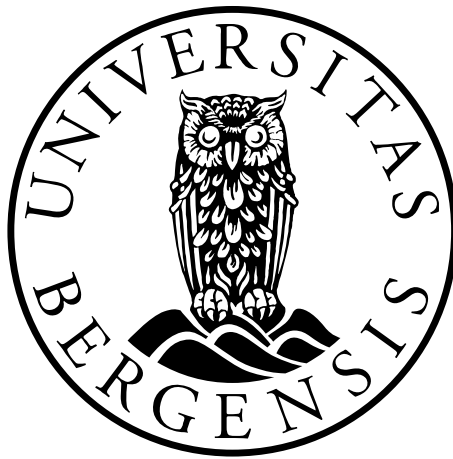


Staying at Work

The role of expectancies and beliefs in health and workplace interventions

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Dissertation for the degree philosophiae doctor (PhD)
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Scientific environment

The work presented here is a collaboration between the research groups SIPA (Social Influence Processes on Adolescent health) at the Research Centre for Health Promotion, Faculty of Psychology (HEMIL), the research group Stress, Health and Rehabilitation at Uni Research Health and the Division of Physical Medicine and Rehabilitation, Vestfold Hospital Trust, Stavern.

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Abstract

Work is an important part of life for the working population, and thus the workplace is an important arena for health promotion. Since low back pain (LBP) constitute the main reason for sick leave among employees, workplace interventions should target these complaints. There is, however, limited evidence regarding prevention and effective treatments of LBP. Therefore, interventions should aim at preventing the negative consequences of LBP, such as sick leave, fear of movement, and inactivity, as research has shown that this is possible. This was the idea behind atWork, a back pain information and reassurance intervention at the workplace. The goal of atWork was to change employees' negative beliefs about back pain, and increase their positive expectancies of being able to stay at work despite back pain. The intervention was based on the Non-Injury Model (NIM), which is developed to understand and treat common LBP. According to this model, the spine is a strong structure, and pain is seldom a sign of injury caused by strain or heavy loadings.

Several studies have shown that interventions based on NIM are effective regarding return to work among LBP patients. However, more information concerning the effect of such interventions in preventing sick leave, in addition to knowledge of possible predictors of effect, is needed. Furthermore, participants' experiences with such interventions would be helpful to increase knowledge of important and helpful aspects with the interventions. It is especially interesting to explore the role of expectancies and common beliefs about back pain, as these factors are specifically targeted in the interventions.

The overall aim of this thesis was to increase knowledge about the influence of expectancies and beliefs in health and workplace interventions. The Cognitive Activation Theory of Stress (CATS) and NIM is the theoretical framework of the thesis.

This thesis consists of three papers; two quantitative based upon data from the atWork study, and one qualitative based upon data from focus group interviews.

atWork was conducted in two Norwegian municipalities in the period 2008-2010. The intervention was provided to all employees in the municipalities (approximately 3,500 employees), and 1,746 of these provided questionnaire data. Paper I was a cross-sectional study based on baseline data from atWork ($n = 1,746$). Paper III was a cluster-randomised controlled trial, where questionnaire data was merged with register data on sick leave up to one year subsequent to the intervention. Only those who consented to obtain register data were included ($n = 846$). Paper II was a focus group study with participants in an outpatient NIM-based intervention. Three focus groups with a total of 10 participants were conducted.

The aim in Paper I was to examine the mediating effect of response outcome expectancies (helplessness and hopelessness) between physical workload and health and between education and health. The results showed that helplessness/hopelessness partially mediated the effect between workload and health for both genders, but the mediating effect between education and health was only significant in women.

The aim in Paper II was to explore how a back pain information and reassurance intervention at an outpatient clinic contributed to increase participants' positive response outcome expectancies. Important aspects were trust in the lecturers and having the information delivered in a comprehensible way. Better understanding of their pain, that it was not a sign of a severe disease, changed their perceptions of how they could live with the back pain.

The aim in Paper III was to explore whether the atWork intervention could prevent sick leave, and if expectancies, beliefs, and level of LBP could predict this effect. The results showed that the intervention could prevent sick leave up to six months subsequent to the intervention. Low levels of pain-related fear were the only variable that predicted the effect of the intervention.

The findings from this thesis show that expectancies and beliefs are important to health, and targeting these factors in interventions can contribute towards participants coping better and staying at work. However, the effect of atWork on sick leave was only present up to six months. Future interventions should explore if repetition of the

intervention message over time can result in a more long-lasting effect. In addition, environmental, structural, and social factors at work should be taken into account, in order to facilitate opportunities for the employees to cope and stay at work.

Sammendrag

Arbeid er en viktig del av livet for den yrkesaktive befolkningen, og arbeidsplassen er derfor en viktig arena for helsefremmende arbeid. Ryggplager utgjør hovedårsaken til sykefravær blant ansatte, og tiltak på arbeidsplassen derfor bør rette seg mot disse plagene. Det er imidlertid begrenset dokumentasjon på forebygging og effektive behandlinger av ryggplager. Tiltak bør derfor ta sikte på å forebygge de negative konsekvensene av ryggplager, som for eksempel sykefravær, frykt for bevegelse, og inaktivitet, siden forskning har vist at dette er mulig. Dette var ideen bak iBedrift, en arbeidsplassintervensjon basert på å gi informasjon om- og ufarliggjøre vanlige ryggplager. Målet med iBedrift var å endre ansattes negative oppfatninger om ryggplager, og øke deres positive forventninger om å kunne være i jobb på tross av plager. Intervensjonen var basert på en ikke-skademodell som er utviklet for å forstå og behandle vanlige ryggplager. Ifølge denne modellen, er ryggraden en sterk struktur, og smerte er sjelden et tegn på skade forårsaket av for eksempel belastninger og tunge løft.

Flere studier har vist at intervensjoner basert på ikke-skademodellen er effektive for retur til arbeid blant ryggpasienter. Det er imidlertid behov for mer informasjon om effekten av slike intervensjoner for å forebygge sykefravær, i tillegg til kunnskap om mulige prediktorer for effekt. For å få mer kunnskap om viktige og nyttige aspekter ved slike intervensjoner, er det også behov for mer informasjon om deltakernes erfaringer med intervensjonene. Det er spesielt interessant å undersøke hvilken rolle forventninger og grunnleggende antakelser om ryggplager spiller, da intervensjonene er spesielt målrettet mot disse faktorene.

Det overordnede målet med denne avhandlingen var å øke kunnskapen om betydningen av forventninger og grunnleggende antakelser om ryggplager, for helse og arbeidsplassintervensjoner. Den kognitive aktiveringsteori om stress og ikke-skademodellen utgjør det teoretiske rammeverket for oppgaven.

Denne avhandlingen består av tre artikler; to kvantitative basert på data fra iBedrift-studien, og en kvalitativ basert på data fra fokusgruppeintervjuer. iBedrift ble gjennomført i to norske kommuner i perioden 2008-2010. Intervensjonen ble gitt til alle ansatte i kommunene (ca. 3500 ansatte), og 1746 av disse fylte ut spørreskjemadata. Artikkel I var en tverrsnittsstudie basert på grunnlagsdata fra iBedrift (n = 1746). Artikkel III var en klynge-randomisert kontrollert studie, hvor spørreskjemadata ble slått sammen med registerdata på sykefravær opp til ett år etter intervensjonen. Bare de som samtykket til å innhente registerdata ble inkludert (n = 846). Artikkel II var en fokusgruppestudie med ryggpasienter som hadde deltatt i en poliklinisk intervensjon basert på ikke-skademodellen. Tre fokusgrupper med til sammen 10 deltakere ble gjennomført.

Målet med Artikkel I var å undersøke om responsutfallsforventningene hjelpeløshet og håpløshet kunne mediere effekten av arbeidsbelastning og utdanning på helse. Resultatene viste at hjelpeløshet/håpløshet delvis medierte effekten mellom arbeidsbelastning og helse for begge kjønn. Den medierende effekten mellom utdanning og helse var kun signifikant blant kvinner.

Målet med Artikkel II var å utforske hvordan en poliklinisk intervensjon som var basert på å gi informasjon om- og ufarliggjøre vanlige ryggplager bidro til å øke deltakernes positive responsutfallsforventninger. Viktige aspekter var tillit til foreleserne og at informasjonen ble formidlet på en forståelig måte. Økt smerteforståelse, og vissheten om at plagene ikke var et tegn på en alvorlig sykdom, endret deltakernes oppfatninger av hvordan de kunne leve med ryggplagene.

Målet med Artikkel III var å undersøke om iBedrift kunne forebygge sykefravær, og om forventninger, grunnleggende antakelser om ryggplager, og grad av ryggplager kunne predikere denne effekten. Resultatene viste at intervensjonen kunne forebygge sykefravær opptil seks måneder etter intervensjonen. Et lavt nivå av smerterelatert frykt var den eneste variabelen som predikerte effekt av intervensjonen.

Resultatene fra denne avhandlingen viser at forventninger og grunnleggende antakelser om ryggplager spiller en viktig rolle for helse. Intervensjoner rettet mot

disse faktorene kan bidra til økt mestring og arbeidsdeltakelse blant deltakerne. Effekten av iBedrift var imidlertid kun til stede de første seks månedene etter intervensjonen. Fremtidige intervensjoner bør derfor undersøke om repetisjon av intervensjonen over tid kan resultere i en mer langvarig effekt. Det bør også tas hensyn til strukturelle og sosiale arbeidsfaktorer, for å bedre mestringsmuligheter for de ansatte, og øke sannsynligheten for at de blir værende i jobb.

List of publications

1. Ree, E., Odéen, M., Eriksen, H.R., Indahl, A., Ihlebæk, C., Harris, A.
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2. Ree, E., Harris, A., Tveito, TH., Indahl, A., & Malterud, K. How can a brief intervention contribute to coping with back pain? A focus group study about participants' experiences. *Scandinavian Journal of Public Health*. 2014;42(8):821-826. doi: 10.1177/1403494814554029.
3. Ree, E., Lie, S.A., Eriksen H.R., Malterud, K., Indahl, A., Samdal, O., Harris, A. A cluster-randomized trial of a peer-based low back pain information and reassurance intervention at the workplace: The effect on sick leave and predictors of outcome. Submitted.

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1. Introduction

1.1 My preconceptions

When I worked as a research assistant on data from the atWork study (a back pain information and reassurance intervention at the workplace) in 2012, I went on a field observation in Tønsberg at an educational non-injury based course for back pain at an outpatient clinic, where I saw with my own eyes what happened to a participant. I sat in the back row and noticed a woman who came into the room before the course started. The way she moved and bent her knees with her back straight when she sat down indicated that she might be uncertain and afraid to move in a way that could worsen her back pain. When the course was over, she grabbed her purse from the floor, swung it over her shoulder, and went easily and freely out of the room without paying attention to her back at all. I was convinced that if everyone with back pain received this non-injury based information, their positive response outcome expectancies would increase and the sick leave rates and number of available treatment options for back pain would decrease. This was the beginning of my interest in the *Non-Injury Model* (NIM). Several success stories from Aage Indahl's practice experiences also encouraged me to explore this model.

My interest in positive psychology and resource-oriented approaches towards individuals evolved when I took my master's degree in health promotion and health psychology at the University of Bergen from 2009-11. The health psychology part was taught by an excellent and inspiring lecturer (now my supervisor Anette Harris) who introduced me to the *Cognitive Activation Theory of Stress* (CATS), a theory that explains how individuals' expectancies might affect health and illness (1). I quickly became fascinated by the theory and the concept of coping, and decided to explore this issue in my master's thesis. The work with my master's thesis also led to my interest in the workplace as an arena for *health promotion*.

In my research group at Uni Research Health, the focus is on individual rather than structural and environmental factors regarding explanatory models and interventions,

which has affected my perspectives when conducting research, as the focus in this thesis is mainly on the individual. However, I have also explored and discussed the role of structural factors such as education and physical workload on health. Most of the research in the group is based on CATS, and most of the interventions that are explored have elements of cognitive therapy in them and are explored through Randomized Controlled Trials (RCT). I have no clinical education or experience and thus my practical knowledge of how coping is acquired and the role of environmental factors is scarce. I wondered why atWork showed an effect on sick leave (2), since preventive health promoting interventions directed towards populations seldom has an effect in RCTs, especially in a short time frame (3). To find out how the atWork intervention worked to increase individuals' coping, I decided to ask the participants. My scientific background is primarily within quantitative methodology, using hypothetic-deductive methods. However, I have used a combination of inductive and deductive methods in this thesis, based on the questions I was interested in exploring.

Based on my previous experiences and knowledge, especially regarding CATS, my preconception was that individual factors such as cognitions and emotions had a stronger impact on health, illness, and sick leave than work-related factors or other factors outside the individual. I also thought that the approach used in atWork would increase the participants' *positive response outcome expectancies* as defined in CATS by reducing their feeling of insecurity regarding their health complaints, which in turn would prevent sick leave.

1.2 Health

“Health is created and lived by people within the settings of their everyday life; where they learn, work, play and love” (4, p.4).

For the past century, health care has been dominated by the biomedical model, which assumes that all symptoms imply disease. In this model, health is defined as the absence of disease, and disease involves pathology or impaired body function that is possible to detect and diagnose (5). The biomedical approach has been criticized for

being reductionist, dualistic, and excluding and for not recognizing the behavioural, psychological, and social aspects of illness (6). Furthermore, it leaves no room for positive aspects of health, or the subjective feeling of illness or complaints.

The founders of the World Health Organization (WHO) proposed a more positive definition of health: "*A state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity*" (7, p.1). The definition has often been criticized for being utopian, as the requirement of complete physical, mental, and social wellbeing would leave most of us unhealthy most of the time (8, 9). The Ottawa Charter on Health promotion added to the original WHO definition by stating that health is "*A resource of everyday life, not the objective of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities*" (4, p.1). Based on the WHO definitions, health is something else or something more than just the absence of disease. The focus is largely on the subjective feeling of being well.

Although subjective wellbeing and perceived health are two different constructs, the correlation between them is strong (10). In the study by Røysamb (10), subjective wellbeing comprised items measuring general life satisfaction. Others have used a multi-dimensional occupational wellbeing construct, where psychosomatic wellbeing constitutes one of the dimensions (11). In this thesis I will emphasize subjective experiences of health and illness, which is measured on a continuum, rather than requiring complete states of physical, social and mental wellbeing. The setting is the workplace. Health is measured by the *Subjective Health Complaints* (SHC) inventory (12), and by a question concerning general health (13).

Subjective health complaints are common complaints that are often characterized by few, if any, objective findings, or the subjective experience is inconsistent with the objective findings (12). The prevalence of SHC in the general population is high, as approximately 90% report one or more subjective health complaints during the past 30 days (12, 14, 15). The complaints also seem to be prevalent in the other Nordic countries (16) and in populations that do not live in industrialized countries (17, 18).

Most people do not seek medical assistance for these complaints, but for some they turn into intolerable conditions with a major influence on quality of life and work participation (12, 19). *Low back pain* (LBP) is the most common single complaint related to sick leave and disability (20-22), making it especially important to target these complaints in sick leave interventions.

Several concepts other than subjective health complaints are used in research referring to the same or similar phenomenon. Other concepts such as psychosomatic complaints, medically unexplained symptoms (MUS), medically unexplained physical symptoms (MUPS), functional disorders, and somatization disorders are often used as labels for common health complaints (23). Common to all of these are a lack of objective findings related to the experience of symptoms. A recent review by Malterud et al. (24) highlights that symptoms do not necessarily indicate a disease, but that it is important to recognize any symptom as real even when it does not fit a medical finding. The term subjective health complaints is a neutral and descriptive term, without assumptions of causality, and with no restrictions regarding diagnosis and intensity of symptoms (25), and is therefore used in this thesis.

1.3 Social inequality in health

The association between *Socioeconomic Status* (SES) and health is well documented (26, 27). Systematic differences in health between socioeconomic groups measured by income, occupation, and education are present both between countries and within countries, and seem to follow a gradient (26-28). Furthermore, these differences are socially produced, unjust and avoidable (29). Reducing social inequalities in health is thus a central task in health promotion, which is reflected in several international and national documents (27, 30-34).

Lower socioeconomic groups have, compared with higher socioeconomic groups, higher prevalence of poor self-reported health (e.g., self-rated general health, subjective health complaints, chronic illnesses, disability), higher prevalence of specific diseases (e.g., myocardial infarction), and higher rates of mortality (35). The

socioeconomic gradient in health is not confined to low-income countries, but is equally prominent in countries with well-established welfare systems (36). Thus, the gradient is also a problem in Norway (31, 37-39), despite the fact that the country is a world leader in living and health standards (40).

The reasons for socioeconomic inequalities in health are explained in different ways, where the question of causality is an important part of the debate. Is poor health a result of low socioeconomic status (social causation), or is low socioeconomic status a result of poor health (social drift or selection)? There is some consensus that the primary causal direction goes from the social environment to health and not vice versa (26, 41, 42). Furthermore, it is debatable through which mechanisms socioeconomic status affects health (41). The explanations can often be classified into structural or individual factors, although these categories are probably interacting. According to McCartney et al. (43), health inequalities are best explained by a structural theoretical perspective, although behavioural theories can provide insight regarding the mechanisms through which inequalities are generated. Eriksen and Ursin (44) have proposed a hypothesis that social inequalities in health might depend on the individuals' response outcome expectancies, acquired by learning and experiences. Psychological responses and behaviour are, however, shaped by the surrounding environment (41). According to the personal view of the leader of the WHO's research group on health inequalities for the past 30 years, Professor Michael Marmot, "*the mind is a crucial gateway through which social influences affect physiology to cause disease*" (42, p.135). I therefore wanted to explore the role of cognitive factors such as expectancies in relation to social inequalities in health in this thesis.

1.4 Work and health

Work constitutes an important part of life for the working population, as most people spend half of their awake time at work. In a large review, Waddel and Burton (45) found evidence that work is generally good for both physical and mental health and

wellbeing, and is also central to individual identity, social and socioeconomic status, social roles, and the economy.

On the other hand, various physical and psychosocial aspects of work can in some instances pose a health risk (45). Material workplace hazards such as exposure to harmful materials and accidents have been reduced in the western world as a result of increased focus on health safety and environment research and management, as well as governmental regulations and introduction of new standards (46). However, there are still aspects related to work and the work environment that can pose a threat to health among employees.

The research literature on work and health is to a large extent concerned with possible long-term strains from work conditions, especially in the back pain literature. High levels of physical workload and mechanical risk factors, such as arm flexion, strain and heavy lifting, increase the risk of musculoskeletal complaints (47-49). For several decades, the focus on risk and strain has dominated the musculoskeletal field. Lately, however, this has been challenged by a *non-injury based approach* to back pain (50, 51). According to the European Guidelines for prevention (52) and management (53) of low back pain, work attendance has primarily positive health effects on low back pain.

The psychosocial working environment is important to health. Several studies have demonstrated that factors such as high job demands, low control, interpersonal conflicts, and effort-reward imbalance can predict both physical and mental health problems (54-59). According to WHO, psychosocial risks are related to the experience of work-related stress (60), where the latter is defined as individuals' responses to demands and challenges that do not match their abilities and knowledge, and thus challenge their ability to cope (61). Employees with high levels of coping report fewer health complaints, despite having high job demands (62). Based on these findings, in this thesis I chose to explore the role of expectancies and physical workload on subjective health.

1.5 Sick leave

Statistics Norway defines sick leave as “*agreed work days that are lost because of own illness*” (63). I will use this definition in this thesis.

Sick leave is a complex phenomenon, and there are differing opinions regarding the factors that are most important for onset and durability of sick leave, and how best to prevent and reduce it. There is less disagreement regarding the possible negative consequences of sick leave. At an individual level, multiple episodes of sick leave are in itself a risk factor for not returning to work (64) and disability is a risk factor for early death (65). Furthermore, sickness compensation constitutes a vast cost to the society, and even marginal reductions and improvements would produce considerable socioeconomic savings. It is therefore important to develop research knowledge about the causes of sick leave, as well as how to prevent and reduce it.

The costs in Norway related to sick leave and disability are twice as high as the average costs of the other OECD countries. The OECD countries spend on average 1.9% of their GDP on sick leave, while Norway spends 4.8% of its GDP (66). The sick leave compensation scheme in Norway is among the most comprehensive in the world. It is often debated whether the generous sick leave schemes are the reason why Norway has one of the world’s highest rates of sick leave. However, it is also debatable whether the sick leave rate in Norway really should be reduced, as it may be the result of an inclusive working life (67, 68). For example, compared with other OECD countries, Norway has high employment rates, even among groups that are often underrepresented in working life, such as women, the elderly, and the disabled (68).

According to Henrekson and Persson (69), more generous sick leave compensations are usually associated with permanent increases in sick leave, and vice versa.

However, sick leave can in some instances serve as a coping strategy (70). It has also been shown that employees who go to work even if they are sick stay sick longer, lower both their own and their co-workers’ productivity, and can infect co-workers

and customers (71). Sick leave is of course often necessary for recovery and used as a part of treatment.

Although some sick leave is necessary, the consequences of sick leave are clear both at the individual and societal level, especially when it is long lasting. However, the causes are not. Diagnoses such as cancer and heart disease account for only a minor part of the sick leave in Norway (22). Subjective health complaints, on the other hand, mainly musculoskeletal complaints, constitute most of the long-term sick leave (14, 21, 22). Of these, low back (LBP) pain is the single complaint that is most strongly related to sick leave and disability (20-22). There are limited evidence regarding prevention (52) and effective treatments (53) of LBP. However, research has shown that it is possible to prevent the negative consequences of LBP, such as sick leave and inactivity (52). Thus, workplace interventions should aim at preventing the consequences of LBP, rather than the complaints itself.

In the research literature, physical and psychosocial working conditions such as heavy lifting, high work pressure, lack of control, high demands, and low social support are often proposed as possible explanations for sick leave (72-75). How individuals perceive and manage stressors at the workplace might have an impact on their decision to stay or return to work. In a study by Olff et al. (76), low levels of coping were related to higher subjectively reported sick leave. Coping is also found to be associated with both the frequency and duration of objective measures of sick leave (77-79). The research literature on the role of expectancies on sick leave in healthy populations is, however, compared with the large amount of research on the working environment, limited. Therefore, I chose to focus especially on the role of expectancies and beliefs on sick leave in this thesis, while the role of the work environment was given less priority.

1.6 The role of health promotion in work-related health

The WHO Ottawa Charter, which was the First International Conference on Health Promotion, emphasized the importance of *health promotion* in order to achieve the

best possible health across the population. The Charter defined health promotion as *“The process of enabling people to increase control over, and to improve, their health”* (4, p.1). The Ottawa Charter argues that in order for individuals to achieve their fullest health potential, they must be able to take control of the things that determine their health. This is closely related to the coping concept.

According to Bandura (80), *self-efficacy* is the most basic determinant of health, and is the essential mechanism for behaviour change and lifestyle choices. However, effort at the organizational level is also necessary in order to facilitate and create opportunities for coping. This is in line with the empowerment ideology in health promotion, where the emphasis of seeing the individual in a social and environmental context is strong. *Empowerment* can be defined as *“a process through which people gain greater control over decisions and actions affecting their health”* (81, p.354). According to Rappaport (82), empowerment implies both a subjective perception of personal control, and a sufficient degree of real social impact. For patients with health complaints that do not fit neatly into the medical agenda, health care providers have an important role in empowering the individuals, recognizing their strengths, and preventing further marginalization due to power inequalities (83).

According to the Ottawa Charter (4), health is created in the venues where people gather, and health promotion must therefore be enacted at these arenas. The working population spends most of their day at work, making workplaces a natural arena for health promotion activity. According to the European Network for Workplace Health Promotion, the workplace provides several advantages for health promotion such as existing structures that can easily be used to deliver health promotion activities and the potential to reach a large number of people (84). In Norway, workplace health promotion is expressed by law, as the first sentence in the Working Environment Act, § 1-1(85), states that the purpose of the law is to *“secure a working environment that provides a basis for a health promoting and meaningful working situation”*. The interventions explored in this thesis have a health-promoting perspective, and health promotion is therefore an important framework of this thesis.

