

# Multidisciplinary intervention versus brief intervention in specialist healthcare

Attempting to improve outcomes for patients on sick leave with  
musculoskeletal pain

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Randi Brendbekken

Thesis for the Degree of Philosophiae Doctor (PhD)  
University of Bergen, Norway  
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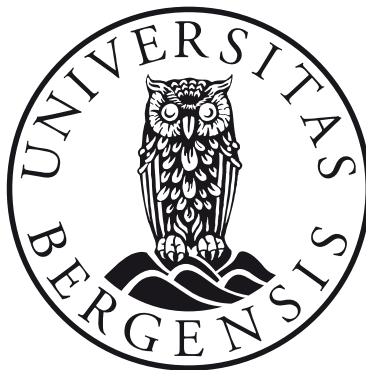
UNIVERSITY OF BERGEN



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## **Scientific environment**

The present PhD project was financed by a three-year PhD grant from the Research Department of Innlandet Hospital Trust, Helse Sør Øst, and the work presented herein is part of a collaboration between Uni Health, a division of Uni Research, Bergen, and the Clinic for Physical Medicine and Rehabilitation, Innlandet Hospital Trust, Ottestad.

The general doctorate programme was carried out within the institutional framework of the Faculty of Clinical Medicine at the University of Bergen. The thesis is presented through the Faculty of Clinical Medicine with supervision from the University of Bergen's Clinical Institute, the Department of Psychosocial Science, the Faculty of Psychology, University of Bergen and the Research Group for Stress, Health and Rehabilitation at Uni Health, Uni Research.

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Finally, I want to thank the most important persons in my life, my dearest children Audun, Nora and Gaute. You are a source of inspiration, recreation and perspective on life to me. Your love, warmth and presence have reminded me that the most important thing in life is not a PhD. Now I look forward to continue my life with you without having a paper to revise or some writing or reading that should be done!

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## Summary

### Background

Musculoskeletal pain (MSK), such as low back pain (LBP), neck pain and widespread pain, is among the most common health problems in industrial countries. Subsequently, MSK is associated with substantial healthcare utilization and a leading cause of sick leave and work disability. The impact on individuals, families and working life is substantial and the societal costs are huge. Most patients have MSK with few or no objective findings. Psychosocial factors are of the most important predictors for long-term disability from MSK and subsequently different multidisciplinary treatment models (MDIs) have evolved over recent last decades.

As part of this PhD project, a multidisciplinary intervention (MI) was developed, primarily aimed at a quicker return to work (RTW) for MSK patients. The MI involved a particular focus on work and psychosocial factors in addition to the somatic complaints and included strengthened patient education (PE) and communication in treatment. The MI was tested against the more established brief intervention (BI), which is mainly focused on musculoskeletal complaints.

### Aims

The main purpose was to clarify whether MI can improve RTW rates within two years over BI in patients on sick leave due to MSK. Secondly, we aimed at identifying predictors for sustainable RTW (s-RTW) and compared patient health, functional ability and coping between groups during 12 months of follow-up.

### Methods

A randomized controlled trial (RCT) was performed with MI and BI as equally sized intervention groups. Patients were referred to specialist healthcare by their general practitioners (GPs) and on sick leave for a maximum of 12 months with MSK. BI is based on the non-injury model (NIM), a non-directive communication and PE approach, and involves a physician and a physiotherapist in the treatment team.



Patients in the BI group met twice at the outpatient clinic: at baseline and at the two-week follow-up stage. The MI was more comprehensive, involved the use of a novel educational communication tool, and focused particularly on psychosocial and work-related factors. The MI was administered by a physician, a social worker and a physiotherapist on the treatment team, and the patients met three times in the outpatient clinic, at baseline, after two weeks and after three months. Data on work participation and sickness benefits were derived from the social insurance register, providing 100% response rate on follow-up data. Questionnaires to identify demographic and clinical variables were filled out by both groups at baseline, and at the three and 12-month follow-ups.

## Results

Out of 534 patients referred by GPs, 284 patients (mean age=41.3 years, 53.9% women) were included and randomized to MI (n=141) and BI (n=143). The mean duration of sickness absence at baseline was 147 days. The treatment drop-out rate was low in both groups (MI: n=7, BI: n=15), indicating that both methods were feasible in a clinical setting. The results showed that MI hastened the RTW process through increased use of partial sick leave (PSL) in the first seven months of the study. At 12 months, there were no differences between groups in terms of either full RTW (f-RTW) (45%: both groups) or partial RTW (p-RTW) (MI=14%, BI=10%). The corresponding numbers at 24 months were: f-RTW: MI=43%, BI=37%, p-RTW: MI=13%, BI=6%. The MI predicted s-RTW, defined as increased work participation, compared to the baseline, for three consecutive months, at the three-month follow-up (OR=2.4), and the subgroup of patients who reported to have *low support at work* benefitted more from MI than BI. The belief that *work was the cause of the pain* predicted s-RTW at three months irrespective of the intervention. *Anxiety/depression* and *duration of sick leave at baseline* were risk factors for an s-RTW.

Secondly, the MI hastened improvements in some of the clinical outcomes: anxiety, depression, somatization and physical functioning. Levels of pain and subjective health complaints (SHCs) followed the same course in the two groups. The MI group

used fewer healthcare services in terms of consulting a GP, at both the three and 12-month follow-ups, as well as reported significantly better perceived coping, physical fitness and satisfaction with treatment than the BI group at 12 months.

### **Conclusion**

An MI with a particular focus on work, psychosocial factors, PE and communication in therapy could speed up the RTW process and the process of improving from mental health complaints and physical functioning among workers on sick leave with MSK, compared to the effects of a BI. Patients receiving MI are more satisfied with treatment, report improved physical fitness and being able to cope with health complaints, and make lesser use of healthcare services, which could also confirm improved coping.

Earlier reconnection with working life could be important, as the length of sick leave is a risk factor for RTW. The reported sense of improved coping in the MI group could be associated with a successful earlier reconnection with work or to faster improvements in clinical outcomes. It may also relate to the strengthened educational process and patient involvement in the MI, which can improve patient adherence to treatment and thereby improve a sense of coping.

However, results so far do not advocate recommending MI before BI to patients on long-term sick leave with MSK, as effect sizes in this study are small to modest and BI performs equally well in the long run for most outcomes. Results should be further improved and cost-benefit analyses should be part of future studies. The identification of subgroups of patients who might benefit more from comprehensive treatment is another future challenge.

## Abbreviations, acronyms and definitions

BI	Brief intervention
BMM	The biomedical model
BPSM	The biopsychosocial model
CATS	The cognitive activation theory of stress
CI	Confidence interval
cLBP	Chronic low back pain
CWP	Chronic widespread pain
DPMR	Department of physical medicine and rehabilitation
f-RTW	Full return to work
FSL	Full time sick leave
GP	General practitioner
HCP	Health care provider
ICF	The International classification of functioning, disability and health
ICIDH	The international classification of impairment, disability and handicap
ISIVET	Interdisciplinary structured interview with a visual educational tool
ITT	Intention to treat
LBP	Low back pain
MDI	Multidisciplinary treatment
MI	Multidisciplinary intervention
MSD	Musculoskeletal disorder
MSK	Musculoskeletal pain
NAV	The Norwegian labor and welfare administration
NDCSS	Non directive communication and social support
NIM	Non injury model
OOW	Out of work

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OR	Odds ratio
PE	Patient education
p-RTW	Partial return to work
PSL	Partial sick leave
RR	Relative risk
RTW	Return to work
SD	Standard deviation
SDM	Shared decision making
s-RTW	Sustainable return to work
URH	Uni research health
WAA	Work assessment allowance
WHO	World health organization

## List of publications

Paper I      Brendbekken, R., Eriksen, H. R., Grasdal, A., Harris, A., Hagen, E. M. & Tangen, T.

**Return to work in patients with chronic musculoskeletal pain: multidisciplinary intervention versus brief intervention: a randomized clinical trial.** *J. Occup. Rehabil.* 2017; 27: 82-91. First Online 24 February 2016.

Paper II      Brendbekken, R., Vakt skjold, A., Harris, A. & Tangen, T.

**Predictors of return to work in patients on sick leave with chronic musculoskeletal pain.** *J. of Rehab. Med.* 2018; 50:193-199. Epub ahead of print 5 December 2017.

Paper III      Brendbekken, R., Harris, A., Ursin, H., Eriksen, H. R., & Tangen, T.

**Multidisciplinary intervention in patients with musculoskeletal pain: a randomized clinical trial.** *Int. J. Behav. Med.* 2016; 23:1-11. First Online 29 April 2015.

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# 1. Introduction and theoretical framework

## 1.1 Background

According to the Global Study of Disease, musculoskeletal disorders (MSDs) are among the main contributors to years lived with disability globally (1, 2). MSDs include a wide range of inflammatory, degenerative and non-specific conditions affecting bones and joints with their adjacent structures, as well as muscles, tendons and ligaments. MSDs are highly prevalent in the general population and affect one in four adults across Europe (3). Subsequently, MSDs impose a significant direct cost burden on healthcare systems and on working life, as it is common within the workforce where it represents a major cause of sickness absence and long-term disability. MSK conditions constitute the major part of all MSDs, with LBP as the most frequent condition (2). Most cases of MSK are non-specific with few or no objective findings; together with mental health problems, MSK represents the most common reason for presentations to primary care where the majority of the cases are managed (3, 4). However, the real burden of overall costs for patients with MSK is connected to a relatively small number of cases with chronic MSK (5-7).

The number of people on long-term work incapacity benefits due to MSK has, in spite of improvements in general health and mortality, increased substantially in Western countries in recent decades (8). In Norway, MSK accounts for about 40% of long-term sick leave cases, with LBP as the most frequent diagnosis (9). The overall costs of MSK to the Norwegian government were estimated to be approximately 70 billion NOK in 2009 (10). The majority of these costs are connected to work disability. It has been a political issue in Norway for several years to prevent long-term sick leave and work disability from MSK. However, the search for effective treatment programmes continues.

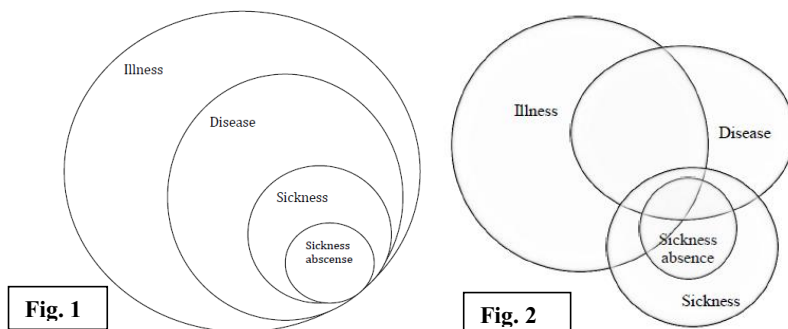
This thesis originates from a Norwegian national project called “A Faster Return”, established in 2007 in specialist healthcare. The project encouraged exploring new strategies and approaches to help people with health problems to stay at or go back to

work. The Department of Physical Medicine and Rehabilitation (DPMR), Inlandet Hospital Trust, was included in the project and assigned the task of setting up an outpatient clinic for patients with MSK.

## 1.2 Health

Few would argue that health is vital to life. However, the distinction between good health and bad health can vary significantly between individuals and cultural systems, as the term relates to subjective, medical (objective) and social aspects (11).

Population studies in the Nordic countries reveal that most people report some sort of illness or ongoing SHC (12, 13). The individual evaluation of *health status* could, however, differ significantly. The concept trilogy of *illness*, *disease* and *sickness* is useful for a better understanding of these differences (14). *Illness* refers to the subjective sense of ill health and ranges from minor symptoms to more severe or acute health problems (15). A *disease* refers to a condition that is diagnosed by a medical expert, while it possible to label a *diagnosis* with reference to medical science (16, 17). *Sickness* refers to the social role that an individual with illness takes or is given by society. The relationship between the concepts has been considered to be simple and totally overlapping (Fig. 1), but studies have found that they interrelate in a more complex manner with relatively less overlapping, indicating that they represent different realities (11) (Fig. 2).



Hypothetical relation between illness, disease, sickness and sickness absence in two different models, modified from Wikman et al. 2005 (11).

To be granted sick leave in Norway, you need to be incapable of working due to a medically accepted diagnosis. The definition of health according to World Health Organization (WHO) from 1948 is: “A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” The definition has been widely criticized as it leaves most people unhealthy most of the time. Given the increasing amount of people living and ageing with chronic diseases, “*complete well-being*” may no longer fit the purpose, but rather increase the risk of medicalization in society. Different proposals for improving the definition of health have been made in recent decades. The best known is the Ottawa Charter emphasizing social and personal resources as well as physical capacity as important aspects of health (18). More recently, Huber et al. suggested changing the definition to “*the ability to adapt and self-manage in the face of social, physical and emotional challenges*” (19). The authors claim that this definition complies better with the disease patterns and health challenges of today and would provide measurements of health and health policies more effectively than the WHO definition.

Given the high prevalence rates of MSK worldwide, combined with the fact that up to 85% of these conditions are non-specific, we might agree that focusing on adaption and self-management seems more suitable than focusing on “*complete well-being*” (20). Guidelines for the treatment of MSK underlines the importance of self-management and adaption as they point to education, stress management, behavioural treatment, physical training and staying active in spite of pain problems as important elements (5, 20-23).

### 1.3 Work and health

Work can be potential harmful to health if the worker is exposed to physical or chemical hazards or occupational injuries, among other factors (24). However, many of these factors have systematically been eliminated, or their detrimental effect has been significantly reduced in modern working life through legislation and systematic health environment management related to work (25). In Norway, our first law regulating potential health hazards in the workplace appeared in 1977 (AML 1977).

Despite a drive to render the workplace less physically demanding, the cases of work-related MSK has increased (26). Psychosocial aspects of work, such as the social organization of work, the degree of job stress, satisfaction with work, experienced job control, job relations and leadership, all matter to health (27). The presence of negative psychosocial factors increases the risk of occupational MSK (25). In a Norwegian survey, it was found that the majority of cases involving MSK (confined to the neck, shoulder and arm) were assessed to be work-related both by the study participants and by the experts (28).

Work is recognized by the WHO as being one of the key social determinants of good health (29). In general, having a job is better for health than not having a job, as work has several obvious advantages. Work provides income and thus economic security. Work defines a social role and identity and is a source of self-esteem, as well as being the major source of a social life for most people and creating a structure for the day and the week (30).

#### 1.4 Sick leave and work disability

Multiple negative effects on the life situation in general have been documented, especially related to leisure activities, sleep and psychological well-being (31). Sick leave as a treatment device could be compared to applying broad-spectrum antibiotics for infections; it works broadly as a general tool but with low precision.

Subsequently, it affects the individual's total life situation and in turn may lead to unintended side effects, such as reduced work motivation, social isolation, inactivity, changed self-esteem, economic strain and secondary health problems, particularly mental ones (31-33). Delayed RTW has become a critical social problem in many societies, affecting not only government economics but also individual quality of life and well-being (34).

There is increasing evidence that, for patients with MSK, the total absence from work over time delays the recovery from the condition (5, 35). Additionally, the longer the duration of sick leave, the more difficult it is for the employee to RTW (36, 37). PSL

could be a way to limit the negative side effects of the absence from work (38). Andren et al. found that employees assigned to PSL recovered to full work capacity with a higher probability than those assigned to full-time sick leave (FSL) (39). PSL is a strategy that many employees find satisfactory (40). A review on benefits and the harmfulness of sick leave concluded with a call for RCTs to evaluate effects on health issues from sick leave (41).

Disability can be explained as “something that restricts or limits”; when related to work, it is usually defined as time off work, reduced productivity or working with limitations due to a clinical condition (42). The term indicates a relation between health and work ability or functioning at work. However, the causes of work disability could be extend beyond health factors and frequently include psychosocial factors, workplace factors and personal factors, such as family matters, beliefs and expectations (43). Additionally, welfare systems and cultural differences contribute to the evaluation of work ability or disability (44). Subsequently, disability could be understood and explained from different perspectives, with different models of disability having evolved during the 19<sup>th</sup> century (43).

In the research on work disability and MSK, several non-medical factors, such as psychosocial and work conditions, have emerged as important (45, 46). The majority of studies has focused on LBP, but it is increasingly accepted that factors associated with disability are complex and that there are similarities across disorders (47, 48).

### **1.4.1 Reasons for sick leave and work disability**

#### *Biomedical factors*

In MSK, the aetiology in most cases is multifactorial and no specific somatic causes can be detected (49, 50). However, clinical guidelines recommend a thorough clinical examination to rule out serious pathology, such as tumour, acute inflammation or infection, often named “red flags”, meaning that specific treatment should be considered (5, 20). Pain intensity and radiating pain have been identified as a predictor for the duration of sick leave in some studies (51, 52). However, pain and disability are not always closely linked as many workers stay at work with pain and

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health problems, a phenomenon known as “presenteeism” (3, 53). Structural findings, such as degenerative changes in the intervertebral discs, vertebrae or facet joints, on the MRI of the spinal column are common, non-specific and weakly associated with pain (54, 55). Although there is evidence for Modic changes in the vertebral endplates, which are associated with LBP, it is not clear how they influence the course of LBP (56). A literature review on the course of LBP concludes that psychosocial and belief-related factors are the most common predictors of outcome. This is similarly the case for acute and chronic LBP (cLBP), although most of the variance in outcome remains unexplained (57). Demographic variables such as gender and age are identified as predictors of the duration of illness in some studies (51, 58). However these results were not reproduced in later studies (6, 59). A recent review on prognostic factors for disability and sick leave in subacute pain patients concluded that, at an individual level, multiple site pain, older age and longer pain duration were potential prognostic factors for disability (60).

#### *Psychosocial and psychological factors*

By the term “psychosocial”, we could understand it to mean “*pertaining to the influence of social factors on an individual’s mind (perceptions, thoughts, feelings) and behavior and the interrelation of behavioral and societal (cultural) factors*” (61). Psychosocial factors are among the most important predictors of chronicity in MSK (46, 62-64). Psychosocial factors can influence the course of acute MSK by interfering in different phases of the clinical condition: at the onset of pain, on seeking and receiving of healthcare and other support, and in the development of chronic pain and work loss (62, 65). Co-morbid psychiatric disorders, especially anxiety and depression, are associated with the development of cLBP (46, 57). Co-morbid depression has predicted work disability in some studies (66, 67), but not in others (68). Negative expectations, fear avoidance beliefs, psychological distress, catastrophizing and passive coping strategies have also been identified as risk factors for non-recovery from MSK (34, 69-72). The patient’s own expectations of recovery seem to be an important factor for sickness absence in cLBP (73). Personal experience of illness and disability and emotional reactions might also influence recovery (74). Former multiple episodes of sick leave can by themselves be risk

factors for non-RTW (75). Low education level and low socio-economic status are also associated with protracted courses and poorer outcomes for LBP (56, 58, 76). Cultural factors, such as welfare systems, labour markets and social factors also influence work disability and sick leave (77).

### *Work-related factors*

Physical, organizational, psychological and societal aspects of work could influence health and increase risk of disability (30). MSK can be triggered by occupational factors, such as repetitive manual tasks, uncomfortable work positions, physically stressful work, lifting or carrying loads, and pushing or pulling loads (78, 79). High job demands, low control and low support at work influence the risk of MSK significantly (52, 80). A model of job strain was developed by Karasek in 1979, which introduced the factors of *job demands* and *control over work* as decisive for the degree of mental strain experienced (81). A job with high demands and low control will be characterized as the most stressful or “high strain” work with a subsequently increased risk of developing health problems related to work. Later on, the parameter *social support* was introduced as a modifier in the model, illustrating that *support* could dampen the negative effects of low control and high demands. However, the relation between physical strain and MSK is inconsistent (58). Steenstra and co-workers identified work demands, accommodation and modified duties, and job satisfaction to be factors predictive of RTW for workers with LBP (59). Adverse psychosocial and societal work factors are associated with the development of MSK and with disability (46).

### *Factors related to healthcare providers*

Healthcare providers (HCPs) need to be conscious that obstacles to work participation may exist at levels beyond somatic complaints. The identification of factors related to work ability should therefore be examined in a comprehensive way. The allotted time for each patient in primary care could be a limitation for the GP in this work. Additionally, HCPs are primarily educated and trained in the biomedical approach to illness and therefore be without the competence or experience to deal with complex disability cases (82). The biomedical approach could lead to

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unnecessary imaging tests, overtreatment, more referrals and more disability (83). Additionally, the evaluation of *work conditions* is not a standard topic when HCPs consult patients with MSK (84). Adverse disability outcomes can be related to communication failures between the employee and the HCP (85). The therapeutic alliance influences the outcome of treatment (86). As MSK is one of the most prevalent health complaints in primary care, the therapeutic alliance could be important to outcomes. Descriptions of successful treatment interventions often cite improved communication as a decisive factor for success (52, 87). Prevailing models of disability management often rely on authoritative or unidirectional communication, leaving the patient (worker) in a passive role (88). Pransky and co-workers suggest that improvements in communication between stakeholders in the RTW process could be the answer to further improve disability outcomes across interventions (87). The implementation of communication in therapy according to a biopsychosocial understanding of disability could support this suggestion and improve RTW outcomes in patients with MSK (89). There is still a considerable influence of the biomedical paradigm in clinical practice (32). As most forms of MSK are non-specific, the sick leave process becomes mainly patient-driven, although modulated through GPs' attitudes, beliefs and personalities (90).

## 1.5 Return to work interventions for musculoskeletal pain

RTW can be conceptualized as 1) “the process of returning a worker to work”, for example through job accommodation or graduated RTW, or 2) as a measurable final outcome of disability: the status of working/not working (91). RTW as a measurable outcome has been defined in several ways: as a categorical variable (as *RTW yes/no*), a continuous variable (as *time to RTW* or to *s-RTW*) or a cumulative variable (duration of *days lost from work*) (91). Consequently, the measurements of, and perspectives on, RTW in clinical practice and in research vary widely (42, 45). The significant body of research in the field of occupational disability has unfortunately been hampered by this heterogeneity, and our ability to predict, understand and facilitate good outcomes is still limited (32, 69, 92). Early RTW research viewed



work status as being dependent on the severity of the clinical condition of the worker, with the ability to return to employment a product of the recovery process, indicating a linear progression of events (92, 93). Nowadays, we acknowledge that the RTW process is much more complex and can be viewed as one that encompasses a series of events, transitions and phases involving interactions with other individuals and with the environment (74, 77, 92). RTW interventions subsequently include a variety of treatment programmes and components in pursuit of improving health, reducing barriers to work and facilitating work participation (94). Hence, physical exercise, patient education, cognitive or behavioural therapy and work accommodation are typical treatment components in these programmes. This variety reflects not only the composite nature of the work disability problem, but also the lack of a unifying model of health and disability related to work participation (42). European guidelines recommend cognitive behavioural therapy, supervised exercise therapy, brief educational interventions and more comprehensive biopsychosocial, multidisciplinary interventions for cLBP patients (20). However, the effectiveness of RTW interventions for MSK is still debated (95).

### **1.5.1 Brief interventions**

BI programmes most often refer to a cognitive and educative approach based on the *NIM* and a *non-directive communication and social support* (NDCSS) in addressing pain and fear avoidance (96). The clinical examination involves a physician and a physiotherapist. The essential features are a diagnostic clarification, a thorough educational, medical examination with reassurance offered about normal findings. A return to normal activity including work is recommended. BI programmes are effective in reducing sickness absence and short-term disability compared to treatment as usual (TAU) for patients with subacute LBP (96-98).

BIs have been applied in several clinical trials in recent decades, with reviews concluding that BIs for patients with subacute LBP are effective in the clinical setting for RTW outcomes compared to no intervention, provided interventions last for a minimum of 2.5 hours (99). Another review found BIs to be superior to usual care in

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terms of RTW and short-term disability (98). However, the effect on RTW and health outcomes for chronic back pain patients remains inconclusive.

### *Non-injury model*

The NIM is based on the knowledge that MSK, including LBP, is mainly non-specific without any objective findings or indications of damage (96, 100). The model was developed in the 1990s for the treatment of LBP and evolved as an alternative to the biomedical model of illness, as normal findings were the most frequent (96). In a biomedical tradition, symptoms related to LBP were assumed to be a sign of illness or damage associated with structural pathology (101). The underlying principles of the NIM are based on the evidence that the back is a robust structure and that LBP is not caused by any wrongdoing (100). The NIM is in accordance with the European guidelines for the management of LBP (20).

### *Non-directive communication and social support*

Communication in the BI is based on NDCSS, which implies that the therapist does not value or judge the patient's evaluations, choices or feelings, but cooperates with an acceptable attitude (102). The information will be provided in a non-directive way, to leave the patient to make conclusions and decide on their own about physical activity. Studies have found better compliance when NDCSS was practised than when applying directive support, which is far more instructive and demanding (103).

## **1.5.2 Multidisciplinary interventions**

Prolonged pain tends to develop into a combination of physical and psychosocial disabilities and various MDIs have evolved to meet this complexity in the clinical picture (94, 104). An MDI generally involves different professions in the treatment team and treatment elements, which more frequently comply with the biopsychosocial model of illness (105). Nevertheless, the effectiveness of MDIs on RTW and clinical outcomes in MSK has repeatedly been questioned along with a call for high-quality trials in the field (23, 106). A review in 2008 concluded that MDIs represent the state of the art of the management of complex, chronic non-malignant pain, although there is no consensus on the content of MDIs or who might benefit

more from a comprehensive approach (107). Various studies have aimed to identify effective RTW strategies over recent decades (32). There is still a call for more knowledge on which treatment components could be more important for subgroups in the MSK patient population (107). A major problem has been the high degree of heterogeneity between studies, making comparisons difficult. However, a Cochrane review found MDIs to be more effective in decreasing pain and disability than TAU and physical treatments, and more effective than physical treatments on RTW outcomes (108). Another review looking at the effectiveness of MDIs on RTW found effects before TAU or conservative treatment for subacute LBP but not for cLBP (109).

