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Doctoral thesis

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Sammendrag

Bakgrunn

Kroniske smerter rammer en betydelig del av befolkningen, og omtrent en tredjedel av norske voksne har opplevd smerter i tre måneder eller mer. Kronisk smerte er en kompleks tilstand med både fysiologiske, psykologiske og sosiale konsekvenser. Kronisk smerte har også samfunnsøkonomiske konsekvenser i form av redusert produktivitet og høye kostnader innen helse. Behandling for kronisk smerte gir i beste fall beskjedne forbedringer, noe som fører til at for mange er det å egenmestre en hverdag med kroniske smerter viktig. Mestringsintervensjoner har blitt viktige tiltak for å styrke personer med kronisk smerte til å aktivt kunne ta del i det å håndtere helsen sin. De norske frisklivssentralene er en del av kommunenes helsetjeneste for personer med økt risiko for, eller som allerede har utviklet sykdom og som har behov for å endre levevaner og mestre helseutfordringer. Frisklivssentralene tar sikte på å være lett tilgjengelige ved at folk selv kan ta kontakt for å delta på aktivitetene som tilbys. Ved enkelte frisklivssentraler har mestringsintervensjoner blitt en del av de tjenestene som tilbys.

Hensikt

Hovedhensikten med avhandlingen var å bidra med kunnskap om forventninger til og effekt av, mestringstilbud for personer med kronisk smerte utviklet og tilbudt av frisklivssentral i en norsk bykommune. Mer spesifikt var hensikten å utforske forventninger til lett tilgjengelige smertemestringstilbud, og å undersøke korttids- og langtidseffekt av et mestringskurs for personer med kronisk smerte ved frisklivssentral.

Metode

En kvalitativ intervjustudie og en randomisert kontrollert studie ble gjennomført. I den randomisert kontrollerte studien ble intervensjonsgruppen tilbudt et gruppebasert kurs om mestring av kronisk smerte. Kurset besto av teori, øvelser med fokus på bevegelighet, samt gruppediskusjoner og utveksling av erfaringer. Kontrollgruppen ble tilbudt lett fysisk aktivitet i gruppe som besto av gåtur og enkle styrkeøvelser. Aktivitetene hadde ukentlige økter over en periode på seks uker, og resultatene ble målt etter tre, seks og 12 måneder. Det primære utfallsmålet var pasientaktivering målt med Patient Activation Measure (PAM). Dataene ble analysert ved bruk av 'linear mixed models'. Den kvalitative studien inkluderte individuelle semi-strukturerte intervju ved baseline før randomisering med et utvalg av deltakerne fra den randomisert kontrollerte studien. Deltagerne ble stilt åpne spørsmål om forventningene til deltakelse i intervensjonene, hvordan smerte virket inn på hverdagen deres, hva de gjorde for

å håndtere et liv med kroniske smerter, og hvilke helsetjenester de tidligere hadde prøvd på grunn av kroniske smerter. De kvalitative dataene ble analysert med bruk av systematisk tekst kondensering.

Resultat

Totalt ble 121 deltakere inkludert i den randomisert kontrollerte studien. Av disse deltok 21 i den kvalitative studien. I den kvalitative studien ble det funnet at deltakerne hadde forventninger som hovedsakelig gjaldt et håp om at deltakelse kunne føre til en bedre hverdag. Forventningene hadde sammenheng med at dette var et tilbud de ikke hadde prøvd før, de så det som en mulighet til å friske opp og få ny kunnskap, til å utvikle seg som menneske, til å møte andre som var i en lignende situasjon og til å få tilgang til helsepersonell på en enkel måte. I den randomisert kontrollerte studien ble det funnet at mestringskurset ikke hadde noen effekt etter tre måneder i forhold til den lette fysiske aktiviteten tilbudt kontrollgruppen. Etter 12 måneder var det en forskjell i det primære utfallsmålet, pasientaktivering, men forskjellen var ikke statistisk signifikant. Begge gruppene hadde forbedringer med hensyn til opplevd smerte siste uke, egenrapportert helse og bedre skåre på en 30-sekunder sitte-stå test.

Konklusjon

Deltagernes håp om en bedre hverdag var en viktig faktor for å engasjere seg i nye tiltak og helsetjenester. Ingen statistisk signifikante forskjeller ble funnet mellom kurset om mestring av kronisk smerte og den lette fysiske aktiviteten tilbudt kontrollgruppen, verken på det primære utfallsmålet pasientaktivering, eller på noen av de sekundære utfallsmålene.

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Summary

Background

Chronic pain affects a substantial portion of the population with about one third of Norwegian adults having experienced pain for at least three months. Chronic pain is a complex condition due to its physiological, psychological and social impacts. Furthermore, it leads to burdens on society due to the socioeconomic consequences related to a reduced productivity and high health care costs. Chronic pain treatments provide modest improvements at best, which leaves many people obliged to self-manage pain and its consequences on a day-to-day basis. Consequently, self-management interventions have become important to empowering people with chronic pain so they can play an active role in managing their health. The Norwegian Healthy Life Centre (HLC) is a community-based public primary health care service that provides interventions related to behaviour changes, health promotion and disease prevention. The HLCs aim to provide easy access by accepting self-referrals for their services. In some centres, self-management initiatives have been added to the services offered.

Aims

The main aim of the thesis was to contribute knowledge related to the expectations towards and the effects that persons with chronic pain get from participating in self-management interventions developed and delivered at a Healthy Life Centre (HLC) in a Norwegian city. More specifically, the aims were to explore the expectations of easily accessible chronic pain self-management interventions and to investigate the short and long-term effects on persons with chronic pain when they participate in a self-management course at the HLC.

Methods

A qualitative interview study and a randomised controlled trial (RCT) were conducted. During the RCT, the intervention group was offered a group-based chronic pain self-management course encompassing education, movement exercises, together with group discussions and sharing of experiences. The control group was offered a group-based low-impact outdoor physical activity that consisted of walking and simple strength exercises. The activities had weekly sessions over a period of six weeks, and the outcomes were measured after three, six and 12 months. The primary outcome measurement used was the Patient

Activation Measure (PAM). The data in the RCT were analysed using linear mixed models. The qualitative study included individual semi-structured interviews at the baseline before randomisation with a sample of participants from the RCT. They were asked open-ended questions about their expectations of participation in the interventions, how they experienced pain in their everyday lives, what they did to manage life with chronic pain and which health care services they had previously received due to chronic pain. The qualitative data were analysed using systematic text condensation.

Results

A total of 121 participants were included in the RCT. Of these, 21 participated in the qualitative study. During the qualitative study, it was found that the participants had expectations that mainly concerned a hope that participation could lead to a better everyday life. The expectations were based on the hope that the interventions represented a new and untried approach, providing opportunities to acquire and to reinforce skills that would foster continuous personal growth, to meet others in similar situations and to easily access professional support. During the RCT, it was found that the self-management course had no effect after three months compared to the low-impact physical activity. After 12 months, there was a difference in the primary outcome, patient activation; however, it was not statistically significant. Both groups improved regarding pain experienced in the previous week, the global self-reported health measure and the 30-second Chair to Stand Test.

Conclusion

The participants' hope to improve their everyday lives was an important factor in engaging in new interventions and healthcare services. No statistically significant differences were found between the chronic pain self-management course and the low-impact physical activity offered to the control group for the primary outcome, patient activation, or for any secondary outcome.

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Abbreviations

ACT	Acceptance and Commitment Therapy
BT	Behavioural Therapy
CBT	Cognitive Behavioural Therapy
CDSMP	Chronic Disease Self-Management Program
CPSMP	Chronic Pain Self-Management Program
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
HLC	Healthy Life Centre
IASP	International Association for the Study of Pain
ICD 11	International Classification of Diseases version 11
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
PAM	Patient Activation Measure
RCT	Randomised Controlled Trial
STC	Systematic Text Condensation
WHO	World Health Organisation
WMA	World Medical Association

List of included papers

Paper I

Torunn Hatlen Nøst, Aslak Steinsbekk, Liv Riseth, Ola Bratås, Kjersti Grønning. *Expectations towards participation in easily accessible pain management interventions: a qualitative study*. BMC Health Services Research (2017) 17: 712. doi: 10.1186/s12913-017-2668-3.

Paper II

Torunn Hatlen Nøst, Aslak Steinsbekk, Ola Bratås, Kjersti Grønning.
Short-term effect of a chronic pain self-management intervention delivered in an easily accessible primary healthcare service- a randomised controlled trial. Re-submitted after revision to BMJ Open. (Accepted 7. Nov 2018).

Paper III

Torunn Hatlen Nøst, Aslak Steinsbekk, Ola Bratås, Kjersti Grønning.
Twelve-month effect of chronic pain self-management intervention delivered in an easily accessible primary healthcare service- a randomised controlled trial. Re-submitted after revision to BMC Health Services Research.

1 Background

This thesis focusses on the self-management and support of chronic pain delivered by an easily accessible health care service. The PhD project that motivated this thesis was part of the larger research project 'Health promotion - Worthwhile? Reorienting the Community Health Care services' at the Norwegian University of Technology and Science, NTNU (https://www.ntnu.edu/chpr/health-promotion-worthwhile). The larger research project was in cooperation with the city of Trondheim and focussed on health promotion in community health care services. The research project included attention towards the Healthy Life Center (HLC), mental health in adolescents and "Joy of Life" nursing homes. This PhD thesis specifically examines the HLC with a distinct focus on a chronic pain self-management course developed and delivered by the HLC in the Trondheim municipality.

In the following paragraphs, a brief presentation of previous and current understandings of chronic pain and pain is provided followed by a description of the impacts of chronic pain and an overview of available treatments. Thereafter, self-management is discussed, including the belonging concepts of self-efficacy and activation. At the end of the section, interventions to support patients' chronic pain self-management are introduced. The final part of Chapter 1 describes easily accessible services for self-management support. The chapter concludes with a description of Norwegian HLCs.

1.1 Chronic pain

Chronic pain affects a substantial portion of the global population (Reid *et al.*, 2011; Turk, Wilson and Cahana, 2011) and is defined by the International Association for the Study of Pain (IASP) as 'pain without apparent biological value that has persisted beyond the normal tissue healing time over three months' (IASP, 1986). This definition include holding three months as the most convenient point of division to distinguish between acute and non-malignant chronic pain, which is a distinction incorporated into the International Classification of Diseases (ICD) version 11 as persistent or recurrent pain (Treede *et al.*, 2015). The definition of chronic pain builds on the understanding of pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of tissue damage' (IASP, 1986). The definition is a result of centuries of ideas and research that explored the concept of pain (Moayedi and Davis, 2013). The

following paragraphs present a brief overview of some of the major historical contributions to the understanding of pain.

The word ‘pain’ is derived from the Latin ‘poena’, which means penalty or punishment (Bial and Cope, 2011; Bendelow, 2013). In the ancient Greece, Plato and Aristotle considered pain an emotional experience. Pain was thus perceived to be experienced by the human heart but from something that originated external to it. During the Renaissance, René Descartes refuted the idea that pain originated from outside the body. He viewed the body as a machine with pain as a disturbance within the machine that passed through nerves to the brain (Bial and Cope, 2011). The descriptions of pain by Descartes was used by Bell nearly 150 years later in the specificity theory, which stated that there are unique receptor mechanisms and pathways that transmit specific information about pain from the periphery to the spinal cord and then to the brain. Goldscheider introduced a following model in 1894 known as the pattern theory, which held that information related to pain was not primarily obtained by the activation of specific receptors and pathways but rather to the pattern of responses in afferent systems (Gatchel *et al.*, 2007).

In 1965, Melzack and Wall published what was considered a ground-breaking theory at the time, known as the Gate Control Theory of Pain (Melzack and Wall, 1965). The theory provided a neural basis for earlier findings that both supported and reconciled the differences between the pattern and specificity theories. Central to the gate control theory is that psychological components, pain fibres and touch fibres meet in different regions within the dorsal horn of the spinal cord and either promote or inhibit the transmission of nociceptive information (Moayedi and Davis, 2013). Some details of the theory have been refuted, but the theory has nevertheless allowed for a more complex understanding of pain due to its inclusion of sensory and emotional components (Waddell, 1992).

All of these investigations on pain and its underlying mechanisms have led towards the contemporary definition of pain recognising it as multidimensional and complex, with several components that interact with each other (Moayedi and Davis, 2013).

At the same time, chronic pain is recognised as a condition that can be present without evidence of and out of proportion to physical damage. Thus, it is argued that chronic pain may be viewed as a distinct condition and a chronic disease in its own right rather than only as a symptom of other diseases (Leadley *et al.*, 2012; Stanos *et al.*, 2016).

1.1.1 Prevalence and impact of chronic pain

Prevalence estimates of chronic pain vary with a typical range between 10 % and 30 % (Reid *et al.*, 2011; Steingrimsdottir *et al.*, 2017). The variation may reflect true differences between populations but may also depend on how chronic pain is defined and assessed by different epidemiological studies (Fayaz *et al.*, 2016; Steingrimsdottir *et al.*, 2017). Most studies have reported a higher prevalence among women, people at a higher age and people with low income and low educational levels (Rustøen *et al.*, 2004a; Tsang *et al.*, 2008; Landmark *et al.*, 2013; Steingrimsdottir *et al.*, 2017). A common estimate of chronic pain in Norway is that approximately one third of the population reports chronic pain (Rustøen *et al.*, 2004b; Breivik *et al.*, 2006; Landmark *et al.*, 2011). In a European survey conducted by Breivik et al. (2006), osteoarthritis and rheumatoid arthritis combined was reported to be the most common cause of chronic pain. Also, a longitudinal study found back pain and osteoarthritis to be the most common causes of chronic pain (O'Brien and Breivik, 2012), whereas another study revealed that for a substantial portion of individuals, a reason for their pain was not established (Rustøen *et al.*, 2004b). In addition, a common feature among those suffering from chronic pain is that the pain is not necessarily located in one region and does not necessarily have one specific cause because multiple pain states are often reported (Stanos *et al.*, 2016).

Chronic pain places a burden on society due to socioeconomic consequences related to reduced productivity and high health care costs (Gustavsson *et al.*, 2012; Landmark *et al.*, 2013). In the European survey, one in four persons with chronic pain reported that pain affected employment status (Breivik *et al.*, 2006). A Swedish study that estimated the direct and indirect costs of patients with a diagnosis related to chronic pain found the costs comparable to one fifth of the total Swedish tax burden, or about one tenth of the Swedish gross domestic product (GDP). The main component of the total costs was related to reduced production associated with sick leave and early retirement (Gustavsson *et al.*, 2012). Pain is also found to be a frequent cause for patients to seek help from health care systems

(Mantyselka *et al.*, 2001). A Danish study showed that people with chronic pain had a significantly higher use of health care services compared to individuals without chronic pain complaints (Eriksen *et al.*, 2004). The same was found in a Norwegian study in which the proportion of individuals seeking health care was higher within the chronic pain group compared to the group of individuals without chronic pain (Landmark *et al.*, 2013).

The costs of chronic pain for society is only one burden. The burden carried by individuals is also significant. The intrusion of chronic pain into everyday life often requires adjustments of goals, plans and expectations (Dezutter *et al.*, 2016). Experiencing chronic pain can have a devastating effect on everyday life, which is illustrated by its associations with social consequences such as loneliness, outsiderness and disabilities (Reid *et al.*, 2011; O'Brien and Breivik, 2012). Pain affects daily activities, including the ability to sleep, exercise and perform household chores, and people with chronic pain describe being less able or no longer able to maintain relationships with family and friends or to attend social functions (Breivik *et al.*, 2006; O'Brien and Breivik, 2012). The affective component of pain incorporates several different emotions, but most are negative, with depression and anxiety having received the most attention (Gatchel *et al.*, 2007). Emotional distress has also been described by patients with chronic pain who have reported feeling rejected by the medical system and believing that they are blamed or labelled as symptom magnifiers and complainers by their physicians, family members and employers when their pain condition does not respond to treatment (Breivik *et al.*, 2006; Gatchel *et al.*, 2007). Managing chronic pain has also been described as challenging due to the task of interacting with a range of different health professionals, which has been attributed to patients' concerns regarding a lack of continuity between the health care services provided (Budge, Carryer and Boddy, 2012).

1.1.2 Treatments for people with chronic pain

The biopsychosocial model has been most influential for the treatment of chronic pain because treatments of today address not only the physiological but also the social and psychological aspects of chronic pain (Borrell-Carrio, Suchman and Epstein, 2004; Gatchel *et al.*, 2007). The biopsychosocial perspective has served as a response to the understanding of disease and illness proposed in the biomedical model, which guided the considerations of health and illness until the mid-20th century (Gatchel *et al.*, 2007). The biopsychosocial

model can be traced to George Engel, who claimed in 1977 that the biomedical perspective was too reductionistic, as it left no room for the social, psychological and behavioural dimensions of illness. He argued that medicine should shift from a biomedical perspective of disease to a biopsychosocial perspective of health (Engel, 1977).

The development of the biopsychosocial model led to a holistic perspective to addressing health-related issues by including a view of illness as a complex interaction of biological, psychological and social factors (Gatchel *et al.*, 2007). The different treatment options among modern pain treatments aim to embrace the different aspects related to chronic pain. The treatments range from pharmacological and interventional treatments delivered by specialist caregivers to non-interventional treatments, such as exercise, psychological approaches and support and advice regarding how to manage everyday life with pain, which is typically provided by primary caregivers (Turk, Wilson and Cahana, 2011; Stanos *et al.*, 2016).

Among the pharmacological treatments, oral drugs have been the mainstay of pain treatment during the last centuries, and opioids are frequently used, although their use for chronic pain is controversial to some degree regarding their efficacy and adverse effects (Stanos *et al.*, 2016). Non-steroidal anti-inflammatory drugs (NSAIDs) have been reported to be effective for chronic pain related to rheumatoid arthritis, osteoarthritis and back pain, and paracetamol is considered a reasonable alternative due to its reduced gastrointestinal complications and low cost (Turk, Wilson and Cahana, 2011).

Another chronic pain treatment approach includes interventional pain medicine. This approach involves the application of various techniques to diagnose or locate sources of pain or to provide therapeutic pain relief, such as nerve blocks and surgery, due to chronic low back pain. Another example is an implantable device, such as spinal-cord stimulation in which electrodes are implanted near the spine or into peripheral nerves to modulate pain processing by inhibiting nociceptive signals (Turk, Wilson and Cahana, 2011).

Exercise treatments for chronic pain are examples of non-interventional treatments that are often incorporated as part of other treatment approaches. Available evidence on physical

activity and exercise for chronic pain suggest that these interventions, which have few adverse effects, could improve pain severity and physical function, and therefore could improve quality of life (Geneen *et al.*, 2017). In the study of Larsen, Nielsen and Jensen (2013); however, it was emphasised that recognising which activities should and should not be performed is important when physical activity is integrated into pain management.

Psychological approaches to pain treatment include interventions using behaviour therapy (BT), cognitive behavioural therapy (CBT) and acceptance and commitment therapy (ACT) (Turk, Wilson and Cahana, 2011; Williams, Eccleston and Morley, 2012; Eccleston, Morley and Williams, 2013). These approaches emphasise coping, adaption, self-management and reduction of disability associated with symptoms rather than elimination of the physical causes of the pain (Turk, Wilson and Cahana, 2011; Eccleston, Morley and Williams, 2013). The goal is typically to decrease maladaptive thoughts by replacing them with thoughts that are more rational (Gatchel *et al.*, 2007; Eccleston, Morley and Williams, 2013). Psychological approaches are often incorporated into multidisciplinary interventions. Although these approaches seem to be more effective than traditional care alone in reducing pain and disability in the long-term, a balance between the use of multidisciplinary interventions is recommended by considering costs in terms of money, resources and time, as they are quite intensive and expensive (Kamper *et al.*, 2015).

1.2 Self-management

Overall, current chronic pain treatments provide modest improvements at best, and thus a substantial group of people struggle with pain on a day-to-day basis (Reid *et al.*, 2011; Turk, Wilson and Cahana, 2011). The ways people manage life with chronic pain are similar to the ways people manage life with other chronic conditions. Accordingly, due to the large number of people suffering from a long-term condition that cannot currently be cured, there has been a gradual increase in initiatives to promote patients becoming engaged and active by supporting them to take charge of their own health and health care (Wagner *et al.*, 2001; de Silva, 2011; National Voices, 2014; Boger *et al.*, 2015). This development has also been influential to the management of chronic pain.

The history of self-management can be linked to developments in the role of the patient. Until the 1960s, the physician was regarded as the authority, and the patient was expected to be a passive recipient of care who did not participate in discussions concerning diagnostics or treatments (Hoving *et al.*, 2010). Gradually, an increased emphasis has been placed on empowering patients by providing education and information (Richard and Shea, 2011). This development has followed changes in other areas of society, such as the self-care movement among feminists, student revolutions at universities in the sixties and seventies and civil rights movements (Hoving *et al.*, 2010). This all influenced an increased focus on patient's rights and an increase in patient advocacy organisations. By the 1990s, more focus was placed on patients being engaged in promotion of their health and making choices related to treatment and treatment goals. Currently, it is well-established that health care cannot be effective without communication based on equality between health providers and patients (Hoving *et al.*, 2010). Self-management and shared decision-making have thus become important cornerstones to empowering patients to adopt active roles in their health care (Elwyn *et al.*, 2010; National Voices, 2014; Boger *et al.*, 2015).

There are several definitions of self-management and what have been described as associated concepts (Richard and Shea, 2011). While self-care describes the ability to care for oneself and to perform activities that are necessary to achieve, maintain or promote optimal health, self-management is referred to as the ability to manage symptoms, treatments, life style changes and psychosocial, cultural and spiritual consequences in conjunction with families, communities and health care professionals (Barlow *et al.*, 2002; Richard and Shea, 2011). Self-management is also understood as a dynamic, interactive and daily process in which individuals engage to manage a chronic condition (Lorig and Holman, 2003) and to encompass the ability to monitor one's condition and to utilise the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life (Barlow *et al.*, 2002).

Common challenges within self-management include recognising symptoms and taking appropriate actions, using medication effectively, managing complex regimens, developing strategies to deal with the psychological consequences and interacting with the health care system over time (Wagner *et al.*, 2001; Richard and Shea, 2011). Central self-management tasks are thus described as involving the medical management of a condition, maintaining,

changing and creating new meaningful behaviours or life roles and dealing with the emotional consequences of having a chronic condition (Schulman-Green *et al.*, 2012). To accomplish this, people require self-management skills, such as problem solving, decision making, resource utilisation, forming of a patient- healthcare provider relationship, and taking action (Lorig and Holman, 2003). More specifically, problem solving includes skills such as problem definition, the generation of possible solutions, including suggestions from friends and health care providers, solution implementation and the evaluation of results, whereas decision-making refers to the day-to-day decisions that must be made in response to changes in a medical condition (Lorig and Holman, 2003).

Schulman-Green et al. (2012) identified three categories of processes for the self-management of chronic illnesses in general. The first category, 'focusing on illness needs', involves self-management tasks and skills necessary for individuals when managing their general health as well as the illness-specific issues of a chronic illness. Therefore, individuals should learn about their chronic illness, take ownership of their health needs and perform health-promoting activities. The second category, 'activating resources', involves resources that are important to optimal self-management and includes family members and friends, community resources and services that assist individuals in managing medical, psychosocial, spiritual and financial needs. The third category 'living with a chronic illness', includes tasks and skills related to coping with the illness and to personal growth as well as to transitioning from a focus on the illness to integrating it into the context of daily life. These tasks involve processing emotions, adjusting, integrating illness into daily life and meaning-making. It is recommended that all these categories are addressed by self-management support interventions (Schulman-Green *et al.*, 2012).

1.2.1 Self-efficacy and activation

An increased recognition of the importance of self-management in the treatment of chronic conditions has led to investigations of what makes people adopt or alternatively, not adopt, to behaviours regarded as beneficial. Several concepts have been examined to obtain a better understanding of self-management processes. One concept that is closely linked with the self-management field in general as well as with managing pain is self-efficacy (Du and Yuan, 2010; Du *et al.*, 2017). Another more recently developed concept in a more generalised and

broader context, which nevertheless builds on self-efficacy, is patient activation (Hibbard *et al.*, 2004; Hibbard and Gilburt, 2014). These two concepts are described in more detail in the following paragraphs.

Within the field of self-management, the concept of self-efficacy is commonly referred to in conjunction with Bandura's social cognitive theory (Bandura, 1977; Lorig and Holman, 2003; Richard and Shea, 2011; Eccles *et al.*, 2012). When defining self-efficacy, Bandura's definition is thus often used to understand self-efficacy as people's belief about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives (Bandura, 1994). A key attribute of this concept lies in the perception of the ability to perform activities (Richard and Shea, 2011). Self-efficacy is thus related to the confidence that a course of action can be successfully executed to accomplish a desired outcome in a given situation, and it predicts the amount of effort that will be expended when attempting to change and to achieve a desired outcome (Bandura, 1994; Bandura 2004). Lorig and Holman (2003) found that enhanced self-efficacy is one of the mechanisms responsible for improvements in health status after participating in self-management programmes. Their assumption is supported by the findings of a Cochrane review on self-management education programmes for people with chronic conditions, which showed that improvements in self-efficacy can lead to an improved quality of life (Foster *et al.*, 2007).

Nicholas (2007) specifically focussed on pain-related self-efficacy and found that an important element in the original formulations of self-efficacy (Bandura, 1977; Bandura, 1994) is related to persistence in the face of obstacles and aversive experiences (Nicholas, 2007). Nicholas (2007) thus held that self-efficacy beliefs for people who experience chronic pain might be expected to involve not only the expectation that an activity can be performed but also the confidence to perform the activity despite pain. Self-efficacy beliefs have been used to explain a range of behaviours and aspects of pain, and self-efficacy is said to influence pain and associated outcomes in at least two ways. First, self-efficacy affects the performance of actions necessary to manage or to control pain itself, and second, perceived self-efficacy can determine the way situations associated with pain are managed (Jackson *et al.*, 2014). For people suffering from chronic pain, self-efficacy thus includes beliefs about their ability to control pain and the negative emotions associated with it to maintain everyday life activities,

including work, to communicate their needs to health care providers and to implement advice to manage pain (Miles *et al.*, 2011). There is some evidence that a higher self-efficacy related to pain management is associated with more positive treatment outcomes, higher return-to-work rates, better adherence to treatment, more effective control of pain and a better prognosis (Miles *et al.*, 2011). Furthermore, a meta-analysis performed by Jackson et al. (2014) presented indications that self-efficacy has significant overall associations with impairment, affective distress and pain severity within chronic pain samples.

The concept of patient activation is important to the self-management field because people who are motivated and confident in their ability to use their knowledge and skills are more likely to be active participants in maintaining and improving their health (Smith *et al.*, 2013). Hence, activation is closely connected to self-management initiatives because self-management requires patients to be empowered and to possess the necessary information, resources and skills to make decisions and to manage their health on a day-to-day basis (Hibbard and Greene, 2013; Grady and Gough, 2014). According to Hibbard and Gilburt (2014), patient activation draws from earlier concepts, such as self-efficacy and readiness to change, capturing elements of both these concepts but that the patient activation has proved to be a better predictor of healthy behaviour over a wider range of outcomes.

Patient activation is a behavioural concept that involves a number of core components of patient involvement, each of which is important to engagement and participation in health care (Hibbard and Gilburt, 2014). More precisely, patient activation is defined as ‘an individual’s knowledge, skill, and confidence for managing their health and health care’ (Hibbard *et al.*, 2005). As such, patient activation is considered a key element in chronic illness models, such as in consumer driven health care approaches and in models that emphasise patient-oriented care (Hibbard *et al.*, 2004; Hibbard and Mahoney, 2010).

Because patient activation is a relatively new concept, Hibbard et al. (2004) called for a measure that includes the elements of knowledge, skills, beliefs and behaviours needed to manage a chronic condition. The patient activation measure (PAM) score has been used to categorise persons according to four stages of patient activation that occur during the process

of becoming a fully competent manager of one's health (Hibbard *et al.*, 2005). At stage one, people do not yet grasp that they must play an active role in their own health and may still believe they can be a passive recipient of care. At stage two, people may lack the basic facts or may have not yet connected the facts with a broader understanding of their health or recommended health regimens. At stage three, people have the key facts and are beginning to take action but may lack the confidence and skills to support new behaviours. Finally, at stage four, people have adopted new behaviours but may not be able to maintain them when life stress or health crises occur (Hibbard *et al.*, 2007).

The development of a patient activation measure has led to an increasing body of knowledge related to patient activation linked to several health processes and outcomes (Hibbard and Cunningham, 2008; Hibbard and Mahoney, 2010; Greene and Hibbard, 2012). People who are more activated are more likely to engage in healthy behaviours, such as regular exercise and a healthy diet, to engage in disease-specific self-management behaviours, such as medication adherence, to obtain preventive care and to seek and make use of health information (Hibbard and Mahoney, 2010; Hibbard and Gilburt, 2014). Furthermore, activated patients who are prepared to play a key role are central to achieving improvements in the quality of care, better health outcomes and less costly health care service utilisation (Hibbard *et al.*, 2007; Mosen *et al.*, 2007). In an examination of the relationships between patient activation and health-related outcomes, Green and Hibbard (2012) demonstrated associations between patient activation and health limiting and health promoting behaviours, clinical indicators and costly health care utilisation. Studies have also shown that patient activation can be modified and increased over time and that interventions typically addressing chronic illnesses in general or for specific diseases are effective in increasing activation (Hibbard and Greene, 2013; Hibbard and Gilburt, 2014). Patient activation has thus become a central outcome to measure in relation to self-management.

1.2.2 Interventions to support chronic pain self-management

Barlow et al. (2002) argued that self-management may be one means to bridge the gap between patient's needs and the capacity of the health care services to meet their needs. However, people do not necessarily self-manage completely on their own, which supports what Dwarswaard et al. (2016) described as patients' expectations of health care professionals

to fulfil a comprehensive role within self-management. Supporting self-management has consequently become a key priority for chronic illness treatment approaches, including chronic pain (National Voices, 2014).

Carnes et al. (2012) defined a self-management program as 'a structured, taught, or self-taught course with distinct components principally aimed at patients, with the goal of improving the participants' health status or quality of life by teaching them skills to apply to everyday situations'. Following a systematic review on self-management education programmes for people with chronic conditions in general, it was concluded that programmes might lead to small short-term improvements in self-efficacy, self-rated health, cognitive symptom management and frequency of aerobic exercise (Foster *et al.*, 2007). Kroon et al. (2014) conducted a systematic review of self-management education programmes for osteoarthritis. Compared to usual care, they found that the programmes slightly improved self-management skills, pain, function and symptoms, whereas no such improvements were found when comparing them to attention control groups. In the following paragraphs, some generic self-management support initiatives that have been influential to the field in addition to examples of relevant studies are presented, followed by specific examples of support for chronic pain self-management.

In the early 1990s, Professor Kate Lorig at the Stanford Patient Education Research Center developed the Chronic Disease Self-Management Program (CDSMP). The CDSMP focusses on symptoms that are common across chronic conditions to test the hypothesis that people with comorbid conditions could benefit when placed in a common intervention programme in contrast to attending only disease-specific education programmes (Lorig, 2014). Studies have shown that the CDSMP may improve behaviours, including an increase in exercise as well as in the practice of cognitive symptom management techniques, such as relaxation (Lorig and Holman, 2003). The programme has become influential to the field of self-management support for both universal and disease-specific interventions (Lorig, 2014).

The Expert Patients Programme is an approach to chronic disease management initiated by the National Health Service (NHS) in the United Kingdom (UK) in 2001 (Department of

Health, 2001; Donaldson, 2003; Kennedy, Rogers and Bower, 2007). The Expert Patients Programme builds on the CDSMP and offers generic courses that teach self-care skills led by lay people or expert patients in the communities (Donaldson, 2003; Kennedy *et al.*, 2013). Kennedy et al. (2007) investigated the effects of such an intervention where participants were recruited through the programmes and by primary care trust staff, press releases and the Expert Patient Programme webpage. The study had no inclusion or exclusion criteria for participation. They found that the intervention yielded improvements in self-efficacy and energy levels compared to a wait-list control and that the intervention was likely to be cost-effective.

An example of a more disease-specific programme derived from the CDSMP is the Chronic Pain Self-Management Programme (CPSMP). The programme builds on the Stanford's Arthritis Self-Management Programme and the CDSMP and targets people with a primary or secondary diagnosis of chronic pain (LeFort *et al.*, 1998). The CPSMP is a form of standardised psychoeducation developed for group presentation in community settings that aims to offer practical tools and information to increase the development of coping skills and to increase participants' confidence and motivation to better manage their symptoms and the daily tasks of living with chronic pain (LeFort *et al.*, 1998). The CPSMP is delivered as a six-week workshop comprised of weekly sessions that last two and a half hours. Most facilities that offer the programme do not require user-fees or referrals and have two trained volunteer leaders with experience in living with chronic pain as facilitators. Participants are encouraged to adopt an active role by setting goals and participating in group discussions and group problem solving. The content of the programme includes topics on how to deal with frustration, fatigue, isolation and poor sleep; exercise to maintain and improve strength, flexibility and endurance; making healthy food choices; communicating with health care providers and family teams, pacing activity and rest and evaluating new treatments (LeFort *et al.*, 1998; Mehlsen *et al.*, 2017; Self-Management Resource Center n.d.).

Various interventions used to optimise and support self-management have been trialled for both generic and disease-specific initiatives. The studies by Lefort et al. (1998) and Mehlsen et al. (2017) have investigated the effects of the CPSMP. LeFort et al. (1998) found that the intervention group had significant short-term improvements in pain, dependency, vitality,

aspects of role functioning, life satisfaction, self-efficacy and resourcefulness compared to a wait-list control group. The study on the Danish version of the CPSMP, however, did not show effects of the intervention when compared to a treatment as usual group (Mehlsen *et al.*, 2017).