2. Theoretical framework

The concept *coping* has received widespread attention, along with the growing interest in stress (86). However, definitions, understanding, theories, and measurements of coping are characterized by inconsistencies.

Individuals cope only when faced with stressors, and thus coping must be discussed with referral to the *stress* concept (86). However, there is also a diversity of definitions and a lack of consensus on the stress concept. It is even difficult to find a definition that most researchers will accept (87). For instance, stress has been defined both as a response to stressors (physical, emotional) (88), as a general activation occurring whenever there is a mismatch between what is expected and reality (physiological, psychological and behavioural) (1) and as an individual's appraisal that the demands s/he faces exceed their resources for coping with the situation (89). Levine and Ursin (87) agree upon three aspects of stress: 1) there is no linear relationship between stress/stressor and the resulting stress response, 2) there is high variability, and 3) the main stimulus is of emotional character. Ursin and Eriksen (1) have brought these aspects in to the *Cognitive Activation Theory of Stress* (CATS), where they present a precise and formal set of definitions to reduce the bewildering use of terms, which may cover the same phenomena. CATS provides an understanding of a fundamental stress response that is simple enough to apply to the most primitive organisms, and complex enough to apply to humans (90). As CATS can be used to explain pathophysiological mechanisms that underlie illness and disability (1), and because it is the theoretical framework underlying the non-injury model as well as the atWork intervention, I have chosen CATS as the main theoretical model for my thesis.

2.1 The Cognitive Activation Theory of Stress (CATS)

In CATS, stress is defined and operationalized by the following four aspects: 1) the stress stimuli (load), 2) the stress experience (processing/filtering of load in the brain), 3) the stress response (general activation/alarm), and 4) the feedback from the

stress response (the activation) (Figure 1).

Cognitive Activation Theory of Stress (CATS)

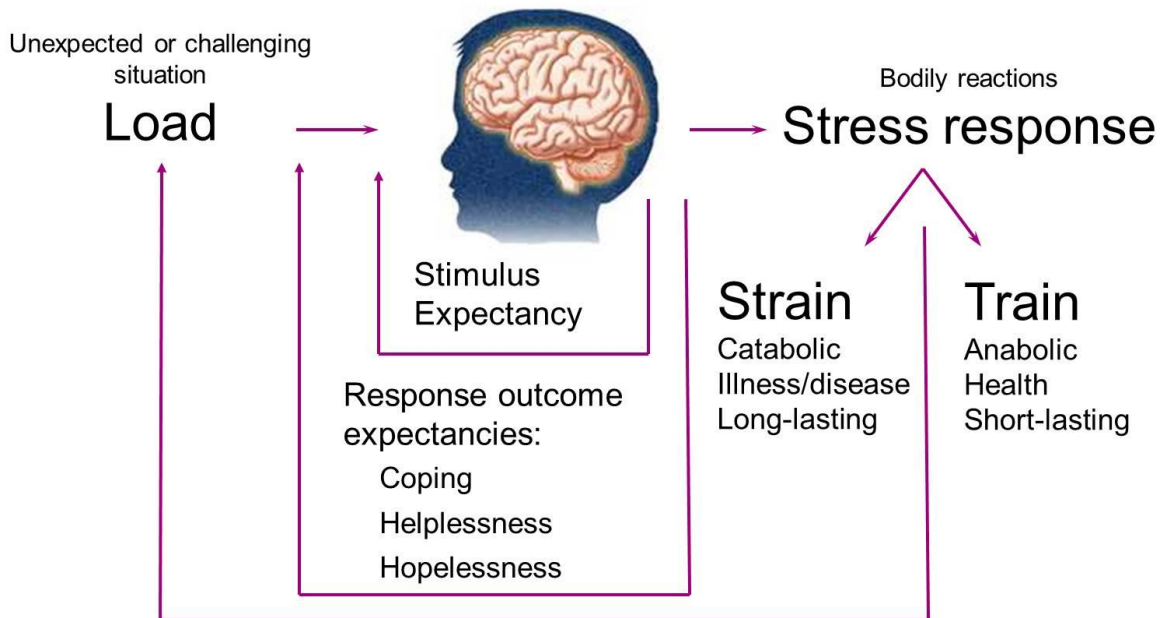


Figure 1. The Cognitive Activation Theory of Stress from Ursin & Eriksen (2004), modified by Eline Ree

Whenever an individual is faced with an unexpected, threatening or challenging situation, activation or a stress response will follow. According to CATS, there is no linear relationship between the load and the stress response, as all stimuli are processed and appraised in the brain. Employees, who wake up in the morning with severe low back pain (LBP), will evaluate the pain. Based on previous experiences and learning, they will make decisions about what it means, how it may affect them, and what to do about it. Different people will perceive and interpret the same situation in different ways, depending on their previous experiences and learning history. How effective the individual believes his or her response to the situation is will be stored in the brain as *response outcome expectancies* (ROE), and will affect how the individual meets unexpected or threatening situations in the future.

CATS proposes three different types of ROE. A positive ROE (*coping*) is the

acquired expectancy that most or all of your responses lead to a positive result. That does not necessarily mean, however, that the response is appropriate or helpful for the individual, for example if s/he expects that bed rest will lead to a positive result regarding their back pain. No ROE (*helplessness*) is the acquired expectancy that there is no relationship between responses and results, which means that the individual expects that, no matter what s/he does, s/he has no influence on the result. Negative ROE (*hopelessness*) is the acquired expectancy that most or all of your responses lead to a negative result. Here, the individual expects that, no matter what s/he does to handle the situation, there will be a negative result, which is also his or her fault.

If the individual expects to cope with the situation, the activation may be brief, which is a necessary response for all species for survival and performance. In this case, the activation leads to a training effect and is no risk to health. It is necessary to be alert if you have a problem you need to solve. Having a positive expectancy is essential for health and possibly also for sickness absence (1, 91). However, if a person expects that s/he will not cope with the situation, the activation may be long lasting and sustained over time. This *sustained activation* may be associated with illness and poor health (92). Thus, it is the individual's experience of the demands and the expectancies of the response outcome that is important for the sustained activation and the possible negative health effects. ROE generalize across different situations, but it is possible to influence individuals' expectancies through interventions aiming at increasing participants' positive ROE. This is the idea behind the atWork intervention. Through information meetings and peer support, atWork seeks to increase the employees' positive ROE and change their expectations about LBP and sick leave (2). I therefore wanted to apply coping perspectives to study the question of work attendance in this thesis.

2.2 Other relevant theories compared with CATS

Lazarus and Folkman (89) developed an influential theory about coping strategies. They differentiate between *problem-focused* and *emotion-focused* coping strategies,

measured by the 'Ways of Coping checklist' (93). The definition of coping differs from the CATS definition by describing coping as the person's "*constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person*" (89, p.141). In CATS, coping is defined as expectancies, not behaviour. According to CATS (1), the strategies individuals use do not necessarily predict their internal state, and therefore it does not predict health. The authors argue that coping predicts health only when it is defined as a positive response outcome expectancy (1).

In his *Social Cognitive Learning Theory*, Bandura (94) argues the importance of *self-efficacy* for health and health behaviour. Self-efficacy is defined as "*beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments*" (94, p.3). Bandura's concept of self-efficacy differs from the CATS concept of coping by representing specific expectancies related to specific situations or contexts instead of general expectancies as proposed in CATS. General expectancies might be less predictive for specific situations than situational self-efficacy. For example, the question "do you believe you will be able to return to work?" will probably predict a return to work more than a general coping question. Specific beliefs related to specific situations are found to be a strong predictor for actual performance (95). However, general expectancies are probably better predictors for general behaviour tendencies, which are what researchers most often attempt to explain in the field of health psychology (95). Furthermore, measuring specific expectancies in specific situations requires a large number of inventories, making it hard to compare findings across different studies, cultures, and situations. There is, however, a research tradition emphasizing general self-efficacy (96), a concept that is very similar to the coping concept in CATS (97). The generalized self-efficacy concept is also related to self-esteem, neuroticism, and locus of control (98).

As opposed to the individual level theories mentioned above, Karasek and Theorell (55) take an organizational and environmental approach in their *demand-control-support model*, which is a leading model in studies of occupational stress. They suggest that different combinations of demands (i.e., work load, role ambiguity),

levels of control/decision latitude (skill discretion and decision authority), and social support at work predict employees' health. A work environment that is characterized by high demands, low control, and low social support, so-called 'high-strain' jobs, constitutes, according to the model, the highest risk for disease and health complaints among employees (55). In CATS, control is not necessarily positive. Hopelessness also involves control, but the expectancy of response outcome is negative and unpleasant. In a study by Eriksen and Ursin (62), coping was found to be more important to health than control. The authors suggest that the individual's expectancies of being able to cope with the demands and stressors s/he meets at work might be of greater importance to health than the actual objective work characteristics (62). However, expectancies are based on previous experiences, and if high demands and low control repeatedly cause problems in achieving the desired outcome, this will probably matter for later expectancies of response outcomes.

Although CATS is the main framework in this thesis, the above-mentioned theories are also relevant, and will be used to complement CATS in the discussion of the findings in this thesis.

2.3 The Non-Injury Model (NIM)

While CATS is a general framework in this thesis, the *Non-Injury Model* (NIM) constitutes a specific framework about low back pain (LBP) in Paper II and Paper III. NIM was developed in the 1990s based on clinical experiences and research as an alternative to a traditional way of thinking about musculoskeletal disorders as biomechanical pathology (51, 99). In the biomedical approach, common LBP is often assumed to be a sign of damage or injury caused by mechanical loading, or structural pathology (100). However, the traditional approach seems inadequate in explaining disc degeneration and back pain (99), and does not seem to be useful as a basis for back pain interventions (101). NIM is in line with the European guidelines in prevention (52) and management (53) of LBP.

NIM is based on evidence showing that the spine is robust (102), and that non-specific LBP is not caused by load such as heavy or “wrong” lifting (99). Studies of identical twins show that environmental factors and physical loadings have modest if any effects on disc degeneration (102-104). Similar results are found in studies involving elite athletes (105, 106), and a narrative review of the twin spine study found some indications that routine physical loading may have benefits to the disc (103). Within the NIM framework, the focus is not on preventing back pain, but on preventing the social consequences of the complaints, such as sick leave and inactivity (51).

Brief interventions based on NIM have shown promising results regarding return to work (RTW) among patients with back pain (99, 107, 108), and in preventing sick leave among employees (2, 109). In the 1990s, a brief intervention based on NIM was tested in a randomized controlled trial, demonstrating the effect on RTW up to five years follow-up (107). The intervention consisted of a routine clinical examination by a doctor of medicine and a “mini back school” at an outpatient clinic, where the goal was RTW among back pain patients, mainly by removing their fear and uncertainty about LBP and help them to avoid focusing on sickness behaviour. A controlled randomized clinical trial (RCT) studying early intervention using a light mobilization programme with a similar approach demonstrated a positive effect on RTW at the one-year follow-up (108).

The brief intervention based on NIM is similar to most of the studies investigating the effect of a non-injury based educational approach, and consists of 1) a therapeutic examination by a physician and physiotherapist, and 2) education about LBP. The purpose of the clinical examination is to exclude red flags, i.e., severe pathology or damage, and to give the patient the reassurance of being properly examined. All procedures, findings and information about the back are explained thoroughly in a *non-directive way*. If no particular disease in need of specific treatment is diagnosed, the goal is to increase the participants’ confidence that the spine is strong and robust, furthermore that being in normal activity including staying at work usually gives the best prognosis (51, 99).

The Active Back project was the first study investigating whether a brief intervention based on NIM also had the effect of preventing sick leave among employees (109). Information about LBP was offered to employees through educational meetings at the workplace, together with peer support and treatment similar to the brief intervention for those who experienced back pain. In a quasi-experimental study, the intervention reduced sick leave due to LBP by 49% and in general by 27% (109). The promising results of the active back project led to the testing of the intervention in an RCT (the atWork project), where the intervention had an effect on sick leave at workplace unit level at the one-year follow-up (2). The atWork intervention is further explored in this thesis; thus NIM constitutes an important perspective throughout this thesis.

2.4 Nondirective Social Support

The information that is provided in the non-injury based brief intervention is based on a *Nondirective Social Support Model*, which implies cooperation and acceptance without judging the participants' feelings and choices, and without assuming responsibility for the participants' performance (110). The participants are offered evidence of the benefits of being active, but not advice to do so. The approach is quite similar to cognitive behavioural therapy, where the goal is that the employees with back problems conclude themselves that activity is best for their complaints (111). The information is supposed to give insight and understanding, making it up to the participants themselves to decide what the information means to them, and whether and how it will affect their lives. In contrast, Directive Social Support is characterized by assuming responsibility for participants' coping and telling them what to do and feel (110, 112).

Nondirective Social Support is found to be related to several positive outcomes in various spheres, such as optimism and hope when received by a family member (113), disease management (110), and increased self-confidence and feelings of control among women who suffer pregnancy loss (114).

3. Overall aim and research questions

The overall aim of this thesis is to develop research knowledge about the role of expectancies and beliefs in health and workplace interventions. This aim is operationalized through the following research questions:

- Can response outcome expectancies explain the association between health, education, and physical workload in a population of municipal employees? (Paper I)
- How do participants in a back pain information and reassurance intervention perceive connections between the intervention and their subsequent coping? (Paper II)
- Does a back pain information and reassurance intervention at the workplace prevent sick leave, and do expectancies, beliefs and level of pain predict this effect? (Paper III)

4. Design, material and methods

There follows below a presentation of the methodological approaches used to explore the research questions in this thesis, in addition to the procedures, ethics and strategies of the analyses. The three sub-studies in this thesis consist of a cross-sectional study (I, hereafter called the *mediation study*), a focus group study (II, hereafter called the *focus group study*), and a longitudinal study (III, hereafter called the *effect study*). Since both the mediation study (I) and the effect study (III) were based on quantitative data from the atWork study, these will be presented together, while the methodology used in the focus group study (II) will be presented in a separate section.

4.1 The atWork study (I and III)

The atWork study was a cluster-randomized controlled trial (CRT) conducted to investigate the preventive effect of a workplace back pain information and reassurance intervention on sick leave among employees. atWork was conducted in two Norwegian municipalities in the period 2008-2010. It was based on the Non-Injury Model (NIM) (99) and CATS (1), and consisted of three components: 1) educational meetings of back pain at the workplace, 2) peer support, and 3) access to an outpatient clinic. atWork is a population-based strategy directed towards the whole working population, aiming to prevent employees becoming sick-listed in the future. Population-based interventions contain no screening of risk (although individuals at risk are also included). The interventions are characterized based on the population segment of interest (115).

4.1.1 Designs

The mediation study (I) had a cross-sectional design with baseline questionnaire data from the atWork study. The effect study (III) had a longitudinal design, with baseline questionnaire data from the atWork study and registry data on sick leave at the one-year follow-up.

In the effect study (III), we explored differences in sick leave between the intervention and control group after participating in the atWork intervention, using a cluster-randomized controlled trial design.

4.1.2 Procedures and Samples

Employees included in the atWork trial were over 18 years of age, worked in one of the two municipalities that were invited to the study, and were Norwegian speaking. There were estimated to be approximately 3,500 employees in total in the two municipalities at the start of the study. Of these, 1,746 responded to baseline questionnaire data, which gave a response rate of about 50%. Questionnaires were sent in electronic and paper format.

The intervention was provided to all workplace units eligible to participate, in the two municipalities (e.g., schools, kindergartens, nursing homes), and thus cluster-randomization of whole units was used, stratified according to workplace units. The municipalities consisted of 135 workplace units that were randomized to three groups:

1. Educational meetings and Peer Support (EPS) (45 units)
2. Educational meetings, Peer Support and access to an Outpatient Clinic (EPSOC) (48 units) or
3. Control group that received treatment as usual (CON) (42 units)

Blinding of the participants was not possible, due to the nature of the intervention. All employees in the two intervention groups (EPS and EPSOC) received two educational meetings, with approximately two to three months' interval between them. When necessary, for example if several of the employees were missing at the first meetings, follow-up meetings were held at the units, of up to four meetings. Each educational session lasted 45 minutes. Health care personnel, mainly physiotherapists, who had received a lot of training regarding what to communicate and in what way, held the educational meetings. The information was provided in a

non-directive way, and was based on the latest research on musculoskeletal pain, in line with the European guidelines for low back pain (52, 53) and NIM (51, 99).

At the first educational meeting, a *peer adviser* was recruited among the units' own staff. The peer adviser was not a health professional, but an employee who received more in-depth education about back pain than was provided at the educational meetings. The peer adviser represented a low-threshold workplace service, with the aim to assist and help colleagues, for example through organization and adjustment of work tasks, to increase the likelihood of the employee staying at work despite back pain.

In one of the intervention groups (EPSOC), the peer adviser could refer employees directly to an *outpatient clinic*. The clinic was aimed at employees who felt the need for something more than educational meetings and a peer adviser; mainly employees who were at risk of becoming sick-listed. At the outpatient clinic, the employee received a brief medical evaluation and more information about backs and back pain. The employees were also offered two educational courses at the clinic, where they received the same information as at the workplace educational meetings, but in more detail.

In the mediation study (I), only baseline questionnaire data were analysed. In the effect study (III), however, baseline questionnaire data were merged with register data on sick leave to investigate the preventive effect of atWork in general, and within different levels of expectancies, beliefs, and LBP. The effect of the intervention on sick leave had already been tested in a study by Odeen et al. (2), who found a statistically significant effect at the one-year follow-up. However, in Odeen's study, sick leave was measured at workplace unit level, based on the municipality's sick leave records. In the effect study (III), the effect of the atWork intervention on sick leave was measured at individual level, while adjusting for sick leave the year before the intervention at unit level, i.e., on workplace unit.

Individuals with missing data on the consent to obtain individual register data on sick leave ($n = 795$), and employees with missing data on the workplace unit ($n = 94$)

were excluded from the study. The latter information was necessary to know which group the employees were randomized to. Thus, the final sample in the effect study (III) consisted of 857 employees, of whom 86.7% were female, with a mean age of 43.9 years. As the results from the two intervention groups were similar and few employees went to the outpatient clinic, the two intervention groups (EPS and EPSOC) were combined, leaving 646 (mean age = 44.2 (SD = 10.81), 86% females) employees in the intervention group, and 211 in the control group (mean age = 43.1 (SD = 11.62), 88.2% females) (see Figure 2). The sample in the mediation study (I) consisted of 1,746 employees, with 81% females and a mean age of 44.2 years. The sample was generally well educated, with a mean of 14 years of education, and 41% of the employees had more than 15 years of schooling.

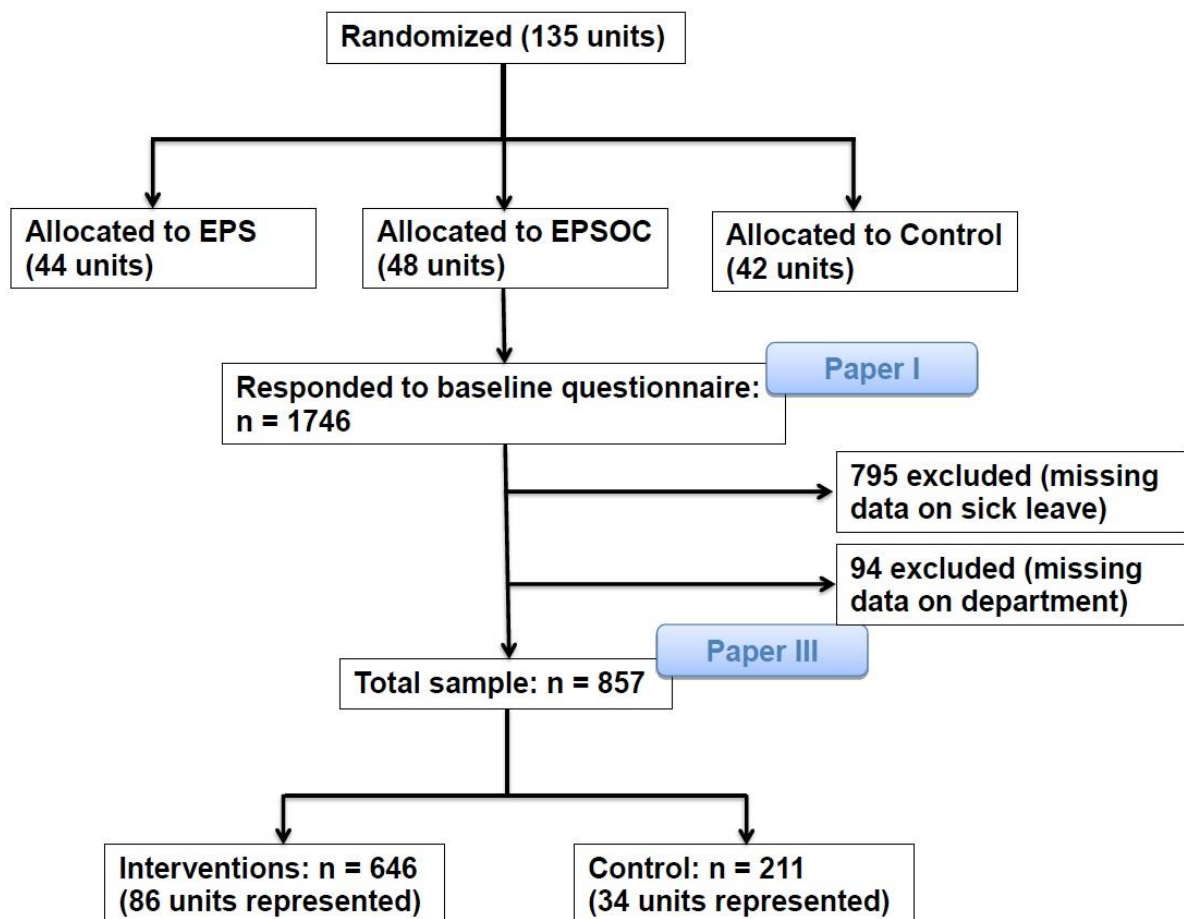


Figure 2. Flow chart of participants in Paper I and Paper III: EPS = Education and Peer Support. EPSOC = Education, Peer Support, and Outpatient Clinic

4.1.3 Ethics

The atWork study was conducted in accordance with the principles of the Declaration of Helsinki (116). The study was approved by the Regional Ethical Committee in western Norway (REK-vest, ID 6.2008.117), recommended by the Norwegian social science data services (NSD, ID 18997), and the privacy authority at Oslo University Hospital (Rikshospitalet, ID 08/2421). In addition, the study was registered in Clinicaltrials.gov (117). All participants signed an informed consent form.

4.1.4 Measures

The mediation study (I)

In the mediation study (I), subjective health complaints and self-rated general health were the *outcome* variables, while the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TOMCATS), years of education and perceived physical workload were the *predictor* variables.

Subjective health complaints (SHC)

Subjective health complaints were measured by The Subjective Health Complaints (SHC) inventory, developed by Eriksen, Ihlebæk and Ursin (12). The scale consists of 29 items concerning the number and severity of common health complaints experienced in the last 30 days, such as headache, neck pain, chest pain, and stomach pain, rated on a four-point scale from 0 = no complaints to 3 = serious complaints.

Self-Rated Health

General health was measured by the single question: "How do you generally rate your health?", with response options ranging from 1 = very good to 5 = very poor (13). The item was reversed, so that higher scores representing better self-rated health.

TomCats (Theoretically Originated Measure of the Cognitive activation Theory of Stress)

TomCats was developed to measure the three response outcome expectancies (ROE) in CATS; no ROE/helplessness (three items), negative ROE/hopelessness (three

items), and positive ROE/coping (one item) (118). Examples of items are: “I really don’t have any control over the most important issues in my life” (helplessness), “All my attempts at making things better just make them worse” (hopelessness) and “I can solve most difficult situations with a good result” (coping). The items are rated on a five-point scale, with scoring possibilities ranging from 1= not true at all to 5 = completely true.

