

Physical activity tracking

Personal activity intelligence (PAI) versus 10000 steps per day and the effects on cardiorespiratory fitness, body composition and blood pressure in inactive overweight and obese

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Abstract

Introduction: Increased amounts of sedentary time, and less physical activity (PA) have become a global concern, and may result in increased risk of cardiovascular disease (CVD). Thus, it has become an important task to increase PA in the general population. Personal activity intelligence (PAI) is a new metric for activity tracking that takes into account age, sex, resting and maximum heart rate (HR), and give an individualised goal for PA. 100 PAI per week has been found to reduce the risk of CVD and all-cause mortality in epidemiological studies, but the link through increased cardiorespiratory fitness (CRF) has not been established in a controlled clinical trial. The aim of this study was to investigate the effects of following the advice of maintaining 100 PAI per week compared to the effects of walking 10 000 steps daily on CRF, blood pressure (BP) and body composition.

Method: 21 obese or overweight men (n=8) and woman (n=13) were randomized to either of two groups; (i) The PAI group (n=10) followed the advice of maintaining a score of 100 PAI for 8 weeks (ii) The step group (n=11) followed the advice of walking 10 000 steps per day. VO_{2max} directly measured with cardiopulmonary exercise testing (CPET), body composition measured with bioelectrical impedance analysis (BIA) and blood pressure (BP), was measured pre- and post-intervention. Analysis of covariance (ANCOVA) was used for comparison between the two groups, and Wilcoxon signed-rank test was used for within group analysis.

Results: No significant differences were found between the two groups. A negative association between mean weekly PAI and increase in absolute maximum oxygen uptake (VO_{2max}) was found (r = -0.712, p=0.031), and a moderate non-significant positive association was found between mean daily steps and increase in absolute VO_{2max} . A significant median increase (p=0.009) in median VO_{2max} relative to body weight was found in the step group, while a non-significant median increase (p=0.051) was found in the PAI group. The largest mean and absolute increase in VO_{2max} was found in the PAI group. Median BF% was significantly (p=0.028) reduced in the PAI group, and median body weight was significantly (p=0.047) reduced in the step group. No significant change in BP was found within the groups.

Conclusion: Participants in both groups improved PA from pre- to post-intervention. Neither of the groups increased median absolute VO_{2max} significantly, and there was no statistically significant evidence that either of the interventions was superior. The increase in relative VO_{2max} is probably explained by decreased body weight. However, a trend towards a large mean increase in CRF was observed in the PAI group. Future randomized controlled clinical trials may use data obtained in this study for sample size estimations.

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Statement of conflict of interest

The leader for CERG, Ulrik Wisløff is one of the inventors, and a stakeholder in the company with the rights for PAI; Beatstack Inc, together with NTNU Technology Transfer Office, Femto Inc, Singsaker Holding and Berre Holding inc. Due to potential conflicts of interests, Professor Ola Dahle, at the Faculty of Medicine and Health Science, NTNU was assigned as an external controller for the study. There are no additional conflicts of interest to declare.

Abbreviations

- ANCOVA Analysis of covariance
- ANOVA Analysis of variance
- App Application
- BF Body fat
- BIA Bioelectrical impedance analysis
- BMI Body mass index
- BP Blood pressure
- BPM Beats per minute
- CPET Cardiopulmonary exercise testing
- CRF Cardio respiratory fitness
- CVD Cardiovascular disease
- DEXA Dual energy x-ray absorptiometry
- FFM Fat Free Mass
- FM Fat mass
- HR Heart rate
- HR_{max}-Maximum heart rate
- HR_{rest} Resting heart rate
- HRR Heart rate reserve
- PA Physical activity
- PAI Personal activity intelligence
- PF Physical fitness
- RER Respiratory exchange ratio
- VE Minute ventilation
- VO₂ Oxygen consumption
- VO_{2max} Maximum oxygen uptake
- $VO_2R VO_2$ reserve

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1 Introduction

1.1 Physical activity, inactivity, and associated risk factors and benefits

Through the selective pressures of evolution, the human species has developed in an environment with high demands for physical activity (PA) (Booth, Laye, Lees, Rector, & Thyfault, 2008). New inventions and technologies like steam, gas, electricity, cars, computers, and the internet were introduced after the industrial revolution, and have resulted in a reduced need for physical effort considering daily tasks (Hallal et al., 2012). As a corollary, increased amounts of sedentary time, and less PA, results in an increased risk of chronic disease (Booth et al., 2008). Physical inactivity is a comparable risk factor to smoking and obesity (I. M. Lee et al., 2012), and increased PA shows beneficial in both primary and secondary prevention of cardiovascular disease (CVD) (Warburton, Nicol, & Bredin, 2006). Awareness of the risks associated with a sedentary lifestyle and the positive effects of PA, has made it an important task for health governments all over the world to increase the PA level in the general population.

As natural selection in an environment with high PA have favoured a metabolic pathway that conserves energy for future deficits in humans (Booth et al., 2008). Reduced PA and increased sedentary time may lead to another increasing problem in the general population; overweight, obesity and the associated lifestyle related risk factors and diseases like diabetes, hypertension and CVD (WHO, 2017a). CVDs alone were responsible for 28,5% of all deaths in Norway in 2015 (Norwegian Institute of Public Health, 2017), and the need to reduce risk factors associated with CVD in the population is obvious.

Several studies have been conducted to investigate the associations between PA, risk factors and mortality for CVD and all-cause mortality. Increased aerobic PA has been associated with decreased blood pressure (BP) in overweight as well as normal weight individuals (Whelton, Chin, Xin, & He, 2002). Increased PA is also associated with reduced risk and mortality for CVD (Tjonna, Lund Nilsen, Slordahl, Vatten, & Wisloff, 2010), and of all-cause mortality (Blair et al., 1995; Blair et al., 1989; J. Myers et al., 2002). Avoiding obesity, maintaining a normal BP, and performing moderate to vigorous PA have been separately associated with lower death rates from coronary heart disease and all-causes (Paffenbarger et al., 1993). Moreover, the reduced risk observed from beginning moderate vigorous PA is associated with

an increased cardiorespiratory fitness (CRF) (D. C. Lee et al., 2011). Conversely, a low CRF is associated with an elevated risk for CVD and all-cause mortality (Wei et al., 1999).

1.2 Physical activity, exercise and fitness

PA, exercise and physical fitness (PF) are according to Caspersen, Powell, and Christenson (1985) terms that describe different concepts which is often confused. First of all, PA describes "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen et al., 1985), while exercise is defined as "a subset of physical activity that is planned, structured and repetitive, and has a final or an intermediate objective; the improvement or maintenance of physical fitness" (Caspersen et al., 1985). PF however, is described as "a set of attributes that are either health- or skill-related. [...] These attributes can be measured with specific tests" (Caspersen et al., 1985). Hence, exercise could be used to increase the overall PA, and therefore also the measureable PF of an individual.

CRF is related to the ability to perform dynamic moderate to high intensity exercise using large muscle groups, for a prolonged period of time (Vanhees et al., 2005). Howley (2001) describes CRF as "the ability of the cardiovascular and respiratory system to supply oxygen to the working muscles during heavy dynamic exercise". This ability to supply the working muscle cells with oxygen is crucial to maintain the aerobic production of ATP trough oxidative phosphorylation in the mitochondria, and the aerobic endurance of an individual depends on the CRF.

1.3 Maximum oxygen uptake (VO_{2max})

Maximum oxygen uptake (VO_{2max}) obtained from a cardio pulmonary exercise test (CPET) is commonly used as an objectively measurement of CRF, and overall PF. Different individual factors are involved in the oxygen transport mechanism and may contribute to limitations in VO_{2max}. These factors involve the haemoglobins capacity to bind oxygen in the blood, the capacity of the lung, the oxygen extraction from the blood to the mitochondria in the skeletal muscles, and the cardiac output, which is the product of the hearts stroke volume (SV) multiplied with heart rate (HR) (Bassett & Howley, 2000). The relative contribution of each of these individual factors in limiting the VO_{2max} have been debated. In the 1970's it was argued that peripheral limitations in the muscles ability to utilize oxygen were dominant in limiting VO_{2max} (B. Saltin et al., 1976), later it became evident that VO_{2max} predominantly is centrally limited by the oxygen delivery capacity (B. Saltin, 1985), and the most important single factor for VO_{2max} is the hearts SV (Bassett & Howley, 2000). Oxygen uptake (VO_2) can be expressed by the Fick equation (Levine, 2008); $VO_2 = Q \cdot (Ca_{o2} - Cv_{o2})$, where VO_2 is the oxygen uptake, Q is the cardiac output (HR \cdot SV), and ($Ca_{o2} - Cv_{o2}$) is the arterio-venous difference in oxygen concentration. The equation implies that constraints in the different factors involved in the oxygen transport can influence VO_{2max} .