In a study by Nicholas et al. (2013; 2017), short- and long-term effects of a self-management programme using CBT and exercise for older adults with chronic pain were investigated. The intervention was delivered by a clinical psychologist and a physiotherapist and had a total duration of 16 hours. The participants were recruited from referrals by general practitioners for treatment at a pain management and research centre. In the short term, the CBT-based programme was more effective than exercise-attention control and a wait-list control on pain, distress, disability, mood and unhelpful or erroneous pain beliefs (Nicholas *et al.*, 2013). Long-term improvements were found when comparing outcomes with the exercise-attention control after 12 months on pain disability, usual pain, pain distress, depression and fear-avoidance beliefs (Nicholas *et al.*, 2017).

Another example of a study on self-management support that included patients with musculoskeletal pain evaluated a group-based self-management program co-delivered by a health professional and a patient (Turner *et al.*, 2015) Improvements were found for patient activation, health-related quality of life, health status, psychological distress and self-management skills after six months (Turner *et al.*, 2015). A study on a novel three-day community-based group intervention for chronic musculoskeletal pain, which also was co-led by a health professional and a patient, did not, however, show an effect when compared to usual care (Taylor *et al.*, 2016).

As illustrated by the examples provided, the contents and characteristics as well as the effects of interventions that promote self-management vary. In their review on self-management interventions for chronic musculoskeletal pain, Carnes et al. (2012) concluded that group-delivered courses that include input from health care professionals were beneficial and that courses longer than eight weeks did not necessarily yield better outcomes than courses of shorter durations. This is in line with the conclusion of Du et al. (2011), who found a duration

of six weeks to be appropriate for chronic pain self-management programmes. In addition, courses with psychological components have shown that benefits are slightly more consistent over time than for courses without this component, but there is still uncertainty regarding what are considered the most effective and cost-effective course components of chronic musculoskeletal pain self-management interventions (Carnes *et al.*, 2012).

1.3 Easily accessible services for self-management support

Chronic pain can be considered a public health issue due to its prevalence and vast consequences (Goldberg and McGee, 2011; Breivik, Eisenberg and O'Brien, 2013; Stanos *et al.*, 2016). The World Health Organisation (WHO) defines public health as 'the science and art of promoting health, preventing disease, and prolonging life through organised efforts of society' (WHO, 1998). The Ottawa charter furthermore defines health promotion as 'the process of enabling people to increase control over and to improve their health' (WHO, 1986; WHO 1998). An aim of public health is to establish conditions for individuals and groups to live healthy lives based on the principle that individuals have the right to the highest attainable standards of health care (Irvine *et al.*, 2006). Public health policies and actions thus involve systematic efforts to promote health and to prevent disease and injuries in addition to laws and regulations to facilitate healthy choices (Povlsen and Borup, 2015).

Current public health challenges include obesity, smoking, alcohol and substance abuse but they also concern challenges related to inequalities in health (Irvine *et al.*, 2006). Health inequality generally refers to differences in the health of individuals or groups for which aspects of health vary across individuals or according to socially relevant groupings (Arcaya, Arcaya and Subramanian, 2015). Health inequity specifically denotes an unjust difference in health due to socially produced differences in health status between population groups that are avoidable and regarded as unfair (Arcaya, Arcaya and Subramanian, 2015; Newman *et al.*, 2015).

For people to lead healthy lives, it is recognised that supportive environments as well as economic resources must be provided (Irvine *et al.,* 2006). One way to improve the overall

health of the population is to ensure that the settings where people live and work are supportive of health and healthy choices (Newman *et al.*, 2015). Providing basic health care services has furthermore been put forward as a suitable action to address health inequities related to social determinants (Blas *et al.*, 2008). Thus, easy accessibility to health care services has been emphasised as a means to minimise health inequities (Riley, 2012).

An emphasis on easy accessibility has also been apparent within the field of self-management (Jerant, von Friederichs-Fitzwater and Moore, 2005; Lalonde *et al.*, 2015). Kennedy, Rogers and Bower (2007) argue that effective self-management support prerequisites an improved access to services, preferably by allowing patients to self-refer based on their own needs for advice and support. For instance, in communications of the NHS in the UK, it is explained that people may encounter various barriers to accessing support during their efforts to access support for self-management. The examples mentioned include the need to be referred to a service before accessing it and an inability to determine where support is provided. Thus, self-referrals and as few eligibility criteria as possible have been suggested as solutions to remove some of the barriers to self-management support (Burd and Hallsworth, 2016).

In recent public health policies, primary care has thus been put forward as an arena suited to support individuals in reaching their highest attainable level of health and to ensure equal access to healthcare services (WHO, 2008; Newman *et al.*, 2015). The WHO's Alma-Ata conference in 1978 described primary care as an 'essential health care made accessible at a cost a country and community can afford, with methods that are practical, scientifically sound and socially acceptable' (WHO, 1978). Primary care has also been pointed to as a most suitable arena for delivering interventions to support people's self-management of chronic illnesses, including chronic pain, due to its easy access and closeness to where people live their lives, and thus manage their health challenges (Ringard, *et al.,* 2013; Grady and Gough, 2014; Lalonde *et al.*, 2015).

1.3.1 The Norwegian Healthy Life Centres

The newly established HLCs of Norwegian primary health care represent an initiative to deliver interventions for behaviour changes, health promotion and disease prevention and to address public health concerns regarding obesity, smoking and alcohol and substance abuse (The Norwegian Directorate of Health, 2016; The Norwegian Directorate of Health, 2018). The Norwegian Directorate of Health (2018) describe the HLC as an inter-disciplinary primary health care service which offers effective, knowledge-based measures for people with, or in high risk of, disease, who need support in health behaviour change and in coping health problems and chronic disease. The HLCs aim to be easy to access by allowing self-referral to their interventions, and in some centres, self-management initiatives have been added as a service. As such, their activities address primary (preventing the onset of illness), secondary (early diagnosis and prompt treatment) and tertiary (rehabilitation when already affected by a disease) prevention measures (The Norwegian Directorate of Health, 2016).

HLCs provide services that aim to ensure equity and to counteract social inequalities in living habits and health in the population (Statistics Norway, 2016). Therefore, people can contact the HLC themselves or through referrals from their general practitioners, physiotherapists or the Norwegian Labour and Welfare Administration. Cooperation with other primary care services, hospitals, non-governmental organisations, private and public organisations and local authorities is furthermore an important aspect of the HLCs as a community-based service (Chrodis, 2017).

The basic services of the HLCs include exercise groups and individually or group-based counselling or courses for increased physical activity, nutrition and tobacco cessation. Many HLCs also offer counselling, support and education on issues related to mental health, sleep and harmful alcohol assumption, and education for broader groups in addition to physical activity groups for the community (Chrodis, 2017). The HLC programs have an individual-centred approach in which an overall aim is to strengthen the individual's control of his or her own health by emphasising empowerment (The Norwegian Directorate of Health, 2016; Chrodis, 2017). The healthy lifestyle programmes last twelve weeks with the option to repeat the programme two times. Before entering a healthy lifestyle programme and at the end of the programme, a health conversation using motivational interviewing as an approach is carried

out. Figure 1 shows how the healthy lifestyle programmes are structured (The Norwegian Directorate of Health, 2016).

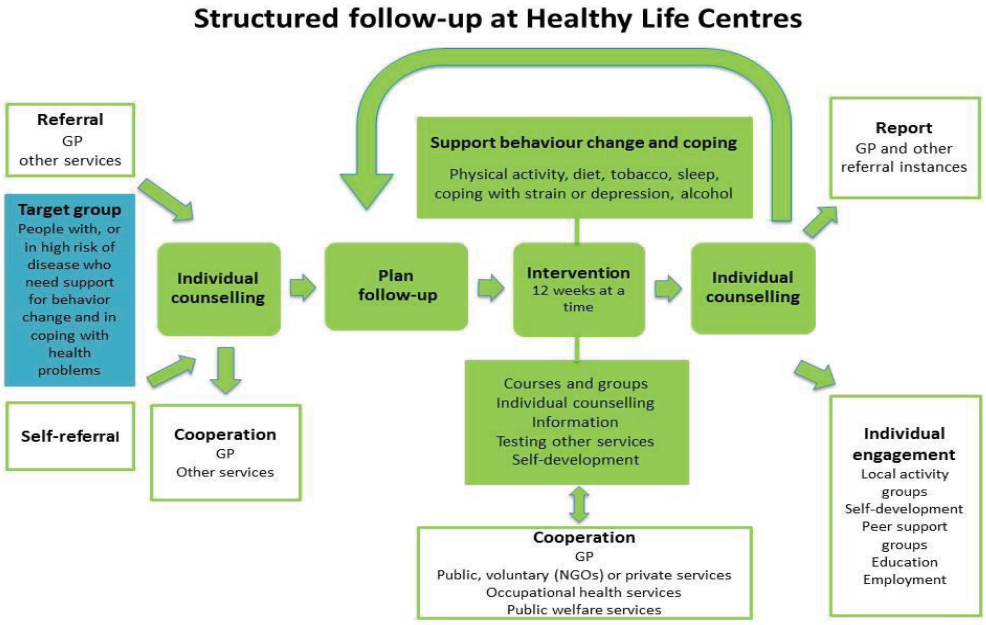

Figure 1. An overview of the structured follow-up for the lifestyle programs at the HLC. Reproduced with permission from the Norwegian Directorate of Health (2016).

There is no obligation for a municipality to establish an HLC, but the Norwegian Directorate of Health recommends that all municipalities create such a centre to manage their preventive health care services. The first HLCs were established in their present form in 2011, and the number of centres are steadily increasing with more than 220 municipalities having established HLCs in 2015 (Statistics Norway, 2016). An early evaluation of the HLCs showed that the centres recruit people who do not participate in other services, such as fitness centres, and that general practitioners who refer patients to HLCs believe that the HLCs offer good services (Båtevik *et al.*, 2008). A later observational study showed an improved health-related quality of life and physical fitness among the participants due to the physical training programmes delivered by HLCs (Lerdal, Celius and Pedersen, 2013).

Other studies have also indicated that participation in HLC programmes can lead to improved physical fitness, weight loss and improved self-perceived health and quality of life and that the changes were maintained one year after the follow-up. However, about half of the participants did not succeed in maintaining beneficial behaviours at the same level after having received physical training at an HLC (Helgerud and Eithun, 2010). In a study conducted by Følling, Solbjør and Helvik (2015), HLCs were described as an inclusive arena with few barriers for attendance.

Currently, no studies have evaluated self-management interventions delivered by HLCs.

2 Aims of the thesis

The main aim was to contribute knowledge related to the expectations towards and the effects that persons with chronic pain get from participating in self-management interventions developed and delivered at a Healthy Life Centre (HLC) in a Norwegian city.

This aim was operationalised into the following research objectives:

1) To explore the expectations of persons with chronic pain related to participation in easily accessible pain self-management interventions (Paper I).
2) To investigate the effects on persons with chronic pain of a group-based chronic pain self-management course compared to a low impact outdoor physical activity after three months (Paper II) and after twelve months (Paper III) related to patient activation and a range of secondary outcomes.

3 Methods

To achieve the research objectives, a qualitative study (Paper I) and a randomised controlled trial (RCT) (Papers II and III) were conducted. The protocol for the entire PhD-project has been published (Nøst *et al.*, 2016), and the flow chart presented in Figure 2 is the same as presented in the published protocol. The studies included in the thesis are shown in the box marked with a dotted line (Figure 2). Flow charts for each of the studies for the RCT are presented in the associated papers.

3.1 Design

An open, pragmatic, two-armed RCT was conducted from August 2015 to December 2017 to investigate the effect of the self-management course. The short-term effect was investigated three months after completion of the intervention (Paper II) and the long-term effect was investigated after 12 months (Paper III).

The investigated intervention, similar to most non-pharmacological, behavioural change and educational interventions, falls under the category of complex interventions implying interventions that encompass several components that can act either independently or interdependently (Craig *et al.*, 2008). An increasing number of RCTs of complex healthcare interventions include qualitative methods to explore phenomena or processes that are difficult to capture using quantitative methods alone (Lewin, Glenton and Oxman, 2009). Hence, a qualitative study with individual face-to-face interviews was conducted at the baseline before randomisation with a subsample of the total study population to explore the expectations related to participating in the trial activities (Paper I).

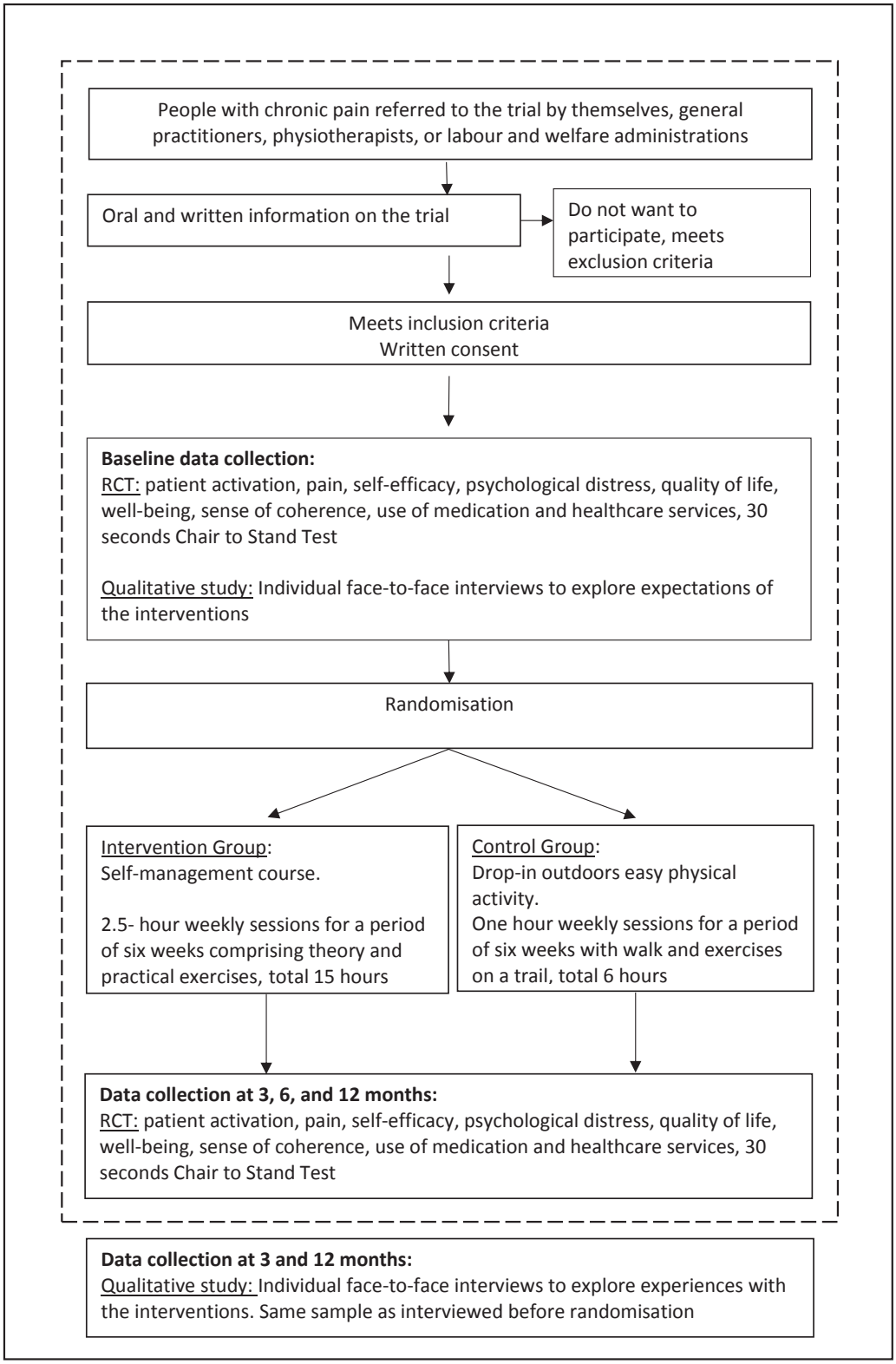

Figure 2. Design of the entire PhD-project. The box with the dotted lines indicates the studies assessed in the thesis.

3.2 Ethical considerations

The studies were conducted in accordance with the Declaration of Helsinki (WMA, 2013). Approval from the Director for Health and Social Affairs in the municipality and from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst) were obtained, and the trial was registered on Clinical Trials.gov in August 2015, number NCT02531282.

The participants were informed both orally and in writing of the study, including information regarding the purpose of the trial and the participants' right to withdraw without stating a reason. A written consent to participate was obtained before enrolment with an additional consent obtained for the qualitative study. Those asked to participate in the interviews were informed that participation in the qualitative study was voluntarily and not a prerequisite to trial participation.

All participants included in the trial were offered an activity, either the chronic pain self-management course or the control group activity, based on the consideration that those who responded due to a need for self-management support should receive a service.

People suffering from chronic pain can be vulnerable. Participation in the trial was perceived not to cause harm, as it did not include any invasive interventions; however, there was still a possibility that reactions due to previous experiences could occur, especially during the interviews, or that adverse or minor events could occur during the interventions. All participants were informed of the possibility to contact the HLC if they had any concerns related to the interventions. The instructors of the interventions registered and acted on any minor or adverse event. Informants in the qualitative study were informed of the possibility to stop the recording for a break and for a debriefing after the interview. One informant chose to make use of the opportunity for a break during the interview.

3.3 Setting

The PhD project took place at the HLC in the Trondheim municipality, a city in central Norway with a population of approximately 190,000. This HLC was established in 2011. Due to The Coordination Reform within Norwegian health care, some self-management initiatives have been transferred from specialist care to primary care (The Norwegian Ministry of Health, 2009; Solberg *et al.*, 2014). Consequently, the HLC in Trondheim added self-management interventions to its services in 2013.

The basic services at the HLC include healthy lifestyle programmes, and one example is the exercise group, which includes both indoor and outdoor physical activities. Examples of the self-management interventions include time-limited group courses focussing on coping with depression and courses on nutrition related to type II diabetes. At the time of the trial, the HLC had 5.5 positions occupied mainly by physiotherapists in addition to dietitians and occupational therapists.

In 2016, 624 people participated in interventions at the HLC in Trondheim. Of these, 271 (women 73%) had not used services at the HLC before. The number of people participating in different interventions at the HLC is increasing, and there was a 78% increase in people self-referring in 2016 since the HLC opened in 2011 (Friskliv og Mestring Trondheim kommune, 2017).

3.4 The interventions

The interventions are described in the published protocol (Nøst *et al.*, 2016) and in Papers II and III. The essence of the descriptions in addition to some supplementary information is provided in the following paragraphs.

3.4.1 The chronic pain self-management course

The HLC staff experienced persistent pain to be a common challenge among their users and decided to initiate a chronic pain self-management course, first as a project in cooperation with neighbouring municipalities and then as a local initiative. The aim of the locally

developed chronic pain self-management course was to increase the participants' knowledge, skills and confidence in managing everyday life with chronic pain (Nøst *et al.,* 2016) by introducing central self-management skills such as goal setting, action planning and problem solving. Furthermore, the purpose of the course was to empower the participants to actively take part in their healthcare.

During the development of the self-management course, the HLC staff and a representative from a patient organisation used recommendations found in the literature on self-management (e.g., Lorig and Holman, 2003) and in the guidelines for the HLC (The Norwegian Directorate of Health, 2016) in addition to personal experiences related to behavioural changes and self-management strategies for chronic conditions. This resulted in a chronic pain self-management course that introduced cognitive and behavioural strategies for pain management (using e.g., Turk and Okifuji, 2002; McCracken and Eccleston, 2003: Thorn B, 2004) and movement exercises based on psychomotor physiotherapy (Dragesund and Raheim, 2008). In addition, the course included group discussions and experience sharing among participants.

Consecutively, the self-management course included a focus on thoughts, emotions and actions related to the pain. The participants were introduced to topics such as pain theory, barriers in everyday life due to chronic pain, problem solving, action planning, goal setting and techniques to deal with fatigue, poor sleep, frustration and isolation. One of the instructors was educated in psychomotor physiotherapy and had extensive experience using this approach at a multidisciplinary hospital pain clinic. Thus, the movement exercises that concluded each session were based on principles from this approach to introduce the participants to relaxation and stretching techniques.

The self-management course was delivered as a 2.5-hour weekly group session during the day (12.30 pm-15.00 pm) for a period of six weeks, amounting to a total of 15 hours. A total of six courses were carried out for the project. Two physiotherapists facilitated the courses. During the entire project period, a total of four physiotherapists were involved in the execution of the self-management course. An outline of the content of the self-management course is available in Paper I and in the guidelines for delivering the course in the appendix of the thesis. To test

the chronic pain self-management course prior to the trial, the HLC offered two rounds of the course as a pilot experiment.

3.4.2 The control group activity

Offering an activity to all participants in the trial was recognised as an ethical and good clinical practice (Schulz, Altman and Moher, 2010). Because physical activity has been found to have beneficial effects for chronic pain conditions (Sullivan *et al.*, 2012,; Ambrose and Golightly, 2015; O'Connor *et al.*, 2015), the control group was offered a group-based physical activity that was already part of the HLC's intervention services, called 'Frisktrimmen'.

The low-impact outdoor physical activity was a weekly one-hour drop-in session during the day (13.00 pm-14.00 pm) for a period of six weeks. The activity was comprised of walking and simple strength exercises carried out on a trail popular for hiking among the municipality's inhabitants. The activity provided an opportunity to meet others with similar health challenges. No education was presented to the control group. Two instructors familiar with physical exercise led the activity. During the project, four instructors were involved in the execution of the control group activity. The instructors of the control group activity received the guidelines for the Frisktrimmen and used the same principles for their activities. As the 'Frisktrimmen' included a drop-in policy, the same was done for the control group activity. The participants in the control group were therefore informed that this was an opportunity they could accept if they desired.

3.5 Participants

Eligible participants for the trial were adults 18 years or older who experienced pain for three months or more and were able to take part in group-discussions in Norwegian. The inclusion criteria were simple and broad to reflect the opportunity for self-referrals and the easy accessibility to interventions at the HLC. Following suggestions from the staff at the HLC and from similar studies on chronic pain self-management interventions, the exclusion criteria included not being able to take part in the activity offered to the control group, chronic pain arising from malignant diseases and not having the capacity to consent.

The HLC usually announces its interventions in the newspaper along with other announcements from local authorities. As this yielded few results, flyers and posters with information about the trial were distributed in the waiting areas of general practitioners and physiotherapists' offices, placed in a separate newspaper advertisement, posted on social media and websites and sent to relevant patient organisations. In addition, information regarding the opportunity to refer people to the trial was given to physiotherapists, general practitioners, the Norwegian Labour and Welfare Administration and relevant departments at the hospital. Those who were interested in participating were encouraged to contact the PhD candidate by either phone or email for additional information and to be screened for the inclusion and exclusion criteria. Those who met the inclusion criteria and none of the exclusion criteria were invited to an appointment to sign the consent form and to be enrolled in the trial. Baseline data were then collected before the participants were randomised using an Internet web-based trial service provided by the Unit for Applied Clinical Research at the Norwegian University of Science and Technology, NTNU.

Recruitment for the entire PhD project, including the qualitative study and the RCT, began in September 2015 and ended in October 2016. The sample size calculation was performed before the enrolment of participants (Nøst *et al.*, 2016). Accordingly, the aim was to include 120 participants. Of the 208 people who responded to the trial announcement, 121 were included. They were randomised to the chronic pain self-management course (n= 60) or to the control group (n= 61). Additional details about the participants' flow through the trial and reasons for exclusion, including the sample size calculation, are provided in Papers II and III.

To explore expectations of participating in the interventions, a sub-sample of participants included in the RCT was asked to participate in a qualitative study. The intention was to recruit participants with different durations of pain, from different age groups and from both genders. Hence, a combination of consecutive and purposeful sampling was used. The selection of participants was initially done by consecutively asking participants if they were able to meet for the baseline assessment at specific time points, which were scheduled with extra time for interviews, i.e., that they wanted to participate and had the time to be interviewed. As a result of this process, a variation in expectations among the participants was expected. After 15 interviews were conducted, the demographic characteristics of the

participants were examined to determine whether the intended variations in the duration of chronic pain, age groups and gender were reached. Hence, the final six participants were recruited following a more purposeful sampling approach that specifically aimed to include more men and younger participants and to include those who at enrolment mentioned previous experiences other than those already included. All but one participant who was asked (did not have time for the interview) to participate accepted and agreed to take part in the qualitative study. Recruitment continued until 21 participants had been interviewed. At this point, it was concluded that sufficient data were obtained to explore the research objective in depth.

3.6 Data collection

Data collection for the qualitative study took place between September 2015 and April 2016. Due to the possibility that the participants wanted to share difficult experiences when they discussed their current expectations, individual face-to-face interviews were chosen rather than focus group interviews (Kvale and Brinkmann, 2010; Malterud, 2013). The interviews were conducted in conjunction with the baseline assessments performed after the participants had completed the questionnaires for the RCT.

A semi-structured interview guide was utilised to ensure all participants discussed the same topics and that all aspects of interest were covered. The themes of the interview guide were based on the aim of the study, informed by relevant literature and by discussions with members of the research group on Patient Education and Participation at the NTNU. The participants were asked open-ended questions with the main question: ‘Can you tell about your expectations towards participation in the interventions?’. This was followed by questions regarding how they experienced pain in everyday life, what they did to manage life with chronic pain and which healthcare services they had previously utilised due to pain.

After the first three interviews, minor changes were made to the sequence of the questions, i.e., the main question was introduced earlier than originally intended to obtain more information regarding their current expectations, but no new topics were added during the data collection period. The interview guide is provided in the appendix. The interviews were

carried out either at the HLC or at the research centre where the PhD candidate's office was located. The PhD candidate conducted all interviews, which were audio recorded and transcribed verbatim by the PhD candidate and a research assistant. The average duration of the interviews was 43 minutes with a range of 23 to 72 minutes.

Self-reported data for the RCT were collected through questionnaires at the baseline and after three, six and 12 months. At the baseline, the PhD candidate was available for questions when the participants completed the questionnaire and supervised the 30-second Chair to Stand Test. For the follow-ups, the participants received the questionnaires by mail and brought completed questionnaires to the follow-up appointments, during which a research assistant blinded for group allocation supervised the 30-second Chair to Stand Test. The research assistant used a protocol that described how to perform the test, and the participants were told not to divulge their allocation. There was one postal reminder for each follow-up, and non-responders were contacted by phone or email, allowing for a delay of up to four weeks.

3.6.1 Primary outcome- The Patient Activation Measure

Based on the literature regarding self-management interventions, participating in the self-management course was expected to strengthen the participants' engagement in and knowledge of available health resources, which would consequently lead to a higher level of patient activation (Nøst *et al.*, 2016). Patient activation was therefore chosen as the primary outcome, and it was assessed using the Patient Activation Measure (PAM) (Hibbard *et al.*, 2004; Hibbard *et al.*, 2005).

The original PAM was developed based on Rasch analyses in a four-stage process, including conceptualising and operationalising activation, pilot testing, psychometric analyses and assessments of the measure's performance using a heterogeneous national probability sample (Hibbard *et al.*, 2004). The process yielded a 22-item unidimensional measure in which the different elements of knowledge, beliefs and skills that constitute activation have a hierarchical order. The hierarchy of item difficulty implies that what is needed to increase activation depends on the person's position on the activation continuum (Hibbard *et al.*, 2004). The development process showed that the precision of the measurement was stable for

several different chronic illnesses, including chronic pain. It was found that those with higher activation reported significantly better health and had significantly lower rates of healthcare utilisation. Self-management behaviours associated with specific conditions were also significantly associated with the measured activation score. Thus, the evaluation of the measure indicated that the measure had a high degree of construct and criterion validity. Reliability was found to be stable across gender, age groups and several chronic conditions. The Cronbach's alpha for the 22-item PAM was 0.91 (Hibbard *et al.*, 2004).

Shortly after the development of the PAM-22, a process was initiated to reduce the number of items while maintaining adequate precision to enhance the measurements' clinical feasibility (Hibbard *et al.*, 2005). Iterative Rasch analyses were performed to identify items that could be eliminated without any significant loss in precision and reliability using the same national probability sample as that used for the development of the original PAM. The analysis yielded a 13-item measurement that had psychometric properties similar to the original 22-item version, which was thus found to be reliable and valid; however, the subgroup analysis suggested a slight loss of precision within some subgroups, such as those with no chronic illness, those 85 years or older, those with poor self-rated health and those with lower income and education levels (Hibbard *et al.*, 2005).

The PAM-13 is a measurement of both responders' beliefs regarding the ability to self-manage and their confidence in taking action (Hibbard and Gilburt, 2014). The measure includes thirteen items, each representing a statement for which the participants indicate their level of agreement on a four-point Likert scale from 1= 'strongly disagree' to 4= 'strongly agree' with an additional not applicable option (Hibbard *et al.*, 2005). The statements measure self-assessed knowledge, beliefs and confidence in the management of health-related tasks (Hibbard and Gilburt, 2014). For instance, participants are asked: 'When all is said and done, I am the person who is responsible for taking care of my health' and 'Taking an active role in my own health care is the most important thing that affects my health' (Hibbard *et al.*, 2005). A high score indicates that the participants are more activated to adopt and to maintain healthy self-management behaviours, even under stress (Hibbard *et al.*, 2005). The PAM-13 responses are added to obtain a raw score from 13 to 52, which is calibrated to a total score between 0 and 100 using the spreadsheet and transformation tables provided by Insignia

Health (2015). The final score, which range from 0- 100, thus represents the person's concept of themselves as an active manager of their health and health care (Hibbard and Gilburt, 2014). In this RCT, the 2014 version of the spreadsheet and calibration table were applied.

The patient activation scores can be divided into four levels of activation that reflect the developmental process of patient activation (Hibbard *et al.*, 2005). Level 1 include the least activated responders with a PAM-13 score ranging from 0.0- 47.0, which suggests that a person may not yet understand that the patient's role is important to healthcare management. Level 2, which include a score ranging from 47.1- 55.1, indicates that a responder lacks the confidence and knowledge to take action. Level 3, with a score ranging from 55.2- 72.4, indicates that a responder is beginning to engage in recommended health behaviours, whereas a level 4 score ranges from 72.5- 100.0 and indicates that a responder is proactive about health and engages in many recommended health behaviours (Greene *et al.*, 2015, Hibbard *et al.*, 2007). Patient activation levels have been used in studies as cut-off values to stratify data, (e.g., Solomon, Wagner and Goes, 2012; Greene *et al.*, 2015; Moljord *et al.*, 2017) and were used for a post-hoc subgroup analysis for this RCT (Paper III).

Researchers in several countries have translated and validated the PAM-13 into their native languages and national settings, including European countries (Rademakers *et al.*, 2016). Most validation studies have included chronic conditions in general (Steinsbekk, 2008; Rademakers *et al.*, 2012; Brenk-Franz *et al.*, 2013; Zill *et al.*, 2013; Graffigna *et al.*, 2015), whereas others have included subgroups, such as osteoarthritis (Ahn *et al.*, 2015), cardiac conditions (Ngooi *et al.*, 2017), dysglycaemia (Maindal, Sokolowski and Vedsted, 2009) and mental illness (Moljord *et al.*, 2015). Validation studies have been performed in a primary care setting (Brenk-Franz *et al.*, 2013), in a surgical setting (Skolasky *et al.*, 2009), an outpatient hospital population (Steinsbekk, 2008), an inpatient hospital population (Prey *et al.*, 2016) and in a mental health outpatient population (Moljord *et al.*, 2015). The studies have shown satisfactory psychometric properties, and the Cronbach's alpha has been the most frequently reported measure (α ranging between 0.77- 0.91). Two Norwegian studies have reported the psychometric properties of the Norwegian translation of the PAM-13. One included a sample of participants in group-based self-management interventions at a hospital (Cronbach's alpha = 0.91) (Steinsbekk, 2008) and the other included patients in mental health

treatment (Cronbach's alpha of 0.87) (Moljord *et al.*, 2015). For the current study, the Cronbach's alpha at the baseline was 0.75.

The PAM-13 has become the most commonly applied version of the patient activation measure, and is widely used to evaluate self-management interventions (Hibbard and Gilburt, 2014). Currently, there is no consensus regarding what is considered a meaningful difference in the PAM score between groups. Moreover, there is no consensus regarding a cut-off level to describe what to recognise as a meaningful change in patient activation. Studies have suggested that a 5-point difference in the PAM is a meaningful difference (Fowles *et al.,* 2009), whereas others have defined a meaningful improvement in patient activation as four points on the PAM-13 scale (Turner *et al.,* 2015). A study on patient education in a hospital setting in Norway, which found a statistically significant improvement in the PAM-13 to be six points (Grønning *et al.,* 2012) informed the sample size calculation of the current study. Although the PAM-13 is commonly used to measure the effect of self-management interventions for chronic illnesses, the measure has not been used often for studies that have specifically focussed on chronic pain. The use of the PAM-13 in a RCT on the effect of patient education on polyarthritis (Cronbach's alpha= 0.80) (Grønning *et al.*, 2012; Grønning *et al.*, 2014) as well its use in an evaluation study of self-management interventions, including those with chronic pain, where the PAM-13 was reported to be sensitive to change (effect size= 0.65) (Turner *et al.*, 2015) are relevant to the current study.

3.6.2 Secondary outcomes

The intervention was also expected to influence several other issues related to managing chronic pain, such as health-related quality of life, pain and emotional distress. Several secondary outcomes were therefore included, which were chosen based on the recommendations from the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) (Turk *et al.*, 2003; Dworkin *et al.*, 2005) and findings from other relevant studies (e.g., Turk *et al.*, 2008; Grønning *et al.*, 2012; Nicholas *et al.*, 2013). The studies were identified through a literature review using the Population, Intervention, Comparison and Outcome (PICO) strategy applying the terms 'chronic pain', 'self-management', and 'intervention' as well as these terms combined with keywords such as 'pain', 'self-efficacy', 'health related quality of life', 'psychological distress', and 'physical

functioning'. The outcomes are presented in Papers II and III, and are only displayed according to the corresponding domain of the IMMPACT (Turk *et al*., 2003) shown in Table 1, including the obtained Cronbach alpha values.