In a previous study of a large sample from Sweden the scale proved high reliability and a clear factor structure (118). However, this was not the case in the atWork sample used in the mediation study (I) and the effect study (III) in this thesis. Factor analyses were conducted as preliminary analyses in the mediation study (I), and did not show a clear factor structure, as items representing the two factors loaded on the same components. Therefore, helplessness and hopelessness were treated as one single factor in both the mediation (I) and the effect (III) studies. Furthermore, coping was not included in any of the analyses in the papers, as it did not correlate significantly with any of the other variables used in the mediation study (I). The Cronbach’s alpha of the helplessness/hopelessness construct in the atWork sample is 0.77.

Education

Years of education were used as a proxy for socioeconomic status, and were measured by the single question “how many years of schooling/studies have you completed in total? (Count the number of years from the first year of primary/elementary school)”.

Physical workload

Perceived physical workload was measured by the single question “do you have heavy/repetitive work?”, rated on a ten-point scale from 0 = not at all to 10 = very heavy/repetitive.

The effect study (III)

In the effect study (III), days of sick leave were the *outcome* variable, while TomCats (see measures in the mediation study(I)), Tampa Scale, Deyo’s back pain myths, and

low back pain (LBP) were the *predictor* variables. In this paper, TomCats was dichotomized based on the mean value (mean = 10.2) into 0 = low (below the mean) and 1 = high (above the mean).

Sick leave

Days of sick leave were measured by individual register data from the Norwegian Labour and Welfare Administration (NAV). In Norway, the first 16 calendar days of a sick leave period are paid by the employer. After this period, NAV covers 100% of the sick-listed individual's past earnings for up to one year. The data used in this study were based on the sickness payment database from NAV. The first 16 days that are paid for by the employer are also available in the registries and are thus included in the present study. The sick leave records are assumed to be accurate because correct registration is required for transfer of payments.

Days of sick leave were calculated for one year before the intervention and one year after the intervention. In the statistical analyses, three-month periods with the number of days on sick leave were calculated, where days of sick leave were measured at three, six, nine and 12 months. Thus, the analyses consisted of four three-month periods prior to the intervention and four three-month periods subsequent to the intervention.

Tampa Scale

The Tampa Scale for Kinesiophobia (TSK) was used to measure pain-related fear (119). The scale normally consists of 17 items related to fear of movement (e.g., "It's really not safe for a person with a condition like mine to be physically active") and (re)injury (e.g., "pain always means I have injured my body") (120). In this thesis a Norwegian version with 13 items rated on a four-point scale from 1 = totally disagree to 4 = totally agree was used (121). The scale has proved high reliability and validity in a sample of acute LBP patients (120). In the analyses, we dichotomized the scale based on the mean value for the sum-score (mean = 25.4) into 0 = low (below the mean) and 1 = high (above the mean).

Deyo's back pain myths

Two items from Deyo's "back pain myths" (122, 123) were used to measure the employees' beliefs regarding LBP. Deyo (122) originally proposed seven common myths about LBP. Two of these were explored in the effect study (III), as these myths are specifically addressed in the atWork intervention, and they are the ones that are most alive in the general population (123). The two myths (1: "Most back pain is caused by injury and heavy lifting" and 2: "Everyone with back pain should have a spine X-ray") are rated on a five-point scale from 1 = totally disagree to 5 = totally agree. In the analyses, we dichotomized the items into 0 = low (totally disagree, disagree, neither disagree nor agree) and 1 = high (agree and totally agree).

Low back pain (LBP)

A single item from the Subjective Health Complaints inventory was used to measure LBP (12). The participants were simply asked if they had experienced LBP in the last 30 days and how severe the pain was on a scale from 0 = no complaints to 3 = severe complaints. In the analyses, we dichotomised the item into 0 = low (no or some complaints) and 1 = high (many or severe complaints).

4.1.5 Statistics*The mediation study (I)*

In the mediation study (I) we used *Structural Equation Modelling* (SEM) with subjective health complaints and self-rated health as dependent variables and education, physical workload, and helplessness/hopelessness as independent variables (see Figure 3). The models were tested for men and women separately, as preliminary analyses showed that a model that constrained all measurement weights to be equal across gender did not resolve in a significant increase in Chi-square when compared with a model that measured all parameters freely. This indicated different measurement models across gender, excluding the use of multi group analysis.

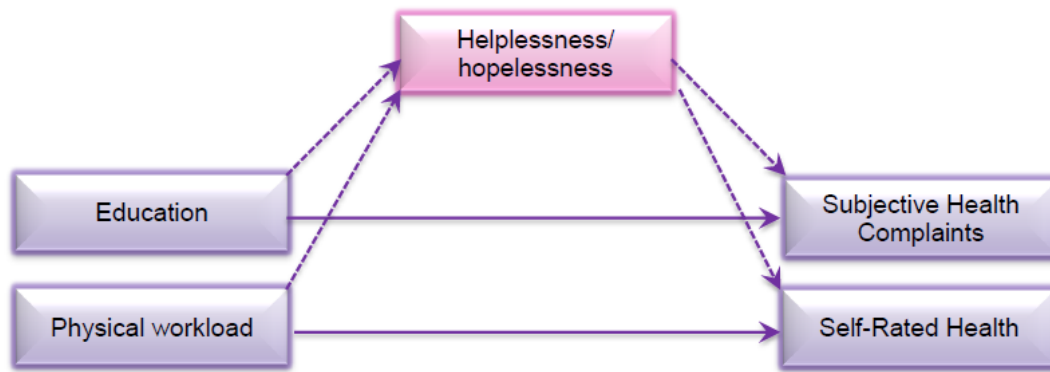


Figure 3. Stipulated relationship between study variables: possible direct effects of education and physical workload on subjective health complaints and self-rated health, and indirect effects through helplessness/hopelessness

Maximum likelihood estimation was used to estimate the models. First, we estimated measurement models of the study constructs. Then we designed a structural model to test the total, direct, and indirect effects between the study variables. The main goal was to test the indirect effect of education and physical workload on the health outcomes mediated through helplessness/hopelessness. However, the direct effects were also measured, as well as the total effects, which include both the direct and indirect effects. Monte Carlo Estimation was used to test whether the indirect effects were statistically significant (124). To evaluate the goodness of fit of the models, we used the following indicators: Root-Mean-Square Error Approximation (RMSEA) and Comparative Fit Index (CFI). An RMSEA value less than 0.05 indicates, according to Brown and Cudeck (125), a good fit, but a value as high as 0.08 represents a fair fit. Furthermore, a CFI value above 0.90 represents a good fit of the model (126), although a cut-off value close to 0.95 has been advised (127). We considered *P*-values below 0.05 as statistically significant.

The effect study (III)

For the effect study (III), sick leave at individual level was the dependent variable for all the analyses. Generalized Estimating Equations (GEE) (128) were used to analyse the effect of the intervention on days of sick leave in three-month periods the year

after the intervention. This approach accounts for the clustered nature of the data (129). Adjusted mean difference scores and 95% confidence intervals with corresponding p-values were calculated for differences in the effect on days of sick leave between intervention and control group. To control for differences in initial sick leave between the intervention and control groups, we adjusted for differences in days of sick leave at unit level, i.e., on workplace unit, the year preceding the intervention.

To test if there were statistical significant differences between the intervention and control group regarding the effect of the predictors (belief in the back pain myths, pain-related fear, helplessness/hopelessness, and low back pain) on sick leave, models including the interaction effect of days of sick leave for the dichotomized (high/low) predictors and intervention were conducted. For significant results, stratified analyses of the high and low levels of the predictors were conducted to explore where the effect occurred.

4.2 The focus group study (II)

4.2.1 Design

In the second study (II), a qualitative *focus group* design was used to get more in-depth information regarding how participants in a brief information and reassurance intervention perceive connections between the intervention and their subsequent coping.

4.2.2 Sample

The purposive sample consisted of 10 employees who, four to six weeks earlier, had participated in a back pain information and reassurance intervention at an outpatient clinic. To participate in the study, we included only those who had perceived the intervention as helpful, and subsequently had returned to or remained at work after participating in the intervention. The sample included three men and seven women

aged 20-67 years. Most of them had struggled with back or neck pain for several years, and were either part- or full-time sick-listed at the time they participated in the intervention. At the time of the focus group interview, all of them worked part- or full-time (auxiliary nurse, school inspector, carpenter, teacher, dentist, preschool assistant).

4.2.3 Procedures

The focus group study (II) is not a part of the atWork study, but is based on participants from the educational course that was offered at the outpatient clinic for employees at risk of being sick-listed due to back or neck pain. This course is now offered to employees in several Norwegian municipalities even if they do not have the atWork intervention at their workplace. Thus, the participants on this course may or may not have participated in the atWork intervention, but the educational meetings in atWork and at the outpatient clinic are similar, and often conducted by the same health personnel. When the employees enter the clinic, they are first given a brief medical assessment by a physiotherapist. They then participate in the educational course for two to three hours, where they receive the same NIM-based information that is presented at the educational meetings in atWork. They are also offered a follow-up consultation if needed. The aim of the intervention is the same as in atWork; to prevent sick leave by reassuring employees that it is safe to stay at work despite back pain. As with atWork, the course is based on NIM (51, 99) and CATS (1). However, as opposed to the population-based strategy used in atWork, this intervention constitutes a high-risk approach, targeted towards individuals with back pain who were either sick-listed or at risk of becoming sick-listed. High-risk approaches are usually characterized by the stage of illness when the intervention occurs (115).

The recruitment of participants to the focus group study (II) was done by the staff at the outpatient clinics. They approached everyone who had participated in the intervention within the last four to six months. Employees who confirmed that they had experienced the intervention as helpful, crucial for their decision to return to or

stay at work, were asked to participate in our focus group interviews. Only participants with positive experiences of the intervention were recruited, as we were interested in how and why the intervention was perceived as beneficial and helpful. Those who were interested in participating received more detailed information by e-mail, and later received a new phone call with a time and place for the interview. The researchers had no contact with the participants before the interview. To facilitate free-flowing conversations within groups with a balance of power and good group dynamics (130, 131), we aimed for variation according to gender, age and occupational status when composing the focus groups. However, difficulties with recruitment set some limits to this.

Three 90-minute focus group interviews were conducted at the same clinic in which the educational course had been carried out. The focus group interviews were audiotaped. The moderator (Kirsti Malterud in one interview, Eline Ree (ER) in two interviews) invited the participants to share stories of how the intervention had helped them cope with their complaints, and which aspects of the intervention they perceived as especially important for their subsequent coping. An observer (ER in one interview and Anette Harris in two interviews) took notes and assessed the atmosphere and interaction between the participants during the interviews. After three focus group interviews, we found that we had sufficient data variation to explore our research question and to conduct a responsible analysis, in line with the recommendations by Morgan (132).

The study was conducted in accordance with the principles of the Declaration of Helsinki (116), and was approved by the Data Protection Official for Research (NSD, ID 32505). All participants signed an informed consent form.

4.2.4 Analysis

Analysis was done with *Systematic Text Condensation* (STC), a cross-case qualitative analysis strategy (133). I (ER) performed the analysis in cooperation with my supervisors Kirsti Malterud (KM) and Anette Harris (AH). Cooperation was not done

to achieve consensus, but to expose the material to different perspectives, as this can provide different nuances of knowledge that might challenge established truths, and thereby strengthen the validity of the findings (130).

The analysis was based on written transcripts of audiotape recordings. The interviews were adjusted based on the learning and experiences we received from the former interviews and during each interview. We recorded a decision trail for the whole process of analysis, showing the development of the analysis from the start until the paper was published. This increased transparency of the process made it easy for us to go backwards and forwards, take new paths, and always know how and why we ended up at a particular place.

STC was performed following four steps:

- 1) reading the transcribed interviews to obtain a general impression of the material and to identify preliminary themes and code groups
- 2) identifying units of meaning related to the code groups we decided upon in the first step
- 3) the content in each of the coded groups were condensed to provide meaning, and
- 4) the contents of each code group was summarized to generalized descriptions and concepts of participants' experiences of how the brief intervention helped them cope with their back pain.

In *Step 1*, we all (ER, KM, AH) read the transcripts and formulated five to eight preliminary themes and then came together and negotiated five code groups based on the themes. "Confidence" is an example of a theme, and "feel confident that it is not dangerous and that it will pass" is an example of a code group (my translations).

In *Step 2* we read carefully through the transcripts to identify units of meaning related to the code groups. This could be short sentences or sections that contained meaningful information related to the code groups.

In *Step 3* we wrote condensates of each coded group, based on the units of meaning. Often, we found that the code groups could be divided into subgroups. For example,

the code group “feel confident that it is not dangerous and that it will pass” was divided into the following subgroups: “fear of a severe disease” and “it is not dangerous even if it hurts, it will pass”. In addition, a key quote to illuminate the main result in each subgroup was identified in this step. Below is an example of the condensate from the subgroup “fear of a severe disease” and related key quote (my translation):

Once I had muscle spasms in my back; I thought that it was the heart and the ambulance picked me up. I did not know whether I had breathing problems because I had back pain or if I had back pain because I could not breathe. It all happened at once. Then I thought that there was something wrong with my heart. If something should happen to my heart now, I think that I would trivialize it and say ‘whatever, it is probably just a muscle in my back’. It is painful and it is unpleasant, but it became apparent [at the course] that nothing dangerous was going on, and now when I know what it is, I feel much safer and relax much more. It may take time before the pain disappears; it may take a week; it may take two weeks; it can take four months, but I know now that it will resolve by itself. Even prolapses disappear, because they dry up. I think it is quite unnatural for people in our age not to have back pain. In a way, it is a part of life. Some days are better than others, and you live with it. My previous worries about cancer in the back or damage to the skeleton were disproved. At the same time, it was reassuring to hear that there were others too who had suspected cancer. I had feared that I needed surgery or something like that, but I realized that that was not necessary. I have a colleague who has just been told that she has two prolapses and I hope she is seeing a doctor who has the sense to know that surgery is not necessary.

“I think that might be the reason why the course worked out so nicely, because you had such a fear in advance, and then you got a very straightforward explanation” (Madeleine)

In the fourth and final step (*Step 4*), the data were recontextualized, translated into English and presented as a third-person narrative voice. The contents of the condensates were synthesized, providing summarized descriptions, stories and concepts of participants' experiences of how the intervention helped them cope with their back pain. Below is an example of a synthesis of the subgroup "fear of a severe disease" with related quote:

The participants told about the relief they felt when they realized that their complaints did not indicate underlying serious disease such as cancer in the back or heart problems. A female teacher told a story of how once she was taken in an ambulance because she thought she had a heart attack. She did not know if she could not breathe because her back ached, or vice versa. It turned out to be just muscle cramps, and she said that if something happened to her heart now, she would probably trivialize it because she is no longer scared when her back hurts. Most of them said that their pain was not due to an injury, it was just muscles that were in spasm. Several of the participants had previously feared that they would have to have a surgery, but now they knew that it was not necessary. They were also eager to tell their friends and colleagues with back pain that there was no need to operate, and they hoped that their friends' doctors had acquired this new knowledge about the back. Even though it hurt, the participants knew that it was not dangerous or life threatening, and thus they felt more safe and relaxed. Furthermore, they were confident that the complaints would not last forever; it could take a day, a week, or several months, but they knew that the pain at one time or another would disappear. Even prolapses would disappear, because they dry up. A teacher in her thirties was sure it was unnatural for human beings not to have complaints in the back, that it was a part of life.

"I think that might be the reason why the course worked out so nicely, because you had such a fear in advance, and then you got a very straightforward explanation" (Madeleine)

After the findings were synthesized in the result section, the text was revised and adjusted, and the subgroup “fear of a severe disease” was finally presented as the first section under the title “Understanding the pain enhanced the participants’ confidence in using their bodies without fear” in the focus group study (II).

5. Summary of results

5.1 Paper I

Ree, E, Odeen, M, Eriksen, H.R, Indahl, A, Ihlebæk, C, Hetland, J, Harris, A.

Subjective Health Complaints and Self-rated Health: Are Expectancies more important than Socioeconomic Status and Workload?

International Journal of Behavioral Medicine 2014; 21: 411-420

The aim was to explore whether response outcome expectancies (as defined by CATS) could explain the association between health and education, and health and physical workload in a population of municipal employees.

The Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats) is developed to measure response outcome expectancies in CATS. The predictive value of TomCats on health was investigated among 1,746 Norwegian municipal employees. Furthermore, the study explored whether response outcome expectancies mediated the effect of education and workload on subjective health, using Structural Equation Models with subjective health complaints and self-rated health as outcomes.

The results indicated that response outcome expectancies as defined in CATS do matter for health. However, the coping item did not have any significant predictive value, and helplessness and hopelessness were treated as one single factor based on the results of factor and reliability analyses. Among women, helplessness and hopelessness partly mediated the effect of education and physical workload on both health outcomes. Among men, helplessness and hopelessness fully mediated the effect of physical workload on subjective health complaints, but could not explain the relationship between education and health.

We conclude that response outcome expectancies are important to health, and in this paper it was more important than education and physical workload, which are well-established predictors of health. The results indicate that response outcome

expectancies might explain some of the relationship between socioeconomic status and health. Since expectancies matter to health, it is relevant to explore how an intervention that is based on CATS and the Non-Injury Model contribute to increase individuals' positive response outcome expectancies. The second paper in this thesis seeks to give some answers to this.

5.2 Paper II

Ree, E, Harris, A, Indahl, A, Tveito, T.H, Malterud, K.

How can a brief intervention contribute to coping with back pain? A focus group study about participants' experiences

Scandinavian Journal of Public Health 2014; 42(8): 821-826

The aim was to explore how participants in a back pain information and reassurance intervention perceived connections between the intervention and their subsequent coping.

Employees who had participated in a back pain information and reassurance intervention at an outpatient clinic were invited to focus group interviews. To participate, they had to perceive the intervention as positive and helpful, and had returned to or remained at work subsequent to the intervention. Ten participants aged 20-67 years were asked about the positive aspects of the intervention, and how it made a difference to them and helped them cope with their work situation and their complaints. Systematic Text Condensation was used for analysis.

According to the participants, trust in the lecturers was among the most important aspects of the intervention. The lecturers were perceived as experts on back pain and they delivered the information in a comprehensible way using metaphors, images of the spine and good examples that made it easy for the participants to understand. Increased understanding of why they felt pain, that it was not a sign of a serious disease or injury, changed their perception of how they could manage and live with their complaints. The participants told stories of how they, after participating in the intervention, dared to do activities they had previously avoided because they feared that it would worsen their pain.

The participants told stories of how the intervention contributed to increased coping and changed their beliefs. This made us question whether a back pain information and reassurance intervention that seeks to increase participants' coping and change negative beliefs about back pain could prevent sick leave, and whether participants'

expectancies and beliefs could predict the effect of the intervention. This was explored in Paper III.

5.3 Paper III

Ree, E, Lie, S.A, Eriksen, H.R, O, Malterud, K, Indahl, A, Samdal, Harris, A.

A cluster-randomized trial of a peer-based low back pain information and reassurance intervention at the workplace: The effect on sick leave and predictors of outcome

(Submitted)

The aim was to investigate whether a back pain information and reassurance intervention at the workplace could prevent sick leave, and if its effect on sick leave differed with high and low levels of belief in back pain myths, pain-related fear, helplessness/hopelessness and low back pain.

A cluster-randomized trial was conducted, where 135 work units in two municipalities were randomized to 1) Educational meetings and Peer Support, 2) Educational meetings, Peer Support, and access to an Outpatient Clinic, or 3) Control group. The outcome was measured from register data on sick leave at an individual level three, six, nine and 12 months after the intervention. Since the outcome was measured at individual level and merged with the questionnaire data, analyses were conducted at individual level while adjusting at unit level for differences in sick leave the year preceding the intervention. Due to similar effects between the two interventions on sick leave and because few participants went to the outpatient clinic, the intervention groups were merged in the analyses ($n = 646$) and compared with the control group ($n = 211$). Generalized Estimating Equations (GEE) were used to assess the effect of the intervention on sick leave, and its impact on sick leave within different levels of back pain myths, pain-related fear, helplessness/hopelessness, and low back pain.

The atWork intervention could prevent sick leave at three and six months subsequent to the intervention. Low levels of pain-related fear predicted the effect of the intervention at three months subsequent to the intervention. None of the other predictors showed any interaction effects with the intervention, and none of the

included predictors showed an interaction effect with the intervention at six, nine, and 12 months.

6. Discussion

6.1 Methodological consideration

“Truth can be stated in a thousand different ways, yet each one can be true”

(134)

To validate is to question (135). Researchers can rarely say yes or no to the question of whether what they have found is true. More important is to appraise what it is true about – what the materials and methods give the opportunity to say something about (internal validity), and how the findings can be transferred beyond the context within which the study was conducted (external validity) (130). In the following sections these issues will be discussed with regard to the findings of this thesis.

6.1.1 Internal validity – the question of relevance

Internal validity refers to whether the researcher has investigated what was intended, and whether the appropriate methods to do so have been used (136). To develop knowledge is always about finding more or less relevant versions of the reality to be explored (130).

This thesis tells several stories, from different perspectives, with the use of different designs and methods. Quantitative designs are suited to quantify effects (such as the effect of atWork on sick leave), and qualitative designs can be used to describe and understand a phenomenon (such as how patients perceive a brief back pain intervention).

In the mediation study (I) and the effect study (III), quantitative designs were used, as we would explore whether expectancies could mediate the effect between education and health, and workload and health (I), whether a work place back pain intervention had an effect on sick leave (III), and whether expectancies and beliefs could predict this effect (III). In the focus group study (II), on the other hand, we would study how

a brief back pain intervention helped participants to cope with their back pain, which can only be explored using a qualitative design.

In the mediation study (I) we used a cross-sectional design. Such a design is suitable for analysing correlations and prevalence, but its use regarding causal relationships is debatable, since all variables are measured at the same point in time (137). The researcher determines the direction of the relationship. We postulated that education and workload would predict health, and that expectancies could explain these relationships. However, the direction might be the other way around, that individuals with health complaints perceive the work environment negatively, as proposed in the study by Bonzini et al. (138). A longitudinal design would be more suited to reveal the causal relationships between the variables. However, we had a strong theoretical and empirical rationale for the stipulated relationships and the directions between them. There is stronger empirical evidence that the primary causal direction goes from the social environment to health and not vice versa (26, 41, 42). Coping is shown to be related both to socioeconomic status (SES) and to health, and to be a better predictor of health than SES (118) and, according to CATS, individuals' response outcome expectancies (ROE) might explain the SES-health link. Nevertheless, caution should be made when drawing inferences about the causality. Our study highlights one out of several other possible links between structural factors such as education and workload with health and gives a rationale for further exploration of these relationships.

Another possible limitation with the mediation study (I), which is also a limitation of the effect study (III), is that the validity of the scale can be questioned. The Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats) was developed to measure ROE as defined in CATS. Aside from this thesis, the scale has only been used once, in a previous study with a large Swedish sample, where the scale proved to have high reliability and a clear factor structure (118). However, the results from the two quantitative papers in this thesis (I and III) do not support the findings in the Swedish sample. Factor analysis revealed that several of the items that theoretically represent helplessness and hopelessness loaded

on the same component. The results of the analysis were unclear and lacked a consistent pattern. It is likely that respondents had difficulty distinguishing helplessness from hopelessness and thus these two variables shared much of the variance in predicting various outcomes. Due to these results, helplessness and hopelessness were treated as one single variable both in the mediation study (I) and the effect study (III). Furthermore, the coping item did not predict any outcomes in any of the studies and did not correlate significantly with the other variables in the studies, therefore was not included in the analyses in either of the two papers.

Similar to the studies in this thesis, the sample by Odeen et al. (118) was population-based, directed towards the working population. However, the latter had a much larger ($n = 11,441$) and heterogeneous study sample with more variance regarding gender and occupational status, which might explain why TomCats had a clearer factor structure than in the current thesis. Furthermore, a significant proportion of the sample ($n = 1,624$) was not working (e.g., due to sick leave) when the questionnaire was answered (118), which might be a reason why there was more variance on the helplessness and hopelessness factors. However, analyses based on the work of the current thesis, especially given the large sample in the mediation study (I) ($n = 1,746$), indicate that the scale is not sufficiently developed. Further development and validation of TomCats is necessary, but might be a challenge for several reasons.

