Abstract

***Objective*:** Chronic musculoskeletal pain (CMP) is a vast problem with profound consequences for both individuals and societies. Increased amount of sedentary time and less physical activity (PA) have become e global concern. PA is a central component of treatment in inpatient rehabilitation patients with CMP. Beside the general positive benefits on physical and mental health, PA also has evident health effects on a variety of disorders. In patients with chronic pain, it is aimed at increasing function and improve pain-related symptoms. Wearable activity trackers (WAT) have shown to be a promising strategy to help facilitate PA in patients with CMP. However, the challenge is getting patients to keep up their PA-levels after rehabilitation. The aim of this study was to evaluate whether feedback from WAT that provide feedback on activity levels increased PA for patients in inpatient rehabilitation with CMP.

Method: 39 patients with CMP (mean age 48) were included in the study. Participants were randomized into an intervention group (n=22) and control group (n=17). The WAT held a population-based algorithm calculating heart rate variability into Personal Activity Intelligence points (PAI). The accompanying application (APP) gave participants in the intervention group (FB-group) feedback about the number of PAI they earned each week. The control group (CON-group) was wearing the same WAT, but they did not receive any information on their activity level. Previous research has shown that those who achieve 100 PAI or more every week over time live for an average more than eight years longer than others. During the study, all participants took part in a traditional inpatient rehabilitation program. The program consists of two periods at the rehabilitation centre with two weeks at home in-between. The study mainly focused on the number of PAI earned during the first week of the home period. Therefore, PAI-scores were estimated after the first 7 days after the patients returned home. To investigate what changes occurred after the intervention, aerobic capacity was indirectly measured by the Åstrand-cycle test. Measurements was done at baseline and post-intervention, when the rehabilitation program was completed.

***Results*:** No significant differences were found between the two groups after the first home-stay week. Participants in the FB-group obtained a mean PAI-score of 125.98 ± 70.5 and participants in the CON-group obtained a mean PAI-score of 123.6 ± 69.6. Mean estimated $VO2_{max}$ (mL/kg/min) increased from pre- to post-intervention in both the FB-group (13,8 %) and the CON-group (10,4 %).

Conclusion: There were no significant differences on the main outcome between the FB-group and the CON-group in our study. This RCT provides no statistical significant evidence in favour of feedback intervention were superior in increasing PA-level. A trend towards a large mean increase in estimated VO_{2max} was observed in both groups from pre- to post intervention.

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Abbreviations

ACT – **A**cceptance and **C**ommitment **T**herapy
APP – **A**pplication
BT - Bluetooth **T**echnology
BMI – **B**ody **M**ass **I**ndex
CMP - Chronic pain and **M**usculoskeletal **D**isorders
CRF - Cardiorespiratory **F**itness
HR – **H**eart **R**ate
HR_{max} – **H**eart **R**ate **M**aximum
HR_{min} – **H**eart **R**ate **M**inimum
HRR – **H**eart **R**ate **R**eserve
PAI - Personal **A**ctivity **I**ntelligence
$VO2_{max}$ – **M**aximum oxygen uptake
LBP – **L**ow **B**ack **P**ain
RPE – **R**ate (rating) of **P**erceived **E**xertion)
RPM – **R**evolutions **P**er **M**inute
PA – **P**hysical **A**ctivity
RCT – **R**andomized **C**ontrolled **T**rial
WAT – **W**earable **A**ctivity **T**rackers
WHO – **W**orld **H**ealth **O**rganization

Contents

1 Introduction

Chronic pain and musculoskeletal disorders (CMP) have reached pandemic proportions and is a leading/major public health problem/concern in the global population (1). The prevalence is high, and CMP have become one of the primary causes of disability, years lived with reduced quality and a leading contributor to great socio-economic consequences (2), (3).

According to data from the Global Burden of Disease Study, Norway had the highest age standardised point prevalence estimates of neck pain in 2017 (4). Furthermore, the level of sickness absence in Norway are among the highest in Europe (5), and statistics from the Norwegian Labour and Welfare Administration (NAV) shows that widespread musculoskeletal disorders are overall the most common and largest contributor for long-term sickness and unemployment (6). Among adults of working age, pain conditions in the lower back and neck are the primary cause of non-fatal health loss measured in disability-adjusted life years (DALY) and overall disease burden in Norway (7), (8). Further, The Norwegian Institute of Public Health has calculated that musculoskeletal diseases constitute 11% of the total health loss in Norway in 2016. In addition to these severe negative consequences for individuals, the societal costs related to musculoskeletal diseases in 2016 were over 255 billion NOK (9). Estimated health care expenditures is of great expense and seems to increase, calculated to be more than twice as high for patients affected by pain complaints compared to those without (7), (10).

About 19% of the adult European population is afflicted with moderate to severe chronic pain. Norway is at the top, with an incidence of approximately 30% (11). Chronic pain affects all ages and social groups but is more common among elderly and people of lower socioeconomic status. As the global population ages, it is predicted that the prevalence and impact of musculoskeletal conditions will continue to increase (12), (13).

Most patients (90%) with musculoskeletal disorders in primary care, is labelled non-specific low back pain (LBP), meaning the symptoms cannot reliably be attributed to a specific nociceptive cause, disease/diagnosis or pathophysiologic mechanisms (14). In addition, previous findings shows 98 % of patients with chronic low back pain reported a high degree

of other health issues (15), i.e., widespread pain, reduced quality of life, fear-avoidance beliefs, mental symptoms, social withdrawal and work disability (16).
Due to its wide range in intensity and duration, defining the concept of pain in a concise and precise manner presents may be challenging. Although there are no standardized measures for detecting chronic pain, The International Association for the Study of Pain (IASP) has defined chronic pain as prolonged, persistent and/or recurrent pain of at least 3 months of duration. Further, the diversity in definitions of the term may account to major differences in the prevalence both globally and at individual level, suggesting it may lead to an overdiagnosis of people minimally afflicted by pain (1), (17). It is also reported that patients often experience a general lack of trust and understanding in encounter with treatment and health professionals. This may contribute to a life with pain becoming even more difficult than necessary (18).

Chronic musculoskeletal pain often involves a complex symptom picture. The aetiology related to development of chronic pain is often unknown, although there seems to be an agreement that the cause is of multifactorial origin. Risk factors for promoting musculoskeletal pain are similar to other non-communicable diseases (NCDs) and strongly related to lifestyle. Known risk factors that have been identified are physical inactivity, obesity, poor sleep, low socioeconomic status (19), smoking and unhealthy diets (17). There is extensive evidence between physical inactivity and development of NCDs (20). There is also compelling evidence that emotional states and psychological disorders interact with the sensory experience of pain (18), (21). For example, almost a third of patients with LBP reported mental disorders (22). Despite the fact that both advances in the understanding of pain and treatment options have developed in the last few years, there is no clear evidence that treatment has led to a lower prevalence of chronic pain in the population. On the contrary, data from domestic large-scale population-based health surveys indicate a slight increase in pain-related diseases (23), (17). Therefore, identifying effective ways to prevent the increasing burden of musculoskeletal disorders at an early stage therefore become even more pressing.