Table 1. Overview of secondary outcomes sorted according to IMMPACT domains

IMMPACT domain:	**Outcome measure:**	**Instrument:**	**Cronbach's α:**	**Reference:**
Pain	Pain severity	Brief Pain Inventory	0.81	(Cleeland and Ryan, 1994)
	Average experience of pain the previous week	Visual Analogue Scale		(McCormack, Horne and Sheather, 1988)
Physical functioning	Pain interference	Brief Pain Inventory	0.86	(Cleeland and Ryan, 1994)
	Health-related quality of life	EuroQoL (EQ-5D-5L)	0.55	(EuroQoL Group, 1990)
	Physical activity	'How often do you on average exercise?'		(Krokstad *et al.*, 2013)
	Lower body strength	The 30-second Chair to Stand Test		(Rikli and Jones, 2013)
Emotional functioning	Anxiety and depression	Hospital Anxiety and Depression Scale	0.73 (HADSD) 0.76 (HADSA)	(Zigmond and Snaith, 1983)
	Well-being	Arizona Integrative Outcomes Scale		(Bell *et al.*, 2004)
	Global self-rated health	'By and large, would you say that your health is……'		(Krokstad *et al.*, 2013)
Coping	Pain related self-efficacy	Pain Self-Efficacy Questionnaire	0.84	(Nicholas, 2007)
	Sense of coherence	Sense of Coherence-13 questionnaire	0.87	(Eriksson and Lindstrom, 2005)

Symptoms and adverse events were reported by the instructors of both groups and are reported in Papers II and III. Participant flow through the trial, including adherence to the treatment regimen, and reasons for withdrawal from the trial are illustrated by the flow charts in Papers II and III.

3.7 Analyses

For the qualitative data, Systematic Text Condensation (STC) was used for the analysis. This is a descriptive thematic cross-case approach that presents the experiences of the participants as expressed by themselves rather than exploring possible underlying meanings of what was said (Malterud, 2012). STC aims to present vital examples of peoples' life experiences rather than to cover the full range of potential available phenomena (Malterud, 2012). As the aim of the qualitative study was to explore expectations of participation in a new intervention, this approach seemed appropriate. According to STC, the procedures for analysis involve a stepwise iterative method of four steps, including an analytic reduction with specified shifts between de-contextualisation and re-contextualisation of data (Malterud, 2012). The steps were carried out following the descriptions by Malterud (Malterud, 2012), which are presented in the following paragraphs.

The first step focusses on forming a total impression of the data. During this step, an overview of the data was established as the research team (the authors of Paper I) read the transcripts from the same three interviews to identify preliminary themes associated with the research question. The PhD candidate also read all transcripts from all the interviews. The authors had experience working with patients who experienced pain and patients in public health settings. Analysing the data with an open mind and with an awareness of the participants' voices was emphasised, while preconceptions were actively strived to put aside. Details regarding the PhD candidate's preconceptions are provided in the chapter on methodological discussions. At the end of step one, each member of the research team listed the preliminary themes they identified, and confluent and diverging issues were discussed until reaching an agreement on the preliminary themes. At this point, all data were handled in Norwegian. Figure 3 illustrates the organisation of the preliminary themes during this step. The mind-map should be read as a history beginning at the top and proceeding clockwise.

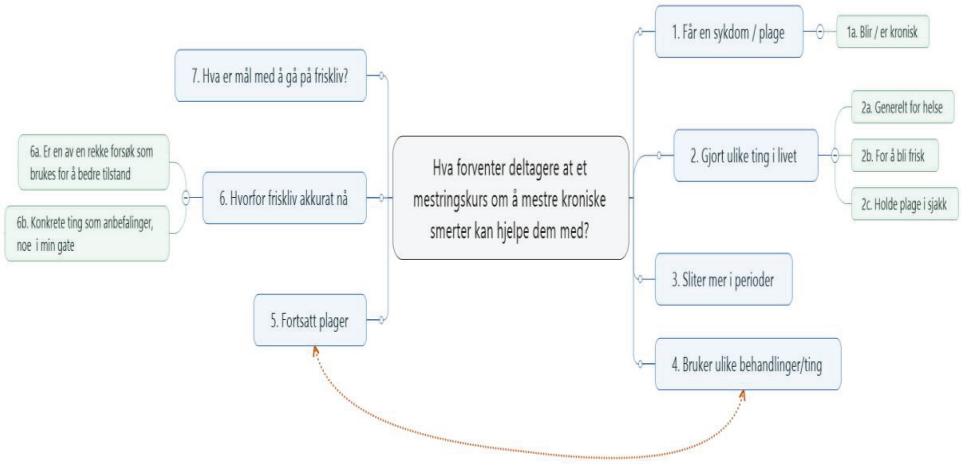

Figure 3. Mind-map illustration of the preliminary themes discussed during the early steps of the analysis (in Norwegian). (Made in MindManager).

The second step involves identifying and sorting meaning units. The transcripts were read again, line by line, to identify meaning units representing parts of the interviews that might elucidate the expectations of participating in the interventions. All of the meaning units were sorted into categories that were potentially related to the previously negotiated themes during step one.

The third step of the analysis includes condensation. This involves reviewing the themes, dividing them into subthemes and developing condensed descriptions for each of the subthemes. The content was reduced to a condensate, combining the content from all the meaning units in the subtheme. A condensate is an artificial quotation that maintains the original terminology as used by the participants as much as possible.

During the fourth and final step of the analysis, data were reconceptualised, meaning that the pieces were put together again. The contents of each condensed description were summarised into an analytical text presented as the final themes in Paper I. Each of the themes was illustrated by relevant quotations. The transcripts were then reviewed again to validate that the synthesis and the illustrative quotations reflected the original context appropriately. In

addition, the theme headings were reconceptualised according to the full transcripts. At this point, the text was translated into English.

A selection of meaning units and themes were presented on several occasions and discussed at meetings by the research group on Patient Education and Participation, NTNU, to obtain extended input for the analyses. The results were also discussed with the HLC and at a national conference that included experts on self-management and learning and mastery interventions.

The analyses of the RCT were planned in collaboration with a statistician at the Unit for Applied Clinical Research at the NTNU. This statistician was consulted for guidance several times during the process. The analyses are described in Papers II and III. In the following paragraphs, some of the supplementary information is presented.

A linear mixed-effects model was used to analyse the RCT data. The longitudinal data in the trial were treated as two-level data. Consequently, the observations (level 1) were viewed as nested within the participants (level 2) recognising each participant as a cluster. This means that the observations for each participant were not independent of each other (Mehmetoglu and Jakobsen, 2017). Furthermore, the order of the observations is relevant, so the 'pre' observations come before the 'post' observations in time. Rabe-Hesketh and Skrondal (2012) described this as a special feature of longitudinal data (the level 1 observations are ordered in time and not necessarily exchangeable). Figure 4 illustrates the order of observations for the study, exemplified by the primary outcome, PAM.

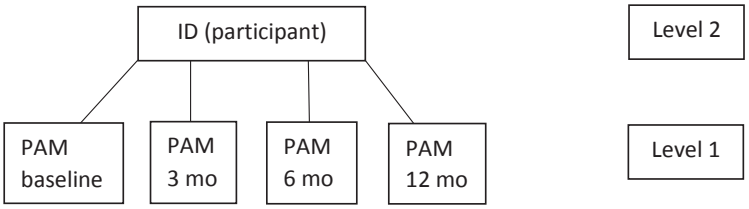

Figure 4. Illustration of the nesting structure and dependency in the two-level data shown with the variables ID and the primary outcome measure, PAM assessed at the four time points.

All randomised participants were included in the analysis within the groups to which they were randomised following an intention to treat procedure. The reasons for any missing data were considered, and missing data were investigated using the applied statistical software. No specific pattern for the missing values was found. Outcomes over time for the chronic pain self-management course and the control group were compared using linear mixed-effects models with the participants specified as a random effect to allow participants to begin with different levels of the outcome in question, and a variable specifying group allocation and time specified as a fixed effect. The variance option restricted maximum likelihood was used to estimate the parameters. Differences between the groups were calculated using linear combinations of coefficients. Predicted residuals were utilised with scatter plots and histograms to investigate whether model assumptions, such as linearity, absence of collinearity, homoscedasticity and normality of residuals, were violated (Rabe-Hesketh and Skrondal, 2012). In addition, regression assumptions were checked using the command 'regcheck' in Stata (Mehmetoglu and Jakobsen, 2017), resulting in satisfactory values.

Per-protocol analyses were performed in which the per-protocol criterion was participants who had been present for a minimum of three of six sessions (Papers II and III). The per-protocol analyses provided similar findings as to the main analyses and are thus not further reported.

For Paper III, a post-hoc subgroup analysis was conducted to explore whether the effect of the intervention on PAM-13 varied among the patient activation levels at the baseline (similar to e.g., Solomon, Wagner and Goes, 2012; Greene *et al.,* 2015; Hibbard *et al.,* 2015; Moljord *et al.,* 2017). A subgroup analysis is typically applied to evaluate the treatment effects for a specific end point within a subgroup of patients defined by baseline characteristics (Wang *et al.*, 2007). A linear regression analysis was used to test for an interaction between baseline patient activation levels and allocations. The dependent variable was the change in PAM-13 from the baseline to 12 months. The independent variables were the PAM-13 levels at the baseline and the allocations (intervention or control group). Due to the number of participants in each of the four activation levels, and similar to an RCT that investigated the effects of a web-based intervention for adults with chronic conditions on patient activation (Solomon, Wagner and Goes, 2012), participants at the first two patient activation levels were combined into a single group.

All analyses were performed using Stata Statistical Software (StataCorp, 2014).

4 Results

In this chapter, a summary of the main results from the three papers is presented. More detailed results are presented in the respective papers. The analyses of Paper II and Paper III are based on the 121 participants included in the RCT. The analyses of Paper I are based on a sub-sample of 21 participants enrolled in the RCT. Table 2 displays the demographic characteristics of the participants included in the three papers. In Figure 5, the changes throughout the trial period for the primary outcome, Patient Activation Measure-13 (PAM-13) separated for the two trial arms, is displayed.

4.1 Paper I

The objective of the study was to explore expectations of participation in easily accessible pain self-management interventions.

The qualitative study with 21 informants found that the expectations towards the easily accessible interventions were related to a hope that participation would lead to a better everyday life. The expectations of participation were based on the interventions representing a new and untried approach that could provide opportunities to gain and reinforce skills, to help the participants experience personal growth, to meet others in similar situations and to easily access professional support.

Most informants said they wanted to see whether the easily accessible interventions could improve their pain management strategies, as it was important for them to actively attempt to alleviate pain. Participating in interventions provided by health care services was perceived as an act of self-care in which the participants could actively manage their health. Some wanted to gain knowledge of new skills and techniques they could use to achieve this aim, while others planned to reinforce skills they already possessed. Meeting others in similar situations was emphasised because support from others was perceived to help alleviate pain. Most informants said they were not concerned about whether interventions were delivered at a hospital or through primary care because the main concern was the opportunity to access interventions when they needed help managing pain.

Table 2. Demographic characteristics of the participants for the three papers

	RCT (Papers II and III)	Qualitative study (Paper I)
Characteristics	(N= 121)	(n= 21)
Female, n (%)	106 (87.6 %)	17 (81 %)
Age years, mean, (SD) (range)	52.7 (11.7) (23- 74)	53.1 (12.5) (32- 74)
Living with someone, n (%)	86 (71.1 %)	13 (62 %)
Highest level of education, n (%)		
lower secondary school or less	8 (6.6 %)	0 (0 %)
upper secondary school	56 (46.3 %)	9 (43 %)
higher education (college or university)	57 (47.1 %)	12 (57 %)
Main reason for pain, n (%):		
musculoskeletal diseases, ICPC-2 chapter L	93 (76.9 %)	15 (71 %)
neuro system diseases, ICPC-2 chapter N	16 (13.2 %)	2 (10 %)
general and unspecified, ICPC-2 chapter A	12 (9.9 %)	4 (19 %)
Pain duration, n (%)		
7- 11 months	2 (1.7 %)	0 (0%)
1- 5 years	24 (19.8 %)	7 (33 %)
6- 9 years	19 (15.7%)	1 (5 %)
10 years or more	76 (62.8 %)	13 (62 %)
More than one chronic condition, n (%)	76 (62.8 %)	13 (62 %)
Work status, n (%)		
working, full or part time	31 (25.6%)	3 (14 %)
disability pension, full or graded	56 (46.3 %)	11 (52 %)
sick leave, full or graded	20 (16.5 %)	3 (14 %)
retired	14 (11.6%)	4 (19 %)

4.2 Paper II

The objective of the study was to investigate the effects on persons with chronic pain after three months of a group-based chronic pain self-management course compared to a low-impact outdoor physical activity delivered through an easily accessible healthcare service on the primary outcome, patient activation, and a range of secondary outcomes.

An RCT including 121 participants randomised to a chronic pain self-management course (intervention group) (n= 60) or to a low-impact, outdoor physical activity (control group) (n= 61) was conducted. The participants mean age was 53 years, and there were more women (88%) than men in the sample. A majority of participants were living with someone (71%). Many of the participants had experienced pain for ten years or more (63%), and more than half (63%) reported having more than one chronic condition. Musculoskeletal diseases were mainly stated as the reason for the pain (77%). Most participants had responded to advertisements in newspapers and social media or email invitations sent to relevant organisations (69%).

The number allocated to each group varied between 7 and 13 (median 10). Ten participants (17%) did not attend the self-management course, and 14 participants (23%) chose not to participate in the control group activity. At the three-month follow-up, 104 participants completed the questionnaire (86%). The participants completing the questionnaire were equally distributed between the two groups.

For the primary outcome, patient activation, there was no statistically significant difference between the groups at the three-month follow-up (estimated mean difference -0.5, CI 95% -4.8 to 3.7, p= 0.802). The question in the Brief Pain Inventory on pain relief was the only secondary outcome indicating a significant difference (estimated mean difference 1.0, 95 % CI 0.01 to 1.9, p= 0.047). Within the groups, there were statistically significant minor changes with a decrease in pain experienced during the previous week for both groups and an increase in the global self-rated health measure for the self-management course group.

A model-based illustration for the changes in PAM within both groups throughout the trial is presented in Figure 5.

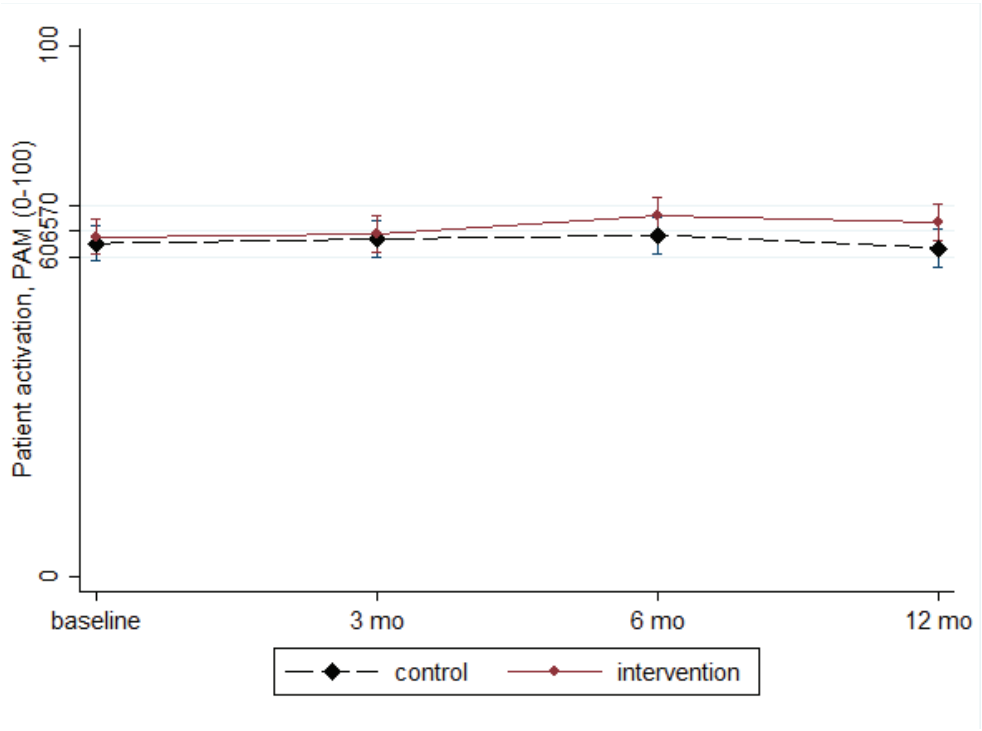

Figure 5. Predictive margins of group allocation with 95 % confidence intervals for the primary outcome, PAM-13 (0-100) including all follow-up assessments (results of Papers II and III).

4.3 Paper III

The objective of the study was to investigate the effects related to patient activation and a range of secondary outcomes on persons with chronic pain of the easily accessible group-based chronic pain self-management course compared to a low-impact outdoor physical activity after twelve months.

The RCT conducted for Paper III included the same 121 participants and interventions as presented in Paper II. Outcomes were measured at six and 12 months after completion of the intervention. At the six-month follow-up, 103 participants (85%) returned the questionnaire, whereas 100 (83%) participants completed the questionnaire after 12 months.

The estimated mean difference at 12 months for the primary outcome, PAM-13, was 4.0 (CI 95 % -0.6 to 8.6, $p= 0.085$), which was not statistically significant at the $p\leq 0.05$ level. There were no statistically significant differences between the groups for the secondary outcomes.

At the 12-month follow-up, within both groups there were statistically significant improvements for pain experienced during the previous week, the global self-rated health measure and the 30-second Chair to Stand Test.

The observed mean change in PAM-13 from the baseline to 12 months increased for those with the two lowest levels of patient activation (level 1 and 2); 10.8 points for the intervention group and 9.2 points for the control group. There were only minor changes for those at patient activation level 3 (1.0 point in the intervention group and -0.6 point for the control group). For those with the highest activation level at the baseline (level 4), there was a decrease in the control group of -12.2 points, but only minor changes in the intervention group (-1.5 points). The test for an overall interaction effect between patient activation levels at the baseline and allocations was not significant ($p= 0.623$).

5 Methodological discussions

The trustworthiness of research depends on a number of research features, including the initial research question, the way data are collected, the way data are analysed and which conclusions are drawn (Roberts and Priest, 2006). Even when the research procedures are followed, trustworthiness cannot be sufficiently produced. Considerations regarding how decisions made initially as well as throughout the research process could affect the results are also necessary (Malterud, 2001; Roberts and Priest, 2006; Creswell, 2014). The interpretability of data could be affected by either systematic errors, often referred to as bias, random errors or limited generalisability (Rothwell, 2005; Spieth *et al.*, 2016). In quantitative research, terms such as 'internal validity', 'external validity' and 'reliability' are often used during methodological discussions (Creswell, 2014), whereas in qualitative research, the terms 'relevance', 'validity', including transferability, and 'reflexivity' are used (Malterud, 2001).

Although the terms used for quantitative and qualitative research differ, the underlying principles are similar (Malterud, 2001). The primary concern is which decisions are made during the research process and how these decisions could have influenced the results. The following methodological discussions are structured according to the research process and discuss the qualitative study and the RCT under the same headings as the main sections in the chapter describing the methods. The first section discusses reflexivity because this is an overarching issue that affects all phases of the research process.

5.1 Reflexivity

An open reflection of the researcher's abilities and the effects the researcher has on the research is a measure of validity (Malterud, 2001). Although such validity is most often reported in qualitative research, it can be a useful measure when considering the trustworthiness of all types of research. This is known as 'reflexivity', which refers to the researcher's background and position and the influence this has on the choice of subject for investigation, the angle of investigation, which methods are considered the most adequate, the decisions regarding analytical samples or interpretations of findings and the framing and communication of conclusions (Malterud, 2001; Creswell, 2014).

My preconceptions mainly originated from my work as a nurse in a surgical ward at a university hospital in which pain was a central aspect of patient care. During my clinical work, I interacted with several patients with pain, although most of them had acute pain commonly treated using pharmacological interventions. Before I began the research project, the HLC was an unfamiliar setting for me. To some degree, I was sceptical regarding whether the nonpharmacological intervention used during the trial could have an effect, and I was unsure whether people would agree to participate in the trial as a result. Although I had no previous experience with primary care interventions, my experiences from clinical practice could have been an asset during the research process, such as in understanding responses and findings. On the other hand, it has been argued that familiarity can potentially mask ambiguous issues that others outside the field might question (Roberts and Priest, 2006).

To enhance reflexivity, multiple researchers can be included, which can result in a broader understanding of the phenomenon due to different approaches to the same subject (Malterud, 2001). In addition to the PhD candidate, the research team for all studies included three supervisors. Two were associate professors in the nursing field, and one was a sociologist and a professor in behavioural sciences in medicine and health service research. For the qualitative study (Paper I), a PhD candidate holding a master's degree in clinical health science with experience in community based public health work took part in the analyses and writing of the paper.

For the quantitative studies (Papers II and III), a statistician was consulted during the planning of the analyses as well as during the analyses and the interpretation of the results. In addition, the research group on Patient Education and Participation at NTNU participated in discussions during several phases of the studies. The preliminary results of the studies were presented and discussed with employees at the HLC, during a research meeting with other PhD candidates focussed on HLCs and at a national conference including experts on self-management and learning and mastery interventions. These steps were taken to increase the understanding of the data and to strengthen the consistency and credibility of the results (Malterud, 2001), especially by including people with more experience in primary care interventions than the PhD-candidate.

5.2 Study designs

The study design of an RCT was chosen to investigate the effect of participating in the self-management course (Papers II and III). RCTs are recognised as suitable to investigate the effect of complex interventions because the design allows for controlling for unknown or unmeasured confounders (Craig *et al.*, 2008). The design of RCTs aims to minimise potential bias in any process at any stage and is recognised as having a high internal validity (Eccles *et al.*, 2003; Spieth *et al.*, 2016). The setting and the research objective led to the selection of an open pragmatic two-armed RCT, as this design was most likely to produce data that could be applicable to clinical practice. Following a computerised randomisation procedure, the participants were assigned to either the intervention or the control group for the entire trial period. There was no possibility of changing trial activity after allocation. The randomisation procedure ensured the validity of the study and minimised selection bias, as all participants had an equal probability to be assigned to either of the groups and no one could influence the random process.

The study design of individual face-to-face interviews was chosen for the qualitative study to explore expectations of participation in chronic pain self-management interventions at the HLC (Paper I). Individual research interviews were deemed suitable to obtain relevant data to answer the research objective. As described in the section on ethical considerations, people suffering from chronic pain can be vulnerable. This was an additional reason for choosing individual face-to-face interviews, as informants might feel more comfortable sharing sensitive and private information in individual interviews rather than in focus groups.

The sequence of the studies, with the data collection for the qualitative study being completed after the baseline measurement but before randomisation in the RCT, was established to avoid interference between the studies, such as reducing the influence on how participants in the qualitative study answered the questionnaires. If the qualitative study had been done separate from the RCT, it could have provided the opportunity to use the results of the qualitative study in the selection of the outcome measures included in the RCT.

5.3 Data collection

Following the Consolidated Standards of Reporting Trials (CONSORT) (Moher *et al.*, 2010), the measure considered to be of greatest importance to relevant stakeholders such as participants and service providers, was pre-specified as the primary outcome. The other outcomes of interest were included as secondary outcomes (Moher *et al.*, 2010).

Patient activation was considered a suitable primary outcome due to its key role in the management of health and healthcare (Hibbard *et al.*, 2004), its role in chronic illness models (Hibbard and Mahoney, 2010) and being a typical aim regarding self-management interventions (Greene and Hibbard, 2012). In previous studies, the psychometric properties of the PAM-13 in various populations and settings have been tested. Thus, considering the aim of the present self-management course and the overall aim of the activities at the HLC, PAM-13 was considered a well-suited primary outcome in the RCT.

According to a systematic review on the outcomes of chronic pain self-management interventions published in 2018, there is no gold standard regarding how to measure the outcomes of such interventions (Banerjee *et al.*, 2018). For most studies, different measures of self-efficacy scales have been applied as proxy measures of self-management with other measures applied for pain, physical function and psychological wellbeing (Banerjee *et al.*, 2018). For the current RCT, the primary outcome, patient activation, builds on the concept of self-efficacy (Hibbard and Gilburt, 2014) and the secondary outcomes were chosen to include the domains recommended for chronic pain interventions, such as pain, physical functioning, emotional functioning and coping (Dworkin *et al.*, 2005). As such, the outcomes selected for the RCT were considered appropriate. Nevertheless, the nature and the role of chronic pain self-management are considered poorly defined as well as poorly understood and researched (Nicholas and Blyth, 2016). Accordingly, although frequently used measures of self-management and chronic pain have been used for this RCT, there may be domains that are not included. For instance, during the qualitative study, it was found that hope and social support were central expectations (Paper I); however, measures of these domains were not included among the outcome measures.

The systematic review of the outcome of chronic pain self-management interventions also showed that little research has been conducted on chronic pain self-management measures' reliability, responsiveness and interpretability (Banerjee *et al.*, 2018). In addition, whether responsiveness represents a measurement property that is distinct from reliability and validity has been an issue of debate (Terwee *et al*. 2003; Puhan *et al.* 2005). To investigate the responsiveness of a measure in terms of the measure's ability to detect real change would preferably require a gold standard (Terwee *et al*. 2003). For many measures in the area of self-management for chronic pain, there are no established cut-off values for clinical significance (Banerjee *et al*. 2018), and there is no common understanding regarding how to interpret the results. Consequently, for some of the measures, there is a lack of knowledge of their responsiveness (Banerjee *et al*. 2018). A lack of responsiveness can lead to a false-negative result, in which a true effect of an intervention is not discovered (Higgins and Green, 2011). As the RCT showed no difference between the groups, a lack of instrument responsiveness could be the cause, though this is not considered a likely explanation.

Internal validity refers to whether the study answers the research question correctly and whether it is as free from bias as possible (Higgins and Green, 2011). Bias can operate in either direction and can lead to underestimation or overestimation of the true intervention effect. It is often impossible to determine the extent to which bias has affected the results of a study. Hence, it is necessary to consider the risks of bias (Higgins and Green, 2011). The participants, personnel and outcome assessors, except for the research assistant, were not blinded during the RCT, which indicates a risk of performance bias and detection bias. It may be that those participating in the intervention group responded favourably because they wanted the HLC to continue to offer the self-management course; however, it is difficult conclusively to determine whether the outcomes were influenced by this possibility. The PhD candidate facilitated most of the outcome assessments (not the 30-second Chair to Stand Test) but was not involved in the development nor the delivery of the interventions, which prevented close interactions between the researcher and the participants, potentially affecting the results.

Collection of data in the RCT was mainly done by the use of questionnaires (Paper II and III). All of the instruments were validated, which indicates that the instruments' validity and

reliability had previously been tested. Thus, the properties used to determine whether the instruments measured what they were intended to measure, including content-related, construct-related and criterion-related validity (Higgins and Green, 2011), were reported by the developers of the different questionnaires. For this RCT, the internal consistency (reliability) of the questionnaires was reported using the Cronbach's alpha (Papers II and III). Assessments of the outcomes followed the same procedure for both groups throughout the trial period, which was described in the published protocol (Nøst *et al.*, 2016). The only outcome not self-reported, the 30-second Chair to Stand Test was performed using the same chair and by giving the same instructions at each follow-up. This was done to keep the possibility of bias at a minimum and to keep the trial internally valid (Rothwell, 2005).

Regarding the qualitative study, a semi-structured interview guide was used for data collection (Paper I) to minimise limitations of the internal validity. The interview guide was used as supporting material to ensure that all aspects of the research question were covered in all the interviews; however, it is possible that not all relevant questions were asked. Nevertheless, the involvement of multiple researchers and the use of literature could be viewed as actions that minimised the potential bias.

The participants in the studies were informed of the researcher's employment as a PhD candidate at NTNU and that the researcher was not connected with the HLC except for the duration of the research project. The researcher's professional background as a nurse was not mentioned unless the participants specifically asked. The informants may have been more comfortable sharing their stories and completing the questionnaires because they knew the researcher would not be present at the actual intervention and that their responses would not have any consequences related to their participation in the interventions. It is possible that the informants in the qualitative study (Paper I) spoke more freely when they considered the researcher as independent from the HLC, but it could be that they would have discussed other topics (Paper I) or answered the questionnaires differently (Papers II and III) had the researcher's professional background been specified initially.

5.4 Analyses

In order to preserve the benefit of randomisation that allows strong inferences about cause and effect in a RCT, all randomised participants were included in the analysis retained in the group to which they were allocated (intention to treat analysis) (Moher *et al.*, 2010). Data were missing in both groups, of which reasons for these are both reported (Papers II and III) and found to be balanced across groups. Hence, important attrition bias due to missing data would not be expected (Higgins and Green, 2011). Furthermore, the analyses of the RCT were done using linear mixed models (Papers II and III). This approach uses all available data and is less sensitive to missing values and for attrition bias (Rabe-Hesketh and Skrondal, 2012). Although no pattern for missing values was detected, the assumptions of missing values completely at random or at random, of which a linear mixed model relies on, could be violated due to missing values at follow-up. All analyses, both for within and between groups' differences, were reported with p-values and confidence intervals (CI) to minimise reporting bias during the RCT (Moher *et al.*, 2010).

There were dropouts during the RCT, and thus the number of persons with follow-up data after 12 months was below the calculated sample size. The power of the study was therefore lower than expected; however, Wood et al. (2014) have argued that an argument of that near significant p-values will become significant when additional data are provided, can lead to a misleading impression and can undermine the principle of accurate reporting. Based on their argument, further discussion of whether the observed differences between the groups could have become statistically significant without dropouts or with more participants included, does not seem appropriate.

Missing values were handled according to the instructions of each of the questionnaires, such as the instructions for the PAM-13, which state that the respondent must answer 10 of 13 items for a valid score (Insignia Health, 2015). Otherwise, inaccuracy and bias could be introduced in the results (Linden, 2015). Therefore, the evaluation of the effect of the intervention on patient activation was limited to only those with valid scores. This was also done for the other questionnaires. Because analyses based on available data tend to be unbiased, although based on a smaller sample size than originally intended (Higgins and

Green, 2011), the selected analytical approach of using mixed models, which include use of all available data, was considered beneficial (Rabe-Hesketh and Skrondal, 2012).

Post-hoc subgroup analyses are often published because unexpected results can lead to new hypotheses which might have important clinical consequences (Dijkman, Kooistra and Bhandari, 2009), although a subgroup analysis can lead to overstated and misleading results (Wang *et al.*, 2007) and can introduce possible bias by confounding other patient characteristics (Higgins and Green, 2011). This is especially the case if conclusions regarding the effect of an intervention are based on the findings of a post-hoc subgroup analysis. Nevertheless, this type of analysis can provide useful information that is valuable for future research.

For Paper III, an exploratory post hoc subgroup analysis was conducted because a discussion arose regarding whether the baseline patient activation level could have an interaction effect with allocation. Furthermore, other studies have shown differences in the effects of interventions between participants at different patient activation levels at the baseline (e.g., Solomon, Wagner and Goes, 2012; Greene *et al.*, 2015; Hibbard *et al.*, 2015; Moljord *et al.*, 2017). To optimise the post-hoc subgroup analysis for this study, all participants yielding data related to changes in PAM-13 scores from the baseline to 12 months were included in the analysis, and the baseline characteristics defining the subgroups were based on pre-randomisation patient characteristics. As only one post-hoc analysis was performed, it was not necessary to adjust for multiplicity; however, the power calculations did not account for the between subgroup treatment effects, and randomisation was not stratified for patient activation levels. Because the analysis of the interactions was also statistically insignificant, extra caution is required when considering the implication of the observed changes of each subgroup.

Complex phenomena have a high risk of measurement errors, especially those based on self-reporting. A random error may be defined as variability in the data that cannot be explained easily and that is reflected in the CI based on the effect estimates (Higgins and Green, 2011). A broad CI indicates high variability (low precision or imprecision), and a narrow CI

indicates low variability (high precision). For many of the outcomes measured in the present RCT, the CIs were broad, and hence attached with low precision. For instance, the CI for the primary outcome, PAM reported in Paper III (CI -0.6 to 8.6), might be interpreted to that the intervention at best can be clinically relevant and at worst to represent little risk. We might on the other hand have perceived it differently had the intervention for instance been regarded to represent a major risk for the participants.

Malterud (2001) underscored that a thorough, well-prepared and well-documented analysis is what distinguishes a scientific approach from a superficial assumption. For the analysis of the qualitative data, STC was the method selected (Paper I). STC is a structured and well-described step-by-step method for the analysis of qualitative data, which is suitable for presenting experiences as expressed by the informants rather than exploring possible and underlying meanings of their statements. This is a method suitable for a thematic analysis of meaning and content across cases (Malterud, 2012). The method was therefore found to be well suited for analysis of the data in the qualitative study (Paper 1). A structured process and engagement from multiple viewpoints and perspectives of others, as initially described related to reflexivity, were included to limit the reduction in the study's internal validity.

5.5 Participants, external validity and transferability

Whereas RCTs are considered to have a high internal validity, their external validity is less precise (Rothwell, 2005). One reason is that only a small proportion of participants with a specific condition participate in a particular trial, which affects the extent to which the results can be generalised into clinical practice and to the general population (Rothwell, 2005). As such, external validity is closely related to the relevance or applicability of the findings (Higgins and Green, 2011). Within qualitative research, transferability is often used to determine validity related to who and what the findings concern (Malterud, 2001).

The issues that potentially affected external validity include the selection and characteristics of the participants (Papers I, II and III). The sample consisted of people who wanted to participate in a trial, which separates them from the global population. It is therefore likely that expectations of people who did not want to participate in the trial were excluded (Paper

I). The criteria for participation were broad and reflected in such the admission practice of the HLC. The criterion related to chronic pain was set according to the IASP definition of pain as lasting for three months or more, similar to other studies (Carnes *et al.*, 2013; Mehlsen *et al.*, 2017; Steingrimsdottir *et al.*, 2017). The risk of reduced external validity due to strict eligibility criteria was therefore limited; however, this does not eliminate issues that may have affected external validity.

