

Project plan

Master Program of Medical Sciences, Master thesis course MEVM06 (hp15)

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Associations between physical activity, sedentary time and the psychological variables self-efficacy, fear-avoidance and pain acceptance; perceived barriers, facilitators and coping strategies for physical activity after a pain management program

A mixed quantitative and qualitative pilot study

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# Introduction

Chronic pain causes major care-seeking, frequent sickness absence and a significant socioeconomic burden for society (1,2). Psychological factors such as fear avoidance beliefs, pain catastrophizing, self-efficacy and pain acceptance have been shown to be associated with disability and impaired physical performance and avoidance behaviour in chronic pain (3). There are multiple barriers for patients with chronic pain to participate and maintain physical activity and exercise (4). Research has shown that rehabilitation pain management programs, so-called multimodal rehabilitation based on the biopsychosocial model have the best effect on physical function and work ability (5). One of the main goals of the rehabilitation is to increase activity and participating in daily life. Physical activity is one of the main components in this process, both as a health factor but also to increase fitness, strength and endurance in order to be able to have a more active daily life.

# Background

## Chronic pain

Pain is a subjective experience and affects the entire human being, both cognitive, emotional as well as behavioural and social components (6). Chronic pain is a complex condition that can be difficult to define. The International Association for the study of Pain classifies pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (7). Chronic pain is usually defined when pain lasts for more than three months. The prevalence of chronic pain is in western countries approximately 20% (8). About one third of primary care visits in Sweden are related to pain, of which more than half are related to chronic pain (5). Chronic pain entails major consequences, such as physiological and psychological disability, decreased quality of life and is a significant socioeconomic burden for society (2).

Pain is a complex experience involving sensory, emotional and cognitive factors. The sensory part includes perception of the intensity, duration and location of the pain. The emotional part is characterized by the emotional impact of the pain experience and the cognitive part is our past experiences and thoughts, which control our different behaviours as a result of the pain. These three parts are always involved in all kinds of pain and interact in different ways during the pain process. The sensory part dominates the acute phase while the other two are more prominent in the long-term pain perspective (9).

## The biopsychosocial model

The traditional biomedical model assumes that there is a direct link between the extent of tissue damage and perceived pain and makes many believe all pain is due to an injury and increased pain is therefore interpreted as an increased injury (10). However, this model cannot explain the complexity of the long-term pain condition, where the pain persists despite the absence of identifiable damage and from this the biopsychosocial model has been developed. The biopsychosocial model is based on a multifactorial perspective where psychological, biological and social factors interact with the pain (11).

## Psychological factors

Several psychological factors have been linked to the perception of and adjustment to chronic pain, that is, psychological factors are both included in pain perception and give rise to secondary effects that may adversely affect the chronic pain patient´s ability to become more active and participate in daily life (12,13).

Fear avoidance beliefs, pain catastrohizing, and pain acceptance are psychological variables associated with disability and impaired physical performance and avoidance behaviour in chronic pain (14). High levels of fear avoidance, catastrophizing and low pain acceptance have been found to predict disability and interference in daily life for individuals with chronic pain (15). Catastrophizing is a central part of the fear-avoidance theory and magnifies the severity and impact of pain. The fear-avoidance model is widely used to explain how psychological factors affect the experience and development of chronic pain and disability. Fear-avoidance is defined as pain-related fear and anxiety, expectations about increased pain that leads to avoidance of activities and increased disability (14,16,17).

Self-efficacy can be described as an individual´s own belief in the ability to cope with a specific task even in the presence of difficulties (18). Self-efficacy has been demonstrated to be particularly important in the process of becoming physically active (19). Rating of poor self-efficacy for physical activity has shown to be one of the most consistent independent predictors of long-term poor outcome of disability and pain (20). The ability to perform activities despite the presence of pain has also been linked with pain-acceptance (21,22).