The biopsychosocial approach are nowadays widely accepted and recommended to use as a framework and experience-based treatment model of chronic pain (18), (24). Cognitive behavioural therapy (CBT) and patient education are important components of the management program in inpatient occupational rehabilitation (25). Clinical guidelines and reports advises physical activity (PA) as a key component in first-line treatment for common

pain conditions (26), (27), (13). PA is regarded as a central part in most intervention programs due to multiple evident health benefits (28).
Despite the fact that several studies demonstrate associations between low degree of PA and back pain (29), (30), (24), there are lack of consensus on the field (31). However, PA has shown to prevent the risk of depression and is associated with reduced risk of sickness absence and disability pension (32), (33), (34).

The World Health Organization (WHO) has declared physical inactivity one of the greatest epidemic threats to the public health worldwide, being identified as the fourth leading risk factor for global mortality (35). It is now a well-established fact that regular PA is essential for a healthy lifestyle. The recently updated WHO guidelines on PA state that all adults should spend at least 150 - 300 minutes of exercise at a moderate intensity or 75 – 150 minutes of vigorous intensity per week, or an equivalent combination of both, including muscle-strengthening activities for all age groups. (36). Despite generally consistent guideline recommendations around the world and the increasing evidence of multiple health benefits associated with regular PA becoming more recognized, approximately one in four (27,5%) of adults and more than 80% of adolescents do not meet these recommendations (36), (37), (38), (39). For patients with CMP, the numbers are even more discouraging, amplifying the need for different response strategies to support people to be more active and combat the increasing burden of sedentary behaviours worldwide.

In the last decade, we have seen a rapid increase in the commercial market of wearable technology, and the landscape are in constant development. Our daily lives are largely influenced by digitalization, and one of the most popular solutions on the wearable tech market is fitness trackers, according to a recent survey (40). A major use of these devices is self-tracking everyday health and fitness (e.g heart rate monitoring, calculate energy expenditure and intensity, monitor sleep patterns and counting steps). Although there are limited evidence that these devices will improve health in long-term (41), the technology offers new opportunities that may help promote healthy behaviours. In the updated PA guidelines, self-monitoring is advocated by WHO. They further addresses the need of device-based advancements in sensor technology to ensure it provides a practical approach to facilitate PA and strengthen population PA surveillance in the future (36). Moreover, they are affordable, easy to use, widely available and increasingly adopted by users of all ages. Thus,

wearables hold great potential as a relatively non-expensive tool to help reduce healthcare cost and improve overall health quality (42).

One major key factor of management of CMP-conditions is to help patients stay committed to health enhancing habits (e.g., adequate levels of PA, stress-relief and sleep) (43). As many interventions manage to improve PA while the intervention is in progress, the challenge is to maintain activity levels within a population that has typically been inactive afterwards (44). Thus, the need for behaviour change techniques is essential, and wearable technology solutions aiming to educate and motivate users towards their goals may be a promising strategy (45).

Personal Activity Intelligence (PAI) is a new, research-based metric for activity tracking, aiming to simplify how much PA per week is sufficient to provide health benefits. The PAI algorithm can be integrated into wearable devices with a freely downloadable application (APP), compatible with most HR-monitors (46). The advice is to achieve a weekly score of 100 PAI or more, as previous research has shown association between an adequate PAI score and significant reduction in the risk of cardiovascular disease (CVD) mortality and other lifestyle diseases (47).

Therefore, to investigate the short-term effects whether feedback from wearable activity trackers (from now on: WAT) increases levels of PA, a randomized controlled trial (RCT) including patients with CMP, taking part in inpatient rehabilitation was performed. Participants were given a wrist-worn activity monitor to track heart rate (HR) and other biometric parameters. The registered data was converted into a PAI-score as a measurement of their PA-level. The primary outcome of the study was to track the activity level in the time period at home in-between the two stays at the rehabilitation centre. This was measured by the number of PAI-points achieved in the time period at home after the 3rd week of the intervention. Secondary outcomes included changes in cardiovascular fitness ($VO2_{max}$) from baseline to the end of the rehabilitation program, as measured by the Åstrand-cycle test.

2 Methods

2.1 Study design

This study was a clinical RCT with a parallel group design. The trial compared two groups: an intervention group (FB-group) receiving feedback on activity level through their smartphone and a control group (CON-group). The primary outcome was to evaluate the short-term effect of wearable technology to increase the level of PA in inpatient rehabilitation. To investigate these effects, daily PA of the participants was monitored by a WAT (Accuro LYNK2, Chicago, IL) during the 6-week intervention. The activity data obtained from the WAT was converted into a PAI-score, and the participants the activity level was measured by the number of PAI-points achieved. Patient characteristics were registered at baseline, while secondary outcome measure was obtained at baseline and week 6.

2.2 Study Population/Participants and recruitment

The participants in this study were recruited from Unicare Helsefort Rehabilitation Centre, Rissa, Norway. Eligible participants were patients taking part in an inpatient rehabilitation program for chronic pain, musculoskeletal, mental- or unspecific disorders. Patients have been referred by a GP to the Regional Referral Clinic that considers an indication for rehabilitation in the specialist health service.
Recruitment of participants were carried out in the period between mid-term August 2019 to January 2020. Patients arrived at the rehabilitation centre in groups of 8 - 10 people throughout the year. Prior to the arrival they received a written invitation to participate in the study. An information meeting was held the day after arrival, where the patients were presented further details about the project and given the opportunity to sign the consent form if they wished to participate.

2.3 Eligibility criteria for participants

Participants were assessed for eligibility to the RCT. The inclusion criteria were:
(*i*) taking part in inpatient rehabilitation at Unicare Helsefort Rehabilitation Centre for chronic pain. Exclusion criteria were:(*i*) patients who did not have a smartphone was excluded, as they would not be able to access the mobile APP and take advantage of the technology used

in the intervention. (*ii*) Wheelchair-bound patients were also excluded, as the technology used in the study could not measure activity correctly for these patients.

2.4 Ethics/ethical considerations

The trial was registered at clinicaltrials.gov (No.: NCT04031092). All participants received and signed a written informed consent prior to the study and were free to withdraw from the intervention at any time without giving any reason. The study was approved by the Regional Ethical Committee for Medical and Health Research Ethics in Central Norway and gave prior approval 2019/800 / REK mid. The project was carried out according to the Declaration of Helsinki.

2.5 Intervention

Data collection took place at Unicare Helsefort Rehabilitation Centre, Rissa, Norway. During the 6-week intervention period, participants took part in the traditional inpatient rehabilitation program for chronic pain and followed the usual treatment that they would normally receive. The participants were informed that participation would not interfere with the normal schedule, and they were asked to maintain their regular PA habits throughout the study.

WATs and the mobile software APP were set-up for all participants, and device pairing completed by test personnel. The Participants were given a brief instruction on how to use the activity tracker and APP after baseline registration. In addition to the WAT, a user guide was handed out, giving participants the opportunity to get familiar with the device and learn how to use the WAT together with the PAI-health mobile APP. Registration started immediately after the participants were equipped with the activity tracker. Contact information was provided to all participants in case of technical problems or questions during the intervention. Some technical issues were solved through telephone correspondence. Participants in both groups received weekly SMS-reminders to ensure that synchronization was completed. In addition, a lottery prize was included to stimulate participation and compliance to the intervention.

