hence, a fully predictive theoretical model of return to work would have to incorporate multi-level modelling of complex dynamic evolution (how systems change over time) as a function of feedback loops between several hierarchical levels accounting for random and non-random variation at each level. Various other fields than health science are faced with these very same challenges of modelling complexity, especially in related fields such as biology and ecology (Rickles et al. 2007, Allen and Giampietro 2014).

Hence, capturing any complex human behaviour, e.g. such as the return to work process, with precision, scope and depth might be beyond reach for any theoretical models. Nevertheless, in aspirations to develop a contextual behavioural science, precision, scope and depth have been emphasized as key: '*The criterion of precision means that only a limited number of analytic concepts apply to a given case; scope means a given analytic concept applies to a range of cases; and depth means analytic concepts cohere across well-established scientific domains'(Hayes et al. 2012).*

An inverse relation between precision and scope is sometimes (often?) the case; i.e. the higher the level of precision reached, the more limited the scope is and vice versa. This may be the case also in more developed theoretical disciplines such as physics. For instance, the Heisenberg uncertainty principle represents a similar paradox, stating that the more accurately you measure the velocity of a particle, the less accurately you know its position and vice versa. Although the latter is an extreme case from quantum mechanics theory, in classical physics theory two or more theoretical models can sometimes explain the same

phenomenon raising the paradoxical question of which model is 'true'. A fun-fact example: How to explain that a helium balloon moves forward inside a plane taking off (trust me for the sake of this example, it does!) while other objects, including the child holding its string, seemingly move backwards? A causal-mechanical explanation of this phenomenon might describe that due to a pressure gradient created in the air of the cabin from the back (high air pressure) to the front (low air pressure), the higher-pressure air will push the balloon forward with respect to the walls of the cabin. However, Einstein would probably propose a more general theory of gravity; e.g. since helium is lighter than air it tends to rise in the gravitational field of the atmosphere and will do so also in the horizontal gravitational field created within a plane accelerating during take-off. The first explanation provides greater 'precision' from a causal-mechanical perspective while the latter theory provides a greater 'scope', i.e. potentially explaining more phenomena in different contexts by the same theoretical model. However, of these two different theoretical explanations to the same phenomena - which one is 'true'? According to Salmon (2013), it is not meaningful to make a general decision on this as pragmatic considerations relating to context should dictate which to use and both of these theoretical models contribute to a scientific understanding of the phenomena (In Bird and Ladyman, pp.362-363.) Similarly, within the medical research tradition, different research methodology, theories and epistemological frameworks can be fitted under the pragmatic paradigm of applied science (Johnson and Onwuegbuzie 2004, Bird and Ladyman 2013, Yilmaz 2013).

In the following, I will adopt the pragmatic approach suggested by the original proponent of the biopsychosocial model, Engel himself (Engel 1980): '*The value of a scientific model is measured not by whether it is right or wrong, but by how useful it is. It is modified or discarded when it no longer helps to generate and test new knowledge'.* Hence, below I first briefly present two of the most utilized models in contemporary clinical settings within occupational rehabilitation. Furthermore, I will review the basic behavioural theories that spawned both the fear-avoidance- and the ACT models particularly relevant to the research presented and discussed later in this thesis. Finally, I will touch upon some relevant sociological theoretical perspectives on institutions and organisations since institutions constitute an important part of the context shaping and affecting individuals' behaviour and decisions of return to work after prolonged sickness absence.

1.3.1 Two popular models in occupational rehabilitation

'The disability prevention paradigm' (also called 'The case-management-ecological model') and 'The International classification of functioning, disability and health' are probably the two most popular models in clinical use for occupational rehabilitation. Both attempts to account for the complex interplay between biomedical, cultural, social and psychological factors involved.

1.3.1.1 International Classification of Functioning, Disability and Health

This model of disability is the one endorsed by The World Health Organisation (WHO) (Figure 1). It was developed as a generic model of disability but extensions specifically describing work-related factors have been published (Heerkens et al. 2004). Despite a growing number of publications based on this model, it has received critique for being too medically focused and lacking conceptual clarity. Hence, a redesign that is more consistent with current and foreseen changing ideas on health has been called upon (Heerkens et al. 2018).

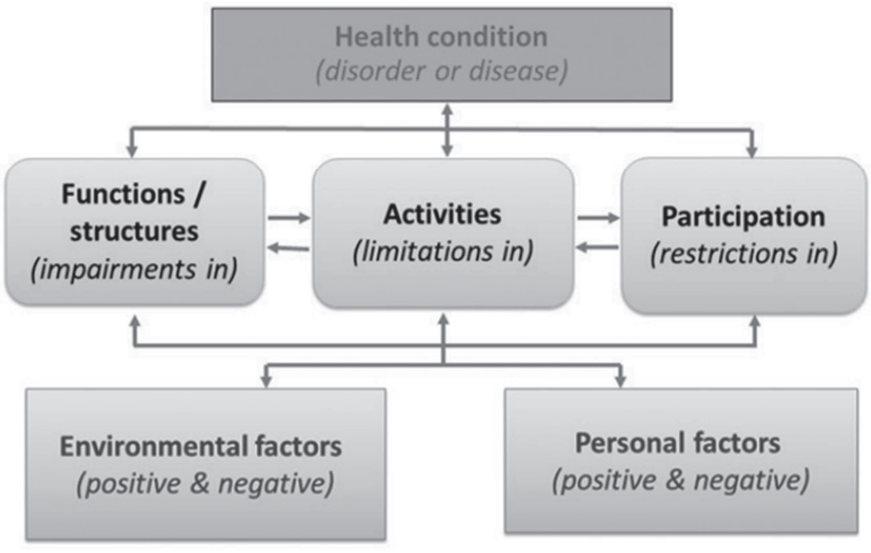

Figure 1 WHO's model for classification of functioning, disability and health.

1.3.1.2 The disability prevention paradigm (case-management-ecological model)

This model originates from research on sick-listed individuals with back pain, from implementation of research done in Sherbrooke, Canada by Loisel et al. (Loisel et al. 1994, Loisel et al. 1997a). Loisel emphasized the importance of the workplace, the compensation system, the healthcare delivery system in his further development of the disability prevention paradigm (Loisel et al. 2001), and finally the importance of the socio-political and cultural context in preventing work disability (Loisel et al. 2005). Although his model was originally developed for back pain, it has been applied to several different disorders and contexts with the aim to reduce work disability (Costa-Black et al. 2013). The model offers one of the most comprehensive visual overviews of the complex interactions of factors that affect work disability (Figure 2). However, a major critique is that the conceptualised model is not operationalized in any way that allow the different variables of worker-context interplay to be tested (Costa-Black et al. 2013), i.e. the model has a large scope but low precision.

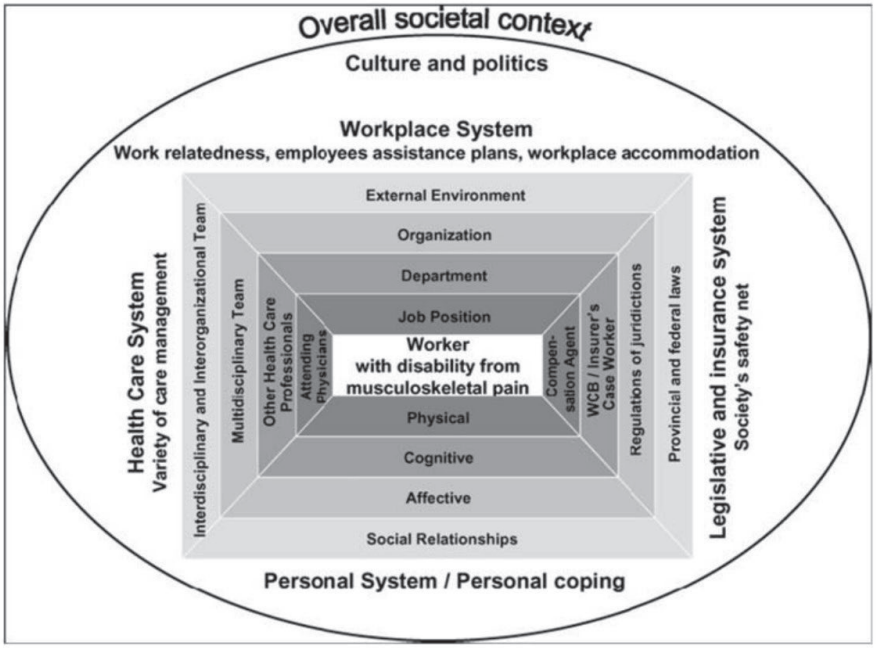

Figure 2 The arena in work disability prevention and occupational rehabilitation.

1.3.2 Behavioural theory and its epistemic roots

Whatever models we are looking at to conceptualize, predict or control the complex interplay of factors involved in the return to work process, human behaviour and its interplay with contextual factors, will be at the core. Hence, the phenomenon of return to work can be incorporated within the framework of general behavioural theories and models as just another class of behaviour shaped by the interplay between context affecting function/structures, activity and participation at the 'internal' level (biomedical health, personal and psychological factors) and at the external level (environmental socio-cultural and societal/organisational context).

To discuss contemporary behavioural theory, we need to revisit some of its' basic theoretical underpinnings that had an impact on the development of most contemporary theory within psychology, behavioural medicine, behavioural economic theory and the social sciences.

1.3.2.1 Radical behaviourism

Of the behavioural research spawned in the early 20th century by the likes of Thorndike, Watson, Pavlov and Skinner, Skinner's works has probably been the most influential. His contribution to behavioural theory is still considered highly relevant today (Iversen 1992, Vargas 2017). During his long active academic career, one of Skinners most important contributions was to initiate the development of an empirically supported theory aiming at prediction and control of behaviour in general. In addition, Skinner also theoretically refined and advocated behaviourism as a basic philosophy of science (Skinner 1953).

The 'radical' part of the behaviourist undertaking was to define behaviour as everything an organism does (Vargas 2017). Thus, radical behavioural theory aims to include both micro- and macro- levels of analysis (behaviour in context), while still being based on relatively basic theoretical concepts. One of the fundamental basic principles is that 'operant conditioning', i.e. how the history of feedback from the environment is what primarily shapes the future behaviour of an organism (see 1.3.2.2 below for more detail). By environment, we often associate the external environment (context) of an organism. However, radical behavioural theory also flexibly aims to incorporate an organism's internal environment (context) at different levels of analysis and can thus intersect with other theoretical

dimensions of behaviour, biology and physics (Vargas 2017). The fundamental axiom is that behaviour is shaped by a stimulus-response interaction between behaviour and the environment and that this 'learning history' can predict future behaviour.

The ultimate ambition of Skinner was to develop a theory of behaviour that could match prediction capabilities of theories in physics and biology (Skinner 1953). This still is a radical notion. It seems a truly ambitious undertaking to develop a theoretical model with such an extensive scope while retaining precision and relevance for any specific human behaviour and context. However, predicting complex behaviour such as returning to work or staying on sickness absence due to common musculoskeletal- or mental disorders, would be within the general scope of radical behavioural theory. To understand how this is operationalized, we need to dig a bit deeper into some of basic concepts of conditioning theory.

1.3.2.2 Basic behavioural theory

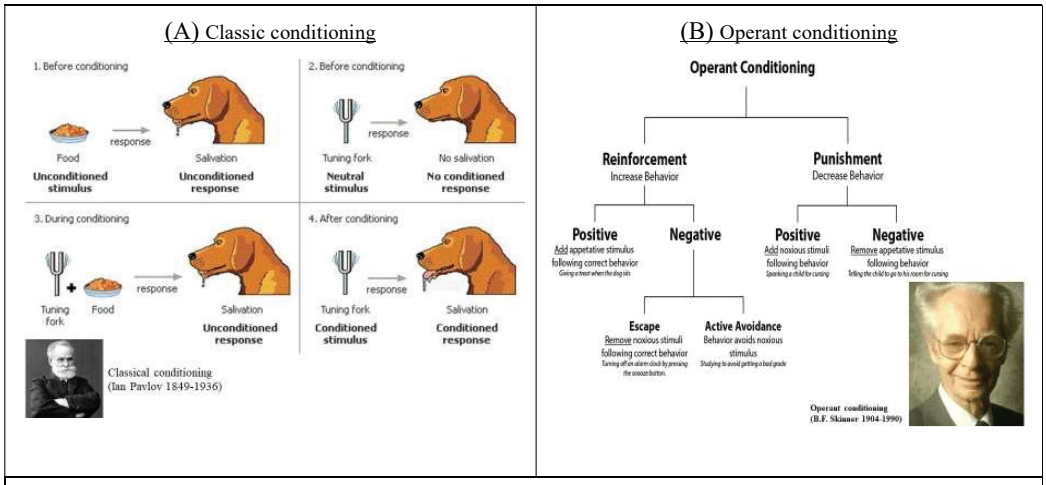

Figure 3 Classic (A) and operant (B) conditioning theory.

From the very beginning, the radical behaviourist research tradition aimed to use objective scientific methods. Since objective methods to study human cognition and emotion were unavailable at the time of the pioneers, they mostly concentrated on observable behavioural

outcomes in controlled scientific settings (i.e. animal behaviour in a laboratory setting). Figure 3 shows the classical conditioning experiments of Pavlov (A) who primarily experimented on dogs (Pavlov 1927), and the operant conditioning model (B) for shaping of behaviour developed by Skinner after numerus experiments primarily on rats and later pigeons (Skinner 1938, Iversen 1992).

In Pavlovian 'classical conditioning' (Figure 3, A), a previously neutral stimuli called the 'conditioned stimulus' is associated with a stimulus already eliciting a reflex called the 'unconditioned stimulus'. In the classic example shown, after a sound was associated with the presentation of food, the same salivation response was elicited by this previously neutral sound ('unconditioned stimuli') as when presenting actual food ('unconditioned stimuli'). A distinction was made between 'appetitive' (desired) and aversive stimuli. However, theories of aversive 'Pavlovian' conditioning (i.e. conditioning by use of aversive stimuli such as pain or other noxious stimulus) was later incorporated in the cognitive concept of fear (Solomon and Wynne 1954, Herrnstein 1969). The concept of 'aversive conditioning' (conditioned fear reactions leading to avoidance behaviour) became the basis for the 'fear avoidance' model that I describe in more detail below (see 0).

Skinners 'operant conditioning' model (Figure 3, B) on the other hand regarded cognition as a black box that generally could not be objectively studied (e.g. cognitive concepts such as 'fear'). Hence, the 'operant conditioning' model emphasised a pragmatic approach of mapping how feedback from the environment shaped the probability of a particular behaviour happening again in the future. Experimentally, Skinner showed that immediate feedback following behaviour either increases the probability of repeating this behaviour in the future (reinforcement) or decreases the probability ('punishment'). According to the model presented above in Figure 3 (B), learning by reinforcement or punishment can be modified by adding (positive) or removing (negative) stimuli. Hence, both adding an aversive stimulus ('positive' punishment) and removing a desired stimulus ('negative' punishment) decreases the probability that a behaviour will occur in the future. Likewise, adding a desired stimulus ('positive' reinforcement) or removing an aversive one ('negative' reinforcement) can function as a reward, increasing the probability that a behaviour will occur in the future.

These basic relations are still being researched, albeit with new methods, e.g. neuroimaging[a] (Wilcox et al. 2015).

Both classical and operant conditioning research included the concept of 'extinction', i.e. that conditioned behaviour and reflexes can be 'unlearned' over time if not being reinforced. However, avoidance behaviour, depending on the strength of the aversive stimuli that conditioned the behaviour, is rather resistant to extinction (Solomon and Wynne 1954, Boren et al. 1959). A plausible explanation is that even when the original (unconditioned) aversive stimuli is revoked, avoidance behaviour continue to be reinforced by its successful non-appearance (see Figure 3, B; 'negative reinforcement'/'avoidance'). In addition, the phenomenon of irreversible avoidance behaviour was coupled later with the cognitive concept of 'fear' and 'anxiety' (Solomon and Wynne 1954, Riccio and Silvestri 1973).

These basic behavioural concepts have since become embedded in most contemporary psychotherapeutic clinical interventions. In addition to psychotherapy, these basic behavioural principles have been extensively embedded in almost all modern practises targeting human behaviour such as in educational and governmental systems, in marketing and advertising. Through the digital revolution, these basic behavioural concepts have been embedded in algorithms used in the design of smartphone apps and by multinational internet-based corporations (e.g. Facebook and Google) to predict and shape human behaviour.

'Successful working' as a truth criterion has been held up as a hallmark for the radical behaviourist research tradition (Hayes et al. 1988), see also 1.3.4 below. The widespread application of the basic theory originating from early 20th century research in behaviourism speaks for itself regarding successful working.

[a] New neuroanatomical and functional brain research finds that appetitive (i.e. desired) and aversive (i.e. avoidant) stimuli are processed in closely integrated anatomical areas of the human brain regulating motivation and behaviour.

1.3.2.3 Cognitive constructs: expectations, self-efficacy and coping

Although the early behaviourists were not inclined to study or incorporate human subjective experience such as cognitive constructs[a], other lines of research emerged that incorporated cognitive constructs in models of behaviour change. Bandura et al. developed and argued for a theory of self-efficacy[b]. He provided experimental evidence that self-efficacy mediated extinction of conditioned stimuli in humans treated with systematic desensitisation for phobic anxiety (Bandura and Adams 1977). He also argued for self-efficacy as a unifying theory of behavioural change (Bandura 1977). Hence, the concept of 'coping' (positive expectations of mastery) have since been incorporated in most conceptual models describing human responses to aversive stimuli, e.g. in cognitive activation theory of stress (Eriksen et al. 2005). Cognitive constructs accounting for a positive expectancy of outcome, such as 'self-efficacy', have become popular. Self-efficacy, and similar expectation constructs affecting coping strategies, is advocated as important processes to target in occupational rehabilitation, particularly for women on long-term sickness absence (Andersén et al. 2018). However, the evidence is not entirely clear since a large prospective study found no association between self-efficacy and return to work (Labriola et al. 2007). The authors of the latter study suggested that low self-efficacy among individuals on sickness absence may be a result of the sickness absence itself rather than a modifiable predictor for return to work (Labriola et al. 2007). Many other cognitive constructs have been developed, including theoretical approaches applicable to therapy. One of the most known is the cognitive model developed by Beck that formed the cognitive behavioural therapy tradition. According to Beck, cognitive therapy is best viewed as "…*the application of the cognitive model of a particular disorder with the use of a variety of techniques designed to modify the dysfunctional beliefs and faulty information processing characteristic of each disorder" (Beck 1993)*. Hence, the content and application of cognitive models are context and condition specific and therefore its detailed literature is too vast to review here. The general cognitive behavioural therapeutic

[a] 'Cognitive constructs' – anything constructed in the mind by subjective sense-impressions

[b] 'Self-efficacy' relates to an individual's expectation of a positive outcome. The construct can best be described as a measurable degree of belief in one's own ability to master a specific task or activity.

model, according to Beck, emphasizes the interaction between 'automatic thoughts', feelings, bodily reactions and behaviour in any particular situation. Cognitive 'core beliefs' (about self, others and the world) and (dysfunctional) 'assumptions' is hypothesised to underlie and feed the 'negative automatic thoughts' triggered in any current situation that determine behaviour.

1.3.2.4 The fear avoidance beliefs model

Figure 4 (page 21) shows the basic components of the fear avoidance model. The fear avoidance model was first outlined by Lethem et al. (Lethem et al. 1983) following the emergence of the biopsychosocial model in medicine. A decade later, Waddell et al. (1993) developed the FABQ (Fear Avoidance Beliefs Questionnaire), presenting preliminary psychometric properties of the construct and establishing predictive utility for return to work in back pain patients of the work disability subscale. The fear avoidance beliefs model aimed, through incorporation of basic behavioural theory, to explain the discrepancy between the high level of disability observed among many individuals with back pain and the lack of objective findings that could explain the disability.

The model describes how pain (unconditioned stimuli) may elicit pain-related fear and thereby associate previously neutral stimuli (conditioned stimuli) through Pavlovian learning. Exemplified, when a previous neutral stimulus, such as 'bending forward', is associated with pain, bending forward acquire the same function and may elicit the same physiological and emotional response as pain itself. Hence, this can explain why avoidance behaviour, e.g. avoiding 'bending forward' may persist even long after pain is relieved.

Evidently, the fear avoidance model of pain rests on the basic behavioural principles of classic and operant conditioning. In addition, cognitive constructs of stimulus expectation (i.e. related to the self-efficacy/coping construct and to some degree the cognitive model) are integrated in the concept of fear avoidance. In consequence, according to the model, fear leads to behavioural avoidance (e.g. avoiding forward bending). Moreover, catastrophizing (e.g. thinking 'If I bend forward my back may snap and I'll end up in a wheelchair') may lead to more generalized avoidance, i.e. avoidance of daily activities believed to be potentially harmful such as physical exercise or work. A growing behavioural pattern of avoidance may in turn cause inactivity and physical deconditioning that potentially further reduce function in a vicious circle of increasing or sustained disability.

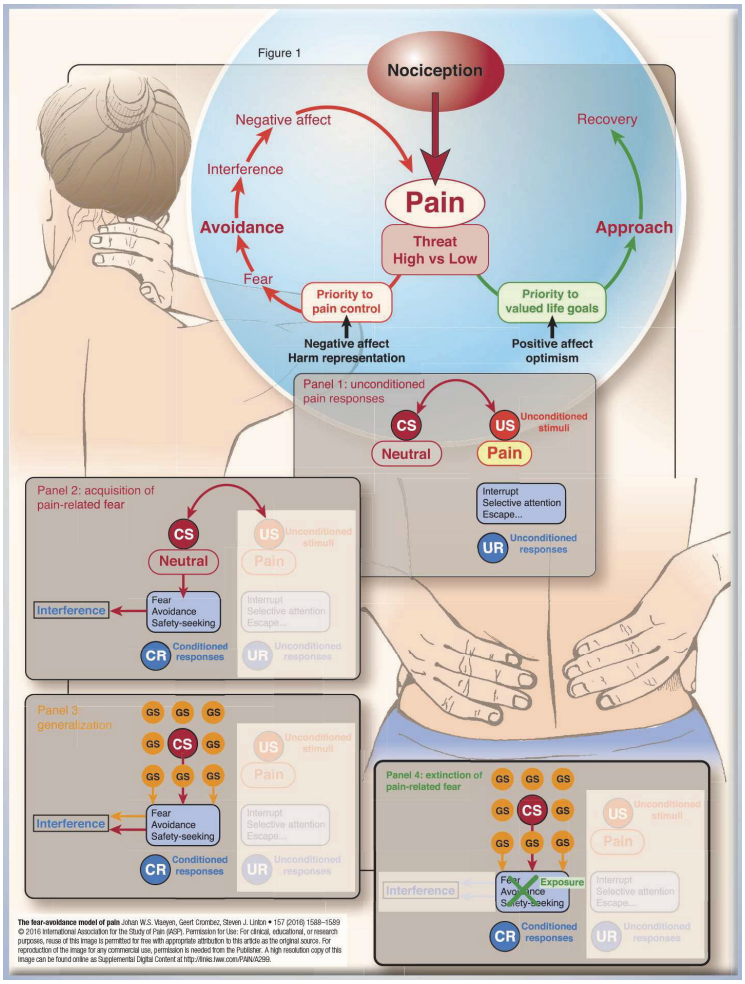

Figure 4 The fear avoidance model.

Developed to explain disability in back pain it was based upon concepts from basic behavioural research. US-unconditioned stimuli (i.e. pain). CS-conditioned stimuli (i.e. arbitrary cues that may be directly associated with pain). GS-generalized stimulus (i.e. arbitrary cues indirectly associated with pain). UR-unconditioned response (i.e. direct response to pain). CR-conditioned response (i.e. learned avoidance response to previously neutral cues). (Vlaeyen, J. W., et al. (2016). "The fear-avoidance model of pain." Pain 157(8): 1588-1589.)

Hence, the use of both behavioural and cognitive components are recommended in clinical rehabilitation interventions for musculoskeletal disorders with an aim to elicit an active coping style (Vlaeyen and Linton 2000).

Among individuals with back pain, the association between high scores on the work subscale of FABQ and prolonged sickness absence has been confirmed (Trinderup et al. 2018). Moreover, there is evidence showing that reduction in FABQ scores predict return to work after outpatient rehabilitation (Marchand et al. 2015b). FABQ scores on the work subscale also partially mediate the effect of education and musculoskeletal complaints on length of sickness absence after occupational rehabilitation (Oyeflaten et al. 2016). However, even though the theory behind the fear avoidance construct originates from psychological research, no studies have so far examined its properties in occupational rehabilitation of mental health disorders.

1.3.3 Behavioural economic theory and the impact of emotional valence

The 'carrot and stick' principle (i.e. similar to operant principles described in 1.3.2.2 above) has generally been accepted as foundation for modelling human rational choices with intention to maximise value. However, especially in models of behavioural choice under risk, sophisticated behavioural economic theory has built on cognitive aspects of expectation. In "expected utility theory' for instance, expectation (a function of expected value and probability of outcome) is incorporated into a mathematical model of decisions under risk. However, in a seminal paper, Kahneman and Tversky (1979) presented a development called 'Prospect theory' where they offered evidence of significant cognitive biases affecting human choice under risk. According to the 'Prospect theory', willingness to take risks increases more with the prospect of avoiding loss than with the prospect of the equivalent gain (i.e. humans are generally more inclined to pay for insurance than lottery tickets even when statistical odds of loss and gain are equivalent). However, their most interesting finding was that when the same set of prospects are framed differently, behavioural probability changes. According to Kahneman and Tversky (1979) they were able to show that, due to cognitively biased expectations, human behaviour can be manipulated into greater risk taking by framing the choice with a prospect of a loss (punishment/negative valence) rather than with the prospect of the equivalent gain (reward/positive valence). Hence, aversion and negative feedback may have a stronger immediate impact on shaping human behaviour than the equivalent rewards. However, there appears to be strong side-effects to aversively motivated behaviour.

Several experiments have shown that negative affective valence narrow focus and reduce creativity thus reducing problem solving ability (Friedman and Forster 2010). An intriguing

experiment exemplifying this mechanism involved two groups of college students assigned to help a mouse escape from a maze. This simple task involved a piece of paper picturing the mouse in a maze and an exit hole through which the student could help the mouse escape by trailing the pencil the correct way through the maze leading the mouse to exit the maze. The assignment took only a few minutes to complete and all the students finished. However, the two groups of college students did this task under different conditions. In the first condition, there was a piece of cheese pictured at the exit hole (positive valence/reward). In the second condition, an owl was chasing the mouse and there was no cheese (negative valence/punishment). Remarkably, the latter group of students performing this task under avoidant motivation (chased by the owl), showed significantly diminished results on subsequent tasks designed to test creative performance (Friedman and Forster 2001). This implies that even small symbolic aversive stimuli can significantly affect performance at work-tasks dependent on creativity or some level of problem-solving capability. Moreover, several studies have found a simple intervention inducing positive valence to increase academic performance. In this intervention, participants only sorted cards with written values[a]. Through sorting the value cards, students choose the one value that they personally felt was the most important to them and their life right now, thereafter, writing down why this was important to them. Randomised trials administering this intervention to negatively stereotyped minority students showed closure of the academic racial performance gap compared to the academic performance of nonminority students (Cohen et al. 2006). Surprisingly, a sustained effect was found at 2 years follow up (Cohen et al. 2009). The same intervention also reduced the academic gender achievement gap between female and male science students in a college-level physics class (Miyake et al. 2010).

Hence, it seems that if creativity and optimal cognitive/academic performance is required for a work task, motivation induced by positive valence and personal values is important. Most contemporary occupations require some level of creativity and cognitive performance. If the work task involves only routine tasks, traditional carrot and stick motivation may suffice.

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[a] 'Values' is here defined as single words denoting different aspects of life factors important to most people such as: 'family', 'friends', 'religion', 'physical exercise', 'mastery' etc.

These findings may have important implications for occupational rehabilitation. However, I am not aware of theories or models within the field of occupational rehabilitation that have integrated these theoretical aspects.

1.3.4 Behavioural contextual science, language & the clinical ACT model

Even though Skinner published 'Verbal behaviour' already in 1957 (Skinner 1957), the radical behaviourist research tradition had until the 1980ies mainly focused on externally observable behaviour. From the 1980s, a new line of research on 'operant' principles in human language and cognition emerged from the radical behaviourist tradition defining behaviour as 'everything an organism does' (Hayes and Hayes 1992). This development led to relational frame theory that extends basic behavioural theories to language and cognition (elaborated in 1.3.4.3 below). Eventually, the advancement of this new theory of language and cognition led the radical behaviourist tradition into a much broader research scope called 'contextual behavioural science'[a] spawning several new clinical applications, including the clinical ACT model (detailed in 1.3.4.4 below). Interestingly, the stance on philosophy of science in contextual behaviourism share many similarities with early Buddhist philosophy (Diller and Lattal 2008). In Buddhism, successful working is defined as 'reduction of suffering'. The contextual behavioural science society claim a similar overall research aim but encourage specific aims to be adapted to specific contexts with specified criteria for successful working.