Considering the different constraints of the individual factors involved in oxygen transport, different forms of exercise will give different adaptations, dependent on the stress inflicted. Exercise with high intensity improve SV and VO_{2max} more than exercise at moderate intensities, as shown by (Helgerud et al., 2007). Thus, to effectively improve VO_{2max} , and hence CRF, the intensity of the exercise seems to be important.

1.4 Blood pressure

There is an independent relation between BP and the risk of CVD, the higher BP, the higher risk (National High Blood Pressure Education, 2004). A majority of individuals above 35 years have above optimal systolic BP (>120mmHg) and diastolic BP (>80mmHg), and face an increased risk of CVD (Stamler, Stamler, & Neaton, 1993). Efforts to prevent elevated BP should therefore be considered to reduce the risk of CVD, and mortality.

Many causal factors for high BP are identified, including inadequate PA and excessive bodyweight (National High Blood Pressure Education, 2004). Among others, weight loss and increased amounts of PA have been shown to lower BP (Arroll & Beaglehole, 1992; Hypertension Prevention Collaborative Research Group, 1997). Adequate levels of PA and control of body weight can both be used as prevention and treatment of hypertension. Since PA is considered an important tool for body weight management, increased PA may thus have an "double" effect on BP.

Even though the mercury sphygmomanometer is considered the "gold standard" for BP measurements, these devices are frequently replaced in many settings, among others because of environmental concerns (Frese, Fick, & Sadowsky, 2011). Automated devices tend to

underestimate systolic and diastolic BP in adults, but operating the mercury sphygmomanometer at a correct manner requires extensive training (M. G. Myers, McInnis, Fodor, & Leenen, 2008). As a consequence, automated devices have become popular, and electronic automated oscillating blood pressure measurement devices have been suggested as a suitable alternative to the gold standard mercury sphygmomanometer in clinical trials (Mengden et al., 2010).

1.5 Body composition

Overweight in adults is defined as a body mass index (BMI) ≥ 25 , while obesity is defined as a BMI ≥ 30 (WHO, 2017a). BMI is widely used in epidemiological studies to look for associations between body fatness and CVD risk, but on an individual level, the accuracy of BMI is more limited (Romero-Corral et al., 2008). Body composition however describes the amount of fat free mass (FFM) and fat mass (FM) relative to total body mass, and more detailed analysis can also consider bone mass and body water (Howley, 2001). Body composition analysis gives a more detailed picture than only body weight, and this is especially important when considering the physiological adaptations to exercise. While total body weight increases, body fat percentage (BF%), may be reduced as a consequence of changes in body composition. BF% is associated with plasma lipoprotein concentrations (Wood et al., 1988). Muscle hypertrophy and other physiological changes often accompany exercise, and this may increase total FFM and body weight. Body composition analysis therefore gives more information than for instance BMI, and BF% has been suggested to be a better predicator of CVD than BMI (Zeng, Dong, Sun, Xie, & Cui, 2012).

"The gold standard for body composition analysis is cadaver analysis, so no in vivo technique may be considered to meet the highest criteria of accuracy" (Wells & Fewtrell, 2006). Of obvious reasons other techniques are more commonly used in clinical examination. While the primary application of dual energy x-ray absorptiometry (DEXA) is bone mineral density measurements for diagnostic use (Toombs, Ducher, Shepherd, & De Souza, 2012), the technique has become the gold standard for body composition measurements, especially on an individual level. However, studies suggest that bioelectrical impedance analysis (BIA) gives valid estimates of skeletal muscle mass (Janssen, Heymsfield, Baumgartner, & Ross, 2000), lean body mass, total body water and adiposity (Houtkooper, Lohman, Going, & Howell, 1996).

The BIA method is simple and quick, but it is also population specific, and have lower accuracy on an individual level than DEXA (Wells & Fewtrell, 2006). Still, the BIA method could give a good indication of the direction of changes in FFM (Wells & Fewtrell, 2006).

A comparison between BIA and DEXA (Volgyi et al., 2008) found that BIA BF% measurements provided systematically lower values than DEXA, from 2-6% in normal BMI men and woman in all BMI categories, but in obese men the differences were smaller. Another study (Gupta, Balasekaran, Victor Govindaswamy, Hwa, & Shun, 2011) found a non-significant underestimation in females and a significant overestimation in males on BF% using BIA compared to DEXA, but there was also good agreement between the two techniques on cohort level. This highlights some of the inaccuracies with the technique. However, the practicality of the BIA method is highly appreciated, and the method has been well validated (Ward, 2012), and BIA is today a commonly used technique in body composition analysis.

1.6 Heart rate

HR is closely associated with energy expenditure, and during dynamic exercise, there exist a linear relationship between HR and VO₂ over a broad range of intensity (Bassett, 2000), this relationship can be explained by the fact that HR is a component of cardiac output together with the hearts SV, and the relation to VO_{2max} is seen through the Fick equation (Levine, 2008).

The variations in HR during exercise can be measured, and correlates with changes in exercise intensity (Karvonen & Vuorimaa, 1988). Traditional methods of describing exercise intensity have been as $%HR_{max}$, and $%VO_{2max}$ (Mann, Lamberts, & Lambert, 2013), where $%HR_{max}$ is used to estimate $%VO_{2max}$ (Howley, 2001), but these traditional methods does not take into account the values at rest.

If both HR at rest (HR_{rest}) and maximum HR (HR_{max}) of an individual is known, heart rate reserve (HRR) can be established by subtracting HR_{rest} from HR_{max} (Howley, 2001). A method that takes into account the resting values of HR is the HRR% (Karvonen & Vuorimaa, 1988), and HRR% at different exercise intensities is found to be equivalent to percentage of VO₂ reserve (%VO₂R) (Swain & Leutholtz, 1997). This latter method has been commonly accepted (Howley, 2001), and is an important tool in exercise physiology.

1.7 Physical activity and health benefits

In the context of PA and PF in a dose response relationship, health is described in terms of morbidity and mortality associated with chronic diseases and risk factors, but also other outcomes like quality of life (Howley, 2001). In a time were daily tasks often omits PA, and time often comes to short, a question arises; how much pain is necessary for a gain in health?

Evidence points to the positive effects of increased PA in the prevention of life style related diseases and risk factors, and according to Warburton et al. (2006) the relation between PA and health status seems to be linear. PA is likely to give health benefits, in form of increased CRF, measured as VO_{2max} , and CRF has been shown to be a better predicator on health than PA (D. C. Lee et al., 2011). This highlights the importance of types of PA that increases VO_{2max} . Several studies have shown that high intensity training works well for this purpose, and that it is possible to gain health benefits with relative little PA if the intensity is high enough (Baekkerud et al., 2016; Helgerud et al., 2007; Rognmo, Hetland, Helgerud, Hoff, & Slordahl, 2004).

Vigorous PA seems to give a decreased risk of all-cause mortality compared to moderate and low intensity PA (Gebel et al., 2015), but one problem with intensive training over time could be the motivation factor. Even though health authorities recommend 150 minutes of moderate or 75 minutes of high intensity PA per week, many does not meet these activity recommendations (WHO, 2017b). In the light of this, it becomes important to motivate people to increase their levels of PA with the correct intensity.

1.8 Activity trackers

The last years, many different devices and applications have entered the market, that might have the potential to motivate to increased levels of PA. Activity trackers measure PA, but a common problem is that they do not necessarily tell the user if they are sufficiently active to improve their CRF, and health.

The concept of walking 10 000 steps started with the marketing campaign for the "Manpo-kei", (Japanese for "10 000 steps meter"), a pedometer released in Japan in the 1960's (Bassett, Toth,

LaMunion, & Crouter, 2017). Achieving 10 000 steps per day has been a popular goal for PA ever since, and has been tested as a health promoting intervention in several studies.

Tudor-Locke and Bassett (2004) have classified PA levels according to daily step count, both accounting for what is considered to be typical daily activity, and voluntarily activities, and they found that; (1) < 5000 steps/day is classified as sedentary behaviour (2) 5000-7499 steps/ day is classified as low activity (3) 7499-9999 is classified as somewhat active (4) \geq 10000 steps/day is classified as active. This may support the general perception that a daily step count above 10 000 is adequate for health benefits.

Pedometers are cheap, and the information they give is easily understood. However, these devices are often not individualized, and says little about how much you have to achieve to gain health benefits, even though it may seem to have become a general truth that 10 000 steps is sufficient general population. A goal of a certain number of steps per day does not take into account the intensity of the activity, which has proven to be important for improved PF in intervention studies (Baekkerud et al., 2016; Helgerud et al., 2007), and to achieve good health in population studies (Gebel et al., 2015; C. P. Wen et al., 2011).