Pain acceptance can be described as non-judgmental experiences, both negative and positive. The actual treatment with Acceptance Commitment Therapy (ACT) in the chronic pain rehabilitation consists of a shift of focus from symptom reduction to identification of valuable directions in life and appropriate measures to achieve the goals that support these values. The purpose is to improve function and reduce the impact of pain in daily life to make it possible to live a life in the direction of the personal values (23). McCracken and colleagues have in several studies investigated the relationship between acceptance and chronic pain and has found that increased acceptance was associated with less pain-related anxiety, avoidance and impairment. The relationships between acceptance and physical function were independent of pain level (24). Increased acceptance of chronic pain has also proved to be associated with higher rating of mental well-being, less numerous of health care visits and reduced intake of analgesics (25). Level of acceptance has also been shown to be a major predictor of functional impairment (26).

## Physical activity, physical inactivity and sedentary time

Physical activity is defined as any bodily movement produced by skeletal muscles that require energy expenditure. Physical exercise is a subset of physical activity that is planned, structured, and repetitive and aims to improve or maintain physical fitness (27). Physical inactivity is defined as less than 150 minutes of physical activity a week with moderate intensity level or less than 75 minutes high-intensity physical exercise and has been identified as the fourth leading risk factor for global mortality (28). Sedentary behaviour is any waking behaviour characterized by an energy expenditure ≤ 1.5 metabolic equivalents (METs), while in a sitting, reclining or lying posture (29).

Regular physical activity is well researched for general health effects and for its effectiveness in the primary and secondary prevention of several chronic diseases (e.g., cardiovascular disease, diabetes, cancer, hypertension, obesity, depression and osteoporosis) and premature death. Globally, around 31% of adults aged 15 and over were insufficiently active in 2008 (men 28% and women 34%). Approximately 3.2 million deaths each year are attributable to insufficient physical activity (28).

Chronic pain patients have in general high levels of physical disability and difficulties in daily activities resulting in a low general activity level (30). This can exert a significant influence on long-term health and overall quality of life and an increased risk for developing a range of comorbid health conditions (31). Physical activity has in several studies been found to be beneficial for chronic pain (32) and is one of the main components in the treatment of chronic pain (33). Chronic pain is associated with significant functional limitations, low levels of physical activity (34) and high levels of sedentary time (35). There are multiple barriers for chronic pain patients to participate and maintain physical activity and exercise (4). Physical activity requires a performance of activity despite the presence of pain or increasing pain. This connects the psychological and behavioural components to the physical activity treatment. This connection is important for the treatment outcome (36).

## Multimodal rehabilitation

Pain management rehabilitation programs, so called multimodal rehabilitation based on the biopsychosocial model, have been shown to have the best effect on the individual's general functioning and work ability in chronic pain conditions. The rehabilitation consists of psychological interventions combined with physiotherapy aimed to increase physical functioning and activity capacity to increase the individual's participation in society (37).

Optimizing the treatment strategies and increasing knowledge on the impact of psychological variables for the outcome of physical activity treatment is needed.

## Multimodal rehabilitation at Skåne University Hospital

The Pain Rehabilitation Clinic at Skåne University Hospital (SUS) in Lund is a specialist clinic offering multi-professional pain analysis, medical assessment and pain rehabilitation for patients with chronic pain. Patients are referred from primary care and from other specialist clinics for examination and assessment of their pain condition. A team consisting of physician, physiotherapist and psychologist carry out the examination and assessment. Approximately 30% of the patients undergoing examination are assessed to benefit from the interdisciplinary pain management program. In addition to the pain management program, a supplementary investigation of an occupational therapist and a social advisor is made. About 200 people undergo the pain rehabilitation program per year. The rehabilitation is group based, interdisciplinary and based on an individually designed rehabilitation plan. The main purpose of the program is to improve the management of the chronic pain and its consequences, to improve ability to work, optimize level of physical activity and increase health-related quality of life as well as increasing the ability to participate in various everyday activities.