2.6 Randomization and blinding

Eligible participants were told that they would be randomly assigned into two different groups, either a feedback group or a control group. The inclusion process continued for five months as the participants entered the rehabilitation centre in their respective groups. Randomization of the participants was performed using a web-based program (WebCRF3) developed and administrated by the Unit for Applied Clinical Research, Norwegian University of Technology, Trondheim, Norway. The participants were randomly assigned to the intervention group (n= 22) and the control group (n=17), stratified for gender.

2.7 Control group

The intervention lasted throughout the 6 weeks where patients resided at the rehabilitation centre. The rehabilitation program is both individual and group based, divided into two periods; first the participants are 2 weeks at the rehabilitation centre, separated by two weeks where they stayed at home throughout the 3rd and 4th week before returning to the rehabilitation centre for the last 2-week period.

One of the primarily aims of the rehabilitation program is to educate the patients on how pain influences their daily lives. The pain management program is based on a biopsychosocial model, focusing on cognitive behavioural therapy in addition to physical exercise.

Exercise programs are individually tailored based on income interview and individual conversations with coordinator/primary contact, taking the patients training status and short- and long-term goals in consideration. 6 lectures are given (e.g., understanding of pain and symptoms, sleep, physical activity, nutrition, coping with stress/management). Physical exercise, both individually and in groups, are aiming to increase cardiovascular and muscular fitness. Example of activities implemented in the rehabilitation program is a combination of cognitive behavioural therapy (e.g., ACT-based group discussions, mindfulness sessions, individual meetings with coordinator) and physical exercise (e.g., individual/group based supervised training sessions and outdoor activities day). Patients are also encouraged to exercise unsupervised (e.g., free-living activity) and take part in other activities during their leisure time. The two groups had an equal amount of supervised exercise sessions during the program. Four times per week the patients were supervised by experienced physiotherapists or exercise physiologists. The sessions took place either at the fitness centre or outdoors, consisting in general of endurance training, resistance training, mobility training/stretching and body awareness.

Both groups were distributed the same activity tracker (Accuro LYNK2), which provided feedback on HR, intensity zone and activity level (PAI-score) via a mobile APP. The control group used an APP with a slightly different design, with limited access to biometric data and did not receive any feedback about their activity level or PAI-score. Participants were asked to wear the device at all day-time activities, both planed and free-living, including water-based activities. Wearing the device at night was optional.
All participants were given an individualized activity program for their home period, which they were encouraged to follow when they returned home after the first two weeks of the rehabilitation stay. Patients were also encouraged to apply what they have learned in the two first weeks and stay physical active at home. The content of this program reflected each patient interests and recommendations (e.g., walk/cycle to work every day, participate in group training once a week or do some housework every day).

2.8 Intervention group

Similar to the control group, participants in the intervention group (from now on: FB-group) followed their respective rehabilitation programs. The only difference between the two groups were that participants in the FB-group used the PAI-health APP, providing instant user feedback on daily and weekly amount of PAI earned via their smartphone. Further information about activities, time spent in different intensity zones and HR from the last seven days is also available in the APP.
The PAI-health APP is freely downloadable and compatible with most Bluetooth-enabled HR-monitors. Data on physical activity and heart rate was measured by the WAT and automatically transmitted wirelessly via Bluetooth (BT) in a standard encrypted link to the PAI-health APP on the participant's mobile phone when the participants synced their device. Trough the PAI algorithm integrated in a wearable device, the APP analyses HR-variations continuously for 7 days to calculate an individual score. To ensure that an adequate amount of PA needed to improve the user's fitness level is reached, each day, the PAI-points earned is recalculated based on their last 7 days of activity, gradually adjusting the user’s current fitness level. To determine fitness age, participants created a user profile and entered their HR, age, gender, height and weight. Information on current average activity level and exercise habits were collected based on a short questionnaire. Participants usual exercise-intensity was obtained by responding to “How hard do you exercise?”. Three response options, “no sweat or heavy breath”, “heavy breath or some sweat” and “push myself to exhaustion” were

answered. According to earlier studies, this corresponds to respectively 44%, 73% and 83% of HRR (48), (49), (50).

2.9 Accuro LYNK2

The Accuro LYNK2 is a small activity wristband (weighting 113.4 g) which provides a continuous stream of HR data from the wrist using an optical sensor. This data is transferred via Bluetooth Technology (BT) to the PAI-Health APP, where the PAI-algorithm asses these data to stipulate a PAI-Score. A five-color LED light indicates the current HR-zone, and a vibration alerts the user when switching between these zones. Adjustable straps for versatility in which the device could be worn either on the wrist and or on the fore-arm or upper-arm. The activity tracker is compatible with the PAI-Health APP and connects through BT. LYNK2 has two different modes: "All-day mode" and "Workout mode". "All-day mode" automatically tracks HR, PAI-score and other biometrics. To record a work-out, the participants was asked to switch to "workout mode" to capture HR every second. Although the device provides continuous HR-data throughout the day, to get the most precise HR-value, participants were encouraged to switch to "training mode" prior to scheduled bouts of exercise. The participants were also told to charge it daily to ensure all data was collected.

2.10 Personal Activity Intelligence

Personal Activity Intelligence (PAI) is a research-based metric for PA-tracking developed by the Cardiac Exercise Research Group (CERG). As mentioned earlier, the purpose of the model design is to make it simple for people to understand and objectively quantify how much PA is sufficient to change their health condition and minimizing risk of lifestyle diseases. Previous research has shown association between an adequate PAI score and reduced risk of cardiovascular diseases (CVD) mortality (46).

PAI considers an individual's age, gender, resting- and maximum HR (min/max) response to any PA, translating it into a score (0 PAI = inactive, 100 PAI = active enough). The PAI-metric has been integrated in self-assessment HR-devices (e.g wearables, smart watches, fitness trackers), to help defining a weekly PAI-score (48). The algorithm behind PAI is based on data obtained from the Health Study in Nord-Trøndelag (HUNT).

The algorithm is intensity dependent, meaning the user have to maintain a relatively high HR to earn and increase PAI-score. An important assumption behind the model design is that the best measurement for exercise intensity at an individual level is the % of heart rate reserve

(HRR) (48). Further, maintaining a PAI Score of <100 per week has been associated with an average of 25% lower risk of CVD and all-cause mortality and increase longevity in epidemiological studies (51).

2.11 PAI Health Research Portal

Participants were registered in the PAI Health Research Portal. The web-based portal also worked as a visualization tool, allowing the research admin to monitor the overall activity status of the participants with the possibility to dive deeper into the data and identify if any of the subjects needed further follow-up or help with their device.

2.12 Unicare Helsefort Rehabilitation Centre rehabilitation program

The rehabilitation approach at Unicare Helsefort is interdisciplinary and multimodal with the use of various elements such as individual and group-based exercise, education on various topics and individual meetings with their primary contact. Individuals admitted to inpatient rehab facilities receive comprehensive rehabilitative care via a tightly coordinated, physician-led multidisciplinary team of professionals. In brief, for patients with chronic pain, the overall aim of the rehabilitation program at Unicare Helsefort is to work on a biopsychosocial perspective to see the whole person in the rehabilitation process. By focusing on cognitive behavioural therapy, patient education, knowledge adapted to physical exercise, as well as awareness and guidance associated to life-related situations according to the specific needs of each individual. The rehabilitation program is divided into 6 weeks, with 2 consecutive weeks stay at Unicare Helsefort, 2 weeks stay at home before the patients return to complete the last 2 weeks. During a stay at the rehabilitation center, the patients schedule consists of 13 group sessions of Acceptance and Commitment Therapy (ACT), led by team coordinators. In brief, patients must decide themselves what their values are. ACT emphasizes accepting both their negative and positive experiences, making use of the patients values to guide them towards their goals (52).