1.9 Personal activity intelligence

Personal activity intelligence (PAI) is an algorithm that considers age, gender, HR_{rest} and HR_{max} and was developed based on PA data and death registry data obtained from the Health study in Nord-Trøndelag (HUNT) (Nes, Gutvik, Lavie, Nauman, & Wisloff, 2017). PAI takes into account which patterns of PA that correlates with health, such as it being intensity dependent. A PAI score \geq 100 per week has been shown to reduce the risk of premature death caused by CVD in epidemiological studies, independent of whether or not general PA recommendations were followed (Zisko et al., 2017). According to Nes et al. (2017), "PAI may have a huge potential to motivate people to become, and stay physically active, as it is an easily understandable and scientifically proven metric that could inform potential users of how much PA is needed to reduce the risk for premature death by premature cardiovascular disease death".

Nes et al. (2017) describes the algorithm behind PAI, and in the supplementary material, the authors point at six assumptions that lay the foundation for the design of the model. The first assumption is that %HRR is the best measurement for exercise intensity at an individual level.

Assumption two refers to Swain and Franklin (2002) about the fact that PA with very low intensity does not contribute to increased CRF, and that a threshold value before PAI points can be collected should exist. Further, based on the findings of Nes et al. (2012), assumption three is that PA with higher intensity reduces the amount of exercise needed to increase CRF, and a nonlinear intensity scaling is therefore used in the model. Next, assumption four explains how the model evaluates the level of exercise as a product of intensity and time, and that the nonlinearly scaled intensity is integrated over time for the assessment of continuous HR data. Assumption five is that the effect on CRF improvement decline with increased level of exercise since the effect of exercise from an inactive baseline is stronger than from an active baseline, and the last assumption is that HR_{rest} and HR during submaximal exercise will be reduced with increased CRF, hence the level of PA needed to gain PAI becomes higher with increased CRF. The assumptions behind the algorithm lays the foundation for our hypothesis.

2 Purpose

As previously stated, CRF seems to be a better predicator of health than PA. Previous works have established an association between PAI score and CVD mortality (Zisko et al., 2017). It may be difficult to investigate this in a clinical trial, but VO_{2max} as a measurement of CRF, is a connection between PA and reduced risk for CVD that there is time to investigate in a randomized trial.

The aim of this study was to investigate the effects of following the advice of maintaining 100 PAI per week compared to the effects of walking 10 000 steps daily, on CRF, blood pressure (BP) and body composition. It was hypothesized that the PAI metric would lead to a larger increase in VO_{2max} compared to the step group

3 Method

3.1 Study design

This master thesis aimed to investigate the effects of two different exercise interventions; the advice of 100 PAI per week, and the advice of walking 10 000 steps per day hereafter referred to as the PAI group and the Step group. The primary outcome of the study was CRF, and secondary outcomes was BP and body composition.

To investigate these effects, a randomized intervention study was performed. Following preintervention testing, the participants in the PAI group were told to maintain a minimum of 100 weekly PAI for 8 weeks, and participants in the step group were told to walk a minimum of 10 000 steps per day during the 8 weeks of intervention. The daily PA of the participants was continuously registered and monitored by study staff during the intervention. All participants received training considering the technology used in the intervention before intervention start, and were followed up during the intervention period by SMS. Participants in the step group with more than 75% of days over 9000 steps, and participants in the PAI group with more than 75% of weeks over 90 PAI was considered to be compliant with the intervention protocol. All participants were invited back for post intervention testing at the end of the intervention period. The results were analysed to investigate effects between and within the different intervention groups considering CRF, BP and body composition.

3.2 Study Population

Recruitment of participants was carried out from October 2017 until December 2017, through social media and posters in the local area. Inclusion criteria was an age between 30-50 years, BMI > 25, and low PA(PAI < 50). Exclusion criteria was cancer, arrhythmia, angina, earlier heart attack, uncompensated heart defects, lung illnesses, uncontrolled hypertension, cardiomyopathy, kidney abnormalities, orthopedic/neurological limitations, planned surgery during the intervention period, not signing informed consent to participate, or participation in other studies.

46 individuals were assessed for eligibility for participation in the study through phone and mail, and 25 individuals were excluded from the study before randomization, not meeting

inclusion criteria. 21 inactive (PAI < 50), obese or overweight (BMI > 25), men (n=8) and woman (n=13) between 30 and 50 years fulfilled the inclusion criteria, and volunteered to participate in the study (mean \pm SD; age, 38.76 ± 5.42 years; BMI, 30.25 ± 3.33 ; PAI, 31.48 ± 20.81 ; VO_{2max}, 39.23 ± 6.84 mL·kg⁻¹·min⁻¹)

3.3 Sample size calculation and statistical power

The primary outcome in this study was CRF, measured as VO_{2max} . A sample size calculation was carried out to estimate the required number of participants in the study. A previous study performed by Baekkerud et al. (2016) on overweight and obese found an increase in VO_{2max} of 2.8 mL·kg⁻¹·min⁻¹ after interval training. Since participants could choose exercise with more modest intensity in our study, a smaller increase in VO_{2max} was expected. With an expected change in VO_{2max} on 1.5 mL·kg⁻¹·min⁻¹ and an expected standard deviation on 2 mL·kg⁻¹·min⁻¹, as well as a level of significance at 0.05, a population of 16 participants would give a statistical power of 0.8.

We were not able to recruit the desired number of participants, which resulted in a smaller sample size, and hence could lower the statistical power in the analysis of the data, but previous studies on change in VO_{2max} with different exercise interventions have been able to detect significant differences with a relative small sample size (Duffield, Edge, & Bishop, 2006; Dunham & Harms, 2012). The study was therefore performed with the 21 individuals eligible for participation.

3.4 Intervention groups

Randomization of the participants was performed by a web-based randomization system developed and administered by the Unit of Applied Clinical Research, The faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway. The participants were randomly assigned to the PAI group (n=10) and the step group (n=11), stratified for gender.

Contact information was provided to all participants in case of problems or questions during the intervention. Some technical difficulties were solved over phone correspondence, and in two cases personal contact; one participant in each group received a new activity monitor after losing, or breaking the previous one. SMS reminders were sent out to participants in both groups weekly.

3.4.1 PAI group

Participants in the PAI group were told to maintain a weekly PAI score over 100 for the 8 weeks of intervention. To monitor weekly PAI, the participants received a Mio slice (Mio Global, Vancouver, BC) used together with the application (app) Mio PAI 2.0 (Mio Global, Vancouver, BC). Instructions were given about how to use the activity tracker together with the app.

The Mio slice provides a continuous stream of HR data to the PAI algorithm that asses this information according to age, gender, resting and maximum HR, to provide a PAI score. HR_{max} of all participants was recorded during the pre-intervention CPET with the Mio slice, and compared to another HR monitor (Polar) with a chest strap. This was to ensure that participants used the activity tracker correctly, and to obtain a precise HR_{max} value to implement in the app. During warm up, compliance between the two HR monitors were verified to be within \pm 5 beats per minute (BPM), and the participants' HR_{max} from the CPET was implemented as the participants' HR_{max} in the PAI app.

The activity tracker shows daily acquired, and weekly PAI scores. While the device provides continuous HR recordings throughout the day, the user also has the option to enter "training mode", which provides a more precise HR value, from more frequent measurements. The app provides further information about activities the last seven days, like time spent in different intensity zones, and HR measurements throughout the day. Data previous to the last seven days disappear from the app.

PAI data was collected manually by inspection of each individual participants' app account by study staff, and automatically by Mio by entering a group code in the app. A bug in the PAI app resulted in some obscured data in the automatically registered material, so the manually registered data was used in the analysis.

3.4.2 Step group

Participants in the step group were told to acquire a minimum of 10 000 steps per day during the intervention period of 8 weeks, monitored by a Fitbit Zip (Fitbit Inc., San Fransisco, CA)

together with the app Fitbit (Fitbit Inc., San Fransisco, CA). Instructions were given about how to use the activity monitor together with the app.

The Fitbit Zip provides information to the user about daily acquired steps, and the user may also choose to see information about the estimated amount of burned calories. The app also gives the user an overview over all previous activity. The daily step count of the participants was continuously monitored and registered by study staff during the intervention by manually logging in to the individual app accounts.

3.5 PAI estimates

In order to estimate the participants' PAI score, information about the exercise habits of the participants were provided from a questionnaire by mail and an interview-questionnaire by phone. The questions regarding the participants exercise habits were used to estimate the participants weekly PAI score using the validated PAI-algorithm described by Nes et al. (2017). The questionnaire contained questions about the participants' exercise habits, including intensity, duration and frequency, described in the paper of Nes et al. (2017). The estimated exercise time per week, was obtained by multiplying the number of exercise sessions with the median duration, while intensity, stated in the questionnaire as "How hard do you exercise?" contained three response options; "no sweat or heavy breath", "heavy breath and some sweat", and "push myself to exhaustion", which according to previous studies (Loe, Rognmo, Saltin, & Wisløff, 2013; Nes et al., 2012; Nes, Janszky, Wisloff, Stoylen, & Karlsen, 2013; Wisløff et al., 2006) respectively correspond to 44%, 73%, and 83% of HRR (Nes et al., 2017).