Several trials have compared the effects on RTW of a work-focused MDI, with the effects of TAU, which is frequently the treatment approach in primary care (110-112). In the Sherbrook model, which consists of multiple elements, Loisel and co-workers found that a workplace intervention as a component of an MDI was superior to a clinical intervention plus graded, physical activity over six to eight weeks, for RTW outcomes in patients with subacute LBP (112). Both the clinical and the occupational interventions were superior to TAU with a hazard ratio (HR) of 2.41 for an RTW. Loisel later recommended future trials to focus on intervention *development* rather than making comparisons with TAU, as it is obviously ineffective (77). Anema et al. replicated Loisel and co-workers' trial in a Dutch setting and found the workplace intervention to be superior to TAU, while graded physical activity had a negative impact on work outcomes (111). RTW was defined as f-RTW for four weeks without partial or full drop-out from work because of LBP. Steenstra concluded that a workplace intervention resulted in a safe and faster RTW compared to a clinical intervention for workers with LBP (113). Lambeek et al. compared an integrated care approach involving a workplace assessment in specialist healthcare and TAU in primary healthcare for patients with cLBP and found a considerable effect of the integrated care programme on RTW compared to TAU after 12 months (114). The primary outcome was f-RTW for at least four weeks and secondary outcomes were functional status and pain. Functional status was much better in the

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case of integrated care at 12 months, but pain improvements were equal. The authors conclude that, in an advanced stage of work disability, integrated care is more effective both for work outcomes and for private life (114).

In a review on intervention characteristics facilitating RTW, the authors concluded that early interventions (within six weeks) and MDIs were beneficial in addition to activating interventions such as a gradual RTW (115). Another review concluded that stakeholder participation and work modification are more effective for RTW and should be preferred (116).

### **1.5.3 Patient education and treatment decisions in therapy**

PE has been part of clinical practice for decades now and reflects how the role of the patient and the role of the HCP have been going through a paradigm shift (117). For centuries, physicians have been allowed to overrule and interfere with patients' preferences when making decisions about treatment (118). Nowadays, the clinician-patient relationship has become more of a partnership and the patient is increasingly seen as responsible for their own health or recovery (119). Patient autonomy is seen as a basic value and underlying premise for the provision of healthcare itself (120). The active involvement of patients in treatment decisions requires an educational process involving the presentation of knowledge and information to the recipient (118). This educational process is of the utmost importance as it could prevent the unnecessary use of healthcare and enhance self-care and the use of active coping strategies (121, 122). There are different models of decision-making in therapy. Shared decision-making (SDM) is one method where the clinician and the patient go through the decision-making process together, consider outcome probabilities, share preferences of treatment and, in the end, reach an agreement on treatment choice (123-125). Good communication skills are vital if the patient is to understand the information presented to them and for the clinician to draw out the patient's beliefs and preferences (125). Studies on the practice of SDM have reported improvements in adherence to treatment, quality of life and well-being, and in patient satisfaction with treatment (123, 126, 127). SDM is furthermore found to be an effective and

useful way to reach treatment agreements, particularly when patients have to make long-term decisions (118).

Thus, the aim of PE is multifaceted: to improve the understanding of the health problem and treatment options, to reduce unanswered questions and concerns, to empower patients to take actions for recovery, and to minimize dependency on HCPs (128). PE is moreover a prerequisite for SDM to be practised, but PE in itself does not automatically induce patient involvement in treatment decisions.

Many types of PE are used in clinical practice. Discussions with or the verbal delivery of information from a health professional are among the most frequent types, together with written content, such as a booklet or a pamphlet.

In clinical guidelines for the treatment of LBP, PE is well integrated (49, 121). A review on the effects of *information* on LBP management concluded that information should be based on a biopsychosocial model, but that the delivery of information alone is not sufficient to prevent absenteeism and reduce healthcare costs (129). The Cochrane Group later reviewed the effects of PE on clinical outcomes and RTW for LBP and found intensive PE to be more effective for acute and subacute LBP than for cLBP (99). The authors found no difference in the effects of various *types of PE*, and it remains unclear what form of PE is preferred and what content, intensity and frequency, which is optimal. Information campaigns on the treatment of LBP on television have been delivered with no effect on sick leave (130). PE for patients with chronic MSK could be an extra challenge as patients with chronic pain frequently report impaired cognitive functioning with concentration, forgetfulness and attention problems among the most severe complaints (131-133). In a cohort of fibromyalgia patients *without depression*, cognitive impairment, particularly memory and vocabulary deficits, were observed (133). Visual displays may be superior to written text in learning and memory (134). Studies have shown that learning from graphic organizers are beneficial to text outlines (135). A Cochrane review concluded that more research is needed to find out which types of PE are the most effective (99).

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## 1.6 Theories and models

### 1.6.1 The biomedical model

The models of illness that underlie our understanding of diseases and illnesses are rarely explicitly discussed or criticized, although they have a huge impact upon medical practice. The assumption that a specific disease underlies all illness has dominated medical thinking and practice for the past century. This model of illness can be referred to as the biomedical model (BMM) characterized by the following basic assumptions: all illness has a single underlying cause, disease is always the single cause and the removal of the disease will lead to a return to health (101). The BMM originates from Virchow who concluded that all disease can be associated with cellular abnormalities (136, 137). The model conceptualizes the human organism as being almost like a “biological machine”, while illness is a consequence of the ill-functioning of the human organism. Disease is described as a linear sequence from cause factor to pathology, to symptoms or manifestations (138). Secondly, the model holds that symptoms and disability are directly related and proportionate to the severity of the biological pathology. In the BMM, the mind and body are functioning as separate and independent entities (139, 140). This complies with Descartes’ dualism of mind and body (141). The physical disorder is superior to the less important or secondary psychological, social and behavioural dimensions in the BMM (138). Fundamental to the model is the belief that the physician is responsible for the control and, ideally, relief of pain (105). Subsequently, communication in the BMM is often unidirectional and characterized by expert teaching or instructing.

The model has intuitive appeal as it complies with our scientific thinking on cause and effect in a linear connection and performs well in the case of uncomplicated injuries, illnesses or pain in acute stages where healing processes are predictable, as well as in ruling out serious pathology, such as tumours, fractures or infections (138). The model is supported by a vast number of biological findings related to illnesses.

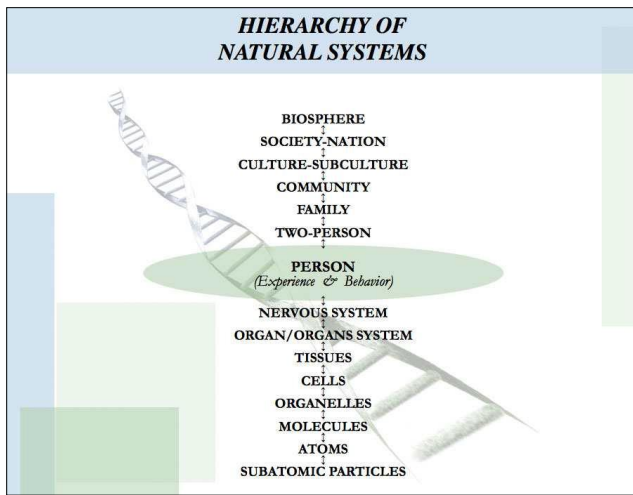
Although the BMM has made huge improvements in medical care, it has also undermined the understanding and effective treatment of many illnesses in the search for pathologic findings.

### **1.6.2 The biopsychosocial model**

Engel proposed a new model of illness where many of the shortcomings from the BMM were addressed (105). The single-cause, single-category and single-effect models of health and illness were replaced by a multicause, multicategory and multieffect model, known as the biopsychosocial model (BPSM). The introduction of the BPSM reflected a paradigm shift in science in general. Engel offered both a philosophy of clinical care and a practical, clinical guide when he proposed this new, holistic model. The BPSM has been especially influential in the area of chronic pain (140).

The BPSM is based on a system approach where Engel claims that nothing exists in isolation. The person is experienced as integrated into a hierarchy of dynamically related natural systems: the cell is part of an organ and a person, a family, a society etc., and these increasingly complex systems are seen as interactive, interconnected and interdependent (Fig. 3.) (89, 105). The BPSM, when applied in medicine, systematically considers the interaction of biological, psychological and social factors in the process of understanding human health, illness and disability in the planning of healthcare. Engel emphasized that the patient's story should be elicited in the context of life circumstances and the clinician should determine which aspects of biological, psychological and social domains are the most important to understand; furthermore, the clinician should provide a multidimensional treatment (142). Ten years after Engel presented the BPSM, Waddell developed an approach to LBP, which was in compliance with the BPSM (49). The BPSM influences how clinicians approach patients while moving towards an egalitarian patient-therapist relationship (85). In the *case management model*, which is based on the BPSM, the patient is an active participant in the rehabilitation process, while the rehabilitation team facilitates the process, reflecting the shift from the HCP-patient relationship, to a multiplayer-

decision maker system, which is influenced by multiple interacting systems (77, 138). The BPSM has been criticized for not clarifying person-environment interaction in relation to the implications for RTW and conception of work ability; more precisely, how natural systems including the work arena influence a person's decisions about their own work ability or work participation (93).



**Fig. 3** The biopsychosocial model (Engel 1977). University of Rochester Medical Education

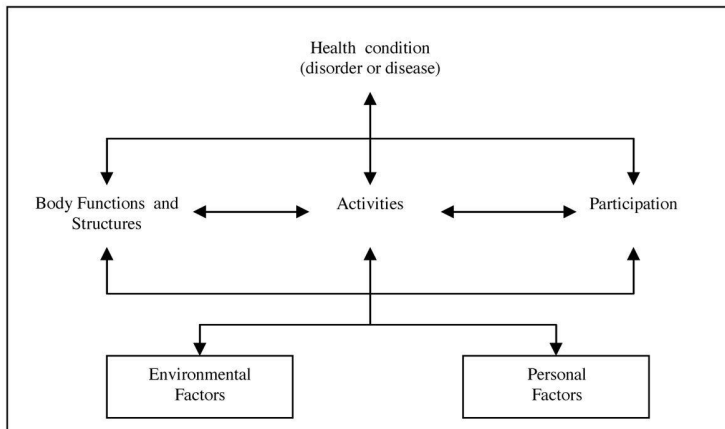
### 1.6.3 International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) was approved as an international tool for describing and measuring function, health and disability by the World Health Assembly in 2001, replacing the outdated International Classification of Impairment, Disability and Handicap (ICIDH) (143, 144). The ICF provides a complex understanding of health and disability in line with the BPSM, including biological, individual and social aspects (145). Before the ICF, health was conceptualized as the opposite of disease or death, and traditional health indicators had typically been related to mortality or morbidity. Disability was seen more as an unrelated entity, as bodily impairments, such as blindness, restricting or limiting the individual in their capacity to take part of daily life activity. The ICF brought these concepts together into a comprehensive description of the multiple dimensions of



human functioning. The ICF has been widely utilized ever since and implemented in various settings and sectors, with rehabilitation medicine as a dominant arena (146, 147). A disability process initiated by a health condition is, according to the ICF, influenced by both environmental factors and personal factors (Fig. 4). The environmental factors include societal attitudes and beliefs, welfare systems, the workplace as well as climate or terrain, while personal factors include age, gender, beliefs, personality, previous experience, coping strategies and education. The BPSM is thus embedded in the ICF, describing how medical, individual, social and environmental factors mutually influence functioning and disability.

The ICF represented an important step forward from the ICIDHS in the understanding of health and functional ability. The model has however been criticized for not being based on theory and for not justifying the BPSM as the underlying model (148). Additionally, work factors have not been specified in the model. Herrkens and co-workers developed a supplemental model to describe work-related factors influencing the health of employees, to fill the terminology gap between professionals in healthcare and in occupational medicine (149).



**Fig. 4** The ICF model: Interaction between ICF components (WHO 2001)

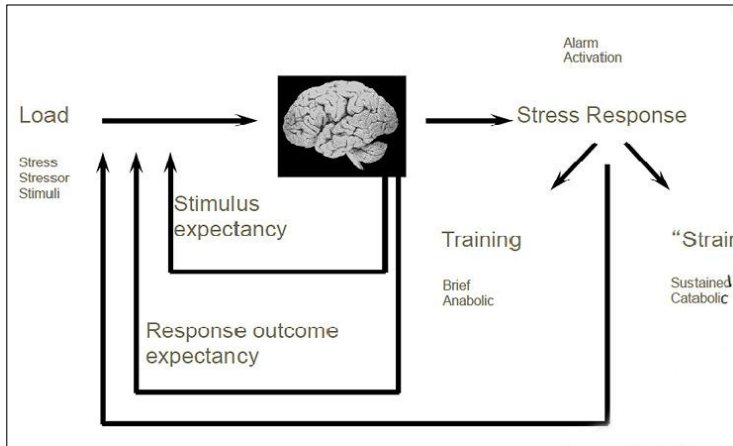
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### 1.6.4 Cognitive activation theory of stress

The cognitive activation theory of stress (CATS) offers a model of understanding how stress and coping are related to health (150). The principles of the model are transferable to the field of sick leave as it presents an explanation, at an individual level, of how the process of coping/non-coping might affect health and influence lifestyle choices through learning (151). Learning is defined either as stimulus expectancy or response outcome expectancy. The CATS describes how the individual, based on available reinforcement contingencies and resources, learns positive outcome expectancy (coping) or negative outcome expectancy (helplessness: that nothing matters whatsoever; or hopelessness: that everything goes wrong) (152). The “load” (stressor) could be any stimulus that is either new or not as you expected it to be (stimulus expectancy). The response to the load is an arousal (stress response), which initiates a cognitive processing of the information (150). The stress response proceeds in one of two possible pathways; either producing a short anabolic response with no pathophysiological effects (train effect) or producing a sustained catabolic response that may have adverse health effects (strain effect). Positive feedback or feedforward mechanisms enhance learning and produce expectancies formed by previous experiences. A positive outcome expectancy (coping) is the expectation that most or all of your actions will produce the desired outcome. When coping fails, negative expectancies, either helpless or hopeless, are acquired. These expectancies could lead to poor health through highly sustained arousal, which can cause somatic changes (153). However, negative expectancies may also lead to poor health through a learning mechanism, where the development of helplessness or hopelessness affects the motivation to make life changes. A helpless individual is less likely to develop and comply with advice about new behaviours as they have learned to believe that there are no relations between actions and reward. An individual experiencing hopelessness is even more susceptible to this, as they expect that everything they do produces a negative outcome. The cognitive brain mechanisms that determine the choice of behaviour follow the rules of learning theory: what expectancies of outcome have been learned, what the rewarding factors for the individual are, what the chances of success are, and how much energy is to be

invested in a particular behaviour. This also means that response outcome expectancies could change with new learning experiences that modify the original expectancy.

The CATS offer an explanation as to why focusing on individual coping is so important in the treatment of patients suffering from chronic MSK. However, the CATS have been criticized for overestimating the power of the individual and the environment in the course of forming behaviour (154, 155).



**Fig. 5** Schematic presentation of CATS, adapted from Eriksen et al. (2005)

## **2. Overall aims and research questions**

The primary aim of the study was to clarify whether MI can improve RTW rates within two years over BI in patients on sick leave with MSK. Secondly, we sought to identify predictors for s-RTW and, lastly, compare patient health, functional ability and coping between groups during 12 months of follow-up.

These aims will be addressed by three different research questions corresponding to the aims of the three different papers:

### Research question 1

Can a comprehensive, educational approach, i.e., the MI, with a particular focus on psychosocial factors and work situation, improve RTW rates for patients on sick leave due to musculoskeletal complaints, before a BI?

### Research question 2

Is s-RTW, defined as increased work participation in three consecutive months, at three and 12-month follow-up, predicted by patient health factors, functional ability, work-related factors or by interventions?

### Research question 3

Is a comprehensive, educational approach, i.e., the MI, with a particular focus on psychosocial factors and work situation, more effective in improving patient health, functional ability and coping than a BI?

### **3. Design, material and methods**

#### **3.1 Design and study population**

This study was an RCT involving sick-listed patients referred to DPMR, Innlandet Hospital Trust, Norway. The study was carried out in the same department. The planning of the study started in 2009 and patients were included in the trial until December 2012. Follow-up was 12 months for health and 24 months for work parameters.

A total of 534 patients with MSK and referred to the DPMR were considered for inclusion in the study. Among these, 284 patients (54% women, mean age 41.3 years) were included and randomized to either MI (n=141) or BI (n=143). The patients were referred from their GP in 48 municipalities in two counties in the south-eastern part of Norway. The GPs had no information that there was a possibility that their patient would be included in a clinical trial.

The following inclusion criteria were applied: age 20-60 years, at least 50% sick leave due to MSK for up to 12 months and at least 50% employed. The exclusion criteria were: pregnancy, current cancer, osteoporosis, recent physical trauma/injury, serious mental illness, rheumatic inflammatory diseases, not capable of understanding and speaking Norwegian, being involved in a health insurance claim. Of the 534 patients considered for inclusion in the trial, 250 were either not eligible or excluded for different reasons.

#### **3.2 Context**

In Norway, all lawful residents are included in the Norwegian public insurance system. This system provides health service benefits and pensions to all members, and payments are administered by the Norwegian Labour and Welfare Administration (NAV). Sick listing is usually provided by the GP and requires a medically

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acknowledged disease. If an employee has been in work for the last four weeks before the sickness incident, they are granted 100% of the ordinary salary in sickness compensation from the first day of the sickness absence and up to one year. The employer covers the first 16 days; thereafter the NAV covers the disbursement. Sick leave can be graded from 20% and up to 99%. After one year, the patient can apply for further benefits if they have not yet returned to work. These benefits come under the name of Work Assessment Allowance (WAA) and constitute approximately 66% of the patient's former income. WAA can be combined with work if the disability constitutes a minimum of 50%. WAA is granted with an upper limit of four years, provided that the patient is going through medical rehabilitation or treatment or is involved in any type of vocational rehabilitation. Patients in this study were on sick leave, either fully or partly, when entering the study; they were also able to convert to WAA during the follow-up. WAA could be fully or partly received (with a minimum of 50%) and combined with work activity.

### 3.3 Sample size

The sample size was calculated before the study and based on data from another RCT study on RTW (97). The calculation was based on transition probabilities calculated for the intervention group in this study, using standard formulas for calculating sample sizes for studies comparing binominal proportions. Provided a power of 80% and a significance level of 5% are achieved, the number of patients in each intervention group of our study was estimated to be 150, giving  $n=300$  for this study.

### 3.4 Procedures and interventions

Both intervention groups received their treatment at the DPMR, Innlandet Hospital Trust, but the location of treatment sessions and the treatment teams was different. The HCP performing the BI was experienced in the method and had recently been audiotaped performing a BI in another clinical trial (156). The HCP providing the MI had received some training in the method in beforehand, and, during the study, they had regular meetings to ensure the equal practice of the method. For practical

reasons, there was no blinding to treatment among the therapists or participants. After inclusion, informed consent was obtained from each participant and allocation was made to a treatment group, while a letter with the date of the baseline treatment intervention was sent to the participants together with a set of questionnaire. In a cover letter, the patient was requested to answer all questions and bring their responses to the appointment at the clinic. Later on, the patients received a questionnaire at the three- and 12-month follow-up. Patients who dropped out of treatment were asked if they were willing to continue filling out the questionnaire and return it by mail.

### **3.4.1 Randomization**

The randomization was concealed and all patients were randomized to either the MI or the BI according to a computer-generated randomization list set up by a statistician at Uni Research Health (URH). A research assistant at the DPMR assigned each study participant an ID number after inclusion and informed consent was given by the participant. URH was informed of the ID number, gender, age and diagnosis. The research assistant then received information from URH via a telephone randomization system about which treatment group the patient should be allocated to. Treatment started as soon as possible after randomization with a maximum delay of two weeks due to a waiting list being in operation.

### **3.4.2 Interventions**

#### *Brief intervention*

A BI is a standardized, cognitive intervention; and, in this study, we applied the BI as described in the study by Molde Hagen (97), which represents a modified and less resource-demanding version of the BI applied by Indahl in his pioneering work on the method (96). Treatment manuals were written and based on current guidelines and the manual used by Hagen (20, 97).

*Baseline assessment:* At the baseline consultation, the patient first met a physician for about an hour and then a physiotherapist for about 1.5 hours. The session with the

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physician, who was a specialist in physical medicine and rehabilitation, included time for the patient to express problems and concerns/worries, followed by a thorough, clinical, educational examination by the physician for the purposes of diagnostic clarification. Any somatic findings were explained and their significance was related to the actual problems, while normal findings were explained in a positive way. If the patient had any X-rays, the radiographs were shown and explained. In the absence of symptoms and clinical findings indicating serious disease, the patient was informed about the good prognosis and the importance of staying active and returning to normal life, including work, as soon as possible. The patient was encouraged to take daily walks and reassured that light activity would be beneficial and do no harm. The following consultation with the physiotherapist comprised a physical examination related to the pain problem. The physiotherapist could draw attention to unfavourable movement patterns, muscle tension or other findings, and advise the patient on exercises, stretching or giving practical advice for coping at home and in the course of daily activities.

*Two-week follow-up:* The follow-up consultation with the physiotherapist after two weeks typically lasted one hour. At this consultation, advice and instructions given at the baseline session were evaluated, while the patient could discuss relevant issues of importance with the physiotherapist. Written reports from the consultations were routinely sent to the GP after each consultation, with a copy issued to the patient.

#### *Multidisciplinary intervention*

An MI represents a novel, cognitive approach; in this case, the method had been worked out in cooperation with therapists at the DPMR during the “A Faster Return” project. The MI involved three therapists in the treatment team, a social worker, a physician and a physiotherapist. The method assessed specific psychosocial and work-related factors and applied a new visual communication tool, namely, the Interdisciplinary Structured Interview with a Visual Educational Tool (ISIVET). The purpose of the ISIVET is to strengthen communication and education in therapy and improve patient engagement in rehabilitation. The MI involved more treatment time with one extra consultation and one extra therapist in the team. Written treatment



manuals were applied, with a detailed description of the content of the different parts of the method. Treatment was based on current guidelines and otherwise individualized due to the ISIVET process.

*Baseline assessment and ISIVET:* The patient consulted with members of the treatment team (a social worker, a physician and a physiotherapist) successively. Each therapist had a specific assignment at the meeting with the patient:

- 1) The social worker provided a survey of the patient's family life, education, finances and work. A star plot named "Work conditions", which is part of the ISIVET, was filled in.
- 2) The physician completed a general medical journal with a thorough physical examination, concluding with a diagnosis according to ICD-10 (17). An educational, physical examination of the patient was performed, in which eventual findings and their relevance to the pain problem was discussed. Normal findings were addressed and discussed in a positive way, as in the BI. A star plot named "Quality of life", which is part of the ISIVET, was filled in.
- 3) The physiotherapist assessed the musculoskeletal problems of the patient and made a physical examination related to the pain problem. The physiotherapist was able to call attention to unfavourable movement patterns, muscle tension or other findings and advise the patient on exercises, stretching or giving practical advice for coping at home and in the course of daily activities.

The ISIVET comprised a manual for filling out two star plots (Appendix 1) for "Work conditions" and "Quality of life" and a table for creating an individual rehabilitation plan. Each star plot had seven axes, representing a parameter relevant to the actual issue. The star plot for "Quality of life" mapped physical complaints, psychological well-being, sleep, energy, physical activity level, social participation and occupational participation. The star plot for "Working conditions" mapped work-related stress, satisfaction with job tasks, work load, collegial relationships, leadership, degree of challenges at work and occupational participation. The scores were set between 1 and 10 where "10" was positioned on the periphery of the axis, indicating an optimally positive situation, whereas "1" was located close to the origin,

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indicating a maximum negative situation. The patient and the therapists used a manual with illustrative examples of situations at different levels and, through discussion, identified the right score for the patient. When all scores were completed, a line was drawn between the seven scores, creating an area in each of the two star plots. The area under the lines was coloured to allow for better visualization for the patient as well as for the therapists. Problem areas or challenges were demonstrated by a lack of colour, while existing resources stood out as coloured areas.

When the sessions with the three different therapists were completed, the whole team met briefly to share findings and discuss possible barriers to work participation. The patient joined the meeting to a final discussion with the team about their situation, health problems and work situation. The two star plots were central in this summing-up phase and informed a discussion with the patient about possible actions. The patient played a major role in this phase by deciding on how to move forward, with reference to the star plot areas. An agreement on actions was written down, which also comprised the patient's rehabilitation plan. Actions were typically related to the cognitive assessment of health and pain, lifestyle, family and work matters. Efforts to increase physical activity on a daily basis were typical. When leaving the clinic, the patient received a paper copy of the star plot with the coloured areas and the rehabilitation plan listed as points to be followed. The complete baseline assessment lasted 3.5 hours.

*Two-week follow-up:* The patient and the physiotherapist met for one hour to evaluate the rehabilitation plan and work through the two star plots in the ISIVET once more. New scores and new areas on the star plots were coloured with a new colour. The visualization of area changes in the star plots was a matter of attention and reflection. Previous advice and actions were highlighted accordingly, and adjustments in the rehabilitation plan were eventually made.

*Three-month follow-up:* The patient met with the whole team for one hour to review the situation and evaluate the interventions so far. The two star plots in the ISIVET

were worked on once again, with areas on them coloured with a third colour. Eventually, they adjusted the rehabilitation plan.

*12-month follow-up:* The physiotherapist contacted the patient by telephone to work out the ISIVET in order to obtain a final measurement and not to evaluate the situation. This involved brief contact lasting about 15 minutes.

### 3.5 Therapists

The patients received their treatment at two different outpatient clinics at the DPMR, Innlandet Hospital Trust. A physician who was specialist in physical medicine and rehabilitation and a physiotherapist delivered the BI. A written manual was used. Both therapists were experienced in the method.

Four physicians, all specializing in physical medicine and rehabilitation, two social workers and four physiotherapists delivered the MI. The team members were the same during the treatment course of one patient. The ISIVET was originally developed by the first author (RB), but was further developed and adjusted at the DPMR during the planning stage of the study. To ensure adherence to the protocol and equal practice of the method, the MI teams held regular meetings for supervision and discussion.