2.13 Measurements

2.13.1 Test procedure

The pre-test was carried out one day after arrival. The post-test was completed on the second last day of the rehabilitation stay. Subsequent to the baseline testing and group allocation,

participants were given the WAT. The test-procedure were identical at both pre- and post-test. Baseline measurements of the participants were registered at the same day. Physiological parameters were sub-maximal VO_{2max} and body mass index (BMI). BMI were calculated as weight divided by height squared.

Each participant's ID, age, gender, height, weight and contact information were registered prior to the test. Anthropometric measures were expressed as standing height (meters) and body weight (kilograms). Standing height was measured with a metric wall tape, nearest 0.5 cm was registered. Measurements were performed in the test laboratory room prior to the cycle test. To ensure validity and reproducibility, measurements were performed at the same time of the day on both pre- and post-test measurements with the subjects wearing light clothing and shoes. Body weight was measured on a calibrated electric scale (Soehnle Body Control Contour F3). Following the physical test performance, each appointment also including a brief guide to the activity tracker and APP (simple paper-based instruction manual on how to use the device). On the test day, participants were told to avoid vigorous activity and abstain from heavy meals within the last two hours before the test. In most cases, both the pre- and post-tests of each individual were carried out at the approximately same time. Due to logistic difficulties, in some cases tests were performed on a separate day.

2.13.2 Åstrand-cycle test

To assess cardiovascular fitness, the Åstrand cycle test was conducted pre- and post-intervention. The Åstrand-test is a submaximal exercise test used to measure indirect aerobic capacity (53). The test was performed on a calibrated ergometer bike (Monark 928E, Monark Exercise AB, Vansbro, Sweden). HR was recorded continuously through each test using a HR-chest strap monitor transmitter (Garmin Premium Heart Rate Monitor, Garmin, USA).

Seat post was adjusted so that the subject had approximately 5-degree bend at the knee during the bottom phase of the pedal stroke. Participants then performed a self-paced 2 min warm-up on the bike while they received further oral instruction about the purpose of the test and the test procedure to be followed. As a guidance of exercise intensity, instructions were also given on how to apply a Borg 6-20 scale (rating of perceived exertion) (54). Immediately following this warm-up, the exercise started. In addition, participants were also informed that they could end the test if they were to experience pain and/or discomfort.

Starting load was subjectively chosen/estimated by the test leader, taking age, gender and training background in consideration. If the work rate was set too high or low, it could be adjusted during the first two minutes of the test. Participants were instructed to sustain a pedal frequency (cadence) of approximately 50 ± 5 revolutions per minute (RPM) during the entire test. If cadence dropped below the required RPM, participants was verbally encouraged to keep the frequency up. The test was approved when the participant reached a HR between 125 and 170 bpm after 6 minutes. If the difference was greater than 5 beats, the subject was told to continue until the HR had reached a steady state level. Rate of perceived exertion (RPE) was recorded at every minute, using Borg scale (6-20). HR was measured and recorded at the end of the fifth and sixth minute of this stage, from which mean HR was calculated when the test was completed. When the test was completed, maximal oxygen uptake (VO_{2max}) (mL, kg^{-1}, min^{-1}) was estimated (55).

2.14 Statistical analysis

The statistical analysis and interpretation of data was performed using IBM SPSS Statistics 25 (SPSS Inc., Chicago, IL.) and Microsoft Excel. Data from the Accuro LYNK2 activity tracker and PAI-scores were obtained from PAI Health Norway. The received PAI-dataset contained much excess data that had to be cleaned before further processing. The datasets were then reviewed to look for abnormal numbers resulting from typing errors or other sources of error. To determine whether the data was normally distributed, the Shapiro-Wilk´s test was performed ($p > 0.05$). Since all datasets had 20 or less participants, the normality was tested with the Shapiro-Wilk's test ($p > 0.05$) as this method is considered to be robust with small sample size observations. In addition, a Q-Q plot was used for a visual check of normality of the data. 95% confidence intervals (CI) were used for precision and 0.05 as the limit, meaning datasets that were above this size would be normally distributed. An independent sampled t-test was used to assess whether there was a significant difference between the two groups. One out of six datasets were normally distributed.

This led to replacing the t-test with a non-parametric method. Here, the Mann-Whitney U test was used to compare the two groups. Descriptive data were expressed as mean ± SD for demographic variables (gender, age, BMI,) and estimated VO_{2max}. The values of the average sub VO_{2max} are given in ml/kg/min. A predetermined *P*-value of 0.05 was considered to indicate statistical significance.

3 Results

3.1 Participant's characteristics

Out of the 65 patients assessed for eligibility, a total of 39 patients, aged 18 - 72 years taking part in inpatient rehabilitation for chronic pain and unspecific disorders was included in the study. Mean age was 48 (SD 9.4). The participants´ mean BMI was 28.4 (SD 5.3) and the majority of the participants were female (85% women).

The participants were randomized and allocated into the two different groups. Of the 39 patients included in the study, 22 were assigned to the FB-group and 17 to the CON-group. 5 participants were accounted as dropouts. See figure 1 for information about the flow of participants.

Table 1. Baseline characteristic of the participants. Values are mean ± SD

	All (n = 34)	FB-group (n = 21)	CON-group (n = 13)
Sex		F = 85%, M = 15%	F = 92.3 %, M = 7.7%
Age (years)	48.2± 9.4	48.2± 8.7	48.2± 10.4
Body mass(kg)	80.5± 14.8	85.7± 15.7	73.6± 10.7
BMI (kg/m^2)	28.4± 5.3	30.0± 6.1	26.2± 3.3

Patient characteristics were registered at the baseline test and are presented in table 1, summarizing descriptive mean value data and changes in physiological parameters from pre- to post intervention.