Contextual behavioural science rests on three theoretical axioms: 1) Functional contextualism, 2) Applied behavioural analysis, and 3) Relational frame theory. In the following, I will briefly review these.

1.3.4.1 Functional contextualism

This first axiom underlying contextual science, is an epistemological stance defining 'truth' as successful working within its context (Hayes et al. 1988). This stance entails that 'truth'

[a] See: www.contextualscience.org/

exists only in relation to an 'ongoing act in context'. Implicitly, since dynamic feedback loops exists between the act and its context (operant conditioning), the content of 'truth' may constantly change even though its function can remain the same. Another important implication of this epistemological stance is that what is 'true' may change if the context changes. In addition, 'truth' is changed if the criteria set for 'successful working' changes.

A metaphor often used to clarify this core philosophical concept for clinicians, is the example of a broken kitchen chair with one loose leg (Harris 2007): A three-legged chair may well be labelled as truly 'dysfunctional' in the context of normal kitchen furniture use. However, if the intention and context is a practical joke (or hoping to injure yourself at work to get a compensation claim), criteria for successful working change and the chair may indeed be very functionally relevant to the particular requirements of this context. Although this is a humorous example, it follows directly from a functional contextual perspective that no emotion or thought can be inherently 'dysfunctional' outside a specific context. It also follows that if the context for emotions, thoughts or bodily sensations changes, the (dys)function may change, even if the content (form) remains the same. To clarify the implications of this concept, I will use a clinical example adapted from Rush Harris (2007):

Imagine a clinical scenario with 5 different people cutting their forearm with a sharp object. While the '*form'* of this behaviour (cutting the forearm) remains the same, behavioural '*function'* may possibly differ; i.e. getting attention, self-punishment, distracting oneself from painful emotions, creating body art or attempting to convince someone that you are unfit for military service or work. This principle also reverts, i.e. different forms of behaviour may serve the same function. Seemingly different form of behaviour such as 'getting drunk', 'overworking', 'extensive physical exercise, or 'cutting ones forearm' may all have the same function, e.g. distracting from painful emotions.

The philosophical core of functional contextualism (exemplified above) underlies all other axioms, theory and the clinical applications of contextual behavioural science.

1.3.4.2 Applied behavioural analysis

The second axiom of contextual science is the method of applied behavioural analysis. This is a way of applying the principles of functional contextualism and contextual behavioural theory to a specific situation. Hence, the basic stance adopted is that human behaviour cannot

be analysed without knowledge of its context. From this perspective, the context is analysed to identify internal and external contextual cues. Internal cues that antecedent behaviour may involve everything going on 'beneath the skin' (e.g. thoughts, feelings, memories, physiological states such as hunger, hormonal cycle or disorders such as back pain, fatigue etc.). External antecedent cues may include all parts of the environmental context (e.g. the personal physical/psychosocial context and the health care/workplace and legislative/insurance context). From the perspective of applied behavioural analysis, internal and external contextual factors may shape behaviour through the consequent feedback on the behaviour in question (i.e. operant conditioning), thus changing the contingencies of antecedent cues for future behaviour. From analysing antecedent cues and conditioned feedback on the behaviour in question, the function, effect and intention/purpose of the behaviour in question is determined.

If this analytic perspective were to be applied to the field of occupational rehabilitation it would analyse return to work behaviour as contingent on cues from all of the external context presented in the disability paradigm (see 1.3.1 above, Figure 2) and expand on this perspective with a similarly complex inner context as that shown for the external arena shown in Figure 2. This would lead to a near complete model when it comes to scope but it would be very complex to operationalize to achieve precision allowing different variables of worker-context interplay to be tested. Applied behavioural analysis is mainly used as a framework for clinically oriented applications and no model based on this perspective has so far been presented for occupational rehabilitation or work disability.

1.3.4.3 Relational frame theory

This third and last axiom expand on the principles of stimulus-response relations derived from basic behavioural theory of (see 1.3.2.2 above, Figure 3) aiming to form a theory of how language and cognition relate to behaviour (Stewart 2015). Hence, relational theory expands on classic and operant conditioning principles in several ways to account for the specific functions that characterize and structure language and cognition in humans.

The uniqueness of the human mind allow, according to relational frame theory, that if the relations A→B and A→C are learned, relations such as B→A, C→A, B→C, C→B, C=B and many more may be derived without a prior learning history. Thus, by relational frame theory the basic concepts of classic and operant relations is expanded with a concept called 'derived

relations'. This concept of 'derived relations' is used to explain how complex behaviour and novel associations arise from language and cognition in ways that the previous theories of classic and operant conditioning cannot explain (Stewart 2015).

Again, to get a practical sense of these concepts, an example based on Harris (2007) may help (most helpful for you as a reader if you aim to follow the instructions and linger to experience the following rather than just reading it quickly):

"*Visualize a lemon. A huge lemon, with a gold-yellow colour like the sun and with a delicious, zesty aroma… Imagine running fingers gently over the skin, feeling every tiny dimple in the surface. Imagine slicing this large lemon in half, holding it up over your open mouth while squeezing out the fresh lemon juice, right onto the tip of your tongue… (Stop reading here and close your eyes for a few seconds visualizing the above. Notice what sensations come up).*

Take the word 'Zooboma' on the other hand. Notice what effect that has upon you. Probably not much. However, Zooboma is a rare tropical fruit that looks and tastes remarkably like a lemon, except that it is about three times bigger than a lemon. Now imagine as vividly as you can that you pick up a yellow Zooboma looking like a lemon (but about the size of a melon), you slice it in half, you open your mouth wide open, and you squeeze out all the juice from the Zooboma, directly onto your tongue. Just imagine your mouth filling up with all the fresh Zooboma juice until your mouth is literally overflowing."

Chances are high that anyone reading the first passage above, or just reading the word 'lemon' (A), will experience several 'private events' such as salivation (B), a tingling feeling on the tongue (C), memories involving lemons (D), thoughts and emotions (F) (i.e. A→BCDF). 'Zooboma' (Z) on the other hand would probably not have had this initial effect for most people. After reading the latter passage above however, the word 'Zooboma' can potentially elicit the same function (Z→ABCDF), maybe with even more intense salivation than the word 'lemon'.

This serves to exemplify the concept of 'derived relations', i.e. how language and cognition enable vast changes in existing networks of stimulus-responses, and how this adds immense complexity while still adhering to the rather simple principles of classic and operant conditioning. There is of course no such fruit called 'Zooboma', it was made up for the sake

of the example and you now have to live with this made-up word in your vocabulary that may induce the same physiological reactions as the word ‘lemon’. This exemplifies how language and cognition processes (e.g. ‘derived relations’), can lead to rather arbitrary changes in stimulus-response networks that again affect behaviour.

In relational frame theory, the phenomenon exemplified above is called transfer of stimulus function. Transfer of the stimulus functions from the word ‘Lemon’ to the word ‘Zoobomba’ explains how the latter can acquire the same response as the first and how both can elicit a similar response to tasting an actual lemon (the unconditioned ‘original’ stimuli). In common plain language, words such as ‘and’, ‘greater than’, ‘smaller than’, ‘similar’ or ‘the same’ can create different derived relations with the potential to transfer and modify stimulus function between existing (previously learned) networks of meaning called relational frames (Dymond and Rehfeldt 2000). Hence, upon extension of the theory of derived relations, additional theoretical concepts such as ‘transfer and modification of stimulus functions’ can be applied to clinical practice with the intention of prediction and control of complex seemingly arbitrary behaviour, cognition and emotion. This theoretical framework accounts for the endless possibilities of the creative human mind to combine learned relations in new ways, a skill that other animals (and infants) do not have. Moreover, relational frame theory can through the concept of arbitrary derived relations, explain how the same cognitive processes can both lead to creative problem solving and cause mental dysfunction.

To give a hypothetical clinical example of complex behaviour: Upon hearing a particular song on the radio (external arbitrary stimuli), the emotional (conditioned) response ‘feeling blue’ is triggered. In the emotional context of ‘feeling blue’, the probability of experiencing negative thoughts and memories increases. A memory of a particular failure in the past, or negative feedback at work may in turn trigger the thought ‘I’m a failure’. In this thought, the vast relations and stimulus functions contained in the meaning of ‘failure’ may transfer to the vast network of relational frames connected to the concept of ‘I’. Since the concept of ‘I’ is present in most relational frames (networks of meaning for the individual), this in turn reinforces ‘feeling blue’ and may elicit thoughts such as ‘My life is pointless’; ‘there is no point in trying to return to work’; ‘I might just as well kill myself’. Hence, such ‘internal’ behavioural conditioned responses may be initiated by arbitrary cues and can be followed by a vicious spiral of reinforcing patterns that may go unnoticed. Alternatively, if brought to

awareness, the context (and hence feedback on the behaviour) can be reframed by the act of observation itself, leading to a change in stimulus function. Hence, some authors have claimed that mindfulness, which always involves self-awareness training, is the ultimate clinical reframing tool (Garland et al. 2017).

Mindfulness, here defined as awareness of whatever is arising with a particular frame of mind that incorporates intentional kindness and openness in the present moment, has been integrated into mainstream psychological theory and practice over the last decades with considerable empirical research support (Shapiro 2009). Hence, also contextual behavioural research has spawned development of new applications of behavioural theory including clinical models that are 'mindfulness based'. Of particular interest and current popularity is the ACT model.

1.3.4.4 The Acceptance and Commitment Therapy model

The clinical ACT model rests on contextual science within the three axioms that have been described in more detail above. ACT is a process-based therapy approach, emphasizing psychological flexibility processes that primarily target change of context rather than content in dealing with difficult thoughts, emotions and bodily sensations. Another element that differentiates ACT from other contemporary psychotherapy approaches is its existentialist emphasis on meaning and life values. This part of the approach is rooted in the tradition of Victor Frankl, a Jewish psychiatrist who in 1946, after surviving the Nazi concentration camps, published his now famous book that was translated into English and reprinted several times with the latest title: 'Man's search for meaning' (Frankl 1992). Victor Frankl claimed that if you increase someone's sense of meaning, you would reduce the distress experienced, even when the objective suffering remains the same. He expressed this in the simple mathematical equation: "*D (istress) = S (uffering) – M (eaning)*". In addition, Frankl quoted Nietzsche saying "*He who has a why to live for can bear almost any how*". Hence, successful working in ACT may be defined as helping human beings to live rich, active and meaningful lives.

The ACT model underpins two of the papers presented in this thesis. Hence, for a visual overview of the model and some clinical examples of application, please refer to the method section of Paper II including the visual presentation of the model given in figure 1 (Paper II, figure 1). In summary, the clinical ACT model contains six core processes within three

domains. The tree domains are: open, aware and active. The first two of these domains (openness and awareness) are based on mindfulness and emphasize the four processes 'here and now', 'self', 'acceptance' and 'defusion' (i.e. perspective taking on thoughts). The two remaining processes relates to the last domain (active) containing clarification of personal 'values' (meaning) and 'committed action', i.e. action guided by the freely chosen personal values. Hence, all processes within the three domains aim to help human beings to live rich, active and meaningful lives related to the criteria of successful working of an ACT intervention as mentioned above.

The ACT model rests on a pragmatic contextual truth criterion (see 1.3.4.1 above). Hence, it is important to acknowledge that the practical application of the clinical model with its specific criteria for 'successful working' may look very different from that of its theoretical foundations. Moreover, delivery and presentation vary by design for different clinical contexts. Hence, the psychological flexibility model in ACT permits several ways to present and implement the model according to pragmatic means. The most common presentation is the visual presentation of the ACT model and its six processes in the 'Hexaflex' (refer to the method section of Paper II). Below I will also give a brief presentation of a different clinical version referred to as 'The ACT-Matrix' (Polk and Schoendorff 2014). This version also illuminates better the basic behavioural theory underlying the clinical application of the ACT model.

Figure 5 below presents the ACT model as a matrix formed by a cross with two axis. The horizontal (x-axis) represents the continuum of behavioural function from aversive behaviour (moving away/avoiding) to behaviour governed by a desired (appetitive) stimuli (moving towards something of personal value). The vertical (y-axis) represents the continuum of inside to outside contexts. Everything beneath the horizontal line represents the context that is privately experienced (mental experiences and everything else happening under the skin). Everything above the horizontal line represents the context of the outside world (i.e. that which can be experienced through the five senses in the present moment). However, both the inside and the outside context can be subjected to mindful awareness (hence the questions).

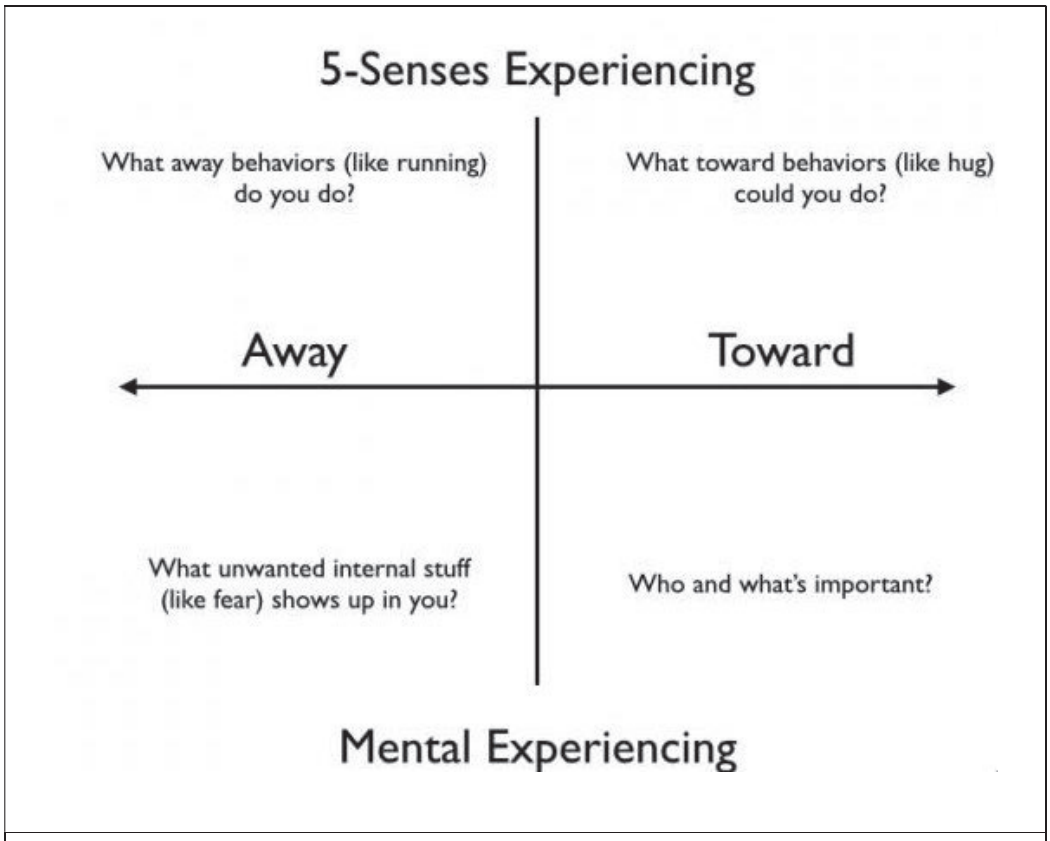

Figure 5 The ACT Matrix.[a]

According to Polk and Schoendorff (2014): *"…the matrix diagram is a dynamic representation that cues movement from psychological inflexibility (the left side of the diagram) to psychological flexibility (the right side)".* From the visual diagram of the ACT-Matrix, the basic behavioural theory underpinning the clinical model is easier to see than many other presentations of the model. That is, the underlying theoretical approach in ACT is to change the function of behaviour from being under control of aversive antecedents

[a] (Kevin Polk); https://contextualscience.org/act_matrix

(negative emotional valence/avoidance) to being under appetitive control (positive valence motivated by personal values). Fostering psychological flexibility also entails enhancing the skill of moment-to-moment awareness in order to notice this difference.

Applied to the context of occupational rehabilitation, behaviour leading to 'return to work' may look the same whether it is motivated by avoidance of a threat (e.g. financial ruin) or motivated by moving towards something of personal value (e.g. 'contributing' or 'social relations' at work'). However, in the context of an ACT intervention, only the latter of the above behavioural motivations is considered a successful outcome per se. Applying for permanent disability pension truly motivated by a personal value such as 'taking care of my health' could also be judged as a success. Hence, fully integrating the ACT model into extensive inpatient multimodal rehabilitation for individuals sick-listed due to common mental- and musculoskeletal disorders in the current project is a novel, original and possibly counterintuitive innovation in the field of occupational rehabilitation. Yet, as presented above (e.g. see 1.3.3 above), it seems that when creativity or cognitive performance is required for a work task, motivation induced by positive valence, such as personal values, may be important for sustained optimal performance and hence possibly successful sustainable return to work.

If we compare Figure 4 with Figure 5 (on page 21 and 31 above), we see how the fear-avoidance model (see 1.3.2.4 above for details) and the ACT model are related. In contrast to the ACT model, the fear-avoidance model is well established in occupational rehabilitation and musculoskeletal healthcare whereas the ACT model initially was used mostly in mental health care. High FABQ scores has been negatively associated with function and return to work. Hence, the fear avoidance model may also be relevant for common mental health disorders through the same general negative effects of fear-avoidance/negative valence that may reduce psychological flexibility and creativity (as previously discussed in 1.3.3 above).

1.3.5 Institutions and organizations

Although institutions and organizations are not the focus of my research, they form a major contextual framework that affect behavioural mechanisms in sickness absence and return to work. A short review of theoretical perspectives from the social sciences on institutions and organizations is therefore relevant.

Richard Scott's definition of institutions reads: *'Institutions comprise regulative, normative, and cultural-cognitive elements that, together with associated activities and resources, provide stability and meaning to social life'* (Scott 2014, p. 56-57). Based on a thorough review of the historical and current theoretical perspectives on this topic, he proposed theoretical aspects revolving around the three 'regulative', 'normative' and 'cultural-cognitive' pillars of institutions formed from 'Neoinstitutionalism' and 'Cognitive-cultural' theory (Scott 2014).

According to Scott 'Neoinstitutionalism' constitutes theoretical views that can be grouped into two distinct perspectives: 1) Historical institutionalism and 2) Rational choice theory. The first of these perspectives (Historical institutionalism) emphasizes studies of how the nature of political systems shapes the character and outcomes of conflicts, distributing power among actors and shaping actors' conceptions (Scott 2014, p. 39). Social-constructivist oriented scholars within this position particularly emphasize how institutions construct their actors while restricting and defining the actor's behavioural repertoire through the process of social construction: '*Choices and possibilities are constrained and conditioned by past choices*', and: '*Institutions, once established, have a continuing effect on subsequent decision-making and institution building episodes*' (Scott 2014, p. 39-40). Hence, within historical institutionalism, historical reconstruction can be the primary study approach. However, it has been criticized for adding too much complexity (Scott 2014).

Rational choice analysts on the other hand, argue that institutions represent deliberately constructed rule systems designed by individuals seeking to promote or protect their own interests. Economic theory, with underlying theoretical concepts such as transaction costs, markets vs hierarchies, optimization, marginality, equilibrium and economic methods of analysis are central to these rational choice perspectives. Hence, rational choice theorists are more likely to ask how institutions solve collective problems experienced by individuals and to examine how institutional mechanisms sustain states of equilibrium (e.g. how the society balances the individual's need for social security with collective interests to keep costs and taxation level down). Historical institutionalists in contrast, tend to emphasize macro perspectives, tracing evolution of institutional forms, asking how institutional mechanisms affects individual behaviour and study mechanisms driving historical change rather than mechanisms of equilibrium (Scott 2014, p. 40-42).

In addition to the *normative* and *regulatory* mechanisms aforementioned, Scott proposes a third *cultural-cognitive* mechanism that maintain the social order within institutions and organizations. Metaphorically speaking culture in this perspective can be exemplified as the '*software of the mind*'. The cognitive aspect of this theoretical perspective also emphasise how external stimuli and inner response is mediated by the individuals' internal representation of their environment: '*To understand or explain any action, the analyst must take into account not only the objective conditions but the actor's subjective interpretation of them*' (Scott 2014, p. 67). These perspectives originate from early strands of cognitive behavioural research that included the organism as an active part mediating stimulus-response relationships established by early behavioural research (see **Error! Reference source not found.**). Other lines of psychological research that challenge the view of individuals as rational beings, has also been included in this perspective (e.g. see discussion on contributions by Kahneman et al. in 1.3.3 above) (Scott 2014, p. 43-44). Above I have only given a brief account of some theoretical perspectives on institutions. To give this vast field of theory (and the Scholars who have contributed) full justice, please refer to Scott's comprehensive review (Scott 2014).

1.4 THE NORWEGIAN CONTEXT

Three institutional elements of the Norwegian context are particularly important and relevant to the research presented in this thesis. The first is the social security scheme in Norway; the second is the Norwegian 'three-party' collaboration model where the worker and the employer unions/associations collaborate closely with the state; and the third is the tradition of inpatient occupational rehabilitation provided in rurally placed institutions. The latter also forms the particular background for specific research aims in this thesis.

1.4.1 The Norwegian labour and welfare service (NAV)

NAV provides the extensive social security scheme in Norway, spending approximately one third of the Norwegian government's annual budget. Membership in this governmental insurance plan is compulsory for all legal residents and (income) taxation is the main source of finance. The employer is only economically responsible for the first 16 days of sick leave. Thereafter, NAV covers all expenses by different benefits related to medically certified sickness absence. The medically certified benefits provided by NAV include sickness

absence, work assessment allowance and permanent disability pension. Medically certified sick leave compensates 100% of wages from the first day of absence up to one year and reimbursement of sick leave absence down to 20% absence is covered. Coverage by NAV is restricted upwards to 6 times an index-adjusted insurance base (i.e. maximum NOK 599.148 in 2019). However, different corporate insurance addendums often ensure full coverage during sick leave that may extend also on other medical benefits provided by NAV. After one year of sickness absence, it is possible to apply for work assessment allowance that compensate 66% of wages for up to 3 years with the possible extension of another 2 years on special terms. Entry into work assessment allowance and permanent disability pension require that ill health is causing around 50% reduced work capacity for any type of work. However, after 50% permanent disability benefits has been granted, utilization of work capacity beyond this is possible and encouraged. Entry into work assessment allowance require an activity plan that explicitly aims for (increased) work participation. Permanent disability pension require medically certified disability that reduce work capacity for any type of work permanently (currently interpreted as at least 7 years duration). Unemployment benefits and other (non-medical) social security benefits are available for individuals without medically certified disability, but usually with less extensive economic compensation.

1.4.2 The Nordic model and the Norwegian three-party collaboration

The Nordic model, established through long-term cooperation between public and private institutions, contribute to creating balancing forces in markets between pillars of economic- and public welfare policies and an organised workforce in the Nordic countries.

Rooted in this model is a longstanding Norwegian 'three-party' collaboration model that gather worker and employer unions in a national collaboration with the state as the third party. Representatives of these three parties discuss, and to a large degree mutually decide on, developments of the social security model and the development of work and health programs on a national scale. This collaboration model creates a context that balances power between the three different interests with particular bearing on financing occupational rehabilitation, which is in the interest of all three parties.

The Nordic model is visualized in Figure 6.

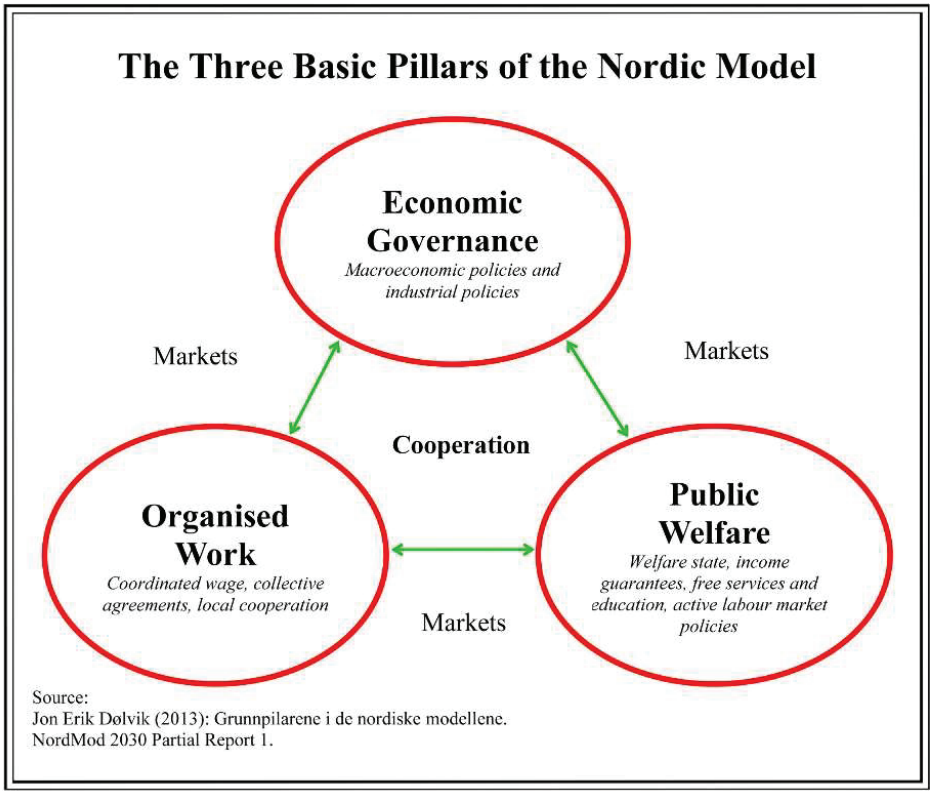

Figure 6 The Nordic three party collaboration model.

1.4.3 The inpatient occupational rehabilitation tradition

In Norway, 3-4 weeks of inpatient occupational rehabilitation has been a mainstream approach for individuals on long-term sickness absence with complex biopsychosocial barriers for return to work. The inpatient rehabilitation tradition has its historical roots in the era of mental asylums and tuberculosis sanatoriums. Rehabilitation centres have since continued to be rurally placed in Norway, often in proximity of a scenic view of nature. In addition to the historical reasons, the inpatient rehabilitation tradition rest on several other factors related to geography, demographical issues and national/regional policies for rural development that might be specific to Norway and the Nordic countries. Nevertheless, similar inpatient rehabilitation traditions exists in several other countries in Europe, e.g. in Germany

where inpatient rehabilitation for musculoskeletal disorders stems from a long-standing spa treatment tradition (Zeidler et al. 2008).

Traditionally, inpatient rehabilitation centres in Norway include participants with different medical conditions and diagnosis in the same group. A multimodal group-based rehabilitation approach is common. Modalities traditionally incorporated are physical exercise, problem solving strategies including coordination of stakeholders and different coping strategies directed at facilitating coping on the individual level (e.g. cognitive behavioural approaches).

1.4.4 The project specific context ('Hysnes Helsefort')

When the Norwegian government in 2010 established a new rural inpatient occupational rehabilitation centre – Hysnes Rehabilitation Centre (Hysnes Helsefort, directly translated: Hysnes Health Fortress), it was financed under a national 'return to work program' (2007-2017) initiated through a 'Three party' collaborative initiative. 180 million NOK was granted over the state budget for 5 years. Despite a 30-40 year long tradition, such inpatient occupational rehabilitation programs had hitherto never been studied in a rigorous design assessing their effect on sickness absence. Hence, the research presented in this thesis is part of a larger project established to evaluate the effects of establishing this new state owned occupational inpatient rehabilitation centre.

The rehabilitation centre was in operation from October 2010 to June 2016, providing different interventions evaluated in randomised trials (Fimland et al. 2014, Aasdahl et al. 2017, Hara et al. 2017a, Aasdahl et al. 2018, Rise et al. 2018, Skagseth et al. 2019b, Gismervik et al. 2020). Personnel working at the rurally located rehabilitation centre mostly commuted daily from the city of Trondheim (50 minutes by fast ferry, 90 minutes by car). The participants stayed at the rehabilitation centre during rehabilitation interventions of different lengths. The length of inpatient stay was 3.5 weeks in the most extensive programme (evaluated in Paper I, II and III). In addition, the centre provided a 4+4 days inpatient rehabilitation programme, evaluated in Paper III and by Aasdahl and co-workers (Aasdahl et al. 2017, Aasdahl et al. 2018). The Department of Physical Medicine and Rehabilitation at St. Olavs University Hospital in the city of Trondheim provided the outpatient comparison intervention for the randomised studies presented in this thesis.