First of all, ROE are not normally distributed in the population, which makes it somewhat difficult to reveal any variance, and to predict relevant outcomes. For example, hopelessness is often associated with adverse factors such as depression, and typically characterizes only a very small portion of the population. Furthermore, although it makes sense theoretically to distinguish between helplessness and hopelessness (1), a person's generally negative affect might make it difficult for him or her to differ between them in a questionnaire. S/he would probably respond negatively to the items constituting both variables due to a generally depressed or bad mood. The lack of discriminant validity might also be caused by method factors, since both variables are similarly formulated with a negative wording, and both measures represents the same method (139). In the two quantitative papers in this

thesis, the problem was solved by treating them as one single factor. However, by collapsing the sub-scales, we ended up with a variable that does not really reflect the underlying theory.

In contrast to the helplessness and hopelessness constructs, most people have high levels of coping, leaving little variance in the responses when using a five-point scale. A homogeneous sample consisting of apparently healthy respondents makes it unlikely to reveal any contrasts using factor analysis, as this method searches for variance in the data set. More variance and stronger predictive effects would probably be achieved by asking about more specific expectancies such as “do you believe you will be able to return to work?”, which would be more in line with the situational self-efficacy construct.

To reveal more of the variance in the population, more response alternatives should be added (i.e., a ten-point scale instead of a five-point scale). To be able to better distinguish between helplessness and hopelessness, revising the wording of some of the items should be considered. A forced three factor solution should also be explored by formulating items with the three ROE as response alternatives, as illustrated by this example: “When I give a task priority, I: (a) usually achieve the goal that I have set (coping), (b) can rarely influence whether the result is going to be good or bad (helplessness), (c) usually mess it up and achieve a bad outcome” (hopelessness). Partly based on the results of the papers in this thesis, I have, in collaboration with my research group, started a process to further develop the TomCats scale.

In the effect study (III), the causal relationship is less problematic than in the mediation study (I), given the use of a follow-up design. A cluster-randomized design was chosen due to practical reasons - as the intervention was implemented at workplace units and to avoid contamination between employees sharing the same work environment. Due also to practical reasons, the control group received treatment as usual, and thus there is a risk that the effect on sick leave in the intervention group is caused by the attention the employees received, rather than the effect of the intervention itself. To avoid this in future research, well-established gold standards

(i.e., the currently best available intervention) could be used as a control to explore whether a new intervention is more effective. Furthermore, because of limited resources and a large number of units and participants, process evaluation and fidelity testing was not conducted. There is limited information on whether the implementation was carried out according to the trial protocol, although observations at the clinics and workplaces indicated adherence to the protocol. The pragmatic design of the RCT, however, ensured a very realistic context that increases the ecological validity of the study.

In the effect study (III), we were interested in the effect of the atWork intervention at individual level, both in order to know exactly when during the first year the effect was present, and to be able to link the predictors in the individual questionnaires to the sick leave outcome. Thus, our research question demanded analysis to be carried out at individual level. The use of registry data on sick leave is a strength of this paper, as such data are considered to be highly accurate. Furthermore, the merging of questionnaire data with objective registry data on sick leave provided independent measurements of predictors and outcome, which excludes the risk of common method bias (140). However, the various units used for randomization and analyses deserve a discussion. Traditionally, analysis in cluster-randomized trials (CRT) has been conducted at the cluster level (141). In our case that would imply that analyses should be conducted at workplace unit level, as in the study by Odeen et al. (2), which was not possible due to the nature of the research question. Applying standard statistical methods can result in spurious statistical findings when analysing CRTs at individual level (141, 142). However, advances in statistics and development now make it possible to also incorporate individual level data in analysis of CRTs (141). Statistical techniques that take advantage of the individual level data and allow for adjustment for the potential co-variables have been developed. By accounting for the intra-cluster correlation, individual level data can be utilized in cluster-randomized designs (141). By analysing at individual level, we were able to take full advantage of the richness in the data set. Rather than focusing on the unit of analysis, Murray (143) argues that it is of greater importance to specify an appropriate model for analysis that matches the underlying structure of the data. We used General Estimating Equations (GEE),

which account for the clustering of data, and are appropriate to use for individual level analysis of CRT (129). To correct for the clustering of data within the unit of randomization, we calculated standard errors based on a robust variance estimator. Furthermore, we adjusted for differences between the intervention and control group in days of sick leave the year before the intervention, where the adjustment was done at unit level, i.e., on workplace unit.

It would be interesting to explore whether the change in the predictors from baseline to follow-up predicted the effect of the intervention, using mediation analyses with the change scores as mediators. Such analyses would not just tell whether an intervention works, but how it works (144). Odeen et al. (2) found that there was a significant decline in the belief in the back pain myths and pain-related fear, but the decline in the latter was not statistically significant different from the control group. When only exploring baseline predictors, as we did in the effect study (III), we cannot tell whether the intervention affected the factors it was supposed to, and whether changes in these factors predicted the effect of the intervention. However, since sick leave was measured at the same time as the predictors at follow-up, it was not possible to conduct such analyses in this paper.

In the focus group study (II), we chose the focus group design because we were interested in concrete stories and experiences regarding the ways in which a brief back pain intervention helped the participants to cope. Such a design is especially suitable for participants who share experiences, as it enables them to interact and express themselves in a flexible discussion (145, 146). Because of our resource-oriented position, we merely included participants with positive experiences of the intervention, who had returned to or remained in work subsequent to participating in the intervention. Thus, we did not have access to the experiences and attitudes of those who did not favour the intervention, which means that the study cannot shed light on what does not work or what could have been better. However, the aim of this study was not to evaluate the intervention, but to obtain a wider understanding of how and why it is perceived as beneficial for many participants. A limitation with the

study is that we do not have information on the prevalence of participants who found the intervention helpful, nor on why several participants declined to participate.

Furthermore, there was a risk that the participants' stories would only reproduce this aim, i.e., telling us what they believed we wanted to hear and what they had learned, as the aim of the intervention was to provide knowledge and insight regarding the non-injury nature of back pain. We were especially aware of this when conducting the interviews. One of the participants had a tendency to speak in general terms, emphasizing what he knew was "the right practice" without referring to his own experiences. However, we then guided the discussion by asking for concrete examples. More specifically, we asked for stories concerning the participants' concrete experiences of what was said and done in the intervention that made a difference for their experience and management of their complaints, as well as what specific aspects of the intervention they perceived as important for their decision to return to or remain at work. Flanagan (147) calls this *the critical incident technique*. Furthermore, we emphasized that we were not there to evaluate the intervention, that there were no right or wrong answers, and that we welcomed all experiences related to the research question.

We conducted three focus group interviews with a total of 10 participants. A common recommendation for sample size in focus group studies is five to eight participants (131, 145). However, in a recent article Malterud et al. (148) propose the concept of "information power" as an alternative to the commonly used saturation concept as a guide for sample size in qualitative studies. Information power regards the potential of the empirical data to provide new knowledge, which depends on 1) the research question (specific or general?), 2) specificity of the sample (dense or sparse?), 3) theoretical framework (applied or not?), 4) the quality of the data (strong or weak?), and 5) the analysis (case or cross-case?). In our study, we had a specific research question regarding the perceived connections between the intervention and subsequent expectancies of coping, with a highly relevant sample to explore this aim. Furthermore, we used CATS as a theoretical framework - a highly relevant theoretical framework used to interpret the data as it was directly related to the

research question. The participants had relevant experiences to reflect upon the questions asked, which strengthens the quality of the data. However, we used a cross-case analysis strategy, which usually requires more participants than when using a case strategy. Altogether, several dimensions in our study provide good information power, and therefore we did not need a larger sample. After conducting three interviews, we had sufficient data to be able to illuminate our research question.

Experience is a subjective phenomenon, not facts about what really happened. Thus, several alternative perspectives, interpretations and conclusions may exist in addition to those we chose to explore and emphasize in our study (130). Different versions of reality can be valid at the same time – it all depends on the individual perception and experience. Our study offers insight into a reality seen by participants, who have perceived a brief back pain intervention as positive and beneficial, and a reality seen by me and my colleagues, when analysing and interpreting the data material.

6.1.2 External validity – the question of context

External validity refers to how our findings can be applied beyond the context in which they were developed (130). The utility of the knowledge is also referred to as pragmatic validity (135).

In quantitative research, external validity is determined by the representativeness of the sample and the generalizability of the findings to other settings. In qualitative studies, the question is not about generalizability and effect sizes, but about *transferability*, i.e., whether the findings make sense beyond themselves (130). By combining various research methods, we obtained a broader understanding of the role of coping in relation to health and sick leave than would be conceivable with only a quantitative or a qualitative design. However, this is not a mixed methods design, which requires a more committed integrative analysis across the two methods (130).

Both in the mediation study (I) and in the effect study (III), the low response rate of approximately 50% limits the external validity of the findings, as it increases the risk of a selection bias. A number of factors influence response rates on questionnaires

(149, 150). The relevance, importance and interest of the questionnaire for the respondents are important factors that affect response rates (151). Thus, questions in the atWork questionnaire concerning low back pain and health might be of less relevance and importance to a sample of healthy employees than for the example in a clinical sample. Furthermore, the atWork questionnaire was quite long, which probably affected the response rate, as shorter questionnaires tend to increase the response rates (149, 150). A full pilot testing of the questionnaire among employees would probably have improved it and contributed to increased response rate, but restrictions of time and budget set limits to such an approach.

A major strength of both the mediation study (I) and the effect study (III) are the relatively large samples. The risk of localization effects and group specific effects are reduced due to the diversity in workplace size and tasks. There was a strong majority of women in both samples (over 80%). Although this is representative for the municipality sector in general (152), caution should be made when generalizing to men and also to private sector employees.

In the focus group study (II), we only invited participants who had perceived the intervention as helpful, and thus the findings are not transferable to all participants in similar interventions, especially those with negative experiences. However, the findings of the positive aspects, whereby the intervention contributed to increased coping among the participants, might be transferable to individuals with musculoskeletal complaints in other settings, for example among workplace employees who are from a less high-risk group than those in the focus group study. Furthermore, the findings might be transferable to individuals suffering from other health complaints when receiving a similar intervention, for example individuals with chronic fatigue symptoms (153). However, whether individuals with other kinds of health complaints or healthy employees in a workplace setting will recall similar experiences as the participants in our study must be explored in other studies.

The sample in the focus group study was relatively small, with a total of 10 employees. Nevertheless, the diversity in our sample in terms of age, gender,

education and occupational status provided rich empirical data on nuances and contrasts in the experiences of the intervention, which increases the external validity. Variability is more important for transferability than sample size and increases the possibility of the findings to develop new and relevant descriptions of the study topic, which can be transferred to other settings or be used to generate new hypotheses (148). Our findings might be valid for several other patients experiencing back pain. Furthermore, the findings might be useful for professionals both in the primary and secondary health care services when communicating with back pain patients.

6.1.3 Reflexivity

Reflexivity implies that researchers acknowledge and consider the meaning of their own perspectives and positions in the research process (130). The question is not whether the researcher affects the research process, but in what way and does it matter?

At the beginning of my PhD work, my overarching preconception was that the approach used in atWork and the brief intervention at the outpatient clinics would increase the participants' positive ROE. My belief was that this would be achieved by reducing their feeling of insecurity regarding their health complaints, and that increased coping and reduced fear would in turn prevent sick leave. This has undoubtedly affected the research process.

During the research process I have actively tried to step aside, take a look at my own role and position, and evaluate the impact of my preconceptions on the research questions, interpretations and conclusions. In particular, my enthusiastic optimism may have resulted in me overlooking possible negative effects of the interventions. I used several tools such as writing a decision trial and a "self-statement", i.e., my preconception before conducting the interviews in the focus group study (II), including what I thought the results would look like and my theoretical framework. Both in the focus group study (II) and the quantitative studies (I and III), I tried to stay open to surprising results during the analyses. Below is an excerpt from my

“self-statement” regarding the results I anticipated from the focus group study (II), written ahead of the interviews and analysis:

The participants talked about eye-opening experiences. Suddenly they realized that it was safe to be at work despite back pain. They said that they were relieved when they were told how strong the spine is. They did not want to stay at home. They were surprised that a prolapse can occur just as easily when sleeping or drinking coffee as when lifting heavy loads.

Although aspects in this excerpt look like some of the results in the final paper, there are several different nuances, and also some surprising findings that were not touched upon at all in the “self-statement”, such as the finding about the importance of the lecturers appearing confident and as experts on back pain. Thus, these strategies for reflexivity made me aware of some examples of how my position and perspectives affected the research process.

My positions and theoretical framework were important for the formulation of the research questions. As discussed previously in this thesis, there are a lot of different approaches in the coping field and choosing one over another obviously has implications for interpretations and research results. All my research questions were related to the CATS theory (1), which implies that my attention has mostly been directed towards the individuals and their expectancies. The theory played a central role in the interpretation of results. In the mediation study (I), we explored CATS in relation to health and socioeconomic status; in the effect study (III) we investigated whether individuals’ expectancies as measured by a scale based on CATS predicted the effect of an educational intervention; and in the focus group study (II) we explored how individuals perceived the relationship between participating in an intervention based on CATS and their subsequent coping.

All authors of the papers in this thesis have a health-related background, and some of us (ER, Aage Indahl, Torill Tveito) have furthermore participated in implementation or evaluation of the atWork intervention. The latter played an important role in the choice of research questions, and in the focus group study (II) this could have

impacted the stories by reproducing the aims of the brief intervention. If the participants thought the focus group interviews were a programme evaluation, they might have responded in terms of what they had learned and what they thought we wanted hear, instead of discussing their actual experiences and concrete stories. However, in all the interviews, we emphasized that we were not there to evaluate the intervention. The surprising finding regarding the lecturers is an example of how we did not only find what we were looking for.

Furthermore, the authors of all three papers were diverse in age, gender, type of education, and occupational and clinical experiences, which provided different perspectives and nuances on the material. An example is the collaboration between three of the authors on the analysis in the focus group study (II). Here, KM, with long clinical experience with back pain patients in general practice and research on marginalized groups, focused on the practical consequences of the intervention, i.e., how participants coped with their daily life. I, on the other hand, had no clinical experience, but had been involved in the evaluation of the intervention and noticed how concrete events in the intervention affected the participants. AH, trained to look for coping, was especially aware of how participants talked about similar experiences in different ways, noticing positive ROE and their beliefs about what they were able to do. We were less concerned with structural and environmental conditions for coping, although this is also important. Taken together, the three of us noticed from different perspectives how positive ROE might increase as a result of different aspects of the intervention, and how these expectancies were expressed in real-life circumstances.

6.2 Discussion of main findings

In this thesis I have demonstrated that response outcome expectancies (ROE) are important to health, and suggest that this may explain the association between education and health and physical workload and health among employees (the mediation study, I). A back pain information and reassurance intervention can contribute to increase participants' positive ROE. According to the participants, trust

and confidence in the health personnel, and having the information delivered in a comprehensible way helped them cope with their pain and were seen as the most important aspects of the intervention (the focus group study, II). Furthermore, we found that a back pain information and reassurance intervention at the workplace, with the aim of increasing employees' positive ROE, could prevent sick leave for up to six months, and that low levels of pain-related fear predict the effect of the intervention (the effect study, III).

In the following sections, I shall discuss the main findings of this thesis in the light of previous research and theory. I will also consider some practical implications for population-based, health promotion interventions at the workplace.

6.2.1 The impact of individual expectancies on health

The mediation study (I) demonstrated that ROE (helplessness and hopelessness) as defined in CATS have a positive impact on health. This is in line with the CATS theory (1) and with previous research findings showing that coping and expectancies are important to health (62, 118, 154-158). The authors of CATS have also suggested that coping might be a possible mechanism between socioeconomic status (SES) and health (1, 44, 159, 160). This was supported by the findings in the mediation study (I), where expectancies partly mediated the effect of education and physical workload on health. The results are in line with previous studies indicating that coping may be an important mechanism for the relationship between SES and health (118, 161). At an individual level, coping is assumed to have both a direct effect on health through sustained activation/arousal, but also an indirect effect through its impact on health behaviour (160). A study by Karademas et al. (162) supports this hypothesis. In their study, helplessness predicted subjective health both directly and indirectly through certain coping strategies such as wishful thinking and emotional reactions.

Individuals who have learned that their actions never lead to the desired outcome will probably not be motivated to change their lifestyle habits. Thus, enhancing individuals' self-efficacy is important to achieve the skills and confidence necessary to make healthy choices and to deal with environmental challenges (80).

A limitation with CATS, however, is that it does not take into account contextual, social or environmental factors. These factors are important for health, and interact with individuals' cognition and behaviour, described as reciprocal determinism by Bandura (163). Expectancies might be one of several mechanisms in the SES-health relationship that add to the already existing knowledge of the influence of environmental, structural, and social factors on health. Several studies have found that physical working conditions (e.g., heavy physical workload, monotony at work) and psychosocial factors at work (e.g., lack of job control, skill discretion and social support) can explain a large part of the social gradient in health (164-166). According to Marmot (28), social conditions such as economic and social security, participation in society and healthy working life are among the main reasons for much of the inequalities in health. Psychological responses and behaviour are, however, shaped by the surrounding environment (41), and thus action on environmental factors will impact on individuals' experiences and learning and thereby on their expectancies and beliefs.

According to Kristenson et al. (160), individuals with low SES tend to be more exposed to negative circumstances, in addition to having fewer protective resources, indicating that social inequalities in health might be a result of a double burden. This might explain the negative relationship between education and helplessness/hopelessness and the positive relationship between physical workload and helplessness/hopelessness in the mediation study (I). Repeated negative reinforcement leads to negative or no ROE, which in turn affects health and health behaviour, and vice versa. Expectancies might also moderate the relationship between SES and health, as shown in the study by Lachman and Weaver (167). In their study, the sense of control (personal coping: e.g., "I can do whatever I decide to do" and perceived constraints in one's life: e.g., "I often feel helpless in dealing with the problems of life") varied along with the participants' income. However, when individuals with low income reported a high sense of control, their health and wellbeing was comparable with the higher income groups. The sense of control

moderated the effects of low income on both physical (self-rated health, functional limitations) and psychological (life satisfaction, depressive mood) outcomes.

Summing up, the mediation study (I) confirms that expectancies partly mediate the effect of education and physical workload on health. Thus, increasing employees' positive ROE might contribute towards decreasing social differences at work among employees, and help them cope with the many challenges the workplace poses.

However, only one question concerning physical workload was used in the paper.

Future research should include validated scales on the role of environmental factors, such as the demand-control-support scale by Karasek and Theorell (55), and further explore the interactive effects of individual and structural factors on health. A study by Schreuder et al. (154) found that coping styles were associated with health and work environment in a large sample of Norwegian and Dutch hospital nurses.

Similarly to the mediation study (I), however, the study was cross-sectional and thus longitudinal studies should be conducted to explore the causal relationships between individual expectancies, workplace factors, and health.

Taken together, the findings of this thesis highlight the importance of enhancing the scientific knowledge about the role of individual factors, such as expectancies, on health. Future studies should explore how these factors relate to structural and environmental factors.

6.2.2 The preventive effect of a workplace intervention on sick leave

The aim of atWork was to prevent sick leave among municipal employees by increasing their positive ROE and change misconceptions and negative beliefs about back pain. In the effect study (III), we found that atWork could prevent sick leave at individual level up to six months after participating in the intervention. This is in line with the study by Odeen et al. (2), showing that the atWork intervention had an effect on sick leave at unit level at the one-year follow-up. A non-randomized workplace intervention similar to atWork also reduced the total sick leave rates by 27% and low back pain-related sick leave by 49% (109).

Positive effects of a non-injury approach are also found in treatment settings, as several studies on outpatient non-injury based interventions have shown an effect on return to work (RTW) in patients with low back pain (LBP) (51, 107, 108). Such interventions are also found to be effective in primary health care, as a systematic review with meta-analysis concludes that primary care-based education on reassurance in patients with LBP is more effective than treatment as usual in reducing LBP-related health care visits (168). The review indicates that the education should be delivered by a physician rather than other primary care practitioners (e.g., a nurse or a physiotherapist), and the authors believe this is because the authority and credibility of the source is critical when the goal is to change patients' beliefs or behaviour (168). The participants in the focus group study (II) also emphasized the credibility of the health personnel providing the information. However, the health personnel at the outpatient clinic, who were mostly physiotherapists, were perceived as greater experts on back pain and more credible than their physicians. Authority is probably a result of both occupational status and performance. Thus, training of physicians and other health professional groups in credible communication of the Non-Injury Model to their patients is possible and should be explored in future research.

The findings in the effect study (III) regarding the effect of atWork on sick leave are in line with a recent RCT among high-risk workers receiving an intervention that included communication and problem-solving skills (169). Compared with treatment as usual, the intervention group improved significantly on work absence due to pain, perceived health, and health care utilization at six months follow-up. Similarly to the participants in atWork (2), the intervention group did not differ from the control group in their rating of pain intensity (169). This indicates, in line with the atWork aim, that the intervention changes the impact of pain on participants' behaviour rather than the pain itself and that the effect of the intervention is not through reduced pain. The findings in the focus group study (II) support this notion, as the participants still had pain after participating in the intervention, but their beliefs and understanding of what they were able to do despite pain had changed.

Although the preventive effect of atWork was restricted to the first six months subsequent to the intervention, it is an important result, especially since population-based preventive interventions often require long-term implementation to affect outcomes (3). This especially accounts for hard outcomes such as sick leave in populations that are basically healthy and present at work (19, 170, 171). According to Tveito et al. (19), 10% of employees account for 82% of the sick leave. A challenge with population-based preventive interventions directed towards the “healthy” 90% who are present at work is that most of the target group does not need the intervention. In his classic paper from 1985, Rose states that there are few grateful patients in preventive medicine, as success is marked by a non-event (172). Twenty years later, the paper is still relevant (173). Since most of the individuals in population-based approaches are going to be all right anyway, such approaches offer only a minor benefit to each individual. He calls this the “prevention paradox” - “*a preventive measure which brings much benefits to the population offers little to each participating individual*” (172, p.38). However, the population approach can change norms that will benefit the most deprived (172). This is an important point regarding the effect of atWork (III), since the change in negative beliefs about back pain in some of the employees has the potential to become a norm over time. Repetition of the intervention message might be necessary in order for a group effect to occur. Based on the natural turnover rate that is present in workplaces, new employees must be educated in order to maintain beliefs at the workplace.

Taken together, the findings in this thesis suggest that targeting expectancies and beliefs are potentially promising approaches for health promotion and prevention of sick leave. However, it might be necessary to repeat the message over time in order to change norms and culture at the work over the long term.

6.2.3 The role of expectancies and beliefs in back pain information and reassurance interventions

The participants in the focus group study (II) shared stories of how new knowledge and changed beliefs increased their positive ROE, and how this affected their

decisions to return to or remain at work. This finding is in line with several studies in the RTW and rehabilitation literature, which have demonstrated the importance of positive expectancies for RTW (174-176). The focus group study (II) demonstrates *how* expectancies and beliefs matter for RTW or remaining at work. For example, a woman described how the reassurance she got on the course changed her beliefs regarding her pain. This also changed her behaviour, from staying home and being careful, to being present at work, pushing herself and tilting patients in and out of beds. After the course, she had positive expectancies that she would manage to stay at work despite pain.

Coping is also found to be associated with both the frequency and duration of sick leave (77-79). For example, active problem-solving and social coping strategies are found to prevent sick leave (78), and a longitudinal study by Jensen et al. (177) showed that fear avoidance beliefs were associated with sick leave, even when controlling for LBP, previous sick leave, age, and work environmental factors.