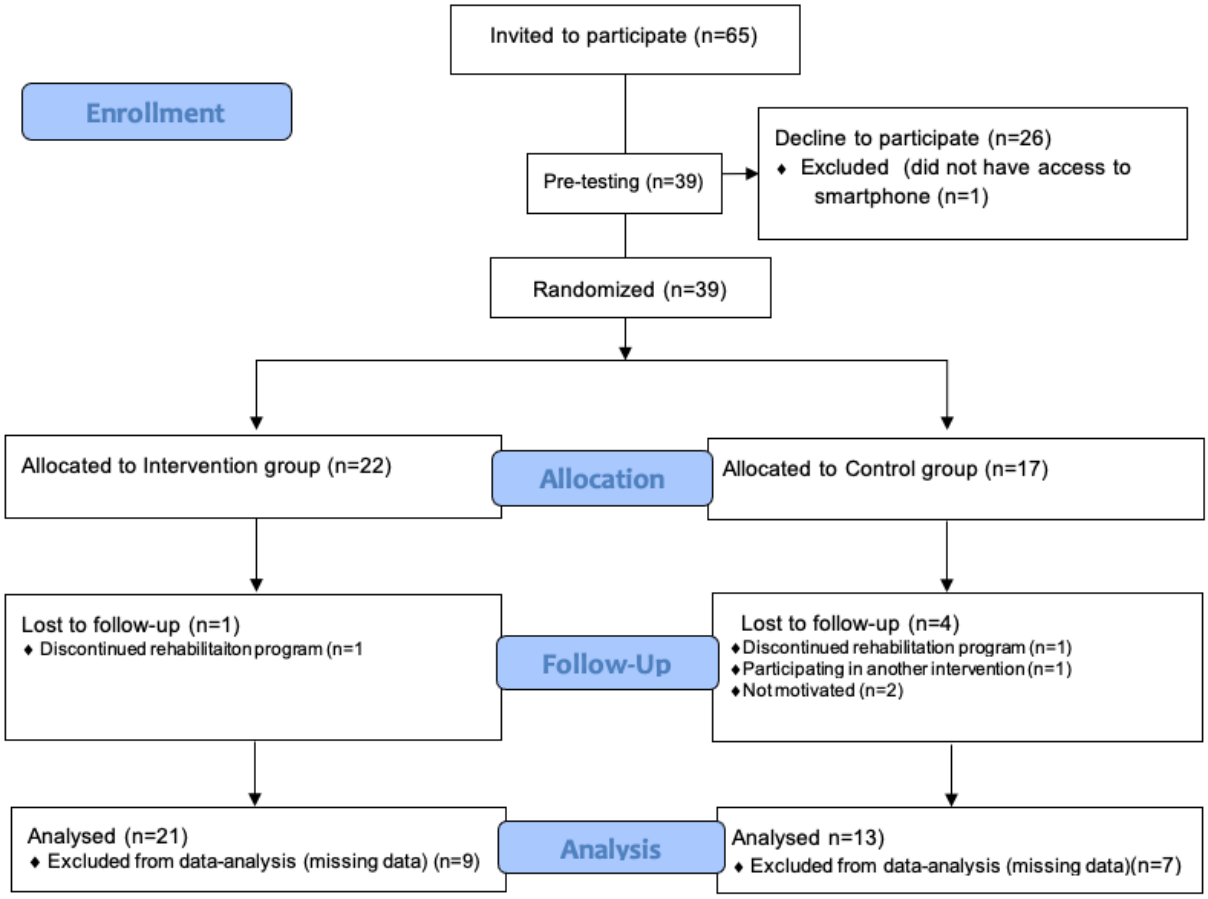

Figure 1 Flow diagram of participants

3.2 PAI-data

Table 2. PAI-total. Values are mean ± SD

	FB-group (n=12)	CON-group (n=6)	Group difference	p-value
Pai-total	125.98 ± 70.5	123.6 ± 69.6	2.41 ± 35.1	0.946

Table 2 summarize the PAI-data. PAI-score was obtained from the seventh day after their first home-period. There was no significant difference in total PAI-score between the two groups after the 1st home- stay week. Participants in the FB-group obtained a mean PAI-score of 125.98 ± 70.5 and participants in the CON-group obtained a mean PAI-score of 123.6 ± 69.6. Out of the 39 participants allocated to the intervention, only 18 were included in the main analysis. PAI-data was obtained from 12 and 6 participants in the FB- and CON-group respectively.

3.3 Cardiorespiratory fitness/VO2max

Table 3 shows estimated maximal oxygen uptake (ml/kg/min) between the two groups from pre- to post-test. Mean $VO2_{max}$ (mL/kg/min) increased from pre- to post-intervention in both the FB-group (13,8 %) and the CON-group (10,4 %).

Mean $VO2_{max}$ was 35.4 ± 6.9 for the FB-group and 34.9 ± 5.6 for the CON-group after completing the 6-week intervention.

There was no statistically significant difference in estimated $VO2_{max}$ between the two groups (p=0.62).

Table 3. Estimated $VO2_{max}$ (mL/kg/min) and BMI (kg/m^2) at pre- and post-test. Values are mean ± SD. FB-group (n=21), CON-group (n=13).

	FB pre	FB post	CON pre	CON post	Change difference between groups	p*
VO_2	31.3 ± 7.1	35.4 ± 6.9	31.6 ± 6.0	34.9 ± 5.6	0.73 ± 1.4	0.62
BMI	30.0 ± 6.2	29.7 ± 6.0	26.2 ± 3.3	26.3 ± 3.1	.078 (-.60 - .35	0.55

* BMI: Mann-Whitney U-test. Other variables two sample t-test

4 Discussion

The overall aim of this study was to investigate whether use of WAT that provide feedback on activity levels increases PA compared to the use of WAT without feedback for patients in inpatient rehabilitation/when being treated for chronic pain.
No statistically significant differences were found between the two groups in the primarily outcome after the 1st week of the home period. Nonetheless, positive changes in estimated mean VO_{2max} (mL/kg/min) were observed in both groups from baseline to 6 weeks end of the intervention.

The lack of effect of the feedback-intervention compared to the CON-group was contrary to what one would expect. Concerning the activity level, the PAI-score in both groups were to some extent abnormally high. However, the interpretation of these results should be treated with great caution due to the small sample size. Although the tests indicate no statistically significant difference between the groups, it is difficult to rely on the results due to the low sample size for the 18 remaining participants included in the PAI-data analysis. In addition, missing data from the CON-group (reduced from 17 to 6 participants) could imply that the groups are no longer randomized. Nevertheless, the general low sample size remains the major issue. This can lead to incorrect rejection of the alternative hypothesis, as there could be a difference even though the data does not support it.

In this study, one should also have the context in mind when looking for explanations for the similarity in the results regarding the PA-levels. The participants PA-behaviours might have been affected by the nature of the study. Since the period in institutional care is largely controlled by the program offered at the rehabilitation centre, a huge part of the intervention was carried out by clinicians. Exercise is an essential part of the rehabilitation program, and this might have contributed to a certain assurance regarding the actual training intensity and overall progression of the PA performed in the first two weeks of the intervention.
Contrastingly, when people are unsupervised, they tend to self-select exercise intensity below their ventilatory threshold (56).
Further, as the PAI-algorithm favours high intensity, assuming adequate PA-intensity is achieved, this should reflect an increase in CRF. This may also be in line with the positive changes in estimated VO_{2max} observed from baseline to the 6-week end of the intervention.

It can also be assumed that the participants included in the PAI-data analysis, were the most compliant with both the PA-maintenance and APP-synchronizing.
Moreover, it should be considered that the final PAI-scores used as measurements were obtained at the 7th day in their first home-week after they left the rehabilitation centre. This is probably too little time for the PAI algorithm to detect differences between the groups. As any PAI-points earned in the last 7-day period expires and the score is recalculated, the algorithm adjusts to the users improved fitness level. The PAI algorithm takes into account the users previous PAI score, meaning it is harder to earn PAI-points. As it is easier to earn the first 50 PAI against the next 50 PAIs, especially for untrained individuals, it is likely that sustaining their PAI-scores over the course of the next 7 days would be harder. This can be explained both by the design of the PAI-model, and due to exercise induced lowering of resting as well as submaximal or maximal HR. (57).