3.6 Test Procedure

Physiological tests were conducted pre- and post-intervention, and the physiological parameters, VO_{2max} , BP and body composition were measured according the criteria given below. In most cases all tests of one individual were performed on the same day, but in a few cases the body composition measurement was performed on a separate day because of logistic difficulties. On the test day, the participants were asked to meet up after fasting a minimum of 2 hours, and were told to avoid strenuous exercise or alcohol consume 12 hours before the test.

3.6.1 Cardio pulmonary exercise testing

Graded exercise on a treadmill or a cycle ergometer is a commonly used during CPET to measure CRF expressed as VO2max. Cycle ergometers, tend to show a lower VO_{2max} than treadmill protocols, this is associated with fatigue in the quadriceps muscle, which may cause inexperienced participants to stop before the true value is obtained (Vanhees et al., 2005). A treadmill protocol was chosen in this study, to avoid such issues.

A CPET was performed using a Metalyzer II (Cortex, Leipzig, Germany) for measurements of VO_{2max} , carbondioxide production (VCO₂), exhaled volume of gas per minute (VE) and respiratory exchange ratio (RER), with participants walking or running according to an individualised protocol on a treadmill (Woodway GmbH D-79576, Weil am Rhein). HR was measured during the test with a HR sensor and monitor (Polar Electro, Kempele, Finland), and Mio slice for the participants in the PAI group. The Metalyser II was calibrated according to the guidelines provided by the manufacturer each test day.

The test started with the participant warming up 10 minutes on the treadmill in self-determined tempo. After warm up, the participant was equipped with a properly sized face mask and head strap, and connected to the Metalyzer II. Immediately after, the test was started, with the initial level based on the participants warm up speed, in an attempt to bring the participant to VO_{2max} within 8-12 minutes (Froelicher & Myers, 2000; Rognmo et al., 2004; Vanhees et al., 2005). After the initial level, speed was increased by 1 km/h or elevation was increased by 2%, approximately every minute, when parameters started to stabilize. End point of the test was voluntarily exhaustion, and criteria for VO_{2max} was an observed VO₂ plateau despite further increase in speed or inclination and a RER value ≥ 1.05 , criteria used in previous works (Helgerud et al., 2007). VO_{2max}, VCO₂ and VE values analysed are mean values of the three highest single VO₂ measurements in a row obtained during the last phase of the test, before the participant stopped walking/running.

3.6.2 Blood pressure

Blodpressure (BP) was measured with CAS 740 (CAS Medical Equipment Inc. Branford, CT) which uses an electric automated oscillometric technique. The BP measurements were conducted following guidelines from Frese et al. (2011), and prior to VO_{2max} measurements to avoid any effects of exhaustion. An appropriate sized cuff was placed on the participants' bare

left arm in line over the brachial artery (as marked on the cuff), with the arm resting on a table, bringing the antecubital fossa closer to heart level. The participant was asked to sit down in this position and relax with both feet placed on the floor for five minutes without talking before measurement were taken. At least two measurements of BP was then performed, and the average systolic and diastolic pressures were calculated. A third measurement was performed if the two first measurements deviated more than ± 10 mmHg.

3.6.3 Body Composition

Body composition was measured with Inbody 720 (Biospace, Seoul, Korea), which uses bioelectrical impedance analysis (BIA). This technique was chosen for its simplicity and practicality, and the technique has been validated against the gold standard DEXA method (Ward, 2012).

The participants were asked to meet up for the test after a fast of minimum 2 hours, and told to avoid strenuous exercise or alcohol consume 12 hours prior to the test to avoid impaired hydration status, this is in accord with the manufacturers manual. At arrival on the test day, the participants were encouraged to empty their bladder before examination, and height was measured using a wall mounted telescopic measuring stadiometer (Seca, Hamburg, Germany) before the body composition analysis. The participants entered the Inbody 720 barefooted, and were instructed to stand still until complete analysis.

3.7 Statistical analysis

It was considered unrealistically that all participants would adhere strictly to the intervention protocol, and a limit for compliance with the protocol had to be determined. A per protocol analysis was used, since per protocol analysis usually better reflect the effects of a treatment than intention to treat analysis (National Center for Biotechnology Information, 2012). Participants in the step group with more than 75% of days over 9000 steps, and participants in the PAI group with 75% of weeks over 90 PAI was considered to be compliant with the protocol, and included in the analysis, while participants unable to achieve this target, or participants lost to follow up were excluded from analysis. Interpretation of data and statistical analysis was performed using SPSS Statistics 25 (SPSS Inc., Chicago, IL.).

3.7.1 Between group analysis

For statistical analysis between groups, analysis of covariance (ANCOVA) was used. ANCOVA is a linear model with elements from analysis of variance (ANOVA) and regression, but while ANOVA looks for differences between two groups means, ANCOVA looks for differences between the different groups adjusted means (LaerdStatistics, 2017a). This type of analysis allows for the control of the covariate, which may be a confounding variable that could affect the result (Laerd Statistics, 2017a). Frison and Pocock (1992), argues that when the focus is on the mean post-treatment response of each participant, ANCOVA is the preferred method, using the mean pre intervention level as a covariate.

An ANCOVA was run to investigate the effects on the two intervention groups' postintervention values of VO_{2max} , BP, and body composition. As it was expected that post intervention values could be affected by the pre-intervention values, the pre-intervention values were used as covariates in the analysis to control for a possible confounding effect.

Assumptions for the ANCOVA was controlled for in compliance with Laerd Statistics (2017a). A linear relationship between pre- and post-intervention values for the two interventions was assessed graphical by visual inspection of a grouped scatterplot of the covariate, independent and dependent variable. Homogeneity of regression slopes was evaluated by the interaction terms (p>0.05) which means that there is no significant interaction between the covariate and the independent variable (Statistics, 2017a). The assumption of normality, was assessed by the numerical and objective Shapiro-Wilk's test (p > 0.05), but since the ANCOVA is robust to deviations in normality (Laerd Statistics, 2017a) analysis could continue with deviations from that assumption, and still provide valid results. No extreme outliers were detected in the data as assessed by cases with standardized residuals greater than \pm 3 standard deviations (LaerdStatistics, 2017a), however some data points find themselves in the outlier area. This did not influence the p-value significantly in a model without those data points, so no actions were taken to remove them. Homogeneity of variances was assessed by Levene's test of homogeneity of variances (p>0.05) and homoscedasticity of variances was assessed by visual inspection of the standardized residuals plotted against the predicted values (Statistics, 2017a). One deviation in the assumption of homogeneity of variances was found in relative VO_{2max} (mL·kg⁻¹·min⁻¹) data (p=0.017), but transformation of the data according to (LaerdStatistics, 2017a) solved this problem. This transformation lead to a deviation in the assumption of normality in the step group (p=0.043), and deviation from the assumption of normality was also present in the case

of body weight (kg) in the step group (p=0.007), BF% in the PAI group (p=0.003), and VO_{2max} (L·min⁻¹) in the PAI group (p=0.014). But as mentioned, ANCOVA is robust to deviations in normality so analysis was continued.

3.7.2 Within group analysis –Wilcoxon signed rank

For within group analysis, a Wilcoxon signed rank test was used to look for any effects from pre to post intervention within each group separately. The Wilcoxon signed rank test could be seen as the non-parametric parallel to the parametric dependent t-test, and is used to determine if there is a median change in paired datasets (Laerd Statistics, 2015), and with a lack of normality, the median could probably reflect the centre of the distribution more accurately than the mean. In each case a preliminary graphical assessment of the histograms of differences in pre and post values was performed to confirm that a symmetry in shape was present, before the test was carried out.

3.7.3 Within group analysis – Pearson correlation

To evaluate the association between mean weekly PAI and mean daily step count and the change in maximum oxygen uptake from pre to post intervention, a Pearson product-moment correlation assessment was performed. This is a statistical tool used to determine the direction of a linear relationship and the strength between two variables (Laerd Statistics, 2017b). The assumption of linearity between the two variables was assessed graphical by visual inspection of a scatterplot of the two variables, outliers and normality was controlled as previously described. Assumptions were met for all variables except the difference in VO_{2max} in the PAI group, which deviated from normality (p = 0.27). The test was run, and the results are reported, since the test is robust to deviations in normality (LaerdStatistics, 2017b).