The role of the physiotherapist is to guide the individual to increased activity and participation to improve body functions and increase physical activity according to the individual's own goals and resources. Cognitive factors such as past experiences, beliefs, assumptions, perceptions, motivation and actions are as important as the physical function (38, 39). All physiotherapy actions are linked to the individual's own activity-related goals. The purpose is to take care of the patient´s resources and so that he/she can be as independent as possible and support implementation and maintenance of a new behaviour. Another important part of the physiotherapist's role is to increase the individual's own believes and confidence in ability to move, so-called self-efficacy (39).

# 3. Objectives

This study has a two-part mixed method design. The objective of the first part is to evaluate the physical activity level and level of sedentary time before and after a pain management programme of total 18 weeks with an intensive phase of 5 weeks and at a 9 week follow up and to analyse the associations between physical activity, sedentary time and the psychological variables self-efficacy, fear avoidance and pain acceptance. The objective of the second part is to explore and understand more about perceived barriers, facilitators and coping strategies for physical activity after a pain management program.

## Research questions

* Does the physical activity level change after a pain management program (18 weeks with a 5-week-intensive phase) and at a 9-week follow-up?
* Does the level of sedentary time change after a pain management program (18 weeks with a 5-week-intensive phase) and at a 9-week follow-up?
* What are the associations between physical activity, sedentary time and self-efficacy, fear avoidance and pain acceptance?
* What are the perceived barriers, facilitators and coping strategies for physical activity after a pain management program at a 9-week follow-up?

# Method

This is an exploratory sequential two phase mixed method design, combined quantitative and qualitative study. The studies will be based on the Medical Research Council (MRC) framework for developing and evaluating complex interventions (40). In mixed methods different types of data are collected and analysed, which may provide a stronger understanding of the problem studied (41).

The first part is a correlative experimental pilot study without a control using accelerometers to measure physical activity and sedentary time and self-report questionnaires, to estimate physical activity, sedentary time and psychological variables before and after a pain management program and at a 9-week follow-up. The second phase will have a qualitative approach based on the findings of the first study. An inductive descriptive design using semistructured interviews will be used. Phenomenographic methodology will be chosen where the aim is to describe and understand different ways in which the individuals perceive a phenomenon in their world (42, 43). At the 9-week follow up some of the participants in the study-group will be chosen for semi-structured interviews, in order to explore and understand perceived barriers, facilitators and coping strategies for physical activity after the pain management program.

## The pain management program

The pain management rehabilitation is team-based and performed in a group with 10 participants. Three groups are rehabilitated in three different teams, in different phases. The program consists of a “starting-up” phase during four weeks, with a meeting once a week and an intensive phase for five weeks, approximately four days a week and a follow-up (2 days) nine weeks after the intensive phase. The program includes physical, practical and psychological training. The physical and activity-based training is individualized in group. The rehabilitation plan based on individually valuable goals and is the guiding principle throughout the rehabilitation period. The rehabilitation plan is evaluated in the last week and a new plan is made for the following practising period. After the intensive phase follows a practice period for nine weeks, when the participant is recommended to actively continue applying new knowledge and coping strategies based on their rehabilitation plan.

## Ethical consideration

Information about the study both verbal and written, the basic ethical principles and collection of written consent will be done during the first starting-up-day. Self-reported questionnaires will be filled in and collected during the second starting up day, in the end of the intensive phase and at the nine-week follow up. Access to all background data will be available through our National Data Base (Nationella Registret för Smärtrehabilitering, NRS). An ethical application to the ethics committee will be made in April 2018.

## Study group, inclusion and exclusion criteria

The study group will consist of approximately 20 patients who participates in the clinic's pain management program for patients with chronic pain during 2018. Demographic variables will be available from the National Pain Register, which all patients have to fill in as a clinical routine.

Inclusion criteria for the pain management program are the following: The patient should be medically examined and have a pain diagnosis, be able to understand Swedish and be able to participate on a full-time basis in different daily activities. Exclusion criteria for the program are pronounced psychiatric illness or acute crisis, active and known abuse of tablets, alcohol or drugs, previously extensive rehabilitation measures without sustainable improvement and imminent socio-economic difficulties.