Both groups in this intervention was wearing the same wrist-worn activity tracker, except the CON-group did not have the ability to view their PAI-score. Nonetheless, wearing an activity-tracker or medical device in itself has shown to have an impact on the patient's awareness (43). This may have contributed to an increase in PA regardless of whether one can see the activity-level data or not. The fact that the participants in this study were observed by test personnel may also have affected the result. Participants might work harder to satisfy investigators and perform better when they know they are participating in a study, and that being monitored in itself might lead to behavioural changes. This is referred to as the Hawthorne-effect (58). Evidence suggests that when people get feedback on their target, and learn that they are below, their effort normally increases (59). As a common barrier to PA participation often reported is lack of ability to self-management. Patel et. al., highlights the importance of engagement strategies to influence sustainable health behaviour change, and WAT are not likely to be the primary drivers for these changes alone (60). Social competition and support have shown to be important factors in increasing adherence to PA behaviours, and individual feedback may play an important role. In some of the participant-groups, the competitive level was high. As social support and receiving encouragement to participate in PA is linked to PA-enhancement, given the fact that the participants in this study underwent the common exercise sessions together (independent of the intervention group) in a social group setting, might also have affected their motivation and effort. If PAI-points were more difficult to obtain for some participants, it might have increased their exercise performance. This is also consistent with earlier findings on interventions aimed at increasing PA,

suggesting that individuals motivated by their own goals and desires are more likely to incorporate and maintain behaviour change (43), (61).

Considering the relatively short duration of the intervention, it is possible that extrinsic motivation to a large extent may have been adequate to motivate participants in both groups. Thus, an apparent potential effect of both the intervention and APP might have diminished, as it would make the two groups more similar. Therefore, it is likely that the combination of the multidisciplinary exercise program and external motivation may have been sufficient to motivate participants in both groups to achieve high PAI-scores. Moreover, living on-site at the rehabilitation centre for 4 weeks could have provided a necessary break from daily life obligations towards social life and work. The regulated schedule with both individual and group appointments could have contributed to a new approach to PA for the majority of the participants. Further, as a main part of the rehabilitation approach is patient education, it is also possible that the comprehensive approach in itself may have contributed to an overall increased health and physical literacy for the participants. As health literacy strongly relates to an individual's motivation, physical competence, understanding and taking responsibility towards their values (43), this may have been sufficient to help the participants take advantage of their PA maintenance. A study by Casey et. al., found that use of objectively measurement of PA in an exercise intervention combined with a ACT-based multidisciplinary program to increase activity levels for people with chronic pain (62).

One possible explanation for the lack of difference in PAI-score between the groups could be that the feedback was to modest and insufficient to enhance the participants' motivation. A longer timeframe might be that a longer intervention period could have provided larger effects and detected between group differences. The two weeks of intervention prior to the home-period might have been too short for the PAI-Health APP to influence further change in PA-levels. This may indicate that the feedback provided by the APP was not efficient enough to induce strong changes between the groups, considering that it is given in combination with a major intervention.
Mercer et al., identified many of the newest generations of WAT to include techniques related to behaviour change, goal setting, social support and rewards. Further, in a systematic review, Lyons et al., identified these key features to be commonly used in clinical behavioural interventions to increase PA, and that WAT may be transferable to clinical inpatient settings (63). Although approaches based on activity monitoring in recent years have been

increasingly exploited in clinical research settings, they are however, often associated with poor long-term compliance (64). According to Mercer et al., the ability to analyse, present data and at the same time give feedback in an understandable way seems to be of importance to avoid the risk of recurrence from WAT. A similar negative effect were shown on overwhelming the user with unnecessary details (64). A systematic review of APP and activity trackers from 2019 showed a moderate positive effect in both PA outcomes and short-term adherence to rehabilitation programs (65). However, the findings should be interpreted in light of some limitations due to heterogenous interventions, high heterogeneity in results and differences in diagnostic groups.

Usability is reported as a key factor to enhance and maintain change in health behaviour, meaning WAT should be easy to use as well as aesthetically and visually appealing (66). Further, individual preferences should be considered when designing and tailoring procedures, as they are important moderators regarding whether or not adults adopt WAT and other health APPs. Previous studies on the use of these devices in older adults highlights the importance of usability, pointing at negative user experiences (e.g., data accuracy, inaccurate and inconsistent readings) to counteract the continued use of WAT (64). Although use of WAT often is associated with positive outcomes regarding PA, perceived usability as an prevalent barrier to the adoption of WAT has been found (66). This is supported by Mercer et. al., who found that WAT that provided real-time feedback to be useful and motivating and led to enhanced self-efficacy to do PA in adults with chronic illness (64). However, the study highlights the need for new ways to overcome digital health literacy. Besides, health literacy strongly relates to an individual's motivation, physical competence, understanding and taking responsibility towards their values (43), this may have been adequate to help the participants take advantage of their PA maintenance. Here, the WAT and APP used in this study may have both strengths and limitations. The device had a simple, modular design (one-button "start/stop" function). Due to its limited interface for displaying tracking results, the device relies on the accompanying APP to access data. To assess their daily PAI-score, participants in the FB-group had to log in to the PAI-health APP manually each time. Some may have found this discouraging. Given the fact that the WAT neither had a watch face display nor provided frequent notifications, a more advanced and suitable device visualizing their PAI-score could have been beneficial. For example, daily PA-reminders, rewards when reaching the recommended 100 weekly PAI, the WAT could provide prompt feedback, which have been shown to increase self-efficacy (67).

Finally, it should be noted that the short-term compliance with wear of the WAT in this intervention was high, which is encouraging for future studies.

4.1 Strengths and limitations of the study

There are a number of strengths and weaknesses that must be taken into account in the assessment of this study. Regarding the positive side, a fundamental strength is the RCT design. As allocation was decided by a randomization program, different prognostic variables should be evenly distributed between the two groups. This is a strength of the study in itself as it reduces the risk of ascertainment bias. Block randomization also allocate an approximately equal number of participants in each group, with stratification for gender, into the two different groups (68).

Another particular strength is the use of objectively measurements of PA. This is considered a strength compared to utilization of questionnaires and self-reported PA-data, which strongly relies on the participants recall (69). This reduces the risk of recall bias and made the data less prone to information bias (70). The use of HR monitoring to provide the participants with objective, readily feedback on PA-level has advantages compared to other conventional measurements (e.g., pedometers, accelerometers), which can have reduced reliability and validity in real life settings (71). In contrast to PAI, which is HR-dependent, these devices do not account for intensity or the body's response to different activities (e.g., cycling, swimming). Aerobic capacity was also objectively measured. Although the results are less accurate compared to a gold standard laboratory VO_{2max} test, the Åstrand-test seems to be adequate to give an impression of the physical capacity in CMP-patients. The reliability and validity of the Åstrand-test is confirmed by several studies (72), (73).

Notwithstanding the above-mentioned strengths, this study has a number of key limitations that should be noted. The primary limitation of the study to be recognized is the small sample size. Due to the relatively small number of participants, caution is needed interpreting these results. Additionally, missing or inadequate PAI-data meant that only 18 of the remaining 34 participants had usable data. This further reduced the sample size in the statistical analysis, and presumably led to a loss of statistical power and increased the probability of type II errors. Due to the relatively small number of participants, caution is needed interpreting these results.

Another weakness is that it did not study long-term effects, as the duration of the intervention only lasted six weeks. Both a longer time frame on the intervention and a larger sample size might have been beneficial and required to evaluate long term and sustainable behaviour change in future research. Another potential shortcoming is the lack of pre-intervention data on important variables such as physical activity and aerobic fitness prior to the rehabilitation stay in the years following conscription. Therefore, it is not possible to distinguish between a lasting fitness effect and effects being due to continuing physical exercise. The long-term effectiveness of WAT in a rehabilitation setting therefore remains unclear. Nor is there any data on participants own perceptions and experiences after being introduced to the WAT, either during the intervention or subsequently.