3.8 Ethical considerations

PA is associated with reduced risk of CVD and all-cause mortality, but there is an increased risk for harmful cardiovascular events during and after PA (Goodman, Thomas, & Burr, 2011). Some risk is associated with PA, exercise and CPET, but the literature indicates that the long term benefits of increased PA (Blair et al., 1995; J. Myers et al., 2002; Tjonna et al., 2010; Warburton et al., 2006) surpass these acute risks for adverse effects that are very rare

(Thompson et al., 2007). Mainly benefits were expected from participating in this study, and participants were free to withdraw from the study at any time.

The study was approved by the Regional Ethical Committee (REK, midt, 2017/1211), and all participants signed a written informed consent. The project was carried out according to the Helsinki declaration.

4 Results

4.1 Study flow

46 individuals who had reported interest in the study were assessed for eligibility. 25 persons were excluded for not meeting the inclusion criteria. 21 volunteers were randomized and allocated in to the two different groups. One participant in each of the two groups did not meet for post intervention tests, and were accounted for as lost to follow up, and excluded from analysis. Figure 1 summarize the flow of participants throughout the study.

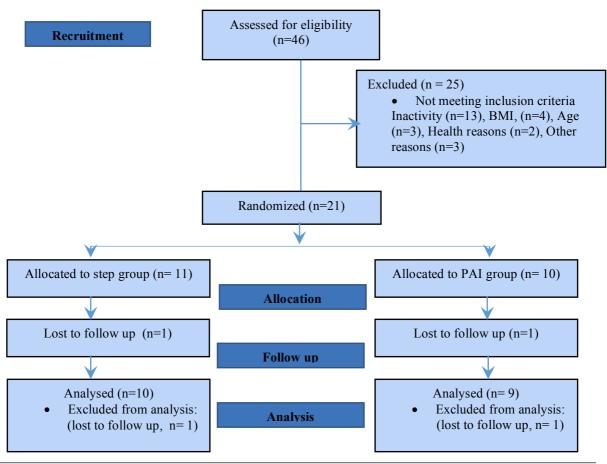


Figure 1 Flow diagram of participants

Participants in the PAI group obtained a mean weekly PAI score of 124.15 ± 55.36 . All participants included in analysis spent at least 75% (6/8 weeks) earning more than 90 PAI. On average the participants spent 6.11 weeks over 100 PAI, and 7.22 weeks over 90 PAI. A statistically significant negative correlation between mean weekly PAI and increase in VO_{2max} was found, (r = -0.712, p=0.031).

The participants in the step group obtained a mean daily step count of 11232 ± 776 steps. All participants spent 75% of days in the intervention with a daily step count over 9000. On average the participants in the step group had 51,3 days with a step count over 10 000 and 52,9 days over 9000 steps. A non-significant positive correlation was found between mean daily steps and increase in VO_{2max} (r = 0.425 p=0.220).

Table 1 summarize descriptive mean value data and changes in physiological parameters from pre to post intervention. Table 2 summarize the statistical significance of the median differences from pre- to post-intervention within each of the two intervention groups.

4.2 VO_{2max}

Mean VO_{2max} (L·min⁻¹) increased from pre- to post-intervention in both the PAI group (5,6%) and the step group (2,9%). Figure 2 shows that mean VO_{2max} increased more in the PAI group than in the step group. The standard error was greater in the PAI group than in the step group however. No statistically significant differences in the effect of the interventions were found between the PAI group and the step group considering VO_{2max} (Table 1). An overview of all VO_{2max} test scores are presented in figure 3.

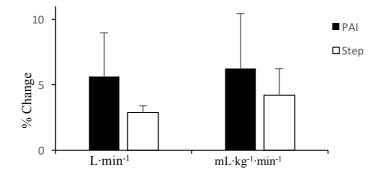


Figure 2 Percent change in mean absolute VO_{2max} (L·min⁻¹) and Vo_{2max} relative to body weight (mL·kg⁻¹·min⁻¹) from pre- to post-intervention for both intervention groups presented as mean and standard error.

No significant median change in VO_{2max} was found in the post-intervention test scores compared to the pre-intervention values for the PAI group, but a non-significant (p = 0.051) median increase (2.02 mL·kg⁻¹·min⁻¹) was present. In the step group however, a statistically significant (p = 0.009) median increase (1.66 mL·kg⁻¹·min⁻¹) in VO_{2max} was found (Table 2).

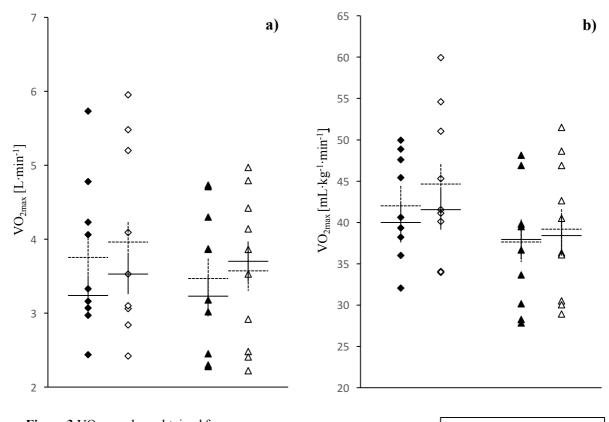
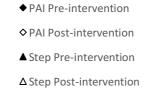


Figure 3 VO_{2max} values obtained from participants in the PAI group (n=9) and step group (n=10) during pre- and post-intervention CPET. Each point represents one participant. Dotted line marks group mean, straight line marks group median **a**) absolute VO_{2max} **b**) VO_{2max} relative to body weight.



4.3 Body composition

A mean decrease in body weight, BF%, and BMI from pre- to post-intervention was found in both groups, while mean FFM decreased modest in the step group, but increased in the PAI group from pre- to post-intervention (Figure 4). After adjustment for pre-intervention values there were no statistically significant differences in post-intervention body composition between the intervention groups (Table 1).

A statistically significant (p = .028) median decrease in BF% was found in the post intervention test scores compared to the baseline values in the PAI group. In the step group, a significant (p=.047) median decrease in body weight was observed (Table 2).

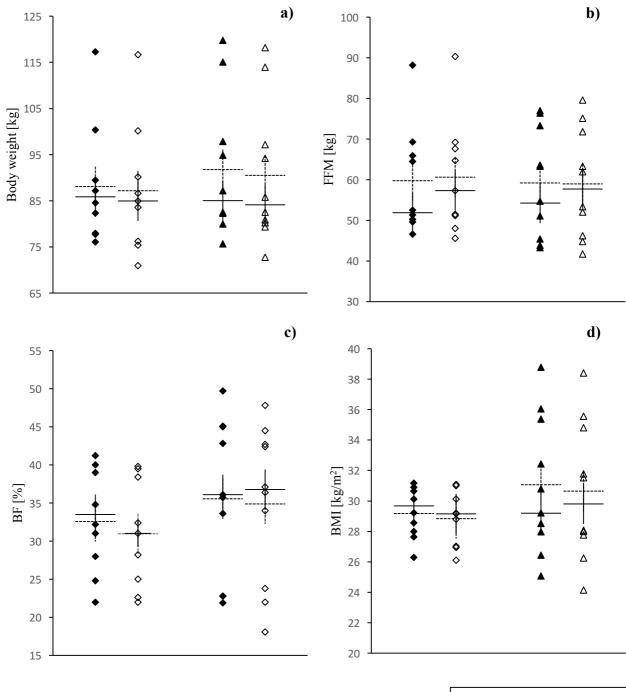
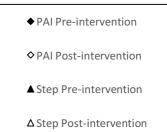
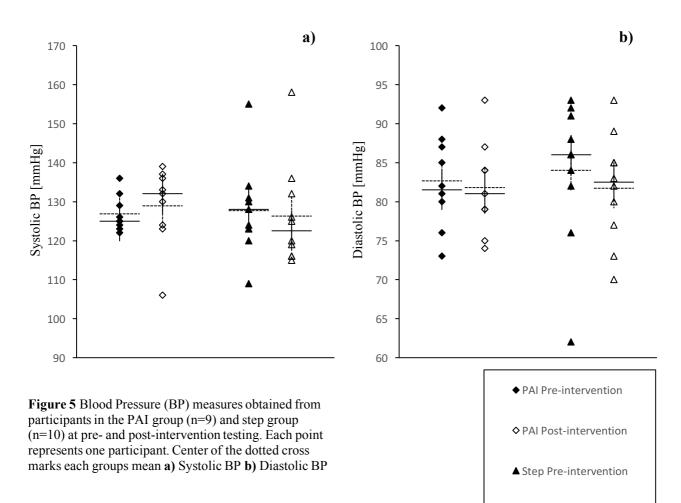


Figure 4 Body composition parameters obtained from participants in the PAI group (n=9) and step group (n=10) at pre- and post-intervention testing. Each point represent one participant. Dotted line marks group mean, straight line marks group median **a**) Body weight **b**) FFM; Fat Free Mass **c**) BF; Body Fat **d**) BMI; Body Mass Index



4.4 Blood pressure

A decrease in mean diastolic BP was found in both groups from pre- to post-intervention, a decrease was also found in post-intervention values for systolic BP in the step group, while an increase in systolic BP were present in the PAI group (figure 5). After adjustment for preintervention BP there were no statistically significant differences in post intervention BP between the two groups, and no significant median changes were found from pre to post-intervention in the two groups (Table 2).