St. Olavs Hospital was responsible for organizing the clinical interventions. The research was carried out in collaboration between St. Olavs Hospital and the Faculty of Medicine and Health Sciences, NTNU - Norwegian University of Science and Technology, both situated in Trondheim, Norway. The research presented in this thesis was largely conducted at the Department of Public Health and Nursing, NTNU in Trondheim. The Central Norway Regional Health Authority initiated and funded the initial phase of the larger research project. Funding parties had no part in design, conduct or publishing of the research.

The new rehabilitation centre welcomed individuals on sickness absence due to musculoskeletal complaints, common mental health disorders, and unspecified or complex symptom disorders (e.g. fatigue). In designing an evidence-based multimodal group-based program that could feasibly provide care for individuals with these diagnoses, physical activity/exercise and other components (e.g. making a return to work plan) was integrated with an ACT approach. The ACT approach was chosen as coping modality due to promising new evidence as a coping strategy for various diagnoses. Clinicians also favoured the implementation of the ACT model due to its clinical flexibility signifying feasibility for group-based delivery among individuals with various diagnoses. Finally, the experiential avoidance concept embedded in the ACT approach, was in line with the fear-avoidance model already established in clinical use for rehabilitation of musculoskeletal disorders.

2 AIMS OF THE THESIS

The overall aim for the Hysnes Helsefort research project was to evaluate the effect of two intervention programs implemented in a newly established inpatient occupational rehabilitation centre. The rehabilitation centre developed and implemented both a short (4+4 days) and a long (3.5 weeks) inpatient rehabilitation program. In the following, these programs are referred to as the 'Short program' (4+4 days of inpatient rehabilitation separated by 2 weeks at home) and 'I-MORE' (3.5 weeks of continuous inpatient rehabilitation). In addition, an outpatient intervention comprising 6 weekly sessions of group ACT was established for comparison in the randomised trials. The outpatient intervention will be referred to as O-ACT (6-7 weeks of outpatient ACT).

ACT was the intended therapeutic approach that would allow merging of participants with musculoskeletal and common mental health disorders in all the group-based interventions. In addition to ACT, the inpatient interventions also comprised a guided physical exercise program and the creation/coordination of a return to work plan. See section 3.4 below for a detailed description of all interventions.

Assessing the effect of I-MORE was the main focus of my work (Paper I of this thesis). Furthermore, I explored whether and how the participants' experiences of I-MORE reflected the intended integration of ACT in all program manuals (Paper II). Finally, since the fear and avoidance beliefs model share several theoretical axioms with the ACT approach, we wanted to assess whether and how fear avoidance beliefs (measured by FABQ scores) changed during the different rehabilitation programs and whether reduced scores were associated with positive occupational outcomes for individuals with musculoskeletal and/or common mental health disorders (Paper III). The aims of the three papers were:

1. To compare the effect on sickness absence of 3.5 weeks of I-MORE to six weeks of O-ACT on sickness absence and self-reported health outcomes.
2. To examine whether and how the intended (ACT) processes of behavioural change were reflected in participants' experiences after taking part in I-MORE.
3. To evaluate whether the inpatient interventions reduced FABQ scores more than O-ACT, and whether baseline FABQ scores and changes (pre- to post-intervention) were associated with future work-participation.

3 METHODS

3.1 GENERAL CONSIDERATIONS

This thesis contains quantitative data from two randomised trials, and qualitative data from a focus group interview study nested in one of the randomised trials.

The United Kingdom Medical Research Council has recommended the integration of qualitative research particularly into randomised trials that assess 'complex interventions', conventionally defined as interventions containing several interacting components (Campbell et al. 2000, 2019). According to this definition, all of the interventions assessed in this thesis were 'complex interventions'. The integration of qualitative and quantitative data is considered to be an essential part of designing and testing such interventions (Moore et al. 2015).

The extension of the CONSORT statement for nonpharmacologic treatments stresses the question of whether and how adherence of participants to interventions is assessed or enhanced (Boutron et al. 2017). Since ACT was integrated into all the interventions assessed, a particular challenge pertained to how fidelity and participants' adherence to ACT could be measured. The most relevant and commonly used clinical quantitative measurement-device is the AAQ-II (Acceptance and Action Questionnaire, second edition), a 7-item questionnaire developed to measure overarching constructs of ACT-specific processes (Bond et al. 2011). However, at the planning stage of our study such questionnaires had not been specifically validated for measurement of adherence to ACT based interventions in randomised clinical trials, nor had the Norwegian version of AAQ-II been validated. Moreover, some researchers argue that the AAQ-II may measure level of distress rather than assessing ACT-specific processes (Wolgast 2014).

In personal communication with Steven Hayes in 2012 it became clear to me that the gold standard comparison used to validate the original AAQ tool in the first place had essentially been interviews with clinicians exerting their clinical opinion of whether participants engaged in ACT-specific processes. Hence, since qualitative data in combination with clinical expert opinion was the gold standard used to validate the original version of the questionnaire, it became apparent that a qualitative approach could serve the pragmatic aim of assessing

adherence by exploring whether and how participants experienced the ACT processes as intended after taking part in I-MORE. This approach could also indirectly aid another pragmatic aim that poses a special challenge when it comes to ACT, namely the assessment of therapist adherence and competence. The Association of Contextual Behavioural Science states that it has decided to forego an official ACT certification process and gives the following rationale on its web-page[a]:

> *"There is no ACT certification process. ACBS, as a community, has decided to forego this, as it could create a hierarchical and closed process which would be antithetical to our values. Rather, we aim to foster an open, self-critical, mutually-supportive community which, working together, builds a progressive psychology more adequate to the challenges of human suffering. There is no such thing as an officially certified ACT therapist."*

Nevertheless, we required therapists to undergo a strict internal training process before they could treat participants included in the randomised trial. Furthermore, from a pragmatic point of view, if participants' experiences after taking part in I-MORE reflect the intended ACT processes of behavioural change, it follows that the therapists' adherence and competence must have been satisfactory.

Hence, the mix of qualitative and quantitative research in this thesis served pragmatic aims in context of the randomised trial presented in Paper I. This is in line with the literature concluding that a pragmatic paradigm provides the most coherent strategy when mixing quantitative and qualitative methods in evaluations of complex interventions (Blackwood et al. 2010).

3.2 DESIGN AND DATA COLLECTION

Paper I and III were based on two randomised clinical trials evaluating the effects of a long and a short inpatient program. The two trials used the same recruitment strategy and both

[a] https://contextualscience.org/act_certification

compared inpatient interventions ('I-MORE' and 'The short program') with the same outpatient comparison program (O-ACT).

Paper II, a qualitative study part, was part of a larger research program nesting qualitative research in the randomised trials; see the protocol article for more details (Fimland et al. 2014). The design of Paper II involved interviewing participants receiving I-MORE after 3 weeks, i.e. at the end of inpatient intervention while still residing at the rehabilitation centre. Hence, papers I-III partially overlap in participants and settings as shown in the schematic overview in Figure 7.

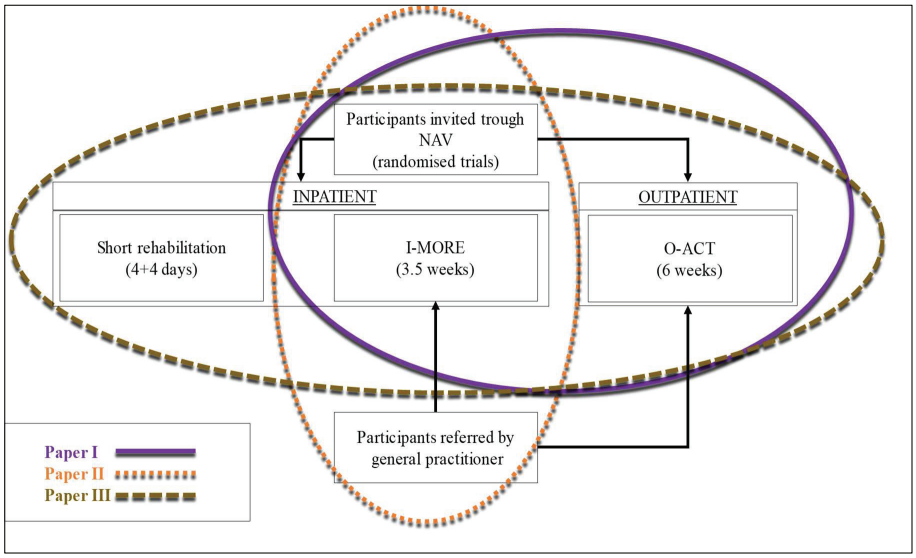

Figure 7 Papers I-III: Overview of the participants included from different contexts.

NAV, the Norwegian national labour and welfare service. I-MORE, Inpatient multimodal occupational rehabilitation. O-ACT, Outpatient acceptance and commitment therapy.

3.2.1 Flow of patients, sample size, randomisation and blinding (Paper I and III)

See figure 1 in Paper III, for an overview of the design and flow of participants in both Paper I and III combined. See figure 1 in Paper I for a detailed overview of the design and flow of participants for Paper I alone.

Paper I evaluated the effectiveness of I-MORE versus O-ACT on sickness absence and sustainable return to work. The sample size for Paper I was calculated based on the primary outcome, i.e. number of sickness absence days, resulting in 80 persons in each arm (Fimland et al. 2014).

Paper III evaluated the effectiveness of I-MORE and the short program versus O-ACT on fear avoidance beliefs. Assessments of other outcomes of the short program trial have been published elsewhere (Aasdahl et al. 2017, Aasdahl et al. 2018).

Both randomised trials were designed in line with the CONSORT statement using parallel groups (Schulz et al. 2010). A flexibly weighted randomisation procedure provided by a third-party unit ensured that the rehabilitation centre had enough participants to run monthly groups. This affected group-sizes differentially, and therefore the primary researchers were not blinded. For the I-MORE study, one of the researchers not involved in the data collection analysed the primary outcomes while blinded to allocation. Participants and clinicians could for obvious reasons not be blinded to allocation.

3.2.2 The ACT model and focus group sampling strategy (Paper II)

Paper II aimed to explore the participants' experiences with I-MORE specifically assessing the implementation of the ACT model. See Paper II and above for operationalized aims and an overview of the ACT model. The focus groups were sampled from the clinical treatment groups in I-MORE to account for different group dynamics developed in different treatment groups, possibly related to the therapist leading them. The rehabilitation centre recruited participants from two different pathways (see Figure 7). Hence, the interviews also included participants who were referred by their general practitioner to participate in I-MORE along with the participants randomised as described in Paper I.

3.2.3 Ethics

The trials were approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241), and registered in https://clinicaltrials.gov/ (No.: NCT01926574).

3.3 PARTICIPANTS

Paper I and III recruited participants between October 2012 and November 2014. Study II recruited participants for focus group interviews between October 2012 and January 2013.

3.3.1 Paper I and III

Eligible participants for the two different randomised trials were identified in the national sick leave registry and invited by NAV (See Figure 1 in Paper III, for an overview of the design and flow of participants in both Paper I and III combined; see Figure 1 in Paper I for detailed information on the flow of participants only for the I-MORE study).

Inclusion criteria for both trials were the same: 1) age 18–60 years; 2) sick listed 2-12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the International Classification of Primary Care, second edition (ICPC-2); and 3) current sick-leave status of at least 50%. Individuals fulfilling these criteria received an invitation to take part in one of the two randomised trials, either assessing I-MORE or the short program. Individuals responding to the invitation answered a short initial eligibility-questionnaire, and, if still eligible, were invited to a multidisciplinary outpatient assessment for final decision on eligibility.

The exclusion criteria were: (1) alcohol or drug abuse; (2) serious somatic disease (e.g. cancer, unstable heart disease) or mental disorder (e.g. high suicidal risk, psychosis, ongoing manic episode); (3) disorders requiring specialized treatment; (4) pregnancy; (5) current participation in another treatment or rehabilitation program; (6) insufficient oral or written Norwegian language skills to participate; (7) surgery scheduled within the next six months; and (8) serious problems with functioning in a group setting, as assessed by a multidisciplinary team.

3.3.2 Paper II

The participants in Paper II were invited to take part in focus group interviews at their first day of I-MORE and the interviews were conducted at the rehabilitation centre 2 days before the end of the I-MORE program. The focus groups were largely the same as the rehabilitation groups and participants hence overlap with those of Paper I (Figure 7). Five focus-group interviews were conducted with 22 participants from 6 different clinical treatment groups

(one focus group combined participants from two different treatment groups). I moderated and audio taped all interviews. The last author of Paper II co-moderated two of the interviews. In addition, the last author stayed at the rehabilitation centre during 3.5 weeks of I-MORE for participatory observation, gathering first-hand experience, contextual and observational background data. She lead-authored a linked qualitative study that included interviews with the participants at the first day of arrival, aiming to investigate expectations and overall experiences with the rehabilitation program (Rise et al. 2015).

3.4 INTERVENTIONS

The following interventions were studied in the three papers presented in this thesis:

1. 'I MORE' (Paper I, II and III)
2. The 'Short program' (Paper III)
3. The outpatient 'O-ACT' program (Paper I and III)

'I-MORE' (3.5 weeks of continuous inpatient rehabilitation), the 'Short program' (4+4 days of inpatient rehabilitation separated by 2 weeks at home) and O-ACT (6-7 weeks of outpatient ACT) were all group-based behavioural change interventions. Hence, the description below follow the checklist for reporting of group-based behavioural change interventions suggested by Borek et al. (Borek et al. 2015). This checklist comprises 26 items grouped into the four themes: (i) intervention design, (ii) intervention content, (iii) participants (i.e. those receiving the intervention), and (iv) facilitators (i.e. the therapists, those delivering the intervention). The checklist item numbers (1-26) have been referred to and marked with '(#)' in the text below.

3.4.1 Intervention design process (i)

All interventions were (1) developed through extensive workshops with discussions between researchers and clinicians aiming to unite best evidence and best practice in development of three original interventions. The process resembled that of intervention mapping (Bartholomew et al. 2016), but was not rigorously reported or published as such.

The general setting (2) and the venue characteristics (3) of the interventions have been described in section 1.4.4 above. Some additional details on the venue characteristics:

The inpatient venue

(Hysnes Helsefort)

The O-ACT venue

(St. Olavs Hospital)

The 'Hysnes Helsefort' rehabilitation centre (inpatient venue) was rurally located. The venue had previously been used for military purposes but had been fully refurbished by the Municipality for the sake of the 'Hysnes Helsefort' project. There was abundance of space and well-equipped facilities placed in the different buildings. The participants stayed in dormitories on site fitted with space for socializing among participants or for relaxing alone with different activities. Participants also had access to training facilities during afterhours. Meals were served in a separate building.

The outpatient (O-ACT) venue: The O-ACT intervention took place within the outpatient back-neck-shoulder pain clinic at St. Olavs University Hospital. The building hosts an extensive outpatient activity in cross-disciplinary cooperation between relevant medical specialties (neurosurgeons, orthopaedic surgeons, and physical medicine and rehabilitation specialists teamed up with physiotherapists). The building was old and had not recently been refurbished. However, most of the surrounding hospital buildings on campus were new and have appealing architecture.

Table 3.4-1 below gives a schematic summary of the total number (4), length (5) and frequency (6) of the intervention elements as well as the duration of the interventions (7).

Table 3.4-1 Overview of the rehabilitation program

	I-MORE	**O-ACT**	**Short program**
Setting	Inpatient rehabilitation centre	Outpatient Hospital clinic	Inpatient rehabilitation centre
Duration	3.5 weeks (supervised sessions: ~45.5 h)	6-7 weeks (supervised sessions: ~18.5 h)	4+4 days, (supervised sessions: ~29 h)
Contents	(groups led by 2 coordinators, various backgrounds)	(groups led by a physician or psychologist)	(groups led by 2 coordinators, various backgrounds)
and qualities	- group discussions (x8, 16 h; ACT based)	- weekly ACT group sessions of 2.5 hours duration (×6, 15 h)	- group discussions (x6, 12 h; ACT based)
	- psychoeducational sessions (×4, 6.5 h)	- group discussion on physical activity (×1, 1 h led by a	- psychoeducational sessions (×1, 2 h)
	- individual meetings with coordinator (×5, 5 h)	physiotherapist)	- individual meetings with coordinator (×2, 2 h)
	- individual meeting with physician (×1, 0.5 h)	- individual sessions (×2, total 2 h with social worker trained in	- individual meeting with physician (×1, 0.5 h)
	- individual and group based supervised physical	ACT)	- Individual and group-based supervised physical
	exercise sessions (×10, 12 h)	- individual closing therapy session in week 6 or 7 with both the	exercise sessions (×8, total 10,5 h)
	- outdoor activities day (×1, 5 h)	social worker and the group therapist present (×1, 0.5 h)	- mindfulness sessions (×4, 2 h) [2]
	- "network day" with 2 group sessions (total 4 h)	- 15 min. mindfulness at the start of group sessions (x 6, total 1.5	- create return to work plan
	- mindfulness sessions (×7, 3.5 h) [2]	h)	In the 2 weeks at home separating the 4+4 days:
	- "walking to work" (×6, total 3 h) [2]	- home practice, including daily mindfulness (15 min. audio	- Meeting with employer, if relevant and permitted
	- create return to work plan	guided) [2]	- At least 2 contacts with team coordinator (telephone
	- at least one weekend at home framed as "home	- a short resume of the program content and the patient's own	or personal)
	practice" [2]	value based action plan was sent to the GP after the individual	- a resume was sent to the GP
	- a resume of the return to work plan was sent to the	closing session.	
	GP		

Adapted from protocol article; Fimland et al. BMC Public Health 2014. [2] Scheduled but not supervised parts of the program. ACT = Acceptance and Commitment Therapy

3.4.2 Intervention content (ii)

The underlying behavioural theory of change (8) and the mechanisms that the interventions were based upon have been extensively described in the introduction (see section 1.3 above).

ACT was integrated in all components of the interventions, including the supervised physical exercise sessions and development of the return to work plan. For description of the clinical ACT model with examples of behavioural change techniques (9) see Paper II and section 1.3.4.4 above. This component of the interventions aimed to facilitate return to work through increasing participants' psychological flexibility, motivation and self-efficacy.

The inpatient programs were constructed around ACT as a general approach to coping and (mindfulness based) mental training. In addition, supervised physical exercise and work-related problem solving were the two other main components. Moreover, psychoeducation on relevant topics, interventions intended to activate and coordinate the social network around the participant and the development of a return to work plan was included.

I-MORE included a 'network day' where the participants could bring who they wanted to the centre aiming to give important others enough insight in the rehabilitation process and content to enable them to support the participant after the program had ended. Most participants brought family or friends, but it was also possible to bring their general practitioner, their employer or other important stakeholders. The short program did not have a network day, but had two weeks at home in-between the 4+4 days at the rehabilitation centre. During the stay at home, a meeting with the employer or other important stakeholders could be arranged if regarded relevant by the intervention coordinator and if the participant gave permission. Most participants opted not to arrange such a meeting. The inpatient interventions also incorporated a protocol for guided physical exercise sessions individually tailoring exercise programs with the aim to increase muscle strength, aerobic capacity and physical function. The content of psychoeducational sessions included standardised PowerPoint presentations and procedures for the development of the return to work plan. Midway and at the end of both inpatient interventions, a summary letter, based on the return to work plan, was sent to the participants' general practitioner and to NAV and the employer if relevant and consented by the participant. For more details on the short program and results, see previous publications (Aasdahl et al. 2017, Aasdahl et al. 2018).

In O-ACT there was one session of psychoeducation on the benefits of physical exercise and supervised exercise sessions were not provided. There were no intervention components intending to activate or coordinate the social network or stakeholders besides facilitating the individual participant in carrying out their own plan according to value based actions. In addition to the six weekly group-based ACT sessions, the participants met twice for individual sessions with a social worker to clarify their values and individually tailor their value based action plan. At the end of the intervention, a summary letter was written and sent to the general practitioner following a final individual session with the participant, the social worker and the group facilitator present. The letter contained the participants' own value based action plan and a short summary of the content of the intervention. The action plan was not a return to work plan per se, although return to work was an important topic during the intervention and many had work related goals.

The detailed clinical protocols for the interventions are only available in Norwegian. These protocols detailed session plans, described session content (10), a suggested plan for activities that could be undertaken in the group sessions (13) and materials that could be given to the participants (12). For instance, in O-ACT this included recommended homework assignments and materials recommended for use by the participants between sessions.

However, even though the protocol specified content for each session and described a logic sequence (11) of progressing content, flexibility was encouraged. Following integration of the basic concepts of ACT such as 'psychological flexibility' and 'workability', all the planned content and sequences could be flexibly changed if deemed useful by the group facilitator. For instance, in O-ACT, the first session started with an ACT technique called 'creative hopelessness' aiming to introduce acceptance and the concept of values. The following sessions focused on each of the 6 core processes of ACT, e.g. the second session built on the first session on acceptance and 'control as part of the problem', introducing 'willingness' as an alternative to control and continuing to introduce the concept of value based living and mindfulness training. The final 6th session aimed to put what had been learned together, focusing on incorporating an attitude of openness, awareness and active living in future life processes. However, all elements of ACT could be used at any given time, and often were so.

The facilitators of all the interventions were supervised by the same ACT-instructor. Quality and fidelity of session delivery (14) were ensured through group-based supervision sessions

involving methods such as video recordings and role-play of challenging session as experienced by the facilitators. For O-ACT there was also occasional arranged peer-reviewed sessions where one of the other therapist would sit in on sessions observing without participating and giving feedback after the session. The general impression for both the inpatient interventions and O-ACT, was that facilitators' delivery of the interventions became more flexible over time as they gained facilitator experience and became more familiar with the contents of the protocol and the ACT model. However, this was not measured.

3.4.3 Participants (iii)

The characteristics of group participants (15) are described in section 3.3 above and how the groups were composed by randomisation (16) in section 3.2.1. Once allocated to a group, there was continuity of group membership (17) and it was not possible for participants to change group at will. Acceptable group sizes (18) were in the range of 4-10, on average 6-8 was deemed ideal.

3.4.4 Facilitators (therapists) (iv)

In the inpatient interventions two 'coordinators' were normally assigned to each treatment group. In O-ACT, one group facilitator was assigned per group (19). There was continuity of group facilitators (20) in all interventions from start to end. The professional backgrounds (21) of the inpatient coordinators were diverse (psychologists, physiotherapists, exercise physiologists, etc.). However, their special competencies were used to facilitate specific program components. Many of the facilitators in the inpatient interventions were young, relatively clinically inexperienced and there was a gender balance. In O-ACT the group facilitators were either one of two male consultant physical medicine and rehabilitation specialists or a male senior clinical specialist in psychology, all middle aged and with relatively long clinical experience. All facilitators were of Norwegian cultural background, except one facilitator in O-ACT with a German background (22).

All facilitators received training (23) in ACT and continuous participation in internal and external workshops ensured intervention delivery and group facilitation (24). The facilitators in the inpatient interventions had to pass an exam showing that they had understood the written instructions (25) given in the intervention protocol before they could facilitate groups of participants enrolled in the randomised trials. The O-ACT facilitators organized a peer-

reviewed process of sitting in on each other's group sessions before facilitating clinical groups with participants included in randomised trials. Continued regular supervision by the same ACT-instructor during the whole study period ensured that the intended facilitation style (26) was in accordance with the ACT principles.

3.5 OUTCOMES

3.5.1 Registry based sickness absence data (Paper I and III)

Participants were followed with registry data for 12 months after inclusion. The primary outcome measure was the between-group difference in the number of sickness absence days (total number of whole workdays lost) at 6- and 12-months follow-up (Paper I). Not receiving any medical benefits was considered as work participation. The number of sickness absence/working days was calculated according to a 5-day workweek and adjusted for graded sick leave and partial employment (Aasdahl et al. 2018). Between-group differences in time until sustainable return to work (4 weeks without sickness absence) was also assessed during 12 months of follow-up for Paper I.

The sickness absence data were obtained from The National Social Security Registry based on medically certified sickness absence, work assessment allowance and changes in permanent disability pension during follow up. Employees at The Norwegian Labour and Welfare Service registered and provided sickness absence data unaware of treatment allocation.

3.5.2 Self-reported quantitative questionnaire data (Paper I and III)

The participants answered the web-based questionnaires at baseline, at the start and the end of the interventions and at 3, 6 and 12 months of follow-up. Detailed time-points for each questionnaire is shown in Table 3.5-1 below.

In Paper I, the questionnaire-based outcomes analysed were pain (Cleeland and Ryan 1994), anxiety and depression symptoms (Zigmond and Snaith 1983), subjective health complaints (Eriksen et al. 1999) and health-related quality of life (Vartiainen et al. 2016). Paper III analysed the FABQ (Waddell et al. 1993) administered the same way in two linked randomised trials. The self-reported health outcomes were measured on continuous scale

scores as described in detail in previous publications (Aasdahl et al. 2017, Aasdahl et al. 2018).

Table 3.5-1 Time-points for questionnaires

	Time-points					
	Baseline	Start of program	End of program	Follow-up		
				3 months	6 months	12 months
HADS[a]	x	x	x	x		x
Pain[b]	x	x	x	x		x
FABQ[c]	x	x	x	x		x
15D[d]		x		x	x	x
SHC[e]		x		x		x

[a] Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983). [b] Brief pain inventory, pain last week on a numeric rating scale (Cleeland and Ryan 1994). [c] Fear Avoidance Belief Questionnaire (Waddell et al. 1993). [d] Health related quality of life (Vartiainen et al. 2016). [e] Subjective Health Complaints Inventory (Eriksen et al. 1999).

3.6 DATA ANALYSIS

Analyses in Paper I and III were performed according to the intention-to-treat principle with per protocol analyses performed where relevant. Per protocol analyses were done by excluding participants who withdrew after randomisation and/or attended less than 60% of the sessions of O-ACT. All statistical analyses in Paper I and III were done using STATA, version 13.1 for Paper I and version 14.1 for Paper III. Precision of the estimates was assessed by 95% confidence intervals (CI) and $p<0.05$ (two-tailed) was considered to be statistically significant.

The qualitative analysis in Paper II followed the outline for analysis of focus group interviews proposed by Massey (2011) while also pragmatically serving other ends in context of the randomised trial presented in Paper I (see also 3.1 above and 5.3 below for more details regarding the general methodological considerations).

3.6.1 Paper I

The primary sickness absence outcome was the number of reimbursed sickness absence days at 6 and 12 months after inclusion. Sickness absence days were compared for the two programs using the nonparametric Mann-Whitney U (Wilcoxon rank sum) test since sickness absence is not normally distributed. We graphically plotted the cumulative median of sickness absence days each month to display differences between the intervention groups as a function of time (see Paper I, Figure 2). We compared time until sustainable return to work using Kaplan Meier survival analysis and the log rank test. Hazard ratios for return to work were estimated using Cox proportional hazard model with the Efron method for ties (Efron 1977). The adjusted model included gender, age, level of education, main diagnosis for sick leave and length of sick leave at inclusion. We calculated time as the number of months from inclusion and censored participants at the first month without sickness absence or at the end of follow-up (12 months). The proportionality hazards assumption was tested using the Schoenfeld Residual test. We also defined sustainable return to work as 2 months without reception of benefits for an additional sensitivity analysis. There was no missing data for the registry-based outcomes.

Self-reported health outcomes were analysed using linear mixed models to account for the dependency of repeated measurements nested within each participant, and to handle missing data with maximum likelihood estimation under the missing at random assumption (Tango 2016). In addition to programme and time, an interaction term between programme and time-points was included in the analyses to assess whether the effects of the programmes differed over time. For Paper I, we specified the linear mixed model with both random intercept and slope allowing individuals to start at different levels and change at different rates with time. We omitted random slope if the full model did not converge.

3.6.2 Paper II

The analysis of data was inspired by the approach suggested by Massey (2011) for analysis of focus groups in evaluation research. All audiotapes were transcribed verbatim and analysis started immediately after transcription of the first interview. We conducted the data-analysis within the group of authors (three medical doctors with different specialities and two public health researchers) aiming for diversity and reflexivity in interpretations of the data through group discussions and contribution from diverse backgrounds during analysis (Mays and Pope 1995). In the initial phase all authors read all transcripts separately adopting an explorative phenomenological approach aiming for 'a fresh, complex and rich description of participants experiences' (Giorgi 2009). Meaning codes were initially assigned to elements of the text and thereafter organized into thematic themes through group discussions between the authors. In a final stage of analysis, we explored how the participants' experiences were reflected within the processes of change intended by the ACT model. For an overview of the analytic framework and examples from the processing of results, see Paper II, Table 1.