### 3.6 Instruments

#### *Demographic baseline questionnaire*

The comprehensive questionnaire at baseline comprised demographic variables, information on education and different aspects of work, self-ratings on health, fitness and physical activity, information related to the sick certification, and the duration and initial/actual extent of sick leave. The following clinically validated questions were applied:

The *Subjective Health Complaints Inventory* (SHC) is a reliable instrument for measuring somatic and psychological complaints over the last 30 days using 29

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questions rated on a four-point scale (from “0” to “3”) (157). The instrument has five subscales: “musculoskeletal complaints” (eight items), “gastrointestinal problems” (seven items), “pseudoneurological problems” (seven items) and “flu” and “allergy” symptoms (seven items in total), in addition to a total score (SHC total), with the maximum value of 87 indicating the highest possible level of complaints that can be measured by this instrument. The subscale “musculoskeletal complaints” correspondingly has a maximum value of 24.

The *Hospital Anxiety and Depression Scale* (HADS) assesses anxiety and depression disorders (158). The scale consists of 14 items that create subscale scores for anxiety (seven items) and depression (seven items). The total score for each subscale is calculated by adding the scores of the individual items (0-3) and ranges from 0 (good) to 21 (poor).

The *Hopkins Symptom Checklist-25* (HSCL-25) measures psychological distress (159). The instrument consists of 25 questions recording the presence and intensity of the most common symptoms of anxiety, depression and somatization. Severity is scored on a four-point Likert scale from 1 (“not at all”) to 4 (“very much/to a severe degree”), with a mean score  $<1.75$  within normal range, while a score  $\geq 1.75$  indicates psychological distress in need of treatment.

The *Norwegian Function Assessment Scale* (Norfunk) measures physical functioning (160). The instrument records different aspects of physical and psychological functioning with 41 questions. The questions on physical function are related to the patient’s ability to walk/stand, to hold/pick, to lift/carry, and to sit. The questions related to psychological function cover the ability to cope, to communicate with others, and to look/listen. The questionnaire covers the function in different activities undertaken during the last week and the answers are scored on a four-point Likert scale from 0 (“no problems”) to 3 (“not able to do the activity”).

The *Eysenck Personality Questionnaire-Nordic* (EPQ-N) is a 12-item true-false questionnaire measuring neuroticism as a personality trait. The maximum score of 12

indicates a high degree of neuroticism. EPQ-N is derived from the 90-item EPQ (161), which measures neuroticism, psychoticism and extroversion.

The *Chronic Pain Acceptance Questionnaire* (CPAQ) is a 20-item assessment divided into two subscales: pain willingness (nine items) and activities engagement (11 items). The scores are set according to a numeric scale from “0” to “6” (highest degree of willingness or engagement), with the CPAQ sum having a maximum score of 120, indicating the highest possible level of willingness to tolerate pain and engage in activities measured by this instrument (162).

*Physical burden of work* and *psychological burden of work* were assessed by the question, “Do you experience your work as a physical (correspondingly psychological) burden?” The three possible answers (yes, no or some) were dichotomized into “yes/some”=1 and “no”=0.

*Support at work* was measured by six items from Theorell, while answers were given using a four-point numeric scale from minimum support to highest degree of support (“1” to “4”), with a maximum score of 24, indicating high support at work from leaders and colleagues (163).

*Burden of work* was measured using the demands/control fraction of Karasek and Theorell (163), including questions on *job demands* (five items) and on *job control* (decision latitude). The job control scale is the sum of two subscales: *skill discretion* (four items) and *decision authority* (two items). The answers are given in the range of 1 to 4, where “4” represents the most burdensome situation.

The *Numeric Rating Scale* (NRS) was applied to measure mean pain during activity, mean pain during rest and mean pain at night during the last 14 days. The severity of pain was scored on a scale from 0 to 10, with 0=“no pain” and 10=“worst possible pain”.

At 12 months, the patients were asked about changes in MSK, coping with pain, satisfaction with treatment and the use of healthcare services outside the trial: 1) How are your complaints now, compared to one year ago? 2) If you still have MSK, how

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do you cope with it now, compared to one year ago? 3) How has this project influenced a) your ability to take care of your own health, b) your ability to cope with complaints, c) your health in general, d) your physical fitness and e) your complaints? The answers were scored on a five-point Likert scale from “much better”=1 to “much worse”=5. Patient satisfaction with treatment on the project was assessed on a seven-point Likert scale from “very satisfied”=1 to “very dissatisfied”=7.

*Cause of the pain:* The study participants were asked about what they believed was the cause of the pain problem, with the possibility of choosing a specific cause (e.g., actual work, strain at home, injury, leisure activity, incorrect treatment, deformity of the body or just “don’t know”).

### 3.7 Statistics

In all three papers, a statistical threshold of  $p < 0.05$  was considered to be statistically significant. Precision was assessed using a 95% confidence interval (CI) and standard deviation (SD). The statistical analyses in Papers I-III were performed using SPSS versions 21 and 23 for Windows, IBM Corporation, Stata versions 11 and 12, and SAS statistical software version 9.2 (SAS Institute).

#### **Paper I**

Register data were used to define the work/social insurance status in each calendar month after inclusion on the trial. The register data provided follow-up information on every participant in both treatment groups for the 24-month follow-up, as well as information on the GP diagnosis that led to sick certification at baseline.

Due to the inclusion criteria, all participants were employed and on sickness benefits at baseline. We defined that, if more than 50% of the working days in a given calendar month were spent on FSL, the status for that month was given as “out of work” (OOW). If more than 50% of the working days in a given calendar month were spent on PSL, the status for that month was given as p-RTW. If no benefits were provided in more than 50% of the working days, the status for that month was f-

RTW. From these data, we constructed a file where each study participant had one of three possible statuses each month for the 24-month follow-up: OOW, p-RTW or f-RTW. Then the monthly proportions of p-RTW and f-RTW were divided by groups and presented graphically on a monthly basis for the 24-month follow-up.

Additionally, we performed multinomial logistic analysis to explore the relative risk (RR) ratios for p-RTW and f-RTW between the groups every month. The analyses adhered to the intention-to-treat principle including all randomized patients irrespective of compliance.

## **Paper II**

In this paper, analyses for predictors of s-RTW on an individual level were performed. s-RTW was defined as increased work participation, compared to baseline, in three consecutive months. National register data were used to define the work/social insurance status for every study participant at baseline and in each calendar month after inclusion on the trial. In every month of the follow-up period, each participant was either out of work, partly working or fully working. At baseline, due to inclusion criteria, they were either out of work or partly working. The status of every follow-up month was compared with the status in the baseline month for every participant, with a “success month” defined as a month with increased work participation compared to the baseline, while a “non-success month” was a month with unchanged or decreased work participation compared to the baseline. If a person had three consecutive “success month” statuses, it was defined as an s-RTW, with the first out of the three months defined as the RTW month.

Baseline questionnaire data were used in the analyses. The interventions were included as study factors as we hypothesized that the MI and the BI could have different effects on work outcome. The odds of s-RTW within three and 12 months, respectively, were analysed using binary multiple logistic regression models, including the following a priori selected, independent variables: 1) The interventions (MI=1, BI=0) and the following variables from baseline questionnaires, dichotomized by splitting the median score (above median score=1, median score and below=0): 2)

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SHCs (SHC total scale), 3) anxiety and depression sum score (HADS), 4) neuroticism (EPQ-N), 5) acceptance of chronic pain (CPAQ), 6) muscular pain (SHC musculoskeletal subscale), 7) support at work and burden of work (Karasek and Theorell). Furthermore, the following variables, which were dichotomized to either yes or no by the given answers, were also included in the model: 8) physically demanding work, 9) psychologically demanding work, 10) whether the study participant believed that work was the cause of the pain and 11) duration of sick leave by baseline (categorized into: 0-91; 92-153; 154-213; and 214-365 days). Cronbach's alpha was calculated for all scales.

For adjustment, the models also included sex and age (20-29; 30-39; 40-49; 50-60 years). Each predictor variable was assessed for interaction with the intervention in the models according to hierarchical elimination. The models' goodness of fit was tested by the Hosmer-Lemeshow test.

### **Paper III**

Changes in participant's scores on depression, anxiety, somatization (HADS and HSCL), function level (Norfunk) and health complaints (SHC) was evaluated within each group by paired samples t-tests comparing three- and 12-month follow-up scores with baseline values. The effect size for the change, i.e., Cohen's *d* for paired values, was assessed. A mixed between-within subjects analysis of variance, with one between the group factors (MI versus BI) and one within the subjects/repeated measures factor (baseline, three months, 12 months), was conducted to assess the participants' scores in relation to the clinical variables. The interaction effects (time by group) were calculated and, when significant, such interaction effects indicated different time courses for the two interventions. Interaction effects were followed up by t-tests for paired samples within each group. Cohen's *d* was calculated between baseline and the three-month follow-up and baseline and the 12-month follow-up using an online calculator (<http://easycalculation.com/statistics/effect-size.php>) based on this formula:  $d = (M_1 - M_2) / (\sqrt{(SD_1^2 + SD_2^2) / 2})$ . Differences in outcomes between the two interventions, in terms of scores for pain measured by the NRS (0-10), were analysed by a t-test for independent samples at three and 12 months. Differences in



outcomes, in terms of the use of health services, patient-evaluated health changes, coping, and satisfaction with treatment at 12 months, were assessed with  $\chi^2$  statistics or Fisher's exact test.

### **3.7.1 Register data**

Register data were used to define the work/social insurance status in each calendar month after inclusion on the trial. The social insurance register provides information about the start and stop dates for payments of sickness benefits, rehabilitation benefits, disability pensions and unemployment benefits. For payments of sickness benefits and disability pensions, we have information about the degree of disability and hence, indirectly, the degree of work participation. Only payments for absences exceeding 16 days are refunded by the national insurance system. Therefore, absences that last 16 days or less are not included in our data.

## **3.8 Ethical approval**

The study followed the Helsinki Declaration and was approved by the Norwegian Regional Ethics Committee in South-eastern Norway (REK 2009/1128) and by the Norwegian Social Science Data Services (ref. 12-4845-3). Participants gave their informed consent by signing the declaration of voluntarily participation before joining the study.

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## 4. Summary of results: overview of papers

The results are given as a summary of papers. All analyses are derived from the same study population of 284 individuals on sick leave with MSK and referred to a specialist outpatient clinic. After inclusion on the study, the patients were randomized to either the MI or the BI. The patients received questionnaires at baseline, and at three- and 12-month follow-ups. Follow-up on clinical data was set for 12 months, follow-up on registry data was set for 24 months. A flow chart for the study is available in Paper I.

### 4.1 Paper I

Randi Brendbekken, Hege R. Eriksen, Astrid Grasdahl, Anette Harris, Eli M. Hagen, Tone Tangen

#### **Return to work in patients with chronic musculoskeletal pain: multidisciplinary intervention versus brief intervention. A randomized clinical trial**

*Journal of Occupational Rehabilitation* (published online February 2016) 2017; 27:82-91

The aim of the first paper was to clarify whether the MI could improve RTW rates over the BI in patients on sick leave and referred to specialist healthcare due to MSK. RTW outcomes were analysed from register data.

We hypothesized that a comprehensive intervention focusing on psychosocial factors and work in addition to somatic complaints would lead to faster RTW than a shorter treatment focusing on somatic complaints alone in patients with MSK. We also hypothesized that the application of the ISIVET educational communication tool would improve patient education and engagement in the rehabilitation process, thereby improving RTW outcomes in the MI group.

Of the 534 patients screened for eligibility, 284 patients were included and randomized to MI (n=141) and BI (n=143). The mean duration of sick leave by inclusion was 147 days (SD=60.1). The register data received after the 24-month

follow-up of the last patient revealed that the study population by baseline constituted 51 different diagnoses prescribed by the GPs (Table 1), with the musculoskeletal group (L-group) representing 83.9%. Register data were analysed at group level and on a monthly basis. Data were differentiated into p-RTW and f-RTW and OOW by the 24-month follow-up. Patients could be either PSL or FSL by inclusion according to the inclusion criteria. The differentiation made it possible to analyse the RTW process in more detail.

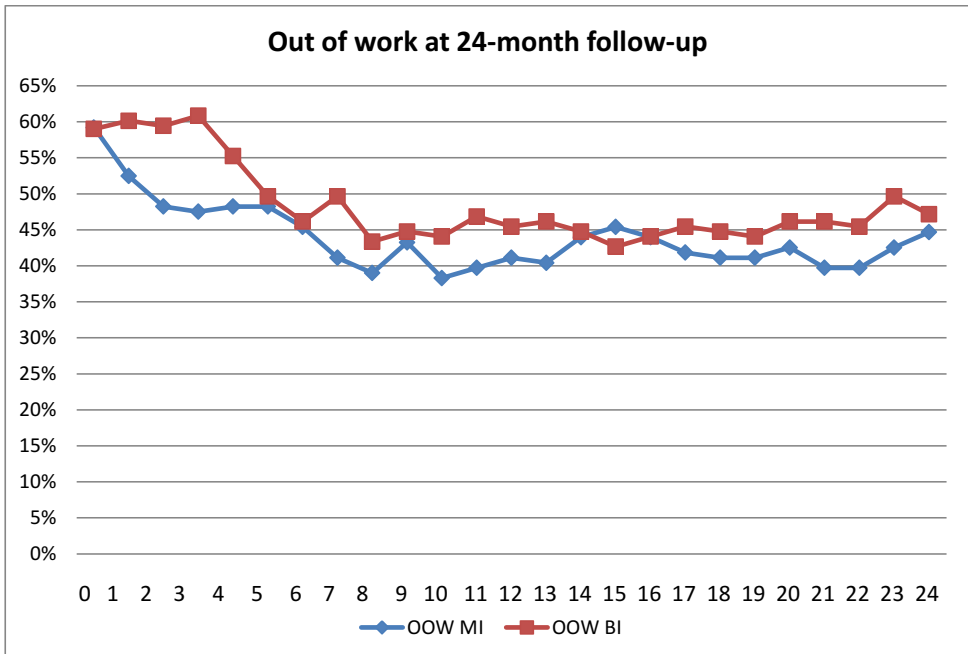
There was a higher probability of p-RTW in the MI group during the first months of follow-up. There were equal probabilities of f-RTW between groups during the 24-month follow-up. By 12 months, 44.7% in the MI group and 44.8% in the BI group were f-RTW. At 24 months, the corresponding numbers were 42.6% and 36.6%.

The results show that the MI to a limited degree speed up the RTW-process and the effect can be explained by the increased use of PSL in the MI group. However, the MI could not improve RTW over the BI by the 12- and 24-month follow-up.

Fig. 5, which is not published in any of the papers, is added below to illustrate the drop in the OOW proportion of the MI group during the first months of the study.

**Table 1.** Sick leave diagnosis prescribed by GPs at baseline derived from registry data

Diagnosis	ICPC code	n	valid %
LBP	L02/L03/L84/L86	109	38.4
Neck pain	L01/L83	34	12.0
Widespread pain, Fibromyalgia	L18	29	10.2
Shoulder pain	L08/L92	22	7.8
Other musculoskeletal diagnosis	L9, L11, L12, L13, L15, L17, L19, L20, L29, L80, L81, L87, L89, L90, L93, L94, L99	44	15.5
Psychiatric	P01, P02, P06, P29, P76, P81	14	4.9
Non-specific	A01, A04, A11, A80, A82	12	4.2
Neurologic	N01, N05, N29, N79, N80	11	3.9
Other diagnoses	B80, B81, D01, F29, K99, R80, S060, S78, T92	9	3.2



**Fig. 5** Descriptive statistics on OOW proportions for the MI group and the BI group (BI) for each of the 24-month follow-ups

The data on PSL and FSL in this paper were analysed on a monthly, group-level basis, meaning we had no opportunity to know whether the same participants were on PSL, on FSL or OOW from one month to another. Nor did we have any information on whom might benefit from which intervention. To meet these limitations, we planned to analyse for predictors and to implement an RTW definition of sustainable work participation.

## 4.2 Paper II

Randi Brendbekken, Arild Vaktskjold, Anette Harris, Tone Tangen

### **Predictors of return to work in patients on sick leave with chronic musculoskeletal pain**

*Journal of Rehabilitation Medicine*, 2018;50(2):193-199.

The aim of this paper was to identify individual baseline predictors for an s-RTW, while including the MI and BI as study factors to see if interventions had any predictive effect on work outcomes. Additional baseline independent study factors were: physical and psychological symptoms, including pain, anxiety/depression and beliefs, in addition to work-related factors and duration of sick leave by inclusion. s-RTW was defined as increased work participation in three consecutive months with the first month as the RTW month. This definition also valued any increase in work participation, which is in line with Norwegian official health policy. Sustainability could be regarded as an outcome quality control and also be helpful in answering the second hypothesis.

The odds ratio (OR) of s-RTW was analysed at three- and 12-month follow-ups using a binary multiple logistic regression model. s-RTW was predicted by the MI at the three-month follow-up (adjusted OR=2.69, 95% CI=1.1-6.8) but not at 12 months (OR=1.13, 95% CI=0.7-1.9). The subgroup reporting *low support at work* benefited more from the MI than the BI (OR=4.2, 95% CI=1.2-14.2) and was the only study factor interacting significantly with the intervention. s-RTW at three months was predicted in the group who believed *work was the cause of the pain* irrespective of the treatment group (OR=2.17, 95% CI=1.1-4.3), while anxiety/depression was a negative predictor for s-RTW (OR=0.45, 95% CI=0.20-0.98). At the 12-month follow-up, the only factor predicting s-RTW was the duration of sick leave by baseline, which was a risk factor (OR=0.63, 95% CI=0.05-0.08).

The results show that patients who receive an MI are more prone to increase their work participation *sustainably* during the first months of the follow-up compared to the effect of a BI. Subgroup analyses revealed only one group to have benefited more from MI, but the OR had a broad CI and the outcome should be interpreted with caution. Generally, few predictors of s-RTW were identified in a fully adjusted model. Symptom burden or cognitive assessment of pain or neuroticism did not predict s-RTW, but anxiety and depressive symptoms and length of sick leave were identified as risk factors for s-RTW. Patients who believe work is the cause of the pain benefited from both the MI and the BI, possibly indicating that the interventions

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are equally effective in treating fear avoidance for work. No other work-related factor predicted RTW.

The major finding that MI predicts s-RTW at three but not at 12 months should be assessed, together with the development of other secondary outcomes, such as health and coping, in order to proceed further in the direction of understanding this finding.

### 4.3 Paper III

Randi Brendbekken, Anette Harris, Holger Ursin, Hege R. Eriksen, Tone Tangen  
**Multidisciplinary intervention in patients with musculoskeletal pain: a randomized clinical trial**

*International Journal of Behavioral Medicine* (published online April 2015)  
2016; 23:1-11

The aim of this paper was to compare and evaluate the development in patient health, functional ability and coping between an MI and a BI treatment group among patients on sick leave with MSK during the 12-month follow-up.

We hypothesized that a more comprehensive intervention, which focused on psychosocial and work-related factors, in addition to somatic complaints, would help to identify factors relevant to the health problem and the sick leave both to the patient and to the treatment team. We also hypothesized that the application of the ISIVET would improve outcomes through enhanced patient education and involvement in treatment decisions, thereby improving adherence to the rehabilitation plan.

The return of the questionnaires dropped from 98% in both groups at baseline to 79% in the MI and 63% in the BI at three months and subsequently 60% and 61% at 12 months. Treatment drop-out was low in both groups.

By the 12-month follow-up stage, the groups showed almost equal improvement in physical symptoms, psychological symptoms and physical functioning with mainly medium-sized Cohen's *d*. By the three-month follow-up stage, the improvements were stronger in the MI group for some of the clinical variables. The recovery

process was analysed and significant interaction effects were found in the case of anxiety, depression, somatization and functional ability, indicating different *time courses* in improvements in these outcomes. There were no differences in improvements in SHCs and pain between groups. The MI group reported significantly less use of GPs in the last three months compared to the BI group, both at three and 12 months, while the groups made equal use of other health services, such as physiotherapists and chiropractors. At 12 months, the MI group reported a significantly better perceived ability to cope with health problems, better physical fitness and higher satisfaction with treatment compared to the BI group.

The differences between outcomes in the treatment groups follow a similar pattern in this RCT. The differences are mainly limited to the first months of follow-up, with the MI group seeming to have stronger effect from the intervention, but the effect sizes are small to modest. At 12 months, the groups are equalized with the exception of some outcomes in the MI group, which we could relate to coping.

## 5. Discussion

The main purpose in this PhD project was to investigate whether an MI can improve RTW rates more than a BI within two years among patients on sick leave with MSK. The second aim was to identify predictors for s-RTW after three and 12 months, as well as compare patient health, functional ability and coping between groups at the 12-month follow-up.

The MI improved RTW rates compared to the BI within 12 months. The effect was small, temporary and explained by increased use of PSL during the first seven months in the MI group. The effect represented a sustainable increase in work participation. There was no difference between groups for RTW at 12 and 24 months.

The MI group improved faster than the BI group in terms of psychological health complaints and physical functioning. Improvements in pain and SHCs followed the same course in the two groups. At 12 months, there were no differences between the groups in terms of health complaints or physical functioning, but the MI group reported less use of GPs, better physical fitness, higher perceived coping with health complaints and higher satisfaction with treatment, compared to the BI group.

Both interventions were educational, based on the NIM and thus aimed at reducing fear avoidance in general. Both applied clinical guidelines as primary treatment principles, although, in the MI group, the treatment plans were individualized according to the patient's preferences, with the intervention more comprehensive and focusing on both psychosocial and work factors.

### 5.1 Interpretation of main findings

The three main research questions will be discussed in sections in accordance with the overall aims.



### **5.1.1 Return to work**

Three main findings warrant discussion: 1) The increased use of PSL in the MI group during the first seven months; 2) the lack of difference in RTW rates between treatment groups at 12 and 24 months; 3) the low RTW rates in general.

#### *Increased use of partial sick leave*

A review of effective RTW interventions for patients sick-listed with chronic MSK found that 32% of the identified high-quality treatments resulted in a faster RTW compared to control treatments (164). The effective treatment programmes were characterized as multifaceted with components including education, information, physical exercise, and psychological, social and work interventions. This treatment profile was similar to the MI in our study and our results on early PSL are in line with these findings. In one study, RTW was faster when physical exercise was combined with job-related interventions (112). Physical exercise was an important part of the rehabilitation plan in both the BI and the MI, while job evaluations were only part of the MI.

Proactive RTW communication was found to hasten RTW (165). The MI team actively recommended RTW in spite of health problems and made an effort to explain why. The star plot area in the ISIVET visualized the value of the work, supporting proactive RTW communication. Dasinger and colleagues reported similar effects, especially in the acute phase of sick leave (166), while, in later phases, work environmental factors and lack of supervisor support seemed to override the effect of HCPs' proactivity on RTW. The positive effect of proactive RTW communication has also been identified in studies of chronic pain patients (167). In the BI, the patients were also encouraged to return to normal activities, including work, as soon as possible, but on a general basis and without a closer evaluation of the actual work conditions. The communication about potential benefits on health of work participation, according to the CATS, may have influenced the patients' outcome expectancies about work participation in a positive way (150). This may also explain the increased use of PSL in the MI group.

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The *decision* whether to remain on sick leave or return to work is largely influenced by the patient's preferences (90, 168, 169). It is reasonable to assume that the actual reduction in sick leave was initiated by the patient or at least in accordance with the patient's preferences. The MI aimed at validating the patient's perspective of both work and life situations in order to find common ground in terms of understanding the patient's situation. The MI also aimed at empowering the patients to become active participants in their own care. These strategies are in line with a *patient-centred approach*, which are beneficial in terms of the trustworthiness in therapists among the patients and outcomes of therapy (170, 171).

Changes in illness perception could also explain the increased use of PSL. Illness perception refers to the subjective experience of health complaints and could be influenced by several factors, including *knowledge* (15). Knowledge influences attitudes and beliefs. The biopsychosocial approach and the ISIVET applied in the MI could have contributed to an increase in the knowledge and understanding of complexity and causal relationships of long-lasting MSK. The understanding of the illness could in itself be therapeutic, particularly if the patient suffers from pain and fear of serious disease (172). Knowledge and changes in illness perception may also change the patient's outcome expectancies and in turn their health (173).

The rehabilitation plan was also individualized according to patients' preferences, thus increasing the probability of patient adherence to the plan and positive outcomes (171). This may have led to a larger improvement in symptoms in the MI group and the patients therefore could have regarded themselves as more able to work.

A recent Cochrane review on workplace interventions for sick leave concluded that workplace interventions reduce the time to RTW in workers with MSK (174). Work issues were evaluated in the MI and advice and activities to improve the situation were part of the discussions. In a Danish study, a multidisciplinary intervention led to a faster RTW compared to the effects of a briefer intervention for a subgroup of patients with low job satisfaction (175). Due to the more comprehensive approach in the MI, disclosing workplace issues was higher in the MI than in the BI.

RTW interventions involving workplaces might actively increase RTW rates, such as in the Sherbrook model, although the results have not been reproduced in later settings (112, 176, 177). Advice and activities to improve the work situation were part of the MI, but it is questionable whether this can be regarded as *a workplace intervention*.

Some studies indicate that more complex patients benefit more from MDIs (178, 179). As our patients were mainly chronic pain patients, we should ask whether PSL and RTW rates could have been further improved if the MI had been extended. The duration of 5.5 hours with the patients is less than on many other MDI treatment programmes (180, 181). However, a review of effective RTW programmes for chronic MSK concluded that the number of contact hours and total treatment period could not explain differences in their effectiveness (164). RTW rates in our BI group were lower than in BI groups in other trials, indicating that our population may have been more difficult to help (96, 97, 180, 181).

#### *Low RTW rates*

At 12 months, the status of 45% in both the MI and the BI groups was f-RTW. After 24 months, the percentages were 43% in the MI group and 37% in the BI group. The RTW rates in both groups were lower compared to other trials. Bultmann et al. compared the effects of a multidisciplinary work intervention involving TAU for patients on sick leave with an MSD for four to 12 weeks and found a 78% (work intervention) and a 62% (TAU) RTW rate at the one-year follow-up stage (180). Moll et al. compared the effects of an MDI and a BI among patients on sick leave for four to 16 weeks with neck or shoulder pain and found a 59% (MDI) and a 58% (BI) RTW rate at one year (181). Jensen et al. compared an MDI and a BI for patients sick-listed with LBP and reported an RTW rate at one year of 71% (MDI) and 76% (BI) (182). Jensen defined RTW as the first four working weeks after inclusion with no social transfer payments. A recent Norwegian RCT in specialist healthcare compared a work-focused intervention with either an MDI or a BI, in which the RTW rates at one year was 70% (work intervention) and 75% (MDI/BI) in patients on sick leave with neck and back pain (183). The patients received the intervention in

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specialist healthcare and RTW was defined as the first five weeks without sickness benefits.