## Outcome measurements

Physical activity activates the body's muscles and can thus be measured both in relation to energy consumption and behaviour. The components that show connection to health is the type of activity and dose, that is: intensity, duration and frequency (28). For health-related effects it is recommended that aerobic physical activity should be performed at an intensity that is at least moderate for at least 150 minutes per week divided into at least three of the week days (28). The outcome of physical activity will be divided in three different categories of intensity: light, moderate and hard. Sedentary time will be handled separately.

Physical activity and sedentary time will be measured with accelerometers. An accelerometer is a small portable sensor, which measure accelerations along the axis of motion. Accelerometers give a total measurement for all physical activities as well as a measure for intensity, duration and frequency (activity pattern) and for sedentary time (44). It has been shown to measure physical activity with a high reliability for individuals with chronic diseases (45). To minimize measurement errors for swimming, bicycling and arm movements, an additional training diary will be handed out for these activities.

## Instrument/accelerometer

The Actilife GT3X has a strong association with oxygen absorption ability, an acceptable connection with energy consumption during activity and high intra and inter-instrument reliability (46,47,48). Actilife records counts, which is the summation of total physical activity and is measured at the rate of 30 Hertz (Hz). The accelerometer value of the total physical activity varies depending on the frequency, duration and intensity of the acceleration. In order to determine the different categories (sedentary, light, moderate and hard physical activity), Freedson adult 1998 cut points will be used, where counts per minute (CPM) define the different categories (49).

Placing the accelerometers around the waist has demonstrated high validity (50). Instructions of the placing of the accelerometer will be written down and handed out. Physical activity and sedentary time will also be measured with three questions from the National Board of Health Indicators on Physical Activity Level (51). These questions ask for the total time of sedentary time, physical exercise and daily exercise for one week and are designed to capture step-by-step improvements even among those who are least active (52).

Self-efficacy will be measured with the Swedish Exercise Self-Efficacy Scale (ESES-S). It is a six-item questionnaire exploring confidence in performing exercise in the presence of difficulties. It has shown to have a moderate test–retest reliability and a respectable internal consistency in a rheumatoid arthritis population. Construct validity was partially supported (53). Fear avoidance beliefs will be measured with the Tampa Scale of Kinesiophobia, the Swedish version TSK-SV (54). This questionnaire has 17 questions between one to four points with options from "do not agree with" to agree entirely "(four questions are inverted). Total score between 17 - 68 points. Higher points indicate higher fear-avoidance. The measured error margin is three points, i.e. a value between 34 and 40 (37 +/- 3), indicates an increased risk of fear-avoidance/kinesiophobia. A minimum of three points is required to count as a change in scale (55). Pain acceptance will be measured with the Chronic Pain Acceptance Questionnaire short form (CPAQ-8), which has demonstrated good psychometric properties and sensitivity to rehabilitation changes (56). The form consists of 8 questions with the two subdivisions "commitment to activity" and "willingness to feel pain.”

## Statistics

Descriptive statistic will be presented with median, range and spread (ordinal data). Demographic variables will be available from the National Pain Register. Accelerometer data will be analysed with Actigraph 5.0 (Actilife 2013, Pensacola , USA) together with participants physical characteristics age length, weight and BMI.

Data processing and analysis will be performed in the Statistical Package for the Social Sciences (SPSS) version 18.0??? Statistical analyses will be made with non parametric tests dependent because of the small sample size. Correlations will be analysed with regression analyses. Physical activity and sedentary time will be the dependent variable and self-efficacy, fear avoidance and pain acceptance will be the independent variables.

All drop-outs will be reported.

# Schedule 2018/2019

April 2018 ethical application.

Autumn/winter 2018 and January-March 2019 collecting data part 1. Spring 2019 collecting data part 2.

Spring/summer 2019 processing of data and completion of work part 1.

Examination Master autumn 2019 part 1.

Continuing processing data and completion of work part 2 autumn/winter (2019/20).

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