In the sample, there were more women than there were men (more than eight out of ten). Previous population-based and epidemiological studies have indicated that more women than men report chronic pain (Rustøen *et al.*, 2004a; Tsang *et al.*, 2008; Landmark *et al.*, 2011), though not in the same proportion as in the current sample. A possible explanation for few men within the sample may be that according to Galdas et al. (2014), men find self-management support more appealing when it is perceived as action-oriented with a clear purpose offering personally meaningful information and practical strategies to integrate into daily life. It is possible that the announcement of the intervention did not reflect this and that men did not respond for this reason. Nonetheless, other self-management studies related to chronic pain have also reported samples with a majority of women (72 % women, (Mehlsen *et al.*, 2017), 64 % women (Turner *et al.*, 2015), 70 % (Kennedy *et al.*, 2007)).

A majority of the participants received disability benefits (two thirds), such as disability pensions and sickness benefits. This could be because chronic pain is a major cause of loss of workdays and has a substantial influence on participation in work life (Breivik *et al.*, 2006; Pike, Hearn and Williams, 2016). Landmark et al. (2013) found that one third of those who reported chronic pain received disability pensions, which was almost four times higher than those who did not report chronic pain. Nevertheless, the high proportion of the current sample who received disability benefits could have occurred because the interventions were delivered during the day. Thus, the sample may have included a larger proportion of people who did not work than the general population of people with chronic pain. If the intervention had been delivered after working hours, more people who were employed may have attended.

Regarding the qualitative study (Paper I), the transferability of the findings is affected by an adequate and sufficiently diverse sample (Malterud, 2001). The intention was to recruit a sample of informants who best represented or had knowledge related to the research question by recruiting participants with different durations of pain, from different age groups and from both genders. To achieve this, a combination of consecutive and purposeful sampling was used. As the self-management course at the time was only delivered in conjunction with the project, it was natural and practical to recruit participants from those already included in the RCT; thus, the informants represented people who actively volunteered to participate in the RCT. According to Malterud, Siersma and Guassora (2015), aim, specificity, theory, dialogue and analysis are items that can be used to systematically reflect upon regarding the number of included informants in qualitative studies. These items were considered during the recruiting process, and the inclusion of new informants concluded after 21 interviews. The sample then included a broad range of expectations regarding participating in the interventions.

6 Discussions of the main findings

The main results of this thesis are related to the expectations of and the effects on persons with chronic pain who participated in easily accessible self-management interventions at a Healthy Life Centre (HLC) in Norwegian public primary health care. Based on the presentation of a chronic pain self-management course and a low-impact physical activity, it was found that persons with chronic pain had expectations related to a hope that participation could lead to a better quality of everyday life. More specifically, the expectations were based on the interventions being something new and untried, an opportunity to gain and reinforce skills, help them to continue to grow as a person, to meet others in similar situations and to access professional support in an easy manner. No statistically significant effects after three or 12 months were found for the primary outcome, patient activation, or for any of the secondary outcomes of the group-based chronic pain self-management course compared to the control group activity. Within both groups, there were statistically significant improvements in pain experienced in the previous week, the global self-rated health measure and the 30-second Chair to Stand Test from baseline to the final follow-up after 12 months.

Discussions of the specific findings in each of the studies are provided in their associated papers. Hence, the following paragraphs discuss the overall findings of the three papers.

6.1 Easily accessible health care services

It was found that easy access to the self-management support was appreciated (Paper I). Accessing support both from health professionals and from peers was considered valuable when managing chronic pain. The informants' appreciation of easy access was similar to findings of other studies in which access to self-management support have been discussed (Jerant, von Friederichs-Fitzwater and Moore, 2005; Lalonde *et al.*, 2015). This may indicate a need among people with chronic pain to easily access support from health professionals. In Paper I, the informants told that they considered participation in interventions an act of self-care that allowed them actively to manage their health; however, they also stated that obtaining access to support from health professionals was sometimes difficult. This may be viewed as utilising self-management skills to locate resources from a variety of sources and to use these resources (Lorig and Holman, 2003). Accordingly, as described in a study by Boger et al. (2015), self-management also includes the tasks people perform to navigate health

services. Other studies on interventions delivered by primary care have emphasised that health care services should support health care management and that barriers to self-management should be prevented (Lalonde *et al.*, 2015; Stanos *et al.*, 2016). It has been argued that a key function of health care services is to provide self-management support interventions (Newman, Steed and Mulligan, 2004; Boger *et al.*, 2015). Notably, it could be equally important to ensure that people have the opportunity to access these interventions.

Access to group-based interventions is valuable because it represents an opportunity to meet others in similar situations and to socialise (Paper I). The latter was emphasised by informants who indicated they missed being part of a community, such as within a work place (Paper I), which is in line with the finding that loneliness and outsiderness are consequences of chronic pain (Reid *et al.*, 2011). The social needs the participants discussed surpassed peer support alone, which is a well-known benefit of participating in such interventions (Stenberg *et al.*, 2016). Social needs also included aspects of support and networking. Thus, access to support from services and health care personnel or lay participants only comprise some needs that must be addressed. Initiatives that include involving communities and voluntary organisations could be a solution, which would encourage positive social and environmental influences on people's health as put forward by WHO initiatives on health promotion and primary health care (WHO 1978; WHO 1986). A community-based health care service such as the HLC, which aims to be easily accessible and at the same time cooperates with voluntary organisations, seems to be well suited to addressing the social needs among people with chronic pain. The HLCs should not necessarily facilitate these social arenas, but they can play an important role by cooperating with other organisations in the communities.

The policy of the HLC to be an easily accessible health service that accepts self-referrals may offer a benefit that other health care services do not necessarily offer. Primary health care incorporates some of the key principles of public health, such as equity and concerns for social, economic and environmental determinants of health (Neuwelt *et al.*, 2009). Furthermore, primary care has been recognised as an optimal context to deliver care for people with long-term conditions because it is accessible and efficient and can address inequalities related to socioeconomic deprivation (Kennedy *et al.*, 2013). The self-referral option for interventions could be one way to ensure that all inhabitants have equal access to

services, highlighting the importance of easy access in a broader context. Moreover, a qualitative study on stakeholders' expectations of HLCs reported that general practitioners supported self-referrals to HLCs' interventions and that the staff of HLCs found that those who self-referred discontinued services less often compared to those who were referred by others (Abildsnes *et al.*, 2016). In the study by Abildsnes et al. (2016) the views of HLC users were not included; however, a recent study on patients with chronic obstructive pulmonary disease showed that the availability of health care professionals is important to self-management, hope and well-being and that a perception that health professionals were not available led to hopelessness (Andersen *et al.*, 2018). Although the study by Andersen et al. (2018) focussed on a chronic illness other than chronic pain, in light of the current results, the impact of health care availability on hope should be considered when designing chronic pain interventions.

Interestingly, it was found that participants in the Expert Patient Programmes in the UK were more affluent and educated than the broader population of patients with long-term conditions (Kennedy *et al.,* 2013). Notably, if the same people participate in interventions both with and without the premise of a referral, then people who do not necessarily possess the knowledge or skills to navigate health care could be excluded. This may indicate that easy access is insufficient as an instrument alone when attempting to reach those with low confidence in their ability to self-manage.

6.2 Self-management interventions at the HLC

The development of the chronic pain self-management course at an easily accessible service in public primary care may be seen as a response to the warranted transfer of interventions from specialist care to primary care (The Norwegian Ministry of Health, 2009). Self-management interventions delivered in primary care are pointed to as essential to meet the increasing population of people living with chronic conditions, such as chronic pain (Lalonde *et al.,* 2015). Furthermore, self-management interventions are recommended to be community-based and delivered close to where people live so that a large number of people can access them (Lorig and Holman, 2003). The HLC's chronic pain self-management course was a new locally developed intervention offered to people with chronic pain. This is also the first RCT to investigate the effect of a self-management course delivered in a HLC setting

(Papers II and III). It has been stated that HLCs should offer effective and evidence-based interventions but that their present guidelines provide sparse guidance regarding how to develop evidence-based programmes in an HLC setting (Abildsnes *et al.,* 2016), which indicates a lack of knowledge of HLC-developed interventions overall. Hence, in the next paragraphs, the content, available competence, practical issues, such as delivery and duration of the course, and acceptance in terms of participants' attendance for the self-management initiative are discussed.

The content of the self-management course included education introducing cognitive and behavioural strategies for pain management, facilitated group discussions and movement exercises to improve body awareness and give relaxation. The content of the course included an introduction to central self-management tasks, such as dealing with the emotional consequences of chronic pain and self-management skills, like problem solving and goal setting (Lorig and Holman, 2003). The course was developed locally at the HLC. Nevertheless, its content was similar to intervention content that follows the Stanford self-management programmes (Self-Management Resource Center n.d.). Moreover, the course also discussed the way chronic pain affects everyday activities and was thus in line with the descriptions by Schulman-Green et al. (2012) on self-management tasks, skills and the self-management processes, which interventions should address. The content was as such similar to the interventions described in the works of Mehlsen et al. (2017), Turner et al. (2015) as well as in the Expert Patient Programme-interventions investigated by Kennedy et al. (2007).

One central self-management skill required to manage the impact of chronic pain involves using the mind to manage pain (Eccleston, Morley and Williams, 2013). Consequently, the use of elements from cognitive behavioural therapy (CBT) has been found to be a useful approach for chronic pain self-management interventions (Turk, Wilson and Cahana, 2011; Williams, Eccleston and Morley, 2012). In the current intervention, the educational component focussed on thoughts, emotions and actions related to pain. The qualitative study provided knowledge about that the participants hoped the course would improve their ability to manage pain using the mind, as they stated that they had little knowledge of cognitive techniques for pain management (Paper I). The presentation of cognitive and behavioural strategies for pain management in the course thus seemed appropriate.

The guidelines for the HLCs state that CBT is an approach and a tool the staff are encouraged to use when working with behavioural changes and supporting self-management of a chronic illness (The Norwegian Directorate of Health, 2016). Thus, it is likely that the staff involved in the intervention had at least the basic skills and tools to deliver a CBT-based intervention. As such, this is in contrast to concerns regarding a lack of the competence and skills necessary to deliver such interventions among professionals in primary care as described in other studies (Solberg *et al.*, 2014; Lalonde *et al.*, 2015; Stanos *et al.*, 2016).

Furthermore, the importance of competence in facilitating group processes was emphasised by Solberg et al. (2014) as especially important for group-based interventions. This has also been emphasised by others in which taking measures to ensure group processes are of high quality and effective have been described as important to maximise patient satisfaction and self-management behaviour changes (Harrison *et al.*, 2011) and to be important for the participants' motivation to participate (Andersen *et al.*, 2014). Facilitating group processes is a common required competence in HLCs because most programmes are group-based. Hence, the instructors involved in the self-management course were experienced in facilitating group processes for both behavioural changes and pain management. Nevertheless, the fact that lack of skills and confidence among professionals regarding self-management support interventions may act as barriers for achieving the potential of primary care as a platform of such interventions (Kennedy *et al.*, 2013) should be reflected upon when planning and delivering easily accessible chronic pain self-management interventions.

The delivery of the course by HLC staff was in contrast to interventions delivered according to the CPSMP and in the Expert Patient Programme, for which the interventions are lay-led (Kennedy *et al.*, 2007; Lorig, 2014). According to the review by Carnes et al. (2012), the delivery of self-management interventions by health care personnel is beneficial, which means that the HLC course is in line with some valid recommendations. However, a recent review on patient education aimed to promote self-management stated that lay participants should be included in the delivery of self-management courses for several reasons, such as to make the information easier to understand (Stenberg *et al.*, 2016). It has though been argued that lay-led interventions have limited effectiveness for persons with disabling and complex pain problems (Nicholas and Blyth, 2016). The broad inclusion criteria in the current study

did not specify the type of pain or how much pain the participants experienced. Hence, the instructors managed variations in both the complexity of pain and the degree of disability the participants experienced. Therefore, it seemed appropriate that health professionals led the self-management course. Nevertheless, including a layperson's perspective to a greater degree could have contributed important perspectives to the self-management course.

The duration of the self-management course, and consequently the low-impact outdoor physical activity offered the control group, was six weeks. This is similar to the duration of the Chronic Pain Self-Management Program (CPSMP) (Self-Management Resource Center n.d.) and Expert Patient Programme-interventions (Kennedy, Rogers and Bower, 2007). It is also in line with the recommendations of Carnes et al. (2012) that interventions that last less than eight weeks are preferable. Although there is a variety of durations for chronic pain self-management interventions, similar to the one investigated in the RCT (Papers II and III), most interventions have a comparable duration of the intervention as a whole (Kennedy *et al.*, 2007; Nicholas *et al.*, 2013; Turner *et al.*, 2015; Taylor *et al.*, 2016; Mehlsen *et al.*, 2017).

The overall attendance of the self-management course was more than 67% and as high as 75% of participants attended half or more of the sessions. This is taken to mean that the intervention seemed feasible from the participants' perspectives; however, as discussed in Paper III, attendance is a poor proxy measure for adherence (Nicholas and Blyth, 2016). As there are no other studies on self-management interventions delivered in this setting, there are no data available for comparison; however, in the study by Abildsnes et al. (2016), an interesting point was made regarding attendance and dropout rates. It was argued that success based on low dropout numbers and few people requiring treatment would favour those who have the easiest access to the services, which would exclude socially and mentally deprived groups even though the potential benefits might be the highest for these groups. Still, few studies have been able to provide evidence regarding who would most likely benefit from self-management interventions. Miles et al. (2011) found that self-efficacy and depression might predict outcomes of interventions that promote self-management of musculoskeletal pain but found no evidence to suggest that interventions should be targeted to specific groups. In contrast, Expert Patient Programme self-management courses have been found to possibly have a protective effect on health-related quality of life for persons with poor health and low

confidence (Reeves *et al.*, 2008). Consequently, it seems that additional efforts could be invested on reaching those with low self-management confidence. It can be suggested that the HLC discuss the target group for their chronic pain self-management intervention. This is an important question to clarify, as the HLC is a service still in the development phase (Abildsnes *et al.,* 2016).

6.3 Effects of the investigated interventions

There were no short-term differences after three months of the self-management course compared to the low-impact outdoor physical activity offered the control group (Paper II). Some studies have shown a short-term effect of interventions similar to the one in the RCT (LeFort *et al.*, 1998; Kennedy *et al.*, 2007; Nicholas *et al.*, 2013), whereas others have concluded there was no short-term effect (Ersek *et al.*, 2008; Taylor *et al.*, 2016; Mehlsen *et al.*, 2017). Thus, evidence of short-term effects due to chronic pain self-management courses is conflicting.

As reported in Paper III, there were no statistically significant long-term effects after 12 months for the self-management course on the primary or the secondary outcomes compared to the low-impact physical activity. Some studies have indicated that self-management interventions may have a long-term effect. For instance, multidisciplinary biopsychosocial rehabilitation for chronic low back pain has led to a small long-term improvement in pain and disabilities (Kamper *et al.*, 2015), and self-management education programmes for osteoarthritis have resulted in small benefits up to 21 months (Kroon *et al.*, 2014). Notably, a review on chronic musculoskeletal pain showed minor or statistically insignificant differences after eight months of group-delivered self-management courses (Carnes *et al.*, 2012). Thus, there is some evidence of minor long-term benefits of chronic pain self-management interventions.

The lack of effect in the current studies indicates that the self-management course delivered in the studied HLC setting does not lead to notable changes for the participants (Papers II and III). Nonetheless, an interesting development was observed in patient activation from three months (Paper II) to 12 months (Paper III). Whereas the two groups had similar developments

in patient activation from the baseline to three months, the developments differed at the six-month follow-up when the intervention group had a greater improvement than the control group (as illustrated in Figure 5). Even if not statistically significant, the observed mean values for the patient activation score for the intervention group was maintained at 12 months, whereas the control group had returned to the baseline score. In general, the maintenance of a high patient activation score may be viewed as a positive effect (Hibbard *et al.*, 2007), and furthermore, patient activation has been found to slightly decrease over time due to the deterioration many people with chronic illnesses experience over time (Rijken *et al.*, 2014).

The explorative post-hoc sub-group analysis reported in Paper III was performed to investigate which groups of participants the course could be best suited for, and subgroups were categorised according to the participants' patient activation levels at the baseline. The test for interaction between allocations and patient activation levels at the baseline was not statistically significant. The observed mean values for the PAM scores improved for both groups from the baseline to 12 months for those at the two lowest activation levels. Those at the highest patient activation level showed a decrease in the PAM-13 score; however, there was a larger decrease for the control group than for the intervention group. Since the interaction effect was not significant, these observations can only provide intriguing considerations.

The obvious question is whether such courses can be better suited for those at the lowest levels of patient activation. According to the developers of the PAM, those at the early stages of activation require interventions designed to increase knowledge regarding their conditions and treatments, while those in later stages require interventions designed to increase their skills and confidence regarding the various self-management tasks (Hibbard *et al.,* 2004). Although the aim of the self-management course was to cover a broad range of knowledge and skills related to chronic pain self-management, the course may have focussed more on basic knowledge related to chronic pain than self-management skills and confidence, which are required at a more advanced level.

Before beginning the trial interventions, the participants expressed a hope that their everyday lives would improve (Paper I). This hope was central to the way they approached new treatments, which is in line with the findings of Eaves, Nichter and Ritenbaugh (2016) that hope is often present when new treatment options are assessed. Meeting participants' expectations including hope has been found to be a significant factor in increasing patient satisfaction (Geurts *et al.*, 2016). There are also studies reporting that participants felt more hopeful about their future after participating in self-management interventions, mainly for interventions that addressed mental illness (Stenberg *et al.*, 2016). Furthermore, a recent study on patients suffering irritable bowel syndrome showed that improved self-management was perceived to be helpful in breaking the cycle of alternating hope and despair (Harvey *et al.*, 2018). In another study on patients who had undergone elective cardiac surgery, hope was found to be a predictor of goal achievement related to self-management behaviour (Bjornnes *et al.*, 2018). Although these studies examined different populations and interventions than in this project, the connection between hope and self-management could be relevant when investigating the effects of the interventions investigated in this thesis.

The significance of social support found in Paper I has been reported also in other studies, mostly in studies that focussed on mental illness (Stenberg *et al.*, 2016). A study on CDSMPs in a region in Canada showed that after one year, the participants indicated that the intervention changed the way they interacted with friends and family and the way they received self-management support from those around them. Moreover, several participants noted a decrease or elimination of a sense of isolation by establishing common ground with others (Johnston *et al.*, 2012). Outcome measures to assess social support should also be considered when investigating the outcomes of interventions like the HLC's chronic pain self-management course.

7 Conclusion

The hope to improve their everyday lives was described by persons with chronic pain to be an influential factor in choosing to engage in new interventions and healthcare services. The chronic pain self-management interventions delivered in a primary care setting were perceived as an opportunity to easily access peer and professional support. Based on the presentation of the content, the participants described expectations of participation in the chronic pain self-management interventions as being related to a hope that participation could lead to a better everyday life. Hope was found to be important for the motivation to self-manage chronic pain, which implies that service providers should be aware of and support patients' hope to improve quality of life.

The randomised controlled trial conducted for this thesis showed no statistically significant effects of the self-management course after three or 12 months for any of the chosen outcomes when compared to a group based low-impact physical outdoor activity.

8 Implications for practice

The findings in this thesis and prior research imply that people with chronic pain want to participate in interventions as part of self-care. Providing easily accessible interventions to support self-management should thus be regarded as an important health care task (Boger *et al.*, 2015; Lalonde *et al.*, 2015). This is especially important due to the current public health challenges regarding the increasing amount of the people living with long-term and non-communicable diseases, including chronic pain, and social inequalities in health care (Irvine *et al.*, 2006; Goldberg and McGee, 2011). To manage what is expected to become an increased demand for health care services in the future, interventions to support and enable people to self-manage their health to the greatest extent possible should be prioritised. An implication for clinical practice is that there should be self-management support interventions that are easily accessible for the targeted population, and based on this thesis, it may be suggested that the HLCs can be a suitable arena. However, caution should be taken when selecting the type of intervention to be offered to ensure that it has an effect in the targeted population.

The importance of social support as part of self-management should encourage health care providers to pay special attention to this aspect when developing interventions targeting people with chronic pain. By incorporating the collaboration HLCs have with voluntary organisations and other community-based services into activities, HLCs can contribute to establishing social networks near participants who expressed this need. Primary health care services are often located near residences and are therefore convenient for people to access (Ringard *et al.*, 2013). The HLCs in Norway are still in the development phase (Abildsnes *et al.*, 2016), which provides them with a unique opportunity to adapt their interventions to their target groups.

9 Implications for research

This is the first RCT to investigate the effect of a chronic pain self-management intervention delivered in an HLC setting. Several steps could be taken to further this research. For instance, several observations of this study make it worthwhile to investigate in qualitative studies participants' experiences related to the interventions and their impacts on chronic pain self-management. Hence, participants experiences with the course and their perceptions regarding whether it affected their lives or what could have been emphasised to bring about change should be explored. This could provide insights into whether there were components of the course that were considered useful or destructive, and whether there were any missing topics. The insights can be valuable when designing chronic pain self-management support interventions in general, and may be of specific value for HLCs that are in the process of establishing self-management activities as part of their services.

Chronic pain is a long-term condition with fluctuating symptoms. It is therefore reasonable to assume that a need for self-management support will occur several times during the trajectory of an illness. Interventions should be sustainable and cost-effective, which makes it necessary to establish interventions that are effective over time. An effect of the self-management course may not have been identified because the two trial activities were too similar. By including a treatment as usual group, the effects of the interventions described in this thesis could be investigated further and over time. The thesis provides knowledge on the importance of hope and social support. Future research should consider including outcome measures to assess these domains in addition to other measures that have been acknowledged essential to interventions that address chronic pain.

The criteria for participation in the interventions were broad to reflect the practices of the HLC. Future research should focus on whether participants' characteristics influence the effects produced by the self-management course. More specifically, further investigations regarding whether this type of intervention is more suited for certain groups, is encouraged.

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Paper I

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RESEARCH ARTICLE Open Access

Expectations towards participation in easily accessible pain management interventions: a qualitative study

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Abstract

Background: People with chronic pain use a range of healthcare services, but they also report a high degree of dissatisfaction with treatments. One reason for dissatisfaction might be participants' expectations towards treatments. The aim of this study was to explore expectations of people with chronic pain towards participation in easily accessible pain management interventions delivered in public primary care.

Methods: A qualitative study using semi-structured individual face-to-face interviews with 21 informants. The informants were recruited among participants enrolled in a randomised controlled trial on the effect of an easily accessible self-management course for people with chronic pain. The data were analysed thematically using Systematic Text Condensation.

Results: Having experienced pain for a long time, there was no specific expectation of a cure or a significant alleviation of the pain. The informants' expectations mainly concerned a hope that participation could lead to a better everyday life. The informants said that hope was important as it motivated them to keep going and continue self-care activities. The hope acted as a driving force towards trying new interventions and maintaining motivation to do activities they experienced as beneficial. Both concrete aspects of the current intervention and an understanding of what interventions in general could offer contributed to the informants hope. The expectations centred about the interventions being something new, as they had not previously tried this service, an opportunity to gain and reinforce skills, to help them continue to grow as a person, to meet others in similar situations, and to access professional support in an easy manner. Participating in interventions provided by healthcare services was seen by some as an act of self-care, where they did something active to manage their health.

Conclusions: Expectations towards the interventions were related to a hope for participation leading to a better everyday life. The role of hope for peoples' motivation to self-care implies that service providers should be aware of and help to maintain hope for a better everyday life. The importance of social support as part of self-care should be acknowledged when developing interventions targeting chronic pain.

Trial registration: ClinicalTrials.gov: NCT02531282. Registered on August 21 2015.

Keywords: Chronic pain, Self-care, Expectation, Health services accessibility, Primary health care, Qualitative research

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Background

Chronic non-malignant pain is a long-term condition estimated to affect approximately 19% of the adult European population [1]. Chronic pain is different from acute pain as it persists when treatment stops [2]. The long-term aspect of chronic pain challenges society with socioeconomic consequences such as early retirement, disability pensions, increased sick leave and healthcare utilization [3–5]. For individuals, its impact has been investigated in several studies, providing insight into physical, social and psychological consequences such as poor quality of life [4, 6], sleep disturbances [1, 5], exhaustion [5, 7], mood disturbances [8, 9], and interference with recreational activities and family responsibilities [4, 10].

Self-care is highlighted as important when managing long-term conditions [11], covering the actions people take to engage in behaviours that improve their health and wellbeing [12, 13]. Among people with chronic pain, typical self-care activities comprise physical activity and exercise [14, 15], alternating between strenuous and less strenuous activities [7, 16], and continuing everyday activities to bring structure and meaning to life [16]. Other self-care activities are aimed at distraction from pain by, for instance, listening to music [17], using heat to relieve the pain [7], and replacing thoughts leading to anxiety with more rational thoughts [18, 19].

The fact that total recovery often is not within reach [10, 20] makes coping with chronic pain a highly demanding and continuously ongoing task [20, 21]. There are a range of different interventions offered to and used by people with chronic pain [22], e.g., medication, surgery and nerve blocks, exercise and physical rehabilitation, psychological treatments, and complementary and alternative treatments. Thus, how people with chronic pain manage healthcare as part of their pain management is a central self-care activity. However, the effects of pain treatments are mostly reported as small to modest [22–24]. In addition, a high degree of dissatisfaction with pain treatments has been described [4, 25, 26].

Peoples' expectations towards treatment are suggested as a possible reason for the dissatisfaction [22], indicating that expectations are important when considering how different types of interventions are experienced. Furthermore, a mismatch between patients' needs and the delivery systems have been found [27], emphasizing the importance of knowing the participants' expectations and aligning these with what the services offer. Expectations have been described as something one could expect or predict to happen, and also as normative or ideal expectations such as aspirations, hopes and desires [28, 29]. Thus, when people with chronic pain seek new treatment options, they are likely to have a range of expectations based on previous experiences with healthcare services [30]. Studies on patients' expectations towards multidisciplinary treatments for pain found that participants expected to take an active part in the programmes and to learn adequate coping strategies to improve their daily life [13, 30]. Other studies on multidisciplinary and comprehensive interventions for chronic pain found that the participants expected to learn about diagnostics, pain causes, and to receive instructions and advice regarding their specific pain management [31, 32].

However, to the best of our knowledge, there is no publication on what people with chronic pain expect from participation in easily accessible pain management interventions. Thus, the aim of this study was to explore the expectations of people with chronic pain towards participation in easily accessible pain management interventions. The study was embedded in a randomised controlled trial (RCT) investigating the effect of an easily accessible self-management course for chronic pain in public primary care.

Methods

This was a qualitative study with semi-structured individual face-to-face interviews. The interviews were conducted from September 2015 to April 2016.

Setting

The study was embedded within a RCT investigating the effect of an easily accessible self-management course in public primary care for people with chronic pain. The protocol for the larger trial with a description of the intervention has been published previously [33]. In the RCT, participants were randomised to a chronic pain self-management course (intervention) or to a drop-in outdoor physical activity (control) [33]. Both activities were delivered at a Healthy Life Centre (HLC) in a city with approximately 190,000 inhabitants in Central Norway.

The HLC is a public service offered by Norwegian municipalities as part of their public healthcare service. The HLCs offer interventions with few barriers for participation and people can attend both with and without referrals from health professionals [34]. The HLCs deliver several group-based activities to support people in health behavioural changes and to manage chronic conditions, ranging from physical activity and exercise groups to smoke cessation programmes and coping with anhedonia courses. While participation in most interventions at the HLC is covered by Norway's public health insurance, some have a small user fee of about USD 36/ EUR 34 for one course. The current HLC initiated the pain self-management course in line with non-disease-specific self-management interventions being transferred from hospitals to primary care. As such, the course aimed to be a supplement to follow-up pain sufferers receive from e.g., general practitioners, physiotherapy delivered in both public primary healthcare and

private, and referrals to specialist care such as organ or disease-specific specialists and multidisciplinary pain clinics located at hospitals.

Participants were recruited to the RCT from general practitioners, physiotherapists, from advertisements in newspapers, websites, social media, and by email invitations to patient organisations. They were informed that the activities would be delivered in groups at daytime for a period of 6 weeks [33]. The participants received information in an information leaflet, in the informed consent and orally when they met for the baseline assessment. There was no user fee in the trial.

Informants and recruitment

The inclusion criteria for the qualitative study was the same as for the RCT; adults of 18 years or older, self-reported pain for 3 months or more, and able to participate in group-discussions in Norwegian. Exclusion criteria comprised not being able to participate in easy physical activity for 1 hour (as in the activity offered the control group), pain arising from malignant diseases, and not having the capacity to consent and participate.

Informants to the qualitative study were recruited by inviting some of the participants enrolled in the RCT. The selection was mainly done by consecutively asking participants if they were able to meet for baseline assessment at specific time points, which was scheduled with extra time for the interviews, i.e., that they wanted to participate and had the time to be interviewed. By asking consecutively, we expected to get sufficient variation among the informants. All but one of those asked (did not have time for the interview), accepted and agreed to take part in the qualitative study.

Recruitment continued until 21 participants had been interviewed. At this point, we considered to have sufficient data to explore the research question in depth.

Data collection and interview guide

The first author conducted all interviews, either at the Healthy Life Centre or in a meeting room at the research centre where the first author was located. The interviews were carried out before randomisation, i.e., before anyone knew whether they were allocated to the intervention or to the control group. Baseline questionnaires and tests of the RCT were completed before interviews to reduce the risk of reporting bias due to the interviews. The interviews lasted between 23 and 72 min (mean duration 43 min). Additional notes and reflections were written down immediately after each interview. To check if the interview guide needed alterations, the first and last author read the transcripts from the first three interviews. Minor changes were made in the sequence of questions but no new topics were added. No repeating interviews were conducted. The questionnaires completed at baseline for the RCT provided demographic data on the informants.

The interview guide was semi-structured with open-ended questions to allow the informants to speak freely. The topics were derived from the research question, literature, and the research group's experience. The main interview question was: "*Can you tell about your expectations towards participation in the interventions*?" Follow-up questions were: "*Can you tell how you experience pain in your everyday life?*", "*Can you tell about the activities you do to live as well as possible?*", and finally, "*Can you tell about the healthcare services you have attended previously?*". The interview proceeded as a conversation with the goal of exploring different aspects of the informants' expectations towards what participation in the interventions could lead to.

Data analysis

The interviews were audio recorded and transcribed verbatim. The data were analysed using Systematic Text Condensation (STC), a descriptive thematic cross-case analysis strategy based on a phenomenological approach [35]. STC was chosen as it is a structured and well described step-by-step method for analysis of qualitative data shown to be suited for presenting experiences as expressed by the informants rather than exploring possible and underlying meaning of their sayings [35].

The analysis followed the iterative four-step procedure of STC [35]. In the first step, the first author read all transcripts. The other authors read the same three transcripts chosen by the first author to be the ones with the most richness of data, to gain an overall impression of the data and to identify preliminary themes. These were discussed, resulting in seven preliminary themes associated with the informants' previous experiences and current expectations. In the second step, the first author systematically reviewed the transcripts line by line to identify meaning units representing all parts of the interviews relevant for the research question. The meaning units were coded, classified and sorted into code groups related to the preliminary themes. These were discussed repeatedly in the author group and thereafter the preliminary themes were adjusted. In the third step, the first author performed a systematic abstraction of meaning units within each of the themes, reducing the content into a condensate that maintained the informants' sayings. All authors read the condensates before another round of iterative discussions, resulting in several adjustments and renaming of the themes. In the final step, the content of the condensates was synthesised into generalised descriptions and concepts, while ensuring that the result still reflected the original context.

The first author identified illustrative citations which were discussed in the author group to choose the ones

most illustrative. The citations were translated by the first author and validated by the co-authors. A person fluent in both Norwegian and English did a back translation from English to Norwegian to verify that the content was present in the translated citations. The citations used to support the results are marked with the informant's gender, age group, and pain duration.

Analysis was data-driven with no theoretical framework as a template. The findings were repeatedly checked against transcripts for validation during the whole process and especially after the final analysis. MindManager [36] and NVivo 11.0 [37] were used as systematisation tools.

Results

Twenty-one informants, 17 females and 4 males, aged 32–74 years (mean age 52 years), were interviewed (Table 1). Only two informants had heard of the HLC before and none knew this was a service that could provide support to manage long-term conditions.

Table 1 Demographic characteristics of the informants

Characteristics	Number
Gender	
Female	17
Male	4
Age (years)	
< 35	2
35–50	7
51–60	6
61<	6
Civil status	
Partner/ married	13
Divorced/ widowed/ single	8
Current work status	
Working	3
Sick leave	3
Disability pension	11
Retired	4
Pain duration (years)	
1–5	7
6–9	1
10 or more	13
Main reason for pain	
Osteoarthritis, rheumatic diseases, osteoporosis	9
Musculoskeletal pain, back pain, fibromyalgia	7
Neurological pain, migraine	3
Injuries after treatment, trauma	2

The informants' descriptions of living with chronic pain were similar to findings in other studies [7, 16, 17, 38], and therefore not elaborated on here. However, to give an impression of the informants' previous experiences of pain and the health services they had used, we have added some information on the informants' background in Fig. 1.

The authors' overall understanding was that expectations towards participation in the easily accessible interventions were related to a hope that participation would lead to a better everyday life. This was a common overarching theme throughout and is presented as the first theme in the results: "Hope for a better everyday life". Expectations in terms of what they hoped to experience were categorized into the following five sub-themes; "Something new and untried", "To gain and reinforce skills", "To continue to grow as a person", "To meet others in similar situations", and "To access professional support in an easy manner".

Hope for a better everyday life

Informants' willingness towards participating in activities, trying new treatments and making changes in life was related to alleviating the pain and its consequences the best way they could. Most informants said they hoped that participation in the easily accessible interventions at the HLC would contribute to a better everyday life, using words like getting new insights, reinforcing skills, and meeting others who shared experiences of living with chronic pain. This was similar to what they said they hoped for when they had attended other services previously. Some informants emphasized that they saw it as important to carry the hope that life could get better despite their chronic condition, while at the same time acknowledging that the pain was likely to persist. It was said that hope was important as it motivated them to keep going and continue self-care activities.