3.6.3 Paper III

Paper III merged data from Paper I and a linked randomised trial (Aasdahl et al. 2018) to examine the effects of three different interventions on changes in the FABQ score. An additional objective was to explore the association between fear avoidance and sickness absence days during follow-up. The number of sickness absence days and self-reported health outcomes were largely analysed the same way as described for Paper I, except that the linear mixed model was simplified by omitting random slope (retaining random intercept in the model). A fixed effects linear regression model was used to assess the association between FABQ at baseline and changes in the FABQ during rehabilitation with the number of work-participation days at 9 months follow-up. For this analysis all participants were included and the merged data from the two randomised trials was treated as a single cohort. All analyses were performed separately for the 2 FABQ subscales. The analyses were performed both unadjusted and adjusted for age, sex and education. A sensitivity analysis adjusting for intervention programme and a per protocol analysis was performed. In addition, the analyses were performed separately for participants with musculoskeletal diagnoses and psychological diagnoses. As there were few participants with unspecific diagnoses (chapter A in ICPC-2), these participants were omitted in the separate analyses.

4 SUMMARY OF RESULTS

Below I present a summary of the main results from the three papers. See the respective papers for a more detailed account of the results.

4.1.1 Paper I

The primary hypothesis tested in this study was that I-MORE would reduce sickness absence more than O-ACT. We used registry data to assess sickness absence outcomes and self-reported health outcomes to assess pain, anxiety/depression symptoms, subjective health complaints and health-related quality of life.

As hypothesized, participants in I-MORE had fewer sickness absence days. At 12-month follow-up the median number of sickness absence days[a] for participants in I-MORE was 85 days (interquartile range [IQR] 33-149) versus 117 days (IQR 59-189) for O-ACT (Mann-Whitney U test; p=0.034). At 6 months follow-up, the median number of sickness absence days was 51 (IQR 27-85) for I-MORE and 65 (IQR 42-97) for O-ACT (p=0.114). The time to sustainable return to work was also shorter for I-MORE. In total, 50 of the 86 participants in I-MORE and 31 of the 80 participants in O-ACT achieved sustainable return to work. The cox regression model gave an unadjusted hazard ratio for return to work of 1.9 (95% CI 1.2 to 3.0) in favour of I-MORE, unchanged after adjusting for age, gender, level of education, length and cause of sick leave (1.9; 95% CI 1.2 to 3.2).

A sensitivity analysis defining return to work as two months without receiving benefits produced a similar hazard ratio. However, in per protocol analysis the unadjusted hazard ratio was reduced to 1.4 (95% CI 0.85 to 2.44, p=0.17) and sustainable return to work rates were reduced from 58% (n=50/86) to 55% (n=38/69) for I-MORE and increased from 39% (n=31/80) to 43% (n=26/61) for O-ACT. A similar pattern of diminishing difference was found in the per protocol analysis of the median number of sickness absence days, increasing

[a] The whole number of days the participants received medical benefits; i.e. adjusted for graded sick leave, employment fraction, and calculated as a 5-day workweek.

by 5 days in I-MORE to 90 (IQR 33 to170) and decreasing by 9 days in O-ACT to 108 (IQR 58 to 156) at 12 months follow-up (p=0.30).

Self-reported outcomes improved for both programs during follow-up except for the number of subjective health complaints that had a statistically insignificant reduction. A reduction of average pain in favour of O-ACT (-1 (CI -1.7 to -0.2) on a 0-10 numeric rating scale) was the only statistically significant group difference found for self-reported outcomes.

4.1.2 Paper II

The aim of this qualitative study was to examine whether and how the intended processes of behavioural change were reflected in participants' experiences after taking part in I-MORE.

The ACT model for behavioural change was fully integrated within the rehabilitation program. It contains three domains (open-aware-active) with two clinical processes for each of the three domains (acceptance & defusion, present moment & self, values & committed action). These six intended processes aim to foster behavioural change through increased psychological flexibility. The ACT model and its underlying axioms has been explained in detail under 1.3.4 above and in the method section of Paper II.

Five focus group interviews were conducted at the end of I-MORE. In summary, the qualitative data analysis found that all three intended domains of the ACT model were reflected in the experiences described by the participants. Some interesting emerging perspectives were: 1) the mix of diagnoses within the same group-based intervention may have facilitated increased openness and thus the model-specific processes within this domain. 2) Within the awareness domain, statements indicating flexible self-awareness processes were scarcely evident in the participants' reported experiences. 3) Even though the participants expressed strong engagements in their personal values and talked about behavioural changes in this direction, they did not mention any actions leading to imminent return to work.

4.1.3 Paper III

The aim of this study was to assess whether the two inpatient occupational rehabilitation programs (short program or I-MORE) reduced fear-avoidance beliefs more than O-ACT. Furthermore, the study aimed to assess whether baseline scores and changes (pre- to post-intervention) in FABQ were associated with future work-participation. Data from two

randomised trials were merged, n=168 in the short trial and n=166 in the I-MORE trial (refer to Paper III, Figure 1 for details).

There was no statistically significant difference on the FABQ scores from baseline to 12 months follow-up for any of the inpatient programs compared to O-ACT (see Paper III, figure 2). A sensitivity analysis corroborated the findings. FABQ scores were reduced for all programs during follow up. The mean reduction in fear-avoidance beliefs for work was 7.0 (SD 11.7) for mental health diagnoses and 4.8 (SD 11.1) for the musculoskeletal diagnoses. For the physical activity subscale, the numbers were 1.4 (SD 5.6) and 3.0 (SD 5.3), respectively.

Merging all participants into a joint cohort, we found associations between changes in the FABQ-work subscale scores from the start to the end of the rehabilitation programmes and the number of work-participation days (See Paper III, Table II). Participants with consistently low scores on FABQ-work had the most work participation days (149 days (95% CI 136 to 162), while those with consistently high scores had 57 days less (95% CI –77 to –37). FABQ-work scores at baseline were associated with number of work-participation days for both musculoskeletal and mental health diagnoses (see Paper III, Table III). The association was stronger, and the explained variance was larger, for mental health diagnoses than musculoskeletal disorders. For FABQ-physical activity, the association with future work participation was weaker.

5 DISCUSSION

The principal findings of the research presented in this thesis is that:

- During one year of follow up there was a statistically significant reduction in sickness absence days in favour of 3.5 weeks of I-MORE compared to 6 weeks of O-ACT, and the participants in I-MORE returned to work faster.
- Self-reported health outcomes (e.g. pain, mental distress and health-related quality of life) improved in both I-MORE and O-ACT over time but the magnitude of improvements did not differ between groups
- 'The change scores for FABQ from baseline to 12-months follow-up did not differ between participants in the two inpatient interventions and in O-ACT.
- The change scores for the FABQ work subscale from baseline to 12-months follow-up was associated with sickness absence. Participants with consistently low scores on FABQ-work had less sickness absence, i.e. those with consistently high scores had worked 57 days less during the 9 months of available follow-up after the interventions ended. Interestingly, for participants sick listed due to mental health disorders the association between FABQ-work scores at baseline and number of workdays during follow up was stronger than for musculoskeletal disorders.
- The intended ACT-processes of behavioural change were well reflected in participants' experiences after taking part in I-MORE, indicating that the ACT model had been successfully implemented and delivered by the therapists in the I-MORE intervention as intended. Flexible self-awareness was scarcely evident in

the participants' statements, maybe indicating that this part of the ACT model is particularly challenging to conceptualize and/or implement.

- Even though the interviewed participants expressed strong engagements in their personal values and talked about behavioural changes in this direction, they did not mention actions leading to imminent return to work.

Before further interpretation of these findings, I would like to discuss some relevant methodological issues.

5.1 VALIDITY AND PRAGMATISM IN ASSESSING COMPLEX INTERVENTIONS

Can we trust the above findings to be 'true'? This is a fair and simple question. However, the answer is complex and requires a definition of the concept of 'truth' and as well as a discussion of the concept of 'validity' in regard to the methods used.

'Truth' is defined in the Cambridge dictionary as *"…a fact or principle that is thought to be true by most people…"*[a]. This definition catches an inherent challenge in the concept of truth since what is 'true' may change according to which proportion or selection of 'most people' you ask as well as the context in which you ask them.

The definition of the word 'valid' has since the 1640s been recorded as "sufficiently supported by facts or authority, well-grounded". However, in its Latin origin, the word '*validus'*, mean "strong, effective, powerful, active"[b]. This original meaning of the word 'valid' fits well to describe that in science, whatever criteria of 'truth' we adhere to, the *methods* applied should be strong and effective in order to make findings replicable by others

[a] https://dictionary.cambridge.org/dictionary/english/truth (accessed 18.02.20)

[b] https://www.etymonline.com/word/valid (accessed 18.02.20)

and therefore are particularly powerful in reaching 'valid' (i.e. trustworthy) conclusions. In other words, scientifically valid methods should to a larger degree than any other methods reach conclusions that can be trusted by *"...most people"*.

5.1.1 Internal and external validity

The scientific discourse (evidence-based medicine in particular) distinguish between internal and external validity. *Internal validity* concerns the reliability (i.e. trustworthiness) of the findings within the study sample (i.e. we can trust that the methods we applied gave reliable results based on the participants we included in the study). *External validity* on the other hand concerns the generalisability of the results outside of the study population and context (i.e. if externally valid, we can trust that these results apply to real life situations and general population). To achieve high external validity, internal validity is a prerequisite and for the sake of both, confounding factors and bias must be kept at a minimum (discussed in section 5.2 below).

A randomised trial ensures high internal validity per design. In addition, the randomised trials in this thesis aimed for high external (ecological) validity. In the design process, we kept in mind the wish to inform future policymaking regarding the implementation of inpatient occupational rehabilitation and needed to ensure relevance to clinical practice and policy-makers. Hence, inclusion/exclusion criteria were kept broad to enable generalizing findings to a larger population and the differences in length of interventions were pragmatically adapted from real life practice. However, pragmatic randomised clinical trials face several methodological challenges regarding the need to balance between internal and external validity (Godwin et al. 2003).

5.1.2 Pragmatic versus explanatory clinical trials

Medicine has a strong pragmatic tradition where results of large and well performed randomised clinical trials is the basis of evidence-based practices (Bird and Ladyman 2013, Ford and Norrie 2016). However, the understanding of the term 'a pragmatic trial' appears to be not well unified in the published literature (Dal-Ré et al. 2018).

A pragmatic randomised trial design is one intended to provide direct support to the decision on whether to deliver an intervention in the 'real-world' with bearing on usual care in clinical practice (effectiveness). An explanatory randomised trial design aims to assess the maximum

potential beneficial effects, i.e. to give an intervention the best chances to demonstrate a beneficial effect under ideal conditions (efficacy) (Ford and Norrie 2016). In practice, pragmatic versus explanatory properties of trial is a continuum rather than a dichotomous distinction and the PRECIS-2 tool, aimed to guide design of clinical trials, scales domains from 1(very explanatory) to 5(very pragmatic) (Loudon et al. 2015).

The PRECIS-2 tool was not available at the design phase of the two randomised trials presented in this thesis. Hence, these trials were never assessed on the nine domains scored in the tool[a]. From a brief assessment, I find that the design of our randomised trials may fall in a category between pragmatic and exploratory on some of the domains, particularly domains such as 'organisation' (the expertise and resources needed to deliver the intervention). In addition, the domain 'recruitment' may be a matter of discussion since participants on sick leave were directly invited to our study while in usual clinical practice they are most often referred by their general practitioner. Nevertheless, the recruitment pathway used in our trials could easily be implemented in standard clinical care if found effective. When it comes to trials using sickness absence as main outcome, policymakers will certainly always be interest in real life applicability and evidence with high external (pragmatic) validity that can inform decisions on whether to implement new interventions.

Hence, I find that the randomised trials presented in this thesis fit the definition for pragmatic trials *"…which inform a clinical or policy decision by providing evidence for adoption of the intervention into real-world clinical practice"* (Ford and Norrie 2016). However, 'real-world clinical practice' often involve complex clinical interventions.

5.1.3 Complex interventions

In its simplest definition 'Complex interventions' *"…are those that include several components"* (Campbell et al. 2000). To elaborate, complex interventions often comprise multiple interacting components with additional dimensions of complexity related to their implementation and the organisational levels they target (Craig et al. 2008). In addition,

[a] See examples of several studies scored here: http://www.precis-2.org/Trials

delivery of complex interventions often rely on several health care professionals (Ford and Norrie 2016). For example, interventions in the occupational rehabilitation context may involve cross-disciplinary coordination of physiotherapist, psychologists, social workers, case managers, return to work coordinators, cognitive behavioural therapists and different medical specialties. Coordinating interventions advocate to get *"…all players on the same side"* (Frank et al. 1998). Hence, due to obvious challenges of standardizing all these factors, complex interventions often require pragmatic trials and are less often found in explanatory trials (Ford and Norrie 2016).

Interestingly, assessing the effects of psychological interventions face challenges due to the inherent complexity of psychotherapeutic processes. Carey and Stiles identify and elaborate on four main problems in this regard (Carey and Stiles 2016): 1) Although the effect of different techniques of treatment can be compared, treatment techniques are only a small part of what contributes to psychological change; 2) The randomised trial design intrinsically suppose improvement to be caused by the psychological treatment agent. However, in psychotherapy *clients* (not the treatment) are the active agents making use of the resources offered to create the effects they themselves desire; 3) Defining what psychological treatment actually is and the standardisation needed to demonstrate a true causal relationship between treatment and improvement, is not really possible (or realistic in real life application); 4) Treatment groups are not homogeneous and the average effect sizes on group level yielded by a randomised trial may have limited utility on the level of the individual.

Although the randomised trial is considered the gold standard method for evaluating effects of clinical interventions, increasingly popular also in other fields than medicine, several still debate the practical value. As Deaton and Cartwright put it *"…RCTs can play a role …but they can only do so as part of a cumulative program …to discover not 'what works', but why things work*" (Deaton and Cartwright 2018). The challenge of assessing 'why things work' is a concern for complex interventions. Hence, it is a custom claim that evaluation of complex interventions requires use of both qualitative and quantitative evidence (Campbell et al. 2000, Moore et al. 2015).

The above arguments regarding complex interventions are all relevant to most trials assessing effects of occupational rehabilitation interventions, including those presented in this thesis.

Hence, these issues should be kept in mind when interpreting the findings. Another important issue potentially affecting validity of finding is bias.

5.2 BIAS AND PRECISION IN RANDOMISED CLINICAL TRIALS

'Bias', in this context, may be defined as *"a systematic deviation from the effect ... that would be observed in a large randomised trials without any flaws"* (Sterne et al. 2019). The main purpose of any randomised trial is to provide an unbiased effect estimate with a high level of precision. 'Precision' is often defined as a *"small confidence interval around an (effect-) estimate, thus increasing confidence in its magnitude"* (Lewis and Warlow 2004). Many factors affect the risk of bias and the precision of the estimates generated by randomised trials. A recent update of the Cochrane risk-of-bias tool emphasize the following domains of bias (Sterne et al. 2019).

5.2.1 Bias arising from the randomisation process

This type of bias occurs if the way participants are allocated affects the outcome. Signal questions used to assess this domain of bias are: 'Was the allocation sequence truly random?", "Was the allocation sequence concealed until participants were assigned to interventions?", and "Does baseline differences between intervention groups suggest a problem with the randomisation process?" (Sterne et al. 2019).

There were some differences between the randomized groups at baseline. For example, in Paper I, fatigue and psychological diagnoses constituted 11% and 39% of participants allocated to O-ACT, versus 6% and 31% of those allocated to I-MORE. Of participants in O-ACT, 4% had (pre-existing) graded disability pension at inclusion versus 9% in I-MORE; and median length of sickness absence at inclusion was 216 in O-ACT versus 204 days in I-MORE. Since the randomisation was managed by a professional third-party randomisation service, these differences should have arose by coincidence through the process of random allocation.

Potential participants were (unknowingly) randomly allocated to receive invitation to the I-MORE or to the Short program trials. The responding participants consented to random allocation between inpatient rehabilitation and O-ACT by accepting the invitation to the multidisciplinary outpatient assessment of eligibility (see section 3.2 above for details). We

used a professional third-party service to randomise the participants after they had visited the outpatient clinic and final eligibility had been confirmed. Participants were informed about what intervention they had been assigned to in a letter written by a research assistant. The randomisation procedure was variably weighted to ensure that the rehabilitation centre had enough patients to run groups in periods of low recruitment. The weighting was not known to other than the principal investigator and the project research assistant who communicated with the randomisation service. Allocation sequence and block size was concealed to researchers, caregivers and the participants. In this way, we ensured that the participants were well informed about the procedure of random allocation while the sequence of randomisation was concealed to both participants and clinicians.

Though I conclude that the risk of bias is low within this domain, but differences between the treatment-groups at baseline may have occurred by chance due to the heterogeneity of the population randomised. Hence, the baseline differences may give rise to 'random confounding' and this may be a relevant discussion in the interpretation of results (Deaton and Cartwright 2018).

5.2.2 Bias due to deviations from intended interventions

This bias occurs when deviation from intended delivery of interventions induces a systematic distortion of the study results. The participants of the study, the clinicians delivering the interventions or the researchers analysing the data can all introduce bias within this domain, e.g. if knowledge of allocation systematically change their behaviours or responses.

Although lack of blinding theoretically can be a source of bias (e.g. due to placebo effects or 'contamination' of the intervention protocol in one intervention by the other), blinding is rarely feasible when assessing complex clinical interventions. Hence, neither participants nor caregivers were blinded to allocation in our trials. Moreover, blinding would not be in line with our pragmatic aim. Since, in real life participants would never be blinded, external validity could even have been compromised by blinding (see relevant discussion in section 5.1 above). In addition, the interventions differed in context, content and timespan that made bias by 'contamination' unlikely.

Self-reported data were collected by web-based questionnaires. The clinicians delivering the interventions had nothing to do with the collection of this outcome data. Employees in NAV

that were unaware of participation (and allocation) in the trials, registered sickness absence prospectively in a national registry as part of their daily routine. The national registry data was later exported and analysed as the main outcome. Placebo effects, which generally are short lasting, is unlikely to affect sickness absence during one-year of follow-up. Hence, I consider the risk of bias due induced by deviation from intended interventions as low.

5.2.3 Bias due to missing outcome data

There were no missing data for outcomes of sickness absence (registry data) and hence, no risk of bias. For the self-reported questionnaires, missing outcome data substantially increased during follow up. However, in the analysis of these data we applied linear mixed effect models (maximum likelihood based methods) that are robust to missing when the pattern of missing is random (Bell et al. 2013). Nevertheless, a missing at random pattern (and therefore ignorable with random effect analysis), cannot reliably be discerned from non-ignorable missing patterns by assessing the data. Hence, although we feel the assumption holds, there will usually be some concern regarding risk of bias due to missing self-reported outcomes in the longitudinal follow up data (e.g. for FABQ in Paper III).

5.2.4 Bias in measurement of the outcome

This type of bias arises from inappropriate outcome measures or if the detection rate of the outcome varies between groups. For example, this can happen if allocation influence the outcome assessment.

Participants had to be on 100% sickness absence during the 3.5-weeks of I-MORE whereas in O-ACT they had the possibility to be on partial sickness absence throughout the whole intervention period. Because of the differences in length and context of the inpatient and outpatient programs in our trials, allocation may have affected the sickness absence outcomes. Particularly, this ‘trapped in rehabilitation’ effect may cause a systematic bias to the disadvantage of I-MORE on sickness absence outcomes. However, we deliberately chose a pragmatic design with different length and context to ensure external validity with relevance to the current common clinical practice. In a real-life situation, participants in inpatient interventions are by nature ‘trapped in rehabilitation’ and an inpatient context will always be more intensive and costly than most outpatient interventions. Thus, by research design, increased demands were put on I-MORE to outperform O-ACT like a real-life

situation. This fits with the intended pragmatic purposes of informing future policies for occupational rehabilitation interventions.

For the primary sickness absence outcome, we counted the number of days on different sickness absence compensation benefits from national registry data (~count of whole workdays lost). In line with the mainstream literature (see Appendix 1), we chose 4 weeks sustainable return to work (no reception of medical benefits as proxy variable) as a dichotomous outcome. We used this variable for analysing survival hazard rates according to the cox model. In a recent systematic review, Etuknwa et al. (2019) defined return to work as 3 months of continuous work without sickness absence work while others have used first day of work and some have also included partial return to work (Voss et al. 2016, and Appendix 1). Hence, arguably we could have operationalized the sustainable return to work outcome in several other ways. However, four weeks without receiving benefits is the most commonly used outcome in the literature and sensitivity analysis (2 and 3 months) provided similar results, which indicate robustness of this outcome in the analysis of our data.

In the preparation of the registry data for analysis, the primary researchers could not be blinded to allocation (due to known unequal group sizes that revealed allocation). However, a separate 'blinded analysis' of the main outcomes was done by a researcher unaware of group sizes to alleviate this potential bias. Overall, the robustness of the registry-based sickness absence outcomes is high. Hence, despite the fact that allocation may have affected the sickness outcomes, I consider the risk of bias within this domain as low bearing the pragmatic trial design in mind and the robustness of outcomes based on national registry data that record actual real-life sickness absence benefits payed by the state.

We chose the FABQ score as the outcome to assess fear avoidance. This has been the most widely used tool in the literature since its original development in 1983 (Slade et al. 1983) and publication of its present form in 1993 (Waddell et al. 1993). However, a review of the evidence for the construct validity and responsiveness of FABQ and other related measures of pain-related fear considered the evidence to be weak (Lundberg et al. 2011). A rasch analysis of the Italian version of FABQ also raised questions about its validity in a population of back-pain patients (Meroni et al. 2015). Hence, after the process of publishing Paper III, we later performed a rasch analysis on the Norwegian version. This study did not support the FABQ as a unidimensional construct and we advised against using this measure for future studies

(Aasdahl et al. 2019a). Hence, since we reported FABQ not to be a valid measure of fear avoidance, it is obvious that the risk of bias in Paper III is high in this regard. However, there is no reason to assume that this bias systematically favoured one or the other intervention groups compared in Paper III (See also section 5.4.4 below where I discuss this problem further).

5.2.5 Bias in selection of the reported results

Bias within this domain may arise from presented results being cherry-picked by the researchers among multiple eligible outcome measurements within the relevant outcome domain or among multiple eligible analysis of such data.

We published our planned outcomes and a pre-specified analysis strategy in a protocol paper (Fimland et al. 2014) as well as in clinicaltrials.gov before outcome data was available for analysis. However, in preparation of the registry data, in operationalising the pre-specified analysis within the statistical software used and in decisions regarding specification of adjusted models and sensitivity analyses, many choices at a level of detail that could not be pre-specified had to be made. Where possible we made these decisions through discussions among the primary researchers before looking at and analysing the data. Hence, I think we have kept the risk of this bias at a minimum.

5.3 REFLEXIVITY AND VALIDITY IN QUALITATIVE RESEARCH

In qualitative research, the researcher often act both as the 'research instrument' gathering data and as the 'the analytic tool' (metaphorically much like the statistical software in quantitative research in addition to the person interpreting the results) (Mays and Pope 1995). Hence, bias is inherent in qualitative research methods. Since bias can never be avoided, reflexivity is key to high methodological standards (Malterud 2001, Tong et al. 2007). The process of reflexivity includes considering how the researcher's preconceptions affects all aspects of the research process. Therefore, researchers background, experiences and their relations to the participants should always be reported (Tong et al. 2007).

In Paper II, I (a medical doctor with specialisation in physical medicine and rehabilitation, training in cognitive behavioural therapy/ACT and a bachelor degree in social anthropology previous to becoming an MD) planned and gathered the data together with the last author (a

professor in public health research with extensive experience in doing qualitative research). The last author also stayed at the rehabilitation centre for participatory observation during 3.5 weeks of I-MORE. Amongst us, we discussed the methodological choices and decided, in addition to more traditional ways of analysing qualitative data, to adopt an analytic strategy proposed by Massey for analysing focus group data in the specific context of evaluation research (Massey 2011). In Massey's approach, while based on a thematic analysis, three levels of latent data analysis (articulated, attributional, and emergent) are emphasized. For our pragmatic aims, we chose the ACT model as a pre-conceptual level of analysis to help assess whether and how the participants experiences reflected the intended ACT processes they were meant to gain experience in (see Paper II, Table 1 for an overview of the analytic framework with examples from the processing of results). Hence, indirectly this analytic strategy allowed us to assess the implementation of the ACT model in I-MORE. Certainly, our preconceptions and the study context of nesting this focus group study in the randomized trial, affected the choice of research question and the analytic strategy. However, we aimed for a high level of reflexivity in this regard.

Including multiple researchers with different backgrounds has been recommended to strengthen the study design and increase reflexivity (Mays and Pope 1995, Malterud 2001). Hence, all authors (with diverse backgrounds) were involved in the analysis of the qualitative data, featuring group discussions to increase reflexivity. Finally, the research in this thesis was done in the context of a large evaluation project with many collaborators. I think that collaborations and group discussions among the large group of experienced researchers with different methodological and clinical backgrounds helped ensure high methodological quality and a high level of reflexivity relevant both to quantitative and qualitative data analysis.

In qualitative research the term 'transferability' (rather than 'external validity') is used to describe *"… the range and limitations for application of the study findings, beyond the context in which the study was done"* (Malterud 2001). For our purposes, transferability may be somewhat limited to the context of implementing ACT in inpatient occupational rehabilitation. The method and the results section of Paper II gives insight into the operationalization of ACT in I-MORE. Although our study context was unique, I believe the main findings in Paper II are transferable and highly relevant to researchers or clinicians

wishing to integrate ACT in occupational rehabilitation interventions elsewhere. In addition, the nesting within a specific randomised trial adds utility to the interpretation of results.

5.4 INTERPRETATION OF FINDINGS AND DISCUSSION OF MECHANISMS

Paper I in this thesis is the first randomised study to assess and show effect on sickness absence of an extensive inpatient intervention for sick-listed individuals with musculoskeletal and common mental disorders. It is also the first study to show effect on sickness absence of an inpatient intervention fully integrated with the ACT model. Paper II assesses participants' experiences with ACT as implemented in I-MORE. Finally, Paper III assesses the associations between FABQ scores and work participation and whether the inpatient program affected FABQ scores more than O-ACT. In addition, papers II and III both contribute to the discussion of potential mechanisms mediating the effect of I-MORE.

5.4.1 The I-MORE study in context of the international literature

To my knowledge, the French study by Nguyen et al. (2017) is the only comparable published study that assessed the effect of inpatient occupational rehabilitation outside of the Nordic context. This study assessed the effects of a 5-day inpatient multimodal intervention compared to usual care. Although the study by Nguyen et al. (2017) was seriously underpowered[a], it is interesting to note that return to work rates and the trend of results were similar.

Albeit without reaching statistical significance (p=0.30), at one year follow up Nguyen et al. (2017) reported a higher return to work tendency among participants in the inpatient intervention compared to usual care (53.3% vs. 41.9%). In the I-MORE study, 58% of the participants (versus 39% of the participants in O-ACT) reached sustainable return to work during one-year follow-up while return to work at 12 months among participants in the Short (4+4 days) program was 43% compared to 39% among the O-ACT participants (Aasdahl et al. 2018).

[a] Nguyen et al. only recruited 12.6% of the pre-planned participants (88/700)

In Nguyen et al. (2017), the multimodal inpatient intervention was composed of exercise therapy, physiotherapy, psychoeducation with the addition of spa-/balneotherapy elements. Hence, several intervention components were similar to I-MORE but the length of I-MORE was much longer (17 vs. 5 days of inpatient stay) which may hugely affects cost effectiveness.

In Germany, which also has a strong tradition of inpatient rehabilitation, Zeidler et al. (2008) estimated the cost of inpatient rehabilitation to be nearly twice the cost of outpatient rehabilitation. A few randomised studies from inpatient settings in Germany have been published. In one of these, a cluster-randomised study, the aim was to assess the effects of an 'add-on' intervention for participants already receiving an inpatient rehabilitation intervention due to back pain. The aim of this study was to reduce recurrent depression which was also the main outcome (Hampel et al. 2019). Although they reported an improved sickness absence outcome, it was a self-reported secondary outcome only available for a proportion of the participants included. Another German add-on intervention study assessed the effect of providing an online psychodynamic intervention after inpatient rehabilitation for psychosomatic, cardiologic, or orthopaedic diagnoses (Zwerenz et al. 2017). The main outcome of this study was participants' '*subjective prognosis of gainful employment*' (i.e. subjective expectations of work ability). Even though participants in the intervention group reported improved expectations, sickness absence itself was not measured after the inpatient intervention nor after the add-on intervention. Hence, since these German studies used different outcomes and assessed the effects of add on interventions rather than inpatient interventions per se, results are not directly comparable to the I-MORE study.