Based on the previous research regarding the role of beliefs on sick leave and the results from the focus group study, it is somewhat surprising that atWork did not have an effect on employees with strong pain-related fear (III), despite the intervention being aimed at targeting employees' fear avoidance beliefs. Nor did the intervention group have a significantly different change compared with the control group on ROE and pain-related fear at the one-year follow-up (2).

The discrepancy in the results in the focus group study (II) and effect study (III) may be explained by the different target groups. atWork is a health-promoting population-based intervention aimed at reaching the whole working population, while the course at the outpatient clinic constitutes a high-risk approach, targeted towards individuals with back pain who were either sick-listed or at risk of becoming sick-listed. The participants in the focus group (II) had personal experiences with and beliefs about back pain, which were available for elaboration and reconsideration. According to them, receiving comprehensible information about back pain from lecturers they had trust and confidence in changed their beliefs and helped them cope with their

complaints. The importance of trust in the professionals and seeing them as experts on back pain were especially emphasized. This aspect might be less prominent in the atWork intervention, as the information meetings were held at the workplace.

Although many of the professionals who held the educational meetings in atWork also held the courses at the outpatient clinic, the setting might have influenced the participants' perception of the professionals. This might especially account for the individuals in atWork with high levels of pain-related fear, making the information less conceivable. In addition, the brief medical examination ahead of the educational course at the outpatient clinic might have laid a foundation for trusting the information on the course. The seeming discrepancy in the results in the two studies is probably also due to the different use of designs, methods and research questions. The focus group study (II) consisted of participants who had perceived the intervention as helpful and were asked about aspects of the intervention that helped them cope. The effect study (III), on the other hand, consisted of all employees who had received the intervention, regardless of whether they were satisfied with the intervention or not.

To improve the practical and scientific value of resource-oriented interventions at work, Briner and Walshe (178) argue that the target group should have relatively low levels of the particular resource that the intervention aims to affect, and that it should be possible to increase that resource in the target group. Furthermore, increasing the resource should have practical significant effects on the specific problem (178). The resources targeted in atWork and at the outpatient clinic are coping and beliefs, operationalized in terms of CATS and NIM. The working population in atWork probably had high levels of coping, which may explain why the participants did not increase coping during the intervention (2). Similar interventions (i.e., atWork and outpatient intervention) might work through different mechanisms depending on the target group. According to Mansell et al. (179) mediation analyses should always be conducted in order to investigate through which mechanisms interventions work for different target groups, in order to increase the knowledge of how treatments for back pain patients can be improved. For example, he states that, although factors such as self-efficacy and fear avoidance are shown to predict RTW and disability, it is less

clear that these factors will improve if they are specifically targeted in interventions (179). Several educational interventions have managed to successfully change participants' beliefs, but without any effect on sick leave (180-182).

Although atWork did not influence coping or pain-related fear, it did have an effect on the participants' beliefs in the back pain myths, which might indicate that the message had been understood and accepted (2). The focus group study (II) shows how beliefs can change expectancies and behaviour. For example, a man had been told that the back was the world's best bumper, which made him realize that weight lifting was not harmful despite having back pain. However, individuals with strong pain-related fear may need more time and repetition of the message in order to change beliefs. This is in accordance with a recent systematic review, arguing that individual characteristics such as unhelpful beliefs are likely to affect the amount of time that is necessary to improve treatment adherence outcomes (183).

Participants with high pain-related fear might also represent a subgroup that is in need of more extensive multidisciplinary interventions than were provided atWork. In general, multidisciplinary interventions (MI) or more extensive interventions are not found to be more cost-effective than brief interventions (BI) (99, 184-187). However, this might not be the case for all employees. In a study by Stapelfeldt et al. (188), individuals with low job satisfaction, no influence on work planning, and at risk of losing their job benefited more from MI than BI, while it was the opposite for individuals with high job satisfaction, influence on work planning, and no risk of losing their jobs. Similarly, in a study by Haldorsen et al. (189), patients with poor prognosis benefited more from an extensive MI than from ordinary treatment or light MI.

Taken together, the findings in this thesis show how a back pain information and reassurance intervention can contribute to increased positive expectancies, changed beliefs and behavioural changes among participants. There are probably different mechanisms operating to produce desired outcomes depending on the target group

(high-risk vs. population-based) and characteristics of the participants (e.g., level of pain related fear).

6.2.4 The role of context and environmental factors on expectancies, beliefs and workplace interventions

Above I have discussed the importance of expectancies and beliefs for health and workplace interventions. Coping does not happen in a vacuum, as it always depends on the individual's learning history and experiences (1). This obviously has implications for interventions. Several studies have shown that work-related and environmental factors predict sick leave (72, 74, 75). In a large cohort from the general population in Norway, it was estimated that 24.6% of long-term sick leave cases could be explained by work-related mechanical exposure (75). Interventions targeting individuals, such as atWork, can affect the learning component, as we saw in the focus group study (II) with changed beliefs and increased coping, and in the study by Odeen et al. (2) with reduced belief in the back pain myths. However, in order to have a long-term effect, new experiences showing that coping is possible are necessary.

If the organization of work, the work environment, and factors outside work do not facilitate opportunities for the employees to cope, it might be difficult for the employees to maintain positive ROE and to stay at work. As a result, the intervention might have long-term paradoxical negative effects, inducing a feeling of guilt and blame in the employees for not being able to carry out what they have learned and perform as expected. Researchers have referred to this as "*the too-much-of-a-good-thing effects*" (190, 191), arguing that, for example, too high levels of optimism, self-efficacy, and self-esteem might lead to inadequate belief in an individual's ability to cope with difficult situations (190). This is in line with a study by Carstens et al. (192), who explored the effect of changes in expectancies of recovery in back pain patients over time. The majority of the patients had stable expectations that corresponded to levels of proximal psychological factors. One subgroup with high baseline levels of expectation for recovery had, however, a decrease in expectancies

over time. This group had, to a larger degree than the group with initial low levels of positive expectations, increased in distress, and unfavourable odds for recovery and RTW. For this group, the baseline values were less predictive of outcome, and the results indicate that a mismatch between expectations and experience is more important for outcome than positive expectancies themselves (192).

It might be that atWork would have a more long-lasting effect if the work environment was addressed in addition to the individuals' expectancies and beliefs, in order to decrease the gap between learned expectancies and actual experiences. Shaw et al. (193) evaluated the extent to which principles of chronic pain self-management could be adapted to the workplace. Their conclusion was that such interventions are generally well suited, but that it might be necessary to tailor the messages and make some changes to incorporate organizational, physical and social aspects of work (193).

Individual-level interventions can help increase employees' expectancies of being able to deal with and manage work-related challenges, either in individuals at risk of being sick-listed, as with the outpatient clinic intervention (II), or in a more long-term health promotion perspective, as with atWork (III). When possible, interventions at the organizational level and targeting the physical and psychosocial work environment in order to facilitate and create opportunities for the employees to cope will probably help maintain the effect at individual level over time. As an example, a study by Linton (169), directed towards both the workers and the workplace, significantly improved perceived health, health-care utilization and work absenteeism due to pain, as compared with treatment as usual. The goal of the worker intervention was to increase the workers' ability to manage obstacles and challenges at work, and the workplace intervention directed towards the supervisors should minimize the impact of psychosocial risk factors at work and create a supportive work environment (169). Several reviews and policy documents state that interventions should take into account both organizational and individual factors for best long-term results on health-related outcomes (194-196). This argument is, to a large extent, based on the

fact that health at work is a result of an interaction between individual characteristics and the organization of the workplace (196).

A final point to take into consideration is the context and situation outside of work. In some cases, sick leave is necessary for the employee to recover from their health problems and obtain the energy needed in order to stay at work. Being present at work despite illness is associated with higher levels of future sick leave, even when adjusting for previous sick leave, health status, demographics, and work-related factors (197). According to Kristensen (70), sick leave should not be regarded merely as something bad that must be avoided, as it provides important functions for the individual and serves as a rational coping strategy.

It might be questioned whether the success of workplace interventions should always be measured in terms of its effectiveness in preventing sick leave, especially since large subjective effects of interventions directed towards employees are shown (170, 171). An integrated health programme among employees had no effect on sick leave, but large and highly significant subjective effects on improvement in health, physical fitness, muscle pain, stress management, maintenance of health, and work situation (171). In the long run, such interventions might also have positive effects on sick leave.

Sick leave is indeed the outcome that produces the largest socioeconomic savings, at least in a short time frame. In the long run, however, subjective effects and changed norms at the workplace can provide positive benefits both for the individual employees and for the organization as a whole. When possible, interventions should aim at facilitating an inclusive working life, where it is acceptable for individuals to stay at work even if they are not able to perform 100% at any given time. Main et al. (198) suggest several considerations that might be required to develop an inclusive workplace culture, e.g., to recognize that it is often not achievable with full symptom-free function, and the need to address not just work disability, but work ability. Coping is not just about staying at work despite pain, but being able to do what is best for each individual at different points in time, and to deal with the complaints and

other challenges life poses. As told by the participants in the focus group study (II), increased coping was due not just to work, but being able to carry out activities in their daily lives, such as exercising and playing with their children and grandchildren, that is, being able to live a normal life despite pain.

Although this thesis mainly focuses on the role of individual characteristics in health and workplace interventions, we also found that physical workload is associated with health (I), and that coping is related to several aspects at work and in daily lives (II). Taken together, environmental, structural and social factors should be accounted for when implementing workplace interventions. This facilitates opportunities for the individuals to cope with their complaints at work and in their daily lives, and probably helps maintain the effect at individual level over time.

7. Conclusions

This thesis shows that:

- Individual expectancies are related to perceived health. In a cross-sectional study, response outcome expectancies could partly explain the associations between physical workload, education, and health.
- Several aspects of a back pain information and reassurance intervention contributed to increased coping, changed beliefs and behavioural change among participants. Receiving comprehensible information by health professionals perceived as experts on back pain helped the participants to cope with their complaints at work and in their daily lives.
- atWork, a back pain information and reassurance intervention at the workplace, could prevent sick leave among employees up to six months subsequent to the intervention, and low baseline levels of pain-related fear predicted the effect.
- The combination of qualitative and quantitative research methods gave different perspectives and increased understanding of the role of expectancies and beliefs in relation to health and workplace interventions.

Altogether, these findings mean that:

- It is important to enhance the scientific knowledge about the role of individual factors such as expectancies and beliefs in health and workplace interventions.
- The targeting of expectancies and beliefs is a potentially promising approach to health promotion and sick leave prevention at the workplace. However, to be able to change norms and culture at work over the long term, it might be necessary to repeat the message over time. Furthermore, it is also important to address environmental, structural, and social factors, in order to facilitate opportunities for the individuals to cope with their complaints at work and in their daily lives.

- Employees with high levels of pain-related fear might benefit from receiving the intervention message at an outpatient clinic instead of at work, as this could foster trust in the health personnel providing the information.

Furthermore, consideration should be given to training GPs in the educational part of atWork, making communication of the intervention message a part of regular practice in primary health care.

8. Future research

The findings from this thesis suggest a need for future research, addressing the following issues:

- How do participants in the population-based atWork intervention experience the relationship between the intervention and their subsequent positive response outcome expectancies?
- What are the mechanisms through which atWork has an effect on sick leave? For example, can a change in expectancies and beliefs during and after the intervention period predict the effect of such interventions?
- What causal pathways exist between expectancies, workload, and health when explored in a longitudinal design?
- Does including an environmental approach in atWork, in order to facilitate and create opportunities for the employees to cope, have a stronger and more long-lasting effect on sick leave than the original atWork intervention?
- How are general expectancies and specific pain beliefs related to each other, and which are most important regarding health and sick leave?
- How can the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats) be further developed in order to distinguish between the helplessness and hopelessness factors?

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Paper 1

Subjective Health Complaints and Self-Rated Health: Are Expectancies More Important Than Socioeconomic Status and Workload?

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Abstract

Background The associations between socioeconomic status (SES), physical and psychosocial workload and health are well documented. According to The Cognitive Activation Theory of Stress (CATS), learned response outcome expectancies (coping, helplessness, and hopelessness) are also important contributors to health. This is in part as independent factors for health, but coping may also function as a buffer against the impact different demands have on health. **Purpose** The purpose of this study was to investigate the relative effect of SES (as measured by level of education), physical workload, and response outcome expectancies on subjective health complaints (SHC) and self-rated health, and if response outcome expectancies mediate the effects of education and physical workload on SHC and self-rated health.

Methods A survey was carried out among 1,746 Norwegian municipal employees (mean age 44.2, 81 % females). Structural Equation Models with SHC and self-rated health as outcomes were conducted. Education, physical workload,

and response outcome expectancies, were the independent 28 variables in the model.

Results Helplessness/hopelessness had a stronger direct effect on self-rated health and SHC than education and physical workload, for both men and women. Helplessness/hopelessness fully mediated the effect of physical workload on SHC for men (0.121), and mediated 30 % of a total effect of 0.247 for women. For women, education had a small but significant indirect effect through helplessness/hopelessness on self-rated health (0.040) and SHC (−0.040), but no direct effects were found. For men, there was no effect of education on SHC, and only a direct effect on self-rated health (0.134).

Conclusions The results indicated that helplessness/hopelessness is more important for SHC and health than well-established measures on SES such as years of education and perceived physical workload in this sample. Helplessness/hopelessness seems to function as a mechanism between physical workload and health.

Keywords Subjective health complaints · Coping · Helplessness · Hopelessness · Socioeconomic status · TomCats · Physical workload

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Introduction

The presence of systematic differences in health between socioeconomic groups as measured by income, occupation and education is well documented [1, 2]. The health gradient is not restricted to low-income countries, but is also present in countries with well-established welfare systems [3]. Compared with higher socioeconomic groups, the lower socioeconomic groups have a higher prevalence of poor self-reported health (subjective health complaints, self-rated general health, chronic pain, and disability), higher incidence of specific diseases, and higher rates of mortality [4].

Subjective health complaints (SHC) are often characterized by few if any objective findings [5], and there is a high prevalence of these complaints in the general population [6, 7]. SHC are also the main reasons for long-term sick leave and disability in Norway [8–10] and other western countries [11]. Self-rated general health is a well-validated and commonly used health indicator, and it is a strong predictor of future mortality and use of health services [12–15]. Individuals in lower socioeconomic groups report poorer self-rated health and more subjective health complaints compared to those in the higher socioeconomic groups [4, 16–19].

However, we still do not know all the mechanisms that might explain the association between socioeconomic status (SES) and health [20]. Occupational factors are important predictors for employees' health [21] and it has been suggested that physical and psychosocial demands and conditions at work may constitute important links between SES and health [19, 22–25]. Physical working conditions (e.g., physical strains in doing the job, monotony at work) have been shown to explain most of the social gradient in self-rated health among a representative sample of Swiss employees [23]. Similarly, in a cohort from Finland, heavy physical working conditions explained a large part of the socioeconomic inequalities in self-rated health [22]. However, the importance of control [22] and the relationship between effort and rewards [25, 26] have also been shown, although coping has been reported to be more important to health than control [27]. Coping are defined and measured in many different ways. The “ways of coping” model, which focuses on coping strategies, is one of the most influential models [28]. However, according to Ursin and Eriksen [29], the strategy chosen does not predict the internal state and thus it does not predict health. In their Cognitive Activation Theory of Stress (CATS) they argue that coping predicts relations to health and disease only when it is defined as positive response outcome expectancy.

The Cognitive Activation Theory of Stress [29] can be used to explain the association between coping and health, and the importance of coping for socioeconomic differences in health. Whenever an individual is faced with threats, challenges, or demands, an increase in arousal or activation will follow. If a person has established positive response outcome expectancies (The CATS definition of coping), this increase in activation is short and has a positive influence on health. If the individual expects that he or she will not cope with the situation or the demands, the activation may be sustained over time, which is associated with illness, disease and possible poor health. In CATS, response outcome expectancies may be positive (*coping*), negative (*hopelessness*), or the individual may have established no (*helplessness*) response outcome expectancy. There is no linear relationship between the challenges or demands the individual is faced with, and the increase in arousal. It is the individual's experience of the demands and the expectancies of the response outcome that is important for the

sustained activation and the possible negative health effects [29]. Coping is shown to be an important predictor for socioeconomic differences in health [16, 30, 31]. Lower scores on the expectancy to cope are demonstrated among individuals with low socioeconomic status, both within and between countries [32]. High level of coping is associated with high social position and social success, in both humans and animals [33]. A large Swedish study, SLOSH [16], has used a newly developed scale to measure expectancies of coping as defined in CATS. In this study, coping was a better predictor for health than socioeconomic status, and the relationship between coping and SES was almost linear. These results might have important practical implications, as it is possible to alter individual's response outcome expectancies. If coping is a link between SES and health, increasing the individuals' expectancies of coping might help to reduce the social gradient in health. Individual differences in the expectancy and ability to cope with the demands faced in life in general and, more specifically, at the workplace, may also be important for how the work characteristics affect the employees [27, 34]. Employees with lower income report lower levels of coping and more obstacles in life [35]. However, coping seems to dampen the negative effects of low income. When individuals with low income report a high level of coping, their health and wellbeing is comparable with the higher income groups. Thus, high levels of coping might make it more likely for employees to manage the consequences of an adverse work environment. Previous studies have also found coping to be an important predictor for subjective health complaints [27, 34, 36, 37], and for self-rated general health [16, 38].

In the present study, education will be used as a measure of socioeconomic status. Education is a well-established measure of socioeconomic status in Norway. There are relatively small differences in income in different occupational status in this country, and education is more comparable across different countries than occupational status and income [39]. Although schooling is an integral part of society in Norway, research has shown that there is a linear relationship between higher education and better health [3].

The aim of this study is to explore the contribution of socioeconomic status, physical workload, and response outcome expectancies in explaining subjective health complaints and general health. It is assumed that socioeconomic status, physical workload, and response outcome expectancies are associated with health. We hypothesize that response outcome expectancies will be a stronger predictor for SHC and self-rated health than education and physical workload. Furthermore, we hypothesize that response outcome expectancies will mediate the effect of education on SHC and self-rated health, and that response outcome expectancies will mediate the effect of physical workload on SHC and self-rated health.

Women generally report more subjective health complaints than men [40], and there might be different mechanisms that

affect health and health complaints in men and women. Therefore, we will explore the hypotheses across gender.

Methods

Participants and Procedure

The sample consisted of 1,746 Norwegian municipality employees (81 % females, mean age=44.2 years (SD=11.5)) recruited from two municipalities in Norway as part of a large randomized controlled trial; “atWork” [41]. All employees above 18 years of age in the municipalities of Kongsberg and Horten, Norway, were invited to participate in the study. At the start of the study, it was estimated to be approximately 1,500 municipality employees in Kongsberg and 2,000 in Horten, giving a response rate of approximately 50 %. The municipalities have a population about 25,000 each. 450 (27 %) of the respondents had 1–12 years of schooling, 534 (32 %) of the respondents had 13–15 years of schooling, and 699 (41 %) of the respondents had more than 15 years of schooling.

The study followed the Helsinki declaration, and was approved by the Norwegian regional ethics committee in western Norway (REK-vest, ID 6.2008.117), the Norwegian social science data services recommended the study (NSD, ID 18997), as well as the privacy authority at the National Hospital (Rikshospitalet, ID 08/2421). All employees gave their informed consent before participating in the study.

Instruments

Outcome Variables

Subjective health complaints were measured by the subjective health complaints inventory [5]. It consists of 29 items of common health complaints experienced during the last 30 days, where the items are rated on a four point scale from 0 = “no complaints” to 3 = “serious complaints”. The items are categorized into five factors: musculoskeletal pain ($\alpha=0.78$), pseudoneurology ($\alpha=0.75$), gastrointestinal problems ($\alpha=0.70$), and allergy ($\alpha=0.57$). In the present study, the subscale “flu” was excluded from the analyses because of seasonal variation. Prior to analysis, sum scores representing the remaining four subscales of subjective health complaints were computed.

Self-rated health was measured by a single question: “How will you generally rate your health?” Respondents were given five response options, from 1 = “very good” to 5 = “very poor”. The scale was reversed so that higher scores indicate better health.

Predictor Variables

Education was used as a measure of socioeconomic status and was measured by the question “how many years of schooling/studies have you completed in total? (count the number of years from the first year of primary/elementary school)”.

Perceived physical workload was measured by the question “do you have heavy/repetitive work?” with a ten point scale ranging from 0 = “not at all” to 10 = “very heavy/repetitive”.

Response outcome expectancy was measured by six items from The Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats), which is developed at Uni Health in Norway [16]. It is a newly developed scale, designed to measure response outcome expectancies in CATS [29]. The scale consists of three factors, which represent the three response outcome expectancies in CATS: positive expectancy/coping (one item), no expectancy/helplessness (three items) and negative expectancy/hopelessness (three items). The three factors consists of the following statements: [1] Coping: “I can solve most difficult situations with a good result” (CATS7), [2] Helplessness: “I really don’t have any control over the most important issues in my life” (CATS4), “all my attempts at changing my life are meaningless” (CATS1), “I wish I could change my life, but it’s not possible” (CATS6), and [3] Hopelessness: “all my attempts at making things better just make them worse” (CATS2), “It’s better that others try to solve my problems than for me to mess things up and make them worse” (CATS5), “I would have been better off if I didn’t try so hard to solve my problems” (CATS3). All items were rated on a five point scale from 1 = “not true at all” to 5 = “completely true”. In a previous study of a Swedish population [16], the scale proved to have high reliability and a clear factor structure.

In the present study, the coping item did not correlate significantly with the other variables in the study, and was therefore not included in the analyses. Furthermore, helplessness and hopelessness are treated as one single factor due to results of factor and reliability analyses. The Chronbach’s alpha of the helplessness/hopelessness construct in the present study is 0.77.

Statistics

AMOS version 20.0 was used to perform structural equation modeling to test the hypothesized models. Maximum likelihood estimation was used to estimate all models. Initially, measurement models of the study constructs were estimated. Subsequently, total, direct, and indirect effects between the

study variables were tested in a structural model. The direct paths from physical workload and education to subjective health complaints and self-rated health were estimated in the model, as well as the indirect paths mediated by helplessness/hopelessness. Monte Carlo Estimation was used to examine the significance of the indirect effects [42]. The following indices were used to evaluate the goodness of fit of the models: χ^2 statistics, Comparative Fit Index (CFI) and Root-Mean-Square Error Approximation (RMSEA). According to Brown and Cudeck [43], a RMSEA value less than 0.05 indicates a good fit, while values as high as 0.08 represents a fair fit. A CFI above 0.90 is considered to be representative of a well-fitting model [44]. In the analysis, the different models were also compared by evaluating the change in chi-square relative to the change in degrees of freedom as all models were nested.

The Full-Informational Maximum Likelihood (FIML) method, within the AMOS 20.0 software, was used to handle missing cases. This method has shown to produce unbiased parameter estimates and standard errors, when data are missing at random [45]. In FIML, missing values are imputed by estimating the likelihood functioning for each individual based on the variables present in the model.

The subjective health complaint factors and the helplessness/hopelessness factor showed a positively skewed distribution. This was expected, as a low score on these variables represents a normal trend in the population. To correct for non-normality, we transformed these variables with logarithmic transformations. However, as this did not affect the results of the analyses, we chose to use the original non-transformed variables in the final analyses and presentation of the results.

Results

The mean, standard deviation, and inter-correlations for study variables are shown in Table 1.