> *"I do not think I will be free from pain. But I do think I can manage it better. I hope it will be better. I believe that it can" (female, over 60 years, pain more than 10 years).*

The following sub-themes present the expectations towards the easily accessible interventions at the HLC and thus how they hoped participation could bring about a better everyday life.

Something new and untried

Most informants spontaneously said they wanted to participate in the study because the HLC represented a new and untried service. They wanted to see if this service could add something new to their pain management. Some informants said the information of the content in

Previous experiences

The informants reported chronic pain for several years. Their pain arose from various causes such as musculoskeletal disorders, rheumatic diseases, trauma, and migraine. Chronic pain affected several aspects of their lives, leading to consequences such as lack of energy, concentration difficulties, mood swings, and a continuous struggle to maintain a rewarding everyday life. Informants highlighted that due to the fluctuating symptoms following their pain condition, some days were good and others worse. The chronic pain had influenced their work ability and social relations. They especially emphasized how they missed being part of a work environment as that had provided opportunities for both development and social interaction.

The informants had used a variety of healthcare services such as physiotherapy, chiropractor, manual therapist, healers, acupuncturists, and multidisciplinary services in specialised care such as multidisciplinary pain clinics and back schools. From their first use of services to seek answers to what was wrong with them, informants told of a process towards realising that the pain was something they were to live with. In this process, they had searched for, and in various degrees found, treatments and self-care activities that could alleviate their pain. This quotation captures the essence of how this process came about:

> "*I went to a lecture about long-lasting pain; I believe it was an arrangement on the "Global day against pain" at the hospital. Yes!, I thought, now I would learn about new research and how they would fix me. So I went to the lecture with great expectations. What I really learned was that my kind of pain, neuropathic pain, they did not know what to do with it. So I went home, crying all the way, because what I had learned was that this was something I had to live with" (female 51- 60 years, pain more than 10 years*).

Fig. 1 An overview of the informants' previous experiences of living with chronic pain and the type of services they have used

the intervention focusing on how to think about pain was new to them as they had little knowledge on cognitive techniques for managing pain. Thus, they were curious about how to approach their thoughts on pain. One informant said that how to use his mind to manage pain was a mystery to him and therefore he wanted to participate. Another informant said it like this:

> *"I just have to figure out how to think about something else, because sometimes, the pain just fills my body and my head so much that I cannot think. That is what I hope the course can give me. Those techniques to get my mind faster out of things" (female 35–50 years, pain more than 10 years).*

Some informants said they were were looking for input on how to alleviate pain without using medication. They experienced some drugs to be limiting as it kept them from, e.g., driving, and they were not comfortable being with grandchildren when they took drugs such as morphine. These informants especially stressed that they hoped to find other ways to alleviate pain as a reason for

their participation. For some, the nature of the interventions indicated participation would not worsen their pain. One informant summed up her expectations on participation like this:

> *"I have nothing to lose by participating. I do not believe it will be revolutionizing my life but I thought that this was yet untried. And suddenly, it could be something there that gives me; yes, maybe I will get a new insight" (female 35–50 years, pain duration 1–5 years).*

To gain and reinforce skills and techniques

Several informants said it was important for them to do something actively to alleviate pain, and referred to how they tried to follow recommendations on nutrition and physical activity. However, some informants described that translating knowledge into practical action was challenging. One informant said she had knowledge on benefits of exercise related to her illness, but she was still looking for the best way to practice it. She hoped participation in a new activity could give her appropriate exercises, in addition to inspiration and a push to establish a routine for physical activity.

Some informants said that in the beginning of their illness they had participated in interventions, hoping and expecting the pain to go away. As their experiences with pain treatments increased, some said they changed preferences for what they looked for. One informant explained how she at first had tried anything to get rid of the pain, but now she had decided to look for activities to make her days as good as possible.

Another informant described that maintaining her health and functional level was a demanding and never-ending task. Therefore, from time to time, she needed interventions to refill her motivation and give her energy to keep using the skills she already had. Another informant had learned techniques at a pain clinic on how to think about something other than the pain. The techniques had faded with time and she therefore wanted to reinforce her skills and hoped that the new interventions would fulfil this need.

> *"I feel that I have been at several health services so to speak, in relation to coping and all that. But of course, one forgets things after a while, and then you have to pick it up again" (female 35–50 years, pain 1–5 years).*

To continue to grow as a person

Some informants hoped participation could contribute to releasing potential in themselves that they considered to be unexpressed. Thus, they wanted to participate in activities that could help them to grow and develop as a person. One informant said she perceived to have good knowledge on how to manage pain but at the same time, she thought it was possible for her to expand her understandings. However, she struggled to find interventions that provided input to bring her further in her pain management.

Others spoke of wanting to develop their skills and talents to reach as far as possible towards their goals in life. For some, this was about finding meaningful activities that challenged them and prevented stagnation. One informant emphasized the importance of learning new things at every opportunity.

> *"Still, I believe I have potential. I mean I can do more, achieve more. I still see that I am capable of development in many ways. And then I think that if I do not improve myself or if I do not learn something new every day, then that belief will die" (male over 60 years, pain more than 10 years).*

For him, it was natural to seek activities like the intervention at the HLC, as he no longer perceived input and opportunities for development at work. Another informant said she wanted to participate because she needed to push herself outside her comfort zone. She looked for opportunities to develop herself since she no longer participated in work life.

To meet others in similar situations

When talking about expectations towards participation, most informants immediately emphasized how important it was to be with other people. They said support from others helped them in their struggles and efforts to hold the pain at bay. Some informants said they had worn out people closest to them, and others described how their condition was difficult for others to understand. One informant expressed that she needed her condition to be recognized as challenging. This made her search for settings where her challenges would be acknowledged. One informant who hoped she would meet people who understood her situation, said:

> *"It is the worst part of having long-term pain. That nobody cares. For no one can truly understand what you really are going through" (female 51–60 years, pain more than 10 years).*

For some informants, being on sick leave or disability pension had led to a lot of available time they wanted to fill with meaningful activities. One informant said she missed having something to do with other people, especially during the daytime. Others said they hoped the intervention could be a regular activity to attend. In addition, they hoped participation would be an opportunity to help others by sharing their own experiences,

but also to learn by listening to other peoples' experiences. One informant who had lived with pain for more than 10 years and had undergone several surgeries had never participated in interventions with others having similar health challenges. She said she was excited about the opportunity to hear how others managed to live with pain. For some, meeting others was also expected to give perspective to their own situations.

"It would be nice to get some input on other ways to manage pain. To have the benefit of others experiences and advice, on how they manage things so to say" (female 51–60 years, pain more than 10 years).

To access professional support in an easy manner

Most informants said they were not concerned whether interventions were delivered at a hospital or in primary care. More important was that there actually was a service available when they needed help to manage the pain. That was something they hoped to have found when they were informed of the HLC concept. One informant said she experienced each attended healthcare service as an assembly line where she came in, was treated, got out and then there was nothing more. To know where to turn for further support was challenging and she was looking for a service she easily could access, even just as a place to call. Another informant summed up her interactions with health services like this:

"In many ways I have missed that someone took care of me. Because no one cares about my health. My GP just writes out prescriptions, and then- was it something else? So, that is what I hope for really. To be taken care of. Because everyone needs that; to be seen" (female 51–60 years, pain more than 10 years).

Some informants had experiences of referrals to services being declined because their condition did not fit the priorities of the service. Others said there were waiting lists for services they wanted to attend, and some found it difficult to manage the costs allocated to treatments. They appreciated the low cost for interventions at the HLC compared to other services they had tried. Some stated the easy access as central for their participation because it enabled them to take control over their healthcare. They said it was important that requests for help were appropriately met. Participating in interventions was described as a way of self-care where they did something active to manage their health. One informant summarised her views like this:

"I believe it is important for society to take care of people so they can be in good shape for as long as possible. Self-care as long as possible. Even though they are not in paid work, I think it is really important. Because if you manage to get people with long-term pain in activity, then you will keep them healthy much longer" (female 51–60 years, pain more than 10 years).

Discussion

The expectations towards the easily accessible interventions were related to a hope that participation could lead to a better everyday life. As the HLC for most of the informants was an untried service, it represented a possibility for maybe finding something new that could make their life with pain a little bit easier. The new and untried intervention provided an opportunity to meet other people, to learn or reinforce skills, and to develop as human beings. This gave hope of maybe having found a service that would be easy to access whenever they needed support to manage their pain.

Expectations that participation could lead to a better everyday life

The informants' expectations were related to a hope for the possibility that despite their chronic condition, everyday life could become better. Consequently, they expressed a willingness to try anything that could contribute to minimising the pain's interference with their everyday life regarding social activities, family responsibilities and participation in work life. Although there are differences in how the term hope is understood in studies among patients, comprising terms such as expectations, aspirations, wants and desires, [28, 29], informants in our study spoke about hope without making such differentiations. Nevertheless, hope has been pointed to as central in how people with pain assess new experiences and adjust their expectations towards treatments [39], and our findings support this.

The informants in our study believed, despite having experienced modest effect of treatments, that it was possible to alleviate the consequences of their pain. As such, our results are consistent with understanding chronic pain as a condition where the pain itself can become secondary to its consequences on everyday life [40]. For the pain level to be substantially reduced, however, the informants expressed few expectations. One reason might be that the information about the interventions content did not encourage expectations of pain relief as it focused more on what they could do themselves to make everyday life better. A recent review, however, found patients' expectations of pain reduction after treatments were high [28]. The contrast to our results might be due to the review in principal concerned interventions delivered in specialist care while the informants in our study were asked about their expectations

towards a non-pharmacological intervention delivered in primary care. Nevertheless, the distinction between ideal and predicted expectations towards outcomes of pain treatment described in the review may be useful for understanding the informants' expectations to the current interventions. Alternatively, it might be that the informants have not experienced substantial or long-lasting improvement in pain level previously and therefore do not consider it realistic to achieve pain relief. If so, that would be in line with patients with extensive healthcare experience not expecting interventions necessarily to alleviate their symptoms [32].

In line with existing knowledge [29], we found that hope could be seen as a driving force towards trying new interventions or services as it was seen as essential for maintaining motivation to do activities experienced as beneficial. The role of hope for motivation to self-care implies that service providers should be aware of and help to maintain patients' hopes. A challenge for the health service, though, is how to support hope without creating unrealistic expectations [29] or despair [41], but rather contributing to a sustained hope that would promote self-care.

Available services when needed

Although there were similarities, some of the expectations towards participation in the easily accessible interventions were in contrast to expectations identified in studies on multimodal and more comprehensive pain programmes [13, 30–32]. Where these studies found that participants had expectations towards health providers' competency [30], learning specific coping techniques [13], and on outcomes related to diagnostics and causes of pain [31, 32], that was not prominent in our study. A possible reason for the difference might be that what the informants' perceived primary care could offer them was different from what they sought in specialist health services. Another reason might be that the easily accessible interventions addressed chronic pain regardless of cause or underlying disease, which were different from studies addressing specific pain conditions [30–32]. Professional education and interdisciplinary treatments are pointed to as important in pain treatment [26]. The informants in this study, however, also emphasised the importance of social support comprising both peers and professionals, as part of their self-care. Notably, the informants saw it as more important that the services were available for them whenever they needed help to manage their pain, than who provided the services or their location.

Having access to services when they recognised a need for support was described as important for the informants' maintenance of self-care. More generally, participating in interventions provided by healthcare services was seen by some as an act of self-care, where they did something active to manage their health. This is similar to Wagner et al.'s description of the patient being the pilot, where the role of the healthcare system is to ensure that the pilots are skilled and capable of getting to their destinations [27]. For health service, though, this poses a challenge of being responsive to the patients' needs when they arise. Hence, strengthening the patient's role as informed and activated requires that service providers are given the leeway to support patients' use of healthcare whenever they need it. However, according to some of the informants this was not always the situation as they had experienced trouble knowing where to turn for help, and requests for help were rejected or postponed. Their experiences exemplify obstacles in the healthcare system when one tries to manage chronic pain, confirming previous findings that access to health services and resources can be difficult [42–44]. This can explain why the informants saw the easy access to the current interventions as a possible solution for their need for a service that was available whenever they needed support to manage their pain.

Strengths and limitations

A strength in the study is the novelty in exploration of expectations towards easily accessible pain management interventions in public primary care. To minimize potential biases during the analysis, preliminary results were discussed with an extended research group to expose the data for different views and perspectives. However, there are some noteworthy limitations. The sampling strategy could have led to a selected sample as the informants were only recruited among participants agreeing to participate in a RCT. It is thus possible we have missed expectations from people who did not want to participate in a trial. Similar to recruitment to other self-management interventions, there were more women than there were men in the sample. Nevertheless, our sample included informants of different ages and different lengths of pain duration, and we perceive the sample to mirror the participants in the larger trial. In addition, the interview setting could have affected the interviews since the informants were interviewed right after they had answered the RCT's questionnaires. However, a review of the interviews showed very few references to the questions, indicating they spoke from experience and not the concepts in the questionnaires.

Conclusion

The informants' expectations were not specifically related to the pain level being diminished or alleviated. Their hope for a better everyday life was the main driving force towards trying new interventions and health services. The participants perceived the primary care-delivered pain

management interventions to be an opportunity for easy access to peer and professional support. The role of hope for peoples' motivation to self-care implies that service providers should be aware of and help to maintain patients' hope for a better everyday life. The importance of social support as part of self-care should be acknowledged when developing interventions targeting chronic pain.

Abbreviations
GP: General Practitioner; HLC: Healthy Life Centre; RCT: Randomised controlled trial; STC: Systematic text condensation

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Availability of data and materials
The raw data supporting the findings in this manuscript can be found at the Department of Public Health and Nursing, Trondheim, Norway. Due to regulations of the Regional Committee for Medical and Health Research Ethics we have to secure the anonymity of the informants. In the raw data, it is possible to identify the informants, and restrictions therefore apply to the availability of these data.

Authors' contributions
THN, AS, OB and KG were responsible for the design of the study. THN performed the data collection and drafted the manuscript. THN, AS, LR, OB and KG participated in data analysis and provided input on the manuscript. All authors read and approved the final version.

Ethics approval and consent to participate
All informants signed an informed consent form after having received oral and written information to enable them to make an informed choice about participation. Those who participated in the qualitative study in addition to the RCT signed an additional consent form regarding the interviews. The informants were informed that participation in the qualitative study was voluntary and not a pre-requisite to trial participation. The trial has obtained approval from the director for health and social affairs in the municipality, and from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Paper II

Title page

Short-term effect of a chronic pain self-management intervention delivered by an easily accessible primary healthcare service - a randomised controlled trial

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Abstract

Objectives: To investigate the effects on persons with chronic pain after three months of a group-based chronic pain self-management course compared to a drop-in, low-impact outdoor physical group activity.

Design: An open, pragmatic, parallel group randomised controlled trial. Analyses were performed using a two-level linear mixed model.

Setting: An easily accessible healthcare service provided by Norwegian public primary healthcare.

Participants: A total of 121 participants with self-reported chronic pain for three months or more were randomised with 60 participants placed in the intervention group and 61 placed in the control group (mean age 53 years, 88 % women, 63 % pain for 10 years or more).

Interventions: The intervention group was offered a group-based chronic pain self-management course with 2 ½-hour weekly sessions for a period of six weeks. The sessions consisted of education, movement exercises and emphasised group discussions. The control group was offered a low-impact outdoor group physical activity in one-hour weekly sessions that consisted of walking and simple strength exercises for a period of six weeks.

Main outcomes: The primary outcome was patient activation assessed using the Patient Activation Measure (PAM). Secondary outcomes measured included assessments of pain, anxiety and depression, pain self-efficacy, sense of coherence, health-related quality of life, well-being and the 30s Chair to Stand Test.

Results: There was no effect after three months of the group-based chronic pain self-management course compared to the control group for the primary outcome, patient activation (estimated mean difference -0.5, CI 95% -4.8 to 3.7, p= 0.802).

Conclusions: There was no support for the self-management course having a better effect after three months than a low-impact outdoor physical activity offered the control group.

Trial registration: ClinicalTrials.gov: NCT02531282

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Strengths and limitations of this study

- This is the first randomised controlled trial (RCT) to investigate the effect of self-management support interventions in a Healthy Life Centre (HLC) setting
- The RCT had broad inclusion criteria to increase the external validity by allowing all persons with self-reported chronic pain for three months or more to participate
- Outcome measures were chosen among valid and reliable instruments recommended for chronic pain trials and used in trials of chronic pain self-management
- The lack of blinding for the participants and the professionals delivering the intervention is a limitation, but the assessor of the objective outcome was blinded to allocation
- The different lengths of intervention for the two trial arms is a limitation; however, they reflect the practices of the HLC

Background

Chronic pain, a long-term condition that affects a substantial portion of the population, presents a challenge for societies and healthcare systems in terms of increased healthcare utilisation, medication use and a reduced workforce.[1, 2] Chronic pain also places a considerable burden on the affected individuals due to its impact on the social, psychological and physical aspects of their quality of life.[2, 3] The individual burden is also evident in the descriptions of how pain affects daily activities, including the ability to sleep, exercise and perform household chores, and individuals describe being less able or no longer able to maintain relationships with family or friends or to attend social functions.[1, 2] The intrusion of the condition into everyday life often requires adjustments to goals, plans and expectations.[4]

Due to the comprehensive impact of chronic pain, treatment options aim to embrace different aspects related to the condition.[5] Thus, the various treatment options range from pharmacological and interventional treatments delivered by specialist caregivers to non-pharmacological treatments, such as exercise, psychological approaches and support and advice regarding how to manage everyday life with pain, typically provided by primary caregivers.[5, 6] Despite the different treatment options offered, chronic pain is perceived as a condition that is not cured but more likely to persist when treatment stops,[7] indicating that in many cases, patients must self-manage pain on an everyday basis.[8]

Self-management includes the actions that people take to recognise, treat, manage and engage in behaviours that affect their health.[9] Furthermore, self-management includes tasks related to the medical management of a condition and maintaining, changing and creating new meaningful behaviours as well as dealing with the emotional consequences of having a chronic condition.[10] Hence, to function effectively as a self-manager, one must have the necessary knowledge, skills and confidence to make favourable choices related to health and healthcare.[11] Required self-management skills are related to problem solving, decision making, resource utilisation, forming a patient-healthcare provider relationship and taking action.[12] Strengthening people's awareness of and capacity to use their own and available resources to self-manage is thus considered a central health service task.[8, 9] There has therefore been an increase in initiatives to promote patients' engagement by supporting them to take charge of their own health and healthcare outcomes.[13, 14] For chronic pain, this

typically include interventions focusing on approaches such as pacing, relaxation, cognitive behavioural strategies and education [15].

Several studies have investigated the effect of self-management support interventions that address chronic pain. Some systematic reviews that summarised chronic pain self-management interventions concluded they have no effect,[16, 17] whereas one systematic review concluded there were minor effects, such as improvements in self-management skills, pain, symptoms and functioning.[18] Furthermore, physical activity and exercise have increasingly been promoted for chronic pain interventions due to their perceived benefits, including improved overall physical and mental health and improved physical functioning.[19] Both aerobic and anaerobic exercise as well as meditation and yoga have been found to have beneficial effects on chronic pain conditions.[20, 21] Furthermore, walking has been suggested as an ideal form of activity for people with chronic musculoskeletal pain due to its ease of accessibility and relatively low impact.[22]

Due to the need for treatment and support over time, people with chronic pain utilise a variety of different healthcare services and have been found to have a significantly higher use of healthcare services compared to individuals without chronic pain.[23] Furthermore, due to the vast consequences and high prevalence of chronic pain, the condition is considered a public health challenge that calls for effective, safe and sustainable interventions.[3, 6] Self-management programmes are recommended to be community-based so that a large number of people can access them.[12] Knowledge related to the effects of chronic pain self-management interventions is increasing; however, most studies that have examined their effects have typically addressed patients with specific diagnoses,[24, 25] targeted specific age groups,[26] focused on lay-led interventions[27, 28] or investigated interventions delivered by specialists and multidisciplinary healthcare services.[29] Hence, little knowledge exists regarding self-management support interventions that address chronic pain delivered via easily accessible healthcare services.

One such service has become a common feature in most Norwegian municipalities because they are encouraged to establish Healthy Life Centres (HLCs) as part of public primary care.[30] These centres focus on health promotion and support for the management of long-term conditions. The HLCs aim to be easily accessible by allowing self-referrals for their interventions, and in some HLCs, self-management initiatives have been added as a service. At present, no studies have evaluated self-management interventions delivered in this setting.

Objective

The aim of this study was to investigate the effects on persons with chronic pain after three months of a group-based chronic pain self-management course compared to a drop-in, low-impact outdoor physical activity delivered through an easily accessible healthcare service on the primary outcome, patient activation and a range of secondary outcomes.

Methods

An open, pragmatic, parallel group RCT was conducted from August 2015 through March 2017. The assessments at the three-month follow-up are reported in this paper. The trial was designed to measure outcomes at six and 12 months as well.[31] The guidelines provided in the Consolidated Standards of Reporting Trials (CONSORT),[32] including its extensions for pragmatic trials[33] and non-pharmacological treatment interventions,[34] were used to guide the presentation of the results. The protocol for the trial has been published previously.[31] There were no changes to the methods after trial commencement.

Setting

The setting for the study was an HLC in a large city in Central Norway serving a population of approximately 190.000 inhabitants. The HLC's aim is to strengthen participants' capacity to use their own and available resources to make behavioural changes and to manage their health.[35] To achieve this, the HLCs offer non-pharmacological interventions with few barriers for attendance, meaning that people can access the service with or without a referral. The RCT took place at a HLC that provides several group-based activities and interventions (e.g. indoor and outdoor physical activities, healthy diet courses and courses focusing on coping with depression or anhedonia). At the time of the RCT, the HLC had 5.5 positions occupied by multidisciplinary health professionals with a bachelor's or master's degree.

Patient and public involvement

To include the perspective of patients, representatives from patient organisations were included when planning the trial and were also available to the instructors during the delivery of the self-management course. The patient organisations representatives were consulted during the process of developing the research questions and choosing the outcome measures. The participants in the trial assessed the burden of the intervention when they met for follow-up assessments and were asked about their experiences during the intervention. The results of the study will be communicated to participants after publication.

Participants

Recruitment for the RCT began in September 2015 and ended in October 2016. Individuals who met the following inclusion criteria were admitted: adults of 18 years of age or older, self-reported pain for three months or more, able to take part in group discussions in Norwegian and a signed agreement to accept randomisation to one of the trial activities after a full explanation of the trial. The exclusion criteria were as follows: inability to participate in low-impact physical activity for at least one hour, pain arising from malignant diseases and inability to consent to study participation.

The opportunity for people with chronic pain to participate in the trial was communicated through posters and information leaflets distributed to general practitioners, physiotherapists, relevant departments at the hospital, Norwegian Labour and Welfare Administration offices and other relevant organisations in the municipality. To encourage self-referrals for the trial, advertisements were also placed in local newspapers, websites, social media and email invitations to patient organisations. Those interested in participating were encouraged to contact the first author by either phone or email.

Procedure

Participants received supplementary information about the trial (i.e. that they would attend one of two activities delivered in groups during the day for a period of six weeks) in the informed consent form and orally in relation to the baseline assessment. Those who met all the inclusion criteria and none of the exclusion criteria were invited to participate in the trial.

Following an individual randomisation procedure from a computer-based Internet trial service provided by a third party (Unit for Applied Clinical Research at the Norwegian University of Science and Technology, NTNU), participants were consecutively randomly allocated to one of two trial arms with a ratio of 1:1 after completing the baseline assessment. Because recruiting men for self-management interventions is a common challenge,[36] stratification for gender was applied to ensure an even balance of men. To do so, a block stratification was used, and those involved in the trial were blinded to the block size.

Immediately after randomisation, the first author informed the participants of their allocation by either phone or email. The participants were further informed that there was no possibility of changing their trial activity after allocation. The blinding of participants and instructors was not possible due to the nature of the interventions; however, the research assistant who conducted the physical ability test at the follow-up appointment was blinded to allocation. A

new course began when approximately 10 participants were allocated to one of the trial arms or when the pre-set date for a course was reached.

All outcomes were measured at the baseline and at three months after completion of trial activity. At the baseline, the self-administered questionnaire was completed with the first author available for questions. For the follow-up appointment, the participants received the questionnaire by mail, and the result of the physical test as well as data related to healthcare utilisation and socio-demographic variables were registered during follow-up appointments. All data were collected in paper form, which were scanned and checked by the first author by comparing them to their corresponding data files.

Ethics

The Regional Committee for Medical and Health Research Ethics in Southeast Norway approved the study (2015/ 1030/ REK sørøst). The participants were informed of the trial both orally and in writing, and written consent to participate was collected from each participant before enrolment. The trial was registered at ClinicalTrials.gov in August 2015 (number NCT02531282).

Outcome measures

Self-reported socio-demographic variables, such as gender, age, marital status, education, work status, main reason for pain categorised according to the International Classification of Primary care-2 (ICPC-2), use of pain medication and whether the individual suffered from more than two chronic conditions, were collected at the baseline assessment. At the follow-up appointment, any changes to these baseline assessments were registered, including changes for work status and medication use. Healthcare utilisation was registered at both the baseline assessment and the follow-up appointments according to the participants' self-reports of visits to general practitioners, physiotherapists, hospitals or rehabilitation centres during the previous three months.

Primary outcome measure

The self-management course aimed to increase the participants' knowledge, skills and confidence in managing everyday life with chronic pain.[31] Patient activation is considered a key element in the management of one's health and healthcare,[11] it is emphasised in chronic illness models[37] and a typical aim of self-management interventions.[38] Hence, because the intervention was expected to strengthen the participants' engagement in and increase their knowledge of their own health resources, patient activation was perceived to be a suitable

primary outcome. Patient activation was assessed using the Patient Activation Measure (PAM).[39] The PAM has been reported as useful for assessing patient engagement in the management of a chronic illness, including chronic pain, and it is sensitive to change across several groups and populations.[39]

The PAM-13 is a unidimensional, Guttman-like measure that contains 13 items representing statements to which the participants indicate their level of agreement on a four-point scale from 'strongly disagree' to 'strongly agree' with an additional 'not applicable' option.[11] The responses provide a raw score from 13 to 52 calibrated to a total score between 0 and 100 using the revised transformation table provided by Insignia Health.[40] A high score indicates that participants are more likely to adopt and to maintain healthy behaviours and self-management of their illness even under stress.[11] The PAM-13 is translated and validated for use in a Norwegian context.[41] Studies have shown that the Norwegian version of the measure is valid and reliable when tested for patient education interventions in a Norwegian hospital (Cronbach's alpha = 0.91)[41] and in a RCT of a hospital's out-patient self-management education for patients with polyarthritis (Cronbach's alpha 0.80).[24] In the present study, the Cronbach's alpha at the baseline assessment was 0.75.

Secondary outcome measures

The secondary outcomes were chosen to cover the domains recommended for chronic pain interventions by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT), [42, 43] including pain, physical functioning, emotional functioning and coping.[43] In addition, systematic reviews and similar studies on self-management were reviewed for relevant outcome measures. To include the possible influence of the intervention on all relevant domains, a total of seven questionnaires, two single-item questions and one physical test were included as secondary outcomes, which are presented in the following sections.

Having chronic pain was the main inclusion criteria, and pain was accordingly an important domain to measure. The short version of the Brief Pain Inventory (BPI) applying a 24-hour recall period was used to assess pain severity and pain interference. The instrument includes four questions related to severity and seven questions regarding interference, all items rated on 0-10 scales with 10 being pain as bad as one can imagine or pain that completely interferes with normal functions. The instrument has an additional item that asks about the percentage of pain relief by analgesics.[44] The instrument has been translated to Norwegian (Cronbach's

alpha 0.87 for pain severity and 0.92 for the interference scale)[45] and has been used in Norwegian studies of a multidisciplinary pain management programme[46] and among patients with osteoarthritis (Cronbach's alpha >0.80).[47] In the present study, the Cronbach's alpha at the baseline assessment was 0.81 for pain severity and 0.86 for pain interference.

In addition, the participants reported experienced pain during the previous week using a one-item, 100-mm Visual Analogue Scale (VAS).[48] The participants were asked to draw a vertical mark on the 100-mm line indicating their average pain during the previous week. The scale's anchoring points were no pain (0) and intolerable pain (100). The VAS scale has been found to be reliable for the assessment of chronic pain.[48]

Psychological distress is commonly reported among individuals suffering from chronic pain, [2, 49] and the use of the cognitive strategies in the self-management course makes psychological distress an important domain to assess. The self-rating instrument, the Hospital Anxiety and Depression Scale (HADS), with 14 items divided into subscales for depression and anxiety,[50] was applied to assess psychological distress. Each item is rated from 'not experiencing a symptom' (0) to 'experiencing a symptom nearly all the time' (3), yielding a total score from 0 to 21 for both subscales of seven items each. The instrument is widely used in studies on chronic pain and has shown good validity and reliability for patients with musculoskeletal pain (Cronbach's alpha for the anxiety subscale 0.83 and for the depression subscale 0.84)[51] as well as in a Norwegian large population study (HUNT) (Cronbach's alpha 0.80 for the anxiety subscale and 0.76 for the depression subscale).[52] It was also used for a study on a chronic pain multidisciplinary rehabilitation programme.[53] In the present study, the Cronbach's alpha at the baseline assessment was 0.73 for the depression subscale and 0.76 for the anxiety subscale.

Self-efficacy is a concept related to the confidence people have that they can successfully execute a course of action to accomplish a desired outcome in a given situation,[54] and as such, it is a domain that could be affected by the intervention. The concept was measured using the Pain Self-Efficacy Questionnaire (PSEQ).[55] The PSEQ assesses participants' beliefs regarding their ability to accomplish various activities despite pain using 10 items, each asking responders to rate their agreement using a scale from 0 to 6 in terms of how confident they are that they can perform an activity at present despite the pain, where 6 equals completely confident.[55] The scale has shown strong psychometric qualities (Cronbach's alpha 0.92)[55] and was previously used in a Norwegian study.[56] In the present study, the Cronbach's alpha at the baseline assessment was 0.84.

The 13-item Norwegian version of the Sense Of Coherence (SOC) scale was used to assess the capacity to respond to stressful situations and remain healthy.[57] The SOC is often related to salutogenesis, which is an essential component of the activities at the HLC.[30] Thus, this was considered a relevant concept to measure. The SOC measures comprehensibility, manageability and meaningfulness through 13 items, each scored using a range from 1 to 7, yielding a total score of 13- 91. A higher score indicates a stronger sense of coherence. The SOC scale has been found to be a reliable, valid and cross-culturally applicable instrument (Cronbach's alpha in 127 studies 0.70-0.92).[57] The Norwegian version of the SOC-13 has among others been used in a study that investigated life satisfaction for people with long-term musculoskeletal pain[58] and in a study on multidisciplinary rehabilitation for persons with chronic musculoskeletal pain (Cronbach's alpha 0.83).[59] In the present study, the Cronbach's alpha at the baseline assessment was 0.87.

The self-management course included topics regarding how to manage everyday life with chronic pain, and hence quality of life was a relevant domain to measure. A generic instrument, the EuroQoL (EQ-5D-5L), was used to assess health-related quality of life.[60] The instrument has five levels to evaluate each of the following dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The levels are: 'no problems', 'slight problems', 'moderate problems', 'severe problems' and 'extreme problems'.[61] The descriptive core was converted to an index value for health status using the Danish value set, giving a range from 1 (perfect health) to 0 (death).[60, 61] The instrument has been validated in similar populations[62] and in a Norwegian context (Cronbach's alpha 0.69).[63] In the present study, the Cronbach's alpha at the baseline assessment was 0.55.

The Arizona Integrative Outcomes Scale (AIOS) was used to measure an overall experience of well-being using a one-item, 100-mm long visual analogue scale.[64] Participants were requested to: 'Reflect on your sense of well-being during the last month. Take into account your physical, mental, emotional, social and spiritual condition and mark the line for your summarised overall sense of wellbeing'. The scale's anchoring points were 'worst you have ever been' (0) and 'best you have ever been' (100).[64] AIOS has been found to be a valid measure of assessing well-being[64] and was previously used in a Norwegian study.[24]

To assess global self-rated health, participants were asked: 'By and large, would you say that your health is: poor, not so good, good, very good or excellent'? The question is similar to a question asked during a major population study in Norway.[65]

Because physical exercise has been found to have beneficial effects on chronic pain,[20, 21] the participants were asked: 'How often do you on average exercise? (by exercise, we mean going for walks, skiing, swimming and working out/ sports): never, less than once a week, once a week, 2-3 times a week or nearly every day'. This question was used for a major population study in Norway.[65]

In addition, an objective measure of physical ability was included using the 30s Chair to Stand Test to measure lower body strength.[66] The test has been validated for a broader population.[67]

Delivery of trial activities

To evaluate the delivery of the trial activities, the instructors completed evaluation forms after each group session to report their own experiences with the delivery and group dynamics as well as whether there were any changes in relation to the guidelines and if any adverse events occurred. Attendance was recorded at each session for both trial activities.

Intervention and control group

Two different teams conducted the intervention and control group activities. The guidelines for carrying out the self-management course, ensuring all groups were offered the same content and material, are available in the published protocol.[31] The low-impact physical activity offered to the control group followed descriptions of a similar activity currently offered at the HLC. There was no user fee for participation, and financial compensation was not offered to the participants.