Several studies have applied non-randomised methods (e.g. propensity score matching) to construct post-hoc control groups in longitudinal cohort/registry datasets and thereby assess effects on sickness absence of participation in different occupational interventions. For instance, in Finland, the effect of a workplace training approach was assessed on sickness absence using such an approach (Leinonen et al. 2019). Similarly, Norwegian registry data has been used to assess effects of a return to work training program (Aakvik 2001). However, selection bias will always be a problem in such non-randomised designs (Aakvik 2001, King and Nielsen 2019). Moreover, to my knowledge, effects of inpatient occupational

rehabilitation interventions have not been assessed using propensity score matching or similar methodology in cohort data internationally or in the Nordic countries.

For Paper I, a two-year follow-up is in preparation that allow tracking of the transition into permanent disability benefits (a seven-year follow-up is also planned). If participation in I-MORE proves to reduce transition into permanent benefits this will have major impact on cost efficacy and willingness for stakeholders to finance such extensive inpatient interventions. Hence, a full-scale health economic evaluation of I-MORE is prepared alongside the follow up studies (Fimland et al. 2014). Moreover, several other relevant studies have been published from our research group.

5.4.2 The I-MORE study in context of other findings from our research group

Aasdahl et al. (2018) reported no effect of short (4+4 days) inpatient rehabilitation compared with O-ACT (same comparative intervention as for the I-MORE study in Paper I). Following the I-MORE study (Paper I), we designed a new randomised study assessing the effects of adding a workplace visit to I-MORE. Based on reviews of the international literature (Cullen et al. 2018) our hypothesis was that the addition of a workplace involvement would improve the effect. However, we found no extra benefit, and even a negative tendency (Skagseth et al. 2019b), which may be due to the timing and the limited amount of contact with the workplace (only one meeting). Nevertheless, Hara et al. (2017a) reported effect on sickness absence of adding a 6 months telephone follow up compared to no follow up after I-MORE. These studies differed slightly in the recruitment strategies (See Figure 7 on page 42). Whereas the telephone follow-up study only recruited participants referred by their general practitioner, the I-MORE and the short study only requited sick-listed individuals responding to an invitation by NAV (i.e. ‘self-referred’). The workplace intervention study recruited both through invitations and through referral from the general practitioner.

The differences in recruitment strategy may have affected the characteristics of the study population, e.g. the level of intrinsic motivation may have differed for those referred by their general practitioner and for those that ‘self-referred’ in response to the invitation. Hence, for purposes of implementation as well as for comparison of results across studies, recruitment strategies and their relevance for external validity should be considered. Particularly, it is difficult to assess external validity of studies across the context of different welfare systems

in different countries. The different randomised trials published by our research group were all based on inpatient interventions that were part of the 'Hysnes project' conducted in Central Norway.

Most previous randomised trials assessing multimodal occupational rehabilitation interventions, in Norway and internationally, were conducted in an outpatient care setting (see Appendix 1 for an overview). Moreover, the previous randomised studies on return to work have primarily assessed interventions within specific diagnostic categories such as 'back pain' or 'depression'. In contrast, all the interventions described in this thesis recruited participants with a broad range of musculoskeletal and common mental health disorders and delivered a unified treatment approach in group based rehabilitation programs based on ACT. This unified treatment approach applying ACT principles to broad diagnostic categories has been a novel approach within occupational rehabilitation. Hence, in context of the results of the randomised trial, the potential mechanisms of ACT in occupational rehabilitation of musculoskeletal and common mental disorders needs a more in-depth discussion.

5.4.3 ACT in occupational rehabilitation - a counterintuitive successful move?

I concluded in Paper II that the ACT specific processes of behavioural change were largely implemented in I-MORE as intended. This indicates that implementation and delivery of the ACT-based intervention protocol in I-MORE was successful. However, contrary to what I expected, there was little talk among the participants interviewed for Paper II about committed actions leading to imminent return to work. This latter finding appears counterintuitive, in the light of clear effects on sickness absence outcomes reported in Paper I and some further discussion of the mechanisms of ACT seems warranted.

A feature of ACT, which distinguishes it from most other psychotherapeutic approaches, is the emphasis on sorting out what is most important in life (values) and directing the therapy to act upon this. According to the findings in Paper II and a related interview study by Rise et al. (2015), participants re-oriented themselves towards what was important in their lives and contemplated how they could take steps to move in this direction. This did not necessarily involve work. Hence, the existential element (focusing on personal values) is interesting in the sense that it may appear dissonant to the clear intent of return to work that most often is the main aim of occupational rehabilitation.

A similar concept to 'values' was described by Friedrich Wilhelm Nietzsche (1844-1900) who stated that "*If you have your 'Why' for life, you can get by with almost any 'How'*" (Nietzsche and Large 1998). A Jewish Austrian professor of neurology and psychiatry, Victor Frankl (1905-1997), adopted and expanded on Nietzsche's principle advocating implementation of an existential approach to psychotherapy. In Victor Frankl's book "Man's search for meaning: an introduction to logotherapy", he describes how his own experiences and observations in concentration camps such as Auschwitz reflected the principles laid out by Nietzsche (Frankl 1992, published originally in German in 1946). His main argument was that since it often is difficult to remove the cause of human suffering in any given setting, it is wiser to concentrate efforts on increasing meaning. Hence, his main argument was that the increase of meaning reduces distress, both in extreme settings (e.g. Auschwitz) and common settings of life (e.g. chronic pain or mental health disorders), when suffering cannot easily be removed. Victor Frankl later expressed this argument in a simple mathematical equation describing how psychological distress (D) is a function of suffering (S) and meaning (M) where the latter is subtracted from former:

$$D = f(S - M)$$

It was this frame of thinking that later inspired the concept of 'values' that, combined with behavioural theories and tradition, formed the clinical ACT model. Hence, even though participants did not talk about imminent return to work, it is possible that the emphasis of meaning brought on by the ACT approach in turn contributed to reduced distress and improved work capacity through the mechanism described above.

During 3.5 weeks of ACT-based inpatient rehabilitation, the participants had abundant time available to sort what was important to them and reorient themselves towards a strategy that provided idiosyncratic meaning to them. Initiation and commitment to value based behavioural change was encouraged. It follows that for the participants, reduced distress and increase coping could theoretically incur without reduction of the problem originally creating suffering and reduced function leading to sickness absence. Another aspect is that reorientation towards an intrinsically positive motivation such as 'values' may bring forth a change from punishment ('aversive') to reward ('appetitive') based motivation. This may have initiated behavioural change. Positive (appetitive) motivation and intrinsic rewards is

known to increase problem solving capabilities and mental capacity in ways that may be relevant for return to work (see discussion of some of this literature in section 1.3.2 above).

Group-based mindfulness approaches have also proven cost-effective among back pain patients (Herman et al. 2017). However, in the context of the randomised trial in Paper I where O-ACT was the comparison intervention, it is unlikely that ACT was the main component mediating the effect of I-MORE on sickness absence (Paper I), even though the inpatient context of I-MORE was more intensive compared to O-ACT. Nevertheless, Paper I, Paper II, and the feasibility study published by Hara et al. (2017b) warrants the utility of ACT as a unified coping framework for musculoskeletal pain and common mental health disorders in the inpatient occupational rehabilitation context.

5.4.4 Utility of FABQ scores in occupational rehabilitation

Changes in the FABQ-work subscale scores from the start to the end of the rehabilitation programmes were associated with the main sickness absence outcome (number of workdays). Consistent low scores on FABQ-work was associated with the most work participation days, while participants with consistent high scores had the lowest work participation.

The association between fear avoidance and work participation in musculoskeletal disorders has already been established by previous research using the FABQ (Marchand et al. 2015b, Oyeflaten et al. 2016, Trinderup et al. 2018) and research using other measure scales such as the Tampa Scale of Kinesiophobia (Wideman et al. 2009, Westman et al. 2011).

In addition to FABQ and Tampa, at least three additional measurement scales of fear avoidance are used: The Fear-Avoidance of Pain Scale, the Fear of Pain Questionnaire and the Pain and Anxiety Symptoms Scale (Lundberg et al. 2011). However, according to a critical review by Lundberg et al. (2011), all of the five measures scales lack sufficient evidence on psychometric properties including strong evidence for construct validity and evidence for responsiveness. The fear avoidance model itself has been under scrutiny (Wideman et al. 2013), further raising concern about the psychological construct validity that these five questionnaires aim to measure. Empirical findings suggest that cumulative risk load with clustering of emotional distress; fear-avoidance and catastrophizing may be likely to predict who will develop prolonged disability (Westman et al. 2011). Interestingly, the research on general psychological theories aiming to explain how psychological factors affect

function and disability, have recently implied an underlying latent common 'p-factor' (psychopathological factor) that is suggested to better predict future outcomes than any individual psychological construct or specific diagnoses (Caspi et al. 2014).

From a pragmatic point of view, even though construct validity is questioned, if changes in FABQ scores could be shown empirically to facilitate return to work, FABQ scores could be targeted as a process measurement of positive change during occupational rehabilitation. However, despite the associations established between changes in FABQ scores and work participation, there was no statistically significant improvement in FABQ scores in favour of any of the inpatient programs. Similarly, Marchand et al. (2015b) did not find evidence for improvement of FABQ scores for participants randomised to work-focused outpatient rehabilitation even though FABQ-scores predicted occupational outcome.

Concerns were rising after discovering that a Rasch analysis of the Italian version of FABQ did not support its use as an unidimensional measure of Fear Avoidance beliefs (Meroni et al. 2015). Hence, in a follow up study to Paper III, our research group did a Rasch analysis of the Norwegian version (by merging data from three different RCTs, n=722). We concluded that *"The FABQ is not a good measure of fear-avoidance beliefs about work or physical activity…"* and recommended to avoid future use of FABQ to measure fear-avoidance beliefs (Aasdahl et al. 2019a). FABQ just does not reliably measure fear avoidance. Rather we found evidence that one or two single items of the FABQ related to expectations could predict work participation in occupational interventions just as good as the whole questionnaire. Hence, we suspect that *"…the predictive property of the FABQ questionnaire is most likely related to expectations rather than fear"* (Aasdahl et al. 2019a). In light of this knowledge, it is unknown if these single expectation items of the FABQ might retain both precision and validity in predictive capabilities for return to work.

Interestingly, from Paper I, the association between FABQ-work scores at baseline and work-participation during follow-up was strongest for psychological diagnoses, although also associated for musculoskeletal diagnoses. If the capacity of FABQ to predict return to work is mainly mediated by the two expectation questions, it might be that this element is particularly important for return to work among participants with mental health disorders (i.e. related to the self-efficacy construct). For musculoskeletal disorders a complex interplay of factors such as genetic dispositions, and anxiety sensitivity level has been shown to affect the level of pain

that again naturally predicts function and return to work after occupational rehabilitation interventions (George et al. 2008, Wideman et al. 2009, Asmundson et al. 2012).

Recently, with the advancement of neuroscience, neurological and physiological substrates for behavioural principles of fear conditioning are being mapped (Maren 2011, Andreatta and Pauli 2015) including functional neuroanatomical correlates that may explain individual variances in dispositional avoidance in humans (Meylakh et al. 2016). Hence, it is plausible that developments in neuroanatomical functional imaging may be a future asset in further understanding the fear-avoidance construct.

5.4.5 General considerations on the discussion of potential mechanisms

Participants in randomised trials are likely to be more motivated than the general population. In addition, the self-selection process that for the most part occurred in the Hysnes trials may have led to selection of motivated participants. Results of twin cohort studies in Norway and Sweden indicate that genetic predisposition might explain around 66% of the variation in permanent disability pension (Gjerde et al. 2013, Narusyte et al. 2020). Hence, it is plausible that only a small proportion of long-term work absentees actually benefit from occupational rehabilitation.

However, the short (4+4 days) inpatient rehabilitation did not show an effect and the recruitment strategy was the same as the I-MORE study (Paper I). Hence, it is possible that I-MORE is more effective or that the participants who accepted the invitation to take part in the two different studies differed (although preliminary analysis indicate similarity of participant characteristics in the two trials). It is known that the family context is associated with work disability. Particularly, ill health of a partner is a separate risk factor for permanent disability pension (Vie et al. 2015). Hence, it is plausible that the family situation played a role in the participants' decision to take part in the I-MORE where they potentially had to stay away from their partner/family during 3.5 weeks. Hence, those with spouses with ill health or other family obligations might have opted out of the I-MORE study.

As previously presented, Paper I reports superior effect of I-MORE compared to O-ACT on sickness absence, but no superior effects on the different self-reported health outcomes; including health-related quality of life. The Short program performed similar to O-ACT both on sickness absence and self-reported health outcomes.

The I-MORE intervention contained three main modalities: physical exercise, constructing a plan for return to work and ACT coping strategies aimed at increasing psychological and behavioural flexibility at a general level. The O-ACT intervention contained mainly the latter modality. The Short program contained the same modalities as I-MORE, albeit in a condensed version both in content and time. Since ACT was the only common modality of both interventions, it seems unlikely that this component can explain the effect on sickness absence of I-MORE over O-ACT. However, since I-MORE contained 45.5 hours of supervised sessions compared with only 18.5 hours in O-ACT a dose-response mechanism is possible. Moreover, due to the inpatient context, with prolonged group interactions and discussions continuing after working hours for 3.5 weeks, it is plausible that all the inpatient program modalities were potentiated.

Only I-MORE provided supervised physical activity. This could be an important facilitating factor in the return to work process. However, a study conducted within our research group, found no difference in effect of I-MORE versus O-ACT on self-reported physical activity, although increased vigorous physical activity was associated with reduction in sickness absence for both intervention groups (Skagseth et al. 2019b). Another study assessed cardiorespiratory fitness objectively (the Åstrand cycle test) in I-MORE participants and found significant improvement in maximal oxygen uptake with further improvement after one year (Nordstoga et al. 2018). Evidence from the general population also suggests that leisure-time physical activity can be protective against long-term sickness absence (Fimland et al. 2018). Hence, it is possible that increased fitness may have played a part for I-MORE participants, even though we were not able to measure an effect on the self-reported outcomes.

Expectations toward return to work and increased self-efficacy is another potential mechanism postulated to mediate the effects of occupational rehabilitation interventions (Andersén et al. 2018). Due to the higher intensity of I-MORE and the making of a return to work plan, it is plausible that I-MORE affected participant's expectations of return to work more than O-ACT. However, despite showing an association between changes in expectations and return to work among participants in both I-MORE and O-ACT, we found no significant superior effect of any of the interventions on changes in return to work expectations (Aasdahl et al. 2019b).

Of participants referred by their general practitioner to receive I-MORE in a related study, 79% reported fatigue (Hara et al. 2017b). Fatigue is known to be a significant predictor of long-term sickness absence even though the actual length of sick-leave seems determined more by the welfare system than the medical condition itself (Sagherian et al. 2019). Fatigue is often considered the result of long-standing psychological- or physiological stress that has overloaded regulatory mechanisms of homeostasis (allostatic load theory) (McEwen and Stellar 1993). Prolonged stress and pain is associated with atrophy of the hippocampus is indicated in both (Vachon-Presseau et al. 2013). As the hippocampus is important for all cognitive functions involved in memory, learning and planning, this may of course be relevant to occupational capacity. Mindfulness practice is associated with increased grey matter in several brain structures, including increase of grey matter in the hippocampus (Fox et al. 2014). An 8-week mindfulness-based stress reduction program, has been particularly researched and has been proven effective in back-pain patients (Cherkin et al. 2016, Cherkin et al. 2017) as well as for other sources of distress such as common mental health disorders (de Vibe et al. 2012). Effects shown for participants in 8-weeks mindfulness based stress reduction programs include increases in hippocampus grey matter compared to waiting list controls. However, even a 4-week mindfulness based stress reduction course has been shown to significantly increase frontal lobe activity (Braden et al. 2016). A dose-response relation on well-being was recently shown for a mindfulness intervention at work (Chin et al. 2019). Hence, it is possible that the effect of I-MORE partially was mediated by a dose-response effect also involving the proposed associations between brain changes and meditation. However, in the lack of data to support it, this is merely speculation.

Interestingly, a blunted salivary cortisol / HPA-axis activation response was indicated for another group of participants in I-MORE compared to healthy controls receiving the standardized Trier stress test (Jacobsen et al. 2014). On a biological level, in long-term stress, a dysfunctional HPA-axis/cortisol response has been suggested as a key marker. Recently, both cognitive behavioural therapy and mindfulness-based stress reduction has been shown to normalize the habituation pattern in cortisol stress response in relation to this particular test (Manigault et al. 2019). This strengthens the hypothesis that the combination of a mindfulness based cognitive therapy approach and physical activity within a potentiating inpatient context, may have mediated return to work by increasing participants' psychological and physiological stress coping capacity. Particularly the potential for stress-relief through a

schedule regulating sleep, physical and social activity during a long inpatient stay, could be relevant.

The intensive inpatient context of I-MORE could have potentiated both the cognitive therapy elements / mindfulness and physical exercise modalities. Hence, working together to increase participants' stress coping capabilities, potentially on both a psychological, brain morphological and physiological level. This in turn, may have increased the participants' occupational capacity enabling their return to work plan. Moreover, I think that a synergy effect between modalities and the extended group-dynamic processes might have played a role. Hence, hitherto, I hold the synergy of different components in the context of 3.5 weeks inpatient care to be the most plausible explanation for the effect of I-MORE on reducing sickness absence. We have limited ways of assessing this hypothesis with the data gathered. Nevertheless, our findings is in line with of a recent systematic review reporting there is best evidence for multidisciplinary interventions and cognitive therapy-based interventions for chronic conditions related to long-term stress (Nazarov et al. 2019).

The workplace is another important arena in occupational rehabilitation. Cullen et al. advocates that work-place involvement as the most effective modality of occupational rehabilitation (Cullen et al. 2018). Interestingly, a workplace intervention was not part of the I-MORE intervention featured in Paper I and we later had indications that it might not be useful to add a workplace visit to this already extensive intervention (Skagseth et al. 2019b). However, increasing evidence indicate that supported employment, involving the workplace in rehabilitation in line with a 'place-then-train' paradigm, effectively increases participation in competitive work regardless of diagnosis (Reme et al. 2015a, Reme et al. 2019, Sveinsdottir et al. 2019).

6 CONCLUSIONS AND CLINICAL IMPLICATIONS

This thesis provides evidence that among individuals on long-term sickness absence due to musculoskeletal and common mental health disorders, a 3.5-week I-MORE program can reduce sickness absence compared with 6 weeks of O-ACT in the year after inclusion. Hence, the findings presented supports the current clinical practice in Norway. Studies with longer follow-up and economic evaluations should be performed.

The ACT model is a novel approach not commonly used in occupational rehabilitation. Fully integrating ACT in occupational rehabilitation has been a new endeavour. The results of focus group interviews with participants imply that for general implementation in occupational rehabilitation, further development of this model, specifically regarding processes of self-awareness and committed action towards work, may be beneficial. More research is needed on whether and how ACT should be adapted to the specific context of occupational rehabilitation.

Finally, there was no evidence that inpatient occupational rehabilitation reduces FABQ scores more than O-ACT. Nor were there any clinically important differences in other self-reported health outcomes (e.g., pain, mental distress and health-related quality of life), although these improved in both I-MORE and O-ACT over time. From a clinical perspective, this may indicate that returning to work and improvement of health-related outcomes may be two different processes that do not necessarily follow each other and that may warrant different measures.

The methodology of the research presented in this thesis had limited ability to unravel ‘the black box of rehabilitation’. The question of which modalities mediate the effects of I-MORE and which participants should be selected for such extensive interventions remains unanswered. Importantly, though, the research shows pragmatic utility for inpatient multimodal occupational rehabilitation, which has been used in Norway for four decades.

7 QUESTIONS RAISED AND SUGGESTIONS FOR FUTURE RESEARCH

- Inpatient interventions are expensive. Even though the evidence presented in this thesis supports the practice of inpatient occupational rehabilitation in Norway, the health economics needs to be assessed. A 2-year follow-up including economic analysis is ongoing, and a 7-year follow up of the participants in I-MORE has been planned to study the between-group differences in transition to permanent disability benefits. However, regardless of the outcome of the health economic analysis, it is probably not feasible to deliver comprehensive interventions such as I-MORE to everyone and we need more evidence on stratified care (who needs what).
- In the field of occupational rehabilitation, there is still a lack of clarity and a paucity of good evidence about whom should receive what and when. Hence, from both a pragmatic and health economic point of view, I suggest that future clinical and research innovations aim to develop and test implementation of stratified care models in occupational rehabilitation. Personalized care models may potentially sort which intervention fits best to each individual case in order to optimize benefits to the individual and reduce costs for society. Static stratification tools have already shown promising results in prediction of return to work (Nicholas et al. 2019, Simula et al. 2020). However, iterative models that learn from feedback loops (e.g. artificial intelligence algorithms such as 'case based reasoning') should also be tested. 'One size fits all' selection should be an obsolete strategy for future research assessing effects of occupational rehabilitation interventions from my point of view. Hence, there is a need for future research to test different selection and prediction strategies, including developing and testing if personalized artificial intelligence algorithms can enhance the effects of multimodal interventions such as I-MORE. We also have limited knowledge on the effects of participants following their own preference in choosing interventions.
- Even though a multimodal approach seems warranted in interventions such as I-MORE, we have little knowledge regarding the optimal mix of modalities, components and contexts of delivery. For instance, although integration of ACT into occupational rehabilitation of common mental health and pain disorders has proven feasible, there is little evidence supporting that the ACT component itself is vital for return to work. Other promising transdiagnostic therapies approaches are emerging,

including ‘Method of levels therapy’ (Mansell et al. 2013, Carey et al. 2014) and emotion-focus exposure treatment for chronic pain patients with comorbid common mental health disorders (Boersma et al. 2019). The feasibility of these and many other therapy approaches have yet not been tested in an occupational rehabilitation context. Comparison of effects of such different approaches can be of interest to explore in future research.

- The impact of the outpatient versus inpatient context per se remains unknown. Exploratory trials assessing mediation and moderation of different context of delivery in addition to the modalities delivered would be useful. Ideally, future research should also be able to decipher how contexts relating to culture, legislation and organisation of the labour marked mediates and moderates the effects of different types of interventions across different countries. Without such a framework in place, it is difficult to judge to what extent results, such as those presented in this thesis, have validity outside its original context.
- The research presented in this thesis does not answer *why* I-MORE was more effective than O-ACT in reducing sickness absence. To answer such research questions with depth and precision I think that it is necessary to develop theoretical frameworks more fit for operationalization and empirical testing than those currently available. Recently an iterative research framework suggested for work-related musculoskeletal disorders (van der Beek et al. 2017) raised debate on the content and appropriate methods for development of such frameworks (van der Beek and Coenen 2019, Winkel and Westgaard 2019). Van der Beeks model was criticised for being too rooted in the medical research tradition, being too mechanistically oriented and lacking perspectives from real word management at the workplace. Such debates show that there is a need for more research developing the theoretical basis for the field of occupational medicine. I think that development of new theoretical frameworks should either be able to account for the complexities of human behaviour to better answer questions of causality (e.g. why I-MORE was effective) or prove pragmatic validity in design and implementation of new interventions. Intervention mapping is a currently popular approach that may serve to exemplify the latter. This is a practical approach structured in 8 steps that utilizes behavioural theory to ensure good design and implementation of new interventions through combining knowledge from clinical practice and research evidence (Bartholomew et al. 2016). However, to

my knowledge, no empirical evidence exists to support the effects of using or not using such specific strategies in the development of new interventions and this should be researched (Intervention mapping was not used for the design of the interventions researched in this thesis but a similar procedure was adopted).

- We did not intervene at the work place in the I-MORE and although intended targeted in the Short trial, only a small proportion of the participants received the optional workplace component. A later study that added a work place visit, in addition to I-MORE, was not able to show additional effect return to work. However, this work place intervention was very limited and was added to an already extensive intervention where the participants were long-term sickness absent. Nevertheless, the work place has been targeted successfully in several international studies. Hence, we need more knowledge on how the workplace should be involved, the right timing of work place interventions and how country-specific legislation and context mediate and moderate the effects of such interventions.
- Due to the recently emerging evidence for supported employment, it would be interesting to compare the effect of individual placement and support to I-MORE in future studies and maybe explore if the combination could be beneficial for selected groups.

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Papers I-III

Paper I

Original article

Scand J Work Environ Health Online-first -article

doi:10.5271/sjweh.3882

Inpatient multimodal occupational rehabilitation reduces sickness absence among individuals with musculoskeletal and common mental health disorders: a randomized clinical trial

by Gismervik SØ, Aasdahl L, Vasseljen O, Fors EA, Rise MB, Johnsen R, Hara K, Jacobsen HB, Pape K, Fleten N, Jensen C, Fimland MS

Three to four weeks of inpatient occupational rehabilitation is mainstream in Scandinavia, but the effects have not been investigated. This is the first study to show that, among individuals on long-term sickness absence due to musculoskeletal- or common mental disorders, 3.5 weeks of inpatient multimodal occupational rehabilitation significantly reduced sickness absence compared with 6 weekly sessions of outpatient acceptance and commitment therapy.

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Refers to the following texts of the Journal: 2006;32(4):257-269 2012;38(2):93-104 [online first; 13 December 2019]

Key terms: cognitive behavioral therapy; fatigue; health services research; inpatient care; inpatient multimodal occupational rehabilitation; mental health; mental health disorder; musculoskeletal disease; musculoskeletal disorder; occupational rehabilitation; physical exercise; problem solving; psychiatry; randomized clinical trial; return to work; sickness absence

Original article

Scand J Work Environ Health – online first. doi:10.5271/sjweh.3882

Inpatient multimodal occupational rehabilitation reduces sickness absence among individuals with musculoskeletal and common mental health disorders: a randomized clinical trial

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Gismervik SØ, Aasdahl L, Vasseljen O, Fors EA, Rise MB, Johnsen R, Hara K, Jacobsen HB, Pape K, Fleten N, Jensen C, Fimland MS. Inpatient multimodal occupational rehabilitation reduces sickness absence among individuals with musculoskeletal and common mental health disorders: a randomized clinical trial. *Scand J Work Environ Health* – online first. doi:10.5271/sjweh.3882

Objectives This study aimed to investigate whether inpatient multimodal occupational rehabilitation (I-MORE) reduces sickness absence (SA) more than outpatient acceptance and commitment therapy (O-ACT) among individuals with musculoskeletal and mental health disorders.

Methods Individuals on sick leave (2-12 months) due to musculoskeletal or common mental health disorders were randomized to I-MORE (N=86) or O-ACT (N=80). I-MORE lasted 3.5 weeks in which participants stayed at the rehabilitation center. I-MORE included ACT, physical exercise, work-related problem solving and creating a return to work plan. O-ACT consisted mainly of 6 weekly 2.5 hour group-ACT sessions. We assessed the primary outcome cumulative SA within 6 and 12 months with national registry-data. Secondary outcomes were time to sustainable return to work and self-reported health outcomes assessed by questionnaires.

Results SA did not differ between the interventions at 6 months, but after one year individuals in I-MORE had 32 fewer SA days compared to O-ACT (median 85 [interquartile range 33–149] versus 117 [interquartile range 59–189)], P=0.034). The hazard ratio for sustainable return to work was 1.9 (95% confidence interval 1.2–3.0) in favor of I-MORE. There were no clinically meaningful between-group differences in self-reported health outcomes.

Conclusions Among individuals on long-term SA due to musculoskeletal and common mental health disorders, a 3.5-week I-MORE program reduced SA compared with 6 weekly sessions of O-ACT in the year after inclusion. Studies with longer follow-up and economic evaluations should be performed.

Key terms cognitive behavioral therapy; fatigue; health services research; inpatient care; musculoskeletal diseases; occupational rehabilitation; physical exercise; problem solving; psychiatry; return to work.

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Musculoskeletal and common mental health disorders are the major causes of disability and working years lost in the western world (1-4). For musculoskeletal disorders, effective occupational rehabilitation programs have comprised multimodal interventions including components such as physical exercise, psychological/behavioral therapy, work-related problem solving and often involvement and coordination of different stakeholders (5, 6). For individuals with musculoskeletal or common mental health disorders, a recent meta-analysis concluded that psychological treatments reduce sick leave more than usual care, albeit with small effect sizes, and inconclusive results as to which form of psychological treatment is the most effective (7).

The worker`s decision to remain off or return to work involves complex interactions between personal beliefs, physical, psychosocial, and system factors and goes far beyond the medical treatment paradigm for any specific diagnosis (8, 9). In addition, co-morbidity between musculoskeletal pain and mental health disorders is high (10–12). Successful occupational interventions for individuals with musculoskeletal disorders have recently inspired the development of similar promising interventions for common mental health disorders (5, 13).