Structural Equation Modeling

By imposing correlations between the study constructs, an overall measurement model of self-rated health, SHC, education, physical workload and helplessness/hopelessness were tested. In the model, subjective health complaints and helplessness/hopelessness were modeled as latent constructs, while self-rated health, education and physical workload were estimated by single observed variables. In order to test for the possibility to apply a multi group analysis, a model freely measuring all parameters ($\chi^2=499.37$, $df=116$) was compared with a model constraining all measurement weights to be equal across gender ($\chi^2=532.44$, $df=124$). The restricted model did, however, resolve in a significant increase in Chi-square ($\Delta\chi^2=33.07$, $\Delta df=8$, $p<0.001$)

Table 1 Inter-correlations between observed variables: Education, Physical workload, the helplessness/hopelessness items (CATS1–CATS6), coping (CATS7), the subjective health complaint factors (musculoskeletal complaints, pseudoneurology, gastrointestinal problems, and allergy), and self-rated health

	Mean (SD)	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.
1. Education	14.5 (9.5)													
2. Physical workload	3.16 (2.5)	-0.24**												
3. CATS1	1.65 (0.8)	-0.15**	0.24**											
4. CATS2	1.50 (0.8)	-0.12	0.17**	0.44**										
5. CATS3	2.01 (1.0)	-0.08**	0.15**	0.37**	0.39**									
6. CATS4	1.64 (0.9)	-0.003	0.07**	0.28**	0.32**	0.35**								
7. CATS5	1.47 (0.8)	-0.10**	0.08**	0.32**	0.37**	0.35**	0.40**							
8. CATS6	1.85 (1.0)	-0.12**	0.14**	0.36**	0.34**	0.36**	0.37**	0.35**						
9. CATS7	3.36 (0.4)	0.08**	-0.08**	-0.22**	-0.23**	-0.25**	-0.19**	-0.19**	-0.22**					
10. Musculoskeletal	5.28 (4.5)	-0.11**	0.26**	0.13**	0.17**	0.17**	0.09**	0.04	0.24**	-0.08**				
11. Pseudoneurology	3.27 (3.2)	-0.05	0.15**	0.17**	0.23**	0.31**	0.22**	0.11**	0.29**	-0.15**	0.54**			
12. Gastrointestinal	1.95 (2.6)	-0.02	0.08**	0.08**	0.13**	0.19**	0.15**	0.05*	0.16**	-0.08**	0.39**	0.48**		
13. Allergy	0.92 (1.6)	-0.02	0.06**	0.07**	0.09**	0.07**	0.06*	0.009	0.09**	-0.044	0.31**	0.32**	0.31**	
14. Self-rated health	3.16 (2.5)	0.12**	-0.22**	-0.21**	-0.23**	-0.25**	-0.20**	-0.14**	-0.33**	0.17**	-0.55**	-0.46**	-0.30**	-0.26**

* $p<0.05$, ** $p<0.001$

indicating a different measurement model across gender, excluding the use of multi group analysis. Consequently, all subsequent analyses were performed separately for women and men.

Table 2 shows the fit of the measurement models and the structural models separately for women and men. In both groups, men and women, the measurement model showed an adequate fit (χ^2 (58)=102.78, CFI=0.95, RMSEA=0.049; χ^2 (58)=396.56, CFI=0.91, RMSEA=0.064, respectively). Moreover, acceptable factor loadings in the range from 0.42 to 0.78 were found for all the latent constructs in the models.

As shown in Table 3, subjective health complaints had a substantial negative association with self-rated health in both genders, while the correlation with education was only significant among women. There were significant positive correlations between subjective health complaints, physical workload and helplessness/hopelessness for both men and women, while helplessness/hopelessness had a significant negative correlation with education and self-rated health. The correlation between helplessness/hopelessness and the other constructs varied from -0.16 to -0.38 in the group of women, and from -0.16 to -0.48 in the group of men.

As shown in Table 2, when estimating the structural model with imposed direct effects without mediational effects in the female group, the fit to the data was poorer as compared to the measurement model (RMSEA=0.075; CFI=0.88). In the direct effect model, there was a significant path between education and self-rated health, but the path between education and subjective health complaints was not significant. When including a

mediational path through helplessness/hopelessness, the fit improved (RMSEA=0.064; CFI=0.91). As hypothesized, the path from education to self-rated health was no longer significant. Therefore, a final model without the paths from education to SHC and self-rated health was estimated. Excluding these paths did not cause a significant increase in χ^2 ($\Delta df=2$; $\Delta\chi^2=1.35$, n.s.) indicating that this model is superior to the initial model based on the principal of parsimony. The final model showed good fit to the data (RMSEA=0.063; CFI=0.91). The paths in the structural model are presented in Fig. 1.

As shown in Table 4, there was a significant positive total effect between physical workload and subjective health complaints ($\beta=0.247$) in the final model for women. A direct effect of 0.173 (70 %) and an indirect effect of 0.074 (30 %) was found. In order to test the significance of the indirect effect, a Monte Carlo calculation was conducted [42], showing that the indirect effect was significant (95 % CI, 0.01–0.03). There was a significant positive total effect between physical workload and self-rated health ($\beta=-0.238$). A direct effect of -0.163 (68 %) and an indirect effect of -0.074 (32 %) were found between these constructs. The Monte Carlo calculation showed that the indirect effect was significant (95 % CI, 0.02–0.03). There was a significant positive but small total effect between education and self-rated health ($\beta=0.040$). While no significant direct effect was found, a significant indirect path of 0.040 (100 % of the total effect) was revealed. A Monte Carlo calculation showed that the indirect effect was significant (95 % CI, 0.00–0.02). The

Table 2 Fit indices and model comparison for tested models

Model	Model fit				Model comparison		
	χ^2	<i>df</i>	CFI	RMSEA	Comparison	$\Delta\chi^2$	Δdf
Total							
M1: Measurement model	449.92	58	0.92	0.057	–	–	–
M2: Direct effect model	635.40	60	0.88	0.068	M1–M2	185.48*	2
M3: Mediation model	449.92	58	0.92	0.057	M2–M3	185.48*	–2
M4: Final model	454.08	60	0.92	0.056	M3–M4	4.16	2
Women							
M1: Measurement model	396.56	58	0.91	0.064	–	–	–
M2: Direct effect model	537.33	60	0.88	0.075	M1–M2	140.77*	2
M3: Mediation model	396.56	58	0.91	0.064	M2–M3	140.77*	–2
M4: Final model	397.91	60	0.91	0.063	M3–M4	1.35	2
Men							
M1: Measurement model	102.78	58	0.95	0.049	–	–	–
M2: Direct effect model	154.30	60	0.89	0.07	M1–M2	51.52*	2
M3: Mediation model	102.78	58	0.95	0.049	M2–M3	51.52*	–2
M4: Final model	105.95	62	0.95	0.047	M3–M4	3.17	4

CFI comparative fit index, RMSEA root-mean-square error approximation

* $p<0.001$

Table 3 Correlation between latent and observed study variables in the measurement model (CFI) by gender

	Mean (SD)	1.	2.	3.	4.
Women					
1. Education (SES)	14.50 (2.93)				
2. Physical workload	3.23 (2.51)	−0.22**			
3. Helplessness/hopelessness	10.02 (3.60)	−0.16**	0.24**		
4. Self rated health	3.02 (0.79)	0.11**	−0.24**	−0.38**	
5. Subjective health complaints	12.63 (9.85)	−0.08*	0.25**	0.38**	−0.68**
Men					
1. Education (SES)	14.48 (3.41)				
2. Physical workload	2.81 (2.34)	−0.33**			
3. Helplessness/hopelessness	10.59 (3.74)	−0.16*	0.25**		
4. Self rated health	3.00 (0.76)	0.20**	−0.12*	−0.38**	
5. Subjective health complaints	10.29 (9.18)	−0.12	0.16*	0.48**	−0.52**

** $p < 0.001$; * $p < 0.05$

squared multiple correlations (R^2) in the final model were 0.177 for SHC and 0.171 for self-rated health.

As shown in Table 2, the direct effect model was poorer as compared to the measurement model (RMSEA=0.070; CFI=0.89) in the group of men. In this model, there was a significant positive path from physical workload to SHC, while the paths from education to helplessness and subjective health complaints and from physical workload to self-rated health were not significant. When including a mediational path through helplessness/hopelessness, the fit improved (RMSEA=0.049; CFI=0.95). As hypothesized, the path from physical workload to SHC was no longer significant. Therefore, a final model without the insignificant paths was estimated. Excluding these paths did not cause a significant increase in χ^2 ($\Delta df=4$; $\Delta \chi^2=3.17$, n.s.), indicating that this model is superior to the initial model based on the principal of parsimony. The final model showed good fit to the data (RMSEA=0.047; CFI=0.95). The paths in the structural model are presented in Fig. 2.

As shown in Table 4, there was a significant positive total effect between education and self-rated health ($\beta=0.134$) in the final model for men. No significant indirect effect was found between these constructs. The total effect between physical workload and subjective health complaints was significantly positive ($\beta=0.121$). While no significant direct

effect was found, a significant indirect path of 0.121 (100 % of the total effect) was revealed. A Monte Carlo calculation showed that the indirect effect was significant (95 % CI, 0.02–0.07). The squared multiple correlations (R^2) in the final model were 0.232 for SHC and 0.154 for self-rated health.

Discussion

The central purpose of this study was to investigate whether response outcome expectancies are a stronger predictor for SHC and self-rated health than education and physical workload, and if response outcome expectancies mediate the effects of socioeconomic status and physical workload on SHC and self-rated health. The results confirmed the first hypothesis of the paper, as response outcome expectancies were a stronger predictor than education and perceived physical workload for subjective health complaints and self-rated general health. This result is similar to a study from Sweden, which used the same scale to measure response outcome expectancies as the current study [16]. Coping was a stronger predictor for self-rated health than both subjective and objective social status in the Swedish study [16]. The authors concluded that coping was one of the mechanisms underlying the association between socioeconomic status and health.

Fig. 1 Parameter estimates for final model in women. The circles represent latent variables. The squares represent observed variables. All path coefficients are significant at $p < 0.01$

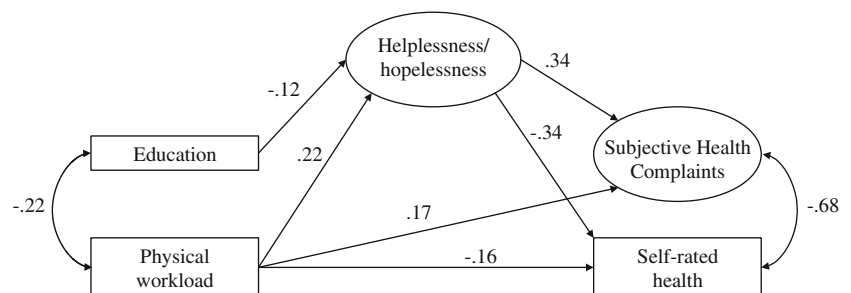


Table 4 Standardized total, direct and indirect effects of education, physical workload and helplessness/hopelessness on subjective health complaints (SHC) and self-rated health for men and women

	Women			Men		
	Helplessness/hopelessness	SHC	Self-rated health	Helplessness/ hopelessness	SHC	Self-rated health
Total effects						
Education (SES)	−0.116	−0.040	0.040	–	–	0.134
Physical workload	0.217	0.247	−0.238	0.251	0.121	–
Helplessness/hopelessness	–	0.344	−0.342	–	0.481	−0.358
Direct effects						
Education (SES)	−0.116	–	–	–	–	0.134
Physical workload	0.217	0.173	−0.163	0.251	–	–
Helplessness/hopelessness	–	0.344	−0.342	–	0.481	−0.358
Indirect effects						
Education (SES)	–	−0.040	0.040	–	–	–
Physical workload	–	0.074	−0.074	–	0.121	–
Helplessness/hopelessness	–	–	–	–	–	–

All effects $p < 0.001$

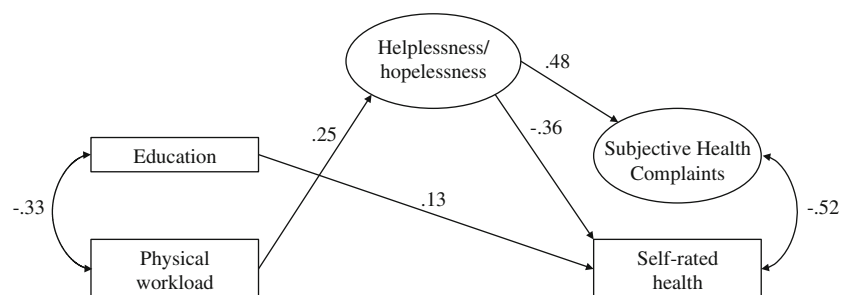
The present study partially supports the hypothesis that coping, or in this case helplessness/hopelessness, might function as a mechanism between socioeconomic status and health, as helplessness/hopelessness fully mediated the effect of education on self-rated health and SHC for the female group. However, the effect of education was small, and for men it had no significant effect on SHC, and only a direct effect on self-rated health. Ihlebæk et al. [7] also found that education was a significant predictor for SHC in women, but not in men. Furthermore, in line with the present study, Ihlebæk et al. [7] found that physical workload was significantly related to SHC for both genders. However, the full model in that study, with several predictors such as lifestyle, work-related factors, etc., explained little of the variance in SHC. The authors suggested that coping and other psychological factors might be of stronger importance for SHC [7].

In the present study, helplessness/hopelessness was a stronger predictor for SHC and self-rated health than education and physical workload. Furthermore, helplessness/hopelessness seemed to be a mechanism between physical workload and health, as it partially mediated the effect of physical workload on SHC and self-rated health for women, and fully mediated the effect of physical workload on SHC for men. This is in

accordance with a previous study that found unfavorable coping strategies to be related to negative work characteristics and poor health [46]. The results of the present study are also in line with a study by Karademas et al. [47], where helplessness had both a direct effect on subjective health, and an indirect effect through certain coping strategies. In the present study, the association between physical workload and the health outcomes were stronger in the female group than in the male group. The results are in accordance with a study of anesthesiology students, where female students more often reported higher concentration demands and limited possibilities to control work compared to male students [48]. The present study indicates that the effect of physical workload on SHC is partially due to individual's lack of coping, especially in men.

The results may be explained within the framework of CATS [29], where the individual's expectancy of being able to cope with the demands and challenges he or she encounters in the workplace are more important for the employees' health than the demands or objective work characteristics themselves. However, the subjective perception of physical workload does not necessarily correspond with the actual physical workload. Research has shown that correlations between subjective perceptions of work conditions and the

Fig. 2 Parameter estimates for final model in men. The circles represent latent variables. The squares represent observed variables. All path coefficients are significant at $p < 0.01$



actual objective work conditions tend to be weak [49, 50]. Christie and Barling [30] suggest that coping and the work environment are dynamic and responsive to each other. In their longitudinal study, individuals who reported lower levels of coping at baseline increasingly perceived more work stressors and health problems over time. The same pattern yielded for individuals who reported more work stressors at baseline, as these perceived less degree of coping over time than those who initially reported less work stressors. In line with the present study, these findings make it reasonable to assume that poor health might partly be a product of individual's expectancies of coping with difficulties.

The main strength of the present study is that it is based on a large and representative sample of Norwegian municipality employees, which provides a good basis for generalization of the results to other worksites. The sample is diverse with regard to work type and workplace size, which reduces the possibility of effects of localization or group specific effects. However, a response rate of about 50 % may limit the validity of the findings. Even though considerable efforts were made to improve the response rate by providing information to the employees about the project, it remained low. The high predominance of women in the sample (about 80 %) represents characteristics of the population in general, as 69 % of all public sector employees are women, with the majority working in the municipalities [51]. In the two participating municipalities, 79 % and 68 % of the employees are women. However, caution should be made when generalizing to private sector employees.

The majority of the participants in this study had higher university education, and the sample was generally highly educated. Thus, the significance of education on health and the relationship between education and helplessness/hopelessness might have been undermined due to small variance. Further studies should investigate the relationship between the variables in a more heterogeneous sample. In addition, the inclusion of more items and preferably validated scales of workload and work characteristics would provide more reliable conclusions regarding the relationship between work characteristics, coping, socioeconomic status, and health.

Although several of the results in the paper were statistically significant, the coefficients and effect sizes were relatively small. This may be a consequence of the large sample size of the study, as large samples make it more likely to achieve statistical significance even with small effect sizes [52]. However, a large sample increases the likelihood that the results are in accordance with the actual population value [52], and even small effect sizes might have important practical significance. For example, as it is possible to influence and alter individuals' response outcome expectancies, coping has important implications for interventions. Thus, for jobs where it is difficult to remove the objective work stressors, interventions should focus on improving the

employees' expectancies of coping. Empowerment interventions aimed at strengthening employees' positive response outcome expectancies may enable the employees to manage the possible consequences of facing a tough work environment, and thereby improve the employees' health and reduce health inequalities in the population. According to Rappaport [53], empowerment involves both a subjective perception of personal control, and a sufficient degree of real social impact. Thus, interventions should focus both on strengthening the employees' positive response outcome expectancies (individual level), and to facilitate and create opportunities to cope (organizational level). At the individual level, Cognitive Behavioral Therapy (CBT) can be used to increase employees' positive response outcome expectancies. The aim of CBT at an individual level is to challenge and change individuals' unhelpful thought patterns in a positive direction by focusing on his or hers previous coping experiences, and gaining new coping experiences through behavioral experiments. In line with CATS, the treatment is based on the belief that coping generalizes, and the goal is for low-coping individuals to obtain expectancies of coping. Examples of such empowerment interventions at the organizational level are individual adjustment of tasks and goals, giving the employees opportunities to participate in goal setting, manageable sub-goals, social support from supervisors and co-workers, and acknowledgement and feedback concerning the employees work achievements.

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Conflict of interest statement None declared.

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Paper 2



ORIGINAL ARTICLE

How can a brief intervention contribute to coping with back pain? A focus group study about participants' experiences

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Abstract

Background: Our aim was to explore how individuals who had participated in a brief back and neck pain intervention perceived connections between the intervention and their subsequent coping. **Methods:** Three focus group discussions were conducted with a sample of ten employees aged 20–67 years, who had participated in a brief intervention for back and neck pain, perceived the intervention as helpful and had returned or remained at work subsequent to the intervention. Participants were invited to share stories of how the intervention had made a positive difference to their work situation and everyday life and helped them cope with their complaints. Systematic text condensation was used for analysis. **Results:** Analysis revealed several aspects of how the participants considered the intervention to be helpful. They emphasized the importance of having the information delivered in a comprehensible way, with the use of practical examples and images of the spine. Discussions revealed the significance of trusting the lecturers and perceiving them as experts. Understanding why they felt the pain and that it was not a sign of serious disease changed the participants' perception of how they could live with the complaints. They told stories of how they had exceeded their previous limits and dared to undertake activities they previously had avoided due to fear. **Conclusions:** Having confidence in the lecturers and seeing them as experts that delivered the information in a comprehensible way helped participants to cope with their pain and was seen as the most important aspects of the brief back and neck pain intervention.

Key Words: Focus groups, back pain, cognitive therapy, health education, health communication, sick leave, psychological adaption

Introduction

Musculoskeletal pain is the most frequent reason for long-term sick leave and permanent disability; for several years it has accounted for nearly 40% of the long-term sickness absence in Norway [1]. Low back pain is the most common single diagnosis within this group [2]. A brief intervention, aimed at enabling individuals to manage the consequences of musculoskeletal pain, has proved successful in reducing sick leave in clinical populations [3–6], and among employees [7,8]. The framework of the intervention is a non-injury model [3,6], introduced using non-directive communication

[4, 9]. According to a *non-injury model*, the back is considered to be a strong structure, capable of tolerating a wide range of movements without damage [3,6]. In the intervention, *non-directive communication* is used to give participants evidence-based information regarding their complaints, allowing them to draw their own conclusions on how to handle their everyday life [4,9]. Participants are not given advice, but offered insight and understanding to make their own decisions.

atWork is a work-based back and neck pain intervention offered to employees. As part of this intervention

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employees who are sick listed, or at risk of becoming sick listed, because of back and neck pain are referred to a brief intervention at an outpatient clinic. At the clinic they are initially given a brief medical evaluation by a physiotherapist to rule out the need for further medical investigation or treatment. Subsequently, the participants are presented information regarding the non-injury nature of back and neck complaints (a course of 2–3 hours), with a follow-up consultation where needed. The take-home message from the intervention is that normal activity, including staying at work, benefits general health and provides the best prognosis for recovery from the complaints. A randomized controlled intervention study in a population of municipal employees showed, at the 1-year follow-up, that the atWork intervention was successful in reducing sick leave [7].

We still do not know why these interventions are perceived as helpful. The Cognitive Activation Theory of Stress (CATS) [10] may be used to explain the impact of a brief intervention on the employees' perception and management of their health complaints and their decision to return to or remain at work. CATS define coping as *positive response outcome expectancy*, which means that individuals who encounter a stressor, expect that their responses to the situation will provide positive outcomes. If the individual copes, the stress response will be short lasting and anabolic.

Some of the authors have clinical experience with back pain patients and some of us have participated in the implementation or evaluation of a brief intervention. We shared the preconception that this approach would increase the participants' positive response outcome expectancies by reducing their feeling of uncertainty regarding their health complaints. In the current study we explored how individuals who have participated in a brief back and neck pain intervention perceive connections between the intervention and their subsequent coping.

Material and methods

A focus-group design was chosen as it enables participants to interact and express themselves with the added value of social interaction [11]. We recruited a purposive sample of employees who 4–6 months earlier had participated in the brief intervention part of atWork, who had experienced the intervention as positive and helpful, and had returned or remained at work subsequent to the intervention. The participants in our study were not the same as those who participated in the RCT, as the intervention is ongoing in several Norwegian counties after the RCT was conducted. The staff at the clinics recruited the participants by contacting everyone who had participated in the intervention within the given time frame. Those who

fulfilled the inclusion criteria were asked to participate in the focus groups. Composing the focus groups, we aimed for variations on gender, age and occupational status, but recruitment set some limits to this.

Data were drawn from three focus groups, with a total of 10 participants. Our sample included three men and seven women aged 20–67 years. All participants were working part-time or full-time (auxiliary nurses, teachers, carpenter, dentist, school inspector, preschool assistant). At the time of the intervention, most of them were on full or part time sick leave. Most of them had struggled with back pain for several years (0.5–15 years).

The interviews took place at the clinic where the brief intervention had been carried out. Each group met once for a 90-minute conversation. The interview followed established focus-group research principles [11,12]. The moderator (ER in two interviews and KM in one) invited the participants to share experiences and tell stories about how the intervention had made a positive difference for their work situation and everyday life, and how it helped them cope with their complaints. An observer took notes during the interviews and evaluated the atmosphere and interaction. After three interviews we found sufficient data variation for a responsible analysis to explore our study question. The study was approved by the Data Protection Official for Research (NSD, ID 32505). Principles of the Helsinki declaration were followed, and written informed consent was obtained from all of the participants.

The interviews were audio-recorded, encrypted, and transcribed verbatim by the first author. Systematic Text Condensation (STC), a descriptive, cross-case analysis strategy, was used [13]. Three of the authors cooperated on the analysis (ER, KM, and AH), not to achieve consensus but to expose data for different views and perspectives [14]. Owing to the diversity of age, educational background, occupational, and clinical experiences, different perspectives and nuances on the material were available.

Results

The analysis revealed several aspects related to how and why the participants considered the brief intervention as helpful. The participants emphasized the importance of having the information delivered in a comprehensible way, with the use of practical examples, metaphors, and images of the spine. The participants stressed the significance of trusting the lecturers as experts. Understanding why they felt pain and that it was not a sign of serious disease, changed the participants' perception of how they could live with it. They gave examples of how they had exceeded their previous limits and now dared to undertake activities

they previously had avoided due to fear. The findings are expanded upon in the text below. Quotations are assigned pseudonyms.

The participants had trust and confidence in the lecturers and perceived them as experts that delivered the information in a comprehensible way

The participants described how the course had given them useful information about the back, presented in a comprehensible manner, using video clips, metaphors, a demonstration of the functions of the spine, including concrete examples and theoretical explanations. It was not just the information provided per se, but how the information was delivered that mattered. A young car enthusiast had been fascinated by the lecturer saying that the back is the world's best bumper. He had seen pictures of how the muscles in the back were supposed to function, and then how the back muscles could tense and cramp, which made him realize that his muscles were tense and did not relax. Several others told similar stories.

The participants emphasized the importance of being able to recognize their own situation in much of what was said during the course. Several said that when they saw drawings of the spine and were given an explanation of how muscle cramps develop, it was as if the lecturers were talking about their personal back pain. Many participants said they found the experience eye-opening as they finally understood where the pain came from, thus making it all more logical and comprehensible.