The self-management course

The HLC staff had considered persistent pain to be a common challenge among users and therefore decided to initiate a chronic pain self-management course. Thus, in cooperation with a representative from a patient organisation, the HLC staff developed an intervention based on the characteristics of self-management courses,[12] recommendations found in the literature on chronic pain self-management (e.g.[68-72]) and the guidelines for the HLC[30] in addition to drawing upon their own experiences related to behavioural changes and self-management of chronic conditions. This resulted in a chronic pain self-management course that included education emphasising cognitive and behavioural strategies,[68-70, 72] and introduction of movement exercises.[73]

The course utilised elements from cognitive behavioural therapy (CBT) because this approach has been found to be beneficial for teaching chronic pain self-management[68-70, 72] by creating a focus on thoughts, emotions and actions related to pain. When discussing the participants' experiences with pain in everyday life, the instructors focused on activating events, beliefs or presumptions related to the events as well as consequences in terms of feelings, physical symptoms and behaviours. The course included topics such as pain theory, barriers in everyday life due to chronic pain, problem solving, goal setting and techniques to deal with fatigue, poor sleep, frustration and isolation. The course aimed to teach skills such as setting specific, functional and realistic goals, activity pacing and structured problem solving. The movement exercises concluding each session aimed to improve balance, posture and breathing, providing the participants with techniques to increase body awareness and the ability to relax based on psychomotor physiotherapy.[71] In addition, the instructors facilitated group discussions and sharing of experiences among participants. Between each session, the participants were encouraged to work on projects, such as an action plan, and to practice the movement exercises. The content of the course is outlined in Table 1.

The self-management course was delivered as 2.5-hour weekly group sessions during the day (12.30 pm - 15.00 pm) for a period of six weeks and a total of 15 hours. The self-management course was facilitated by two HLC physiotherapists experienced in working with behaviour changes, coping and chronic pain. One of the physiotherapists was educated in psychomotor physiotherapy and had extensive experience from a multidisciplinary hospital pain clinic.

PLEASE INSERT TABLE 1 ABOUT HERE

The control group activity

Offering an activity to all participants in the trial was recognised as ethical and a good clinical practice.[74] Because physical activity has been found to have beneficial effects on chronic pain conditions,[20-22] the control group was offered a group-based physical activity that was already available as an activity at the HLC. The low-impact physical activity was a weekly one-hour drop-in session during the day (13.00 pm - 14.00 pm) for a period of six weeks, which consisted of walking and simple strength exercises (e.g. squats and push-ups against a tree or a bench). The activity was adjusted to the participants' physical abilities to make it both easily accessible and rewarding. The groups met outdoors on a popular hiking trail. The activity provided an opportunity to meet others with similar health challenges. Participation was voluntary, which is in line with the drop-in policy for this type of activity at the HLC.

Two dedicated instructors familiar with physical exercise led the activity. The instructors encouraged the exchange of information among the participants rather than answering questions and giving advice themselves. Hence, there was no education for the control group.

Sample size

The findings of an RCT that investigated the effect of an educational programme on patients with polyarthritis where the PAM was one of the secondary outcomes, were used to calculate the sample size.[24] The aim was to identify clinically important differences between the intervention group and the control group with a significant difference defined as six points of difference for the primary outcome (PAM-13) between the baseline and the 12-month follow-up assessments. The sample size was calculated using a mixed linear model assuming a correlation within participants to be 0.5 with a standard deviation (SD) of 13. The significance level was set to 5% and the power to 80 %, generating a necessary number of 55 participants for each trial arm. Thus, the aim was to recruit 120 participants, allowing for five dropouts for each trial arm.

Statistics

Descriptive statistics were used to describe the characteristics of the participants at the baseline assessment. Distributions of all outcome measures were examined with graphical displays and descriptive statistics and found to be approximately normally distributed. Patterns of missing values were investigated and determined to be missing at random. The confidence level was set to 95 %, and a p-value of ≤ 0.05 was a-priori considered statistically significant. No interim analysis was performed.

The mean scores for all observed outcomes at the baseline and at the three-month follow-up assessments were calculated independently. Changes in work status and pain medication (categorical data) were analysed using Pearson Chi-Square test or Fisher's exact test. Frequency of healthcare utilisation at the follow-up was analysed with t-tests. The effect of the intervention was assessed using an intention to treat (ITT) and per protocol procedures. To take the intra-class correlation between measurements in the same subject into account, the analyses were performed using a two-level linear mixed model.[75] Mixed models allow for the use of all available data in the presence of dropouts, and thus there was no need for multiple imputations.[75] Hence, the analyses included all available data from all randomly assigned participants.

In the two-level linear mixed-effects model, outcome measures over time for the two trial arms were compared using participant identification (ID) specified as a random effect. The effect of intervention and time was specified as fixed with the following three values: 1) 'baseline', 2), 'control three months' and 3) 'intervention three months', acknowledging that differences between groups at the baseline were due to chance. The random effect for participant ID aimed to allow participants to begin at different levels of the outcome in question. Regression assumptions were checked by running the command 'regcheck' in Stata,[76] resulting in satisfactory values for assumptions of homoscedasticity, normally distributed residuals and influential cases.

Per-protocol analyses included participants who had been present at a minimum of three out of six group sessions. The per-protocol analyses provided only minor changes in the estimates and did not change any conclusions about the interventions. They are thus not further reported.

The first author performed the analyses, which were overseen and discussed with the co-authors and a statistician. All analyses were performed using Stata 14 (StataCorp. 2014. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

Results

Of the 208 people who responded to the trial announcement, 87 declined to participate after receiving additional information or did not meet the inclusion criteria, leaving 121 participants suitable for inclusion. The number of eligible participants and their flow through the study is displayed in the flow chart in Figure 1.

At the three-month follow-up, 17 people did not respond. They were equally distributed for intervention and control, leaving 52 available cases for each trial arm. Of the remaining participants (n=104), seven participants did not attend the follow-up appointment but returned the questionnaire by mail, leading to missing data regarding changes in marital status, work status, use of pain medication, healthcare utilisation and the 30s Chair to Stand Test, as these categories comprised the data collected during the follow-up appointment.

PLEASE INSERT FIGURE 1 ABOUT HERE

Figure 1. Participants flow through the study

Participants

Most participants responded to advertisements in newspapers, social media or email-invitations sent to relevant organisations (68.6 %). Twenty-one participants (17.4 %) responded after receiving information at a physiotherapist's office, and two participants (1.7 %) received information at their general practitioners' offices. Another 14 (11.6 %) participants referred to the HLC by their general practitioners for other reasons were considered by the HLC staff to potentially benefit from participation in the trial and were thus referred to and included in the trial after meeting the inclusion criteria.

The participants' mean age was 53 years (SD 11.7, range 23- 74 years) (Table 2). There were more women (88 %) than men in the sample, and the majority lived with someone (71 %). Many of the participants had experienced pain for 10 years or more (63 %), and more than half (63 %) reported more than one chronic condition. Musculoskeletal diseases were the most commonly reported causes of chronic pain (77 %). The baseline characteristics of the participants are shown in Table 2.

PLEASE INSERT TABLE 2 ABOUT HERE

Delivery of trial activities

Overall, there were six self-management course groups and six physical activity groups. The number of participants allocated to each group varied between seven and 13 (median 10). Ten participants did not attend the self-management course, and 14 participants chose not to participate in the control group activity. For the self-management course groups, the average overall attendance was 67.1 % (range for the different groups: 50.0 % - 79.6 %), and for the physical activity groups, the average overall attendance was 44.4 % (range for the different groups: 21.2 % - 73.3 %).

The instructors of the self-management course reported that the participants were engaged and active by taking part in discussions and sharing experiences. The instructors reported that in some sessions, they spent less time presenting slides because the participants preferred using more time to discuss and to reflect on the subjects. In some groups, there were participants who had difficulty practicing some of the movement exercises. Two adverse events were reported during the self-management courses: one participant had an anxiety attack, and one participant reported benign paroxysmal positional vertigo after performing a movement exercise. The symptoms were gone within a short time; however, the benign paroxysmal positional vertigo led to hospital admission.

The instructors for the low-impact outdoor physical activity described participants as interacting with each other and taking part in the suggested exercises. After three group sessions, the meeting place for the activity was changed because the participants preferred to end the activity near a café. Some participants found it difficult to participate during the winter due to slippery trails, and one adverse event during which a participant pulled a leg muscle was reported. A general practitioner was consulted, and the symptoms were gone within a few weeks.

Outcome measures

The observed and estimated scores for all outcomes are presented in Table 3.

Primary outcome

For the primary outcome, patient activation, there was no support for the self-management course having a better effect after three months than a drop-in, low-impact outdoor physical activity (estimated mean difference -0.5, 95 % Confidence Interval (CI) -4.8 to 3.7, p= 0.802).

Secondary outcomes

For the secondary outcomes, only the question in the BPI measuring pain relief by analgesics showed a statistically significant small difference between the groups with an estimated mean difference of 1.0 (95 % CI 0.01 to 1.9, p=0.047). Within groups, estimated mean change in experienced pain during the previous week showed statistically significant changes for both groups, with a reduction in pain of -7.9 (95 % CI -13.1 to -2.7, p= 0.003) for the intervention group and -6.6 (95 % CI -11.8 to -1.4, p= 0.014) for the control group. Within the intervention group, there was a small but statistically significant improvement in global self-rated health (estimated mean change 0.2, 95 % CI 0.01 to 0.4, p= 0.032).

For most of the participants, there was no change in work status (83.5 % unchanged), pain medication (75.3% unchanged) or frequency of healthcare utilisation from baseline to follow-up (data not shown). There was no statistical significant differences between the groups for these variables.

PLEASE INSERT TABLE 3 ABOUT HERE

Discussion

There was no effect of the group-based chronic pain self-management course after three months compared to the drop-in, low-impact physical activity on either the primary or the secondary outcomes.

This study contributes knowledge to the field of easily accessible chronic pain self-management support given that previous research has largely focused on interventions that address specific diagnoses or specific age groups and has investigated lay-led interventions or interventions delivered by specialist and multidisciplinary healthcare services. However, the study only included data collected three months after the completion of the intervention, and thus short-term effects can only be discussed. The lack of blinding is a limitation of the study, but due to the nature of the interventions, blinding was not possible. Furthermore, even if the possibility of bias due to data loss at follow-up cannot be disregarded, it is unlikely that such bias would influence the two groups differentially and thereby affect the results of the study. It should be noted that the two trial arms received interventions of different lengths, and the power calculation for the trial was conducted with regard to the primary outcome from the baseline to 12 months based on a study in which the comparator did not receive an intervention activity.[24] Hence, a difference between the two groups regarding the primary outcome of six points may be difficult to detect after three months. Valid and reliable outcome measures were chosen in accordance with recommendations from the IMMPACT;[42] however, although a wide range of outcomes was chosen to encompass domains the intervention could affect, other measures may have been more sensitive to changes caused by the intervention.

The self-management course included education applying cognitive and behavioural strategies, group discussions and exercises for body awareness and relaxation during six weekly sessions. This is similar to interventions in other studies, some of which have shown an effect[26, 27, 77] and others that have not.[28, 78] For instance, a study on older adults with chronic pain showed no effect of a chronic pain self-management course using CBT components,[78] whereas another study conducted in a similar population did show a significant effect in favour of a CBT-based chronic pain self-management course compared to both an exercise-attention control and a waiting-list group when expanding the intervention.[26] A lay-led chronic pain self-management programme of equal length and similar content to the intervention in the present study showed no effect compared to a usual

care control.[28] Evidence of an effect of chronic pain self-management courses similar to the type provided in this study is thus conflicting.

The present study included broad inclusion criteria that targeted chronic pain in general, which is important because those living with chronic pain have different origins of pain and experience different impacts of the condition.[2, 3] By inviting a broad range of participants, those with chronic pain who considered themselves to be in the targeted group and able to benefit from the interventions could be reached. Accordingly, a strength of this study is the broad inclusion criteria that targeted chronic pain in general. Even though this reflects the persons targeted by the HLC, thus increasing the external validity of the study, the broad inclusion might also be a reason for not finding an effect, as there are ranges of conditions that can be the cause of chronic pain, which in turn may require different management strategies. It might thus be that all self-management strategies the participants potentially may benefit from are difficult to target specifically in a generic self-management course.

During the RCT, there was no usual care control group. Consequently, a possible reason for not finding a clear difference in the effect between the two groups could be that the control group activity had an effect equal to that of the self-management course. Physical activity and exercise are relevant chronic pain interventions that are believed to improve quality of life and functioning.[19] Walking has been found to be a feasible, acceptable and safe intervention for people with rheumatoid arthritis,[79] and it is recommended for people with chronic musculoskeletal pain.[22] In addition, tailored physical activity has been found to be promising for back or upper body pain,[80] whereas there is low to moderate evidence for the efficacy of walking related to the reduction of low back pain.[81] However, in the present study, there were no significant changes after three months (i.e. within group changes) to support a clear effect of the drop-in, low-impact physical activity.

Nevertheless, there were improvements in experienced pain during the previous week within both groups, indicating an effect on experiencing pain. This could either be due to the interventions or due to taking part in the trial. The question in the BPI that measured pain relief by analgesics showed a statistical significant difference between the groups; however, this BPI item is described as not useful in some studies, [82] and as the clinical relevance of the item in relation to a non-pharmacological intervention is uncertain, the finding is not further discussed. Nevertheless, there are studies on self-management interventions that have shown improvements in pain,[26, 77] indicating that such interventions could be the cause. For instance, according to Nicholas et al., the pain self-management course group reported

significantly less severe usual pain at the one-month follow-up compared to the exercise-attention control group,[26] and LeFort et al. showed that participants in a psychoeducation programme for chronic pain self-management had reduced bodily pain compared to a wait-list control group.[77] However, there have also been cases in which both the intervention and the usual care control group reported a reduction in pain.[28] As suggested by Mehlsen and colleagues,[28] improvement in pain might thus be due to natural fluctuations in symptoms or in the condition itself. Hence, to separate the effect of interventions and the effect of time, an additional observation group would be needed.

The HLCs aim to offer easily accessible services, providing interventions to support people in managing long-term conditions.[30] This is not something that is routinely measured. If it had been, the PAM applied in this study could have been used because it reveals participants' understanding of their roles in the care process and how competent they feel in assuming the roles.[11, 39] The baseline PAM score in this study was around 63, which is in the higher range. Because positive self-management behaviours at the baseline can result in no change in patient activation after interventions, maintaining a relatively high level of the behaviours over time can be viewed as a positive result.[83] This study indicates that self-management interventions delivered via easily accessible healthcare services may be a safe contribution to patients' efforts to self-manage chronic pain because there were few reported adverse events related to participation. However, no effect of the self-management course was found on any of the chosen outcomes when compared to the low-impact physical activity. This might be due to the intervention simply having very little or no effect; however, it may also be related to the time span from the intervention to the follow-up assessment. Increasing one's ability to self-manage chronic pain will most likely take time, and it might therefore be unrealistic to expect an effect after three months.

Conclusions

During this RCT, there was no support for the self-management course having a better effect after three months than drop-in, low-impact outdoor physical activity sessions offered the control group. It is still unclear whether the interventions can have long-term effects. This should be investigated further because the changing of perceptions towards pain most likely take time.

Abbreviations

CBT: Cognitive Behavioural Therapy; HLC: Health Life Centre; RCT: Randomised Controlled Trial; CONSORT: Consolidated Standards of Reporting Trials; ICPC-2: International Classification of Primary Care 2. Edition; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 Dimensions 5 Level; AIOS: Arizona Integrative Outcome Scale; SD: Standard Deviation; CI: Confidence Interval; IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

Declarations

Ethics approval and consent to participate

All informants signed an informed consent form after having received oral and written information to enable them to make an informed choice regarding participation. Approval for the trial was obtained from the director for health and social affairs in the municipality and from the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication

Not applicable.

Availability of data and materials

De-identified datasets are available from the corresponding author upon reasonable request.

Competing interest

The authors declare that they have no competing interests.

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Authors' contributions

THN, AS, OB and KG were responsible for the design of the study. THN performed the data collection, analysed the data and interpreted the results along with AS, OB and KG. THN drafted the manuscript. All authors provided input for the manuscript and read and approved the final version.

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Table 1. Outline of the self-management course

Session:	**Main topics:**
1	What is pain? Understanding the difference between acute and chronic pain. Elements from CBT in relation to pain. My everyday life and the everyday circle. Movement exercises; focusing on the jaw.
2	My challenges. What stops me in achieving what I want? Focus on problem solving. The thoughts' influence on everyday life. Elements from CBT. Movement exercises; focusing on easing of tension.
3	How to cope better in everyday life? Acceptance, self-efficacy, and sorting. Self-confidence, self-esteem, and self-image. Movement exercises; focusing on easing of tension using stretch and release, or hold and release.
4	Goal setting. How to make an action plan. Set smart goals for yourself. Movement exercises; focusing on different techniques for stretch and release.
5	"I can- I have a choice!" How to make good choices. How to manage pain more appropriate. Movement exercises.
6	The way ahead. Summarize the whole course. How will you use what you have learned? Information on activities at the HLC and in the municipality.

Table 2. Participants' characteristics at baseline.

Characteristics	ALL (N= 121)	INTV (n= 60)	CTRL (n= 61)
Female, n (%)	106 (87.6 %)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD), (range)	52.7 (11.7) (23- 74)	52.1 (11.4) (27- 71)	53.3 (12.1) (23- 74)
Living with someone, n (%)	86 (71.1 %)	43 (71.7 %)	43 (70.5 %)
Highest level of education, n (%)			
lower secondary school or less	8 (6.6 %)	4 (6.7 %)	4 (6.6 %)
upper secondary school	56 (46.3 %)	28 (46.7 %)	28 (45.9 %)
higher education (college or university)	57 (47.1 %)	28 (46.7 %)	29 (47.5 %)
Main reason for pain, n (%):			
musculoskeletal diseases, ICPC-2 chapter L	93 (76.9 %)	46 (76.7 %)	47 (77.0 %)
neuro system diseases, ICPC-2 chapter N	16 (13.2 %)	10 (16.7 %)	6 (9.8 %)
general and unspecified, ICPC-2 chapter A	12 (9.9 %)	4 (6.7 %)	8 (13.1 %)
Pain duration, n (%)			
7- 11 months	2 (1.7 %)	2 (3.3 %)	0 (0 %)
1- 5 years	24 (19.8 %)	12 (20.0 %)	12 (19.7 %)
6- 9 years	19 (15.7%)	11 (18.3 %)	8 (13.1 %)
≥ 10 years	76 (62.8 %)	35 (58.3 %)	41 (67.2 %)
More than one chronic condition, n (%)	76 (62.8 %)	32 (53.3 %)	44 (72.1 %)
Work status, n (%)			
working, full or part time	31 (25.6%)	13 (21.7 %)	18 (29.5 %)
disability pension, full or graded	56 (46.3 %)	33 (55 %)	23 (37.7 %)
sick leave, full or graded	20 (16.5 %)	8 (13.3 %)	12 (19.7 %)
retired	14 (11.6%)	6 (10.0 %)	8 (13.1 %)
Pain medication, n (%):			
prescription-only	51 (42.1 %)	23 (38.3 %)	28 (45.9 %)
without prescription	41 (33.9 %)	19 (31.7 %)	22 (36.1 %)
do not use pain medication	29 (24.0 %)	18 (30.0 %)	11 (18.0 %)
Healthcare utilization, last 3 months:			
visits general practitioner, mean (SD)	1.9 (1.9)	1.6 (1.7)	2.1 (2.0)
visits physiotherapist, mean (SD)	4.8 (6.3)	4.5 (5.9)	5.1 (6.8)
stays rehabilitation centre, mean (SD)	0.07 (0.3)	0.1 (0.3)	0.05 (0.2)
visits hospital outpatient clinic, mean (SD)	0.6 (1.1)	0.5 (0.9)	0.6 (1.3)
admission hospital, mean (SD)	0.1 (0.7)	0.2 (1.0)	0.02 (0.1)
number of days, mean (SD), (range)	0.1 (0.8) (0-8)	0.2 (1.2) (0-8)	0.02 (0.1) (0-1)

INTV: intervention group; CTRL: control group; ICPC- 2: International Classification of Primary Care, Second edition; SD: standard deviation

Table 3. Observed mean (SD) at baseline and 3 months, and estimated differences (95 % Confidence Intervals (CI)) within groups from baseline to 3 months and difference between groups at 3 months

		Observed		**Estimated**			
				Within groups Baseline to 3 months		Between groups 3 months	
	Group	Baseline mean(SD)	3 months mean (SD)	Diff (95 % CI)	*p*-value	Diff (95 % CI)	*p*-value
PAM-13	INTV	63.9 (13.2)	64.3 (14.3)	0.4 (-2.9 to 3.6)	0.829	-0.5 (-4.8 to 3.7)	0.802
(0-100) ↑	CTRL	63.0 (12.9)	64.2 (12.0)	0.9 (-2.3 to 4.0)	0.576		
BPI, severity	INTV	18.2 (6.5)	17.1 (7.2)	-1.1 (-2.6 to 0.5)	0.171	-0.6 (-2.6 to 1.5)	0.599
(0-10) ↓	CTRL	18.8 (5.6)	18.1 (7.7)	-0.5 (-2.1 to 1.0)	0.520		
BPI, interference	INTV	29.2 (14.0)	28.4 (13.9)	-1.5 (-5.1 to 2.1)	0.419	-0.3 (-5.1 to 4.6)	0.913
(0- 10) ↓	CTRL	32.6 (13.1)	30.1 (17.5)	-1.2 (-4.9 to 2.4)	0.516		
BPI, pain relief	INTV	3.4 (3.3)	4.0 (3.2)	0.6 (-0.1 to 1.2)	0.115	1.0 (0.01 to 1.9)	0.047
(0- 10) ↑	CTRL	3.5 (2.9)	3.0 (2.8)	-0.4 (-1.1 to 0.3)	0.268		
VAS, Pain last week	INTV	62.7 (18.2)	54.8 (20.2)	-7.9 (-13.1 to -2.7)	0.003	-1.4 (-8.0 to 5.3)	0.691
(0- 100) ↓	CTRL	62.8 (15.1)	56.1 (20.6)	-6.6 (-11.8 to -1.4)	0.014		
HADS, depression	INTV	4.4 (3.0)	4.6 (3.4)	0.1 (-0.6 to 0.8)	0.844	0.03 (-0.9 to 1.0)	0.955
(0- 21) ↓	CTRL	5.1 (3.1)	4.9 (3.7)	0.04 (-0.7 to 0.7)	0.902		
HADS, anxiety	INTV	7.8 (3.4)	7.5 (4.2)	-0.5 (-1.2 to 0.2)	0.159	-0.7 (-1.6 to 0.2)	0.147
(0- 21) ↓	CTRL	8.1 (3.6)	8.3 (3.7)	0.2 (-0.5 to 0.8)	0.558		
PSEQ	INTV	38.1 (10.5)	38.7 (12.0)	0.7 (-1.9 to 3.2)	0.594	1.7 (-1.7 to 5.1)	0.332
(0-60) ↑	CTRL	37.5 (10.4)	37.0 (11.7)	-1.0 (-3.5 to 1.5)	0.439		
SOC-13	INTV	61.4 (12.4)	62.1 (13.4)	0.6 (-1.6 to 2.8)	0.590	0.1 (-3.0 to 3.1)	0.972
(13- 91) ↑	CTRL	61.8 (13.0)	62.8 (12.7)	0.6 (-1.7 to 2.8)	0.623		
EQ-5D-5L	INTV	0.63 (0.14)	0.61 (0.16)	-0.01 (-0.04 to 0.02)	0.641	-0.04 (-0.1 to 0.01)	0.095
(0- 1) ↑	CTRL	0.61 (0.14)	0.64 (0.18)	0.02 (-0.003 to 0.06)	0.071		
AIOS	INTV	46.3 (21.3)	44.8 (18.9)	-1.0 (-6.6 to 4.6)	0.729	2.3 (-4.9 to 9.4)	0.531
(0- 100) ↑	CTRL	43.4 (18.5)	41.3 (19.5)	-3.3 (-8.8 to 2.3)	0.251		

Global health	INTV	2.1 (0.89)	2.4 (0.93)	0.2 (0.01 to 0.4)	0.032	0.2 (-0.1 to 0.4)	0.153
(1- 5) ↑	CTRL	2.2 (0.69)	2.2 (0.88)	0.02 (-0.2 to 0.2)	0.846		
Physical activity	INTV	4.0 (0.87)	4.0 (1.06)	0.1 (-0.1 to 0.3)	0.527	0.1 (-0.2 to 0.4)	0.557
(1- 5) ↑	CTRL	4.0 (1.02)	3.9 (0.73)	-0.01 (-0.2 to 0.2)	0.875		
30 s Chair to Stand	INTV	12.5 (4.1)	12.6 (5.6)	0.2 (-0.8 to 1.2)	0.660	-0.7 (-2.0 to 0.7)	0.353
↑	CTRL	11.5 (4.0)	12.7 (4.7)	0.9 (-0.1 to 1.9)	0.086		

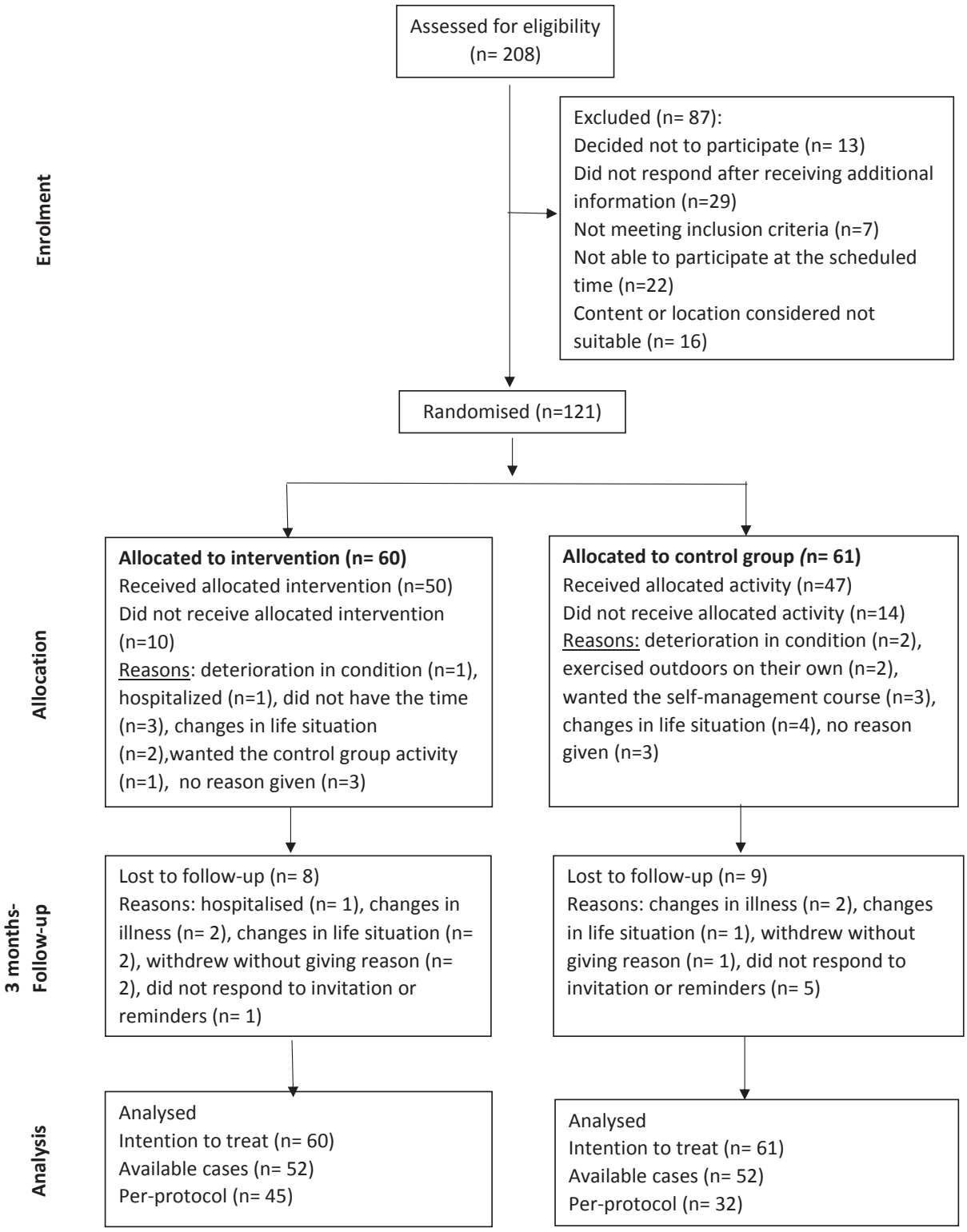
SD: Standard deviation; INTV: Intervention group; CTRL: Control group; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcome Scale.

Estimates presented are from linear mixed effects model (unadjusted) without random slope.

↑ Increase in scores indicates improvement.

↓ Decrease in scores indicates improvement.

The numbers of participants for each outcome at 3 months varied between 97- 104 due to some missing responses.


Enrolment
Assessed for eligibility (n= 208)
Excluded (n= 87):
Decided not to participate (n= 13)
Did not respond after receiving additional information (n=29)
Not meeting inclusion criteria (n=7)
Not able to participate at the scheduled time (n=22)
Content or location considered not suitable (n= 16)
Randomised (n=121)
Allocation
Allocated to intervention (n= 60)
Received allocated intervention (n=50)
Did not receive allocated intervention (n=10)
Reasons: deterioration in condition (n=1), hospitalized (n=1), did not have the time (n=3), changes in life situation (n=2),wanted the control group activity (n=1), no reason given (n=3)
Allocated to control group (n= 61)
Received allocated activity (n=47)
Did not receive allocated activity (n=14)
Reasons: deterioration in condition (n=2), exercised outdoors on their own (n=2), wanted the self-management course (n=3), changes in life situation (n=4), no reason given (n=3)
3 months-Follow-up
Lost to follow-up (n= 8)
Reasons: hospitalised (n= 1), changes in illness (n= 2), changes in life situation (n= 2), withdrew without giving reason (n= 2), did not respond to invitation or reminders (n= 1)
Lost to follow-up (n= 9)
Reasons: changes in illness (n= 2), changes in life situation (n= 1), withdrew without giving reason (n= 1), did not respond to invitation or reminders (n= 5)
Analysis
Analysed
Intention to treat (n= 60)
Available cases (n= 52)
Per-protocol (n= 45)
Analysed
Intention to treat (n= 61)
Available cases (n= 52)
Per-protocol (n= 32)

Paper III

Title

Twelve-month effect of chronic pain self-management intervention delivered in an easily accessible primary healthcare service - a randomised controlled trial

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Abstract

Aim: To investigate the effects related to patient activation and a range of secondary outcomes on persons with chronic pain of the easily accessible group-based chronic pain self-management course compared to a low-impact outdoor physical activity after twelve months.

Methods: An open, pragmatic, parallel group randomised controlled trial was conducted. The intervention group was offered a group-based chronic pain self-management course with 2.5-hour weekly sessions for a period of six weeks comprising education that included cognitive and behavioural strategies for pain management, movement exercises, group discussions and sharing of experiences among participants. The control group was offered a drop-in, low-impact, outdoor physical activity in groups in one-hour weekly sessions that included walking and simple strength exercises for a period of six weeks. The primary outcome was patient activation assessed using the Patient Activation Measure (PAM-13). Secondary outcomes included assessments of pain, anxiety and depression, pain self-efficacy, sense of coherence, health-related quality of life, well-being and the 30-second Chair to Stand Test. Analyses were performed using a linear mixed model.

Results: After twelve months, there were no statistically significant differences between the intervention group (n=60) and the control group (n=61) for the primary or the secondary outcomes. The estimated mean difference between the groups for the primary outcome PAM was 4.0 (CI 95 % -0.6 to 8.6, p= 0.085). Within both of the groups, there were statistically significant improvements in pain experienced during the previous week, global self-rated health measure and the 30-second Chair to Stand Test from the baseline to 12 months.

Conclusions: No long-term effect of the chronic pain self-management course was found in comparison with the low-impact physical activity intervention for the primary outcome patient activation or for any secondary outcome.

Trial registration: ClinicalTrials.gov: NCT02531282. Registered on 21 August 2015.

Keywords: Chronic pain, long-term effect, patient activation, primary health care, self-management

Background

Nearly one in five individuals (19 %) in the adult European population have chronic non-cancer pain [1, 2], and certain countries such as Norway, have an even higher prevalence (30%) [1, 3]. Chronic pain is usually referred to as persistent pain lasting for three months or more [4] with a majority of individuals reporting symptoms beyond one year [1, 5]. Chronic pain is characterised by extensive and fluctuating symptoms [5, 6] with a broad impact on quality of life [5], and thus it requires a range of strategies for self-management [7]. Self-management refers to one's ability to manage the chronic condition and its treatment, to adopt to physical and psychological changes and to adhere to lifestyle modifications [8]. For chronic pain, self-management strategies often refers to methods a person uses to limit the impact of pain on everyday life, moods and functions, both at home and work [9]. This typically includes activities such as physical activity [10], activity pacing [11], and a focus on how to use one's mind to manage pain [12].

As a crucial element to reducing the impact of chronic pain, at both the individual and the population levels, affected individuals must play a central role in the management of the pain and its associated consequences [9]. This includes both self-management activities performed by the individuals and healthcare services that aim to support patients apply self-management strategies [9, 13]. Interventions that support self-management emphasise the process of central self-management skills, such as self-efficacy development, self-monitoring, goal-setting and action planning, decision-making, problem-solving, self-tailoring and partnerships between the views of patients and health professionals [14]. Patient activation, which includes the knowledge, skills and confidence people have to manage their health, is a concept closely connected to self-management initiatives because self-management requires people to be empowered and to possess the necessary information, resources and skills to make decisions and to manage their health on a day-to-day basis [15]. Typically, the aim of self-management interventions is thus to empower people to be active partners in healthcare by providing information and skills to enhance the ability to self-manage health [16].

The processes of adopting to new self-care activities and developing self-management skills are likely to require time [17, 18]. The ability to self-manage can be described as a continuum, with individuals exhibiting varying levels of ability when new strategies must be practiced, which result in positive experiences to change perceptions towards pain [18]. Consequently, there is a need for knowledge related to pain self-management interventions' effects over time. To some degree, this has previously been investigated. In one review of

multidisciplinary biopsychosocial rehabilitation for chronic lower- back pain, small long-term improvements in pain and disability were observed [19]. Another review of osteoarthritis, for which pain is a common symptom, showed small benefits in terms of self-management skills, pain osteoarthritis symptoms and functions up to 21 months, although the clinical importance of these benefits was unclear [20]. Another review of chronic musculoskeletal pain showed minor or statistically insignificant differences after eight months of group-delivered self-management courses [21]. Thus, there is some evidence for the long-term benefits of chronic pain self-management interventions, although the evidence is inconsistent [22]. Accordingly, there is still a need for more research on the long-term effects of chronic pain self-management interventions [23].