Acceptance and commitment therapy (ACT) is a recent development within cognitive behavior therapy with empirical support as a coping strategy for a broad range of clients (14), including for individuals with musculoskeletal and common mental health disorders (15–17). A Swedish randomized pilot study reported fewer sickness absence (SA) days in women with musculoskeletal complaints receiving ACT (18). Furthermore, ACT has successfully been implemented as a coping modality in group-based interventions for sick-listed individuals with different diagnoses (12, 19, 20).

We have previously compared a short (8 days) inpatient rehabilitation program to group-based outpatient ACT (O-ACT) for patients sick-listed due to musculoskeletal or common mental health disorders. We found no significant differences in SA between this short inpatient program and 6 weeks of O-ACT during one year of follow-up (21), and there were negligible differences in self-reported health outcomes (22). However, in Norway, 3–4 weeks of inpatient multimodal occupational rehabilitation (I-MORE) is common for individuals with complex biopsychosocial barriers for return to work. Effects of such programs have never been assessed in a rigorous design.

The aim of this study was to compare the effect on SA of 3.5 weeks I-MORE to the 6 weekly sessions of O-ACT. We hypothesized that the more comprehensive I-MORE would reduce SA compared to O-ACT.

Method

The Regional Committee for Medical and Health Research Ethics in Central Norway approved this open label parallel randomized clinical trial (No.: 2012/1241), registered in clinicaltrials.gov (No.: NCT01926574), and adhered to the CONSORT statement (23). The study protocol is published elsewhere (24).

Eligibility criteria

Participants aged 18–60 years sick-listed (2–12 months, current sick leave status ≥50%) due to a musculoskeletal, psychological, or general and unspecified disorder (eg, fatigue) as classified by ICPC-2 (the International Classification of Primary Care, second edition) were included. The exclusion criteria were: (i) alcohol or drug abuse; (ii) serious somatic disease (eg, cancer, unstable heart disease) or mental disorder (eg, high suicidal risk, psychosis, ongoing manic episode); (iii) disorders requiring specialized treatment; (iv) pregnancy; (v) current participation in another treatment or rehabilitation program; (vi) insufficient oral or written Norwegian language skills to participate; (vii) surgery scheduled within the next six months; and (viii) serious problems with functioning in a group setting, as assessed by a multidisciplinary team.

Recruitment of participants

The Norwegian Labor and Welfare Administration identified and randomly invited potential participants from its records. Potential participants were asked to respond to the invitation either in writing or by telephone contact with a project co-worker. The project co-worker excluded individuals that self-reported any of the exclusion criteria. We invited the remaining candidates to outpatient assessment of eligibility consisting of individual appointments with a psychologist, a physiotherapist and a physician. This multidisciplinary team made a joint decision on whether the eligibility criteria were met.

Randomization and blinding

Eligible participants were randomized to either I-MORE or O-ACT. The Unit of Applied Clinical Research (third party) at the Norwegian University of Science and Technology (NTNU) conducted the randomization by a flexibly weighted procedure, which ensured that the rehabilitation center had enough participants to run monthly groups in periods of low recruitment. One of the researchers analyzed the primary outcomes while blinded to allocation. It was not feasible to blind primary researchers in preparation and analysis of the dataset due to knowledge of the unequal group sizes.

Interventions

The I-MORE program was provided at Hysnes rehabilitation center located in a rural setting one-hour travel from St. Olavs hospital in the city of Trondheim, Norway. I-MORE lasted 3.5 weeks and was more comprehensive than O-ACT, which mainly consisted of group-based ACT (2.5 hours/week for 6 weeks) at St. Olavs hospital. The length of the inpatient and outpatient interventions reflected common clinical practice. I-MORE comprised various treatment modalities such as physical exercise, work-related problem solving and a development of a written return-to-work plan in addition to ACT, whereas O-ACT consisted mainly of ACT. Mindfulness was integrated in several elements within both interventions. Details of the two programs are described in table 1 and in the protocol article (24). Adherence to- and competence in ACT was ensured by the same peer reviewed ACT trainer through video supervision and mentoring of the clinicians in both interventions.

Outcome measures

The primary outcome measures were the cumulative number of SA days (total number of whole workdays lost) within 6 and 12 months follow-up (see statistics section for details). Secondarily, time until sustainable return-to-work (4 weeks without SA) was assessed up to 12 months. The SA data are based on medically certified SA, work assessment allowance and changes in permanent disability pension during follow up, obtained from the National Social Security Registry. Employees at the Norwegian Labor and Welfare Service registered and provided SA data. They were blinded to treatment allocation.

Self-reported secondary health outcomes were pain (25), anxiety and depression symptoms (26), subjective health complaints (27) and health-related quality of life (28), all measured as continuous scale scores and described in detail previously (21, 22). The participants answered web-based questionnaires at baseline, at the start and the end of the interventions, and at 3, 6 and 12 months of follow-up.

Sample size

The sample size calculations are described in detail elsewhere (21, 29). An average SA of 60 [standard deviation (SD) 40] and 90 (SD 60) days for I-MORE and O-ACT respectively, would require 61 persons for each group. We aimed to include 80 persons in each arm allowing for 20% attrition or loss to follow-up.

Statistical analysis

The cumulative number of SA days at 6 and 12 months after inclusion were calculated and compared for the two programs using the Mann-Whitney U-test (30). Sickness absence days were calculated according to a 5-day workweek adjusted on a monthly basis for part-time employment, partial sick leave and changes in permanent (partial) disability benefits, enabling a count of cumulative days compensated with benefits (total number of whole workdays lost) (21). We graphically displayed differences by plotting the median number of SA days in each intervention group as a function of time (cumulative median). For time until sustainable return to work, Kaplan Meier curves were estimated and compared using the log rank test (30). Return-to-work hazard ratios were estimated using the Cox proportional hazard model and the Efron method for ties (31), with and without adjustment for gender, age, education, main diagnosis for sick leave and length of sick leave at inclusion. Time was calculated as the number of months from inclusion, and participants were censored at the first month without SA or at the end of follow-up (12 months). The proportionality hazards assumption was

Table 1. Overview of the rehabilitation programs [a] [ACT= acceptance and commitment therapy; GP=general practitioner.]

	Inpatient multimodal occupational rehabilitation (I-MORE)	Outpatient acceptance and commitment therapy (O-ACT)
Location	Inpatient rehabilitation center	Outpatient Hospital clinic
Duration	3.5 weeks (supervised sessions: 45.5 hours)	6–7 weeks (supervised sessions: 18.5 hours)
Contents and qualities	- group discussions (×8, total 16 hours; ACT based) - psychoeducational sessions (×4, total 6.5 hours) - individual meetings with coordinator (×5, total 5 hours) - individual meeting with physician (×1, 0.5 hours) - supervised physical exercise sessions (×10, total 12 hours) - outdoor activities day (×1, 5 hours) - "network day" with 2 group sessions (total 4 hours) - mindfulness sessions (×7, total 3.5 hours) [b] - "walking to work" (×6, total 3 hours) [b] - create return to work plan - at least one weekend at home framed as "home practice" [b] - a resume of the return to work plan was sent to the GP	- weekly ACT group sessions of 2.5 hours duration (×6, total 15 hours led by physician or psychologist) - group discussion on physical activity (×1, 1 hour led by a physiotherapist) - individual sessions (×2, total 2 hours with social worker trained in ACT) - individual closing therapy session in week 6 or 7 with both the social worker and the group therapist present (×1, 0.5 hours) - 15 minutes mindfulness at the start of group sessions (× 6, total 1.5 hours) - home practice, including daily mindfulness (15 minutes audio guided) [b] - a short resume of the program content and the patient's own value based action plan was sent to the GP after the individual closing session.

[a] Adapted from protocol article; Fimland et al. BMC Public Health 2014.

[b] Scheduled but not supervised parts of the program.

tested using the Schoenfeld Residual test (32). Self-reported health outcomes were analyzed as repeated measurements over time using linear mixed models (33), modelled without random slope (only random intercept) if the full model did not converge. Analyses were performed according to 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 O-ACT.

We performed sensitivity analyses with sustainable return to work defined as 2 and 3 months without receiving benefits. We considered P<0.05 (two-tailed) to be statistically significant. Precision of the estimates was assessed by 95% confidence intervals (CI). All analyses were done using STATA 13.1 (StataCorp, College Station, TX, USA).

Results

Of 3808 persons invited to take part in the study, 271 accepted the invitation and 166 were randomized to I-MORE (n=86) or O-ACT (n=80). See figure 1 for information about the flow of participants, dropouts and missing data.

Participants' characteristics

The mean age of the participants was 46 (SD 9.5) years and the majority was women (79%). About 60% of the participants did not have education beyond high-school level, and the median length of sick-leave reimbursement during the last 12 calendar months prior to inclusion was 210 calendar days (IQR 170-265). Baseline characteristics for the two intervention groups showed only minor differences (table 2).

Sickness absence and return to work

The I-MORE participants had a median of 85 (IQR 33–149) SA days at 12-month follow-up, significantly less than the O-ACT group with 117 days (IQR 59–189; Mann-Whitney U-test; P=0.034). At 6 months follow-up, the median number of SA days was 51 (IQR 27–85) for I-MORE and 65 (IQR 42–97) O-ACT, respectively (Mann-Whitney U-test; P=0.114), see figure 2.

In total, 50 of the 86 participants in I-MORE and 31 of the 80 participants in O-ACT achieved sustainable

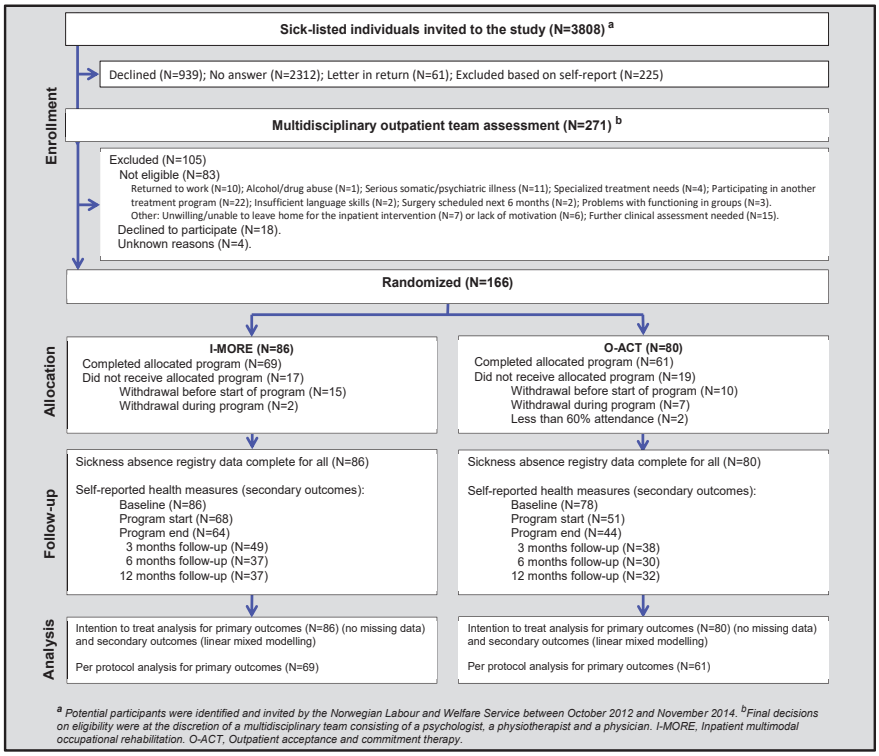

Figure 1. Flow of participants in the study.

Table 2. Participants' baseline characteristics. [HADS=hospital anxiety and depression scale ICPC2=international classification of primary care, 2nd edition; I-MORE=inpatient multimodal occupational rehabilitation; IQR=interquartile range; NRS=numeric rating scale; O-ACT=outpatient acceptance and commitment therapy; SD=standard deviation.]

Variables	I-MORE (n = 86)		O-ACT (n = 80)	
	N (%)	Mean/median (SD/IQR)	N (%)	Mean/median (SD/IQR)
Age [a]		46.3 (8.7)		45.2 (10.4)
Women [a]	70 (81)		61 (76)	
Higher education (university/college) [b]	32 (37)		34 (43)	
Work status [a, b]				
No work	11 (13)		6 (8)	
Full time	54 (63)		53 (66)	
Part time	21 (24)		21 (26)	
Graded disability pension [c]	9 (10)		6 (8)	
Sick leave status at inclusion [a]				
Full sickness benefit	35 (41)		36 (45)	
Partial sickness benefit	48 (56)		38 (48)	
Work assessment allowance [d]	3 (3)		6 (8)	
Length of sick leave at inclusion [a, e]		204 (163–265)		216 (177–265)
Sick leave diagnoses (ICPC-2) [a]				
Musculoskeletal diagnosis	54 (63)		40 (50)	
Psychological diagnosis [f]	32 (37)		40 (50)	
Anxiety HADS score (0–21) [b]		7.4 (3.9)		8.6 (4.1)
Depression HADS score (0–21) [b]		5.7 (4.2)		6.6 (4.0)
Average pain NRS (0–10) last week [b]		5.0 (2.0)		4.8 (2.2)
Strongest pain NRS (0–10) last week [b]		6.5 (1.9)		6.2 (2.5)

a Based on registry data.
b Based on self-reported data.
c Individuals working ≥50% at inclusion alongside graded permanent disability pension.
d Work assessment allowance is a medical benefit usually received after reaching the maximum of one year on sick leave benefits in Norway.
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.
f Four I-MORE and nine O-ACT participants with fatigue and one I-MORE participant with perinatal distress included here.

return to work. Figure 3 shows the Kaplan-Meier plot. The difference between the programs was statistically significant (log rank test, P=0.009). The unadjusted return-to-work hazard ratio was 1.9 (95% CI 1.2–3.0), in favor of I-MORE and was unchanged after adjusting for age, gender, level of education, length and cause of sick leave (1.9; 95% CI 1.2–3.2).

The sensitivity analyses defining return to work as 2 and 3 months without receiving benefits showed similar hazard ratios (1.8 and 1.7) as the main analyses.

Per protocol analysis

The median number of SA days during 12 months follow-up was 90 (IQR 33–170) versus 108 (IQR 58–156) days for I-MORE (N=69) and O-ACT (N=61), respectively (P=0.30). The respective sustainable return-to-work rates were 55% (N=38) and 43% (N=26) and the unadjusted hazard ratio was 1.4 (95% CI 0.85–2.44, P=0.17).

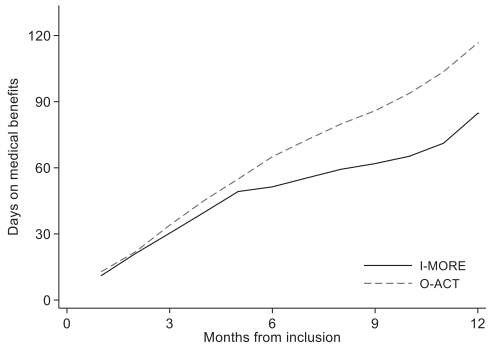

Figure 2. Sickness absence days during 12 months of follow up (cumulative median) for participants in inpatient multimodal occupational rehabilitation (I-MORE) and outpatient acceptance and commitment therapy (O-ACT).

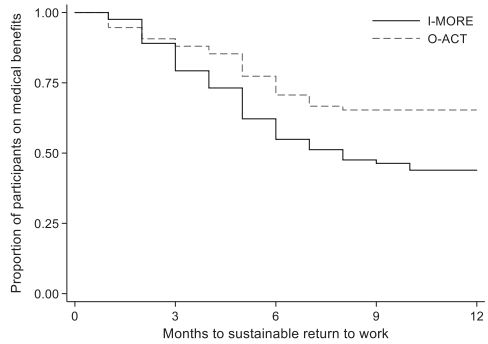

Figure 3. Time to sustainable return to work (Kaplan-Meier survival analysis) for participants in inpatient multimodal occupational rehabilitation (I-MORE) and outpatient acceptance and commitment therapy (O-ACT)

Self-reported health and quality of life

There were no statistically significant differences between the programs in these secondary outcomes during 12 months of follow-up, except for a small difference in average pain in favor of O-ACT (estimated mean difference -0.95, 95% CI -1.7– -0.2 on a 0–10 numeric rating scale). Both groups improved anxiety, depression, and quality of life outcomes during follow up (table 3).

Discussion

As hypothesized, I-MORE reduced SA more than O-ACT, and the time to sustainable return to work was

Table 3. Self-reported health outcomes. Numbers are estimates from unadjusted linear mixed models with random intercept and slope. I-MORE=inpatient multimodal occupational rehabilitation; O-ACT=outpatient acceptance and commitment therapy; CI=confidence interval.]

	Follow-up times	I-MORE (n=86)		O-ACT (n=80)		Effect estimates [a]	
		Mean	95% CI	Mean	95% CI	Mean	95% CI
Quality of life [b] (0–1) [c]	Start intervention	0.78	0.76–0.80	0.77	0.74–0.79		
	3 months	0.82	0.80–0.85	0.81	0.78–0.83		
	6 months	0.82	0.80–0.84	0.82	0.79–0.85		
	12 months	0.82	0.79–0.85	0.83	0.80–0.86	-0.02	-0.06–0.02
Depression [b] (0–21) [d]	Baseline	5.7	4.9–6.6	6.6	5.7–7.5		
	Start intervention	5.9	5.0–6.8	7.1	6.1–8.0		
	End intervention	4.9	4.1–5.8	6.0	5.0–7.0		
	3 months	4.8	3.8–5.8	6.0	4.9–7.0		
	12 months	4.7	3.5–5.9	5.1	3.8–6.3	-0.72	-2.3–0.9
Anxiety [b] (0–21) [d]	Baseline	7.4	6.5–8.2	8.6	7.7–9.5		
	Start intervention	7.7	6.8–8.5	8.4	7.4–9.3		
	End intervention	6.3	5.4–7.2	8.3	7.3–9.3		
	3 months	6.3	5.4–7.3	7.9	6.9–9.0		
	12 months	6.1	5.0–7.2	6.6	5.4–7.8	-0.22	-1.7–1.3
Average pain [b] (0–10) [e]	Baseline	5.0	4.5–5.4	4.8	4.4–5.3		
	Start intervention	4.5	4.0–4.9	4.6	4.1–5.1		
	End intervention	4.1	3.7–4.6	4.5	4.0–5.0		
	3 months	4.5	4.0–5.0	4.2	3.7–4.8		
	12 months	4.7	4.1–5.3	3.9	3.2–4.5	-0.95	-1.7– -0.2
Strongest pain [f] (0–10) [e]	Baseline	6.5	6.0–6.9	6.2	5.7–6.7		
	Start intervention	5.8	5.3–6.3	5.7	5.2–9.3		
	End intervention	5.7	5.2–6.3	5.6	5.0–6.2		
	3 months	5.9	5.3–6.5	5.8	5.2–6.5		
	12 months	5.8	5.1–6.6	5.0	4.2–5.8	-0.82	-1.9–0.3
Health complaints (0–87) [g]	Start intervention	16	14–18	17	15–20		
	3 months	15	13–17	16	14–18		
	12 months	15	13–17	16	14–18	-0.35	-3.1–2.4

[a] Estimated mean differences from start of intervention, I-MORE minus O-ACT.
[b] Improvement for both interventions over time (P<0.05).
[c] Measured by 15D.
[d] Measured by the Hospital Anxiety and Depression Scale.
[e] Measured by numeric rating scale (pain last week).
[f] Improvement over time for O-ACT (P=0.01).
[g] Measured by the Subjective Health Complaints Inventory total score (modelled with random intercept only due to lack of convergence).

shorter for I-MORE. Self-reported health outcomes (pain, distress and health-related quality of life) were largely similar between the groups during one year of follow up.

Our previous investigation of a shorter (8 days) inpatient program did not reduce SA compared to O-ACT (21). We are not aware of other studies that have examined the effect of a comprehensive inpatient occupational rehabilitation program comparable to our current study. In Norway, an intensive outpatient program consisting of six hours of daily activities for four weeks showed no overall effect on return to work compared to ordinary treatment in primary care (34). However, the same research group later reported that the individuals with the most complex problems returned to work faster when given the intensive rehabilitation program (35). Also, in a Norwegian study providing work-focused cognitive therapy combined with job support to individuals with common mental disorders, only the sub-group of individuals with the most complex problems and the longest SA benefitted from the intervention, and the effect on increased work participation was sustained after 4 years of follow up (36). Similar to the aforementioned studies (35, 36), the individuals in our study were long-term sickness absent (median 210 days in the preceding year).

Several factors could explain the superiority of I-MORE versus O-ACT impact on SA. As this study did not utilize a factorial design, it is not possible to ascribe the superiority of I-MORE to specific contrasts. The most notable differences between the programs were that I-MORE was inpatient, more intensive and multimodal – incorporating physical exercise and psychoeducational sessions. Living at the rehabilitation center for 3.5 weeks provided a break from daily life and gave more time for contemplation, discussion with peers, and integration of new coping strategies. The regulated schedule and a fixed wake-up time may have provided a frame for improved sleep and better coping with fatigue (37, 38). Psychoeducational sessions alone did not enhance return to work in a Danish study (39), but in synergy with other components of an inpatient multimodal intervention it might have contributed positively. We previously reported that a sub-sample of

participants in I-MORE improved their cardiorespiratory fitness during the program, and increased further after a year (40). Still, we found little support that differences in self-reported health outcomes (table 3), or changes in expectancies about return to work (41), could explain the differences in SA between programs. This is in line with other studies observing that returning to work and improving health outcomes are not necessarily concurrent events (42, 43). Moreover, participants in O-ACT did not create a return-to-work plan, but an action plan in accordance with their most important values. This may also explain why I-MORE improved work outcomes compared with O-ACT.

Workplace involvement is considered a critical factor in effective return to work programs (6), but our results suggest that I-MORE interventions can be successful without this component. Another study from our group provided no evidence that adding a workplace intervention could further improve work participation outcomes (44). Finally, also considering our previous negative findings of a shorter inpatient program (21), our results support the current practice in Norway of 3–4 weeks of inpatient occupational rehabilitation.

A particular strength of this randomized study is the use of high-quality sick leave registry data, which assured complete data regarding SA and return to work. In contrast, less than half of the participants answered the questionnaires at the 12-month follow-up. Assuming missing at random, the mixed-model approach alleviates this problem by applying likelihood-based analyses using all available data (33). The number of missing questionnaires were fairly similar for the two groups at 6 and 12 months, but we cannot disregard the possibility of an attrition bias for the secondary outcomes. Blinding of participants and caregivers regarding allocation was not feasible. Primary researchers were not blinded in preparation of the dataset. However, one of the authors were blinded to allocation and performed a separate analysis of the primary outcome measures before commencing with further analyses and discussing the findings. Moreover, the employees at the Norwegian Labor and Welfare Service that prospectively register SA data were unaware of group allocation. Another particular strength of the study design was that the Norwegian Labor and Welfare Service invited participants among those fitting the eligibility criteria in the registry, eliminating referral bias and potentially increasing the external validity of the results. However, only 38% (of 3808 invited) responded, and only 271 underwent a full clinical multidisciplinary eligibility assessment (figure 1). Since we do not know how many of those not responding that would have fulfilled the eligibility criteria, we cannot rule out a "self-selection" bias, possibly limiting the generalizability of the results to situations with similar recruitment methods. Another issue is that participants had to be willing to leave their home for 3.5 weeks to participate in I-MORE. Moreover, the differences in SA diminished in the per protocol analysis. This could be explained by the different patterns of withdrawal in I-MORE (before start) and O-ACT (during the intervention). It is conceivable that individuals that were able to return to work when the intervention started, would opt for this rather than 3.5 weeks of inpatient rehabilitation. Conversely, weekly O-ACT could be combined with work, making it unnecessary to withdraw before the program started. In addition, individuals who were unable to participate once a week were probably those least able to work. A limitation of our study is that we have no information on how O-ACT would have compared to usual care. Another limitation is that no scoring of therapists' adherence to or competence in ACT was done. However, the same peer-reviewed ACT trainer supervised clinicians in both interventions. In addition, a focus group interview study showed that all the relevant ACT processes of behavioral change were reflected in the I-MORE participants' experiences (20).

Finally, since legislation, social security systems and occupational rehabilitation services differ extensively between countries; one should consider contextual factors before implementing this intervention, especially in parts of the world other than the Nordic countries.

Concluding remarks

Among individuals on long-term SA due to musculoskeletal or common mental health disorders, I-MORE over 3.5 weeks reduced SA compared with 6 weekly sessions of O-ACT in the year after inclusion. Studies with longer follow-up and economic evaluations should be performed.

Acknowledgements

This study was funded by the Norwegian Government (allocated through the Central Norway Regional Health Authority), KLP (national public sector occupational pension scheme) and the Research Council of Norway. The funders had no role in the study design, collection and analysis of data, writing up results or the decision to publish this paper.

We thank all involved at Hysnes Rehabilitation Center, Department of Pain and Complex Symptom Disorders and Department of Physical Medicine and Rehabilitation at St. Olavs University Hospital, as well as the Norwegian Labor and Welfare Service (NAV) for help with collecting data and carrying out the study. We thank project assistant Guri Helmersen for valuable assistance.

The authors declare no conflicts of interest.

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Received for publication: 23 January 2019

Paper II

Taylor & Francis
Taylor & Francis Group

Disability and Rehabilitation

ISSN: 0963-8288 (Print) 1464-5165 (Online) Journal homepage: https://www.tandfonline.com/loi/idre20

The acceptance and commitment therapy model in occupational rehabilitation of musculoskeletal and common mental disorders: a qualitative focus group study

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To cite this article: Sigmund Ø. Gismervik, Marius S. Fimland, Egil A. Fors, Roar Johnsen & Marit B. Rise (2019) The acceptance and commitment therapy model in occupational rehabilitation of musculoskeletal and common mental disorders: a qualitative focus group study, Disability and Rehabilitation, 41:26, 3181-3191, DOI: 10.1080/09638288.2018.1490824

To link to this article: https://doi.org/10.1080/09638288.2018.1490824

Published online: 16 Aug 2018.

Paper III

J Rehabil Med 2019; 51: 175–182

ORIGINAL REPORT

CHANGES IN FEAR-AVOIDANCE BELIEFS AND WORK PARTICIPATION AFTER OCCUPATIONAL REHABILITATION FOR MUSCULOSKELETAL- AND COMMON MENTAL DISORDERS: SECONDARY OUTCOMES OF TWO RANDOMIZED CLINICAL TRIALS

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Objectives: **To assess: (*i*) whether changes in the Fear-Avoidance Beliefs Questionnaire (FABQ) were greater for multicomponent inpatient rehabilitation vs outpatient cognitive behavioural therapy, and (*ii*) whether baseline scores and changes (pre- to post-intervention) in FABQ were associated with future work-participation.**

Methods: **Individuals sick-listed for 2–12 months were randomized to inpatient multicomponent rehabilitation (3.5 weeks or 4+4 days) or outpatient cognitive behavioural therapy (6 sessions/6 weeks).**

Results: **A total of 334 subjects were included. There were no significant differences on FABQ between the in- and out-patient programmes during follow-up. Participants with consistently low scores on the work subscale had more work-participation days, followed by those who reduced their scores. Participants who increased, or had consistently high scores had the least workdays. For the physical activity subscale, the associations were weaker. FABQ-work scores at baseline were associated with number of work-participation days for both musculoskeletal and psychological diagnoses, and more strongly for the latter group.**

Conclusion: **This study suggests that FABQ could be a useful prognostic tool for individuals on sick leave due to musculoskeletal or psychological disorders. There was no evidence that inpatient occupational rehabilitation reduces FABQ scores more than outpatient cognitive behavioural therapy.**

Key words: return to work; sick leave; musculoskeletal diseases; mental health.

Accepted Jan 15, 2019: Epub ahead of print Feb 5, 2019

J Rehabil Med 2019; 51: 175–182

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LAY ABSTRACT

Psychological factors are important in sick-listed workers' return to work process. The fear-avoidance model suggests that negative beliefs about pain and its consequences may lead to catastrophizing thoughts and avoidance of activities believed to be harmful or to worsen the pain. This study evaluated whether the Fear-Avoidance Beliefs Questionnaire (FABQ), was associated with future work outcomes for sick-listed workers in occupational rehabilitation. FABQ is traditionally used for individuals with low-back pain, but this study also used it for individuals with common mental health disorders. The results suggest that the FABQ could be a useful prognostic tool for individuals on sick leave due to both musculoskeletal and psychological disorders.