 Δ Step Post-intervention

0 1 2	0 1	1 1	0 1		
	PAI (n=9)		Step (Between group	
-	Pre	Post	Pre	Post	p-value ^a
Body Composition					
Body weight (kg)	88.14 ± 13.25	87.23 ± 14.08	91.8 ± 15.11	90.54 ± 15.26	0.633
FM (kg)	28.36 ± 5.05	26.64 ± 5.49	32.6 ± 10.96	31.55 ± 11.02	0.492
BF (%)	32.56 ± 6.82	30.99 ± 7.09	35.55 ± 10.27	34.88 ± 10.30	0.345
FFM (kg)	59.79 ± 13.47	60.60 ± 14.09	59.19 ± 13.39	58.99 ± 13.42	0.253
BMI (kg/m ²)	29.17 ± 1.68	28.83 ± 1.80	31.06 ± 4.49	30.63 ± 4.56	0.800
BP					
Systolic BP (mmHg)	126.89 ± 4.59	128.89 ± 10.18	127.70 ± 11.87	126.30 ± 13.19	0.384
Diastolic BP (mmHg)	82.67 ± 6.00	81.78 ± 5.97	84.00 ± 9.25	81.70 ± 7.01	0.639
СРЕТ					
$VO_{2max}(L \cdot min^{-1})$	3.75 ± 1.04	3.96 ± 1.28	3.47 ± 0.96	3.57 ± 1.02	0.562
$VO_{2max}(mL\cdot kg^{-1}\cdot min^{-1})$	41.99 ± 6.25	44.62 ± 8.98	37.61 ± 7.60	39.19 ± 8.14	0.635
HR _{max} (BPM)	188 ± 10	185 ± 11	189 ± 13	188 ± 10.7	0.422
VCO ₂ (L·min ⁻¹)	4.12 ± 1.10	4.26 ± 1.35	3.86 ± 0.98	3.88 ± 1.12	0.565
VE (L·min ⁻¹)	126.33 ± 30.78	125.71 ± 36.08	116.00 ± 29.48	118.09 ± 32.21	0.174
RER	1.12 ± 0.05	$1.12 \pm .04$	1.13 ± 0.04	1.11 ± 0.05	0.480
Speed _{max} (km·h ⁻¹)	9.2 ± 1.2	10.1 ± 2.0	8.7 ± 1.8	8.9 ± 2.0	0.261
Inclination _{max} (%)	9.2 ± 1.0	9.7 ±1.2	8.7 ±1.3	8.7 ± 1.49	0.287

Table 1 Changes in physiological parameters from pre- to post-intervention in both groups.

All values are unadjusted means ± standard deviations. FM, Fat Mass; BF, Body Fat; FFM, Fat Free Mass; BMI, Body Mass Index; BP, Blood Pressure; CPET, Cardio Pulmonary Exercise Testing; VO₂, oxygen uptake; HR, Heart rate; VCO₂, Carbon dioxide production; VE, Pulmonary Ventilation; RER, Respiratory Exchange Ratio. ^a p-values obtained from ANCOVA between groups using pre-intervention values as covariate.

	PAI (n=9)			Step (n=10)				
	Pre	Post	Diff	p-value ^a	Pre	Post	Diff	p-value ^a
Body composition								
Body weight (kg)	84.60	85.00	-0.60	0.260	84.90	84.20	-1.45*	0.047
FM (kg)	29.10	26.40	-1.40	0.069	30.65	30.85	-1.20	0.114
BF (%)	32.20	31.00	-0.60*	0.028	35.90	36.75	-0.30	0.386
FFM (kg)	52.50	57.30	0.20	0.260	59.00	57.70	-0.65	0.374
BMI (kg/m ²)	29.21	29.15	-0.16	0.260	30.00	29.81	-0.50	0.059
BP								
Systolic BP (mmHg)	125.00	132.00	5.00	0.441	126	122.50	-1.00	0.552
Diastolic BP (mmHg)	82	81.00	-1.00	0.437	86	82.50	-3.00	0.096
СРЕТ								
$VO_{2max}(L \cdot min^{-1})$	3.33	3.53	0.03	0.214	3.52	3.70	0.09	0.058
$VO_{2max}(mL \cdot kg^{-1} \cdot min^{-1})$	40.60	41.52	2.02	0.051	38.07	38.40	1.66**	0.009
HR _{max} (BPM)	193	183.00	1.00	0.372	183.50	186.50	-2,50	0.515
$VCO_2(L \cdot min^{-1})$	3.73	3.94	-0.03	0.514	3.91	4.08	0.00	0.759
VE (L·min ⁻¹)	113.88	111.21	-3.69	0.594	113.66	115.65	1.69	0.203
RER	1.10	1.10	-0.01	0.159	1.13	1.09	-0.02	0.092
Speed _{max} (km·h ⁻¹)	9.00	10.00	0.50	0.057	8.75	8.75	0.00	0.157
Inclination _{max} (%)	10.00	10.00	0.00	0.102	8.5	8.00	0.00	1.00

Table 2 Median test scores and differences from pre to post-intervention

Data are presented as medians. Diff, Median difference from pre to post intervention; FM, Fat Mass; BF, Body Fat; FFM, Fat Free Mass;

BMI, Body Mass Index; BP, Blood Pressure; CPET, Cardio Pulmonary Exercise Testing; VO₂, oxygen uptake; HR, Heart rate; VCO₂,

Carbon dioxide production; VE, Pulmonary Ventilation; RER, Respiratory Exchange Ratio. ^ap-values obtained from Wilcoxons signed-rank test.

* Significant differences (p < 0.05) within group from pre to post intervention; ** Significant differences (p < 0.01) within group from pre to post intervention.

5 Discussion

No significant differences were found between the two groups after eight weeks of intervention. However, in the PAI group a significant median decrease in BF% was found, and in the step group a significant median decrease in body weight and a significant increase in relative VO_{2max} was found. In addition, a non-significant increase (p=0.051) in relative VO_{2max} was found in the PAI group. The decrease in body weight probably explains most of the increase in VO_{2max} relative to body weight in both groups. Both non-significant and significant improvements of other CVD risk factors were observed in both groups.

5.1 Increased Physical Activity and health benefits

All participants increased their PA from pre- to post-intervention. This is clear in the PAI group who went from a mean daily PAI score below 50 to over 100. However, pre-intervention data was self-reported, and are not directly comparable. The step group is more difficult to compare with pre-intervention PAI scores. Nevertheless, if the activity classifications provided by Tudor-Locke and Bassett (2004) is used, its seems reasonable to place participants in the step group in the "sedentary" or "low active" category with < 5000 or 5000-7499 steps per day, respectively, based on their exercise habits. Furthermore, CRF was poorer in the step group than in the PAI group at baseline, which could also indicate a lower level of PA. Therefore, it seems likely that the step group have improved their daily PA.

5.1.1 Cardiorespiratory fitness

No significant changes were observed in absolute VO_{2max} after an increase in PA from an inactive baseline, though non-significant improvements were observed in both groups. Participants' increase of PA during the intervention is independently associated with a reduced CVD risk, but CRF is a better predicator of CVD (Williams, 2001). This is also supported by D. C. Lee et al. (2011) who states that CRF is a better predicator of CVD and all-cause mortality than PA, and by Aspenes et al. (2011) who found that peak oxygen uptake was associated with reduced CVD risk. Both intervention groups improved mean CRF from pre- to post-intervention testing. The mean improvement in both relative and absolute VO_{2max} , was largest in the PAI group. However, statistical analysis of medians contradicts the trends observed in the mean values. No statistical significant median increase in CRF was observed.

Benefits of increased CRF is found to negate adverse effects of several CVD risk factors, so that individuals with major risk factors and higher CRF typically have the same or reduced morbidity compared to their inactive counterpart (Elagizi, Archer, & Lavie, 2018). This is important in an overweight and obese population, were several risk factors may be present. Indeed, the benefits of habitual PA seems to be an important contributor to CRF, DeFina et al. (2015) reviewed the effects of PA and CRF on health and found that aerobic training studies lasting for 5 months or more with moderate to vigorous intensity exercise typically increase estimated VO_{2max} 15-25%, while a study by B. Saltin et al. (1968) illustrates the adverse effects of sedentary behaviour; inactivity in men at bed rest for 3 weeks decreased VO_{2max} by 26%. More modest changes in CRF were found after the 8 weeks of intervention in our study, still the increased PA from both interventions may counteract the risks associated with the relative inactive baseline of the participants, and prolonged intervention could have the potential to increase in CRF further.