There was broad agreement among the participants that trusting the expertise of the lecturers and having confidence in them was important. A female auxiliary nurse said that no one had ever explained the difference between muscular tension and nerve terminals to her before. Most of the participants shared the perception of the lecturers as experts on back pain. Several said that they viewed the lecturers as more thorough than their GPs and that they had used more easily understood language. A 20-year-old health care apprentice who had struggled with back pain for 5–6 years said:

I got the impression that it was said with.... that the lecturer had great professional expertise and knew what she was talking about (Cathrine)

Understanding the pain enhanced the participants' confidence in using their bodies without fear

The participants described the relief they felt when they realized that their pain was not a sign of cancer

or heart problems. Now they knew that their pain was not due to a serious disease, it was just muscle cramps. Several of them had previously feared that they would need surgery, but now they were convinced that it was not necessary. They were eager to tell friends and colleagues with back pain about this, hoping their doctors also had acquired this new knowledge of the back. One of them said that he now understood that even prolapses would disappear, because they dry up. A teacher in her thirties quoted the following as a reason for gaining great benefit from the course:

I think that might be the reason why the course worked out so nicely, because you previously were so worried, and then you got a very straightforward explanation (Madeleine)

Most of the participants spoke about how they were no longer afraid to use their body. They felt able to move their backs even if it was hurting, because they knew why they felt pain, and they were confident that it was not harmful. Several said that their back did not hurt less when they used it, but their understanding of how they could use it, in leisure and at work, had changed. Some of them were no longer afraid of heavy lifting at work or, for example, to help patients in and out of bed. Many of the participants said that if they felt pain they would just go on. If it got too bad, they would take a pain killer and not care too much about it; they would not quit the activity anyway. A quote from one of the men illustrates the impact of the course on his thoughts and beliefs regarding back pain:

To me it's the knowing... that I haven't got cancer in my back... it's like... that psychological effect, that you can do something even if your back hurts a little (Ben)

Exceeding previous limits and doing things they never dared do before provided benefit and space in everyday life

In addition to describing how the intervention made a positive contribution on cognitive aspects (what the participants think and believe), the participants also conveyed its influence on behavioral aspects (what they actually do). Several participants described how, after the course, they had discovered that pushing themselves beyond previous limits turned out to be not only tolerable but actually beneficial. Numerous stories illustrated how far they would go, such as walking up a steep and slippery hill within a time limit. Often, they realized that it was possible to do more than they thought they could. Many participants said that while previously they had become

exhausted or restricted their movements in relation to a specific activity, they were now able to move more freely and spontaneously. A female auxiliary nurse explained that she now dared to turn around without thinking much about it, where previously she took great care in an attempt to prevent pain. This woman had struggled with back pain for 7–8 years, and explained how she now dared to push herself despite feeling pain:

Previously, I was not able to do anything. Nothing. But now – I grit my teeth in order to get up. I must get up, even if I need someone to help me (Nathalie)

The participants talked not only about pushing previous limits, but also about doing new things, to move and use their bodies in ways they did not dare before. The participants talked about how, after the course, they felt safe to go for walks and to exercise, which many of them had not done previously. A woman explained that she had joined her grandchildren on the sledging hill, and a younger man started exercising several times a week, mostly weight-lifting, but also running and swimming. Previously, this man did not exercise at all because he was afraid that it could hurt his back. Many participants gave similar examples, like an auxiliary nurse in her mid-sixties who had struggled with back pain for 10 years:

Before I did not dare to tilt patients up in their bed when I was at work, I dare that now (Charlotte)

Discussion

The analysis demonstrated that having confidence in the lecturers and seeing them as experts that delivered the information in a comprehensible way was by the participants seen as the most important aspects of the atWork brief intervention. Understanding their back pain changed the participants' understanding of how they could live with it. The participants exceeded their previous limits, and dared to do things they never dared to before. Below, we discuss the strengths and limitations of these findings.

Strengths and limitations of the study

The aim of this study was not to evaluate the effect of the intervention, as this has previously been done [7]. Since we wanted to know more about *how* and *why* the intervention was perceived as beneficial by many participants, we only included participants with a positive experience who were at work after the intervention. We did not invite the less successful participants to share their experience and attitudes, therefore

the study is limited in shedding light on what does not work or what could have been better.

Participants who signed in to our focus groups might be the most verbally gifted, perhaps the most self-confident. Yet, since our theoretical perspective was a resource-oriented one [10,15], such voices might be especially suited to mediate experiences perceived as positive. The impact of some important aspects of the intervention on the participant's expectancies of coping might be transferable to participants suffering from other subjective health complaints, such as chronic fatigue syndrome, fibromyalgia, or mental health complaints, when receiving a similar intervention [16,17]. However, whether patients suffering from these kinds of health complaints will recall similar stories needs to be explored in another study.

Owing to challenges with recruitment, the groups were small, with three and four participants in each group. A common recommendation is five to eight participants in each focus group [18]. Yet most authors point out that there is no definite answer on sample size in focus groups, what matters is that the data is sufficiently powerful to illuminate the research question [19,20]. A small sample might raise the issue of how representative such a sample is. However, in qualitative studies, sufficient variation in the material is more important than representativity [14]. The participants in our study were quite diverse regarding age, gender, background and experiences. Furthermore, the group dynamics were good, and we collected information on substantive events, illustrative stories and the experiences of all the participants.

Several of the authors are health professionals, as well as researchers. This might have impacted the stories by reproducing the aims of the intervention [21]. However, we emphasized that we were not there to evaluate the intervention, and the participants did not sound like they were evaluating it.

What does this study add?

Previous studies of brief interventions with non-directive communication of information based on a non-injury model are mainly quantitative, studying the effect of the intervention in terms of reduced sick leave [3,5,7,22]. There is a lack of studies exploring participants' experiences of this specific intervention.

Our study adds to previous knowledge by describing the modes in which information recognized as beneficial is communicated and perceived. Our participants emphasized the benefit of the information being provided in an understandable language, with the use of relevant examples, metaphors, and images. Also, in line with previous studies, having professionals perceived as

experts, positive and encouraging, appear to be important aspects of an intervention [16,23]. Our findings transcend previous knowledge by emphasizing the significance of having trust and confidence in the lecturers, which seemed to be one of the most important aspects of this intervention.

Previous studies have emphasized the impact of social support, and being understood and believed by healthcare personnel and significant others, as beneficial aspects of back pain interventions [23,24,27,28]. In a study of patients with Chronic fatigue syndrome (CFS)/Myalgic encephalomyelitis (ME), feeling accepted and believed by the therapist turned out to be one of the most important factors of the treatment [30].

Rather than talking about being believed by healthcare providers, the participants in our study talked about the opposite: the importance for them to trust and believe in the healthcare providers. In the current study, participants talked about how the intervention helped them live a normal life despite having pain, instead of talking about pain reduction. Aspects referring to the non-directive communication of the intervention were not raised by the participants. However, this was not surprising, since the issue of non-directive communication had not been explicitly mentioned during the intervention. Furthermore, our study was not an evaluation of the intervention per se, but a more specific exploration of what the participants found useful.

The study adds to previous knowledge about how coping may be processed, expressed, and enacted. Whilst other studies describe how interventions may provide strategies for pain control and setting limits [24,29], our study presents knowledge about how the intervention helped the participants to push previous limits and stop trying to control their pain. It was not the strategies themselves that were important, rather how the intervention changed their understanding of their pain and what they could do, and how this impacted their experience of back pain in daily life.

The positive and helpful aspects of the intervention on the participants' perception and management of their back and neck complaints can be explained by the Cognitive Activation Theory of Stress. One common aspect raised by all participants, is that the intervention increased their expectancies of the ability to cope with their back pain in daily life. A number of histories revealed that the participants had improved their expectancies of coping, referring to "before the course I..." as opposed to "now I...". Knowing why they felt pain, that it was not harmful, and that they could not make it worse by carrying out normal activity, helped them to cope. The participants' coping were not about controlling their pain or being able to affect it, but being able to live with it

and knowing that they could do whatever they wanted to. In accordance with the CATS framework [10], our study reveals concretely how coping in the sense of positive response outcome expectancies may be enhanced by learning and subsequent experiences.

Implications

Our findings highlight the importance of how healthcare providers deliver information to back pain patients, and that patients have trust and confidence in them. These findings might suggest specific training for GPs and physiotherapists on what kind of information they should provide to their patients with back pain, and how they can provide it in a comprehensible and useful way.

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Conflict of interest

None declared.

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Paper 3

The effect on sick leave and predictors of outcome: A cluster randomized trial of a low back pain information and reassurance intervention at the work place

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Abstract

Aims: To investigate the preventive effect of a work place educational back pain intervention on sick leave at individual level and to identify possible predictors that may prevent sick leave for the participants.

Methods: Work-units in two municipalities were cluster-randomized to (1) educational meetings and peer support (45 units), (2) educational meetings, peer support, and access to an outpatient clinic if needed (48 units) or (3) control (42 units). Both intervention groups had educational meetings with information about back pain based on a “non-injury model”. A “peer advisor” was selected among their colleagues. Outcome was days of sick leave at individual level at 3, 6, 9 and 12 months, adjusting for previous sick leave at unit level. Due to similar effect on sick leave the two intervention groups were merged ($n=646$) and compared to controls ($n=211$). Predictors were different levels of belief in back pain myths, pain-related fear, helplessness/hopelessness, and low back pain.

Results: The intervention group had significantly less days of sick leave at 3 months (4.9 days, $p=.001$) and at 6 months (4.4 days, $p=.016$) follow-up, compared to the control group. At three months, a low level of pain-related fear was the only predictor for intervention effect (8.0 less days of sick leave, $p < .001$).

Conclusions: A work place educational back pain intervention may prevent sick leave up to six months. Low score on pain-related fear was a predictor of the intervention.

Trial registration ClinicalTrials.gov, registration number: NCT00741650

Key words: work intervention; health education; health communication; psychological adaption; helplessness; hopelessness

Introduction

Neck and low back pain (LBP) are the most common complaints related to long-term sick leave and disability in Norway [1], and LBP is globally related to more disability than any other condition [2]. Despite great research effort, the evidence regarding prevention of LBP is scarce [3]. It seems difficult to prevent low back pain, but research has shown that this is possible to prevent the consequences of low back pain, such as sick leave, fear of movement or injury and inactivity [3]. Therefore, it is important to prevent these negative consequences of LBP [3].

Brief interventions based on a “*Non-Injury Model*” (NIM) with the aim to prevent consequences of LBP have shown success in increasing return to work (RTW) in clinical populations [4-6], and in preventing sick leave among employees [7, 8]. NIM is proposed by Indahl [4], and is in line with the European guidelines for the prevention of LBP [3].

According to NIM, the spine is considered to be a strong structure and pain is seldom a sign of an injury or disease caused by strain, but rather a functional disturbance [4]. Interventions based on NIM are effective regarding RTW among LBP patients for a substantial proportion of the participants [3-6]. More information concerning possible predictors for effect of such interventions in preventing sick leave will provide valuable knowledge for future interventions.

For those who are already on sick leave due to LBP, fear avoidance beliefs, low internal health locus of control, and negative expectancy of recovery are negative predictors for RTW [6, 9, 10]. Fear avoidance beliefs are associated with sick leave, even when controlling for LBP, previous sick leave, age and work environmental factors [11]. However, evidence from non-clinical populations is scarce, and it is therefore of interest to explore if beliefs and expectancies are valid as predictors of remaining at work in a non-patient population.

In the current study, we have explored this issue in a sample of Norwegian employees who participated in atWork, a cluster randomized controlled trial of a workplace intervention based on NIM. The aim with atWork was to prevent and manage negative consequences of LBP in a population of municipal employees, and it proved to be effective in preventing sick leave at group level at one year-follow up [8]. The current study contributes with continuous individual-level data on sick leave among employees who participated in atWork, consenting to gather individual data.

Changing misconceptions about low back pain and enable the employees to cope with back and neck pain at the workplace, is the core of atWork. The Cognitive Activation Theory of Stress (CATS) [12] is therefore an important theoretical framework for the intervention. CATS defines coping, which is essential for health, as the acquired expectancy that most or all responses lead to a positive result. Hopelessness (negative response outcome expectancy) and helplessness (no response outcome expectancy) on the other hand, are associated with sustained activation, which may have major implications for health [12].

The aim of the current study was to investigate the effect of atWork on sick leave at individual level, and to investigate whether belief in back pain myths, pain-related fear, helplessness/hopelessness, and LBP predict the effect of the atWork intervention.

Materials and Methods

Participants and procedure

In the period 2008-2010, all employees in two Norwegian municipalities were invited to participate in the atWork intervention. It was estimated to be around 3500 employees in total in the two municipalities at the initiation of the study. The effect of the intervention on sick leave at unit level and details of procedure and interventions are published elsewhere [8]. Since the intervention was carried out in workplace units, a cluster-randomized design was

chosen. 125 work units (clusters) in the municipalities were randomized into three groups: (1) educational meetings and peer support, (2) educational meetings, peer support and access to an outpatient clinic, or (3) control group that received treatment as usual (Figure 1).

Randomization of whole units, stratified according to sectors (i.e., schools, nursing homes etc.) was done at Uni Health using computer generated, random numbers. Due to the nature of the intervention, it was not possible to blind participants of their allocation.

All employees who were randomized to any of the intervention groups received 2-4 educational meetings at the workplace. At these meetings evidence-based information about LBP based on NIM and the European guidelines for LBP was presented [6, 7]. At each work unit, a peer advisor was selected among the employees. The peer advisor was a colleague who received a brief education regarding back pain, and should assist colleagues with information and support to increase their likelihood to stay at work. Additionally, in the intervention group with access to an outpatient clinic, the peer advisor could, if needed, directly refer the employee to the clinic.

The control group did not receive any intervention. Both the control group and the intervention groups were free to receive treatment as usual from GPs and the remaining Norwegian health care system.

At baseline, 1746 employees responded to the questionnaire, giving a response rate of approximately 50%. Informed consent was obtained separately for registry data and survey, and in the current study, we excluded employees with missing data on consent to obtain individual registry data on sick leave ($n=795$). Furthermore, participants with missing data on workplace unit ($n=94$) were excluded, as this information was necessary to know which group the participants were randomized to. The two intervention groups were combined into a single intervention group, because few workers went to the outpatient clinic, and the result from either intervention was similar on sick leave. Consequently, 646 (mean age = 44.2 years

(SD = 10.81), 86% females) constituted the intervention group, and 211 (mean age = 43.1 years (SD = 11.62), 88.2% females) the control group (Figure 1).

INSERT FIGURE 1 HERE

Ethics

The study followed the Helsinki declaration, and was approved by the Norwegian Regional Ethics Committee in Western Norway (REK vest, ID 6.2008.117). The Norwegian Social Science Data Services recommended the study (NSD, ID 18997), as well as the privacy authority at the Oslo University Hospital (Rikshospitalet, ID 08/2421).

Instruments

Outcome variable. *Sick leave* was measured at individual level by individual registry data from the Norwegian Labour and Welfare Administration (NAV). In Norway the employer pays the first 16 calendar days of a sick leave period. After the 16 day period, NAV covers the disbursement with sick leave benefits equal to 100% of past earning. The available data were based on the sickness payment database from NAV. In cases where the employees were sick listed for more than 16 days, these 16 days were also included in the data material. In the present study the number of days on sick leave was calculated for the 12 months both prior to and after the intervention.

Predictor variables. All predictor variables were measured at baseline.

Low Back Pain (LBP) was measured with a single item from the Subjective Health Complaints (SHC) inventory [13], asking if the participants had experienced LBP in the last 30 days. The item was rated on a four-point scale from 0 = “no complaints” to 3 = “serious complaints”. The item was dichotomized to 0 (no or some complaints) and 1 (much or severe complaints).

Attitudes and beliefs regarding LBP were measured by two items from Deyo's "back pain myths" [14]. Originally, Deyo [14, 15] proposed seven myths that represent misconceptions regarding LBP. Two of these myths were explored in the current study, as these are specifically addressed in atWork [8], in addition to being the most prevalent in the general population [15]: 1) "Most back pain is caused by injury and heavy lifting" (Myth lifting) and 2) "Everyone with back pain should have a spine X-ray" (Myth X-ray). The items were rated on a five-point scale from 1 = "totally disagree" to 5 = "totally agree". The items were dichotomized to 0 = "totally disagree", "disagree", "neither disagree nor agree", and 1 = "agree" and "totally agree".

Pain related fear was measured by the Tampa Scale for Kinesiophobia (TSK). The scale consists of 13 items measuring fear of back (re)injury due to movement [16, 17], rated on a four-point scale from 1 = "totally disagree" to 4 = "totally agree". The scale was dichotomized based on the mean value for the sum-score (mean = 25.4) into 0 = low (below the mean) and 1 = high (above the mean).

Helplessness and Hopelessness were measured by six items from the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats) [18], designed to measure response outcome expectancies in CATS [12]. The scale consists of three factors, representing the three response outcome expectancies in CATS. In the current study, helplessness and hopelessness were treated as one single factor based on factor analysis from a previous publication from the same sample [19]. Examples of statements are: "I really don't have any control over the most important issues in my life" (helplessness), and "all my attempts at making things better just make them worse" (hopelessness). All items were rated on a five-point scale from 1 = "not true at all" to 5 = "completely true". The scale was dichotomized based on the mean value (mean = 10.2) into 0 = low (below the mean) and 1 = high (above the mean).

Statistical analyses

Differences between the intervention and the control group at baseline on the predictor variables were tested with independent-samples t-tests.

Means, standard deviations, and percent of participants on sick leave in three-month periods one year before and the year after the intervention were calculated. Means and 95% confidence intervals were calculated for sick leave days stratified by the predictors (high/low) in the intervention and control group the year after the intervention.

Sick leave days in three-month periods the year after the intervention were analyzed using generalized estimating equations (GEE) [20]. Using this approach, corrections for the clustered nature of the data were accounted for [21]. The analyses were based on least squares estimators and identity link function. Standard errors were calculated based on a robust variance estimator, corrected for clustering of data. Differences in days of sick leave the year preceding the intervention were adjusted for in the analyses to control for differences in initial sick leave between the intervention and control group. Adjustment was done at unit level, i.e. on workplace department.

For differences in effect on days of sick leave between intervention and control group, adjusted mean difference scores and 95% confidence intervals with corresponding p-values were calculated. Models including the interaction effect of days of sick leave for the dichotomized (high/low) predictors and intervention were conducted to test if there were statistically significant differences between the intervention and control group regarding the effect of the predictors on sick leave. For significant results, stratified analyses of the predictors were conducted to calculate the effect within the two categories (high/low).

The statistical analyses were performed using SPSS® version 21.0 (IBM Corporation, Armonk NY, USA) for Windows. P-values less than 5 % (0.05) were considered statistically significant.

Results

Descriptive statistics

There were no statistical significant differences at baseline between the intervention and control group in the predictor variables (Table1).

The prevalence of days of sick leave the year before the intervention differed between the intervention and the control group (Table 2). Mean scores for overall sick leave days, stratified by high and low baseline scores on the predictor variables in the intervention and control group are presented in Table 3.

INSERT TABLE 1 HERE

INSERT TABLE 2 HERE

INSERT TABLE 3 HERE

The effect of the atWork intervention on sick leave

The adjusted analyses showed a statistically significant effect of the intervention on days of sick leave the first six months subsequent to the intervention (Table 4). Employees in the intervention group had on average an effect of 4.9 less days of sick leave the first three months and 4.4 less days of sick leave the next three months after participating in the intervention, compared to the control group (Table 4). See Table 3 for means and 95% CI. There was no statistically significant effect of the intervention on days of sick leave subsequent to the first six months (Table 4).

The effect of the intervention on sick leave within different levels of beliefs, expectancies and low back pain

There was a statistically significant difference in the effect of the intervention on days of sick leave for the different levels of pain-related fear measured at baseline the first three months (Table 4). Thus, stratified analyses of this predictor were conducted to calculate the effect within the two categories (high/low). The adjusted mean difference between the intervention and control group on low pain-related fear the three first months was 8.03 (95% CI: -12.88 – -3.17, $p < .001$), indicating that employees in the intervention group with low (≤ 25.4) scores had on average an effect of 8.03 less days of sick leave the first three months after participating in the intervention, compared to the control group (See Table 3 for means and 95% CI). There was no statistically significant effect of the intervention for the levels of pain-related fear subsequent to the first three months.

There were no statistically significant differences in effect of the intervention between individuals with high and low scores on the other predictor variables (back pain myths, helplessness/hopelessness and low back pain) (Table 4). Thus, stratified analyses of these predictors to calculate the effect within the two categories were not conducted.

INSERT TABLE 4 HERE

Discussion

The main aim of this study was to investigate if there was an effect of atWork on sick leave, and to identify baseline characteristics with the participants that could contribute to preventing sick leave. There was an effect on sick leave the first six months subsequent to the intervention.

This is in line with, but expands on the findings by Odeen et al. [8] by showing individual effects among those consenting to gather individual data and also showing exactly when

during the first year the effect occurred. Our result regarding the short-term effect is also in accordance with a previous similar intervention study among LBP patients [5]. However, effects on RTW are found for up to five years in a clinical population [6]. In a clinical setting the message is tailored to fit the individual need, which might result in a stronger effect than in the atWork study designed to reach all employees present at work. Still, the effect of atWork on sick leave is important, since population-based preventive interventions often requires long-term implementation for an effect to occur [22].

In the current study, low scores on pain-related fear predicted effect of the intervention. The result is in accordance with a recent systematic review of back pain interventions showing that high fear-avoidance beliefs at baseline were associated with poor treatment outcomes in terms of more pain and/or disability and less RTW [10]. Also in line with the present study, Staal et al. [23] found that workers with scores equal to or above the median on fear avoidance beliefs at baseline return to work more slowly after participating in a graded activity intervention than those with scores below the median.

While expectancies are generalized, pain-related fear represent specific beliefs regarding fear of movement or (re)injury when in pain, which might explain why pain-related fear was the only significant predictor in this study. In a previous qualitative study, participants in an educational intervention similar to atWork, emphasized trust in the professionals and improved understanding as important aspects contributing to their coping with the complaints [24]. Strong pain-related fear can hamper confidence in the professionals and the information they receive at the intervention. Furthermore, the non-injury model might be more conceivable for employees with low pain-related fear. For employees with low or moderate scores on pain-related fear, atWork might provide the reassurance they need to be able to stay at work despite pain. Employees with strong and deep-rooted pain-related fear may need something else, e.g. more extensive, multidisciplinary treatments than what was provided in

atWork, or an intervention targeting pain related fears, including performance of practical tasks. Cognitive behavior therapy (CBT) has shown to be effective in reducing avoidance, catastrophizing, and disabling beliefs among LBP patients [25]. CBT elements and enhancement of trust in the professionals might hence be incorporated in the workplace intervention.

Strengths and limitations

A major strength of the current study is that the outcome is measured by registry data on sick leave that are considered highly accurate and thus reduce the risk of measurement errors. The low response rate of approximately 50% might increase the risk of non-response bias and limit the validity of the findings. Despite low response rate, the sample is relatively large. Due to the sample diversity regarding workplace size and work tasks, the possibility of group specific effects and localization effects are reduced. However, caution should be made when generalizing to private sector employees and to men. The high predominance of women in the sample (87.2%) is representative for the municipality sector in Norway [26]. It would have been relevant to investigate whether men and women have different effect of the intervention, but the low number of men in the study could not justify such analyses.

A limitation of the current study is that we cannot exclude the possibility of confounding variables as the unit of randomization was different from the unit of analysis. However, adjustment for sick leave the year before the intervention and for clustering of the data within the unit of randomization justifies the analyses. A strength of the study is that all unit types (e.g. kindergartens, nursing homes etc.) were represented in the sample, and there were no systematic dropout from any unit types on responses to the questionnaire.

The current study contributes to increase knowledge concerning the effect of a work place based low-cost and low-threshold sick leave intervention. Municipal employees have

relatively high sickness absence compared with employees in private and state-level public sector [27]. This study addresses one of the sectors with the highest rates of long-term sick leave.