Psychological factors are important in prevention of disability and promotion of return to work (RTW) (1). One model to explain how psychological factors influence disability in patients with low-back pain is the fear-avoidance model (2, 3). This model describes how negative beliefs about pain and its consequences may lead to catastrophizing and avoidance of activities believed to be harmful or to worsen the pain, which again may lead to inactivity and reduced functioning (3). One of several questionnaires developed to measure fear-avoidance beliefs is the Fear-Avoidance Beliefs Questionnaire (FABQ) (4), consisting of 2 subscales: work and physical activity.

High fear-avoidance beliefs have repeatedly been associated with lower RTW rates (5–7). However, few studies have evaluated whether RTW interventions reduce fear-avoidance beliefs (8). A recent study of patients with neck or back pain participating in a multidisciplinary intervention found no difference in FABQ scores within 4 months follow-up between interventions with added work-focus vs conventional rehabilitation (9). However, with reduced FABQ-work scores (12 points or more) the odds for RTW increased at 12 months of follow-up.

The FABQ was developed for patients with low-back pain. However, avoidance of activities believed to be harmful by the patient, as described in the fear-avoidance model, is not specific for low-back pain. Hence, the physiological responses seen in patients with back pain have common features with responses seen in anxiety

Journal Compilation © 2019 Foundation of Rehabilitation Information. ISSN 1650-1977 doi: 10.2340/16501977-2520

and depression disorders (3). There is also considerable overlap in symptoms between different diagnoses, such as back pain, anxiety and depression (10, 11). Øyeflaten et al. (6) found that FABQ was a prognostic factor for RTW in a group of participants with mixed diagnoses. However, we are not aware of studies that used the FABQ specifically for psychological disorders.

In Norway, there is a long tradition of offering inpatient occupational rehabilitation to patients with different diagnoses, mainly musculoskeletal complaints, anxiety, depression and unspecific diagnoses. We recently evaluated the effects of 2 inpatient occupational rehabilitation programmes. Both were compared with an outpatient programme consisting of group-based cognitive behavioural therapy (12, 13). One of the inpatient programmes (3.5 weeks) enhanced RTW compared with the outpatient programme [14] (personal communication), while the other (4+4 days) had no effect on RTW (13).

The present study evaluated whether inpatient occupational rehabilitation reduced fear-avoidance beliefs more than outpatient cognitive behavioural therapy. As the inpatient programmes were more comprehensive and included several work elements intended to reduce fear-avoidance beliefs about work (e.g. work-related problem solving) and physical activity (e.g. supervised exercise sessions), it was hypothesized that the inpatient programmes would reduce fear-avoidance beliefs more than the outpatient programme. Furthermore, we assessed whether baseline scores and changes (pre- to post-intervention) in FABQ were associated with future work-participation.

METHODS

Study design and participants

This study is based on data from 2 randomized clinical trials. Both trials were designed with parallel groups (Fig. 1) (12). The first trial compared a short inpatient multicomponent occupational rehabilitation programme (4+4 days) to a less comprehensive outpatient programme (6 sessions during 6 weeks) (hereafter referred to as the short inpatient and outpatient programmes, respectively) for individuals on sick-leave due to musculoskeletal, unspecific, or common mental health disorders. The second trial compared a long inpatient programme (3.5 weeks) with the

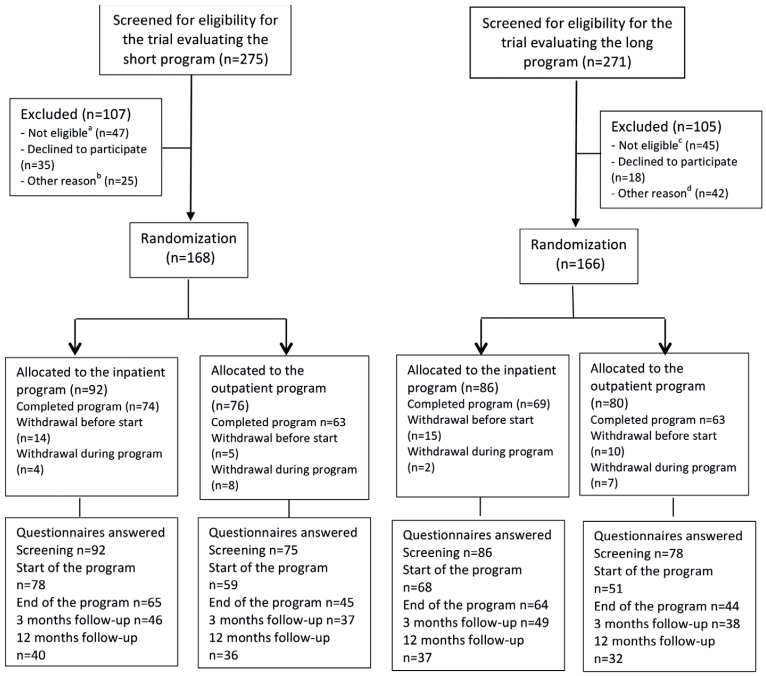

Fig. 1. Flow of participants in the study. [a]Not eligible: serious somatic/psychiatric illness ($n = 20$), a specific disorder requiring specialized treatment ($n = 10$), currently participating in another treatment programme ($n = 15$), insufficient Norwegian comprehension ($n = 1$), scheduled surgery next 6 months ($n = 1$). [b]Other reason: not met ($n = 10$), medical assessment not completed ($n = 8$), not motivated ($n = 5$), no longer on sick-leave ($n = 2$). [c]Not eligible: participating in another treatment programme ($n = 22$), serious somatic/psychiatric illness ($n = 11$), specialized treatment needs ($n = 4$), problems with functioning in groups ($n = 3$), surgery scheduled next 6 months ($n = 2$), insufficient language skills ($n = 2$), alcohol/drug abuse ($n = 1$). [d]Other reason: medical assessment not completed ($n = 15$), no longer on sick-leave ($n = 10$), not motivated ($n = 6$), inability to participate in an inpatient intervention ($n = 7$), unknown ($n = 4$).

same outpatient programme (hereafter referred to as the long inpatient and outpatient programme, respectively). The primary outcome was sickness absence days. The study protocol and results from one of the randomized trials have been published, and the description of the methods is partly overlapping with previous studies (12, 13, 15). The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (no.: 2012/1241), and is registered in clinicaltrials.gov (no.: NCT01926574).

Eligible participants were aged 18–60 years, and sick listed 2–12 months with a diagnosis within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the International Classification of Primary Care, second edition (ICPC-2). The current sick-leave status at inclusion had to be at least 50% off work. Sick-listed individuals fulfilling the inclusion criteria were identified in the Social Security Registry and randomized to receive an invitation to either the long or the short trial. Invited participants completed a short initial questionnaire assessing eligibility. Those eligible were invited for an outpatient screening assessment. Exclusion criteria were: (*i*) alcohol or drug abuse; (*ii*) serious somatic (e.g. cancer, unstable heart disease) or psychological disorders (e.g. high risk of suicide, psychosis, ongoing manic episode); (*iii*) disorders requiring specialized treatment; (*iv*) pregnancy; (*v*) currently participating in another treatment or rehabilitation programme; (*vi*) insufficient oral or written Norwegian language skills to participate and benefit from group sessions and complete questionnaires; (*vii*) scheduled for surgery within the next 6 months; or (*viii*) serious problems with functioning in a group setting.

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 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Rehabilitation programmes

The *inpatient programmes* consisted of group-based acceptance and commitment therapy (ACT) (16), a form of cognitive behavioural therapy (third-generation), individual and group-based physical training, mindfulness, education on various topics, and individual meetings with the coordinators in work-related problem-solving sessions and creating a RTW plan. One programme lasted 3.5 weeks and the other 4+4 days (with 2 weeks at home in-between).

The *outpatient programme,* which was identical in the 2 trials, consisted mainly of group-based ACT once a week for 6 weeks, each session lasting 2.5 h. The common component for the inpatient and outpatient programmes was ACT, in which the aim was to facilitate RTW through increased psychological flexibility (17), which presumably would increase self-efficacy and RTW expectations. A more detailed description of the programmes has been published previously (12).

Outcomes

Questionnaires. Self-reported data on fear-avoidance beliefs and other questionnaires were collected via web-based questionnaires answered at screening before inclusion (baseline, T0), at the start (T1) and the end of the programme (T2), and at 3 months (T3) and 12 months (T4) of follow-up after the end of the programmes.

Fear-avoidance beliefs were recorded using the FABQ (4). It consists of 2 subscales: (*i*) a 7-item work subscale (FABQ-Work, range 0–42 points), and (*ii*) a 4-item physical activity subscale (FABQ-Physical activity, range 0–24 points). To make the questionnaire usable for participants with other complaints than back pain, "complaints" replaced "pain" and "body" replaced "back". There are no established cut-offs for minimal detectable change in FABQ, but 12 points have been suggested for the work subscale and 9 for the physical activity subscale (18).

Other variables registered by questionnaires at the start of the rehabilitation programmes were anxiety and depression symptoms (measured using the Hospital Anxiety and Depression scale (HADS) (19)), mean pain last week, level of completed education (dichotomized as high (college/university) or low) and employment status (dichotomized as having a current job, or not).

Sick-leave register data

Sick leave was measured using data from the Norwegian National Social Security System Registry. All individuals receiving any form of sickness or disability benefits in Norway are registered by their social security number. The data consisted of all individual registrations of periods with any medical benefits.

Work participation was measured as the number of days not receiving medical benefits during 9 months of follow-up after the end of the rehabilitation programmes. It was adjusted for graded sick leave, employment fraction, and calculated as a 5-day work-week, yielding 196 possible working days.

Randomization and blinding

If the outpatient screening was passed, the second randomization allocated the participant to either the inpatient or the outpatient programme (Fig. 1). A project co-worker performed the first randomization. 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 centre had enough participants to run monthly groups in periods of low recruitment.

It was not possible to blind the participants or the caregivers for treatment. The researchers were not blinded.

Statistical analysis

Sample size was calculated based on the primary outcome, i.e. number of sickness absence days, resulting in 80 persons in each arm (12).

Linear mixed-effects models were used to compare scores on the FABQ-work and physical activity subscale over time between the inpatient and outpatient programme, separately for the 2 trials. In addition to programme and time, an interaction term between programme and the 5 time-points (T0–T4) was included in the analyses to assess whether the effects of the programmes differed over time. A random intercept for person was included in the models to allow the participants to start at different levels. The main analyses were not adjusted for baseline characteristics, but the sensitivity analysis was adjusted for sex, age and education level to assess the robustness of the results. In a second sensitivity analysis, a per protocol analysis was performed, excluding participants who withdrew after randomization and/or attended less than 60% of the sessions in the outpatient programmes.

To assess whether changes in fear-avoidance beliefs during rehabilitation were associated with work-participation days

linear regression was used. The 2 FABQ subscales were dichotomized into low risk and moderate/high risk using the cut-offs recommended by Wertli et al. (7). For the FABQ-work subscale a score of less than 21 was categorized as low risk and for the physical activity subscale a score of less than 14 was categorized as low risk. Based on the 2 categories, the participants were classified into 4 groups (for the 2 subscales separately) based on their scores at the start (T1) and the end of the rehabilitation programmes (T2): (*i*) consistently low fear-avoidance beliefs; (*ii*) increasing from low to high scores; (*iii*) decreasing from high to low scores; and (*iv*) consistently high fear-avoidance beliefs. The new categorical variable was included in the regression analyses. The analyses were performed both unadjusted and adjusted for age, sex and education. In addition, a sensitivity analysis adjusting for intervention programme was performed (in addition to the aforementioned variables). All analyses were performed separately for the 2 FABQ subscales. To evaluate the association between FABQ at baseline (T0) and future work participation for the different diagnosis groups, linear regression was used and the analyses performed separately for participants with musculoskeletal diagnoses and psychological diagnoses. As there were few participants with unspecific diagnoses (chapter A in ICPC-2) they were not included in these analyses. For the association analyses, participants from both trials were included.

p-values (2-tailed) < 0.05 were considered statistically significant. Precision was assessed using 95% confidence intervals (95% CI). All analyses were performed using STATA 14.1 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX, USA: StataCorp LP).

RESULTS

The flow of participants through the 2 trials is illustrated in Fig. 1. After screening, 168 participants remained in the short trial and were randomized to the short inpatient programme ($n = 92$) or the outpatient programme ($n = 76$). In the long trial, 166 participants were included and randomized to the long inpatient programme ($n = 86$) or the outpatient programme ($n = 80$). The number of people who answered the questionnaires decreased steadily through the study (Fig. 1).

Participant characteristics

The mean age of the participants was 45 years and most were women (79%). Approximately half had a musculoskeletal sick-leave diagnosis (54%), while 37% had a psychological diagnosis, and 9% a diagnosis from the general and unspecified chapter of ICPC-2. Most participants (65%) worked full-time before they were sick-listed, 18% worked part-time, 12% did not have employment, and 5% had a graded disability pension. The median number of sickness absence days at inclusion was 217 (interquartile range (IQR) 179–268). Baseline characteristics of the participants in the intervention vs the comparator were similar in both trials (Table I).

Table I. Baseline characteristics of participants

	Short trial		Long trial	
	Short inpatient programme ($n = 92$)	Short outpatient programme ($n = 76$)	Long inpatient programme ($n = 86$)	Long outpatient programme ($n = 80$)
Age, years, mean (SD)	45.0 (8.7)	45.1 (9.6)	46.3 (8.7)	45.2 (10.4)
Women, *n* (%)	71 (77)	62 (82)	70 (81)	61 (76)
Higher education[a], *n* (%)	45 (49)	31 (41)	32 (37)	34 (43)
Work status, *n* (%)				
No work	15 (16)	7 (9)	11 (13)	6 (8)
Full-time	57 (62)	52 (68)	54 (63)	53 (66)
Part-time	15 (16)	16 (21)	12 (14)	18 (23)
Graded disability pension	5 (5)	1 (1)	9 (10)	3 (4)
Sick-leave status[b], *n* (%)				
Full sick-leave	41 (45)	35 (46)	35 (41)	36 (45)
Partial sick-leave	45 (49)	36 (47)	48 (56)	38 (48)
Work assessment allowance	6 (7)	5 (7)	3 (3)	6 (8)
Main diagnoses for sick-leave (ICPC-2)[b], *n* (%)				
A – general and unspecified	9 (10)	7 (9)	5 (6)	9 (11)
L – musculoskeletal	48 (52)	40 (53)	54 (63)	40 (50)
P – psychological	35 (38)	29 (38)	27 (31)	31 (39)
Length of sick leave at inclusion[b,c], median days (IQR)	224 (189–262)	229 (187–275)	204 (163–265)	216 (177–265)
HADS, mean (SD)				
Anxiety (0–21)	7.8 (4.4)	7.4 (4.3)	7.4 (3.9)	8.6 (4.1)
Depression (0–21)	6.7 (4.3)	6.0 (4.1)	5.7 (4.2)	6.6 (4.0)
Pain level, mean (SD)				
Mean pain (0–10)	4.7 (2.3)	4.6 (2.0)	5.0 (2.0)	4.8 (2.2)
FABQ, mean (SD)				
Work (0–42)	20.9 (11.5)	19.9 (11.5)	21.4 (11.8)	23.2 (11.1)
Physical activity (0–24)	9.1 (6.1)	8.1 (6.9)	8.8 (7.2)	9.5 (7.1)

[a]Higher (tertiary) education (college or university).
[b]Based on data in the medical certificate from the National Social Security System Registry.
[c]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.
SD: standard deviation; HADS: Hospital Anxiety and Depression scale; FABQ: Fear Avoidance Beliefs Questionnaire; IQR: interquartile range.

Changes in fear-avoidance beliefs

There was no statistically significant difference in the short trial between the 2 programmes in fear-avoidance beliefs from baseline to 12 months of follow-up, for either FABQ-work scores (1.82, 95% CI –2.19 to 5.83) or FABQ-physical activity scores (1.36, 95% CI –0.75 to 3.47). Both programmes showed a reduction in scores for both the work and physical activity subscales during follow-up (Fig. 2). Similarly, in the long trial there was no statistically significant difference between the 2 programmes on FABQ-work (1.14, 95% CI –2.94 to 5.22) or FABQ-physical activity (0.08, 95% CI –2.51 to 2.67). Also in the long trial, both programmes showed a reduction for both subscales (Fig. 2). Neither of the sensitivity analyses changed the findings (results not shown).

Associations between change in fear-avoidance beliefs and future work participation

There was an association between changes in the FABQ-work subscale scores from the start to the end of the rehabilitation programmes and work-participation days during 9 months of follow-up (Table II). Participants with consistently low scores had the most work-participation days (149 days (95% CI 136–162)), while those with consistently high scores had 57 days less (95% CI –77 to –37). Of 163 participants who answered the questionnaire at both the start and the end of the programme, 20 reduced their FABQ-work scores. These participants had 23 fewer work days (95% CI

Table II. Associations between changes in scores on the Fear Avoidance Beliefs Questionnaire (FABQ: work and physical activity) before and after rehabilitation with work participation during 9 months' follow-up

		Number of work-participation days			
Change	*n*	Crude mean	Crude mean difference[a]	Adjusted mean difference[a,b]	95% CI for adjusted mean difference
FABQ-Work					
Consistently low	73	151	ref	ref	ref
Decreasing	20	125	–26	–23	–52 to 5
Increasing	11	97	–54	–53	–89 to –18
Consistently high	59	91	–60	–57	–77 to –37
FABQ-Physical activity					
Consistently low	159	127	ref	ref	ref
Decreasing	15	102	–25	–22	–54 to 11
Increasing	17	106	–20	–15	–46 to 16
Consistently high	20	82	–44	–41	–69 to –12

Fear-avoidance beliefs measured by FABQ. For the work subscale a cut-off of 21 was used to categorize fear-avoidance beliefs as high or low and for the physical activity subscale a cut-off of 14 (7). Based on participants' scores at the start and end of the rehabilitation programmes a new categorical variable was created classifying each participant as having: (*i*) consistently low fear-avoidance beliefs; (*ii*) increasing from low to high scores; (*iii*) decreasing from high to low scores; and (*iv*) consistently high fear-avoidance beliefs. The estimates are based on linear regression analyses.
[a]Mean difference: difference in number of days at work relative to the reference group (0).
[b]Adjusted for age, sex and education level. Predictions made with covariates constant at their mean.

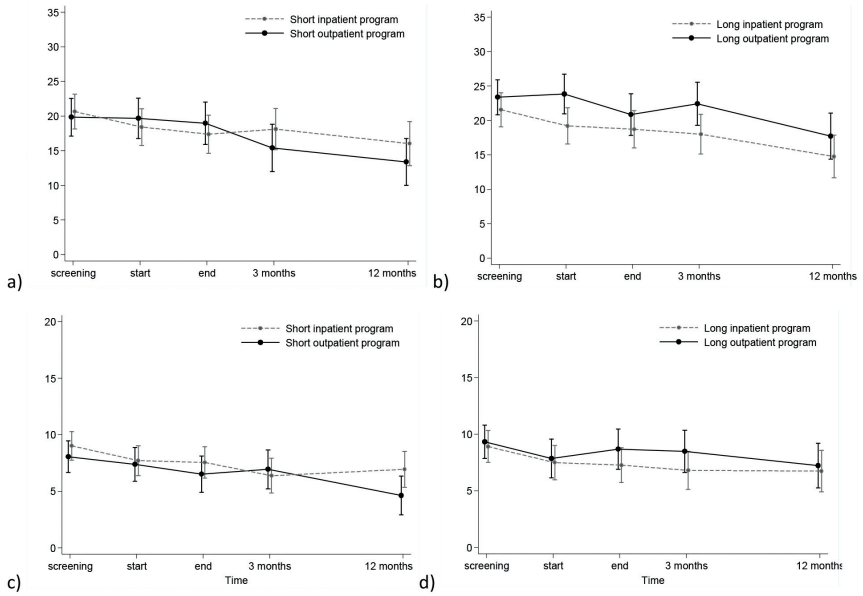

Fig. 2. Fear Avoidance Beliefs Questionnaire (FABQ) scores for the 2 programmes in the short and long trial during follow-up. Data are estimated means with 95% confidence intervals for: (a) FABQ work in the short trial, (b) FABQ work in the long trial, (c) FABQ physical activity in the short trial, and (d) FABQ physical activity in the long trial. Analyses performed with linear mixed-effects models.

Table III. Associations between participants' fear-avoidance beliefs at baseline and number of work-participation days during 9 months of follow-up, for musculoskeletal and psychological diagnoses

	Number of work-participation days[a]					
	Musculoskeletal diagnoses			Psychological diagnoses		
Baseline	*n*	Crude mean difference[b]	Adjusted mean difference (95% CI)[b,c]	*n*	Crude mean difference[b]	Adjusted mean difference (95% CI)[b,c]
FABQ-Work, per unit	162	−1.5	−1.5 (−2.3 to −0.6)	106	−2.2	−2.4 (−3.4 to −1.3)
FABQ-Physical activity, per unit	176	−0.6	−0.5 (−1.9 to 1.0)	116	−2.9	−2.8 (−4.6 to −1.1)

Estimated from linear regression analyses separately for the 2 main diagnoses groups. As there were so few participants with unspecific diagnoses (chapter A in ICPC-2) they were not included in these analyses.
[a]Estimated from linear regression analyses. [b]Mean difference: difference in number of days at work as the FABQ score increase by 1 point.
[c]Adjusted for age, sex and education level. Analysed with covariates constant at their mean.
FABQ: Fear Avoidance Beliefs Questionnaire; CI: confidence interval.

–52 to 5) than those with consistently low scores, while those increasing their scores had 54 fewer work days (95% CI –89 to –18).

For the FABQ-physical activity subscale, there was a weaker association between changes in FABQ-scores and work participation during follow-up (Table II). Participants who reduced their FABQ-scores had 22 fewer work days (95% CI –54 to 11) than those with consistently low scores, while those increasing their scores had 15 fewer days (95% CI –46 to 16). Those with consistently high scores had 41 fewer work days (95% CI –69 to –12).

The sensitivity analyses including adjustment for intervention programme in addition to age, sex and education, showed similar results (results not shown).

FABQ across different diagnoses

Participants with psychological diagnoses had lower scores than those with musculoskeletal diagnoses on both FABQ-subscales at baseline (mean 18.7 (SD 10.7) vs 23.1 (SD 11.7) for FABQ-work and mean 5.8 (SD 6.5) vs 11.0 (SD 6.4) for FABQ-physical activity, respectively). Of participants answering the FABQ at both baseline and 12 months of follow-up, 74% with a psychological diagnosis and 63% of those with a musculoskeletal diagnosis, reduced their FABQ-work score. For the physical activity subscale, the numbers were 45% and 67%, respectively. The mean reduction in fear-avoidance beliefs for work was 7.0 (SD 11.7) for psychological diagnoses and 4.8 (SD 11.1) for the musculoskeletal diagnoses. For the physical activity subscale the numbers were 1.4 (SD 5.6) and 3.0 (SD 5.3), respectively.

FABQ-work scores at baseline were associated with number of work-participation days during 9 months of follow-up for both musculoskeletal and psychological diagnoses (Table III). The association was stronger, and explained variance was larger, for psychological diagnoses (0.16 vs 0.08). Baseline scores for the physical activity subscale were associated with work-participation days for those with psychological diagnoses, but not for musculoskeletal diagnoses. The explained variance was small for both groups (<0.01) for this subscale.

Participants with missing questionnaires

Participants with missing questionnaires at 12 months were somewhat younger (mean age 44 years (SD 9.6) vs 48 years (SD8.2)), and more likely to be men than women (66% vs 54%). Baseline scores for the 2 FABQ subscales were similar for those not responding and those responding (work subscale 22.0 (SD 11.6) vs 20.5 (SD11.3); physical activity subscale 9.4 (SD 6.9) vs 8.2 (SD 6.6)).

The median number of work-participation days during follow-up was similar for participants who answered the FABQ at both the start and the end of the programmes compared with those answering only at one time-point, and thus were excluded from the analyses (work subscale 123 days (IQR 81–182) vs 116 days (IQR 64–178); physical activity subscale (119 days (IQR 70–180) vs 125 days (IQR 69–178)).

DISCUSSION

There were no differences in fear-avoidance beliefs about work or physical activity between inpatient occupational rehabilitation and outpatient cognitive behavioural therapy during 12 months of follow-up. The change in FABQ-work during the programmes was associated with the number of work days during 9 months of follow-up. For FABQ-physical activity, the association with future work participation was weaker. The association between fear-avoidance beliefs at baseline and future work participation was stronger for those with psychological complaints than for those with musculoskeletal complaints.

The lack of additional effect of the inpatient programmes on fear-avoidance beliefs was not in line with our hypothesis. However, the results are in line with a previous study comparing effects of work-focused and standard rehabilitation on FABQ (9). FABQ was

reduced after all the programmes in our study, but the reductions were smaller than the suggested minimal detectable change (18). This was surprising, as the inpatient programmes included physical activity designed to reduce fear of movement. Fear-avoidance beliefs about work were targeted by work-related problem solving through group discussions and creating an individual RTW plan. It is possible that graded work exposure at the workplace could have been more effective. However, the participants had been sick-listed for approximately 7 months on average; hence changing their fear-avoidance beliefs could be difficult. Another possible explanation is the use of ACT as the cognitive behavioural therapy. A key component in ACT is acceptance, meaning that participants are encouraged to acknowledge and accept their symptoms rather than try to control them. This could result in participants accepting, and thus reporting, more fear-avoidance beliefs after participating in the programme than they otherwise would, which might explain the small reductions observed (20). This might explain why one of the inpatient programmes was successful in terms of RTW despite small changes in fear-avoidance beliefs. Conversely, previous studies have suggested that the responsiveness of the FABQ might be low (18, 21), which should be evaluated further in future research.

The results of the current study indicate that using a cut-off between low-risk and medium/high-risk patients could be useful to predict whether patients will RTW. The cut-offs recommended by Wertli et al. (7) were used. These cut-offs are widely used in Norway, as they are included in the Norwegian neck and pain registry, used at back- and neck-pain clinics at all university hospitals. We are not aware of previous studies assessing the association between FABQ and future work participation using these cut-offs. Our findings are in line with a study by Staal et al. (22) reporting that participants with high fear-avoidance beliefs (median-based cut-offs: work 26; physical activity 16) returned to work more slowly than those with low scores. Due to the limited number of participants, it was not possible to differentiate between medium- and high-risk patients in the present study, and this should be done in future studies. As FABQ-work measures fear-avoidance beliefs about work specifically, it is not surprising that this subscale had a stronger association with future work participation than the physical activity subscale.

Øyeflaten et al. (6) found FABQ-work to be a strong predictor for RTW in a group of participants with mixed diagnoses (musculoskeletal, psychological and unspecific diagnoses). However, we are not aware of studies evaluating the FABQ separately for diagnoses other than musculoskeletal complaints. The reduction in fear-avoidance beliefs was quite similar for the 2 diagnosis groups during follow-up, despite participants with psychological diagnoses having lower baseline values. The results also suggest that the work subscale is associated with future work participation for participants with psychological disorders. The association was, in fact, somewhat stronger for this diagnosis group than for the musculoskeletal group. Avoidance behaviour is seen in many psychological disorders. However, the FABQ could measure different characteristics for the 2 diagnosis groups. In psychological disorders, it might be measuring a more central part of the disorder itself, and not just a prognostic factor. This could also explain why the physical activity subscale showed a stronger association with future work participation for participants with a psychological diagnosis, compared with those with a musculoskeletal diagnosis.

The main strengths of this study were the randomized design and the use of registry data to assess sickness absence. The latter ensured no recall bias or missing data. Some limitations of this study should be addressed. Firstly, the response rate was low on follow-up questionnaires, gradually decreasing, from approximately 100% for the first questionnaire to 40–47% at 12 months' follow-up. At the start and the end of the programme there were more missing questionnaires for the outpatient programmes, which we assume is due to organizational differences, as the inpatient participants answered the questionnaire at the centre, while the outpatient participants had to answer them at home. For the rest of the time-points, the response rate was similar between the programmes. To compare between-group changes over time, linear mixed models were used, which are less sensitive to missing values in outcome data. However, these models rely on the assumption of "missing at random", and the possibility of bias due to differential loss to follow-up cannot be disregarded. The observed association between FABQ and future work had low precision, due to the low number of participants answering questionnaires at both the start and end of the programmes. However, other than the loss of statistical power, we do not expect missing questionnaires to affect these results significantly. We do not expect that those replying would differ from those not replying, in the association between the change on FABQ and work-participation days. Finally, in order to make the FABQ questionnaire usable for participants with conditions other than back pain, some of the wording was changed. Hence, the questionnaire was an adapted version of the previous validated version.