Because improvements of HR_{max} do not occur, it is clear that changes in cardiac output must be attributed to changes in the in SV (Helgerud et al., 2007). As the most important single factor for VO_{2max} is the SV, an improvement in absolute VO_{2max} should involve improvements of the SV. As Helgerud et al. (2007) demonstrated, aerobic high intensity intervals improve SV and VO_{2max} more than moderate exercise. We found that relative VO_{2max} (mL·kg⁻¹·min⁻¹) increased more than the absolute VO_{2max} in both groups. This may suggest that the significant increase in relative VO_{2max} observed in the step group is explained by the significant decrease in body weight. The could also be the case for the non-significant increase in relative VO_{2max} in the PAI group, who experienced a non-significant decrease in body weight. This is supported by another study (Sothern, Loftin, Blecker, & Udall, 2000) who explained significant increases in relative VO_{2max} while absolute VO_{2max} remained constant with decrease body weight. However, the significant median reduction in BF% and the non-significant increase in FFM observed in the PAI group suggest that beneficial changes in body composition has occurred which may suggest that additional beneficial changes in body composition have occurred.

5.1.2 Body composition

Reduction of body weight leads to increased relative VO_{2max} , but the main effect of body weight on VO_{2max} is according to Goran, Fields, Hunter, Herd, and Weinsier (2000), explained by FFM. The authors argue that excess body weight (fat) does not necessarily affect the ability to consume oxygen, but leads to reduced sub-maximum aerobic endurance, while increased FFM predicts higher absolute VO_{2max} . Thus, weight loss among overweight and obese may results in increased relative VO_{2max} , which improves sub-maximal performance, and therefore should ease daily tasks. This is in line with Bassett and Howley (2000) who assert that while VO_{2max} sets the upper limit for energy production, it does not alone determine the endurance performance. Importantly the major part of daily PA requires only sub-maximum levels of VO_{2max} , and a weight reduction might improve the capability of performing daily tasks like walking, which have been reported to be more strenuous in obese than normal weight individuals (Mattsson, Larsson, & Rossner, 1997). However, importantly in the context of future long-term weight loss, a maintained FFM and hence, a maintained resting metabolic rate are desired (Stiegler & Cunliffe, 2006). Reduction in BF% without reduction, or preferably with an increase in FFM is the ideal. Reduction in body weight nevertheless, seems to be by favourable in overweight and obese.

BF% have been found to be a better predicator of CVD than BMI (Zeng et al., 2012), and the relationship between PA, PF, BP and lipoproteins is found to be highly influenced by body fatness (Twisk, Kemper, & van Mechelen, 2000). Increased PA has been found to have effects on BF% that resulted in advantageous effects on plasma triglyceride concentrations (Leaf, Parker, & Schaad, 1997). This is also supported by Wood et al. (1988) who found that both total body weight and BF% was reduced significantly with a diet intervention and an exercise intervention independently, and that fat loss resulted in favourable changes in plasma lipoprotein concentrations. Interestingly, the diet group experienced a significant loss of FFM, which was not apparent in the exercise group. With regard to what is already mentioned about FFM and weight reduction in the previous paragraph, this is relevant in the context of our findings. The PAI group experienced a significant reduction of BF%, but a non-significant increase in FFM, while the step group experienced a non-significant reduction of both parameters. The significant reduction of BF% in the PAI group may have resulted in improvements in plasma lipoprotein concentrations, though this was not investigated, and caution must be taken using this interpretation. Nevertheless, a decrease in BF% seems to have improved the relative VO_{2max} in the PAI group, and since obesity is associated with numerous risk factors for CVD an all-cause mortality (Oktay et al., 2017), these risk factors may have been reduced. Furthermore, future weight reductions might benefit from the a sustained or improved FFM in the PAI group.

A study by (Thompson et al., 1997) found that no weight loss was necessary for improved lipoprotein concentrations, however, only modest changes in lipoprotein concentrations were found after prolonged periods of exercise. Yet another study (Halverstadt, Phares, Wilund, Goldberg, & Hagberg, 2007) propose that exercise induce significant favourable changes in lipoprotein profile independent of BF% changes. This is also supported by Kraus et al. (2002) who found that beneficial improvements in lipoprotein concentrations related to the amount of PA, but not to intensity or improvement in fitness. Beneficial changes in body composition probably most likely occurred in the PAI group, but the implications on lipoprotein concentration not known.

5.1.3 Blood Pressure

A non-significant decrease in diastolic BP was found in both groups, while a non-significant increase in systolic BP was found in the PAI group, and the step group saw a non-significant decrease in systolic BP. A reduction in BMI and BP with increased PA is supported by Bravata, Smith-Spangler, and Sundaram (2007), who found that using pedometers increased PA and increased health through decreases in BMI and BP. More surprising was the non-significant increase in systolic BP in the PAI group. This is contrary to a meta-analysis by Whelton et al. (2002) who found that aerobic exercise reduced BP in both hypertensive and normotensive, overweight, and normal weight individuals at all frequencies, intensities and types. This is also supported by other meta-analysis (Fagard & Cornelissen, 2007; H. Wen & Wang, 2017). Nevertheless, no significant differences were found, and BP seems to not have been heavily influenced by the interventions.

5.2 Activity trackers and PA

The effects of walking 10 000 steps have been well investigated (Castres, Tourny, Lemaitre, & Coquart, 2017; Choi, Pak, Choi, & Choi, 2007; Hallam, Bilsborough, & de Courten, 2018; Yuenyongchaiwat, 2016), but no previous published material, have obtained directly measured PAI scores as a measured of PA in intervention studies.

5.2.1 Step counting

Physical and mental health are closely linked (Osborn, 2001), for instance, depressive symptoms are related to CVD risk factors. Hallam et al. (2018) investigated the effects of a walking program of 10 000 steps for 100 days. The authors found that participation in a step

program improved mental health, and that participation could be well as important as the target itself. Yuenyongchaiwat (2016) was also interested in the effects of walking 10 000 steps per day on physical and mental health in overweight participants, and found that a step program improved both mental and physical condition in form of reduced body weight, BMI and BP. These findings are further supported by Castres et al. (2017) who found that body mass, BMI and BF% decreased significantly after following a walking program of 10 000 steps per day. The health benefits of different intervention were walking 10 000 steps per day have been the target are well accounted for in previous studies. Bravata et al. (2007) suggest that having a step goal might be a key motivational factor for increasing PA, whether or not the goal is 10 000 steps or another individualized goal. This seems to be the case for the step group in our study as well, they increased their PA, and probably gained some health benefits in form of reduced body weight.

In their review of the 10 000 step goal Choi et al. (2007) finds that there is a typically deficiency of about 4000 steps in routine daily activities that must be filled with other activities to reach the goal of 10 000 steps. This is consistent with Tudor-Locke and Bassett (2004) who classify individuals with a daily step count above 10 000 as "active". In addition Tudor-Locke et al. (2011) looks at the relationship between intensity and cadence and finds that 100 steps/minute represents a value that indicates moderate intensity, 30 minutes with this cadence represents 3000 steps. The recommendations from The American Heart Association (AHA) about at least 30 minutes of moderate-intensity PA can be met by achieving 10 000 steps per day, if the steps that comes on top of daily routine is performed with moderate intensity (about 3000 steps with moderate intensity). A meta-analysis by Murphy, Nevill, Murtagh, and Holder (2007) on walking intervention studies found that sedentary healthy individuals who engage in a program of regular brisk walking improve their CRF. Thus, it seems likely that health benefits of walking 10 000 steps daily are the result of some sort of moderate to vigorous intensity PA on top of daily routinely PA. As mentioned earlier, the different beneficial effects of walking 10 000 steps daily are well documented. The findings in our study are not clear, but they indicate that the step intervention used in the study gave increased health benefits, primarily in form of weight loss. The weight loss observed may also be attributed to diet changes, which were not controlled for in the study, and not solely due to increased PA. The lack of improvements in CRF in the step group might be due to inadequate intensity of the PA. Step counters do not take intensity into account, and it seems like health benefits from walking 10 000 steps come from

moderate to vigorous activity on top of the steps taken during daily routine PA. Therefore, our findings are somewhat in accord with previous literature.