Differences in percentages of RTW rates in these studies compared to our study may be related to differences in the definition of RTW or the use of different statistical methods. The RTW rates in the aforementioned clinical trials were estimated with survival analyses (Kaplan-Meier) and regression analyses (184), where the outcome was an accumulated size and not a descriptive status at 12 months, as in our study (181-183). Other studies define RTW as cumulative sickness absence hours during follow-up (180). This way of reporting work activity gives a more precise picture of work disability during follow-up (185).

Compensation policy variables and labour market may also influence sick leave (77, 186, 187). The somewhat lower RTW rates in several Norwegian studies, compared to studies from other countries, could be due to the Norwegian welfare system where patients are granted full sickness compensation the first year of sick leave and about two thirds of sickness compensation for several years thereafter. A recent Norwegian multicentre study comparing the effects of a BI and BI + either: a) cognitive behavioural therapy b) seal oil or c) placebo oil in patients with LBP, reported f-RTW rates in groups between 47-56% at 12 months (156).

The generous Norwegian welfare system could leave us with weak incentives to RTW, particularly during the first year of sick leave. Earlier Norwegian trials have shown that chronic MSK patients over the years have multiple transitions between periods of longer periods of sick leave and partial or full employment, thereby avoiding permanent disability (188, 189). National unemployment rates may also influence RTW. In Norway, these have been low, between 3% and 4% since about 1997 (190). However, two former Norwegian RCTs comparing BIs with TAU achieved RTW rates of 68% and 70% in their BI groups at 12 months, which is far above our 45% (96, 97). However, the difference could be explained by different study populations as patients in these two studies were recruited by inviting all patients in the area who had been on sick leave for eight weeks for LBP in order to

participate in the trial. The patients who were included were randomized to either a BI in specialist healthcare or to continue seeing their GP. In our case, the study population was recruited from ordinary referrals to specialist healthcare. We found that, although 136 different GPs had referred patients to the trial, most of them only referred one or two patients. This indicates a highly selected population as MSK is a common reason for presenting to primary care where it constitutes up to one third of a GP's workload over the course of a year (4, 191, 192). By inclusion, the patients had been on sick leave for an average of 147 days (SD=60), indicating a group experiencing mainly chronic MSK. Long periods of sick leave are known predictors of poor outcomes concerning RTW (193, 194).

*Equal RTW rates in the BI and the MI group at the one- and two-year follow-up stage*

RTW rates were similar for the MI and the BI groups at the one- and two-year follow-ups. The results are in line with other studies about patients on sick leave with MSK where the BI and the MDI performed equally well in terms of RTW (156, 181, 182). The results are also in line with a Norwegian trial comparing the effects of a work-focused MDI with a BI or a conventional MDI in specialist health (183) where the patients were on sick leave for an average of 140 days. The results are however in contrast with those reported by Bultmann and colleagues who found significant improvements in RTW status at the one-year stage of a tailored work rehabilitation programme, compared to the effects of conventional care management (180).

More active workplace involvement as part of an MDI has been found to be more effective than control interventions regarding RTW in patients with primarily acute or subacute LBP (111, 112). Lambeek et al. included cLBP patients and concluded that an MDI was more effective than TAU (114). In a Cochrane review on workplace interventions for preventing work disability, the authors suggested that they were effective in reducing sickness absence among workers with MSK (195). A workplace intervention was defined by “changes to the workplace or equipment, changes in work design and organisation, changes in working conditions or work environment and occupational management with active stakeholder involvement of (at least) the

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worker and the employer”. The review was updated in 2015, with the authors then concluding that a workplace intervention reduced time to the first RTW in workers on sick leave with MSK, compared to the effect of usual care, but that RTW rates in the long term are not affected (174). The MI in our study had a particular but also limited focus on the work situation and was probably not classifiable as a multidisciplinary work intervention, although the work situation was evaluated and discussed, with initiatives directed at the work situation frequently part of the rehabilitation plan.

Other trials have revealed subgroups benefiting from either a BI or an MDI in terms of RTW. Women have been found to benefit more from an MDI compared with a BI and/or TAU in patients with chronic widespread pain (CWP) (178). Another trial on cLBP and RTW found BIs to be more beneficial than MDIs for men (196). In our paper on predictors, gender did not predict s-RTW, either at three or 12 months (197). Jensen et al. found in the course of subgroup analyses that MDIs were beneficial to a vulnerable group of patients at risk of losing their job (182).

It seems difficult to identify efficient RTW interventions in studies of patients with chronic MSK mainly due to the heterogeneity of the patient group. A recent Cochrane review concluded that MDIs were more efficient than physical treatment but not TAU for RTW in patients with cLBP (108). Management of chronic MSK may require alternative approaches and subgroup knowledge to tailor interventions according to a risk profile. In our study, about 10% were diagnosed with fibromyalgia, 12% were diagnosed with neck pain and 7.8% with shoulder pain. This could explain the relatively low RTW results. The Cochrane review also stated that there is little scientific evidence for the effect of MDIs on CWP and fibromyalgia (23). Patients with chronic upper-extremity MSK have a higher degree of sick leave than LBP sufferers (198, 199).

### **5.1.2 Predictors of sustainable return to work**

s-RTW on an individual level is defined as increased work participation in three consecutive months, compared to baseline. The process of RTW is complex and may involve multiple transitions between working, being partly or being fully out of work

after work rehabilitation (188, 189). It would be valuable to discover whether increased work participation is limited to four weeks or is more sustainable. Analyses revealed that MI was the strongest predictor for s-RTW at three months.

Earlier studies on predictors for outcomes of MSK focused more on predictors for prolonged sick leave or disability, rather than on factors predicting RTW (73, 200). Jensen and co-workers found seven factors to predict unsuccessful RTW in patients with LBP within one year, among them, pain score, bodily distress, low expectation of RTW, and blaming work for the pain (200). A review of predictors of sickness absence in patients with cLBP concluded that, due to the heterogeneity of studies, no core set of predictors could be established (73). Dekkers-Sanchez and co-workers explored promoting factors for sustained RTW through interviews with vocational rehabilitation professionals and concluded by recommending combined, tailor-made interventions in a holistic approach involving the employee and their environment in order to address the multicausality of work disability and maximize RTW outcomes (201). This latter recommendation complements elements of the MI in our study and could help to explain the finding that the MI predicted s-RTW at three months. Another explanation could be that the MI changed patients' *expectancies* about RTW (150). In a recent publication on predictors of RTW in patients with long-lasting LBP, high expectancies of RTW was a strong predictor for RTW (202). The comprehensive evaluation of work factors, combined with the communication of the value of work, could have influenced the response outcome expectancy concerning work participation as described in the CATS (150). If work actually turned out to be a beneficial next step, positive feedback could have dampened the stress response and facilitated a continuation of work participation.

In the present study, a subgroup of patients who experienced low support at work benefited more from the MI than the BI in terms of RTW. The OR had a wide confidence interval so the finding should be interpreted with caution. A review of work-related risk factors for LBP reported strong evidence for low social support in the workplace being a risk factor for back pain (203). Dissatisfaction with support at work should be visualized in the ISIVET and discussed with the patient. The

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identification of this subgroup and the handling of this finding in the ISIVET could explain why the MI was beneficial for RTW in this subgroup. Our finding could be related to another study on RTW for patients with MSK, which found that a subgroup of patients who were vulnerable to the loss of work benefited more from an MDI than a BI (204).

Multiple pain sites, higher levels of pain and widespread pain are found to predict poor work outcomes after sick leave (205, 206). Levels of pain did not predict outcome in our population, but *the belief that work was the cause of the pain* was a predictor for s-RTW at three months. This belief could be related to fear avoidance beliefs for work (FABW), which are found to be more prevalent in chronic pain than acute pain and to be a risk factor for non-RTW (200, 207-209). A reduction in FAB is found to predict RTW (210). Our finding could be related to such a change in FABW, possibly through the educative approach based on NIM in both interventions (96, 100).

The length of sick leave by baseline was a risk factor for non-RTW at 12 months, and is thus a well-known predictor (36, 37, 211, 212).

We identified only three predictors of s-RTW in our study. This is in line with a review evaluating risk and prognostic factors of MSK classified into ICF dimensions (213). The authors found strong evidence of poor job satisfaction as a risk factor for LBP, and having fear avoidance beliefs and meagre support at work as a risk factor for persistence of LBP; but, first and foremost, they found high evidence that a number of factors was not prognostic. Laisne et al. recently reviewed biopsychosocial predictors of prognosis for patients with MSK (69). They concluded that it remains difficult to identify a clear set of prognostic factors in MSK, although outcomes seem to be determined more by psychosocial factors than biomedical factors. The authors recommend a biopsychosocial approach from the onset of health complaints and call for more homogenous models and measurement methods.



### 5.1.3 Effects on health and coping

The results of this trial followed the same pattern in terms of primary and secondary outcomes. At three months, there was a larger improvement in health complaints, physical functioning, somatization, anxiety and depression in the MI group compared to the BI group, but the effect sizes were small to medium. By 12 months, there were no differences between the treatments groups concerning these parameters. However, the MI group reported lower use of GPs, better physical fitness, higher perceived coping with health complaints and higher satisfaction with treatment compared to the BI group.

#### *Health effects*

The faster improvements in health in the MI group could be secondary to increased work participation, as work is a determinant of good health (30). However, the reverse causality, that health improvements causes increased work participation, cannot be excluded based on these data. Studies attempting to address the effects of PSL versus FSL on health show inconsistent results (116, 214, 215). Sieurin and co-workers found that patients on PSL believed that part-time work was good for their health (216). In 2013, Shiri and co-workers assessed the health effects of early PLS in an RCT comparing PSL with FSL, and concluded that PSL improved self-related general health and health-related quality of life in the early stage of work disability (217). Additionally, PSL did not aggravate pain-related symptoms or functional ability.

Another possible explanation for our findings is that a comprehensive approach is found to be more beneficial for clinical outcomes than a less comprehensive approach for chronic pain patients (107, 108, 218). Reme et al. found no differences in RTW between groups at one year, but the most comprehensive intervention was superior to the BI on general health and patient satisfaction with treatment for patients on sick leave with MSK (156). However, Moll et al. found that an MDI performed equally well with a BI on health outcomes in patients on sick leave with MSK (181).

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MSK *improvements* were similar in the BI and the MI in our study both at three- and 12-month follow-ups. This is in line with other studies on RTW interventions for MSK, where effect sizes on health outcomes are equal after brief versus more comprehensive interventions at the one-year follow-up (156, 182, 210). *The work disability paradigm* claims that cLBP or MSK is not only a clinical pain problem, but also a problem involving work and psychosocial factors (82). RTW programmes for chronic MSK should therefore focus more on regaining normal activity *in spite of pain problems* than on reducing symptoms (20, 30, 82, 219). One might question if the differences in time course for some clinical outcomes in our study are clinically relevant as effect sizes are mainly small. However, considering that chronic pain is a complex condition with a high degree of co-morbidity and somatization, even small changes could be of clinical relevance.

### *Coping*

Maladaptive pain coping behaviour was identified as a strong predictor of persistent disabling LBP in a systematic review (220). The patients in the MI group reported higher perceived coping with health problems at the one-year follow-up when they were asked to evaluate their coping abilities. They also reported less use of GPs at both three- and 12-month follow-ups, which could also be a sign of improved coping.

A sense of coping could be due to positive outcome expectancy (150). It may also relate to actual coping *experiences* and perceived self-efficacy. Bandura and his co-workers found that people's behaviour is strongly influenced by their confidence in the ability to perform certain tasks (221). Given that the patients in our trial constituted a selection of mainly chronic pain patients referred from primary care, we could assume that attempts were made to rehabilitate them in different ways in primary care without success. This could leave us with a sample with a history of experiences of helplessness and hopelessness related to health problems and work participation (150). As the rehabilitation plan was tailor-made and agreed in cooperation with the patient, it could have strengthened both the outcome expectancy and the confidence in ability at the follow-up stage (222). Interventions practising SDM have been found to be more beneficial in terms of health outcomes and coping

in the case of fibromyalgia patients (223). Furthermore, patients who are engaged in decision-making are generally more motivated towards making lifestyle changes and thus their outcomes are better (224). When the patient adhered to the rehabilitation plan, it may have provided the patient with a strengthened sense of self-efficacy and positive coping expectancies. Improved expectancies about coping may also influence lifestyle choices in a positive direction (225).

If the intervention succeeds in explaining and reassuring the patient about their medical state, fear avoidance behaviours may be reduced. This could further promote change in behaviour and the sense of coping, as fear avoidance beliefs are common obstacles to rehabilitation in pain patients (209).

However, effective communication is a prerequisite for a number of these effects to occur. Communication in therapy influences outcome and coping (226, 227). Communication in therapy strongly influences therapeutic relations, which again influence outcomes (228). In a study on chronic pain patients and how the patient-physician relationship could promote the resilience process, three main themes were identified: the doctor providing psychological support, the doctor promoting patients' health literacy related to chronic pain and its treatment, and empowering patients to find the right treatment (229). These findings correspond more with elements in the MI than the BI. The MI with the ISIVET represents a patient-centred approach in the frame of the biopsychosocial understanding of illness, while the BI primarily focuses on the individual. The ISIVET sought to individualize treatment due to patient preferences and facilitate education about the problem area. The patients were offered an opportunity to participate in their care in ways that enhance partnership and understanding. The MI group also reported high satisfaction with treatment. This could indicate that more comprehensive interventions are more in line with the needs and expectations of patients with chronic MSK.

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## 5.2 Strengths and limitations

The RCT design is a major strength of this study. The randomization was concealed, computer-generated and based on age and gender. This guaranteed equally sized groups. A research assistant, who was not involved in the treatment, was informed about treatment allocation for each patient. The blinding of treatment is recommended to prevent bias, blinding either the patients or the therapists in this study was not possible. The low loss to follow-up on treatment in both groups, indicate the interventions are feasible in a clinical setting. All included patients were analysed on work outcomes as intention-to-treat, regardless of drop-out of treatment. Among other strengths of this study are the large sample sizes, the long follow-up time for work outcomes, and the use of register data for work outcomes and validated questionnaires on secondary outcomes. Register data gave access to complete information on sickness benefits for every participant at every month of follow-up. These types of longitudinal data on work outcomes could be particularly useful when studying a population with MSK, as they give access to fluctuations in sick leave over time (230) as workers with chronic MSK are at risk of recurrent sick leave (231).

The patients in the trial were selected from ordinary referrals to the outpatient clinic and rather broad inclusion criteria were applied (referred due to MSK and sick-listed for one to 12 months). No extra effort was made to recruit patients. This suggests that the study population resembles patients in a specialist healthcare outpatient clinic. However, only 284 (53%) of the 534 patients who were expected to be eligible due to inclusion/exclusion criteria were included and randomized. Of these, 107 were excluded due to not meeting criteria, while 100 refused to participate. Another 43 could not be reached by telephone, which may also have been a sign of declining. The relatively large number of patients declining to participate could limit the external validity of the study as the recruited population typically differs from the population not recruited in terms of age, sex, severity of disease, education and social class (232). It might have been interesting to know the reason why patients declined to participate, but we have no data to analyse for this issue. However, the number of

eligible patients not invited to participate or who decline to participate in RCTs is estimated to be between 20% and 80% (232). Our analyses revealed that the study population (n=284) was referred by 136 different GPs, with most GPs only referring one or two patients; only a few referred more than four patients. This indicates the population was highly selected as we know that those with MSK are among the most prevalent patients in GPs' practices (4, 10). The referred patients are presumably those who are difficult to help or to diagnose in primary care.

External validity could have been improved if we had performed a multicentre study instead of a single-centre study (233).

We cannot exclude a Hawthorne effect (a placebo/nocebo effect) on both the MI and the BI. Such effects can hamper external validity. However, both treatments were performed in specialist healthcare and both were comprehensive, compared to most other regular treatments in healthcare in Norway. We may therefore assume that nocebo effects were minimized. Besides, the patients were unaware of any details about the intervention to which they were not allocated.

The treatment teams were separated, reducing the risk of mixing between the two interventions. Audio- or videotaping was not performed, limiting the possibility to evaluate the treatment teams' adherence to the manual. The ISIVET was a new tool, and the MI teams practised regular meetings to ensure equal practice of the method. The BI method was well known to the therapists on the BI teams. One limitation was the participation of less experienced and a greater number of therapists on the MI teams compared to the BI teams. The first author (RB) had developed the first draft of the ISIVET, but the final version of the tool was developed at the DPMR during the planning of the study. RB participated in the study and treated 29 patients as part of an MI team. However, outcomes were not based on ISIVET evaluation scores, but on scores from the questionnaires and national register data, thus reducing the possibility of bias.

Loss to follow-up on questionnaires can also produce attrition bias, which may influence both internal and external validity (234). The return rate of the

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questionnaires declined to 79% (MI) and 66% (BI) at three months, and 60% (MI) and 61% (BI) at 12 months, reducing the validity of data in secondary outcomes in Paper III. This did not affect the predictor analyses in Paper II as we used baseline data where the response rate was close to 100% in both groups. There were no significant differences in baseline scores between non-returners and returners of questionnaires at 12 months except from the HSCL depression score, which was significantly lower among the non-returners (mean=1.47, SD=0.46) compared to the returners (mean=1.60, SD=0.55). This might indicate that the non-returners had fewer mental health complaints compared to the returners, which could have influenced the outcomes in Paper III.

A very homogenous study population could be good for the internal validity, but often hamper the external validity of a study. Clinical trials are often explained as either explanatory or pragmatic (235). Based on the setting of this trial, the broad inclusion criteria, the heterogeneous patient population and the individualized rehabilitation plan, we consider this trial to be a pragmatic trial. Pragmatic trials are designed to provide estimates of treatment effects that are generalizable to clinical practice (235). Participants may have been receiving other healthcare during the study and patients in the treatment groups may not have received the exact same treatment as treatment were tailored to their needs. The 51 different diagnoses of the present trial population indicate a heterogeneous population, which could have increased external validity. It may also indicate a population with a high degree of co-morbidity, increasing the possibility that other health problems than MSK were a barrier to work participation. Co-morbidity in patients with MSK could decrease RTW rates (236). The exclusion of individuals with poor Norwegian skills hampers the external validity. We might expect results in our trial to be transferable to patients with chronic MSK who are on long-time sick leave and have been referred to specialist healthcare. Transferability might be limited by context, such as the welfare system, as the generous Norwegian welfare model with its sickness benefits and regulations, as well as dismissal protection, could act as a placebo in relation to RTW, at least for the first year of sick leave. Studies from other countries with a less

generous welfare system or dismissal regulations report higher RTW rates (111, 180, 204, 237).

At the time of planning our study, reviews recommended MDIs for the management of complex, chronic non-malignant pain (107); but, for RTW outcomes, recommendations of MDIs were inconsistent, although both MDIs and BIs were reported to be superior to TAU (23, 109, 164, 238). Brox et al. recommended, in a review, delivering brief education interventions to cLBP patients to increase RTW; however, the control group received TAU rather than another active treatment in specialist health (98, 239).

We could question whether the two interventions in our trial were too similar to expect a main difference in outcome. However, the MI put considerably more weight on patient education and involvement in the process of working out a rehabilitation plan. This might have influenced the patients' outcome expectancies and be a major explanation of the differences in outcomes between treatment groups, albeit on a small scale.

### **5.2.1 Statistical considerations**

This trial applied validated questionnaires, which were sent to the study participants by post to be filled out at home. The questionnaires assessed sociodemographic, work- and health-related factors. The data on work participation were provided by register data. This assessment allowed us to analyse the interaction between work, health and demographic factors. Although a few more individuals dropped out of treatment in the BI by the two-week follow-up stage (15 versus 4 in MI), the risk of attrition bias was low.

The main outcome was RTW by three and 12 months, although we had data for 24 months. We differentiated RTW into f-RTW and p-RTW and OOW on a monthly basis for each individual. Another Norwegian multicentre study also differentiated between f-RTW and p-RTW on a monthly basis and defined increase in work participation, compared to baseline, as a success criterion for RTW (156). It did not

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call for three consecutive months with increased work participation. Other studies have defined RTW as retrieving no compensation from the NAV for a four-week period (111, 114, 182) or for a five-week period (183). A review of RTW definitions concluded that different definitions are highly correlated and give similar results in terms of prediction (240). The multinomial logistic analysis explored the RR ratios for p-RTW and f-RTW between groups every month for the 24 months of follow-up. Multiple analyses increased the risk of finding significant differences by chance. The month-by-month status concerning work participation was reported on a group level. We do not know whether individuals RTW at one month continued to stay at work in the subsequent months. Therefore, we defined s-RTW as increased work participation for three consecutive months compared to baseline, with the first month as the s-RTW month. Analyses revealed that, by the 12-month follow-up stage, 63.8% of the MI group and 58.7% of the BI group had achieved s-RTW at some point.

In the prognostic model in Paper II, the included variables were dichotomized, meaning that we could perform logistic regression. Dichotomization offers the possibility to include both nominal and ordinal data as independent variables in the regression model; conversely, this leads to a loss of information in the analyses, a loss of statistical power and a decreased probability of detecting an effect that is present, that is, a Type II error (241). The fact that we also dichotomized the outcome variable (s-RTW) fully amplifies this effect with a systematic loss of measurement information. When selecting study factors for the model, one should select formerly known predictors (242) and all potential prognostic factors should be included to avoid *omitted variable bias*, which may induce underfitting of the results and successively poor transportability to other populations (242, 243). For patients on long-term sick leave with MSK, there is no consensus about all of the possible predictive factors, so the selection of factors included in this trial was partly informed by clinical experience and partly by existing empirical data on prognosis for RTW after sick leave. The risk of including too many variables in the model is present, with an overfitting of results as a possible outcome (244). Neither do we know if all the important predictive variables were included. We did not adjust for education, which



we intended to, as we found that the answers on education in the questionnaires left us with the category labelled as “other” difficult to define.

The power calculations were performed for the main outcome, RTW, and should have been adequate for the calculations in Papers I and III. However, the number of patients was too small for subgroup analyses. Analyses of differences in outcome between different diagnostic groups or gender might have been relevant to perform. Dividing the population into four groups did not offer enough strength.

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## 6. Conclusions

This thesis summarizes the results from an RCT by comparing the outcomes of two interventions in specialist healthcare. The trial is pioneering work on the novel ISIVET tool, which is part of the MI.

The results show that MI and BI performed equally well in terms of RTW after one and two years in a population sick-listed with chronic MSK and referred to specialist healthcare. The less resource-demanding BI is therefore sufficient for RTW outcomes in the long run for this patient group. The MI did however speed up the RTW process through the increased use of PSL in the first months of follow-up, which could be valuable as an earlier RTW may reduce the risk of recurrent sick leave.

Patients who believe that *work causes the pain*, benefit from both interventions for RTW, and BI might be sufficient for this effect. Otherwise, we cannot conclude that either MI or BI is beneficial for any particular subgroup, although there is the possibility that patients experiencing *low support at work* benefited particularly from the MI for work outcomes.

The MI group reported faster improvements in mental complaints and physical functioning, equal improvements in pain, and stronger improvements in coping and physical fitness compared to the effects of the BI at 12 months. Together with the high satisfaction with treatment in the MI group, we can assume that there are elements in the MI that were more beneficial, compared to the BI, for this patient group. We suggest that these beneficial effects are related to improved communication in therapy, strengthening patient education and involvement in treatment decisions, with a subsequent positive influence on outcome expectancies. However, results so far do not advocate the use of a more resource-demanding intervention for all patients.

A large number of interventions exists to facilitate and hasten RTW after sickness absence due to MSK. The key question, "*What works and for whom?*", has not yet been answered, primarily due to the heterogeneity of studies. Finally, we must

consider the Norwegian welfare system to be a possible barrier to RTW, limiting the effects of any RTW intervention in a Norwegian setting.

## 7. Future research

In spite of the vast body of research on RTW interventions for patients with chronic MSK, we found no consensus on how to treat these patients or who might benefit more from what kind of approach. This trial included elements of established significance: a multidisciplinary biopsychosocial approach, patient education and a focus on work and on communication in therapy. A major impact of these elements on outcomes is however missing as the BI almost performs as well as the MI in the long run. There are possibly too many similarities between the methods to expect a significant difference. The overall RTW rates were low, indicating a study population that is difficult to rehabilitate for work. At this time, out of the two interventions, we can say that the BI seems sufficient for this group to reach their potential for improvement.

However, the MI demonstrated consistent results, but with small effect sizes, while the assessment revealed no obviously adverse effects and the patients reported high levels of satisfaction with treatment. As the field of knowledge involves a continuous search for active elements in the RTW process, we could consider further exploring the importance of communication in therapy for this patient group. In a future clinical trial, we suggest including a population on sick leave for up to six and not 12 months, as the length of sick leave predicts non-RTW. We could also combine the BI and the ISIVET and involve workplace stakeholders more actively as this was insufficient in this trial. The possibility of involving the GP in follow-up consultations, for example, at three and six months should also be considered. That would ensure a longer follow-up time for the rehabilitation plan and at a lower cost than in specialist healthcare. The involvement of the GP, who is the gatekeeper of the sickness certificate, could be beneficial for RTW outcomes. The GP also has direct communication with the NAV.

A control group could be allocated to a BI in specialist healthcare, while cost-benefit analyses should be part of any trial.