Conclusion

This study did not find any evidence to show that inpatient occupational rehabilitation reduced FABQ scores more than outpatient cognitive behavioural therapy. An

association between changes in FABQ and future work participation was found. Participants with decreasing fear-avoidance beliefs had more work-participation days than those with consistently high or increasing fear-avoidance beliefs. Those with consistently low fear-avoidance beliefs had the most working days. The association was stronger for the work subscale than for the physical activity subscale. The results indicate that using a cut-off between low-risk and medium/high-risk patients could be useful in clinical practice to predict work participation. A novel finding is that baseline scores for the FABQ were associated with future work participation for participants with psychological diagnoses, indicating that this questionnaire might be useful to patient groups other than those with low-back pain, although further research is needed to substantiate this.

ACKNOWLEDGEMENTS

The authors thank project co-worker Guri Helmersen for valuable assistance, Tryggve Skylstad at the Norwegian Welfare and Labor Service for providing lists of sick-listed individuals, and Ola Thune at the Norwegian Welfare and Labor Service for providing sick leave data and insight to the National Social Security System Registry. We also thank clinicians and staff at Hysnes Rehabilitation Center and the Department of Physical Medicine and Rehabilitation at St Olavs Hospital, and the participants who took part in the study.

Funding. The Liaison Committee between the Central Norway Regional Health Authority and the Norwegian University of Science and Technology; The Research Council of Norway; and allocated government funding through the Central Norway Regional Health Authority.

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Appendices

Appendices

Appendix 1 Characteristics of relevant randomized trials published on multimodal occupational interventions (studies marked '' showed effect).*

Study	Diagnosis for sick leave	RTW-outcomes [a]	Intervention content	Comparison	Employment and notes[b]
Musculoskeletal complaints					
*Lindstrom et al. (1992) Sweden	Low back pain	Time to RTW and number of sickness absence days during 12 months of follow-up	A graded activity program: measurements of functional capacity, a work-place visit, back school education and progressive exercise program	Usual care	Employed
*Indahl et al. (1995) Norway	Low back pain	Time to RTW	Brief intervention[c]	Usual care	N/R
*Loisel et al. (1997b) Canada	Back pain	Time to RTW during 12 months of follow-up	Three interventions: 1) Clinical intervention: visit to a back pain specialist and back care school 2) Occupational intervention: a worksite evaluation to determine need for job modifications 3) Full intervention: combination of 1 and 2	Usual care	Employed
(Haldorsen et al. 1998) Norway	Musculoskeletal pain	Percentage of RTW in the two groups during 12 months of follow-up	Multimodal treatment: structured examination, physical treatment, cognitive behavioural modification, education, examination of work situation	Usual care	Employed
*Hagen et al. (2000) Norway	Low back pain	Relative risk for RTW at 3, 6 and 12 months	Brief intervention[c]	Usual care	No employment criteria. Mostly employed (>90%)

*Anema et al. (2007) The Netherlands	Low back pain	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Two interventions[d]: 1) Work place intervention: workplace assessment and modifications. Case management involving all stakeholders. 2) A clinical intervention with graded activity (gradually increasing exercise)	Usual care according to the Dutch occupational guideline for low back pain	Employed
*Bultmann et al. (2009) Denmark	Musculoskeletal disorders	Cumulative sickness absence hours at different intervals up to 12 months of follow-up	Coordinated and tailored work rehabilitation: work disability screening, formulation and implementation of a coordinated, tailored and action-oriented work rehabilitation plan developed by an interdisciplinary team	Conventional case management	Employed
*Lambeek et al. (2010) The Netherlands	Low back pain	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Integrated care: workplace intervention (identifying obstacles for RTW, finding solutions), graded activity program (exercise, encouraging activity despite pain) and coordination of communication and care.	Usual care	Employed
(Vermeulen et al. 2011) The Netherlands	Musculoskeletal disorders	Time to RTW (28 days without relapse) during 12 months of follow-up	Participatory return-to-work program: a stepwise procedure aiming for a consensus-based RTW-plan, with the possibility of a temporary (therapeutic) workplace	Usual care for workers without employment: vocational rehabilitation guidance	Unemployed and temporary agency workers
(Jensen et al. 2011) Denmark	Low back pain	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Brief intervention[c] + hospital-based multidisciplinary intervention: identifying obstacles for RTW, developing an RTW plan, contact with work place and job centre to discuss/coordinate relevant initiatives.	Brief Intervention[c]	Employed
(Myhre et al. 2014) Norway	Neck or back pain	Time to RTW (5 weeks without relapse) during 12 months of follow-up	Thorough clinical examination, information about findings and reassurance about physical activity being safe +	Same thorough clinical examination as the intervention group +	Employed

			Work-focused rehabilitation (multicentre): discussing obstacles for RTW, telephone contact with employer, creating an RTW plan	Existing treatments at the 2 included hospitals: comprehensive multidisciplinary rehabilitation (neck and back school) or brief intervention[c]	
(Brendbekken et al. 2016) Norway	Musculoskeletal pain	Partial or full RTW at 12 and 24 months of follow-up	Multidisciplinary intervention: assessment of barriers for work participation and maintaining factors for pain, creating a rehabilitation plan	Brief intervention[c]	At least 50 % employment contract
(Reme et al. 2016) Norway	Low back pain	Proportions with increased work participation at 12 months of follow-up	3 different interventions, all combined with brief intervention[c]: 1)Tailored CBT 2) soy oil 3) seal oil	Brief intervention[c]	No employment criteria. Percentage employed N/R
(Gross et al. 2017b) Canada	Musculoskeletal conditions	Number of days receiving wage replacement benefits and recurrence rates during 12 months of follow-up	Motivational interviewing added to standard rehabilitation (graded activity, therapeutic exercise, RTW planning and work accommodations	Standard rehabilitation	No employment criteria. 70% employed
(Moll et al. 2017) Denmark	Neck or shoulder pain	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Brief intervention[c] plus multidisciplinary intervention: case manager coordinating communication between stakeholders, RTW plan, optional workplace involvement.	Brief intervention[c]	Employed

(Nguyen et al. 2017)	Back pain	RTW at 12 months follow up (self-report)	Inpatient spa therapy for 5 days: Spa (2hr/day), exercise therapy (45 min/day), group education (45 min/day) and self-study.	Usual care	Employed
Mental health disorders					
*van der Klink et al. (2003) The Netherlands	Adjustment disorder	Reports among others: time to partial and full RTW, duration of sick leave and recurrence during 12 months of follow-up	Activating intervention: graded activity approach (identifying stressors and solving strategies, putting them into action and gradually increase activities). Contact with the company`s management.	Usual care by occupational physicians	Employed
*Blonk et al. (2006) The Netherlands	Work-related psychological complaints (anxiety, depression, burnout)	Time to partial and full RTW among outcomes	2 interventions: 1) CBT 2) Brief CBT combined with a workplace and an individual focused intervention. Both included graded activity	Two brief sessions with a general practitioner	Self-employed
(van Oostrom et al. 2010) The Netherlands	Distress	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Workplace intervention: involving the employee and their supervisor, identify obstacles for RTW and creating an RTW plan	Usual care according to the Dutch guideline for occupational physicians	Employed
(Vlasveld et al. 2013b) The Netherlands	Major depressive disorder	Time to RTW (4 weeks without relapse) during 12 months of follow-up	Collaborative care: a care manager coordinating care, problem solving treatment (a brief structured psychological intervention aimed at learning problem solving skills), a workplace intervention (workplace assessment, work adjustments and making an RTW plan)	Usual care	Employed

*Reme et al. (2015b) Norway *Overland et al. (2018)	Common mental disorders[e]	Increased or maintained work participation at 12 months of follow-up 4 year follow-up assessing 3 different outcomes	Integrated individual work-focused CBT with job support (facilitate workplace adaptions or identification of appropriate employment)	Usual care	No employment criteria. 8% unemployed
(Lammerts et al. 2016a) The Netherlands	Common mental disorders	Time to RTW in competitive employment (28 days without relapse) during 12 months of follow-up	Participatory supportive RTW-program: identifying obstacles for RTW and making an RTW plan with help of an RTW coordinator and labour expert. Referral to a vocational rehabilitation agency offering the participant competitive jobs.	Usual care according to the Dutch guideline for occupational physicians	Without employment contract
(Finnes et al. 2017) Sweden	Depression, anxiety and exhaustion disorder	Number of sickness absence days during 9 months of follow-up	3 interventions: 1) Individual sessions of CBT (Acceptance and commitment therapy) 2) A workplace dialogue intervention: facilitating constructive worker- supervisor dialogue, agreeing on a rehabilitations plan 3) A combination of 1) and 2)	Usual care	Employed
(Dalgaard et al. 2017) Denmark	Work-related adjustment disorder or mild depression	Time to RTW (4 weeks without relapse) during 10 months of follow-up	Work-focused CBT with an optional workplace intervention (1-2 meetings at the workplace)	Two: 1) clinical assessment, but no treatment 2) no assessment	Employed
(Salomonsson et al. 2017a) Sweden	Common mental disorders	Number of sickness absence days during 12 months of follow-up	2 interventions: 1) RTW-intervention: early contact with workplace, identifying obstacles for RTW and making an RTW plan 2) A combination of 1) and CBT	CBT	N/R

Musculoskeletal and mental health diagnoses in the same program					
(Lytsy et al. 2017)	Mental illness and chronic pain	RTW at 12 months follow up and reimbursed days using register data	2 interventions 1) Multidisciplinary assessment and individually tailored outpatient multimodal rehabilitation 2) Acceptance and commitment therapy (individual therapy sessions)	Usual care	Women without employment (On benefits for a mean of 7.5 years)
(Aasdahl et al. 2018) Norway	Musculoskeletal, psychological or general and unspecified	Number of sickness absence days during 6 and 12 months of follow-up	Short (4+4 days) inpatient multimodal occupational rehabilitation: Acceptance and commitment therapy, physical training, mindfulness, psychoeducation, work-related problem solving and creating an RTW plan	Outpatient group-based Acceptance and commitment therapy.	No employment criteria. 13% unemployed
*Gismervik et al. (2020)	Musculoskeletal, psychological or general and unspecified	Number of sickness absence days during 6 and 12 months of follow-up	3.5 weeks of inpatient multimodal occupational rehabilitation: Acceptance and commitment therapy, physical training, mindfulness, psychoeducation, work-related problem solving and creating an RTW plan	Outpatient group-based Acceptance and commitment therapy.	No employment criteria. All on sick-leave benefits

(Adapted from Aasdahl and Fimland 2019 with permission from the authors)
RTW: return to work
N/R: not reported
CBT: cognitive behaviour therapy
[a] RTW is more precisely described in terms of time off benefits when reported in the article. Follow-up time is reported when described in the article.
[b] Most studies do not clearly distinguish between self-employment and employment
[c] Brief intervention: consists of a thorough examination by a physician, explanation of findings and pain using a non-injury model. Reassurance and advice about staying active. A follow-up by a physiotherapist with the same message. Often 1-2 booster sessions.
[d] First participants were randomised to the workplace intervention or usual care. Participants still sick listed at 8 weeks were randomised to the clinical intervention or usual care.
[e] Diagnosis after a psychological evaluation based on informal self-reports of symptoms. Participants were not necessarily sick listed, could also be at risk of sick leave.

Appendix 2 Questionnaires used in Papers I and III

Følelser

HADS

(21)
Vi er klar over at følelser spiller en stor rolle ved de fleste sykdommer. Hvis vi vet mer om følelser, vil han/hun bli bedre i stand til å hjelpe deg. Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter du kryss for ett av de fire svarene som best beskriver dine følelser den siste uken. Ikke tenk for lenge på svaret - de spontane svarene er best.

. Jeg føler meg nervøs og urolig	○ Mesteparten av tiden ○ Mye av tiden ○ Fra tid til annen ○ Ikke i det hele tatt
. Jeg gleder meg fortsatt over tingene slik jeg pleide før	○ Avgjort like mye ○ Ikke fullt så mye ○ Bare lite grann ○ Ikke i det hele tatt
. Jeg har en urofølelse som om noe forferdelig vil skje	○ Ja, og noe svært ille ○ Ja, ikke så veldig ille ○ Litt, bekymrer meg lite ○ Ikke i det hele tatt
. Jeg kan le og se det morsomme i situasjoner	○ Like mye nå som før ○ Ikke like mye nå som før ○ Avgjort ikke som før ○ Ikke i det hele tatt
. Jeg har hodet fullt av bekymringer	○ Veldig ofte ○ Ganske ofte ○ Av og til ○ En gang i blant
. Jeg er i godt humør	○ Aldri ○ Noen ganger ○ Ganske ofte ○ For det meste
. Jeg kan sitte i fred og ro og kjenne meg avslappet	○ Ja, helt klart ○ Vanligvis ○ Ikke så ofte ○ Ikke i det hele tatt

(22)

(fortsatt fra forrige side)

. Jeg føler meg som om alt går langsommere	○ Nesten hele tiden ○ Svært ofte ○ Fra tid til annen ○ Ikke i det hele tatt
. Jeg føler meg urolig som om jeg har sommerfugler i magen	○ Ikke i det hele tatt ○ Fra tid til annen ○ Ganske ofte ○ Svært ofte
. Jeg bryr meg ikke lenger om hvordan jeg ser ut	○ Ja, jeg har sluttet å bry meg ○ Ikke som jeg burde ○ Kan hende ikke nok ○ Bryr meg som før
. Jeg er rastløs som om jeg stadig må være aktiv	○ Uten tvil svært mye ○ Ganske mye ○ Ikke så veldig mye ○ Ikke i det hele tatt
. Jeg ser med glede frem til hendelser og ting:	○ Like mye som før ○ Heller mindre enn før ○ Avgjort mindre enn før ○ Nesten ikke i det hele tatt
. Jeg kan plutselig få en følelse av panikk	○ Uten tvil svært ofte ○ Ganske ofte ○ Ikke så veldig ofte ○ Ikke i det hele tatt
. Jeg kan glede meg over gode bøker, radio og TV	○ Ofte ○ Fra tid til annen ○ Ikke så ofte ○ Svært sjelden

(9)

BPI - Brief Pain Inventory

. Vennligst sett et kryss under det tallet som best beskriver de sterkeste smertene du har hatt i løpet av den siste uka.	○ (Ingen smerter) 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 (Verst tenkelige smerter)
. Vennligst sett et kryss under det tallet som best beskriver de svakeste smertene du har hatt i løpet av den siste uka.	○ (Ingen smerter) 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 (Verst tenkelige smerter)
. Vennligst sett et kryss under det tallet som best angir hvor sterke smerter du har i gjennomsnitt.	○ (Ingen smerter) 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 (Verst tenkelige smerter)

FABQ - Fear and Avoidance Behaviour Questionnaire. Endring 10.06.2011: Vises alltid, endret begrep til plager i stedet for smerter.

(57)

Hvordan påvirker plagene din fysiske aktivitet?

Kryss av fra 0 (helt uenig) til 6 (helt enig) for hvert utsagn for å angi hvor mye fysiske aktiviteter som å bøye seg, løfte, gå eller kjøre bil vil påvirke dine plager.

	(Helt uenig) 0	1	2	(Usikker) 3	4	5	(Helt enig) 6
Plagene mine ble forårsaket av fysisk aktivitet	○	○	○	○	○	○	○
Fysisk aktivitet forverrer plagene mine	○	○	○	○	○	○	○
Fysisk aktivitet kan skade kroppen min	○	○	○	○	○	○	○
Jeg bør ikke utføre fysiske aktiviteter som kan forverre plagene mine	○	○	○	○	○	○	○
Jeg kan ikke utføre fysiske aktiviteter som kan forverre plagene mine	○	○	○	○	○	○	○

(58)

Betinget: Vises bare hvis man angir å ha eller har hatt jobb.

Hvordan påvirker plagene jobben din?

Kryss av fra 0 (helt uenig) til 6 (helt enig) for hvert utsagn for å angi hvordan dine plager påvirker jobben din. </br>Hopp over spørsmål som ikke er relevante for deg.

	(Helt uenig) 0	1	2	(Usikker) 3	4	5	(Helt enig) 6
Plagene mine ble forårsaket av arbeidet mitt eller et uhell på jobben	○	○	○	○	○	○	○
Arbeidet mitt gjør plagene mine verre	○	○	○	○	○	○	○
Jeg har fremsatt erstatningskrav for plagene mine	○	○	○	○	○	○	○
Arbeidet mitt er for tungt for meg	○	○	○	○	○	○	○
Arbeidet mitt forverrer eller kan forverre plagene mine	○	○	○	○	○	○	○
Arbeidet mitt kan skade kroppen min	○	○	○	○	○	○	○
Jeg burde ikke utføre det vanlige arbeidet mitt med mine nåværende plager	○	○	○	○	○	○	○
Jeg kan ikke utføre det vanlige arbeidet mitt med mine nåværende plager	○	○	○	○	○	○	○
Jeg kan ikke utføre det vanlige arbeidet mitt før plagene er behandlet	○	○	○	○	○	○	○
Jeg tror ikke jeg vil være tilbake på det vanlige arbeidet mitt innen 3 måneder	○	○	○	○	○	○	○
Jeg tror ikke jeg noen gang vil være i stand til å komme tilbake til den jobben	○	○	○	○	○	○	○

QUALITY OF LIFE
New 15D/Harri Sintonen

_____
Pasient spørreskjema

Vennligst les gjennom alle svaralternativene til hvert spørsmål før du plasserer et kryss (x) for det alternativet som best beskriver din nåværende tilstand. Fortsett på samme måte for alle 15 spørsmålene. Gi bare ett svar på hvert spørsmål.

SPØRSMÅL 1. **BEVEGELIGHET**
1 ( ) Jeg er i stand til å gå normalt (uten vanskelighet) innendørs, utendørs og i trapper
2 ( ) Jeg er i stand til å gå uten vanskelighet innendørs, men utendørs og/eller i trapper har jeg litt problemer.
3 ( ) Jeg er i stand til å gå uten hjelp innendørs (med eller uten et hjelpemiddel), men utendørs og/eller i trapper bare med betydelig vanskelighet eller med hjelp fra andre.
4 ( ) Jeg er i stand til å gå innendørs kun med hjelp fra andre.
5 ( ) Jeg er fullstendig sengeliggende og ute av stand til å bevege meg omkring.

SPØRSMÅL 2. **SYN**
1 ( ) Jeg ser normalt, dvs. jeg kan lese aviser og tekst på TV uten vanskelighet (med eller uten briller).
2 ( ) Jeg kan lese aviser og/eller tekst på TV med litt vansker (med eller uten briller).
3 ( ) Jeg kan lese aviser og/eller tekst på TV med betydelige vansker (med eller uten briller).
4 ( ) Jeg kan ikke lese aviser eller tekst på TV hverken med briller eller uten, men jeg kan se godt nok til å gå omkring uten hjelp.
5 ( ) Jeg kan ikke se godt nok til å gå omkring uten en hjelper, dvs. jeg er nesten eller helt blind.

SPØRSMÅL 3. **HØRSEL**
1 ( ) Jeg hører normalt, dvs. normal tale (med eller uten et høreapparat).
2 ( ) Jeg hører normal tale med litt vansker.
3 ( ) Jeg hører normal tale med betydelige vansker; i samtaler må stemmer være høyere enn normalt.
4 ( ) Jeg hører selv sterke stemmer dårlig; jeg er nesten døv.
5 ( ) Jeg er helt døv.

SPØRSMÅL 4. **PUST**
1 ( ) Jeg er i stand til å puste normalt, dvs. uten å være kortpustet eller ha andre pustevansker.
2 ( ) Jeg er kortpustet under tungt arbeid eller sport, eller når jeg går raskt på flat mark eller i slak motbakke.
3 ( ) Jeg er kortpustet når jeg går på flat mark med samme tempo som andre på min alder.
4 ( ) Jeg blir kortpustet selv etter lett aktivitet, f.eks. når jeg vasker meg eller kler på meg.
5 ( ) Jeg har pustevansker nesten hele tiden, selv i hvile.

SPØRSMÅL 5. **SØVN**

1 ( ) Jeg er i stand til å sove normalt, dvs. jeg har ingen problemer med å sove.
2 ( ) Jeg har lette søvnproblemer, f.eks. vanskelig for å falle i søvn eller våkner av og til om natten.
3 ( ) Jeg har moderate søvnproblemer, f.eks. forstyrret søvn eller føler jeg ikke har sovet nok.
4 ( ) Jeg har store søvnproblemer, f.eks. må bruke sovemedisiner ofte eller rutinemessig, eller våkner om natten og/eller for tidlig om morgenen.
5 ( ) Jeg lider av alvorlig søvnløshet, f.eks. er søvn nesten umulig selv med bruk av sovemedisiner, eller jeg forblir våken det meste av natten.

SPØRSMÅL 6. **SPISING**

1 ( ) Jeg er i stand til å spise normalt, dvs. uten hjelp fra andre.
2 ( ) Jeg er i stand til å spise selv med mindre vansker (f.eks. langsomt, kløhete, skjelvende, eller med spesielle hjelpemidler).
3 ( ) Jeg trenger noe hjelp fra en annen person for å spise.
4 ( ) Jeg er ute av stand til å spise selv i det hele tatt, slik at jeg må mates av en annen person.
5 ( ) Jeg er ute av stand til å spise i det hele tatt, slik at jeg mates enten med slange eller intravenøst.

SPØRSMÅL 7. **TALE**

1 ( ) Jeg er i stand til å snakke normalt, dvs. klart, hørbart og flytende.
2 ( ) Jeg har lette vansker med å snakke, f.eks. famler av og til etter ord, mumler eller endrer stemmeleiet.
3 ( ) Jeg kan gjøre meg forstått, men min tale er f.eks. oppstykket, nølende, stotrende eller stammende.
4 ( ) De fleste mennesker har store vansker med å forstå hva jeg sier.
5 ( ) Jeg kan bare gjøre meg forstått med fakter.

SPØRSMÅL 8. **VANNLATING/AVFØRING**

1 ( ) Min blære og tarm fungerer normalt og uten problemer.
2 ( ) Jeg har lette problemer med min blære- og/eller tarmfunksjon, f.eks. vansker med å urinere, eller løs eller hard avføring.
3 ( ) Jeg har betydelige problemer med min blære- og/eller tarmfunksjon, f.eks. "uhell" av og til, eller alvorlig forstoppelse eller diaré.
4 ( ) Jeg har alvorlige problemer med min blære- og/eller tarmfunksjon, f.eks. regelmessig "uhell", eller behov for kateterisering eller klyster.
5 ( ) Jeg har ikke kontroll over min blære- og/eller tarmfunksjon.

SPØRSMÅL 9. **VANLIGE AKTIVITETER**

1 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter (f.eks. arbeid, studier, husarbeid, fritidsaktiviteter) uten vanskelighet.
2 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter noe mindre effektivt eller med litt vanskelighet.
3 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter mye mindre effektivt, med betydelig vanskelighet, eller ikke fullt ut.
4 ( ) Jeg kan bare klare en liten del av mine vanlige aktiviteter fra tidligere.
5 ( ) Jeg er ute av stand til å klare noen av mine vanlige aktiviteter fra tidligere.

SPØRSMÅL 10. **MENTAL FUNKSJON**

1 ( ) Jeg er i stand til å tenke klart og logisk, og min hukommelse fungerer godt.
2 ( ) Jeg har litt vansker med å tenke klart og logisk, eller min hukommelse svikter meg av og til.
3 ( ) Jeg har merkbare vansker med å tenke klart og logisk, eller min hukommelse er noe redusert.
4 ( ) Jeg har store vansker med å tenke klart og logisk, eller min hukommelse er betydelig nedsatt.
5 ( ) Jeg er stadig forvirret eller desorientert for sted og tid.

SPØRSMÅL 11. **UBEHAG OG SYMPTOMER**

1 ( ) Jeg har ikke fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
2 ( ) Jeg har lett fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
3 ( ) Jeg har tydelig fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
4 ( ) Jeg har alvorlig fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
5 ( ) Jeg har uholdbart fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.

SPØRSMÅL 12. **DEPRESJON**

1 ( ) Jeg føler meg overhodet ikke trist, melankolsk eller deprimert.
2 ( ) Jeg føler meg litt trist, melankolsk eller deprimert.
3 ( ) Jeg føler meg middels trist, melankolsk eller deprimert.
4 ( ) Jeg føler meg svært trist, melankolsk eller deprimert.
5 ( ) Jeg føler meg ekstremt trist, melankolsk eller deprimert.

SPØRSMÅL 13. **STRESS**

1 ( ) Jeg føler meg overhodet ikke engstelig, stresset eller nervøs.
2 ( ) Jeg føler meg litt engstelig, stresset eller nervøs.
3 ( ) Jeg føler meg middels engstelig, stresset eller nervøs.
4 ( ) Jeg føler meg svært engstelig, stresset eller nervøs.
5 ( ) Jeg føler meg ekstremt engstelig, stresset eller nervøs.

SPØRSMÅL 14. **LIVSKRAFT**

1 ( ) Jeg føler meg frisk og energisk.
2 ( ) Jeg føler meg litt sliten, trett eller svak.
3 ( ) Jeg føler meg middels sliten, trett eller svak.
4 ( ) Jeg føler meg svært sliten, trett eller svak, nesten utslitt.
5 ( ) Jeg føler meg ekstremt sliten, trett eller svak, totalt utslitt.

SPØRSMÅL 15. **SEKSUELL AKTIVITET**

1 ( ) Min helsetilstand har ingen ugunstig virkning på min seksuelle aktivitet.
2 ( ) Min helsetilstand har en liten virkning på min seksuelle aktivitet.
3 ( ) Min helsetilstand har en betydelig virkning på min seksuelle aktivitet.
4 ( ) Min helsetilstand gjør seksuell aktivitet nesten umulig
5 ( ) Min helsetilstand gjør seksuell aktivitet umulig.

Helseproblemer siste 30 døgn

På den neste siden nevnes noen vanligehelseplager. Vi vil be deg om å vurdere hvert enkelt problem/symptom, og oppgi **i hvilken grad duhar vært plaget** av dette i løpet av de siste tretti døgn, og **antall dager** du har vært plaget.

Eksempel
Hvis du føler at du har vært *en del* plaget med forkjølelse/influensa siste måned,og varigheten av plagene var *ca. en uke*, fylles dette ut på følgende måte:
Sett ring rundt tallet som passer best.

Nedenfor nevnes noen alminnelige helseproblemer	Ikke plaget	Litt plaget	En del plaget	Alvorlig plaget	Antall dager plagene varte (omtrent)
1. Forkjølelse, influensa	0	1	(2)	3	7

NB! Det er viktig at du fyller ut både *hvor plaget* du har vært, og *omtrentantall dager* du har vært plaget siste tretti døgn.

Helseproblemer siste 30 døgn

Nedenfor nevnes noen alminnelige helseproblemer (sett ring rundt tallet som passer)		**Ikke plaget**	**Litt plaget**	**Endel plaget**	**Alvorlig plaget**	**Antall dager plagene varte (omtrent)**
1.	Forkjølelse, influensa	0	1	2	3	…….
2.	Hoste, bronkitt	0	1	2	3	…….
3.	Astma	0	1	2	3	…….
4.	Hodepine	0	1	2	3	…….
5.	Nakkesmerter	0	1	2	3	…….
6.	Smerter øverst i ryggen	0	1	2	3	…….
7.	Smerter i korsrygg	0	1	2	3	…….
8.	Smerter i armer	0	1	2	3	…….
9.	Smerter i skuldre	0	1	2	3	…….
10.	Migrene	0	1	2	3	…….
11.	Hjertebank, ekstraslag	0	1	2	3	…….
12.	Brystsmerter	0	1	2	3	…….
13.	Pustevansker	0	1	2	3	…….
14.	Smerter i føttene ved anstrengelser	0	1	2	3	…….
15.	Sure oppstøt, «halsbrann»	0	1	2	3	…….
16.	Sug eller svie i magen	0	1	2	3	…….
17.	Magekatarr, magesår	0	1	2	3	…….
18.	Mageknip	0	1	2	3	…….
19.	«Luftplager»	0	1	2	3	…….
20.	Løs avføring, diaré	0	1	2	3	…….
21.	Forstoppelse	0	1	2	3	…….
22.	Eksem	0	1	2	3	…….
23.	Allergi	0	1	2	3	…….
24.	Hetetokter	0	1	2	3	…….
25.	Søvnproblemer	0	1	2	3	…….
26.	Tretthet	0	1	2	3	…….
27.	Svimmelhet	0	1	2	3	…….
28.	Angst	0	1	2	3	…….
29.	Nedtrykt, depresjon	0	1	2	3	…….

Before [the rehabilitation program] it was all or nothing. It has been very helpful coming here and getting into my head that what I need to address is to neither overdo things nor do nothing.

Katie

(Age 20+, mental health disorder, sick leave <1 year)

ISBN 978-82-326-5018-7 (printed ver.)
ISBN 978-82-326-5019-4 (electronic ver.)
ISSN 1503-8181

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Norwegian University of
Science and Technology