Because changing perceptions and behaviours towards pain most likely require time, the effects of interventions should be investigated over different time spans. The authors have previously investigated the effect after three months (submitted for publication, described in [24]) of a group-based chronic pain self-management course delivered by an easily accessible healthcare service in primary care. The investigations did not reveal any statistically significant differences in favour of the self-management course compared to a low-impact physical group activity. Because a period of three months may be too short for participants to benefit from an intervention, the assessments of the effects of the self-management course also warranted a more long-term perspective.

The aim of this study was therefore to investigate the effects related to patient activation and a range of secondary outcomes on persons with chronic pain of the easily accessible group-based chronic pain self-management course compared to a low-impact outdoor physical activity after twelve months.

Methods

The study design was an open, pragmatic, parallel group, randomised controlled trial (RCT) conducted from August 2015 to December 2017. The protocol for the trial [24] has been published previously. There were no changes to the methods described in the protocol after the trial's commencement.

Ethics

The participants were informed about the trial both orally and in writing, and a written consent to participate was collected before enrolment. The Regional Committee for Medical

and Health Research Ethics in South East Norway approved this study (2015/ 1030/ REK sørøst). The trial was registered at Clinical Trials.gov in August 2015 (NCT02531282).

Setting

The trial setting was a Healthy Life Centre (HLC) in a major city in central Norway that serves a population of approximately 190,000 inhabitants. The HLCs are part of Norwegian public primary healthcare services. The services aim to reach persons of all ages at risk of developing, or those who already have developed, a non-communicable disease and who require help to change health behaviours and to manage health challenges [25]. People can attend HLC activities with or without a referral [26]. In line with the general self-management initiatives increasingly shifting from specialised healthcare services to primary healthcare services in Norway [27], the HLCs are gradually incorporating self-management support activities as part of their services.

Participants

The trial inclusion criteria were adults 18 years or older, with self-reported pain for three months or more who were able to take part in group discussions in Norwegian. In addition, they agreed to accept randomisation to one of the trial interventions after a full explanation of the trial. The exclusion criteria included an inability to participate in a low-impact physical activity for one hour, pain arising from malignant diseases, and lacking the capacity to consent.

Recruitment for the trial was communicated through posters and information leaflets distributed to general practitioners, physiotherapists, relevant departments at the hospital, Norwegian Labour and Welfare Administration offices and other relevant organisations in the municipality. Advertisements were placed in local newspapers, websites, social media and email invitations to patient organisations. Those interested in participating were encouraged to contact the first author by either phone or email. The first author checked the eligibility criteria, provided additional information about the trial and scheduled appointments for baseline assessments.

Description of the interventions

Both the self-management course and the low-impact, outdoor physical activity were developed by the HLC staff. There was no user fee for participation or any other financial support offered to the participants in either of the groups.

The self-management course

The chronic pain self-management course, developed locally by the HLC staff in cooperation with a patient organisation representative, aimed to increase the participants' knowledge, skills and confidence in managing everyday life with chronic pain [24]. The course was developed in accordance with the characteristics of such interventions [14], recommendations in the literature (e.g., [28-32]), the guidelines of the HLC [25], and personal experiences working with behavioural changes and the self-management of chronic conditions. Hence, the course addressed central self-management skills such as goal setting, action planning, and problem solving, and focussed on empowering the participants to play an active role in their healthcare. The chronic pain self-management course included education introducing cognitive and behavioural strategies for pain management [28-30, 32], pain theory, discussions of barriers in everyday life due to chronic pain, problem solving, goal setting and techniques to deal with fatigue, poor sleep, frustration and isolation. For the movement exercises concluding each session, principles from psychomotor physiotherapy were applied [31]. The purpose of the exercises was to improve balance, posture and breathing, and to provide participants with techniques to increase body awareness and their ability to relax. In addition, the course emphasised group discussions and sharing of experiences among participants.

The self-management course was delivered as a weekly 2.5-hour group session during the daytime (12.30 pm- 15.00 pm) for six weeks, for a total of 15 hours. Two dedicated employees with professional backgrounds as physiotherapists experienced in working with behavioural changes, coping and chronic pain facilitated the self-management course. One of the physiotherapists involved in developing and delivering the course was educated within psychomotor physiotherapy and had extensive experience from a multidisciplinary hospital pain clinic.

The guidelines regarding how to carry out the self-management course are available through the published protocol [24].

The control group activity

The low-impact physical outdoor activity offered to the control group was an existing activity at the HLC. This activity was chosen because it offered a group activity with an opportunity to meet others with similar health challenges and because physical activity have shown beneficial effects on chronic pain conditions [33-35]. The low-impact outdoor physical

activity was delivered as a weekly one-hour, drop-in session during the daytime (13.00 pm - 14.00 pm) for six weeks for a total of six hours. Two instructors familiar with physical exercise led the activity, which consisted of walking and simple strength exercises (e.g., squats and push-ups against a tree or a bench). A popular hiking trail was used for the activity. The participation was voluntarily, which is in line with the drop-in policy for this type of activity at the HLC. There was no educational information presented to the control group.

Procedure, randomisation and blinding

Following the baseline assessments, the participants were consecutively, individually and randomly allocated to one of the two trial arms using a computer-based Internet trial service provided by a third party (Unit for Applied Clinical Research at the Norwegian University of Science and Technology, NTNU). A 1:1 ratio and a stratification for gender were used. Those involved in the trial were blinded to the block sizes.

Immediately after the randomisation, the participants were informed of their allocation by either phone or by an email from the first author. The research assistant who conducted the physical ability test at the follow-up appointments was blinded to allocations; otherwise, it was an open study.

The outcomes were assessed at the baseline, and at three, six and twelve months after the completion of the intervention. The assessments after six and twelve months are reported here. At the baseline, the self-administrated questionnaire was completed with the first author available for questions. For the follow-up appointments, the questionnaires were collected when the participants met for the 30-second Chair to Stand Test.

Outcome measures

Participants' characteristics, such as gender, age, marital status, education, employment status, main reason for pain categorised according to the International Classification of Primary care-2 (ICPC-2) and whether the individual suffered more than two chronic conditions were collected at the baseline assessment. At the follow-ups, the participants were asked whether there were any changes to these characteristics. Healthcare utilisation was measured based on self-reported visits to general practitioners, physiotherapists and hospitals or rehabilitation centres during the previous three months.

Primary outcome

The chronic pain self-management course was hypothesised to strengthen the participants' engagement in and knowledge of available health resources, which consequently was

expected to lead to a higher level of patient activation. Thus, patient activation was chosen as the main outcome [24], and was measured using the Patient Activation Measure, PAM-13 [36]. The PAM-13 contains 13 statements to which the participants indicate their level of agreement on a four-point Likert scale, from 1= 'strongly disagree' to 4= 'strongly agree' with an additional 'not applicable' option. The raw score is transformed to a total score ranging from 0 to 100 [37], with higher scores indicating that the individual is more activated to adopt and to maintain healthy behaviours and self-management strategies for their illness, even under stress [38]. When participants answered that a statement was not applicable to them, the data was treated as missing. A total score was generated if participants answered at least 10 of the 13 statements [37].

The PAM-13 scores can be divided into four levels of activation [36]. Level 1 (score 0.0-47.0) indicates that a person may not yet understand that the patient's role is important. Level 2 (score 47.1- 55.1) indicates a lack of confidence and knowledge to take action. Level 3 (score 55.2- 72.4) indicates that a person is beginning to engage in recommended health behaviours, whereas level 4 (score 72.5- 100.0) indicates that a person is proactive regarding their health and engages in several recommended health behaviours [39, 40]. Patient activation levels have been used in studies as cut-off values to stratify participants and to investigate the effects of interventions in accordance with the different levels [39, 41, 42].

The PAM-13 is considered useful for assessing patient engagement in the management of chronic illness, including chronic pain, and for assessing sensitivity to changes in several groups and populations [36, 38, 43]. The measure has been translated into Norwegian (Cronbach's alpha 0.91) [44]. Studies have shown that the Norwegian version of the measure is valid and reliable when tested for patient education interventions in a Norwegian hospital [44], in a RCT of hospital out-patient self-management education for patients with polyarthritis (Cronbach's alpha 0.80) [45] and in a RCT of mental health treatment (Cronbach's alpha= 0.87) [41]. In this study, the Cronbach's alpha at the baseline was 0.75.

Secondary outcomes

Several secondary outcomes were chosen in consideration of the recommendations from the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) [46, 47], systematic reviews on self-management [16, 21, 22, 48] and findings from studies on persons with chronic pain and self-management (e.g., [45, 49, 50]).

Experiencing chronic pain was the main inclusion criteria. Therefore, pain severity and pain interference were assessed using the Brief Pain Inventory (BPI) [51].The instrument includes four questions related to severity and seven questions regarding interference, and all items are rated on 0- 10 scales, with 10 being pain as bad as one can imagine, or pain that interferes completely. In addition, the instrument includes one item that asks about the percentage of pain relief with the use of analgesics [51]. The instrument has been translated to Norwegian (Cronbach's alpha 0.87 for pain severity and 0.92 for the interference scale) [52] and has been used in Norwegian studies of a multidisciplinary pain management programme [53] and among patients with osteoarthritis (Cronbach's alpha >0.80) [54]. In the current study, the Cronbach's alpha at the baseline was 0.81 for pain severity and 0.86 for pain interference.

The experience of pain during the previous week was assessed using a one-item 100 mm Visual Analogue Scale (VAS) [55]. The participants were asked to draw a vertical mark on the 100 mm line indicating their average pain during the previous week. The scale's anchoring points were no pain (0) and intolerable pain (100). The VAS has been validated and found to be reliable in the assessment of chronic pain [55].

Psychological distress is commonly reported among individuals suffering chronic pain [2, 5], which makes psychological distress a relevant domain to assess. Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS), which consists of 14 items divided into two subscales, with seven items each for depression and anxiety [56]. Each item is rated from not experiencing symptoms (0) to experiencing symptoms nearly all the time (3). This instrument has shown good validity and reliability for patients with musculoskeletal pain (Cronbach's alpha for the anxiety subscale 0.83 and for the depression subscale 0.84) [57] as well as in a Norwegian large population study (HUNT) (Cronbach's alpha 0.80 for the anxiety subscale and 0.76 for the depression subscale) [58]. In the current study, the Cronbach's alpha at the baseline was 0.73 for the depression subscale and 0.76 for the anxiety subscale.

Self-efficacy is a concept closely linked to patient activation that concerns the confidence people have that they can successfully execute a course of action to accomplish a desired outcome in a given situation [59]. This was measured using the Pain Self-Efficacy Questionnaire (PSEQ), which specifically assesses beliefs regarding one's ability to accomplish various activities, despite the pain [60]. The PSEQ includes 10 items that respondents rate on a scale from 0 to 6 regarding how confident they are that they can perform an activity at present despite pain, where 6 equals completely confident [60]. This scale has

shown good psychometric qualities (Cronbach's alpha 0.92) [60] and has been translated for use in a Norwegian study (Cronbach's alpha not reported) [61]. In the current study, the Cronbach's alpha at the baseline was 0.84.

To experience a sense of coherence has been suggested to be a suitable coping strategy for people with chronic musculoskeletal pain [62]. A sense of coherence is often related to salutogenesis, which is fundamental to the activities at the HLC [25]. Therefore, this was perceived to be a relevant aspect to measure, and the Sense of Coherence (SOC) scale [63] was included as an outcome measure. The 13 items of the scale measure the perception of the environments' comprehensibility, manageability and meaningfulness, with each item scored using a range from 1 to 7. The score of each item is summed to a total score, with a range from 13- 91. The higher the score, the stronger the sense of coherence. The SOC scale has been found to be a reliable, valid and cross-culturally applicable instrument that measures how people manage stressful situations and stay well (Cronbach's alpha in 127 studies 0.70-0.92) [63]. The Norwegian version of the SOC-13 has been used in a study of patients with long-term musculoskeletal pain (Cronbach's alpha not reported) [64] and in a study on multidisciplinary rehabilitation for patients with chronic musculoskeletal pain (Cronbach's alpha 0.83) [65]. In the current study, the Cronbach's alpha at the baseline was 0.87.

Living with chronic pain often affects people's health-related quality of life [66], and the self-management course included discussions regarding how to manage an everyday life with chronic pain. The generic health-related quality of life was assessed using the EuroQoL (EQ-5D-5L) [67]. This instrument provides five levels to answer each of the dimensions, which include mobility, self-care, usual activities, pain/ discomfort, and anxiety/ depression [68]. The descriptive score was converted to an index value of health status using the Danish value set, giving a range from 1 (perfect health) to 0 (death) [67, 68]. The instrument has been validated in similar populations [69], as well as in a Norwegian context (Cronbach's alpha 0.69) [70]. In the current study, the Cronbach's alpha at the baseline was 0.55.

In addition to the assessment of health-related quality of life, the participants' experiences related to global well-being during the previous month was assessed using the Arizona Integrative Outcomes Scale (AIOS) by means of a one-item 100 mm long VAS [71]. The question asked was 'Reflect on your sense of well-being during the last month. Take into account your physical, mental, emotional, social and spiritual condition, and mark the line for your summarised overall sense of wellbeing'. The scale's anchoring points were 'worst you have ever been' (0) and 'best you have ever been' (100) [71]. The AIOS has been found to be

a valid measure for assessing well-being [71], and it has previously been used in a Norwegian study [45].

In addition, the participants' global self-rated health was assessed using the question 'By and large, would you say that your health is:' followed by the options 'poor', 'not so good, 'good', 'very good' and 'excellent'. This question is similar to a question asked in a major population study in Norway [72].

Because chronic pain can affect physical functioning and physical exercise has been shown to have beneficial effects on chronic pain [33, 34], two questions were included related to physical functioning. First, physical activity was assessed based on the average number of times participants exercised per week using the question: 'How often do you exercise on average? (exercise refers to walking, skiing, swimming and working out/ sports)' followed by the options 'never', 'less than once a week', 'once a week', '2-3 times a week' and 'nearly every day'. This question was used in a major population study in Norway [72] and in investigations of associations between exercise and chronic pain [73]. Second, as an objective measure of physical ability, the 30-second Chair to Stand Test was used to measure lower body strength [74]. This test has been validated for a wider population [75].

Sample size

The findings of a RCT investigating the effect of a patient education programme for patients with polyarthritis in which the PAM was one of the secondary outcomes was applied to calculate the sample size [45]. Thus, the sample size was calculated to detect a clinically important difference, defined as six points on the PAM-13 from the baseline to the 12-month follow-up. A linear mixed model was used assuming the correlation among the participants to be 0.5, with a standard deviation (SD) of 13 [45]. The significance level was set to 5 %, and the power was set to 80 %, which yielded a number of 55 participants for each trial arm. Allowing five dropouts in each trial arm, the aim was to recruit 120 participants.

Statistics

All the outcome measures were found to be approximately normally distributed. The confidence level was set at 95 %, and the predefined cut-off level for statistical significance was set at $p \leq 0.05$. No interim analysis was performed.

The effect of the intervention was assessed using intention to treat (ITT) and per-protocol (PP) analyses. The PP criterion was that participants had been present for a minimum of three

of the six sessions. The PP analyses provided similar findings and did not change any conclusions regarding the interventions. Thus, they are not further discussed.

The results report on the between group differences used to investigate the effect of the intervention from the baseline to12 months. Furthermore, the within group changes are reported from the baseline to six and 12 months to describe the changes that occurred within the groups at the follow-ups.

Analyses of the primary and secondary outcomes were performed using a linear mixed model. The participants' identification number (ID) was specified as a random effect to allow participants to begin at different levels of the outcome in question. The effects of intervention and time were specified as fixed with the following values: 1) 'baseline', 2) 'control 6 months', 3) 'intervention 6 months', 4) 'control 12 months' and 5) 'intervention 12 months', acknowledging that differences between groups at the baseline were due to chance. The missing data were managed using the mixed linear model. The regression assumptions were checked [76], resulting in satisfactory values. The analyses of the estimated changes from the baseline to six months and from the baseline to 12 months were performed separately.

Changes in the work status, and pain medication (categorical data) since the last assessment were analysed using Pearson's Chi-Square test or Fisher's exact test. The frequency of healthcare utilisation during the previous three months was compared between the groups using t tests.

One exploratory post-hoc subgroup analysis was performed to investigate whether changes in the primary outcome (PAM-13) varied according to patient activation levels at the baseline. The reason for performing this analysis was that there was a discussion after the study began regarding which groups of participants the course could possibly be best suited for, partly due to a qualitative study based on interviews about expectations towards the intervention with a selection of the participants in the RCT [77]. Because there were few participants at the lowest patient activation levels, patient activation levels 1 and 2 were combined, creating three subgroups. A linear regression analysis was performed to test for an interaction between the baseline patient activation level and allocation. The dependent variable was the change in PAM-13 from the baseline to twelve months. The independent variables were the PAM-13 level at the baseline and allocation (intervention or control group).

The first author performed the analyses, which were overseen and discussed with the co-authors and a statistician. All the analyses were performed using Stata Statistical Software (Release 14; StataCorp LP, 2014, College Station, TX, USA).

Results

Participant flow

The flow of the participants through the trial is shown in Figure 1. Of the 208 people contacting the trial, 121 participants were included and randomised to either the chronic pain self-management course group (n= 60) or the low-impact physical activity group (n= 61). The number of participants who answered the questionnaires at the follow-ups were equally distributed to the trial arms, and 100 participants completed the final follow-up (83 %).

PLEASE INSERT FIGURE 1 ABOUT HERE

Figure 1. Participants flow through the study

Baseline characteristics

The groups were comparable at the baseline. They consisted of mostly women (88 %), the mean age was 53 years (SD= 11.7, range= 23- 74) and the majority (71%) lived with someone (Table 1). Six of ten (63 %) had experienced pain for 10 years or more. Musculoskeletal diseases were reported as the main reason for the pain (77 %), and more than half of the participants (63 %) had chronic conditions in addition to chronic pain, such as diabetes and chronic respiratory diseases. The baseline characteristics of the participants are presented in Table 1.

PLEASE INSERT TABLE 1 ABOUT HERE.

Implementation of interventions

In total, six self-management course groups and six low-impact physical activity groups were delivered between September 2015 and December 2016 with 7- 13 participants in each group. Ten participants (17 %) did not attend the self-management courses, while 14 (23 %) did not participate in the control group activities. Those allocated to the self-management course attended 4.2 of the six sessions on average, and 45 participants (75 %) attended half or more of the sessions. The participants allocated to the low-impact physical activity groups attended, on average, 2.7 of the 6 sessions, and 32 participants (52 %) attended half or more of the sessions.

In the intervention group, two adverse events were reported during the sessions; one participant had an anxiety attack, and one participant reported benign paroxysmal positional vertigo after performing one of the movement exercises. In the control group, there was one adverse event in which a participant pulled a leg muscle during a walk. The symptoms of all of the reported events disappeared within a short time, and no adverse events were reported thereafter.

Outcome

The observed mean scores at 12 months for the primary outcome, PAM-13, were 66.7 for the intervention group and 62.2 for the control group (Table 2). The estimated mean difference between the groups was 4.0 (CI 95 % -0.6 to 8.6, $p= 0.085$), which was was not statistically significant at the $p\leq 0.05$ level.

PLEASE INSERT TABLE 2 ABOUT HERE

There was no statistically significant change from the baseline to 12 months for PAM-13 within the groups, either for the intervention (estimated mean change 3.1, CI 95 % -0.4 to 6.5, $p= 0.081$) or the control group (estimated mean change -1.0, CI 95 % -4.5 to 2.5, $p= 0.585$). There was a statistically significant change from the baseline to six months with improvement in patient activation for the intervention group (estimated mean change 4.0, CI 95 % 0.4 to 7.5, $p= 0.027$) but not in the control group (estimated mean change 1.4, CI 95 % -2.2 to 5.0, $p= 0.445$).

For the secondary outcomes, there were no statistically significant differences between the groups at the 12-month follow-up.

From the baseline to six-months, there were statistically significant changes within both groups with an improvement in the experience of pain during the previous week and on the global self-rated health measure. Within both groups, there were statistically significant changes from the baseline to 12 months with an improvement in pain experienced during the previous week measured by the VAS (intervention: -7.0, CI 95 % -12.5 to -1.4, $p= 0.014$; control: -6.5, CI 95 % -12.2 to -0.8, $p= 0.026$), for the global self-rated health measure (intervention: 1.4, CI 95 % 1.2 to 1.7, $p< 0.001$; control: 1.6, CI 95 % 1.3 to 1.8, $p <0.001$) and the 30-second Chair to Stand Test (intervention: 2.2, CI 95 % 1.4 to 3.1, $p < 0.001$; control: 2.8, CI 95 % 1.9 to 3.6, $p< 0.001$).

At the 12-month follow-up, there was no statistically significant differences between the groups in work status or in pain medication (approximately four out of five participants without changes in both groups) (data not shown). The changes in the use of healthcare services were only minimal and no difference between the groups for either of these variables was found.

The exploratory post-hoc sub-group analysis showed that the mean change in PAM-13 from the baseline to twelve months increased for those with the two lowest levels of patient activation (level 1 and 2); 10.8 points for the intervention group and 9.2 points for the control group. There were only minor changes for those at patient activation level 3 (1.0 point for the intervention group and -0.6 point for the control group). For those with the highest activation level at the baseline (level 4), there was a decrease in the control group of -12.2 points, but only minor changes in the intervention group (-1.5 points). The test result for an overall interaction effect between the patient activation level at the baseline and allocation was not significant (p= 0.623).

Discussion

After twelve months, there were no statistically significant differences between the intervention group and the control group either for the primary outcome patient activation, or for any of the secondary outcomes. Within both of the groups, there were statistically significant changes related to an improvement in pain experienced during the previous week, the self-rated health measure and the 30-second Chair to Stand Test from the baseline to twelve months.

As outlined, PAM-13 is a suitable primary outcome for measuring activation in self-management support interventions [78, 79]; however, at present, there is no consensus regarding a cut-off level to represent a meaningful change in the PAM-13. A study on patient education in a hospital setting in Norway, which showed a statistically significant improvement in PAM-13 on six points [45], informed the sample size calculation in the present study. Fowles and colleagues on the other hand suggested that a five-point difference in the PAM can be interpreted as a meaningful difference in PAM scores [80], whereas Turner and colleagues defined a meaningful improvement in the patient activation as four points on the PAM-13 scale [43]. Thus, the estimated mean difference of four points found in this study is at best on the borderline of being a clinically relevant difference, although the finding was not statistically significant.

A possible reason for not finding an effect could be that the self-management skills and strategies introduced by the course did not result in changes that motivated the participants to include them as part of their pain management. Nicholas *et al*. [81] found that those who adhered regularly to self-management strategies presented by a multidisciplinary pain management programme (e.g., goal-setting, activity pacing, thought management and stretch exercises), had better outcomes one year later in comparison with those who adhered to them inconsistently or rarely during the programme. The average attendance for the self-management course was on average 4.2 of six sessions, and 75 % of the participants attended half or more of the sessions; however, attendance is a poor proxy measure for adherence to behavioural changes [9]. The extent to which the participants practiced the strategies presented by the self-management course both during the course and after the course is unknown. Hence, the participants may not have practiced the self-management strategies presented by the course, and if they did not, an effect could consequently be difficult to identify.

Furthermore, there were no organised follow-ups after the intervention, meaning that there was no additional support for the participants to maintain behavioural changes. New strategies should be practiced and should result in positive experiences in order to change perceptions towards pain [18]. The role of health professionals can be relevant [9], as it is most likely those who experience that they do not succeed in managing their pain who reach out to health professionals for support, advice and guidance [9, 16]. Because clinical practice guidelines for chronic pain recommend self-management along with other treatments [9, 22], it could be that combining a self-management course with other interventions in parallel with or over time, would enhance the participants ability to self-manage chronic pain[18].

During the follow-up, there were improvements within each of the groups for the global self-rated health measure, the 30-second Chair to Stand Test and pain experienced during the previous week. As the intervention addressed persons with chronic pain, the changes in pain experienced by the participants is of particular interest. The intervention group had an estimated change after 12 months in experienced pain indicating an improvement of approximately 11.5 % (from 62.7 to 55.5), which is less than what has been considered minimal or little change when using VAS to measure pain (15- 20 %) [82]. No statistically significant improvements were found based on the assessments of pain severity and pain interference using the Brief Pain Inventory (BPI). Thus, it is not likely that the intervention had a clinical meaningful effect on pain experience.

Given the variations in types of pain, diagnoses and associated challenges for those with chronic pain as well as the different environmental and treatment contexts, there is unlikely to be a single self-management method or strategy suitable for all [9]. Based on the explorative post-hoc sub-group analyses an improvement was observed from the baseline to 12 months for those at the lowest activation levels regardless of allocation, whereas those at the highest patient activation levels had a decrease in their PAM-13 score; however, more so in the control group than in the intervention group. As this was an explorative analysis and the test result for interaction between patient activation levels and allocations was not significant, no conclusions can be drawn. Some RCTs have shown that those at the lower patient activation levels have benefited the most from a web-based intervention for adults with chronic conditions [42] and self-referrals to a mental health treatment [41]. Moreover, a study on self-management courses provided by the Expert Patients Programme in the UK showed the programme to have a protective effect on health-related quality of life for those with low confidence compared to those who scored better for self-efficacy and confidence [83]; however, a Finnish RCT on the effect of a patient portal with electronic messaging showed that those with the highest patient activation level at the baseline experienced the greatest effect from the intervention [84].

This diversity of effects indicates that it might be a connection between baseline patient activation-levels and the type of self-management intervention. One hypothesis could be that some interventions are better suited for those at certain activation levels. However, based on the description of the interventions in the studies referenced above, it is difficult to characterise the contents as advanced or not. Nevertheless, the observations of this study along with findings from other studies provide intriguing considerations and raise interesting questions that should be investigated further. For instance, could the type of activities investigated in the current study be especially suited for the target group of the HLCs, meaning those who need help to change health behaviours and manage health challenges, and more specifically, those in the lower patient activation levels?

Strength and limitations

The main strengths of this study is the RCT design. In addition, it is one of few studies to have evaluated the effect of a self-management intervention developed locally at an HLC.

The characteristics of the participants in the present study limits the generalisability of the findings. For example, people with chronic pain who experience major psychological or

physical implications related to their pain condition, and are thus in need of more extensive interventions, were not included.

It cannot be ruled out that other outcome measures would have been more sensitive to an effect from the intervention, but this is not very likely given the wide range of outcome measures covering domains recommended for chronic pain studies [82] and self-management [16, 22, 48]; however, some factors central to the participants might not have been covered because in a qualitative study with a sample of the participants from this RCT it was found that hope and social support were central expectations towards participation in the interventions [77]. The number of participants who completed the questionnaires decreased gradually throughout the trial despite efforts to encourage participants to attend the follow-up appointments, and thus the number of observations at follow-up was less than the sample size calculation. The sub-group analysis, which was an exploratory post-hoc analysis, should ideally have been pre-planned. If the overall interaction between the sub-groups and allocations had been significant, the results would have been considered less reliable than those from the main analyses.

Conclusion

In this study, no long-term effect of the chronic pain self-management course was found compared with a low-impact physical activity intervention delivered via an easily accessible service on the primary outcome patient activation or on any of the secondary outcomes. To understand more of how the intervention was perceived, the participants' experiences related to the intervention should be further investigated.

Abbreviations

CBT: Cognitive Behavioural Therapy; HLC: Health Life Centre; RCT: Randomised Controlled Trial; CONSORT: Consolidated Standards of Reporting Trials; ICPC-2: International Classification of Primary Care 2. Edition; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 Dimensions 5 Level; AIOS: Arizona Integrative Outcome Scale; SD: Standard Deviation; CI: Confidence Interval; IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

Declarations

Ethics approval and consent to participate

All informants signed an informed consent form after receiving oral and written information to enable them to make an informed choice regarding participation. The trial was approved by

the director for health and social affairs in the municipality, and by the Regional Committee for Medical and Health Research Ethics (REK) (2015/ 1030/ REK sørøst).

Consent for publication

Not applicable.

Availability of data and materials

De-identified datasets are available from the corresponding author on reasonable request.

Competing interest

The authors declare that they have no competing interests.

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Authors' contributions

THN, AS, OB, and KG were responsible for the design of the study. THN performed the data collection, analysed the data, and interpreted the results along with AS, OB and KG. THN drafted the manuscript. All authors provided input for the manuscript, and read and approved the final version.

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Table 1. Baseline characteristics of participants

Characteristics	ALL (N= 121)	INTV (n= 60)	CTRL (n= 61)
Female, n (%)	106 (87.6 %)	53 (88.3 %)	53 (86.9 %)
Age years, mean (SD), (range)	52.7 (11.7) (23- 74)	52.1 (11.4) (27- 71)	53.3 (12.1) (23- 74)
Living with someone, n (%)	86 (71.1 %)	43 (71.7 %)	43 (70.5 %)
Highest level of education, n (%)			
lower secondary school or less	8 (6.6 %)	4 (6.7 %)	4 (6.6 %)
upper secondary school	56 (46.3 %)	28 (46.7 %)	28 (45.9 %)
higher education (college or university)	57 (47.1 %)	28 (46.7 %)	29 (47.5 %)
Main reason for pain, n (%):			
musculoskeletal diseases, ICPC-2 chapter L	93 (76.9 %)	46 (76.7 %)	47 (77.0 %)
neuro system diseases, ICPC-2 chapter N	16 (13.2 %)	10 (16.7 %)	6 (9.8 %)
general and unspecified, ICPC-2 chapter A	12 (9.9 %)	4 (6.7 %)	8 (13.1 %)
Pain duration, n (%)			
7- 11 months	2 (1.7 %)	2 (3.3 %)	0 (0 %)
1- 5 years	24 (19.8 %)	12 (20.0 %)	12 (19.7 %)
6- 9 years	19 (15.7%)	11 (18.3 %)	8 (13.1 %)
10 years or more	76 (62.8 %)	35 (58.3 %)	41 (67.2 %)
More than one chronic condition, n (%)	76 (62.8 %)	32 (53.3 %)	44 (72.1 %)
Work status, n (%)			
working, full or part time	31 (25.6%)	13 (21.7 %)	18 (29.5 %)
disability pension, full or graded	56 (46.3 %)	33 (55 %)	23 (37.7 %)
sick leave, full or graded	20 (16.5 %)	8 (13.3 %)	12 (19.7 %)
retired	14 (11.6%)	6 (10.0 %)	8 (13.1 %)
Pain medication, n (%):			
prescription-only	51 (42.1 %)	23 (38.3 %)	28 (45.9 %)
without prescription	41 (33.9 %)	19 (31.7 %)	22 (36.1 %)
do not use pain medication	29 (24.0 %)	18 (30.0 %)	11 (18.0 %)
Healthcare utilization, last 3 months:			
visits general practitioner, mean (SD)	1.9 (1.9)	1.6 (1.7)	2.1 (2.0)
visits physiotherapist, mean (SD)	4.8 (6.3)	4.5 (5.9)	5.1 (6.8)
stays rehabilitation centre, mean (SD)	0.07 (0.3)	0.1 (0.3)	0.05 (0.2)
visits hospital outpatient clinic, mean (SD)	0.6 (1.1)	0.5 (0.9)	0.6 (1.3)
admission hospital, mean (SD)	0.1 (0.7)	0.2 (1.0)	0.02 (0.1)
number of days, mean (SD), (range)	0.1 (0.8) (0-8)	0.2 (1.2) (0-8)	0.02 (0.1) (0-1)
PAM-13 level at baseline	N= 119	n= 58	n= 61
Level 1	16 (13.4%)	9 (15.5%)	7 (11.5%)
Level 2	12 (10.1%)	3 (5.2%)	9 (14.8%)
Level 3	61 (51.3%)	32 (55.2%)	29 (47.5%)
Level 4	30 (25.2%)	14 (24.1%)	16 (26.2%)

INTV: intervention group; CTRL: control group; ICPC- 2: International Classification of Primary Care, Second edition; PAM-13: Patient Activation Measure 13

Table 2. Observed mean (SD) at baseline, 6 months and 12 months. Estimated differences (95 % Confidence Interval (CI)) within groups from baseline to 6 months and from baseline to 12 months, and differences between groups at 12 months