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## **9. Appendix**







# Return to Work in Patients with Chronic Musculoskeletal Pain: Multidisciplinary Intervention Versus Brief Intervention: A Randomized Clinical Trial

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**Abstract** *Objective:* This randomized clinical trial was performed to compare the effect of a new multidisciplinary intervention (MI) programme to a brief intervention (BI) programme on return to work (RTW), fully and partly, at a 12-month and 24-month follow-up in patients on long-term sick leave due to musculoskeletal pain. *Methods:* Patients (n = 284, mean age 41.3 years, 53.9 % women) who were sick-listed with musculoskeletal pain and referred to a specialist clinic in physical rehabilitation were randomized to MI (n = 141) or BI (n = 143). The MI included the use of a visual educational tool, which facilitated patient-therapist communication and self-management. The MI also applied one more profession, more therapist time and a comprehensive focus on the psychosocial factors, particularly the working conditions, compared to a BI. The main features of the latter are a thorough medical, educational examination, a brief cognitive assessment based on the non-injury model, and a recommendation to return to normal activity as soon as possible. *Results:* The number of patients with full-time RTW developed similarly in the two groups. The patients receiving MI had a higher probability

to partly RTW during the first 7 months of the follow-up compared to the BI-group. *Conclusions:* There were no differences between the groups on full-time RTW during the 24 months. However, the results indicate that MI hastens the return to work process in long-term sick leave through the increased use of partial sick leave.

*Trial Registration:* <http://www.clinicaltrials.gov> with the registration number NCT01346423.

**Keywords** Return to work · Sick leave · Chronic pain · Work disability · Coping

## Introduction

Musculoskeletal disorders are amongst the primary causes of work disability in Western societies and thereby represent enormous costs to the community in economic terms [1]. Painful disorders of the back, neck and upper limbs are the most frequently used diagnoses, with sickness absence, long-term incapacity for work and permanent disability as frequent consequences [2]. In Norway nearly half of all sickness absence is due to a musculoskeletal pain diagnosis with low back pain (LBP) as the largest single cause [3].

Health measures in Western societies are improving, but sickness benefits and disability claims due to musculoskeletal disorders increase [4]. Maintaining activity including work, in spite of muscular pain, is an important part of the recovery process as the opposite delays recovery [5–7]. The process of return to work (RTW) is therefore clearly a major concern in this patient group [8, 9].

The journey from acute muscle pain to long-term sickness, work absenteeism and disability has been widely investigated. Such studies have revealed that psychological and social factors, as well as somatic pathology, influence

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chronicity and disability [10]. When the duration of sickness-absence due to musculoskeletal pain exceeds 8 weeks, the prognosis worsens and the probability of RTW is reduced [8, 9, 11].

The process of RTW in chronic pain can be conceptualized as a complex human behaviour change, where the patient her/himself takes the final decision on RTW or not. However, the general practitioner (GP) is the main gatekeeper of access to sickness benefits [12]. The patient's own evaluation of their RTW is influenced by several personal, social, economic and work-related factors [13–15]. According to behaviour models, a change in behaviour is influenced by knowledge, attitudes, norms and self-efficacy [15, 16]. Banduras [17] Social Cognitive Theory posits a multifaceted causal structure to explain how human motivation, behaviour and well-being are regulated. In this model, self-efficacy beliefs, goals, outcome expectations and perceived environmental impediments and facilitators, all operate together as regulators of motivation and behaviour. This corresponds to the suggestion that interventions in sick-listed, chronic pain patients should not primarily focus on pathology but rather, on adapting to a complex situation which should include giving more attention to coping, self-management skills, environmental factors, workplace support and patient education [18]. This may enhance the patient's positive response outcome expectancies (coping). According to the Cognitive Activation Theory of Stress (CATS), such improvements will dampen the stress response, which, in the next step, might help patients towards a more constructive handling of complaints [19].

In general, the multidisciplinary approach (MDA) is accepted as a reasonable approach to treat chronic pain patients, as this should be regarded as multicausal [20–22]. In a recent Cochrane review, MDA was found to be favourable in decreasing pain and disability compared to usual care [23]. However, the effects on the RTW of multidisciplinary interventions for chronic muscular pain have been conflicting [7, 23, 24].

The majority of chronic musculoskeletal pain conditions including LBP, are characterized by the lack of objective, pathological findings although the patients present numerous additional subjective health complaints and experience reduced work ability [25]. The GP's assessment concerning sick leave must, to a great extent, rely on the patient's description of his/her condition in combination with the GP making an effort to understand the workplace environment and the actual work demands. Several studies have revealed a need to expand clinicians practice in this field, as many GP's do not readily engage in workplace discussions with the patient [26, 27]. There is growing evidence that occupational factors influence disability and that GP's proactive communication related to health and workplace

strategies is of major importance to RTW [28]. This calls for approaches where clinicians more actively assess occupational factors and health complaints together in the rehabilitation process.

In this study, we applied a multidisciplinary intervention (MI) that is tailored to highlight the complexity of long-term pain problems. The MI included an assessment of work, family situation, lifestyle, coping strategies and health problems. The MI applied a novel educational tool, the Interdisciplinary Structured Interview and a Visual Educational Tool (ISIVET), to establish an overall picture of the patient's situation through visualization. The underlying hypothesis was that this design could introduce a new cognitive approach to cope with health problems. This might strengthen the motivation of patients to go through with changes, thereby improving the actual coping and resuming work. The active control group received a brief intervention programme (BI), based on a non-injury model which has proved particularly effective on RTW in patients with sub-acute LBP [29–32]. The non-injury model is based on the understanding of the back or the body as a robust structure where pain should not necessarily be taken as a sign of injury caused by inappropriate behavior or any wrongdoing. This view is communicated to reduce pain-initiated fear and secondly to encourage natural movements and reduce tense and awkward movements which often come from the belief that pain is caused by an injury of the body and that care, protection and restrictions are mandatory which comply with the injury-model.

## Objectives

The objective of the study was to test if a MI is more effective than a BI on RTW in patients sick-listed due to musculoskeletal pain. We hypothesized that the MI would be superior to BI in increasing RTW over a period of a 24-month follow-up.

## Materials and Methods

### Study Design, Recruitment and Participants

This study was a randomized clinical trial which took place at two different outpatient clinics at the Department of Physical Medicine and Rehabilitation (DPMR), Inlandet Hospital Trust, Norway, from 2011 to 2013. All of the patients from two different counties in the south-eastern part of Norway, sick-listed for musculoskeletal pain and referred to the DPMR, were considered for participation. The study followed the CONSORT statement for reporting of randomized trials.

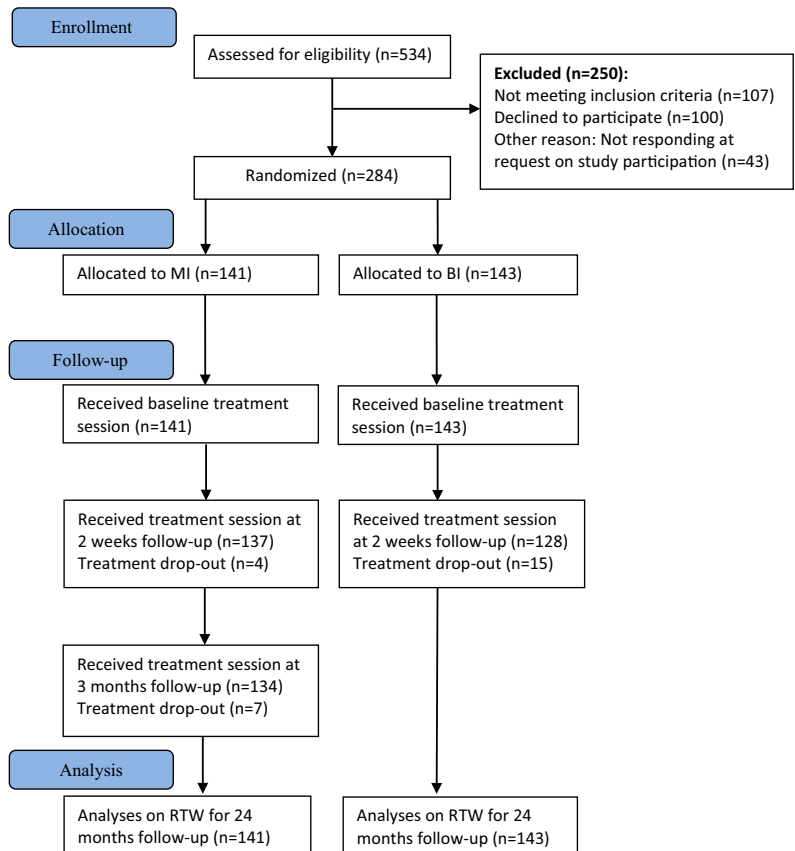
The inclusion criteria were: aged between 20 and 60 years, a sick leave degree between 50 and 100 % due to musculoskeletal pain and for <12 months, and at least 50 % employment contract. The exclusion criteria were: pregnancy, current cancer, osteoporosis, recent physical trauma/injury, serious mental illness, rheumatic inflammatory diseases, not capable of understanding and speaking Norwegian, or being involved in an on-going health insurance claim.

A total of 534 patients were screened for eligibility, whereby 250 were found to not be eligible for different reasons (Fig. 1). This study included 284 patients referred from 136 different GPs. These patients were randomized to either MI (n = 141) or BI (n = 143). The two interventions were performed by different teams and no clinician working in the MI-team ever worked in the BI-team. The time from inclusion/randomization to baseline assessment at the clinics was between one and 2 weeks.

**Context**

All lawful residents of Norway are included in the Norwegian public insurance system. This provides health service benefits and pensions for all members of the National Insurance Scheme, administered by the Norwegian Welfare and Labour Administration (NAV). When a worker, due to a medically acknowledged disease, is sick-listed by his/her GP, the workers’ compensation programme, which is administered by NAV, provides 100 % coverage for lost income from day one until the person can work again, up to 52 weeks. The employer covers the first 16 days. After 1 year, the NAV covers the long-term rehabilitation benefits or disability pension, providing approximately 66 % of the patient’s former income. These benefits can also be combined with work if the disability constitutes a minimum of 50 %.

**Fig. 1** Flowchart of participation in treatment sessions: *MI* multidisciplinary intervention, *BI* brief intervention, *RTW* return to work



## Interventions

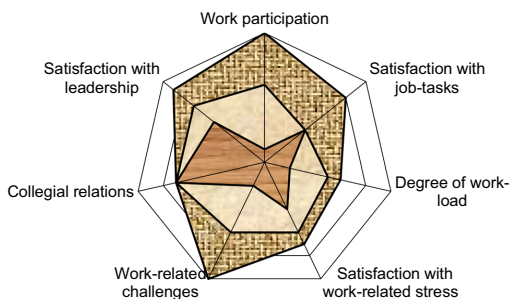
### *The Multidisciplinary Intervention with the ISIVET*

**Baseline Assessment** Initially, the patient met each of the three members of the multidisciplinary team successively (social worker, physician and physiotherapist). The social worker first interviewed the patient about their family life, social life, education and economics and then collaborated with the patient on scoring the ISIVET-figure “Working conditions” (Fig. 2). This evaluated seven different issues: work-related stress, satisfaction with job-tasks, workload, collegial relationships, leadership, degree of challenges at work and occupational participation.

The physician first interviewed the patient about the family’s health, as well as his/her former and present health. Then the physician conducted a physical examination, concluding with an ICD-10 diagnosis. Finally the physician and the patient collaborated on scoring the ISIVET-figure “Quality of life”. This evaluates the following issues: physical complaints, psychological wellbeing, sleep, energy, physical activity, social participation and occupational participation.

The physiotherapist assessed the musculoskeletal problems of the patient and conducted a physical examination.

The ISIVET comprised a manual and the two figures, which were star-plots with seven axis representing seven different issues. The scores on each axis were set between 1 and 10, with “10” positioned in the periphery of the star-plot, indicating an optimally positive situation. Meanwhile, “1” was located in the centre of the star-plot, indicating a maximum negative situation. The manual gave illustrating examples of situations at different scoring levels and, through discussion, the patient and the clinician identified the right score for every issue. When all of the scores were completed, a line was drawn between the scoring points, which produced an area in each figure. The area was coloured for better visualization for the patient, as well as



**Fig. 2** The ISIVET-figure “Working conditions”, assessed three times

for the clinicians. The problem areas were demonstrated by a lack of colour, while existing resources stood out as the coloured area.

When the sessions with the three clinicians were completed, the whole team met briefly to share their findings and general impression of the patient and her/his situation. The possible barriers to work-participation, maintaining factors to the pain problem and eventually other important issues, were highlighted. Following this, the patient joined the team for an evaluation on the total situation including health problems and work. The two figures with their coloured areas were central in this phase and when discussing problem solving and possible fields of actions. The patient played a major role in deciding the ways to go forward, with guiding from the areas and with the team as a counselling partner. The agreement on the actions was written down in a list, which constituted the patient’s rehabilitation plan. The actions were typically related to the handling of pain and fear avoidance, to lifestyle, particularly physical activity, and to family or work matters. When leaving the clinic, the patient received a paper-copy of the ISIVET-figures with the coloured areas and the rehabilitation plan listed as the points to be followed. The complete baseline assessment lasted 3.5 h.

**Two-Week Follow-Up** The patient met the physiotherapist for 1 h to evaluate the rehabilitation plan and work through the ISIVET once more. New areas were coloured with a second colour (Fig. 2). The visualization of the delta-areas was a matter of attention and reflection. Previous advice and actions were highlighted according to this, and adjustments to the rehabilitation plan were eventually made.

**Three-Month Follow-Up** The patient and the whole team met for 1 h to sum up the situation and evaluate the interventions so far. The ISIVET was worked through and new areas were coloured with a third colour. Eventually, they adjusted the rehabilitation plan.

During the study period, four different physicians, all specializing in physical medicine and rehabilitation, two different social workers, and four different physiotherapists were engaged in the MI-treatment. The total face-to-face-time spent with the patient during the MI was 5.5 h.

### *The Brief Intervention (BI)*

BI as applied in this study, is based on the studies by Indahl [30, 31] and Hagen [29], and we used the modified version of BI which is described in Hagens work.

The BI comprised two sessions: a baseline session lasting about 2.5 h including separate consultations with a

physician and a physiotherapist, and a two-week follow-up with the physiotherapist for about 1 h.

The BI is based on a non-injury-model for LBP. It aims to reduce fear and concern and help the patient to stay active despite the pain, unless “red flags” [33] are identified, emphasizing the fact that the back is a strong and robust structure and that return to normal activity would be beneficial. The essential feature of the method is giving the patient time to express problems, worries and thoughts. This is followed by a thorough medical, educational examination, where any somatic findings are explained to the patient. The patient is informed about the good prognosis and importance of staying active.

Therapist treatment manuals were based on the current guidelines [7] and the manual used by Hagen [29]. A physician, who was a specialist in physical medicine and rehabilitation, and a physiotherapist, carried out the BI. Both of the therapists were experienced in the method. The total face-to-face-time spent with the patient during the BI was 3.5 h.

## Data and Outcome

The social insurance register provides information about the start and stop dates for payments of sickness benefit, rehabilitation benefits, disability pension and unemployment benefits. For payments of sickness benefits and disability pension, we have information about the degree of disability and hence, indirectly, the degree of work participation. Only the payments for absences exceeding 16 days are refunded by the National Insurance. Therefore, absences that last 16 days or less are not included in our data.

We used the register data to define the work/social insurance status in each calendar month after inclusion in the trial. The register data provided follow-up data on every participant in both treatment groups for the 24-month follow-up.

Due to the inclusion criteria, all of the participants were employed and on sickness benefits at baseline. We defined that, if more than 50 % of the working days in a given calendar month were spent on full-time sick leave, the status for that month was given as “out of work” (OOW). If more than 50 % of the working days in a given calendar month were spent on partly sick leave, the status for that month was given as “partly return to work” (p-RTW). If no benefits were provided in more than 50 % of the working days, the status for that month was “fully return to work” (f-RTW). From these data, we constructed a file where each study participant had one of three possible statuses each month for the 24-month follow-up: OOW, p-RTW or f-RTW.

The primary outcome of this study was RTW fully and partly, at the 12-month and 24-month follow-up.

## Sample Size

The sample size calculations were based on the results from a previous RCT on BI in low-back pain [29]. With a power of 80 % and a significant level of 5 %, the total number of participants needed for this study was calculated to be 300.

## Randomization and Blinding

The randomization was concealed and the patients were randomized to either MI or BI, according to a computer-generated randomization-list, which was set up by a statistician at Uni Research Health (URH). The list was stratified by age and gender. A research assistant, who was not involved in the treatment, contacted URH and was informed about which treatment the patient should receive. There was no blinding to the treatment of therapists or participants.

## Statistical Methods

Descriptive statistics based on the groups for the 24-month follow-up were performed (Fig. 3), in addition to a multinomial logistic analysis to explore the relative risk (RR) ratios for p-RTW and f-RTW between the groups every month (Table 2). *P* values <0.05 was considered statistically significant. The analyses adhered to the “intention-to-treat” principle. The data were analysed using SPSS 21.

## Ethical Considerations

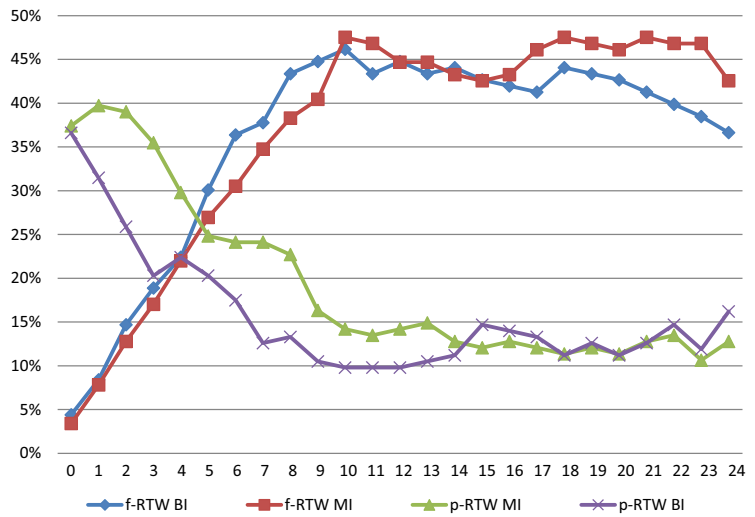
The research was carried out in compliance with the principles in the Helsinki declaration. The Norwegian Regional Ethical Committee and the Norwegian social science data services approved the study [34, 35]. Personal confidentiality was guaranteed and informed consent was signed by each participant, with emphasis on the right to withdraw from the study at any time without any explanation.

## Results

### Patient Characteristics

The baseline characteristics of the patients are presented in Table 1. The mean duration of sick leave by inclusion was 147 days (SD = 60.1). Due to the waiting time from inclusion to baseline assessment (between one and

**Fig. 3** Descriptive statistics on work status in valid % of multidisciplinary intervention group (MI) and brief intervention group (BI): proportions fully returned to work (f-RTW), partly returned to work (p-RTW) for both groups at each month for 24 months follow-up



**Table 1** Demographic and clinical characteristics by baseline [number (n) and valid percent (%)], divided by intervention groups, multidisciplinary intervention (MI) and brief intervention (BI)

Variables	MI (n = 141) n (%)	BI (n = 143) n (%)
<b>Demographic</b>		
Age (mean, SD)	40.9 (9.8)	41.6 (9.5)
Women	77 (54.6)	76 (53.1)
Married or cohabitant	107 (75.9)	110 (77.0)
<b>Children</b>		
None	25 (17.7)	31 (21.7)
1–2	75 (53.2)	73 (52.5)
<b>Level of education</b>		
Public school, 1–12 years	104 (73.8)	91 (63.6)
University/college, >12 years	24 (17.0)	28 (20.6)
<b>Work related variables</b>		
<b>Employment degree</b>		
Partial (≥50 %, <100 %)	39 (28.3)	30 (25.4)
Full time	99 (71.7)	103 (74.6)
<b>Working time</b>		
Shift <sup>a</sup>	47 (34.6)	52 (38.2)
<b>Sick-leave degree</b>		
Partial (≥50 %, <100 %)	51 (36.2)	52 (36.4)
Full-time	85 (60.4)	85 (59.2)
<b>Job security: “Do you have a job to return to?”</b>		
Yes	124 (91.9)	127 (92.0)
<b>Demands at work</b>		
Physically demanding	76 (55.1)	74 (52.5)
Mentally demanding	40 (29.2)	28 (19.9)

<sup>a</sup> Working both day and night-time

2 weeks), 11 patients (3.9 %) were no longer sick-listed by baseline. Education limited up to 12 years was more predominant in the MI-group (73.8 %) compared to the BI-

group (63.3 %). The dominant diagnoses in accordance with ICPC-2 [36] were: low back pain L02/L03/L84/L86 (39.5 %), neck pain L01/L83 (12.1 %), widespread

pain/fibromyalgia L18 (10.7 %) and shoulder pain L08/L92 (7.8 %). The study-population was given a total of 51 different diagnoses. Of these, the L-group represented 84.2 %. There were no significant differences between the intervention groups regarding sick-leave duration or distribution of the different medical conditions by baseline.

### Return to Work

There were no differences between the MI-group and BI-group on f-RTW during the follow-up period of 24 months. The highest RR was 1.42 (95 % CI 0.87–2.33,  $p = 0.17$ ), which was in the 23rd month. In all of the other months, the RR was closer to unity (Table 2, Fig. 3).

At 12 months of the follow-up, 63 patients (44.7 %) in the MI-group and 64 patients (44.8 %) in the BI-group were f-RTW. The corresponding numbers at 24 months were: 60 (42.6 %) in the MI-group and 52 (36.6 %) in the BI-group.

In three of the first 7 months after baseline, significantly more patients were p-RTW in the MI-group compared to the BI-group. The highest RR was at the seventh month: RR = 2.31 (95 % CI 1.19–4.51,  $p = 0.01$ ). The corresponding numbers for the second month was: RR = 1.86 (95 % CI 1.10–3.14,  $p = 0.02$ ) and for the third month: RR = 2.24 (95 % CI 1.28–3.91,  $p < 0.01$ ).

By 12 months, 59 patients (41.8 %) in the MI-group and 65 patients (45.5 %) in the BI-group were still OOW. The

corresponding numbers by 24 months were 63 (44.7 %) in the MI-group and 68 (47.6 %) in the BI-group.

### Discussion

In this study of patients on long-term sick leave due to musculoskeletal pain, there were no significant differences on RTW between the patients who received MI or the patients receiving BI at 12 months or 24 months of the follow-up. However, patients in the MI-group returned to work faster than patients in the BI-group. This is illustrated by the differences between the groups in proportions fully out of work (OOW): At 3 months of the follow-up, the proportion OOW in the MI-group was reduced to 48 %, while in the BI-group it was slightly increased to 61 % compared to the baseline levels.

A number of factors prolong musculoskeletal pain. Some are obviously related to the individual, others to the workplace [37] or to compensation systems [38]. Multidisciplinary interventions comply with the possibility that barriers to work-participation exist at multiple levels and have proven beneficial to facilitate RTW in low back pain [23]. As psychosocial factors predict the long-term incapacity of musculoskeletal disorders [39], interventions focusing on these aspects should be of clinical value.

In our study, the MI-group received a more comprehensive approach, which included more therapist time, one

**Table 2** Partly return to work (p-RTW) and fully return to work (f-RTW) for the Multidisciplinary Intervention group compared to the Brief Intervention group (reference group)

Months follow-up	p-RTW		f-RTW	
	RR	95 % CI <sup>a</sup>	RR	95 % CI <sup>a</sup>
1	1.45	0.88–2.39	1.07	0.44–2.56
2	1.86	1.10–3.14*	1.07	0.53–2.18
3	2.24	1.28–3.91**	1.15	0.61–2.18
4	1.53	0.87–2.68	1.13	0.62–2.03
5	1.26	0.70–2.28	0.92	0.53–1.60
6	1.40	0.75–2.61	0.85	0.50–1.45
7	2.31	1.19–4.51*	1.11	0.66–1.87
8	1.90	0.97–3.72	0.98	0.59–1.64
9	1.61	0.77–3.37	0.93	0.57–1.54
10	1.67	0.77–3.61	1.18	0.72–1.95
11	1.62	0.75–3.53	1.27	0.78–2.09
12	1.60	0.74–3.46	1.10	0.67–1.81
13–23	Results not reported			
24	0.85	0.42–1.71	1.25	0.75–2.06

Differences between the groups were estimated by multinomial regression analysis with “fully out of work” as reference category. Risk Ratio (RR), 95 % Confidence Interval (CI) with  $p$  values are presented

<sup>a</sup> Indicates  $p$  value

\*  $p$  value  $<0.05$ ; \*\*  $p$  value  $<0.01$

more profession, more focus on psychosocial factors, in particular work and workplace adaptations, compared to the BI-group. The 2 h difference in therapist time might contribute to improved results on p-RTW in the MI-group. The MI also applied the ISIVET, which was constructed to improve patient-therapist communication, facilitate patient and therapist insight in the entirety of the situation, and improve the patient's autonomy and thereby, their engagement in their own rehabilitation. The ISIVET aimed to raise awareness of the value of work participation through visualization of large areas in the star plot. It also aimed to motivate patients to choose to work at least partially, if not fully, in spite of their health complaints, with the suggestion that work is healthy. If areas were small, the possibility of alternative work was questioned by the clinicians.

However, the MI did not increase the proportion of patients who were f-RTW at 12 months or 24 months, compared to the BI. However, the results of p-RTW are in accordance with the conclusion of a recent Cochrane review and of the findings of Loisel and his co-workers, where a combination of a clinical intervention and an occupational intervention was associated with a faster RTW [40, 41]. The workplace intervention in the MI-group was limited to the discussion and planning of workplace adaptations between the patient and the team at the clinic. The patient was responsible for initiatives at the workplace, which was part of the patient-oriented coping strategy for the MI.

The MI-group improved faster than the BI-group on mental and physical symptoms, functional ability and coping, but these results are published elsewhere [42].

The treatment of musculoskeletal pain is primarily given by the GP but more complex cases are eventually referred to the specialist health care [7, 20]. In this study, the GPs who referred the patients did not know that their patients might be enrolled in a clinical study. It is reasonable to assume that our study-population is regarded by the GPs as difficult to treat, as they were referred to specialist health care and on long-time sick leave with musculoskeletal pain, which in itself gives a poor prognosis. This might explain the relatively low RTW-proportion in both groups. It might also explain why it was difficult to achieve better results, even with a more comprehensive approach and in spite of improvements in health, coping and function abilities, as described in an earlier paper [42].

A possibility that the patient is determined not to go back to work or, for some reason, do not want to return to their former workplace represents information that is not necessarily accessible to the therapists. The majority of the participants had low education and physically demanding jobs, thereby representing mostly blue-collar workers with

fewer opportunities to find alternative work. This might also contribute to the low proportions of RTW in this study.