Implications

Knowledge of individuals who benefit from work place interventions is important for authorities regarding whom to focus in such interventions. Still, excluding workers with high levels of pain-related fear seems unrealistic as well as unethical. The intervention has a preventive approach towards all employees present at work. More knowledge of characteristics about individuals with high scores on pain-related fear, and why they do not respond to interventions such as atWork is needed. Furthermore, future studies should explore mediational effects, i.e. whether expectancies and beliefs change as a result of the intervention, and if these changes predict effect on sick leave.

Conclusions

The atWork intervention had an effect on days of sick leave at individual level the first six months subsequent to the intervention, and low levels of pain related fear predicted the effect. There were no differences in effect of the intervention between individuals with high and low scores on helplessness and hopelessness, belief in the back pain myths and low back pain. Since the effect of atWork on sick leave was limited to the first six months, indicating a need for repetition of the intervention message, the educational part of atWork should be considered implemented as a part of regular practice in primary health care.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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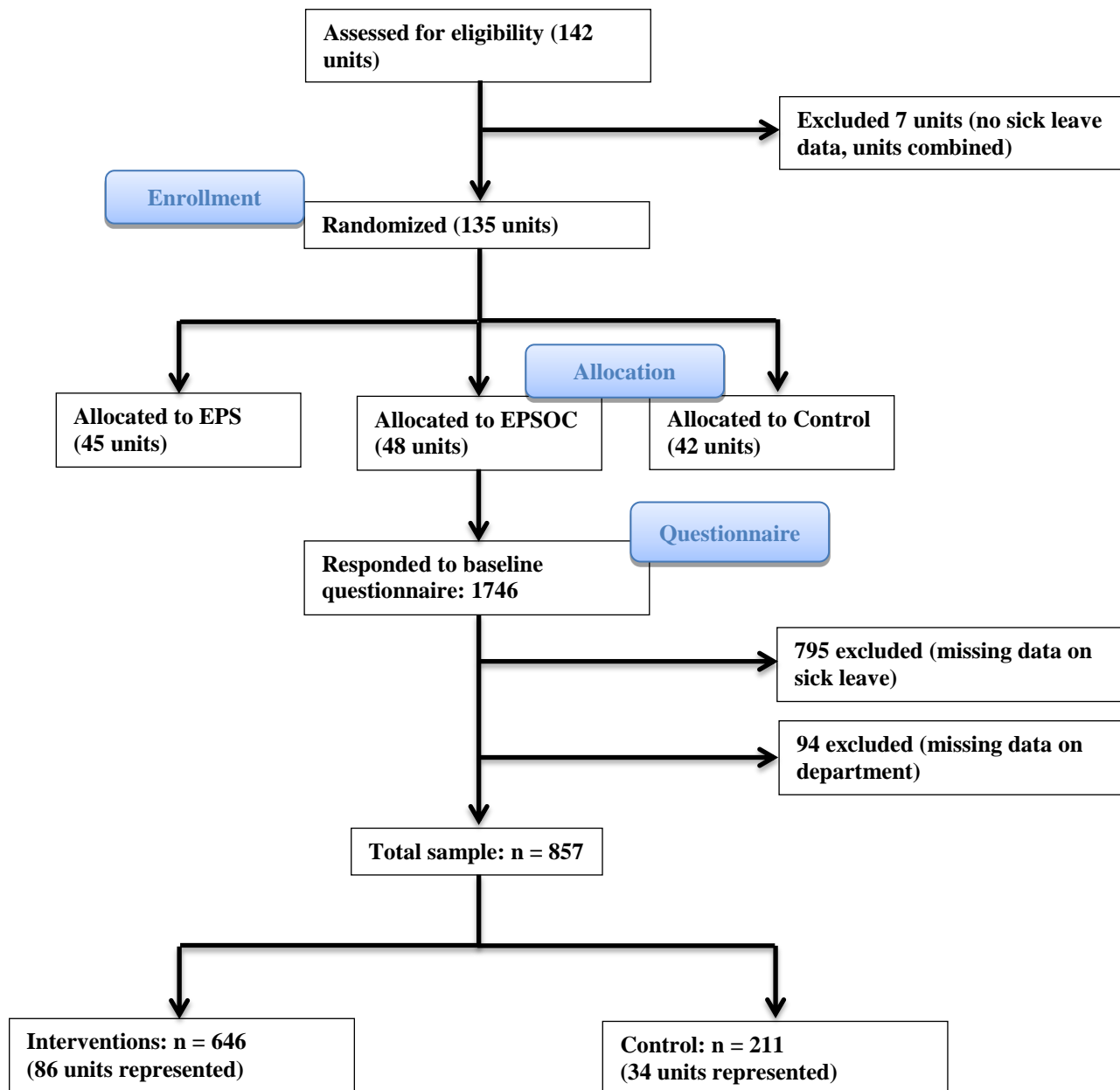


Figure 1. Flow chart of participants: EPS = Education and Peer Support. EPSOC = Education, Peer Support and Outpatient Clinic.

Table 1: Number, percentages, means and standard deviations (SD) in the intervention and control group for the predictor variables: Low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness. Differences between groups at baseline tested with independent-samples *t*-tests.

	Intervention	Control	Intervention	Control	<i>t</i> -value	<i>p</i> -value
	<i>n</i> (%)	<i>n</i> (%)	Mean (SD)	Mean (SD)		
Low back pain (0-3)^a	635	206	0.96 (0.9)	1.10 (40.9)	-1.76	.079
Low	434 (68.3)	128 (62.1)				
High	201 (31.7)	78 (37.9)				
Myth lifting (1-5)^b	620	206	3.26 (0.9)	3.22 (1.1)	0.46	.645
Low	408 (65.8)	125 (60.7)				
High	212 (34.2)	81 (39.3)				
Myth X-ray (1-5)^b	614	203	3.05 (1.1)	3.04 (1.2)	0.03	.976
Low	134 (66.4)	134 (66.0)				
High	206 (33.6)	69 (34.0)				
Pain-related fear (13-46)^c	623	207	25.36 (6.2)	25.47 (5.8)	-0.23	.816
Low	331 (53.1)	108 (52.2)				
High	292 (46.9)	99 (47.8)				
Helplessness/hopelessness (6-30)^d	628	205	10.32 (3.6)	10.01 (3.5)	1.06	.289
Low	363 (57.8)	127 (62.0)				
High	265 (42.2)	78 (38.0)				

^aLow scores = no or some complaints; high scores = much or severe complaints

^bLow scores = totally disagree, disagree, neither disagree nor agree; high scores = agree and totally agree

^cLow scores = on and below the mean (≤ 25.4); high scores = above the mean (> 25.4)

^dLow scores = on and below the mean (≤ 10.2); high scores = above the mean (> 10.2)

Table 2. Mean and standard deviation (SD) of sick leave days in blocks of three months the year before and after the intervention, and percent of participants on sick leave for one or more days during the three months periods.

	Months 12-9	Months 9-6	Months 6-3	Months 3-0	Months 0-3	Months 3-6	Months 6-9	Months 9-12
Intervention (<i>n</i> = 646)								
Mean (SD)	9.26 (23.1)	8.66 (22.6)	8.96 (23.7)	7.18 (21.1)	6.51 (18.3)	9.26 (23.7)	10.50 (24.8)	9.63 (23.3)
% on sick leave	19.2	18.4	16.6	15.9	16.9	17.0	21.2	20.3
Control (<i>n</i> = 211)								
Mean (SD)	6.48 (19.9)	6.52 (18.9)	4.39 (15.5)	8.01 (22.6)	9.28 (23.8)	11.45 (27.3)	8.51 (23.1)	7.37 (20.5)
% on sick leave	14.2	14.2	10.9	15.2	18.5	19.9	17.5	19.0
Total (<i>n</i> = 857)								
Mean (SD)	8.58 (22.4)	8.13 (21.8)	7.84 (22.1)	7.38 (21.5)	7.19 (19.8)	9.80 (24.6)	10.01 (24.4)	9.08 (22.7)
% on sick leave	18.0	17.4	15.2	15.8	17.3	17.7	20.3	20.0

Table 3: Unadjusted mean scores and 95% CI for sick leave days stratified by high and low baseline scores on low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness in the intervention and control group.

		Intervention	Control
		Mean (95% CI)	Mean (95% CI)
Low back pain_low^a	0-3	5.93 (4.33 - 7.54)	8.02 (4.03 - 12.02)
	3-6	7.50 (5.48 - 9.51)	9.63 (5.17 - 14.10)
	6-9	7.52 (5.55 - 9.50)	8.34 (4.44 - 12.24)
	9-12	6.29 (4.56 - 8.01)	5.30 (2.35 - 8.25)
Low back pain_high	0-3	8.08 (5.16 - 10.98)	10.22 (5.06 - 15.37)
	3-6	13.48 (9.60 - 17.36)	13.99 (7.51 - 20.46)
	6-9	17.33 (13.07 - 21.60)	9.33 (3.91 - 14.75)
	9-12	16.70 (12.53 - 20.87)	11.04 (5.48 - 16.60)
Myth lifting_low^b	0-3	6.50 (4.70-8.29)	10.33 (5.92 - 14.74)
	3-6	9.74 (7.44 - 12.03)	11.93 (6.90 - 14.74)
	6-9	10.12 (7.78 - 12.45)	9.27 (5.07 - 13.47)
	9-12	9.49 (7.26 - 11.72)	6.12 (3.03 - 9.21)
Myth lifting_high	0-3	7.12 (4.60 - 9.65)	7.14 (2.80 - 11.46)
	3-6	9.48 (6.12 - 12.85)	9.77 (4.42 - 15.11)
	6-9	12.34 (8.67 - 16.00)	7.86 (3.05 - 12.68)
	9-12	10.70 (7.34 - 14.07)	9.77 (4.45 - 15.07)
Myth X-ray_low^b	0-3	5.98 (4.28 - 7.68)	8.92 (4.98 - 12.87)
	3-6	8.22 (6.07 - 10.37)	10.22 (5.77 - 14.68)
	6-9	8.80 (6.59 - 11.02)	6.87 (3.41 - 10.32)
	9-12	7.60 (5.56 - 9.63)	6.40 (3.25 - 9.56)
Myth X-ray_high	0-3	8.24 (5.41 - 11.06)	8.45 (3.34 - 13.55)
	3-6	12.18 (8.48 - 15.88)	10.94 (4.73 - 17.16)
	6-9	15.13 (11.15 - 19.13)	10.83 (4.61 - 17.04)
	9-12	14.51 (10.68 - 18.34)	9.93 (4.21 - 15.64)
Pain-related fear_low^c	0-3	5.03 (3.39 - 6.66)	10.52 (5.68 - 15.35)
	3-6	9.62 (7.05 - 12.19)	11.84 (6.55 - 17.13)
	6-9	10.17 (7.61 - 12.74)	8.71 (4.21 - 13.22)
	9-12	8.76 (6.36 - 11.17)	7.06 (3.17 - 10.94)
Pain-related fear_high	0-3	8.14 (5.68 - 10.59)	7.40 (3.43 - 11.38)
	3-6	9.27 (6.54 - 12.01)	10.60 (5.43 - 15.76)
	6-9	11.23 (8.22 - 14.23)	8.32 (3.92 - 12.73)
	9-12	10.89 (8.06 - 13.72)	8.02 (3.96 - 12.08)
Helplessness/hopelessness_low^d	0-3	4.36 (2.88 - 5.84)	6.70 (3.22 - 10.18)
	3-6	7.92 (5.68 - 10.16)	9.67 (5.40 - 13.94)
	6-9	9.07 (6.66 - 11.48)	6.24 (2.59 - 9.88)
	9-12	8.09 (5.90 - 10.29)	5.24 (2.26 - 8.23)
Helplessness/hopelessness_high	0-3	9.56 (6.84 - 12.28)	13.63 (7.29 - 19.97)
	3-6	11.07 (7.93 - 14.21)	14.90 (7.90 - 21.89)
	6-9	12.63 (9.43 - 15.84)	12.42 (6.62 - 18.23)
	9-12	11.52 (8.45 - 14.59)	10.86 (5.38 - 16.34)

^aLow scores = no or some complaints; high scores = much or severe complaints

^bLow scores = totally disagree, disagree, neither disagree nor agree; high scores = agree and totally agree

^cLow scores = on and below the mean (≤ 25.4); high scores = above the mean (> 25.4)

^dLow scores = on and below the mean (≤ 10.2); high scores = above the mean (> 10.2)

Table 4: Adjusted mean difference with 95% CI for the intervention and control group in effect on days of sick leave, and for the interaction effect of days of sick leave for the two levels (high/low) of low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness and intervention. Differences between groups were tested with generalized estimating equations (GEE) adjusted for days of sick leave the year preceding the intervention and workplace unit.

	Months	Mean diff (95% CI)	p-value
Intervention vs Control	0-3	-4.94 (-7.79 - -2.08)	.001
	3-6	-4.36 (-7.90 - -0.82)	.016
	6-9	-0.18 (-3.69 - 3.33)	.922
	9-12	-0.94 (-3.61 - 3.80)	.961
Low back pain (low vs high)^a	0-3	-1.24 (-8.16 - 5.68)	.725
	3-6	0.43 (-7.56 - 8.43)	.915
	6-9	7.63 (-0.30 - 15.55)	.059
	9-12	3.48 (-4.86 - 11.83)	.413
Myth lifting (low vs high)^b	0-3	4.47 (-2.37 - 11.32)	.200
	3-6	2.56 (-7.36 - 12.48)	.612
	6-9	4.28 (-4.47 - 13.04)	.338
	9-12	-1.78 (-9.21 - 5.65)	.639
Myth X-ray (low vs high)^b	0-3	1.58 (-6.55 - 9.72)	.703
	3-6	2.09 (-7.84 - 12.02)	.679
	6-9	1.22 (-8.27 - 10.72)	.801
	9-12	2.24 (-6.23 - 11.10)	.621
Pain-related fear (low vs high)^c	0-3	7.58 (0.24 - 14.91)	.043
	3-6	2.25 (-9.05 - 13.55)	.696
	6-9	2.79 (-6.39 - 11.97)	.551
	9-12	2.51 (-4.53 - 9.56)	.485
Helplessness/hopelessness (low vs high)^d	0-3	-3.05 (-10.45 - 4.35)	.419
	3-6	-3.40 (-12.96 - 6.15)	.485
	6-9	-3.95 (-12.20 - 4.30)	.348
	9-12	-3.51 (-10.10 - 3.09)	.297

^aLow scores = no or some complaints and high scores = much or severe complaints

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^cLow scores = on and below the mean (≤ 25.4) and high scores = above the mean (> 25.4)

^dLow scores = on and below the mean (≤ 10.2) and high scores = above the mean (> 10.2)

Appendix



UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

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Dato: 11.02.08

Deres ref.:

Vår ref.: S-08054b

S-08054b iBedrift - Helserelatert mestring Arbeidsplassen som arena for helse- og mestringsforståelse i forhold til muskelskjelettplager [6.2008.117]

Søknad mottatt 08.01.08 med følgende vedlegg: Informasjonsskriv med samtykkeerklæring; forskningsprotokoll; spørreskjema; fax vedr. tidligere tilrådd/godkjent prosjekt S-06459b datert 7. januar 2008.

Komiteen behandlet søknaden i sitt møte den 31. januar 2008. Prosjektet er vurdert etter lov om behandling av etikk og redelighet i forskning av 30. juni 2006, jfr. Kunnskapsdepartementets forskrift av 8. juni 2007 og retningslinjer av 27. juni 2007 for de regionale komiteer for medisinsk og helsefaglig forskningsetikk.

Forskningsetisk vurdering

Dette prosjekt skal evaluere effekten av en pedagogisk tilnærming til håndtering av muskelskjelettplager, gjennom et opplæringsprogram som tilbys kommunalt ansatte i noen kommuner i Øst- og Sør-Norge. Komiteen er av den oppfatning at dersom slik opplæring kan bidra til å få ned antall sykmeldinger, uførepensjonering i noe omfang, så vil nytten både for den enkelte og for samfunnet kunne være stor, men vi har noen merknader til prosjektledelse, databehandling og informasjonsskriv.

Det framstår som uklart hvem som er ansvarlig for prosjektet. I søknaden er Erik Lindh oppgitt som ansvarlig, mens overlege Indahl oppgis som ansvarlig i informasjonsbrevet. I henhold til Helsinkideklarasjonens artikkel 15 skal "Medisinsk forskning som omfatter mennesker, kun foretas av vitenskapelig kvalifiserte personer og ledes av en person med medisinsk klinisk kompetanse". Komiteen vil derfor påpeke at overlege Åge Indahl må være prosjektleder for dette prosjektet.

Vedlagt søknaden følger et kartleggingsskjema (spørreskjema), som skal benyttes ved oppstart, etter 12 måneder og etter 24 måneder. Det opplyses i informasjonen til alle ansatte at alle skjemaene skal fylles ut anonymt. Siden det skal innhentes informasjon om den enkelte deltakers sykefravær, og muligens også forbruk av helsetjenester, så antar vi at det vil bli benyttet en form for koding eller koblingsnøkkel, og datamaterialet vil dermed være aidentifisert, og ikke anonymisert. Dette, samt et punkt om innhenting av opplysninger om forbruk av helsetjenester, må inn i informasjonsskrivet/samtykkeskjemaet.

Informasjonsskriv/samtykkeerklæring

1. Det må framgå av informasjonsbrevet hvem som har finansiert prosjektet.
2. Prosjektet er planlagt som en randomisert studie, men slik at randomisering skal skje på hvert virksomhetsområde. Deltakerne randomiseres til enten til fullt program, kun informasjon eller ingen tiltak. Det framstår imidlertid som uklart hva gruppen som ikke får tiltak egentlig får ettersom det under avsnittet *Forskningsprosjektets gjennomføring* står "Prosjektledelsen vil to til tre ganger komme til din arbeidsplass for gi informasjon og kurs om muskel/skjelettplager, og om hvordan iBedrift gjennomføres i praksis. Din arbeidsgiver har allerede gitt alle ansatte anledning til å delta ved disse kursene". Det kan framstå som om kursene tilbys til alle i

- bedriften, dette må klargjøres slik at det framgår tydeligere hva de ulike randomiserte gruppene får av tilbud.
3. Dersom det stemmer at opplysningene vil være aidentifisert må det framgå hvordan koblingsnøkkel tenkes oppbevart, jfr. merknad ovenfor.
 4. Samtykkeerklæringen bør inneholde et punkt, om samtykke til innhenting av opplysninger om forbruk av helsetjenester.

Vedtak

Prosjektet godkjennes under forutsetning av at de merknadene som er anført ovenfor blir innarbeidet før prosjektet settes i gang. Revidert informasjonsskriv og samtykkeerklæring må sendes komiteen til orientering.

Komiteens avgjørelse var enstemmig.

Komiteens vedtak kan påklages (jfr. Forvaltningslovens § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes til REK Sør-Øst B (jfr. Forvaltningslovens § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. Forvaltningslovens § 29). Det bes presisert hvilke vedtak/vilkår som påklages og den eller de endringer som ønskes. Se informasjon om klageadgang og partsinnsynsrett på <http://www.etikkom.no/REK/klage>

Med vennlig hilsen


Tor Norseth
Leder


Jorunn Lindholt
Sekretær

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5015 BERGEN

Vår dato: 07.07.2008

Vår ref: 18997 / 2 / SM

Deres dato:

Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 08.04.2008. Meldingen gjelder prosjektet:

18997

Behandlingsansvarlig

Daglig ansvarlig

iBedrift - Helse relatert mestrings

UNIFOB AS, ved institusjonens øverste leder

Hege Randi Eriksen

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/forsk_stud/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, <http://www.nsd.uib.no/personvern/prosjektoversikt.jsp>.

Personvernombudet vil ved prosjektets avslutning, 31.12.2022, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen



Bjørn Henrichsen



Siv Midthassel

Kontaktperson: Siv Midthassel tlf: 55 58 83 34

Vedlegg: Prosjektvurdering



Ombudet forstår det slik at prosjektet gjøres i samarbeid med Spesialsykehuset for Rehabilitering (SSR). Denne meldingen omfatter kun den behandling som UNIFOB er behandlingsansvarlig for. Ombudet registrerer at SSR har søkt Rikshospitalets personvernombud om lagring og oppbevaring av data. Ombudet legger til grunn at databehandling/ansvarsfordeling formelt er avklart mellom UNIFOB og SSR og anbefaler at det utarbeides en avtale som bl.a. omfatter ansvarsfordeling, ansvarsstruktur, hvem som initierer prosjektet, bruk av data og evt. eierskap.

Det legges til grunn at utvalget informeres om alle sider av prosjektet, jf. informasjonsskriv av 03.07.2008. Ved henvisning til at prosjektet er tilrådd av ombudet bør ombudets fulle navn benyttes, dvs. Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste. For øvrig anbefales det at samtykkeerklæring og spørreskjema legges i atskilte konvolutter. Så lenge spørreskjema og samtykkeerklæring kan kobles via referansenummer (påført før utsending) er det ikke nødvendig at disse returneres sammen.

Ombudet forstår det slik at QuestBack As er databehandler for prosjektet. Det forutsettes at det foreligger avtale mellom QuestBack As og UNIFOB for den behandling av data som finner sted, jf. personopplysningsloven § 15.

Utvalget er informert om at de kan bli kontaktet for evt oppfølgingsstudier.

Dersom det ikke foreligger nytt samtykke til videre deltakelse innen prosjektslutt 31.12.2022, vil datamaterialet anonymiseres ved at direkte og indirekte personidentifiserbare opplysninger fremgår, navneliste/koblingsnøkkel og spørreskjema makuleres.

Ombudet legger til grunn at prosjektet er tilrådd av Regional komité for medisinsk og helsefaglig forskningsetikk med merknader.

Ombudet minner om at det må sendes egne meldinger for evt. oppfølgingsstudier i god tid før utvalget kontaktes og datainnsamling igangsettes.

Anette Harris
HEMIL-senteret
Universitetet i Bergen
Christiesgt. 13
5015 BERGEN

Vår dato: 03.01.2013

Vår ref:32505 / 3 / LT

Deres dato:

Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 21.12.2012. Meldingen gjelder prosjektet:

32505	<i>Hvordan erfarer pasienter et kortvarig behandlingsopplegg for ryggproblemer?</i>
Behandlingsansvarlig	Uni Research AS, ved institusjonens øverste leder
Daglig ansvarlig	Anette Harris

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, <http://www.nsd.uib.no/personvern/meldeplikt/skjema.html>. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, <http://pvo.nsd.no/prosjekt>.

Personvernombudet vil ved prosjektets avslutning, 01.08.2015, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen


Vigdis Namtvedt Kvalheim


Lis Tenold

Kontaktperson: Lis Tenold tlf: 55 58 33 77
Vedlegg: Prosjektvurdering

Personvernombudet for forskning



Prosjektvurdering - Kommentar

Prosjektnr: 32505

Det gis skriftlig informasjon og innhentes skriftlig samtykke. Personvernombudet finner skrivet godt utformet, men forutsetter at det også angis dato for prosjektslutt, her 01.08.2015. Personvernombudet legger til grunn for sin godkjenning at revidert skriv ettersendes før det tas kontakt med utvalget.

Personvernombudet finner at det samles inn og registreres sensitive personopplysninger om helseforhold, jf. personopplysningsloven § 2 nr. 8 bokstav c.

Innsamlede opplysninger registreres på pc i nettverk tilknyttet Internett tilhørende Uni Research AS og på privat pc. Personvernombudet legger til grunn at bruk av privat pc er i tråd med Uni Research AS sine rutiner for datasikkerhet.

Innsamlede opplysninger anonymiseres og lydbåndopptak makuleres ved prosjektslutt, senest 01.08.2015. Med anonymisering innebærer at navnelister slettes/makuleres, og ev. kategorisere eller slette indirekte personidentifiserbare opplysninger. Ved publisering vil ingen enkeltpersoner kunne gjenkjennes.