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Associations between physical activity, sedentary time and psychological variables; perceived barriers and facilitators for physical activity after a pain management program: a pilot study

Submission date	**Recruitment status**	[X] Prospectively registered
28/06/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2021	Signs and Symptoms	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic pain causes frequent sickness absence and a significant burden for society. 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. There are multiple barriers for patients with chronic pain to participate and maintain physical activity and exercise. Regular physical activity is well researched for its general health effects and for its effectiveness in the prevention of several chronic diseases (e.g., heart disease, diabetes, cancer, high blood pressure, obesity, depression and osteoporosis) and premature death. Chronic pain patients have in general high levels of physical disability and difficulties in daily activities resulting in a low general activity level. Physical activity has in several studies been found to be beneficial for chronic pain and is one of the main components in the treatment/rehabilitation of chronic pain. The aim of the first part of this study is to evaluate the physical activity level and level of sedentary time before and after a pain management programme, and to analyse the associations between physical activity, sedentary time and the psychological variables self efficacy, fear avoidance and pain acceptance. The aim 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.

Who can participate?
Patients with chronic pain who participate in the clinic's pain management program during autumn 2018

What does the study involve?
The pain management rehabilitation is team-based and performed in a group with 10 participants. The program consists of a starting up phase over four weeks with a meeting once a week, an intensive phase for about four days a week for five weeks, and a follow-up (2 days)

about two months later. The program is standardized and includes physical, practical and psychological training. The physical and activity-based training is individualized in group. The rehabilitation plan is based on individually valuable goals. It 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 9 weeks, when the participant is recommended to actively continue applying new knowledge and strategies based on their rehabilitation plan. Physical activity is measured with an accelerometer and questionnaire. 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. It has been shown to measure physical activity with a high reliability for individuals with chronic diseases. Self-efficacy, fear-avoidance and pain-acceptance are measured with questionnaires. The questionnaires are filled in before and after the pain management program and at the follow-up after 9 weeks. The accelerometer is used for one week before and one week after the program and for one week after the follow-up. In the second part of the study, 5-6 participants are selected for interviews exploring perceived barriers, facilitators and coping strategies for physical activity.

What are the possible benefits and risks of participating?
The results of this study will hopefully help to improve physical rehabilitation for patients with chronic pain. Participants may become more physically active. Data in this study is considered to be sensitive and will therefore be handled with the utmost care and confidentiality under the Personal Data Act. All data is anonymous in processing and data analysis, i.e. no personal code number or other identifiable data will be able to be linked to individual data. Data is encoded to allow linkage between accelerometer data and the National Register of Pain (NRS register). The information is protected at the highest possible level. A code key will be used to identify outcomes with individuals in order to be able to interview based on a certain result (such as those with high or low physical activity level, to further explore barriers and facilitating factors through further interviews). All sensitive material will be locked up safely in the clinic.

Where is the study run from?
1. Skåne University Hospital (Sweden)
2. Lund University (Sweden)

When is the study starting and how long is it expected to run for?
January 2018 to June 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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2. Prof. Åsa Tornberg

Contact information

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Scientific

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Associations between physical activity, sedentary time and the psychological variables self-efficacy, fear-avoidance and pain acceptance; perceived barriers and facilitators for physical activity after a pain management program. after a pain management program: a pilot study

Study objectives
The hypothesis is that higher self efficacy and pain acceptance and lower fear avoidance predict a higher level of physical activity and lower levels of sedentary time after the pain management program and at the two month follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board at Lund University, Sweden, 31/05/2018, ref: LU-Dnr 2018/340

Study design

Exploratory sequential two-phase mixed method design, combined quantitative and qualitative study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic pain

Interventions
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. 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 study will be based on the Medical Research Council (MRC) framework for developing and evaluating complex interventions. 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. Some of the participants in the study-group will be chosen for semi-structured interviews, in order to explore and understand perceived barriers and facilitators for physical activity after a pain management program.

The study group will consist of approximately 15-20 patients who participates in the clinic's pain management program for patients with chronic pain during the autumn 2018. The pain management rehabilitation is team-based and performed in a group with 10 participants. 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) approximately two months after the intensive phase. The program is standardized and includes

physical, practical and psychological training. The physical and activity-based training is individualized in group. The rehabilitation plan based on individually valuable goals, 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 9 weeks, when the participant is recommended to actively continue applying new knowledge and strategies based on their rehabilitation plan.

Physical activity will be measured with accelerometer and questionnaire. 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. It has been shown to measure physical activity with a high reliability for individuals with chronic diseases. Self-efficacy, fear-avoidance and pain-acceptance will be measured with questionnaires. All questionnaires, but the self-efficacy scale, are included in the clinic's national quality register (NRS). The questionnaires will be filled in before and after the pain management program and at the the follow-up after nine weeks.The accelerometer will be measured during one week before, one week after the program and during one week after the follow-up. In the second part of the study, 5-6 persons will be selected for semi-structured interviews exploring perceived barriers, facilitators and coping strategies for physical activity.

Intervention Type
Behavioural

Primary outcome measure
1. Physical activity and sedentary time measured with accelerometer Actilife GT3X. Physical activity will be divided into three categories: sedentary, moderate and strong physical activity. To determine the different categories, Freedson adult 1998 cut points will be used, where counts per minute (CPM) define the different categories.
2. Physical activity and sedentary time will also be measured with three questions from the National Board of Health Indicators on Physical Activity Level. 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

Measurements will be made at:
Baseline one week before program (the 5 week intensive phase): questionnaires will be filled in one week before program and accelerometer will be worn during one week before the program (Saturday-Saturday)
At the end of program: questionnaires will be filled in at the end of the program and accelerometers will be worn during one week after rehab program (Saturday-Saturday)
At follow up 9 weeks after program: questionnaires will be filled in at follow up and accelerometers will be worn during one week after the follow up

Secondary outcome measures
1. Self-efficacy measured with the Swedish Exercise Self-Efficacy Scale (ESES-S)
2. Fear avoidance beliefs measured with the Tampa Scale of Kinesiophobia, the Swedish version TSK-SV
3. Pain acceptance measured with the Chronic Pain Acceptance Questionnaire (CPAQ-8)

Measured at baseline (one week before the program), at the end of the program, and at follow up 9 weeks after the program

Overall study start date

15/01/2018

Completion date
31/08/2019

Eligibility

Key inclusion criteria
The pain rehabilitation program has the following inclusion criteria:
1. The patient should be medically examined and have a pain diagnosis and be assessed by the team-examination to benefit from the interdisciplinary pain management program
2. Be able to understand Swedish
3. Be able to participate on a full time basis in different daily activities

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
The target number was 15-20 persons

Key exclusion criteria
The pain rehabilitation program has the following exclusion criteria:
1. Pronounced psychiatric illness or acute crisis
2. Active and known abuse of tablets, alcohol or drugs,
3. Previously extensive rehabilitation measures without sustainable improvement
4. Imminent socio-economic difficulties.

Date of first enrolment
20/08/2018

Date of final enrolment
30/10/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Pain Rehabilitation
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Lund
Sweden
22241

Study participating centre
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Sponsor type
University/education

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ROR
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22241
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smartrehab.sus@skane.se

Sponsor type
Hospital/treatment centre

Website
https://vard.skane.se/skanes-universitetssjukhus-sus/om-oss/.../smartrehabilitering/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1 scientific paper, presentations at pain conferences

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as it is a small pilot study with only 15-20 participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		05/04/2018	02/04/2019	No	No