The Norwegian sickness compensation system offers 100 % salary compensation from day one for up to a year. After that period, the patient is covered by 66 % compensation of salary through a rehabilitation allowance or disability pension. This generous compensation system might undermine the process of RTW through weak economic incentives for the patients to get out of sick leave in both groups.

The MI-group had a total of three sessions with therapists during a three-month period and the BI-group had two sessions. Given that these patients were on long-time sick leave, it was perhaps too optimistic to hypothesize that a limited intervention would increase RTW extensively.

### Limitations and Strengths of the Study

The primary strengths of this study constitute the study design with the randomization giving comparable groups, and the relatively large sample included. Secondly, the use of register data, leaving us with information on work participation and sickness-compensation every month for 24 months of the follow-up for all of the patients included. Furthermore, both treatments were based on written manuals and were easy to describe. Different teams did the BI and the MI, reducing the possibility of mixing the two methods. The BI-method was well known to the therapists involved, and they had recently been videotaped and quality assured in performing BI in another trial [43]. The therapists performing the new MI-method practised regular meetings and supervision to ensure adherence to the protocol and equal practice of the method. The sickness-certificates were prescribed by the GP's and not by the physicians in the study, reducing the possibility of a biased prescription from therapists in the study. Finally; the drop out of treatment was low in both groups indicating that the treatment is feasible in clinical practice and that the results are reliable.

Some limitations should also be mentioned. First of all; there were many similarities in the two treatment methods and this could influence the possibility to come out with significant differences in the outcome. Both were based on a non-injury- and a bio-psychosocial model in pain assessment, and both practised patient education. Furthermore, both methods had an intervention limited to the individual level; the patient. We could therefore not explore the effect of environmental factors, nor could the therapists involve a third part directly, which might have been valuable in the process considering the significance of psychosocial factors in chronic pain [4]. The occupational intervention in MI was limited to the assessments of different aspects of the work-situation and the discussion with the patients on possible

fields of action, while the follow-up on the eventual workplace interventions was the patient's own responsibility. This might not be sufficient to achieve actual changes. External support with RTW-planning and process might have improved the results as there is evidence that workplace intervention improves time until first and lasting RTW among workers with musculoskeletal disorders [41]. In the BI-group, there were fewer and more experienced therapists compared to the MI-group. If the therapists in the MI had less confidence of their role due to less experience, it might have influenced the interaction with the patient and through this, the outcomes, as there is evidence that what the doctor and other health professionals say and do has a powerful influence on outcomes [44]. There was no use of audiotaping to ensure adherence to the protocol in this study and there was no blinding of patients or therapists of practical reasons. The patients knew they would get one out of two possible interventions. Both were given in the specialist health care and both were comprehensive compared to ordinary services patients experience in the health care system. The lack of blinding of the patients might therefore be a limited weakness to this study. And finally, multiple analyses were performed increasing the risk of finding significant differences by coincidence. However, the results on p-RTW showed a continuous trend towards differences in the first 14 months. This trend supports the validity of the three significant  $p$  values.

### Concluding Remarks

A comprehensive MI focusing on work and psychosocial factors could not increase RTW at 12 months and 24 months in patients with chronic musculoskeletal pain, when compared to the effect of a less resource-demanding BI. However, the MI hastened the return to work process through the increased use of partial sick leave during the first months of the follow-up, compared to the BI. Longer treatments that more actively involve the workplace, combined with structural changes in sickness compensation and labour marked, might be necessary to decrease the proportion of patients on long-term sick leave for musculoskeletal pain.

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## PREDICTORS OF RETURN-TO-WORK IN PATIENTS WITH CHRONIC MUSCULOSKELETAL PAIN: A RANDOMIZED CLINICAL TRIAL

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**Objective:** To assess the predictive effect of a multidisciplinary intervention programme, pain, work-related factors and health, including anxiety/depression and beliefs, on return-to-work for patients sick-listed due to musculoskeletal pain.

**Design:** A randomized clinical study.

**Methods:** A total of 284 patients were randomized to either a multidisciplinary intervention programme ( $n=141$ ) or to a less resource-demanding brief intervention ( $n=143$ ). Work participation was estimated monthly from register data for 12 months. Return-to-work was defined as increased work participation in 3 consecutive months.

**Results:** In the adjusted model, return-to-work by 3 months was associated with a multidisciplinary intervention programme (odds ratio (OR)=2.7, 95% confidence interval (95% CI)=1.1–6.9), the factor “belief that work was cause of the pain” (OR=2.2, 95% CI=1.1–4.3), anxiety and depression (OR=0.5, 95% CI=0.2–0.98), and by an interaction between the multidisciplinary intervention and perceived support at work (OR=0.3, 95% CI=0.1–0.9). At 12 months, only duration of sick leave was associated with return-to-work (OR=0.6, 95% CI=0.5–0.8).

**Conclusion:** Multidisciplinary intervention may hasten return-to-work and benefit those who perceive low support at work, but at 12 months only duration of sick leave at baseline was associated with return-to-work.

**Key words:** multidisciplinary rehabilitation; return-to-work; sickness absence; sick leave; randomized clinical trial; prognostic factors; musculoskeletal pain.

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Musculoskeletal pain is a major cause of sickness absence and work disability worldwide. In Western countries, painful disorders of the back, neck and upper limbs are the most frequently reported causes, with work disability, long-term absence and permanent disability as consequences (1). The prevalence of sick certification and incapacity benefits due to these conditions has increased substantially in most Western countries in recent decades (2), while, in Norway,

approximately half of all sickness absences are due to musculoskeletal pain (3). Most of these conditions are non-specific with little objective pathology, but research has revealed an extensive psychiatric and somatic comorbidity in this patient group (4). In a cohort of 635 patients on long-term sick leave, 55% had psychiatric-somatic comorbidity, with the combination of fibromyalgia/myalgia and depression being the most frequent (5).

Pain is a multidimensional phenomenon, comprising biological, psychological, social and existential elements. Thus, a number of predictors have been associated with the development and persistence of muscular pain. Some of these are work-related, such as physical demands at work or low job satisfaction, while others are psychiatric and affective risk factors, such as anxiety, expectations, fear avoidance or low mood (6, 7). To date, there is general consensus that chronic musculoskeletal pain conditions are multi-causal and comorbid (8), with multidisciplinary treatment being a recommended approach in the treatment of chronic pain (9, 10). The effectiveness of treatment with regards to health and quality of life could, however, differ from its effects on occupational outcomes. The literature on occupational outcomes has focused more on identifying predictors for disability than RTW among these patients (11, 12). Systematic reviews of the effectiveness of RTW programmes have concluded that knowledge, psychosocial, physical and work conditioning, possibly combined with relaxation exercises, are effective treatment components (12, 13). Studies of predictors of RTW have identified factors associated with the patient (functional ability, pain intensity, beliefs and expectations about recovery, RTW and low levels of education), the therapists (healthcare provider type, communication in therapy) and work (physical demands at work, job satisfaction, having unskilled work) (14, 15). In addition, depressive symptoms are associated with prolonged sick leave (16).

The process of RTW following a period of long-term sick leave reflects the complexity of the clinical picture, as medical, psychological, work and social factors often need to be addressed. This complies with the biopsychosocial model of disability. A multidisciplinary approach is recommended, but there is still no consensus on the content or dosage of these resource-demanding interventions. More information

about the predictors of the effect of multidisciplinary programmes on RTW is needed (12) in order to tailor interventions and possibly avoid applying resource-demanding programmes to individuals who might benefit to the same extent from a more limited intervention.

A major motivation for this paper was the desire to analyse predictors for a more sustainable RTW on an individual level, with RTW defined as increased work-participation in 3 consecutive months, and to determine whether the 2 interventions had different effects on RTW defined in this way. In addition, the analysis aimed to determine whether patient- or work-related factors, measured at baseline, could predict (sustainable) RTW by 3 and 12 months' follow-up. Former publications from this study have examined differences in improvements in health, physical functioning, coping and RTW between groups at 3 and 12 months' follow-up (17, 18).

The aims of this study were, therefore (i) to assess the predictive effect of a multidisciplinary intervention (MI) vs the active comparator and less resource-demanding brief intervention (BI) on RTW in patients with long-term musculoskeletal pain problems; and (ii) to assess whether RTW in this group of patients is predicted by work-related factors and/or subjective experience of pain and health.

## METHODS

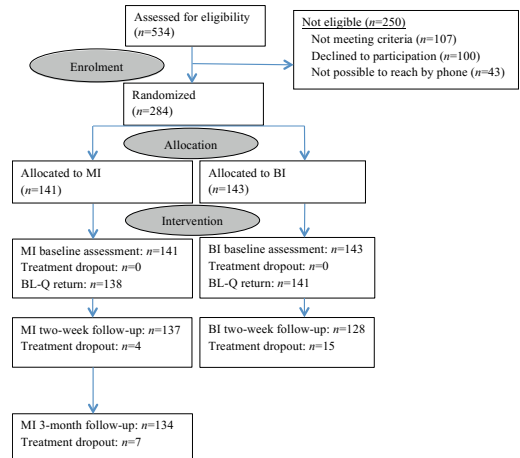
### Design

The study was a randomized clinical trial with a 12-month follow-up period, exploring the effect of 2 different interventions (MI and BI), including possible predictive factors on RTW, at the 3- and 12-month follow-up stages. The effects of the interventions on sick leave, RTW and secondary outcomes have been published elsewhere (17, 18).

**Trial registration.** The trial was registered at the US National Library of Medicine's ClinicalTrials.gov (<http://www.clinicaltrials.gov>), registration number NCT01346423.

### Participants

A total of 284 patients, with a mean age of 41.3 years, of whom 53% were women, were randomized to either MI ( $n=141$ ) or BI ( $n=143$ ) (Fig. 1). They were recruited from a list of patients who were on sick leave due to musculoskeletal pain and who were referred to the Department of Physical Rehabilitation, Innlandet Hospital Trust, Norway, in the period 2011–2013. Patients were referred by their general practitioner (GP) who had no knowledge that their patient might be enrolled on a clinical trial. Inclusion criteria were: age 20–60 years, at least 50% sick leave for no longer than 12 months due to musculoskeletal pain, and at least 50% employed. Exclusion criteria were: pregnancy, current cancer, osteoporosis, recent physical trauma/injury, serious mental illness, rheumatic inflammatory diseases, not capable of understanding and speaking Norwegian, or being involved in an ongoing health insurance claim.



**Fig. 1.** Allocation and treatment flowchart. BL-Q: baseline questionnaire; MI: multidisciplinary intervention; BI: brief intervention.

On inclusion, all participants completed a comprehensive set of questionnaires before they received baseline treatment.

### Study context

All lawful residents of Norway are included in the Norwegian public insurance system. This system, which provides health service benefits and pensions, is administered by the Norwegian Welfare and Labour Administration (NAV). When a worker is certified sick by their GP, the workers' compensation programme, administered by the NAV, provides 100% coverage for lost income from day 1 until the person can work again, for up to 52 weeks. The first 16 days are covered by the employer. After 1 year, the NAV covers long-term rehabilitation benefits or a disability pension, equating to approximately 66% of the person's former income. These benefits can also be combined with work if the disability constitutes a minimum of 50%.

### Multidisciplinary intervention programme

The MI included 3 consultations at the outpatient clinic: at baseline, after 2 weeks and after 3 months. The baseline assessment was the most comprehensive part, lasting approximately 3.5 h. The patient met each of the 3 members of the multidisciplinary team in succession, with each therapist assessing different aspects of the patient's health and work situation, as follows. The *social worker* interviewed the patient about their work situation, family life, social life, education and economics. The *physician* interviewed the patient about their former and present health, and that of their family, and conducted a physical examination, which concluded with a diagnosis according to the International Classification of Diseases, 10<sup>th</sup> edition (ICD-10). The *physiotherapist* assessed the patient's musculoskeletal problems and conducted a physical examination. In addition, the social worker and the physician collaborated with the patient using the novel Interdisciplinary Structured Interview with a Visual Educational Tool (ISIVET) (17). The ISIVET comprises a manual and 2 star plots with 7 axes. The first star plot, named "Working conditions", evaluates 7 different aspects of the patient's work

situation, while the second star plot, named “Quality of life”, evaluates 7 aspects of health and social life. The evaluation itself involves a scoring process that results in a coloured area for each of the 2 star plots, thereby visualizing the resources (coloured area) and the challenges (non-coloured area) connected to the work and life situation. In this study, the 2 figures with their areas were central when the team and the patient, at the end of the baseline consultation, were evaluating the situation in order to make a rehabilitation plan. The main aim of the MI was to strengthen the patient’s motivation and ability to make changes in their own life and, in particular, choose activities and RTW in spite of the pain problems. Details of the ISIVET method are given in this randomized clinical trial (RCT) (17).

The patient had a follow-up with the physiotherapist after 2 weeks and with the whole team after 3 months. Both follow-ups lasted approximately 1 h and included working through the ISIVET once more, leading to an evaluation and, eventually, adjustment of the rehabilitation plan. The total face-to-face-time spent with the patient during the MI was 5.5 h.

#### *Brief intervention programme*

The BI comprised 2 sessions: a baseline session lasting approximately 2.5 h, including separate consultations with a physician and a physiotherapist, and a 2-week follow-up with the physiotherapist for approximately 1 h. The BI applied in this study was based on a study by Molde Hagen (19). BI programmes have proven beneficial for low back pain, neck pain and fibromyalgia/widespread pain (20, 21).

The BI is based on a non-injury model, whose goal is to reduce fear and concern, as well as help the patient to stay active despite pain, unless serious pathology is identified, emphasizing the fact that the body is a strong and robust structure and that return to normal activity is beneficial. Essential features of the method include giving the patient time to express problems, worries and thoughts, followed by a thorough medical, educational examination, where any somatic findings are explained to the patient. The patient is informed about the positive prognosis and the importance of staying active. The total face-to-face-time spent with the patient during the BI was 3.5 h.

#### *Instruments and outcome measures*

The comprehensive questionnaires at baseline comprised demographic variables, information on education and different aspects of work, self-ratings on health, fitness and physical activity, information related to the sick certification, and the duration and initial/actual extent of sick leave. The clinically validated questionnaires described below were applied.

The *Subjective Health Complaints* (SHC) inventory is a reliable instrument measuring somatic and psychological complaints over the previous 30 days using 29 questions rated on a 4-point scale (from 0 to 3) (22). The instrument has 5 subscales: “musculoskeletal complaints” (8 items), “gastrointestinal problems” (7 items), “pseudoneurological problems” (7 items) and “flu” and “allergy” symptoms (7 items in total), in addition to a total score (SHC total), with a maximum value of 87 indicating the highest possible level of complaints that can be measured by this instrument. The subscale “musculoskeletal complaints” correspondingly has a maximum value of 24. Cronbach’s alpha for musculoskeletal complaints=0.65, gastrointestinal problems=0.71, pseudoneurological problems=0.70, flu=0.65, allergy=0.48.

The *Hospital Anxiety and Depression Scale* (HADS) assesses anxiety and depression disorders (23). HADS consists of

14 items that create subscale scores for anxiety (7 items) and depression (7 items) and a sum-score for both scales. The score for each subscale is calculated by adding the scores of the individual items (0–3) and ranges from 0 (good) to 21 (poor). Only the sum-score anxiety/depression was used in this study, and Cronbach’s alpha for this scale was=0.86.

The *Eysenck Personality Questionnaire-Nordic* (EPQ-N) is a 12-item true-false questionnaire measuring neuroticism as a personality trait. The maximum score of 12 indicates a high degree of neuroticism. EPQ-N is derived from the 90-item EPQ (24), which measures neuroticism, psychoticism and extroversion. Cronbach’s alpha for EPQ-N=0.84.

The *Chronic Pain Acceptance Questionnaire* (CPAQ) is a 20-item assessment divided into 2 subscales: pain willingness (9 items) and activities engagement (11 items). The scores are set according to a numerical scale from 0 to 6 (highest degree of willingness or engagement), with the CPAQ sum has a maximum score of 120, indicating the highest possible level of willingness to tolerate pain and engage in activities measured by this instrument (25). Cronbach’s alpha for CPAQ sum=0.64, pain willingness=0.81, activities engagement=0.84.

*Physical burden of work and psychological burden of work* were assessed by the question: “Do you experience your work as a physical (correspondingly psychological) burden?” The 3 possible answers (yes, no, some) were dichotomized into “yes/some”=1 and “no”=0.

*Perceived support at work* was measured by 6 items from Theorell, while answers were made using a 4-point numerical scale from minimum support to highest degree of support (1–4), with a maximum score of 24, indicating high support at work from leaders and colleagues (26). Cronbach’s alpha for support at work=0.82.

*Burden of work* was measured as the demands/control fraction of Karasek et al. (26), including questions on *job demands* (5 items) and questions on *job control* (decision latitude). The job control scale is the sum of 2 subscales: *skill discretion* (4 items) and *decision authority* (2 items). The answers are given on the range of 1–4, where 4 represents the most burdensome situation. Cronbach’s alpha for job demands=0.73, skill discretion=0.55 and decision authority=0.78.

Regarding *cause of the pain*, the study participants were asked about what they believed was the cause of the pain problem, with the possibility of choosing a specific cause (e.g. actual work, strain at home, injury, leisure activity, incorrect treatment, deformity of the body or just “don’t know”).

#### *Return-to-work*

The national register data was used to define the work/social insurance status in each calendar month after inclusion in the trial. The register data provided follow-up data on every participant in both treatment groups for 12 months of follow-up, as well as information on the GP diagnosis that led to sick certification at baseline. Every month of the follow-up period, each participant was either out of work, partly working or fully working. At baseline, due to inclusion criteria, they were either out of work or partly working. The status of every follow-up month was compared with the status in the baseline month for every participant and defined a “success month” as a month with increased work participation compared with the baseline, while a “non-success month” was a month with unchanged or decreased work participation compared with the baseline. If a person had 3 consecutive “success month” statuses, this was defined as RTW, with the first out of the 3 months defined as the RTW month.

### Statistical analyses

The odds of RTW within 3 and 12 months, respectively, were analysed using binary multiple logistic regression models, including all the following *a priori* selected, independent variables (1–4):

1. Intervention variable (MI=1 and BI=0).
2. Variables that were dichotomized by splitting the median score (above median score=1, median score and below=0):
  - Subjective health complaints (SHC total scale)
  - Anxiety and depression (HADS)
  - Neuroticism (EPQ-N)
  - Acceptance of chronic pain (CPAQ)
  - Muscular pain (SHC musculoskeletal subscale)
  - Support at work
  - Burden of work (Karasek & Theorell).
3. Variables dichotomized to either yes or no by the given answers:
  - Physically demanding work
  - Psychologically demanding work
  - Whether the study participant believed that work was the cause of the pain.
4. Duration of sick leave was categorized into: 0–91; 92–153; 154–213; and 214–365 days.

For adjustment, the models also included sex and age (20–29; 30–39; 40–49; 50–60 years). Each predictor variable was assessed for interaction with the intervention in the models according to hierarchical elimination. The models' goodness of fit was tested by the Hosmer-Lemeshow test. The significance level was set at 5% for all tests. The odds ratios (ORs) with 95% confidence interval (95% CI) are reported.

## RESULTS

### Patients' characteristics

Baseline characteristics are shown in Table I. The mean duration of sick leave by inclusion was 147 days (SD 60.1 days). As there was some waiting time (1–2 weeks) from inclusion to baseline assessment, 8 patients (MI=2, BI=6) were no longer certified sick, but worked full-time at baseline. These patients were included in the analyses as non-RTW as they were unable to increase their degree of work participation compared with baseline.

### Diagnosis at baseline

The dominant diagnoses according to the International Classification of Primary Care 1998 (ICPC-2) (27) were low back pain (39.5%), neck pain (12.1%), widespread pain/fibromyalgia (10.7%) and shoulder pain (7.8%). The sample comprised a total of 51 different diagnoses, of these 238 (83.8%) were musculoskeletal diagnoses, while 14 (4.9%) were psychiatric diagnoses, 11 (3.9%) were neurological diagnoses, and 21 (7.4%) were other diagnoses. However, all patients were referred because of musculoskeletal pain problems. The ICPC diagnoses on the sickness certificates were av-

**Table I.** Baseline characteristics of participants ( $n = 284$ ) divided according to multidisciplinary intervention (MI) and brief intervention (BI)

	MI ( $n = 141$ )	BI ( $n = 143$ )
Age, years, mean (SD)	40.9 (9.8)	41.6 (9.5)
Level of education, mean (SD)		
Public school, 1–12 years	104 (73.8)	91 (63.6)
University/college, > 12 years	24 (17.0)	28 (20.6)
Health variables, mean (SD)		
Pain at rest, NRS (0–10)	4.75 (2.23)	4.45 (2.21)
Pain during activity, NRS (0–10)	6.62 (1.93)	6.26 (2.11)
HADS sum (0–21)	10.2 (6.0)	10.0 (6.6)
EPQ-N sum (0–12)	4.5 (3.1)	4.0 (3.3)
SHC sum (0–87)	20.1 (9.4)	18.4 (9.4)
SHC muscular (0–24)	10.6 (4.2)	10.1 (4.4)
CPAQ sum (0–120)	62.9 (15.3)	61.7 (15.1)
Sex, $n$ (%)		
Women	77 (54.6)	76 (53.1)
Number of sick leave days, $n$ (%)	143.2 (56.6)	149.6 (62.9)
Work situation, $n$ (%)		
Employment degree		
Partial ( $\geq 50\%$ , < 100%)	39 (28.3)	30 (25.4)
Full-time	99 (71.7)	103 (74.6)
Working time		
Shifts	47 (34.6)	52 (38.2)
Extent of sick leave		
Partial ( $\geq 50\%$ , < 100%)	51 (36.2)	52 (36.4)
Full-time	85 (60.4)	85 (59.2)
Job security: "Do you have a job to return to?"		
Yes	124 (91.9)	127 (92.0)
Demands at work		
Physically demanding	76 (55.1)	74 (52.5)
Psychologically demanding	40 (29.2)	28 (19.9)
Work regarded as cause of the pain problem, $n$ (%)	84 (59.6)	89 (62.2)
Positive expectations regarding RTW, $n$ (%)	82 (59.9)	82 (58.2)

NRS: numerical rating scale; HADS sum: Hospital Anxiety and Depression Scale total score; EPQ-N sum: Eysenck Personality Questionnaire-Nordic version total score; SHC sum: Subjective Health Complaints (Eriksen & Ursin) total score; SHC muscular: Subjective Health Complaints (Eriksen & Ursin) musculoskeletal complaints subscale; CPAQ sum: Chronic Pain Acceptance Questionnaire total score.

ailable when we received the social insurance register data at the end of the study.

### Return-to-work

By the 3-month follow-up stage, 25.5% ( $n = 36$ ) in the MI group and 20.3% ( $n = 29$ ) in the BI group were categorized as RTW ( $p = 0.29$ ). By the 12-month follow-up, the proportions were 63.8% ( $n = 90$ ) and 58.7% ( $n = 84$ ), respectively ( $p = 0.38$ ).

### Predictors for return-to-work

The adjusted OR for RTW within 3 months in the MI group, compared with the BI group, was 2.69 (95% CI: 1.06–6.85), while it was 1.13 (0.67–1.91) within 12 months (Table II). RTW after 3 months was also significantly associated with *believing that pain was caused by work* (OR: 2.17, 95% CI: 1.11–4.26) and with *anxiety/depression* (OR: 0.45, 95% CI: 0.20–0.98). There was an interaction between intervention and *perceived support at work* (OR: 0.24, 95% CI: 0.07–0.85), indicating that those with low perceived support at work

**Table II.** Adjusted odds ratios (OR) and 95% confidence interval (95% CI) for return to work (RTW) by 3- and 12-month follow-up

	3-month follow-up <sup>1</sup>		12-month follow-up <sup>1</sup>	
	OR	95% CI	OR	95% CI
Intervention	<b>2.69</b>	1.06–6.85	1.13	0.67–1.91
Psychological burden of work <sup>a</sup>	0.76	0.38–1.53	1.16	0.63–2.12
Physical burden of work <sup>a</sup>	2.28	0.85–6.17	1.70	0.79–3.63
Pain caused by work <sup>b</sup>	<b>2.17</b>	1.11–4.25	1.29	0.75–2.22
Workload <sup>c,d</sup>	0.95	0.50–1.82	0.66	0.38–1.14
Support at work <sup>a</sup>	1.64	0.65–4.12	1.08	0.62–1.87
Subjective Health Complaints (22) <sup>a</sup>	1.33	0.58–3.03	0.68	0.32–1.42
Anxiety and depression <sup>d,e</sup>	<b>0.45</b>	0.20–0.98	0.70	0.36–1.37
Neuroticism <sup>e,f</sup>	0.72	0.33–1.55	0.73	0.38–1.41
Acceptance of chronic pain <sup>f,g</sup>	1.30	0.69–2.47	1.22	0.71–2.11
Muscular pain <sup>a</sup>	0.82	0.38–1.78	1.77	0.88–3.59
Duration of sick leave <sup>g</sup>	0.90	0.66–1.22	<b>0.63</b>	0.49–0.82
Intervention and support at work <sup>h</sup>	<b>0.24</b>	0.07–0.85	Eliminated	
Age <sup>i</sup>	1.07	0.78–1.47	0.89	0.68–1.17
Sex	0.84	0.45–1.57	1.00	0.58–1.74

<sup>a</sup>Continuous variable dichotomized by a split at the median score: below median = 0, above median = 1. <sup>b</sup>Study participant believes work is cause of the pain (yes = 1, no = 0). <sup>c</sup>Workload = work demands/work control (Karasek & Theorell). <sup>d</sup>Hospital Anxiety and Depression Scale total score. <sup>e</sup>Eysenck Personality Questionnaire-Nordic. <sup>f</sup>Chronic Pain Acceptance Questionnaire. <sup>g</sup>Categorized into 4 groups: 0–91; 92–153; 154–213; and 214–365 days. <sup>h</sup>Interaction term; the other interaction terms were eliminated from the model, as none of the other factors had a statistical significant interaction with the intervention. <sup>i</sup>Categorized into 4 groups: 20–29; 30–39; 40–49; and 50–60 years. <sup>j</sup>Goodness-of-fit (Hosmer-Lemeshow) for the model: 3 months,  $p = 0.94$ , 12 months,  $p = 0.45$ .

benefitted significantly more from MI compared with BI (Table III). For RTW after 12 months, *duration of sick leave* was the only significant predictor (OR: 0.63, 95% CI: 0.49–0.82). All interaction variables were eliminated from the 12-month model. Five baseline questionnaires (MI=3, BI=2) were never returned, and baseline information on these individuals were included as missing values.