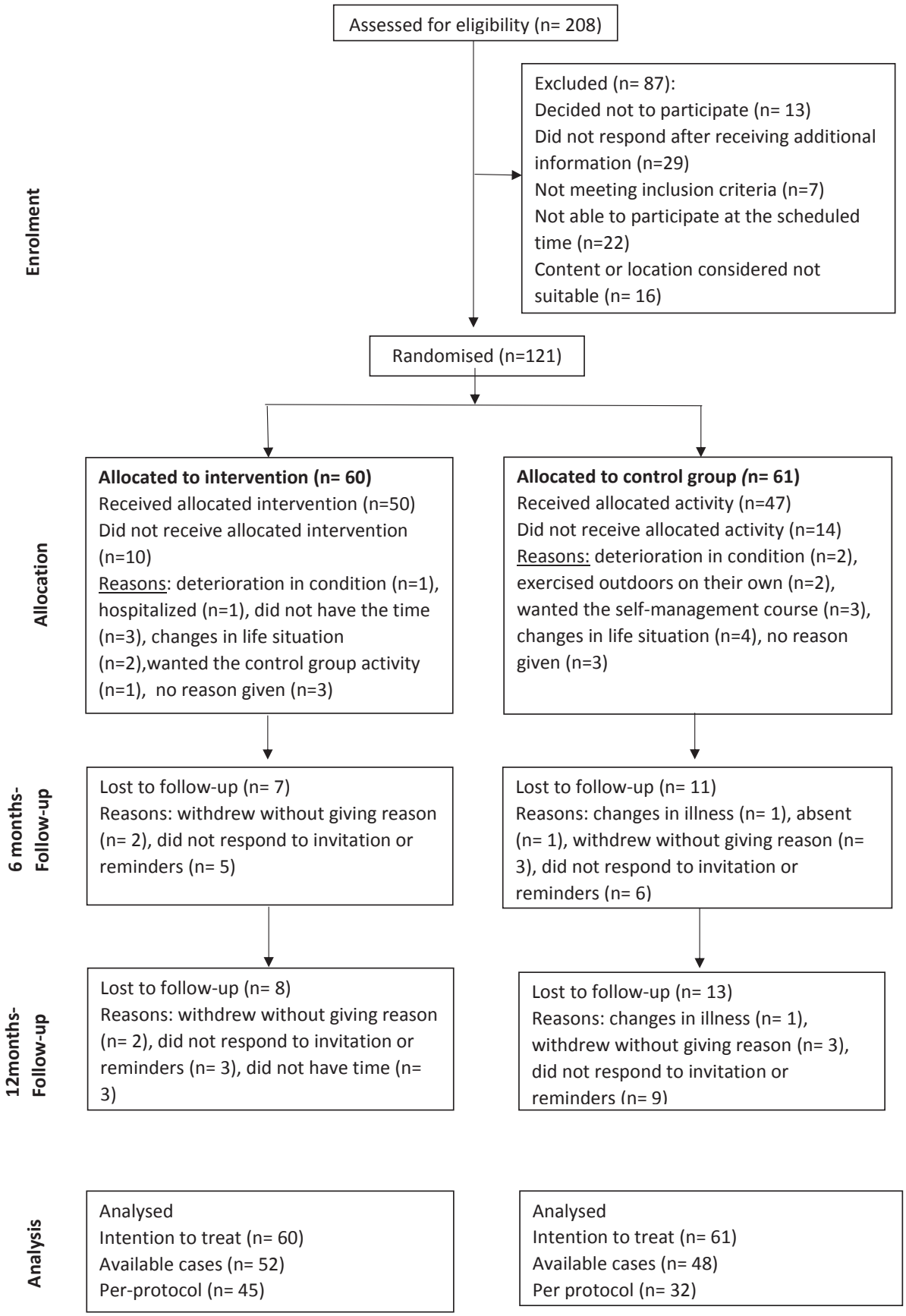
		Observed			**Estimated**					
					Within groups Baseline to 6 months		Within groups Baseline to 12 months		Between groups 12 months	
	Group	Baseline mean(SD)	6 months mean (SD)	12 months mean (SD)	Diff (95 % CI)	*p*-value	Diff (95 % CI)	*p*-value	Diff (95 % CI)	*p*-value
PAM-13 (0-100) ↑	INTV	63.9 (13.2)	67.7 (14.5)	66.7 (14.3)	4.0 (0.4 to 7.5)	0.027	3.1 (-0.4 to 6.5)	0.084	4.0 (-0.6 to 8.6)	0.085
	CTRL	63.0 (12.9)	64.9 (12.4)	62.2 (10.0)	1.4 (-2.2 to 5.0)	0.445	-1.0 (-4.5 to 2.6)	0.587		
BPI, severity (0-40) ↓	INTV	18.2 (6.5)	17.4 (7.4)	17.4 (6.8)	-0.8 (-2.4 to 0.8)	0.320	-0.5 (-1.8 to 0.9)	0.486	0.6 (-1.3 to 2.4)	0.526
	CTRL	18.8 (5.6)	18.1 (6.6)	17.4 (6.1)	-0.5 (-2.1 to 1.1)	0.550	-1.1 (-2.5 to 0.3)	0.124		
BPI, interference (0- 70) ↓	INTV	29.2 (14.0)	27.9 (16.0)	25.9 (14.5)	-1.6 (-5.2 to 2.0)	0.379	-3.3 (-6.7 to 0.1)	0.061	-2.6 (-7.3 to 2.0)	0.269
	CTRL	32.6 (13.1)	30.8 (15.0)	31.0 (15.0)	-0.5 (-4.3 to 3.2)	0.779	-0.6 (-4.2 to 2.9)	0.728		
BPI, pain relief (0- 10) ↑	INTV	3.4 (3.3)	4.0 (2.8)	6.3 (14.5)	0.6 (-0.2 to 1.4)	0.134	2.9 (0.5 to 5.2)	0.017	2.9 (-0.1 to 5.8)	0.055
	CTRL	3.5 (2.9)	3.4 (2.9)	3.4 (2.9)	-0.1 (-0.9 to 0.8)	0.894	-0.003 (-2.4 to 2.4)	0.998		
VAS, pain (0- 100) ↓	INTV	62.7 (18.2)	53.9 (21.5)	55.5 (23.6)	-8.7 (-14.2 to -3.3)	0.002	-7.0 (-12.5 to -1.4)	0.014	-0.5 (-7.6 to 6.7)	0.901
	CTRL	62.8 (15.1)	56.1 (19.3)	56.0 (19.6)	-6.5 (-12.1 to -1.0)	0.021	-6.5 (-12.2 to -0.8)	0.026		
HADS, depression (0- 21) ↓	INTV	4.4 (3.0)	4.8 (3.9)	4.8 (3.5)	0.4 (-0.4 to 1.1)	0.329	0.3 (-0.5 to 1.0)	0.468	0.3 (-0.7 to 1.3)	0.525
	CTRL	5.1 (3.1)	5.1 (3.7)	5.0 (3.6)	0.2 (-0.6 to 1.0)	0.672	-0.1 (-0.8 to 0.7)	0.883		
HADS, anxiety (0- 21) ↓	INTV	7.8 (3.4)	7.1 (4.5)	7.2 (4.3)	-0.7 (-1.4 to 0.002)	0.051	-0.6 (-1.3 to 0.2)	0.132	0.1 (-0.9 to 1.2)	0.798
	CTRL	8.1 (3.6)	7.8 (3.7)	7.5 (3.1)	-0.5 (-1.3 to 0.2)	0.163	-0.7 (-1.5 to 0.1)	0.072		
PSEQ (0-60) ↑	INTV	38.1 (10.5)	39.1 (12.8)	39.1 (12.1)	1.0 (-1.5 to 3.3)	0.452	0.5 (-1.9 to 3.0)	0.678	1.5 (-1.9 to 4.9)	0.387
	CTRL	37.5 (10.4)	37.6 (10.8)	37.2 (11.2)	-0.7 (-3.2 to 1.7)	0.554	-1.0 (-3.5 to 1.6)	0.453		
SOC-13 (13- 91) ↑	INTV	61.4 (12.4)	62.8 (15.2)	63.4 (15.5)	1.1 (-1.4 to 3.5)	0.401	1.1 (-1.4 to 3.5)	0.393	0.5 (-2.9 to 3.9)	0.771
	CTRL	61.8 (13.0)	63.7 (12.9)	62.1 (12.4)	1.5 (-1.0 to 4.0)	0.231	0.6 (-1.9 to 3.0)	0.657		
EQ-5D-5L (0- 1) ↑	INTV	0.63 (0.14)	0.64 (0.16)	0.63 (0.15)	0.02 (-0.01 to 0.05)	0.174	0.002 (-0.03 to 0.03)	0.896	-0.03 (-0.1 to 0.1)	0.206
	CTRL	0.61 (0.14)	0.65 (0.14)	0.64 (0.16)	0.04 (0.004 to 0.07)	0.029	0.03 (-0.002 to 0.06)	0.069		

AIOS (0- 100) ↑	INTV	46.3 (21.3)	51.8 (19.1)	45.1 (16.6)	6.5 (0.9 to 12.1)	0.023	0.2 (-5.8 to 6.1)	0.960	1.7 (-5.6 to 8.9)	0.649
	CTRL	43.4 (18.5)	45.5 (16.2)	43.3 (16.4)	0.8 (-5.0 to 6.5)	0.797	-1.5 (-7.7 to 4.6)	0.625		
Global health (1- 5) ↑	INTV	2.1 (0.89)	3.5 (0.9)	3.6 (0.9)	1.4 (1.1 to 1.6)	<0.001	1.4 (1.2 to 1.7)	<0.001	-0.1 (-0.4 to 0.2)	0.363
	CTRL	2.2 (0.69)	3.6 (0.7)	3.8 (0.6)	1.4 (1.1 to 1.7)	<0.001	1.6 (1.3 to 1.8)	<0.001		
Physical activity (1- 5) ↑	INTV	4.0 (0.87)	4.0 (1.0)	4.0 (0.9)	-0.002 (-0.2 to 0.2)	0.985	0.01 (-0.2 to 0.2)	0.927	0.01 (-0.3 to 0.3)	0.929
	CTRL	4.0 (1.02)	4.1 (0.8)	4.0 (0.8)	0.1 (-0.1 to 0.3)	0.356	-0.003 (-0.2 to 0.2)	0.976		
30 s Chair to Stand ↑	INTV	12.5 (4.1)	13.3 (6.6)	15.0 (4.7)	0.9 (-0.4 to 2.2)	0.161	2.2 (1.4 to 3.1)	<0.001	-0.5 (-1.7 to 0.7)	0.383
	CTRL	11.5 (4.0)	12.8 (5.6)	14.4 (3.7)	1.0 (-0.4 to 2.3)	0.153	2.8 (1.9 to 3.6)	<0.001		

SD: Standard deviation; INTV: Intervention group; CTRL: Control group; PAM-13: Patient Activation Measure; BPI: Brief Pain Inventory; VAS: Visual analogue Scale; HADS: Hospital Anxiety and Depression Scale; PSEQ: Pain Self-Efficacy Questionnaire; SOC-13: Sense of Coherence; EQ-5D-5L: EuroQoL 5 dimensions 5 level; AIOS: Arizona Integrative Outcomes Scale.
Estimates presented are from linear mixed effects model (unadjusted) without random slope.
↑ Increase in scores indicates improvement.
↓ Decrease in scores indicates improvement.

The numbers of participants for each outcome at 6 months varied between 96- 103 due to some missing responses.

The numbers of participants for each outcome at 12 months varied between 85- 100 due to some missing responses.


Enrolment
Assessed for eligibility (n= 208)
Excluded (n= 87):
Decided not to participate (n= 13)
Did not respond after receiving additional information (n=29)
Not meeting inclusion criteria (n=7)
Not able to participate at the scheduled time (n=22)
Content or location considered not suitable (n= 16)
Randomised (n=121)
Allocation
Allocated to intervention (n= 60)
Received allocated intervention (n=50)
Did not receive allocated intervention (n=10)
Reasons: deterioration in condition (n=1), hospitalized (n=1), did not have the time (n=3), changes in life situation (n=2),wanted the control group activity (n=1), no reason given (n=3)
Allocated to control group (n= 61)
Received allocated activity (n=47)
Did not receive allocated activity (n=14)
Reasons: deterioration in condition (n=2), exercised outdoors on their own (n=2), wanted the self-management course (n=3), changes in life situation (n=4), no reason given (n=3)
6 months-Follow-up
Lost to follow-up (n= 7)
Reasons: withdrew without giving reason (n= 2), did not respond to invitation or reminders (n= 5)
Lost to follow-up (n= 11)
Reasons: changes in illness (n= 1), absent (n= 1), withdrew without giving reason (n= 3), did not respond to invitation or reminders (n= 6)
12months-Follow-up
Lost to follow-up (n= 8)
Reasons: withdrew without giving reason (n= 2), did not respond to invitation or reminders (n= 3), did not have time (n= 3)
Lost to follow-up (n= 13)
Reasons: changes in illness (n= 1), withdrew without giving reason (n= 3), did not respond to invitation or reminders (n= 9)
Analysis
Analysed
Intention to treat (n= 60)
Available cases (n= 52)
Per-protocol (n= 45)
Analysed
Intention to treat (n= 61)
Available cases (n= 48)
Per protocol (n= 32)

Appendix

1. Approval from the Regional Committee for Medical and Health Research Ethics
2. Study information with consent to participate; for the RCT and for the qualitative study
3. Interview guide
4. Guidelines for delivery of the self-management course as presented in additional file to the published protocol
5. Announcements applied when recruiting participants

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Gjøril Bergva	22845529	30.06.2015	2015/1030 REK sør-øst D
			Deres dato:	**Deres referanse:**
			12.05.2015	

Vår referanse må oppgis ved alle henvendelser

Torunn Hatlen Nøst
Høgskolen i Sør-Trøndelag

2015/1030 Effekt og erfaring med en helsefremmende intervensjon ved Frisklivssentral for mennesker med kronisk smerte

Forskningsansvarlig: Høgskolen i Sør-Trøndelag, Trondheim kommune
Prosjektleder: Torunn Hatlen Nøst

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst D) i møtet 10.06.2015. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektleders prosjektbeskrivelse
Prosjektet skal undersøke effekt, forventning, opplevelse og erfaring med en helsefremmende intervensjon for personer med kroniske smerter ved frisklivssentral (FLS) sammenlignet med en mindre omfattende intervensjon samme sted (gågruppe ledet av instruktør). Den helsefremmende intervensjon er et kurs "Mestring av langvarige smerter" som er et nyopprettet tilbud ved Friskliv og mestring i Trondheim. FLS er en kommunal arena hvor målgruppen er personer med behov for støtte og hjelp til å endre levevaner. FLS fokuserer derfor på helsefremmende faktorer og mestring av egen helse. Prosjektet vil undersøke effekten av intervensjonen (randomisert kontrollert studie) og utforske hvordan det å leve med langvarige smerter påvirker hverdagen, motivasjon for å delta i en helsefremmende intervensjon ved FLS og om intervensjonen oppleves som nyttig for de som deltar (kvalitative individuelle intervju).

Vurdering
Formålet med prosjektet er å teste ut en ny intervensjon, et kurs som kalles "Mestring av langvarige smerter", som ikke har blitt testet ut systematisk tidligere. Om lag 160 personer med kronisk smerte, henvist til FLS fra fastlegen, randomiseres til det nyopprettede kurset eller til en mindre omfattende intervensjon (gågruppe). Man skal undersøke effekt, forventning, opplevelse og erfaring med kurset. Data samles inn ved hjelp av spørreskjema og kvalitative intervjuer.

Komiteen har vurdert søknaden og har ingen innvendinger mot at prosjektet gjennomføres som beskrevet i søknad og protokoll.

Vedtak
Med hjemmel i helseforskningsloven § 9 jf. 33 godkjenner komiteen at prosjektet gjennomføres.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder 31.12.2021. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil

31.12.2026. Forskningsfilen skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Rådgiver

Kopi til: helge.garasen@trondheim.kommune.no
Høgskolen i Sør-Trøndelag ved øverste administrative ledelse: postmottak@hist.no

Forespørsel om deltakelse i forskningsprosjektet

«Mestring av langvarige smerter»

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie som skal undersøke *effekten av helsefremming ved Friskliv og mestring.*
Studien er en del av et større prosjekt som undersøker helsefremming ved Friskliv og mestring. Studien foregår i samarbeid mellom Høgskolen i Sør-Trøndelag (HiST), NTNU og Trondheim kommune. Studien finansieres av Norges Forskningsråd og NTNU.

Hva innebærer studien?
Hvis du samtykker til deltakelse, vil du bli tilfeldig fordelt (loddtrekning) til å delta på kurset «Mestring av langvarige smerter» *eller* «Fysisk aktivitet i gruppe».

1) Kurset «Mestring av langvarige smerter» varer i 6 uker, a 2,5 timer hver gang, og inkluderer teori og praktiske øvelser. Følgende tema belyses: smerter (fysisk og psykisk), kroppsbevissthet, holdning, balanse, respirasjon, ledighet/ bevegelsesevne og avspenning.
Kurset holdes i Friskliv og mestrings lokaler i Trondheim.

2) «Fysisk aktivitet i gruppe» varer i 6 uker. Tilbudet blir individuelt tilpasset og inkluderer en time gåtur i gruppe per uke. Mestring og treningsglede vektlegges, og det er ingen krav til fysisk evne utover å kunne gå i en time.

Du må også fylle ut spørreskjema og delta på en enkel fysisk test (sitte ned og stå opp fra stol) før oppstart, og etter 3, 6 og 12 måneder. Noen av de som deltar vil også bli spurt om å delta i intervju om sine forventinger og om sine erfaringer.
Når undersøkelsen er avsluttet, vil resultatene bli publisert i anerkjente medisinske og helsefaglige tidsskrift. Enkeltpersoner vil ikke kunne gjenkjennes i publikasjoner.

Mulige fordeler og ulemper
Vi kjenner ikke til at denne studien vil medføre noen ulemper for deg. Fordelen for deg er at du får delta på et tilbud som er ment å hjelpe personer med langvarige smerter.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg (spørreskjema mm) skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

Prosjektet starter den 19.07. 2015 og vil bli avsluttet innen 31.12.2021. Bearbeidelse og publisering av data vil kunne skje innen to år etter prosjektets slutt, og datamaterialet anonymiseres innen 31.12.2023.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre oppfølging ved Friskliv og mestring. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på side 3.

Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte doktorgradsstipendiat Torunn Hatlen Nøst på telefon 73 41 25 34 eller e-post torunn.h.nost@ntnu.no.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Informasjon om utfallet av studien
Hvis du ønsker informasjon om resultatet av studien kan du kontakte doktorgradsstipendiat Torunn Hatlen Nøst på telefon 73 41 25 34 eller e-post torunn.h.nost@ntnu.no.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Forespørsel om deltakelse i forskningsprosjektet

«Mestring av langvarige smerter»

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie «Mestring av langvarige smerter» for å undersøke hvilke forventninger mennesker med langvarige smerter har til Frisklivssentralen, og hvilke erfaringer de har gjort seg etter å ha deltatt på tilbud ved Frisklivssentralen.

Denne studien er en del av et større prosjekt som undersøker helsefremming ved Friskliv og mestring. Studien foregår i samarbeid mellom Høgskolen i Sør-Trøndelag (HiST) og Trondheim kommune, og finansieres av Norges Forskningsråd og HiST.

Hva innebærer studien?
Hvis du samtykker til deltakelse i denne studien, ber vi deg om å stille til 3 intervju. Ett intervju **før** du tilfeldig fordeles til kurset «Mestring av langvarige smerter» *eller* «Fysisk aktivitet i gruppe», ett intervju **3 måneder** etter tilbudet avsluttes og ett intervju **12 måneder** etter avsluttet tilbud.

Hvert intervju varer i ca. 1 time. Det gjøres lydopptak av samtalen.

Mulige fordeler og ulemper
Intervjuet kan muligens bringe opp minner fra sykdomshistorien din. Hvis dette blir ubehagelig, kan du ta pause eller avslutte intervjuet.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Prosjektet starter den 19.07. 2015 og vil bli avsluttet innen 31.12.2021. Bearbeidelse og publisering av data vil kunne skje innen to år etter prosjektets slutt, og datamaterialet anonymiseres innen 31.12.2023.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre oppfølging ved Friskliv og mestring. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på side 3.

Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte doktorgradsstipendiat Torunn Hatlen Nøst på telefon 73 41 25 34, eller e-post torunn.h.nost@hist.no.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Informasjon om utfallet av studien
Hvis du ønsker informasjon om resultatet av studien, kan du kontakte doktorgradsstipendiat Torunn Hatlen Nøst på telefon 73 41 25 34, eller e-post torunn.h.nost@hist.no.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Tema intervjuguide – intervju før randomisering

Mål:

- *Hvilke forventninger har informanten til kurset – deretter gå-gruppen hvis informanten havner i kontrollgruppen – hva tenker han om det?*
- *Har informanten noen tanker om hva disse tiltakene kan bidra med sammenlignet med andre ting han har gjort /gjør i hverdagen for å ha det best mulig? Hvis ikke vet det, spør om hva han har prøvd av annen behandling). Så første spørsmål er:*

1. Kan du si noe hvilke forventinger du har til dette tilbudet?
   Hva tror du disse tiltakene i frisklivssentralen kan bidra med for at du skal få det bedre? (Spør om kurset først, så «gå-gruppen».

   Hva tenker du at dette tilbudet kan gi deg?

   a. I forhold til andre tilbud du har prøvd?

   b. Har du noen tanker om dette kan være noe annet enn det du har deltatt på før?

   c. Hva tror du kan være ulikt?

2. Kan du fortelle hvordan du opplever smerter i hverdagen din?

   a. i forhold til familien?
   b. i forhold til jobb?
   c. i forhold til sosialt, fritid?

3. Kan du fortelle hva du gjør i hverdagen for at du skal ha det så bra som mulig – føle at du har et godt liv?

   a. Hva bruker du å gjøre /tenke når du opplever utfordringer (<- ressurser). Fortell litt om hvilke gode egenskaper du har som du kan bruke for å håndtere utfordringer?

   b. Hva gjør det med deg/ fører det til?

   c. Hva kan andre gjøre for at du skal få brukt disse ressursene på best mulig måte for deg?

4. Kan du si noe om hva god helse er for deg?

   a. Hva er en god dag for deg?

   b. Må du gjøre noe spesielt for å få en god dag? Hva? Forklar/ fortell

5. Kan du fortelle litt om hvilke behandlingstilbud /hjelp du har prøvd ut for å håndtere smertene dine?

a. Fastlege, fysioterapeut, psykolog?

b. Smerteklinikk, smerteteam?

c. Rehabiliteringsopphold?

d. Lærings- og mestringstilbud?

e. andre lavterskeltilbud – treningsgrupper osv

6. Kan du fortelle litt om hva de ulike «behandlingene» du har prøvd har bidratt med/ hjulpet deg med?

a. Kunnskap, ferdigheter?

b. Treningstips?

c. Fellesskap med andre

d. Trygghet til å håndtere utfordringen selv?

7. «Loddtrekningen» vil vise hvilken gruppe du kan komme i. Håper du å komme i en spesiell gruppe?

a. Kan du si noe om hvorfor?

b. Har du noen forventinger til hva tilbudet kan hjelpe deg med?

c. Har du noen forventinger til hva som kan endre seg etter at du har vært med på tilbudet?

8. Er det noe du ønsker å legge til?

Guidelines for the self-management course

DAY 1 12.30- 1500	Materials/ methodology
- Welcome - Introduction - Presentation of the participants and instructors	Use slides and give handouts Each gives a short presentation of themselves
Lecture: - What is pain? Understand differences between acute and chronic pain - How does pain affect us? - Elements from CBT in relation to pain	Use slides- give handouts. Encourage to discussion and questions
BREAK	Social interaction
Lecture continuous: - Aim for the course - My expectations - My everyday life	Use slides- give handouts Dialogue Questions to ask: What are your expectations to the course? What do you want to achieve?
Task: Map your everyday activities in the everyday circle	Ask if anyone wants to share their thoughts and experiences with the mapping
Homework: Fulfil your everyday circle	
Movement exercises: - Relaxation of the jaw region: Open wide- hold- release Making underbite Moving the jaw from side-to-side	

DAY 2 12.30- 1500	Materials/ methodology
- Welcome	Dialogue
- Short repetition of day 1.	
- Go through homework assignment	
Lecture:	Use slides- give handouts
- Today's topic: My challenges	Dialogue
- What stops me in achieving what I want?	
- My challenges: sleeplessness, pain, others expectations, my own expectations, fear of pain, time, economy?	
Task: - Find solutions! Problem solving.	Discussion Ask if anyone wants to share an experience
BREAK	Social interaction
Lecture continuous:	Use slides- give handouts
- My challenges- my solutions	Dialogue
- The thoughts' influence on everyday life	
- Elements from Cognitive behavioural therapy	
Task: Why is it important what I tell myself?	Ask if anyone wants to share thoughts and reflexions.
Movement exercises:	
- Easing of tension: Relaxing using monotone and slow movements	

DAY 3 12.30- 1500	Materials/ methodology
- Welcome - Short repetition of day 2.	Dialogue
Lecture: - Today's topic: How to better cope in everyday life? - What gives me energy? - How do I cope and manage challenges? - What choices do I have? - What encourage activation?	Use slides- give handouts Dialogue Ask if anyone wants to share an experience
BREAK	Social interaction
Lecture continuous: - Acceptance- self-efficacy- sortation - The "Should, ought-to and must-do's" - How to say "no". When would it be better to say "yes"? - Self-confidence; self-confidence, self-esteem and self-image	Use slides- give handouts Dialogue
Task: My qualities and my skills. Using elements from CBT: - Which activities gives me better self-efficacy? - Which activities in my life gives and takes my energy?	Ask if anyone wants to share thoughts and reflexions.
Movement exercises: - Easing of tension using stretch and release, or hold and release.	Reflections upon what happens with the breath and the tension when stretching, holding, realising and afterwards?

DAY 4 12.30- 1500	Materials/ methodology
- Welcome - Short repetition of day 3. Lecture: - Today's topic: Goal setting - What do I want to achieve? - What are my choices? - What motivates me in working towards my goals? - Why is this important for me? - What is a goal? SMART goals: **s**pecific, **m**easurable, **a**cceptable, **r**ealistic, **t**ime-scheduled	Dialogue Use slides- give handouts Repetition from day 2 Dialogue
BREAK Lecture continuous: - How to make an action plan - Goals and subsidiary objectives	Social interaction Use slides- give handouts
Task: My action plan - Set SMART goals for yourself. - Use subsidiary objectives as part of your action plan	Ask if anyone wants to share thoughts and reflexions on their action plan.
Homework: Fulfil your action plan. Work on your goal setting.	
Movement exercises: - Different techniques for stretch and release using one arm and one leg, using both arms and legs.	Reflections upon what happens with the breath and the tension when stretching, holding, realising and afterwards?

DAY 5 12.30- 1500	Materials/ methodology
- Welcome	
- Short repetition of day 4.	Dialogue
- Go through homework assignment	Ask if anyone wants to share his or her goals and experiences on working with their action plan.
Lecture:	
- Today's topic: I can- I have a choice!	Use slides- give handouts
- Repetition on day 1: How to cope better in my everyday life?	Dialogue Discussion
- How to make good choices: How can I manage challenges more appropriate?	Ask if anyone wants to share an experience
- How to talk over your own interpretations	
BREAK	Social interaction
Lecture continuous:	
- How to manage pain more appropriate	Use slides- give handouts
- How do I think, interpret, and react?	Dialogue
- What do I do about it? To talk over your interpretations and thoughts.	
- Which strategies for management do I use? Problem-oriented, emotion-oriented, avoidance.	Ask if anyone wants to share thoughts and reflexions.
Task:	
How are you getting along with your goals?	
- New goals?	
- Reconsider your action plan?	
- Reconsider your subsidiary objectives?	
Movement exercises:	
- Focus on contact with the foundation. From back- or a sitting position, finding techniques for a good rest on the foundation.	Reflection upon what happens with the breathing and contact with foundation when using the different techniques?

DAY 6 12.30- 1500	Materials/ methodology
- Welcome	Dialogue
- Short repetition of day 5.	
Lecture:	
- Today's topic: The way ahead	Use slides- give handouts
- Summarize the whole course	Dialogue and discussion
- The aim for the course: - understand pain - change focus from pain to functioning - increased self-understanding, self-efficacy, sense of coping and better self-image - get to know your own resources and become active in managing your own health - increase activation level	
- Repetition of techniques and strategies we have taught, both theoretical and for movement exercises	
- Repetition on how to create smart goals and action plans	
BREAK	Social interaction
Lecture continuous:	
- The CBT elements we have used in the course (situation- interpretation-emotion->talk over)	Use slides- give handouts
- How has the self-management course answered to your expectations?	Dialogue
- What is your standpoint now?	How has life been since day 1?
- How will you use what you have learned?	Ask if anyone wants to comment on the content and delivery of the course
- Information on other activities at the HLC and in the community	

In addition, the movement exercises implies:

- Working on balance in a sitting, standing, and walking position.
- To rise from a sitting to a standing position using different techniques,
- Transferring weight from one side to the other, and from a backwards to a forward position.
- Bending and stretching knees and arms, rotation of upper part and lower part of the body.
- Massage with helping aids like sticks under the foot, balance-pad and balls with knobs.

Advertisements for recruiting participants

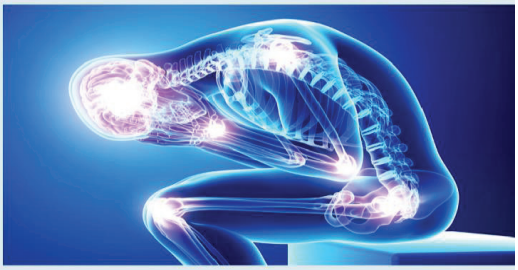
DELTAGERE SØKES TIL FORSKNINGSSTUDIE

«Mestring av langvarige smerter»

NTNU har i samarbeid med Trondheim kommune igangsatt et forskningsprosjekt for å undersøke effekt av tiltak ved Friskliv og mestring.

Til denne studien søker vi personer

- over 18 år
- med smerteutfordringer i mer enn 3 måneder
- som kan delta i gruppediskusjoner på norsk
- Som kan delta i lett fysisk aktivitet i en time



Deltakelse i studien innebærer å bli tilfeldig fordelt (loddtrekning) til å delta på kurset «Mestring av langvarige smerter» eller «Fysisk aktivitet i gruppe».

Studien er godkjent av Regional komite for medisinsk og helsefaglig forskning.

Kan dette være noe for deg?

Ta kontakt med doktorgradsstipendiat Torunn Hatlen Nøst
e-post: torunn.h.nost@ntnu.no, tlf. 73 41 25 34.

NTNU
Kunnskap for en bedre verden

FRISKLIVSSENTRALEN LÆRING OG MESTRING
Trondheim kommune

NTNU

MESTRING AV LANGVARIGE SMERTER

Vil du være med i en studie ved Friskliv og mestring?

Foto: Colourbox

Tilbudet er for deg som lever med smerteutfordringer som har vart i mer enn 3 måneder. Du må være over 18 år, kunne delta i gruppediskusjoner på norsk og kunne være i lett fysisk aktivitet.

Studien er en del av et forskningsprosjekt i samarbeid med NTNU.

Deltakelse i studien innebærer at du enten deltar på kurset **«Mestring av langvarige smerter»** *eller* i kontrollgruppen som får tilbud om **«Fysisk aktivitet i gruppe»** (loddtrekning).

1) Kurset «Mestring av langvarige smerter» varer i 6 uker, a 2,5 timer hver gang, og inkluderer teori og praktiske øvelser.
Kurset holdes i Friskliv og mestrings lokaler i Valøyveien 12 på Tempe i Trondheim.

Innhold i kurs:

- ✓ Kunnskap om balansen mellom hverdagskrav og egenopplevd situasjon
- ✓ Teori, praktiske øvelser og refleksjon i forhold til smerteutfordringer
- ✓ Praktisk øving med anvendelse av metodene/teknikkene. Fokus på avspenning

2) «Fysisk aktivitet i gruppe» varer i 6 uker. Tilbudet blir individuelt tilpasset og inkluderer en time aktivitet i gruppe per uke. Mestring og treningsglede vektlegges, og det er ingen krav til fysisk evne utover å kunne gå i en time i marka eller på Ladestien.

Kan dette være noe for deg? Ta kontakt med doktorgradsstipendiat
Torunn Hatlen Nøst, e-post: torunn.h.nost@ntnu.no,
tlf. 73 41 25 34.

Påmelding tas imot gjennom hele 2016

Deltagere i studien må fylle ut spørreskjema og delta på en enkel fysisk test (sitte ned og stå opp fra stol) før oppstart, og etter 3, 6 og 12 måneder. Noen av de som deltar vil også bli spurt om å delta i intervju om sine forventinger og om sine erfaringer.

Vi tar imot henvendelser og påmeldinger gjennom hele 2016.

Foto: Colourbox

Forskningsprosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskning.

Kan dette være noe for deg?

Ta kontakt med
doktorgradsstipendiat
Torunn Hatlen Nøst,
e-post: torunn.h.nost@ntnu.no,
Tlf. xx.

For mer informasjon om innhold i kurset:

xx

xx

Mestring av langvarige smerter

Tilbud om deltagelse i studie ved Friskliv og mestring, Trondheim

Foto: Colourbox

FRISKLIVSSENTRALEN Trondheim kommune
LÆRING OG MESTRING

NTNU
Kunnskap for en bedre verden

FRISKLIVSSENTRALEN LÆRING OG MESTRING
Trondheim kommune

Friskliv og Mestring i Trondheim kommune

har utarbeidet kurset
«Mestring av langvarige smerter».

Målgruppe:
Kurset er for deg som har hatt smerteutfordringer i mer enn 3 måneder, er over 18 år og kan delta i gruppediskusjoner på norsk.

Innhold i kurset:

- ✓ Kunnskap om balansen mellom hverdagskrav og egenopplevd situasjon
- ✓ Teori, praktiske øvelser og refleksjoner i forhold til smerteutfordringer
- ✓ Praktisk øving med anvendelse av metodene/teknikkene, fokus på avspenning

NTNU
Kunnskap for en bedre verden

Forskningsstudie

Kurset er en del av et forskningsprosjekt i samarbeid med NTNU, Senter for helsefremmende forskning.

Forskningen vil undersøke opplevelse og nytte av å delta på tilbud for å mestre langvarige smerter.

Hva innebærer det å være med i studien?

Deltakelse i studien innebærer å bli tilfeldig fordelt (loddtrekning) til å delta på kurset «Mestring av langvarige smerter» *eller* «Fysisk aktivitet i gruppe».

1) Kurset «Mestring av langvarige smerter» varer i 6 uker, a 2,5 timer hver gang, og inkluderer teori og praktiske øvelser.
Kurset holdes i Friskliv og mestrings lokaler i Valøyveien 12 på Tempe i Trondheim.

Oversikt over tema i kurset:

	Kl	Tema
1.	12.30 – 15.00	Hva er smerte? En aktiv hverdag
2.	12.30 – 15.00	Hvilke utfordringer kan smerte gi i hverdagen – hva stopper meg?
3.	12.30 – 15.00	Mål – hva vil jeg oppnå og hvordan?
4.	12.30 – 15.00	Hvordan mestre hverdagen bedre?
5.	12.30 – 15.00	Jeg klarer – jeg har valg!
6.	12.30 – 15.00	Veien videre

2) «Fysisk aktivitet i gruppe» varer i 6 uker. Tilbudet blir individuelt tilpasset og inkluderer en time fysisk aktivitet ute i gruppe per uke. Mestring og treningsglede vektlegges, og det er ingen krav til fysisk evne utover å kunne gå i en time.