Another limitation is that neither participants nor researcher could be blinded. In addition to function as contact person during the intervention, the researcher was responsible for recruitment, testing and the statistical analysis. This is not ideal, since it could have resulted in ascertainment bias. Finally, a potential limitation of the study is that it could have included secondary health outcome measures by using assessment tools such as self-reported questionnaires. Thus, it could have targeted several perspectives on health-related quality of life outcomes (e.g., EQ5D), average pain (e.g., Visual Analog Scale (VAS)) and anxiety and depression symptoms (e.g., HSCL-25).

4.2 Future perspectives

To date, WAT have not been commonly used in standard conventional treatment for patients with chronic pain in Norway (74). In the field of exercise- and public health science, the use of WAT is estimated to increase rapidly in the coming years. This may indicate that this kind of studies would be more feasible and relevant now than ever to help bridge the knowledge gap. The primarily aim was to look at the activity measured during the first week of their home period. The main challenge regarding the maintenance of the achieved PA-behaviour change is according to findings, however, to create a transition between being in treatment and coming home. By placing more emphasis on preparing patients for the maintenance phase of the process of change while they are still in treatment, for example influence motivation, perhaps they are more likely to be able to maintain their level of PA afterwards. Therefore, WAT may be a promising supplement for facilitating a more active lifestyle, reduce the burden of clinic time and avoid recurrence. Further, this study might indicate that equivalent effects can be expected in other clinical treatment practices.

4.3 Conclusion

In conclusion, no significant differences in the main outcome were found between the two groups. This study provides no evidence to draw the conclusion that feedback on PA-level is superior compared to the control group. However, high PAI-scores in both groups are positively associated with enhanced levels of objectively measured PA, which should be noted. Further, the results from the Åstrand-test showed a significant increase in estimated VO_{2max} in both groups after 6 weeks intervention. Due to a small sample size the findings should be interpreted with caution. Nonetheless, the results from this study give some indicators that may help both clinicians and patients in the assessment of PA as a feasible supplement in treatment of chronic pain. Future studies should investigate the long-term effect of WAT to approach the most effective way to help increase PA in rehabilitation programs. The external validity of this study can be extended to the main group of individuals with CMP who seek care in primary and specialist treatment.

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Appendix

Appendix 1 Written consent agreement

Appendix 2 Ethical approval

Appendix 1: Written consent agreement

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

Bruk av kroppsbåren sensorteknologi for å øke fysisk aktivitet i døgnbasert rehabilitering for pasienter med langvarige smerter

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å undersøke om bruk av aktivitetsmålere som gir tilbakemelding om hvor aktiv man er, kan være med å øke aktivitetsnivået hos personer som deltar i døgnbasert rehabilitering for langvarige smerter. Du forespørres om deltakelse siden du skal delta på rehabilitering for langvarige smerter på Unicare Helsefort. Forskningsprosjektet er et masterprosjekt i regi av Institutt for nevromedisin og bevegelsesvitenskap ved NTNU.

HVA INNEBÆRER PROSJEKTET?

Mange som deltar i rehabilitering øker mengden fysisk aktivitet så lenge programmet varer. Utfordringen for mange er å vedlikeholde mengden fysisk aktivitet etter man kommer hjem. I denne studien vil vi undersøke om det å bruke en aktivitetsmåler som gir deg tilbakemelding om hvor aktiv du er øker aktivitetsnivået ditt. Vi vil også undersøke om det har en effekt på smerter og om det påvirker andre plager som angst og depresjon i tillegg til helserelatert livskvalitet.

Deltakere i studien vil bli delt i to grupper med loddtrekning. Begge gruppene vil bruke aktivitetsmålerne (armbånd) mens man deltar i rehabiliteringsprogrammet ved Unicare Helsefort (inkludert hjemmeperioden). Den ene gruppen vil få tilbakemelding om hvor aktiv man er via en mobilapplikasjon (mobilapp), mens den andre gruppen ikke får noen tilbakemelding (kontrollgruppen). På denne måten kan vi undersøke om tilbakemelding øker aktivitetsnivået.

Å være med i prosjektet vil ikke påvirke rehabiliteringsprogrammet ditt på Unicare Helsefort. Det eneste som kommer i tillegg er informasjon om bruk av aktivitetsmåleren. Mens du bruker aktivitetsmåleren må du åpne mobilapplikasjonen minst en gang i uken for å sikre overføring av aktivitetsdata fra armbåndet.

I prosjektet vil vi innhente og registrere opplysninger om deg. Informasjon om aktivitetsnivået ditt vil vi samle gjennom aktivitetsmåleren. I tillegg vil vi bruke informasjon vi samler for alle deltakerne på smerterehabilitering. Dette omfatter testing av fysisk form, vekt og spørreskjemainformasjon om ulike plager (smerter, angst, depresjon) og helserelatert livskvalitet.

MULIGE FORDELER OG ULEMPER

Det er ingen kjent risiko eller bivirkninger ved å delta i forskningen. Å delta vil kreve at du bruker aktivitetsmåleren mens du deltar i rehabiliteringsprogrammet (inklusive hjemmeperiodene). Mens man bruker aktivitetsarmbåndet bør man åpne mobilapplikasjonen minst en gang per uke for å synkronisere aktivitetsdata. Utover dette vil prosjektet ikke kreve noe ekstra fra deg da vi ønsker å bruke den informasjonen som du allerede gir som en del av det vanlige rehabiliteringstilbudet ved Unicare. Blir du trukket ut til å være med i gruppen som får tilbakemelding vil du få informasjon om ditt aktivitetsnivå via en mobilapplikasjon. Blir du trukket ut til den andre gruppen (kontrollgruppen) så vil ikke forskningen gi deg noen direkte fordeler, utenom at du bidrar til utvikling av ny kunnskap.

Etter prosjektet er avsluttet vil det loddes ut en iPad til en deltaker. Alle deltakere vil motta et lodd for hver uke man synkroniserer aktivitetsdata med mobilapplikasjonen minst to ganger.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling.

Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Lene Aasdahl, 93224342, lene.aasdahl@ntnu.no

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene.

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 Lene Aasdahl (prosjektleder) som har tilgang til denne listen.

Opplysningene om deg vil bli anonymisert fem år etter prosjektslutt.

FORSIKRING

Som pasient ved Unicare Helsefort er du dekket av pasientskadeloven.

OPPFØLGINGSPROSJEKT

Det er ikke planlagt noen oppfølgingsprosjekt. Men hvis det blir aktuelt så vil vi kontakte deg for å høre om du er ønsker i å delta.

GODKJENNING

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning 2019/800/REK midt.

Bruk av sensorteknologi i rehabilitering for pasienter med langvarige smerter

Etter ny personopplysningslov har dataansvarlig NTNU (Institutt for nevromedisin og bevegelsesvitenskap) og prosjektleder Lene Aasdahl et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke.

Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet kan du ta kontakt med masterstudent Viktor Øverhus Hassel, epost: viktoroh@stud.ntnu.no, 45480501 eller prosjektleder Lene Aasdahl, e-post: lene.aasdahl@ntnu.no, 93224342

Du kan ta kontakt med institusjonens personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet: Thomas Helgesen, e-post: personvernombud@ntnu.no

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

.....	_____
Sted og dato	Deltakers signatur
	.....
	Deltakers navn med trykte bokstaver

Appendix 2: Ethical approval

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Ramunas Kazakauskas	73597510	24.06.2019	2019/800/REK midt
			Deres dato:	Deres referanse:
			30.04.2019	

Vår referanse må oppgis ved alle henvendelser

Lene Aasdahl
ISM

2019/800 Bruk av kroppsbåren sensorteknologi for å øke fysisk aktivitet i døgnbasert rehabilitering for pasienter med langvarige smerter

Forskningsansvarlig: Norges teknisk-naturvitenskapelige universitet
Prosjektleder: Lene Aasdahl

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK midt) i møtet 05.06.2019. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Komiteens prosjektsammendrag: I prosjektet skal man undersøke om aktivitetsnivået til pasienter med langvarig smerteproblematikk øker når de bruker en aktivitetsmåler som gir tilbakemelding om hvor aktive de er. Man skal også undersøke om den eventuelle økningen i aktivitetsnivå har en effekt på fysisk form, vekt, livskvalitet, smerter, angst og depresjon. Studiens utvalg skal bestå av ca. 60 pasienter som er innlagt for rehabilitering ved Unicare Helsefort, hvorav halvparten skal få tilbakemelding om sitt aktivitetsnivå. Bortsett fra forskjellen i tilbakemelding følger begge gruppene samme standard behandlingsforløp, og alle opplysningene det søkes tilgang til innhentes som en del av ordinær behandlingsrutine. I tillegg til data fra aktivitetsmåleren omfatter disse opplysningene maksimalt oksygenopptak, vekt, høyde, samt spørreskjemainformasjon om angst, depresjonsplager, smerte og helserelatert livskvalitet. Studien er samtykkebasert. Studien er en del av en Master i bevegelsesvitenskap.

Saksopplysninger: Du opplyste 07.05.2019 om at det er skjemaet HSCL-25 som skal brukes til å måle angst og depresjon i dette prosjektet, ikke vedlagte HADS. Det ettersendte HSCL-25-skjemaet ble lagt til saksdokumentene.

Inhabilitet
Komiteens leder, Vibeke Videm, og komiteens representant for psykologi, Roger Hagen, ble vurdert som inhabile og deltok ikke i vurderingen av søknaden.

Forsvarlighet
Komiteen har vurdert søknad, forskningsprotokoll, målsetting og plan for gjennomføring. Komiteen har kommentarer til rekrutteringsprosedyren og til hvilken institusjon som skal være forskningsansvarlig. I tillegg ber vi om noen endringer i informasjonsskrivet. Utover dette har vi ingen forskningsetiske innvendinger til prosjektet. Under forutsetning av at vilkårene nedenfor tas til følge vurderer REK at prosjektet er forsvarlig, og at hensynet til deltakernes velferd og integritet er ivaretatt.

Kommentar til rekrutteringsprosedyren
For å sikre at de forespurte får tilstrekkelig betenkningstid til å vurdere sin deltakelse forutsetter vi at dere

Besøksadresse:
Fakultet for medisin og helsevitenskap Mauritz Hansens gate 2, Øya helsehus

E-post: rek-midt@mh.ntnu.no
Web: http://helseforskning.etikkom.no/

sender ut informasjonsskrivet sammen med innkallelse til behandling. I tillegg forutsetter vi at pasientene svarer på spørsmålet om deltakelse til forsker ikke behandlende helsepersonell. En slik fremgangsmåte vil minimere mulig opplevelse av press om deltakelse og skille bedre mellom hva som er behandling og hva som er forskning.

Forskningsansvarlig institusjon
Komiteen oppfatter at forskningsdata skal samles inn som en del av ordinær utredning og behandling ved Unicare Helsefort. Vi vurderer at studiens klinikknærhet gjør det naturlig at Unicare Helsefort er forskningsansvarlig institusjon, i tillegg til NTNU. Komiteen forutsetter at NTNU og Unicare Helsefort avklarer detaljene rundt ansvarsforholdene seg imellom.

Komiteen ber deg avklare med Unicare Helsefort hvem som skal være kontaktperson for forskningsansvarlig institusjon. I utgangspunktet vil dette være institusjonens øverste leder, men ansvaret kan være delegert til andre. Vennligst send navn, stilling og epostadresse på kontaktperson til vår e-postadresse rek-midt@mh.ntnu.no med «REK Midt 2019/800» i emnefeltet.

Endring av informasjonsskriv
Komiteen ber deg om å endre informasjonsskrivet i tråd med følgende punkter:

1. I innledende avsnitt må du oppgi hvorfor deltakerne spørres.
2. Forsikring: Komiteen oppfatter at data skal samles inn som en del av ordinær utredning og behandling ved Unicare Helsefort. Deltakerne vil da omfattes av pasientskadeloven. Vi ber derfor om at det under «Forsikring» opplyses om at deltakerne er dekket av pasientskadeloven.

Vilkår for godkjenning

1. Komiteen forutsetter at Unicare Helsefort påtar seg ansvaret som forskingsansvarlig institusjon, i tillegg til NTNU.
2. Du må sende inn revidert informasjonsskriv, samt navn, stilling og epostadresse til kontaktperson for forskningsansvarlig institusjon. Vennligst benytt e-postadressen rek-midt@mh.ntnu.no og «REK midt 2019/800» i emnefeltet. Prosjektet kan ikke igangsettes før vi har bekrefter at informasjonsskrivet er endret i henhold til våre merknader.
3. Komiteen forutsetter at informasjonsskrivet sendes ut sammen med innkallelse til behandling og at pasientene svarer til forsker.
4. Komiteen forutsetter at du og alle prosjektmedarbeiderne følger institusjonens bestemmelser for å ivareta informasjonssikkerhet og personvern ved innsamling, bruk, oppbevaring, deling og utlevering av personopplysninger.
5. Av dokumentasjonshensyn skal opplysningene oppbevares i 5 år etter prosjektslutt. Du og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil. Opplysningene skal deretter slettes eller anonymiseres.
6. Komiteen minner om at de aller fleste kliniske studier skal registreres i det offentlig tilgjengelige registeret www.clinicaltrials.gov. Du er selv ansvarlig for å avklare om forskningsstudien er omfattet av kravet til registrering.
7. Du skal sende sluttmelding på eget skjema, jf. helseforskningsloven § 12, senest et halvt år etter prosjektslutt.
8. Dersom du vil gjøre endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må du sende endringsmelding til REK, jf. helseforskningsloven § 11.
9. Komiteen forutsetter at ingen personidentifiserbare opplysninger kan framkomme ved publisering eller annen offentliggjøring.

Vedtak

Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Med hjemmel i helseforskningsloven § 10 godkjennes

prosjektet på de vilkår som er gitt.

Komiteens beslutning var enstemmig.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK midt. Klagefristen er 19. august. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ragnhild Støen
PhD
Avdelingssjef/førsteamanuensis
Nestleder, REK midt

Ramunas Kazakauskas
rådgiver

Kopi til:jorunn.helbostad@ntnu.no; postmottak@ntnu.no