## DISCUSSION

By the 3-month follow-up, patients who received the MI seemed more prone to RTW than patients who received the BI, adjusted for confounders and the other study factors. This result was not found 12 month follow-up. RTW was also predicted by *believing that pain was caused by work, while anxiety and depression* was a negative predictor. The subgroup reporting low support at work (LSW) (lower than median) benefitted more from the MI, compared with the BI, with an OR for

**Table III.** Return-to-work (RTW) at 3-month follow-up, split by intervention and support at work (high vs low)

Intervention	RTW <sup>a</sup>		Non-RTW <sup>b</sup>	
	High support	Low support	High support	Low support
MI <i>n</i> (valid %)	12 (23.1)	21 (26.6)	40 (76.9)	58 (73.4)
BI <i>n</i> (valid %)	16 (26.2)	12 (15.4)	45 (73.8)	66 (84.6)

<sup>a</sup>Missing = 3. <sup>b</sup>Missing = 11.

MI: multidisciplinary intervention; BI: brief intervention.

RTW=4.2 (95% CI=1.2–14.2). This was the only study factor that interacted significantly with the intervention. By the 12-month follow-up, the *duration of sick leave at baseline* was a negative predictor for RTW.

Both interventions in this study are based on the biopsychosocial model of disability (28) and both practiced patient education. The MI, which had an additional 2 h therapist time and a social worker in the team, was a more comprehensive intervention than the BI, focusing on work in particular, as well as psychosocial factors and communication.

Reviews on the efficacy of MIs on RTW, compared with other treatment modalities, have shown conflicting results (10, 12, 13, 29). However, our findings are in accordance with studies in which a clinical intervention combined with an occupational intervention is associated with a faster RTW (30, 31). A recent Cochrane review concluded that workplace interventions reduce the time to RTW, as well as improve pain and functional status in workers with musculoskeletal disorders (32). This RCT found that the MI group improved more rapidly than the BI group in terms of physical and mental symptoms, along with reporting less use of health services and a better ability to cope (17). Van der Giezen et al. (33) found that interventions combining psychosocial aspects, health and work predicted RTW in chronic low back pain, which is in line with our results. On the other hand; the potential for increasing RTW rates by applying more extensive interventions, such as the MI, might be through the earlier mobilization of individuals who would have chosen to RTW at a later time, as the MI did not predict RTW by 12 months. From a 1-year perspective, this effect of a hastened RTW represented sustainable work participation.

Improved communication between patients and therapists can improve coping and outcomes (34). The application of the ISIVET could have contributed to our results on RTW, by supporting and encouraging the patient to choose work in spite of pain problems when areas on the star plot were large, or to apply for alternative work or employment when areas were small. The therapists argued that work is generally beneficial for health and well-being. The MI also included initiatives directed at improving the work situation, where relevant. These aspects of the MI may also explain why individuals with LSW benefitted more from an MI than a BI in terms of RTW.

More therapist time has proven beneficial in treatments for psychiatric disorders (35), but the differences are comprehensive. The additional 2 h of therapist time in the MI compared with the BI is unlikely to explain RTW differences between the groups on its own, given that the patients were mainly chronic pain patients with complex problems.



The participants in our study were referred by their GP to specialist treatment and, on average, had been certified sick for 5 months on entering the study. They presumably represented a selection of patients who are difficult to help in primary care. This could explain the relatively low rates of RTW by 3 months follow-up and could explain why a more comprehensive intervention was more effective than a BI. In a comparable RCT within specialist healthcare, patients with comprehensive problems were found to RTW at a higher rate after receiving an MI compared with those receiving treatment as usual (36).

Fear-avoidance beliefs and negative expectations are significant prognostic risk factors for improvements in relation to chronic pain and RTW (6, 37). Fear avoidance related to work has furthermore been found to be more prevalent among those experiencing chronic pain than acute pain (38). This could be associated with our own finding, that RTW within 3 months was predicted on the belief that work was the cause of the pain, given that this belief was a major reason behind leaving work, while the interventions applied contributed to a correction of this belief. Both interventions were based on the non-injury model (39), both practised patient education, and therapists argued that activity is beneficial as long as there are no signs of serious disease. The MI and BI are both designed to deal with fear-avoidance beliefs. The correction of these beliefs could explain why patients who believed that work was the cause of pain seemed to RTW more quickly.

Comorbidity in chronic musculoskeletal pain is extensive and influences chronicity and disability (4, 5). The presence of psychological distress, in particular, is a predictor for chronicity and disability (40). This corresponds to our findings that anxiety/depression at baseline was a negative predictor for RTW.

Duration of sickness absence is a well-known predictor of disability in chronic pain (40), which corresponds with our findings at 12 months.

#### *Study limitations and strengths*

The primary strengths of this study were its design, randomization (which allowed for comparable groups), relatively large sample size and use of register data, which provided us with information on work participation and sickness compensation for every patient for all months of follow-up. In addition, both treatments were based on written manuals and were easy to describe. As separate teams provided the MI and the BI, this reduced the possibility of mixing the 2 methods. The BI was well known to the therapists involved, who had recently been videotaped and quality assured in performing BI on another trial. The therapists performing the new MI participated in regular meetings and

supervision to ensure adherence to the protocol and consistent practice of the method. The sick certificates were issued by the GP in cooperation with the patient, rather than by physicians on the study, reducing the possibility of a biased diagnosis. Finally, the dropout rate from treatment was low in both groups, indicating that the treatment was feasible in terms of clinical practice and that the results are reliable.

Education was omitted as an adjustment factor because information on education was reported inaccurate on questionnaires for 12% (MI=7%, BI=16%) of the study sample. This might be a weakness of this study, as level of education can be associated with outcomes (2). However, the possibility that the 2 groups differ significantly in terms of education level, is reduced by the randomization. Another limitation concerned the similarities in the 2 treatment methods. Both were short-term interventions based on a non-injury and biopsychosocial models for pain assessment, and both practised patient education. There was no use of audiotaping in order to ensure adherence to the protocol in this study; nor was there any blinding of patients or therapists for practical reasons. Audiotaping might have strengthened the study due to quality control of treatment teams.

#### *Conclusion*

The MI, focusing, in particular, on the work situation, appeared to hasten RTW in patients who were certified sick with musculoskeletal pain, and to be beneficial for those who perceive LSW, compared with the BI. However, from a 1-year perspective, there was no difference between the MI and BI regarding RTW. Patients who believed work was the cause of their pain were found to RTW faster in both groups. Psychiatric comorbidity was a negative predictor for RTW at the 3-month follow-up, as was duration of sick leave by baseline at the 12-month follow-up.

The MI, as applied in this study, represents a novel approach. Further studies are needed to draw conclusions about the effects of this method compared with those of BI.

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# Multidisciplinary Intervention in Patients with Musculoskeletal Pain: a Randomized Clinical Trial

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## Abstract

**Background** Musculoskeletal pain is associated with comorbidity, extensive use of health services, long-term disability and reduced quality of life. The scientific literature on effects of treatment for musculoskeletal pain is inconclusive.

**Purpose** The purpose of this study is to compare a multidisciplinary intervention (MI), including use of the novel Interdisciplinary Structured Interview with a Visual Educational Tool (ISIVET), with a brief intervention (BI), on effects on mental and physical symptoms, functioning ability, use of health services and coping in patients sick-listed due to musculoskeletal pain.

**Method** Two hundred eighty-four adults aged 18–60, referred to a specialist clinic in physical rehabilitation, were randomized to MI or BI. Patients received a medical examination at baseline and completed a comprehensive questionnaire at baseline, 3 months and 12 months.

**Results** Both groups reported improvements in mental and physical symptoms, including pain, and improved functioning ability at 3 and 12 months, but the MI group improved faster than the BI group except from reports of pain, which had a

similar course. Significant interactions between group and time were found on mental symptoms (anxiety ( $p < 0.05$ ), depression ( $p < 0.01$ ), somatization ( $p < 0.01$ )) and functioning ability ( $p < 0.01$ ) due to stronger effects in the MI group at 3 months. At 3 and 12 months, the MI group reported significantly less use of health services (general practitioner ( $p < 0.05$ )). At 12 months, the MI group reported better self-evaluated capability of coping with complaints ( $p < 0.001$ ) and they took better care of their own health ( $p < 0.001$ ), compared to the BI group.

**Conclusion** The results indicate that the MI may represent an important supplement in the treatment of musculoskeletal pain.

**Keywords** Randomized clinical trial · Chronic musculoskeletal pain · Multidisciplinary treatment · Patient education tool

## Introduction

Musculoskeletal pain conditions such as fibromyalgia and low back pain are, in the majority of cases, unspecific and composite [1]. Although non-malignant, they represent substantial suffering and economic loss for the individual itself and for the society due to frequent contacts with the health care system, absence from work and reduced quality of life [2–6]. In Norway, musculoskeletal diagnoses represent about 45 % of the long-term sick leave [7]. Most of the patients have other subjective health complaints as well, where pathological findings are absent or substantially less than expected, compared to the reported intensity of the complaints [8]. There is general consensus in the literature that these conditions are multicausal [9] and comorbid [8, 10, 11]. Psychological and social factors, as well as somatic pathology, influence chronicity and

**Trial Registration** <http://www.clinicaltrials.gov>, with registration number NCT01346423

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disability [12]. This indicates that the optimal treatment should focus on several aspects of the patient's life [1, 12, 13]. Improved incorporation of patient preferences into treatment recommendations can improve adherence to treatment and thereby improve the clinical outcomes [14]. Multidisciplinary treatment is a well-accepted and well-documented method to treat chronic pain [13, 15, 16], and education combined with physical exercise produces some positive effects in long-term follow-up for fibromyalgia and musculoskeletal pain [13]. The European guidelines for low back pain state that the optimal content of multidisciplinary programs requires further research, but behavioural treatment and stress management are important components of these programs [1]. There is, however, a lack of systematic content or description of such, in many of these programs.

The aim of this study was to compare the effects of a multidisciplinary intervention (MI) and a brief intervention (BI), on mental and physical health complaints, functioning ability and coping in patients on long-term sick leave due to musculoskeletal complaints. The study is part of a randomized clinical trial (trial reg. nr. NCT01346423) where return to work was the main outcome.

## Material and Methods

Five hundred thirty-four patients with musculoskeletal pain referred to a specialist outpatient clinic, at the Department of Physical Medicine and Rehabilitation, Innlandet Hospital Trust, Norway, between 2011 and 2013, were considered for participation in the trial. Patients were referred from general practitioners (GPs) in 48 municipalities in two different counties in the south-eastern part of Norway. The inclusion criteria were as follows: age between 20 and 60 years, at least 50 % sick leave due to musculoskeletal pain for less than 12 months and at least 50 % employed. The exclusion criteria were as follows: pregnancy, current cancer, osteoporosis, recent physical trauma/injury, serious mental illness, rheumatic inflammatory diseases, not capable of understanding and speaking Norwegian or being involved in an on-going health insurance claim. Of the 534 patients, 250 were either not eligible or excluded for different reasons. Two hundred eighty-four (mean age 41.3 years, 54 % females) patients were included in the study and randomized to either MI ( $n=141$ ) or BI ( $n=143$ ) (Fig. 1). The patients included were referred from 136 different GPs who referred between one and eight patients each.

## Interventions

The two interventions were given by different teams and at two different outpatient clinics.

### *The MI with the ISIVET*

**Baseline Treatment Session** A social worker, a physician and a physiotherapist performed the MI. Initially, they consulted the patient successively. Each consultation was two-parted: First, an interview and, eventually, a physical examination and, secondly, the use of ISIVET.

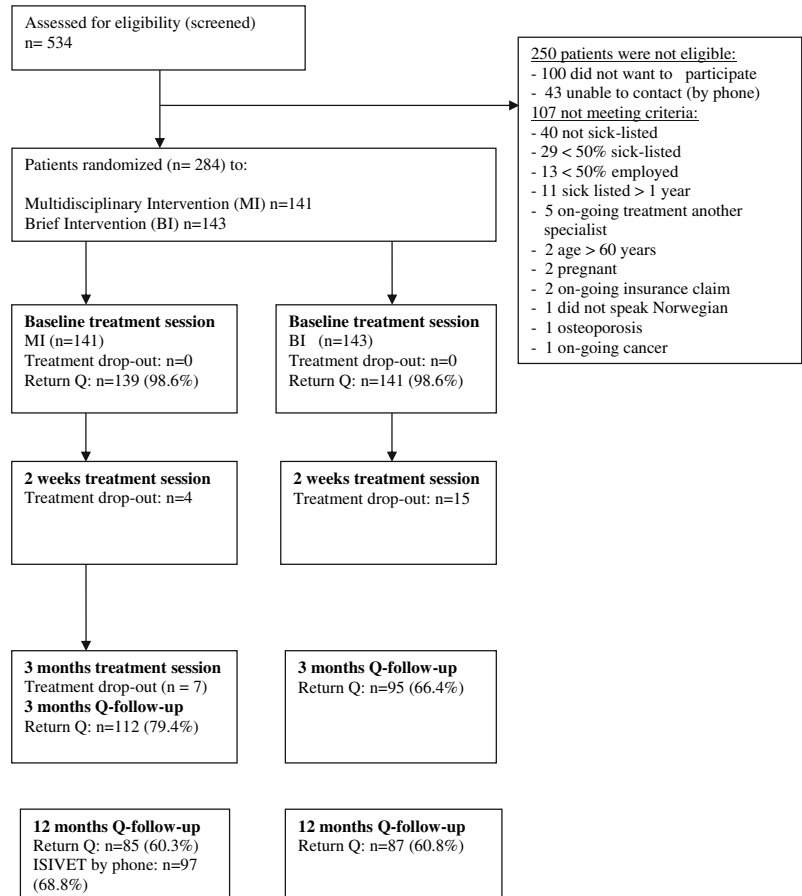
In the first part, the social worker interviewed the patient on her/his social situation (family life, social life, education, economics) and work situation, while the physician did a comprehensive interview covering past and present physical and mental health for the patient and his/her family. The physician also elaborated on coping and fear avoidance in relation to the pain problems, in addition to a physical examination, concluding with a diagnosis according to ICD-10. The physiotherapist assessed the musculoskeletal problems of the patient through interview and a physical examination.

During the second part of each consultation, the therapists used the ISIVET. The method is developed by the first author (RB) and consists of two figures, a manual, a table for filling out a rehabilitation plan and a list where possible rehabilitation initiatives are categorized. Each figure is a star plot with seven axes representing different variables (Fig. 2). Each axis has the range from 1 (centrally) to 10 (peripherally). The patient scored her/himself with assistance from the therapist and guiding from the manual, on each variable on this numeric scale, where "1" indicates a maximum negative situation whereas "10" indicates an optimally positive situation. The manual gives illustrating examples of the situation at different levels. Patient and therapist read the manual together, and through discussion, they identified the right score for each variable and marked it on the actual axis in a paper version of the figure. When all scores were completed, a line was drawn between the seven scores giving an area in each of the two figures. The area under the lines was coloured for better visualization for the patient as well as for the therapists. Problem areas or challenges were demonstrated as lack of colour, while existing resources stood out as coloured area.

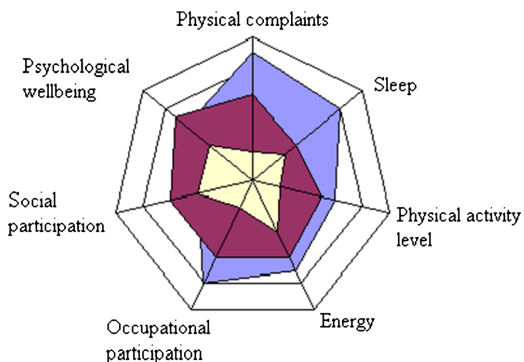
The first figure "working conditions" included the following variables: work-related stress, satisfaction with job tasks, workload, collegial relationships, leadership, degree of challenges at work and occupational participation. It was filled out during the consultation with the social worker. The second figure "quality of life" included the following variables: physical complaints, psychological well-being, sleep, energy, physical activity, social participation and occupational participation and was filled out during the consultation with the physician and the physiotherapist.

When the sessions with the three therapists were completed, the whole team met briefly, sharing their

**Fig. 1** Flowchart of participation, in treatment sessions and questionnaires (Q) follow-up



findings and general impression of the patient and her/his situation at work and at home. Possible barriers to



**Fig. 2** Example of figure “quality of life” filled in three times

work participation, maintaining factors to the on-going pain problems and, eventually, other important issues were highlighted. The patient then joined the meeting to a final discussion with the team on her/his situation, health problems and work situation. The two figures from the ISIVET were central when discussing possible fields of actions. The patient decided ways to go forward, and agreement on actions was written down in a table and categorized according to the standardized protocol. These action items comprised the patient’s rehabilitation plan and were typically related to cognitive assessment of health, as fear avoidance and catastrophic thinking, lifestyle and, if relevant, family and work matters. Actions could also involve physical exercise or increased daily physical activity. When leaving the clinic, the patient received a paper copy of the figures with the coloured areas and the rehabilitation plan listed as points to be followed. A copy of the complete medical



record was sent both to the GP and the patient. The baseline assessment lasted about 3.5 h.

*After 2 weeks*, the patient and the physiotherapist met for about 1 h to evaluate the rehabilitation plan and work through the ISIVET once more. New scores and new areas were marked in the figures made at baseline, and areas were coloured with a new colour (Fig. 2). Visualization of delta areas in the star plot was matter of attention and reflection. Previous advice and actions were highlighted according to this, and adjustments in the rehabilitation plan were eventually made.

*After 3 months*, the patient met with the whole team for about 1 h to sum up the situation and evaluate the interventions so far. The ISIVET was worked through, and new areas on the figures were coloured with a third colour. Eventually, they adjusted the rehabilitation plan.

*At 12 months follow-up*, the physiotherapist contacted the patient by phone to score the two figures in the ISIVET a last time. This was a brief contact that lasted about 15 min.

To ensure adherence to the protocol and equal practice of the method, the MI team had regular meetings for supervision and discussions. Four physicians, all specializing in physical medicine and rehabilitation, two social workers and four physiotherapists did the treatment. The team members were the same during the treatment course of one patient. Audiotaping was not used.

### *The BI*

BI is a standardized intervention based on the studies by Indahl [17] and Molde Hagen [18], and details on the method are described in the pioneer work of Indahl [10, 17].

BI comprised of two sessions. The baseline session lasted about 2.5 h and included separate consultations with the physician and the physiotherapist. After 2 weeks, the patients had a follow-up session with the physiotherapist for about 1 h.

The basic principle of the BI is the non-injury model, emphasizing the lack of any objective signs of injury [17, 19] and the non-directive communication [20, 21]. BI has proven more effective on return to work (RTW), health complaints and functional ability, than usual care both for chronic low back pain and non-specific muscular pain conditions [18, 20]. The goal is to reduce fear and concern through a thorough medical examination with explanations of each step and education about a physiological model on musculoskeletal pain. Any somatic findings are explained. The patient is informed about the good prognosis and the importance of staying active.

A physician who was specialist in physical medicine and rehabilitation and a physiotherapist did the BI. Both were

experienced in the method. Therapist treatment manuals were written for the intervention, based on current guidelines [1] and on the manuals used by Indahl and Molde Hagen [10, 18]. Audiotaping was not used. The physician had been videotaped giving BI in another trial [22]. A copy of the medical record was sent both to the GP and the patient.

### **Randomization and Blinding**

The randomization was concealed, and patients were randomized to either MI or BI, according to a computer-generated randomization list set-up by a statistician at Uni Research Health (URH). URH received information on ID number, gender and age, and a research assistant, not involved in the treatment, contacted URH and was informed on which treatment that the patient should receive. For practical reasons, there was no blinding to treatment of therapists or participants.

### **Dropout from Randomized Treatment**

Patients who dropped out of treatment were asked if they were willing to continue filling out questionnaires and return them by mail.

### **Questionnaires**

The patients received the questionnaires by mail and filled them out at baseline and at 3 and 12 months follow-up. The following questionnaires were applied:

*The Hospital Anxiety and Depression Scale (HADS)* covered symptoms of anxiety and depression [23]. HADS consists of 14 items, of which seven measures anxiety and seven depressive symptoms. Scores are made on a four-point Likert scale ranging from 0 (“not at all”) to 3 (“very often”) on symptoms experienced during the last week, providing 21 as a maximum sum score for each subscale. A cut-off score of eight and above is used as an indication of possible, anxiety or depressive disorder.

*The Hopkins Symptom Checklist-25 (HSCL-25)* measures psychological distress [24]. The instrument consists of 25 questions recording the presence and intensity of the most common symptoms of anxiety, depression and somatization. Severity is scored on a four-point Likert scale from 1 (not at all) to 4 (“very much/to a severe degree”), and a mean score <1.75 is within normal range, while a score ≥1.75 indicates psychological distress in the need of treatment.

*The Norwegian Function Assessment Scale (Norfunk)* measures four aspects of physical function and three aspects of psychological function during the last week by 41 questions [25]. Physical function is related to the patient’s ability to walk/stand, hold/pick, lift/carry and sit.

Psychological function covers the ability to be attentive, communicate, work in team, handle responsibility, handle challenges of daily life, deal with criticism, cope with anger, communicate with others and to look/listen. The answers are scored on a four-point Likert scale from 0 (“no problems”) to 3 (“not able to do the activity”).

*Subjective Health Complaints (SHC) inventory* is a reliable instrument measuring somatic and psychological complaints experienced during the last month [26]. It contains 29 items covering the most frequent subjective health complaints from different parts of the body. Severity is scored on a four-point Likert scale from 0 (not at all) to 3 (“seriously”). The instrument has five subscales: musculoskeletal complaints, gastrointestinal problems, pseudoneurological problems, flu and allergy symptoms in addition to a total score (SHC total).

*Pain* was measured with a Numeric Rating Scale (NRS). The patients were asked about mean pain in the back, the neck, the foot and during activity, at rest and at night for the last 14 days. The severity of pain was scored from 0 (“no pain”) to 10 (“worst possible pain”).

At 3 and 12 months, the patients were asked if they had been treated by GP, chiropractor or physiotherapist or had received other treatment during the last 3 months and, if so, for how many sessions.

At 12 months, the patients were also asked about changes, compared to 1 year ago, in complaints, general health, coping with health complaints, ability to take care of their own health and physical fitness. They were also asked about satisfaction with the treatment. Answers were scored on a five-point Likert scale from 1 (“much better”) to 5 (“much worse”) except from patient satisfaction with treatment which was assessed on a seven-point Likert scale from 1 (“very satisfied”) to 7 (“very dissatisfied”).

## Statistics

A mixed between–within-subjects analyses of variance with one between-group factor (MI vs. BI) and one within-subjects/repeated measures factor (baseline, 3 months, 12 months) were conducted to assess the effect of the two interventions on participant scores on depression, anxiety, somatization (HADS and HSCL), functional ability (Norfunk) and health complaints (SHC). The interaction effects (time  $\times$  group) were calculated, and when significant, such interaction effects indicate different time courses for the two interventions. Interaction effects were followed up by *t* tests for paired samples within each group. Cohen’s *d* was calculated between baseline and 3 months follow-up and baseline and 12 months follow-up using an online calculator (<http://easycalculation.com/statistics/effect-size.php>) based on this formula:  $d = M_1 - M_2 / (\sqrt{(SD_1^2 + SD_2^2) / 2})$ . Differences for outcomes between

the two interventions in scores on pain measured by NRS were analyzed by Mann–Whitney *U* test for independent samples at 3 and 12 months. Differences for outcomes in use of health services, patient-evaluated health changes, coping and satisfaction with treatment at 12 months were assessed with  $\chi^2$  statistics or Fisher’s exact test. Sample size calculations were in accordance with RTW expectations, which are part of this RCT but described in another paper, and based on data from Hagen et al. [18]. The calculation was based on a power of 80 % and a significant level of 5 % giving an *N* for this study of 300.

## Ethical Considerations

The study followed the Helsinki declaration and was approved by the Norwegian Regional Ethics Committee in south-eastern Norway [27] and by the Norwegian Social Science Data Services [28]. Participants gave their informed consent by signing the declaration of voluntarily participation before entering in the study.

## Results

### Demographic and Baseline Data

The study population comprised 284 individuals (mean age 41.3 years, 53.9 % women). Two hundred seventeen (76.4 %) of the patients were married or cohabitant, 195 patients (68.7 %) reported education limited to primary school ( $\leq 12$  years), 56 patients (19.7 %) had no children, and 238 patients (83.8 %) reported 80 % employment or more. Mean duration of sick leave during the 8-month period before entry to the study was 143 days (SD=56.6) in the MI group and 150 days (SD=62.9) in the BI group. The dominant diagnoses in accordance to ICPC-2 [29] were as follows: low back pain L02/L03/L84/L86 (39.5 %), neck pain L01/L83 (12.1 %), widespread pain/fibromyalgia L18 (10.7 %) and shoulder pain L08/L92 (7.8 %). The whole study population constituted 51 different diagnoses, the L group representing 84.2 %. There were no differences in pain diagnoses between the groups at baseline.

### Lost to Follow-Up

The dropout of treatment was low in both groups (Fig. 1). Return of questionnaires dropped to 60.3 % in the MI group and 60.8 % in the BI group at 12 months (Fig. 1). There were no significant differences in baseline scores between returners and non-returners of questionnaires, except from the score on HSCL depression where the non-returners scored significantly lower (mean=1.47, SD=0.46) compared to the returners (mean=1.60, SD=0.55), giving a *p* value <0.05 of the difference.

### Changes in Anxiety, Depression and Somatization

Anxiety and depression measured with HADS and somatization and depression measured with HSCL showed a significant interaction between group and time, indicating that the BI group and the MI group differed significantly on these subscales (Table 1). By 3 months, the MI group reported improvements on anxiety, depression and somatization (all  $p$  values  $<0.01$ ) measured with HADS and HSCL, while the BI group reported a significant worsening on HADS anxiety ( $p<0.01$ ) and a smaller improvement on anxiety, depression and somatization measured with HSCL (all  $p$  values  $<0.05$ ) compared to the MI group. However, at 12 months, the groups were similar, with both groups reporting significantly improvements on all subscales.

### Changes in Functional Ability

Functional ability measured with Norfunk showed a significant interaction between group and time, indicating that the BI group and the MI group had a significantly different time course on the functional ability (Table 2). The MI group had significant improvements from baseline to 3 months on six of seven subscales and on the total score (all  $p$  values  $<0.01$ ), while the BI group had significant, but weaker improvements on two subscales ( $p<0.05$ ). By 3 months, the Cohen's  $d$  was larger on all items of the Norfunk in the MI group compared to the BI group, which had negative value on three subscales, indicating deterioration. By 12 months, both groups had significant improvements from baseline, but with no significant differences between the groups.

**Table 1** Effects of multidisciplinary intervention (MI) and brief intervention (BI) on anxiety, depression and somatization measured by the Hospital Anxiety and Depression Scale (HADS) and Hopkins Symptom Checklist (HSCL)

	MI		BI		Interaction effect <sup>c</sup> (time × group)	
	Mean (SD) <sup>a</sup>	$d^b$	Mean (SD) <sup>a</sup>	$d^b$	$F$ value	$p$ value
HADS anxiety						
Baseline <sup>d</sup>	5.59 (3.29)		5.51 (3.70)			
3 months <sup>e</sup>	4.82 (3.34)**	0.27	5.74 (4.12)**	-0.02		
12 months <sup>f</sup>	4.53 (4.25)**	0.24	4.79 (4.08)**	0.28	3.79	0.02
HADS depression						
Baseline <sup>d</sup>	4.58 (3.42)		4.50 (3.55)			
3 months <sup>e</sup>	3.83 (3.35)**	0.32	4.86 (4.11)	-0.06		
12 months <sup>f</sup>	3.71 (3.85)**	0.21	3.99 (3.65)*	0.23	10.89	<0.00
HSCL somatization						
Baseline <sup>d</sup>	2.01 (0.54)		1.95 (0.58)			
3 months <sup>e</sup>	1.74 (0.49)**	0.63	1.87 (0.70)*	0.15		
12 months <sup>f</sup>	1.69 (0.57)**	0.61	1.73 (0.67)**	0.40	8.01	<0.00
HSCL anxiety						
Baseline <sup>d</sup>	1.47 (0.41)		1.45 (0.40)			
3 months <sup>e</sup>	1.35 (0.34)**	0.38	1.42 (0.43)*	0.17		
12 months <sup>f</sup>	1.32 (0.39)**	0.40	1.33 (0.44)**	0.39	2.17	0.12
HSCL depression						
Baseline <sup>d</sup>	1.54 (0.48)		1.55 (0.56)			
3 months <sup>e</sup>	1.35 (0.38)**	0.50	1.50 (0.58)*	0.19		
12 months <sup>f</sup>	1.39 (0.49)**	0.36	1.40 (0.59)**	0.38	4.14	0.02

\* $p<0.05$  and \*\* $p<0.01$  based on paired samples  $t$  test within each group compared with baseline assessment

<sup>a</sup> Paired  $t$  test, comparing baseline and 3 months, and baseline and 12 months. Separate tests for the BI group and the MI group

<sup>b</sup> Cohen's  $d$  for paired values. A negative Cohen's  $d$  indicates a worsened score compared to baseline. Small effect  $d=0.2$ , medium effect  $d=0.5$ , large effect  $d=0.8$

<sup>c</sup> A mixed between-within-subjects analyses of variance comparing the effect of the BI and the MI intervention (Wilks' lambda),  $F$  value and interaction effects.  $P$ -values  $<0.05$  indicate significant different time courses for the two interventions

<sup>d</sup> Baseline MI:  $n=139$  (98.6 %), BI:  $n=141$  (98.6 %)

<sup>e</sup> 3 months: MI:  $n=112$  (79.4 %), BI:  $n=95$  (66.4 %)

<sup>f</sup> 12 months: MI:  $n=85$  (60.3 %), BI:  $n=87$  (60.8 %)

**Table 2** Effects of multidisciplinary intervention (MI) and brief intervention (BI) on different aspects of functional ability (Norfunk)

	MI		BI		Interaction effect <sup>c</sup> (time × group)	
	Mean (SD) <sup>a</sup>	<i>d</i> <sup>b</sup>	Mean (SD) <sup>a</sup>	<i>d</i> <sup>b</sup>	<i>F</i> value	<i>p</i> value
Norfunk all items						
Baseline <sup>d</sup>	1.44 (0.28)		1.44 (0.30)			
3 months <sup>e</sup>	1.33 (0.29)**	0.43	1.40 (0.33)	0.10		
12 months <sup>f</sup>	1.32 (0.34)**	0.38	1.30 (0.29)**	0.51	5.52	0.01
Coping, handle responsibility, attention, concentration, work, tolerate stress						
Baseline <sup>d</sup>	1.44 (0.41)		1.42 (0.44)			
3 months <sup>e</sup>	1.31 (0.38)**	0.36	1.48 (0.55)	-0.10		
12 months <sup>f</sup>	1.36 (0.44)*	0.24	1.31 (0.38)*	0.27	5.80	0.01
Ability to hold, to pick, to write, to drive, to cook, to dress/undress						
Baseline <sup>d</sup>	1.37 (0.33)		1.36 (0.33)			
3 months <sup>e</sup>	1.27 (0.34)**	0.33	1.32 (0.36)	0.08		
12 months <sup>f</sup>	1.25 (0.35)*	0.34	1.21 (0.30)**	0.48	3.44	0.04
Ability to stand, to walk flat, to walk stairs, to shop						
Baseline <sup>d</sup>	1.55 (0.52)		1.58 (0.50)			
3 months <sup>e</sup>	1.45 (0.47)**	0.29	1.47 (0.45)	0.19		
12 months <sup>f</sup>	1.38 (0.48)**	0.35	1.39 (0.48)**	0.43	1.17	0.31
Ability to lift, to carry, to laundry, to housekeep						
Baseline <sup>d</sup>	1.73 (0.51)		1.71 (0.50)			
3 months <sup>e</sup>	1.53 (0.51)**	0.34	1.58 (0.50)*	0.24		
12 months <sup>f</sup>	1.46 (0.47)**	0.50	1.46 (0.42)**	0.63	0.99	0.37
Ability to sit, to be a passenger in car/bus/train						
Baseline <sup>d</sup>	1.41 (0.55)		1.42 (0.55)			
3 months <sup>e</sup>	1.22 (0.41)**	0.39	1.28 (0.47)*	0.21		
12 months <sup>f</sup>	1.22 (0.41)**	0.36	1.21 (0.37)**	0.45	1.28	0.28
Ability to communicate verbally, written and by phone, to cooperate, to perceive messengers						
Baseline <sup>d</sup>	1.26 (0.35)		1.26 (0.35)			
3 months <sup>e</sup>	1.24 (0.34)	0.08	1.32 (0.41)	-0.12		
12 months <sup>f</sup>	1.29 (0.40)	-0.06	1.28 (0.37)	0.00	0.76	0.47
Ability to watch TV, listen to radio						
Baseline <sup>d</sup>	1.07 (0.19)		1.08 (0.24)			
3 months <sup>e</sup>	1.06 (0.20)	0.07	1.12 (0.29)	-0.12		
12 months <sup>f</sup>	1.09 (0.27)	-0.18	1.07 (0.24)	0.02	3.77	0.03

\* $p < 0.05$  and \*\* $p < 0.01$  based on paired samples *t* test within each group compared with baseline assessment

<sup>a</sup> Paired *t* test, comparing baseline and 3 months, and baseline and 12 months. Separate tests for the BI group and the MI group

<sup>b</sup> Cohen's *d* for paired values. A negative Cohen's *d* indicates a worsened score compared to baseline. Small effect  $d = 0.2$ , medium effect  $d = 0.5$ , large effect  $d = 0.8$

<sup>c</sup> A mixed between-within-subjects analyses of variance comparing the effect of the BI and the MI intervention (Wilks' lambda), *F* value and interaction effects. *P*-values  $< 0.05$  indicate significant different time courses for the two interventions

<sup>d</sup> Baseline MI:  $n = 139$  (98.6 %). BI:  $n = 141$  (98.6 %)

<sup>e</sup> 3 months: MI:  $n = 112$  (79.4 %). BI:  $n = 95$  (66.4 %)

<sup>f</sup> 12 months: MI:  $n = 85$  (60.3 %). BI:  $n = 87$  (60.8 %)

## Changes in SHC

There were no significant interactions between group and time for any of the SHC subscales (Table 3). This indicates that the

two interventions did not affect SHC differently. The Cohen's *d* was larger on all items by 3 months in the MI group compared to the BI group, and the changes from baseline to 3 months were, overall, larger in the MI group by 3 months. By 12 months, the

**Table 3** Effects of multidisciplinary intervention (MI) and brief intervention (BI) on subjective health complaints (SHC)

	MI		BI		Interaction effect <sup>c</sup> (time × group)	
	Mean (SD) <sup>a</sup>	<i>d</i> <sup>b</sup>	Mean (SD) <sup>a</sup>	<i>d</i> <sup>b</sup>	<i>F</i> value	<i>p</i> value
SHC total						
Baseline <sup>d</sup>	20.13 (9.38)		18.42 (9.39)			
3 months <sup>e</sup>	16.12 (8.97)**	0.48	17.34 (10.51)*	0.16		
12 months <sup>f</sup>	15.71(10.22)**	0.42	15.25(10.44)**	0.42	2.20	0.11
SHC musculoskeletal complaints						
Baseline <sup>d</sup>	10.62 (4.24)		10.07 (4.36)			
3 months <sup>e</sup>	8.78 (4.37)**	0.47	8.83 (4.62)**	0.30		
12 months <sup>f</sup>	8.22 (4.73)**	0.50	7.89 (4.79)**	0.57	1.64	0.20
SHC pseudoneurological symptoms						
Baseline <sup>d</sup>	4.96 (3.20)		4.79 (3.59)			
3 months <sup>e</sup>	3.79 (3.11)**	0.43	4.56 (3.69)	0.11		
12 months <sup>f</sup>	3.61 (3.57)**	0.39	3.95 (3.55)**	0.33	1.40	0.25
SHC gastrointestinal symptoms						
Baseline <sup>d</sup>	2.67 (2.91)		1.97 (2.53)			
3 months <sup>e</sup>	2.13 (2.40)*	0.24	2.16 (2.71)	0.02		
12 months <sup>f</sup>	2.29 (2.72)	0.15	1.94 (3.27)	0.11	0.29	0.75
SHC allergy symptoms						
Baseline <sup>d</sup>	1.13 (1.81)		0.91 (1.43)			
3 months <sup>e</sup>	0.82 (1.35)*	0.20	0.89 (1.35)	-0.03		
12 months <sup>f</sup>	0.74 (1.16)*	0.23	0.62 (1.08)*	0.21	2.21	0.11

\* $p < 0.05$  and \*\* $p < 0.01$  based on paired samples *t* test within each group compared with baseline assessment

<sup>a</sup> Paired *t* test, comparing baseline and 3 months, and baseline and 12 months. Separate tests for the BI group and the MI group

<sup>b</sup> Cohen's *d* for paired values. A negative Cohen's *d* indicates a worsened score compared to baseline. Small effect  $d = 0.2$ , medium effect  $d = 0.5$ , large effect  $d = 0.8$

<sup>c</sup> A mixed between-within-subjects analyses of variance comparing the effect of the BI and the MI intervention (Wilks' lambda), *F* value and interaction effects. *P*-values  $< 0.05$  indicate significant different time courses for the two interventions

<sup>d</sup> Baseline MI:  $n = 139$  (98.6 %). BI:  $n = 141$  (98.6 %)

<sup>e</sup> 3 months: MI:  $n = 112$  (79.4 %). BI:  $n = 95$  (66.4 %)

<sup>f</sup> 12 months: MI:  $n = 85$  (60.3 %). BI:  $n = 87$  (60.8 %)

effect sizes were similar for the groups, due to improvements in the BI group from 3 to 12 months, leaving the two groups similar.

### Changes in Pain

Pain by activity (MI group = 6.62 (1.93), BI group = 6.26 (2.11)) and back pain (MI group = 5.97 (2.28), BI group = 5.69 (2.44)) was the main pain problem in both groups at baseline. Both groups had reduction in their average pain levels during the follow-up, but there were no significant differences between the groups at 3 or 12 months on pain by activity or back pain (results not shown).

### Use of Health Services by 3 and 12 Months

By 3 and 12 months, the MI group had consulted their GP significantly less than the BI group ( $p < 0.05$ ): By 3 months

19.4 % in the MI group and 31.8 % in the BI group had received treatment by their GP during the last 3 months, with about equal mean number of treatment sessions: MI = 3.0 and BI = 2.8. By 12 months, the corresponding numbers were 11.8 and 18.5 %, mean MI = 2.5 and BI = 2.3 ( $p < 0.05$ ). There were no significant differences between the groups in consulting other therapists at 3 or 12 months follow-up.

### Changes in Health Complaints/Symptoms, Coping and Satisfaction with Treatment

By 12 months, there were no significant differences between the groups in self-evaluated changes in complaints ( $\chi^2$  (1,  $n = 171$ ) = 3.4); 85 individuals (96.5 %) in the MI group and 86 (98.8 %) in the BI group reported that they still had musculoskeletal complaints. By 12 months, the MI group reported significantly better ability to cope with problems ( $\chi^2$  (1,  $n = 168$ ) = 22.5,  $p < 0.001$ ),

better ability to take care of their own health ( $\chi^2(1, n=165)=17.3, p<0.001$ ) and better physical fitness ( $\chi^2(1, n=165)=15.1, p<0.01$ ) compared to the BI group. The MI group also reported significantly higher satisfaction with the treatment ( $\chi^2(1, n=170)=41.8, p<0.001$ ).

## Discussion

Comparing the effects of a multidisciplinary intervention (MI), including use of the novel Interdisciplinary Structured Interview with a Visual Educational Tool (ISIVET), with a brief intervention (BI) on patients sick-listed due to musculoskeletal pain, revealed no significant differences between groups on mental and physical symptoms and functional ability at 12 months follow-up. However, patients in the MI group had significantly better effect on anxiety, depression, somatization and functional ability at 3 months follow-up, compared to the BI group, and at 12 months follow-up, the MI group reported better ability to cope with their problems, higher ability to take care of their own health and better physical fitness in spite of the same level of pain, and they consulted their GP less than patients in the BI group both at 3 and 12 months.

In Norway, treatment of musculoskeletal pain is primarily done by the patients' GP. Chronic and more complex cases are eventually referred to specialist health care [13, 30, 31]. It is reasonable to assume that our study population consists of chronic and more complex cases, as they had been sick-listed for, on average, 147 days and were referred by their GPs to specialist health care. The GPs had no prior knowledge that their patients might be enrolled into a clinical study.

Typically, episodes of acute musculoskeletal pain including LBP recover quickly, but patients who do not recover tend to have more complex disorders where social factors, work conditions, psychological and somatic factors play together in perpetuating the condition [5, 32–34]. Clinical psychosocial factors predict long-term incapacity of musculoskeletal disorders [35], and multidisciplinary treatments including a psychosocial approach have been proven effective for complex illnesses [15, 36] and are well accepted in treatment of chronic pain [13, 15, 16]. The MI patients received more extensive, multidisciplinary treatment, compared to the BI patients. This may explain why the MI was more effective than the BI at 3 months follow-up, on anxiety, depression, somatization and functional ability. The baseline mean scores on anxiety and depression were low for both groups. A tendency to somatization among these patients where they express stress in somatic symptoms rather than psychologically might indicate that changes in even low scores could be of clinical importance.

Improved communication between patient and health professionals can influence health outcomes and coping in a positive way [37–39]. ISIVET is constructed to improve communication, patient involvement, mutual understanding and enhancing

of the therapeutic alliance. Filling in the ISIVET figures with the therapist may represent a communication where the patient experiences that her/his opinion and experiences are respected and made relevant, leading to a mutual insight and understanding of the situation between patient and therapist. In BI, the communication was a more traditional doctor–patient relationship where the patient was given information and advices about physical activity and exercises to improve their muscle pain.

Earlier trials have shown that patients who are engaged in decision making are more motivated for changes in lifestyle and their clinical outcomes are better [38, 40]. In shared decision making (SDM), the patient's autonomy is strengthened and the relationship with the therapist and the patient is improved [41]. The application of ISIVET in assessment of health complaints can facilitate patient empowerment and SDM. This may lead to improvements of patient satisfaction, adherence to treatment and better health outcomes [42].

Educational tools can influence the patient's expectations and outcomes in a beneficial way compared to traditional health information [43]. When combining education and physical exercise, there are some positive long-term effects for fibromyalgia and musculoskeletal pain [13]. Application of ISIVET where a visualization of the patient's situation was established as coloured areas in the ISIVET figures may facilitate the patient's insight and understanding of the complexity of the situation. This might improve the adherence to the rehabilitation plan. At 12 months, the MI group reported better ability to handle health problems and better physical fitness and they had less use of health care services in spite of fairly the same levels of pain and health complaints as the BI group.

## Limitations and Strengths of the Study

The dropout of treatment was low, but the return of questionnaires at 12 months follow-up (~60 %, both groups) might affect the generalizability of the study. However, analyses showed that non-returners of questionnaires at 12 months had significantly lower scores on HSCL depression at baseline compared to returners. Multiple analyses were performed, possibly increasing the risk of finding low *p* values by coincidence. The patients in the MI group received more therapist time, which may have influenced the results. For practical reasons, there was no blinding of patients or therapists for the different treatments. The treatment sessions were unfortunately not videotaped, but therapists in the BI group had been videotaped previously [22]. Manuals were written for both treatments to ensure equal practice of the methods. The BI group had fewer and more experienced therapists compared to the MI group; however, the therapists in the MI group had regular meetings and supervision. The first author developed the ISIVET and treated 29 patients. However, the outcomes were based on the questionnaires that patients filled in at home before the consultations, not on scores in the ISIVET.

## Conclusions

The results indicate that the new MI may represent an important supplement in the multidisciplinary therapeutic work in patients with chronic musculoskeletal pain and that visualization, shared decision and multidisciplinary assessment can reinforce the effect of treatment. The MI with the ISIVET should be applied in new studies to see if results could be reproduced or improved further.

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**Conflict of Interest** Randi Brendbekken, Anette Harris, Holger Ursin, Hege R. Eriksen and Tone Tangen declare that they have no conflict of interest.

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## MANUAL FOR UTFYLING AV STJERNEDIAGRAM

Prinsipp: Jo høyere score, jo mer positivt og også jo større areal i figuren.  
 1 er laveste score, 10 er høyeste.  
 Du eksemplifiserer hva de ulike nivåene tilsier i praksis.  
 Pasienten scorer i forhold til sine egne normer (hva som er godt nok/standard for han/henne)

### STJERNEDIAGRAM - LIVSKVALITET

Kvalitet/ Score	1	3	5	8	10
<b>Fysiske plager</b>	Invaliderende fysiske plager som setter det meste av normal aktivitet til side, evt. mest sengeliggende, dagene domineres av disse plagene, ingen aktivitet er ikke berørt. Livsutfoldelsen er kraftig begrenset.	Har relativt store fysiske plager, hver dag er preget av dette og de fleste aktiviteter er berørt av dette. Begrenser mange aktiviteter.	Har moderat uttalt med fysiske plager. Fungerer greit i forhold til mange gjøremål, men har også daglig visse aktiviteter som ikke kan gjennomføres el. må "porsjoneres" ut.	Fungerer bra i forhold til mange aktiviteter. Kan ha gode dager med tilnærmet normal funksjon, men like vanlig at dagene er noe preget.	Ingen fysiske besvær utover det som anses normalt. Har ingen fysiske hindringer/begrensninger som er forårsaket i kroppslige forhold.
<b>Psykiske plager</b>	Betydelig plager med angst, indre uro eller følelse av tristhet, nedstemthet. Følelsen er konstant tilstede, overveldende. Preger enhver situasjon.	Kjenner daglig på indre uro og/el. bekymring. Påvirker disposisjoner	Moderat uttalte plager med angst/indre uro eller nedstemthet i en slik grad at livet ikke kjennes så godt som det kunne/burde vært	En viss uro el. bekymring men også mange dager med fravær av slik.	Helt ordinær følelse av indre ro og velvære. Ingen nedstemthet eller depressive tanker/uro/bekymringer om fremtid, helse etc.
<b>Søvn</b>	Dårlig, hver natt er preget av søvnløshet mesteparten av natta	Betydelig redusert søvnkvalitet og minst 50% redusert antall timer med søvn	Innsøvnings-problemer eller problemer med mange oppvåkninger el. tidlig oppvåkning. Redusert søvnkvalitet minst halvparten av nettene.	Bare helt sporadiske søvnproblemer, max 1-2 netter per uke.	Sover helt normalt og føler seg uthvilt etter natten, ingen tidlig oppvåkning.
<b>Energi-nivå/ Over-skudd/ Tretthet</b>	Føler seg helt tappet for krefter og overskudd. Store problemer med å ta initiativ. Passiv. Ligger mye.	Slitenhetsfølelse konstant til stede. Har sluttet med mange gjøremål	Kjenner til daglig på manglende overskudd. Vegrer seg for gjøremål. Må hvile el. avstå fra ting daglig	Har dager hvor overskudd og energi er tilfredsstillende men dager hvor mangel på energi dominerer	Har det nødvendige overskudd, holder sitt ønskede aktivitetsnivå uten vansker
<b>Fysisk aktivitets-nivå</b>	Inaktiv, ingen regelmessig fysisk egenaktivitet med tanke på trening	Kun sporadisk, ikke ukentlig	Regelmessig 0-1 ganger ukentlig	Regelmessig 2-3 ganger ukentlig	Fysisk aktivitet, kondisjonsbasert, minst 3-4 ganger ukentlig og minst 30 min hver gang.
<b>Sosial deltagelse</b>	Sosialt isolert, ufrivillig, som representerer en stor forandring fra slik det ellers har vært.	Helt sporadisk sosial deltagelse, langt mindre enn hva behovet tilsier	Har noe sosial deltagelse, men savner mer, har klart mindre enn behovet egentlig tilsier.	Brukbart men ikke optimalt med sosial deltagelse. Ønsker seg regelmessig noe mer	Har sosial deltagelse som fullt ut dekker de behov vedkommende har.
<b>Yrkes-deltagelse</b>	Ingen, 100% sykemeldt	75% sykemeldt	50% sykemeldt	25% sykemeldt	I full jobb (i sin stilling om den er fulltid el. deltid)

## STJERNEDIAGRAM - YRKESFORHOLD

Kvalitet/ Score	1	3	5	8	10
<b>Tilfredshet med arbeidsinnhold</b>	Misliker arbeidsoppgavene.	Trives ikke noe særlig med arbeidsoppgavene noen er greie.	Trives brukbart med arbeidsoppgavene	Synes det er greie arbeidsoppgaver. Trives godt.	Fullt ut tilfredsstillende. Stortrives med arbeidsoppgavene
<b>Tilfredshet med arbeidsmengde</b>	Helt håpløst (altfor mye el. altfor lite). Veldig frustrert over situasjonen.	Konstant "overloaded" med jobb. Føler seg stort sett alltid på etterskudd.	Brukbar mengde jobb, periodevis for mye men har like mange perioder med kontroll på sit.	Godt tilpasset arbeidsmengde. Føler seg bare av og til frustrert over arbeidsmengde, ikke ukentlig.	Perfekt dosering av arbeidsmengde, klarer å ta unna fortløpende, føler seg effektiv og produktiv.
<b>Tilfredshet med grad av stress</b>	Overveldende mye stress, hver dag, hele tiden. Følelse av mangel på kontroll hele tiden.	Et stressnivå som preger arbeidet på et generelt grunnlag, stort sett daglig og kilde til frustrasjon mer enn halvparten av arbeidstiden/ Dagene	Tidvis stress som negativt påvirker arbeidsdagene, omtrent 50/50	Stort sett et stressnivå som ikke gjennomsyrrer arbeidssituasjonen	Helt perfekt mengde stress, kun positivt det som er. God følelse av kontroll.
<b>Tilfredshet med grad av utfordringer</b>	Altfor lite eller mye utfordringer. Ressursene står overhode ikke i samsvar med krav.	Generelt sett sparsomt med utfordringer	Greit med utfordringer, en god del oppgaver som i positiv forstand gir mulighet til egne vurderinger og problemløsning	Jevnt over bra med utfordringer. Langt opp mot hva jeg synes er tilfredsstillende og nødvendig.	Perfekt samsvar mellom utfordringer og ressurser. Følelse av "FLYT" sone. Får brukt seg i positiv forstand. Opplevelse av læring og utvikling.
<b>Tilfredshet med kollegiale forhold</b>	Helt håpløse kollegiale forhold. Avstand og mangel på kontakt og mellommenneskelig engasjement	Ikke spesielt gode kollegiale forhold. Egentlig en viss belastning å forholde seg til arbeidsmiljøet.	Greie relasjoner og stort sett bra klima mellom ansatte. Trives greit.	Gode kollegiale forhold. Føles som et ekstra pluss ved jobben.	Svært gode kollegiale forhold, støttende og deltagende miljø. God kommunikasjon
<b>Tilfredshet med ledelse</b>	Fravær av ledelse, kaotisk og uoversiktlig, unnfallem, kritikkverdig, respektløs	Misfornøydhet med ledelsen på flere viktige områder.	Greie ledelsesforhold men skulle gjerne ønsket bedring på en del områder.	Stort sett fornøyd med ledelsen både ledelsesfaglig og menneskelig	Svært bra ledelse, tilstedeværelse, tydelighet, god kommunikasjon, tilbakemeldinger og respekt
<b>Grad av yrkesdeltagelse</b>	100% SM Ingen yrkesaktivitet	75% SM	50% SM	25% SM	Full yrkesdeltagelse Ingen SM





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