5.2.2 Personal activity intelligence

Contrary to step counters, PAI gives an intensity dependent goal using HR_{max} and HR_{rest}. HR is closely associated with energy expenditure, and as mentioned earlier, during dynamic exercise, there exist a linear relationship between HR and VO₂ over a broad range of intensity (Bassett, 2000). In addition, %HRR seems to be equivalent to %VO₂R (Swain & Leutholtz, 1997; Swain, Leutholtz, King, Haas, & Branch, 1998). This may be used to estimate the intensity needed during PA to achieve increased CRF, and indeed, Swain and Franklin (2002), suggest that there is support for the use of such a threshold value of 45% of VO₂R in well trained individuals, and 30% of VO₂R in individuals with lower PF. By incorporating this in their assumptions, the PAI algorithm gives an individualised intensity based PA score (Nes et al., 2017). This suggest that 100 PAI might be a better target than a fixed number of steps. Furthermore, any activity of choice could be performed, as long as it raises HR, and give PAI points, contrary to step counters that rely on ambulatory activities. However, no significant differences were found between the PAI group and the step group in our study. Some differences in significant changes within the groups were present, but no evidence was found to draw the conclusion that either of the interventions were superior considering improvements of CRF.

With basis in the assumptions for the PAI algorithm, a higher PAI score should reflect more time spent in intensities that promote increased CRF. PAI uses a continuous stream of HR measurements to ensure that adequate intensity of PA is achieved. If adequate intensity of the PA is maintained, this should result in favourable changes in VO_{2max} . Therefore, it was surprising to find a negative correlation between mean weekly PAI and increase in absolute VO_{2max} . However, Nes et al. (2017) did not find any additional benefits in form of reduced CVD risk or all-cause mortality with a score above 100 PAI. Still it is surprising that additional exercise with intensities adequate to "earn" PAI points did not lead to increases in CRF. This finding could however be explained by technical challenges or user-mistakes of the PAI device. Incorrect HR measurements for instance were reported from participants, while others reported PAI points to disappear after synchronizing their device. Whatever the reasons, PAI scores without the corresponding PA intensity, or PA intensities without the corresponding PAI points may have been present.

5.2.3 Free-living activity

A study on overweight inactive adults found that the improvement in CRF in the cohort undertaking aerobic interval training in real life settings were modest (Lunt et al., 2014). The authors suggest that the most likely reason was reduced adherence to the exercise program when moving beyond a research clinic setting. Motivation seems to be important to maintain PA. Considering that motivation it is important to find types of activities that may motivate to continued PA. In this context PAI seems to have an advantage over conventional step counters, since all activities that raises HR adequately gives PAI points. Evidence points at extrinsic regulation (outcomes of exercise) to be important in the initial phase of training while predominantly intrinsic motivation (the experience of exercise) might be more important for longer term exercise (Teixeira, Carraça, Markland, Silva, & Ryan, 2012). This is supported by (Kilpatrick, Hebert, & Bartholomew, 2005) who finds that motives like enjoyment and challenge were more abundant motives for participating in sports, while motives for conventional exercise were more extrinsic.

We found that both the Fitbit Zip and the Mio slice had the ability to increase PA, when participants had a goal to work for. Considering the short duration of the interventions (8 weeks), extrinsic motivation may have been adequate to motivate participants in both groups. Step counters do not account for intensity, and do not give the user feedback on intensity. Contrary, the PAI metric accounts for intensity, which is important in improving CRF. In addition, PAI metric allows for different types of activities, which might be an important intrinsic motivational factor on long term.

5.2.4 Body weight management

Changes in body weight was observed in the study, and the step group saw a significant reduction in body weight. This does not necessarily imply improved health; "The health benefits of leanness are limited to fit men, and being fit may reduce the hazards of obesity" (C. D. Lee, Blair, & Jackson, 1999). Regardless, literature supports a lifestyle with PA as important for the management of body weight (Jakicic, Rogers, Davis, & Collins, 2018), and participants in the study may have been motivated to loose body weight considering their overweight or obese state at baseline. Evidence is also pointing in the direction that the intensity of PA have to be moderate too vigorous to influence body weight regulation, and that the most effective way to regulate body weight is to couple PA with dietary modification (Jakicic et al., 2018). Although the step group saw a reduction in body weight, the partial contribution of increased

PA and dietary change is unclear, since diet was not controlled in this study. It is likely that a dietary change may have contributed to the weight reduction observed. Further, it is important to motivate overweight and obese not only to focus on body weight management, but also the positive effects of PA.

5.3 Strengths and limitations of the study

5.3.1 Randomization

In this study we used a randomization program that conceals the next participants' allocations, and participants were block randomized with stratification for sex, into the two different groups. This is a strength of the study, that reduce the risk of ascertainment bias, since allocation was decided without direct involvement from study staff, and different prognostic variables should be evenly distributed between the groups (Chalmers et al., 1981; Gluud, 2006). In addition, block randomization provided an approximately equal number of participants in each group, and stratification of sex contributes to further distribution of prognostic differences (Altman & Bland, 1999; Gluud, 2006).

It became apparent that differences between the two intervention groups considering CRF existed at pre-intervention. Participants with lower VO_{2max} at baseline may have a greater potential to improve than participants with higher VO_{2max} , this may have introduced bias. However, it is recommended not to test for significant differences at baseline (de Boer, Waterlander, Kuijper, Steenhuis, & Twisk, 2015), and ANCOVA uses covariates to deal with this potentially confounding problem.

5.3.2 Blinding

Unfortunately, it was not practically possible to achieve complete blinding of test personal for the study in this master thesis. The same person in the study staff was responsible for recruitment, contact with participants throughout the study, physiological testing, and statistical analysis. This is not ideal, and may introduce ascertainment bias (i.e. test personnel might favour a certain outcome and this could influence participants' performance). However, systematic errors may have been reduced by the fact that the same person performed all tests and used the same equipment.

5.3.3 Adherence to the intervention

The ideal case would be if participants followed the PA advice in the allocated intervention strictly. The nature of the study however, in free living, makes it difficult to control for anything other than PA monitored by either the Mio slice or the Fitbit zip. This means that participants may have engaged in activities that was not recorded by their devices, and it is not possible to say anything about the intensity or type of PA in the step group, though they were told to walk 10 000 steps. In addition, diet was not controlled for, and this may have influenced weight changes.

5.3.4 Technical difficulties

Participants in the PAI group reported problems with their devices. This included problems with synchronizing their devices with the app, and inaccurate HR measurements. No published studies have validated the HR measurements of Mio slice, but the photoplethysmography technique in the Mio slice is in general used in many other wrist worn activity monitors that have been examined. A study by Dyrstad and Hausken (2014) highlights the differences between estimated energy expenditure between accelerometers and HR monitors. By comparing accelerometers and HR monitors during different exercise forms, they found great variability. Another study by Wallen, Gomersall, Keating, Wisløff, and Coombes (2016) concluded that all tested HR watches accurately measured HR, but estimates for energy expenditure was poorer. This finding is also supported by Shcherbina et al. (2017) who finds that wrist worn devices give accurate estimates of HR, but not energy expenditure in laboratory settings, and by Weiler, Villajuan, Edkins, Cleary, and Saleem (2017) who found HR measurements from wrist worn activity trackers to be accurate. Other studies indicate that HR measurements gets poorer with increased intensity, and that more research are needed before clinical trials, which require a high level of accuracy and reliability for HR measurements can rely on this technique (Cadmus-Bertram, Gangnon, Wirkus, Thraen-Borowski, & Gorzelitz-Liebhauser, 2017). Wang, Blackburn, Desai, and et al. (2017) also support the notion that wrist worn HR monitors in general are most accurate during rest, and that the accuracy diminishes with increased intensity.

Measures were taken to avoid problems with HR measurements prior to intervention. During the verification of HR between the Mio slice and the Polar device, some deviations were found

in both positive and negative direction, consistent with the literature. Some major deviations were found, but these were corrected by adjusting placement of the Mio slice on the arm. However, these deviations could be a problem during unsupervised conditions. Incorrect HR measurements from the Mio slice, thus might have disturbed the data obtained on PA.

The technical difficulties may have influenced the motivation of the participants. Motivation might be difficult to measure, but it has been found that when it comes to motivation, higher goals increase performance in different tasks (Locke & Latham, 2002). If PAI points for some reason was more difficult to obtain for some participants, this may have led to increased exercise performance, and thus elevated CRF benefits. When people get feedback about their target, and find they are below, they usually increase their effort (Matsui, Okada, & Inoshita, 1983), while participants that by some reason easily achieved the target of 100 PAI may have lowered their exercise performance. This might also have contributed to the negative correlation found between increase in VO_{2max} and PAI points obtained.

5.3.5 Study design

This master thesis is the first study to investigate the effects of adherence to a PAI protocol on CRF and other health outcomes. This makes the study design a strength of the study. An intervention period of 8 weeks is commonly used, and makes this study comparable to other intervention studies. However, a longer intervention period could provide larger effects. A low sample size is however a limitation, that may have reduced the likelihood of detecting effects, and a small sample size increases the effects of pure coincidences. Some effects were however statistically significant within the groups, and these findings indicate trends that may be further investigated in future research.

Another strength of the study is the use of objectively measurements of PA. Many previous studies have investigated effects of PA using self-reported data, and information bias may be a problem with that kind of studies (Chalmers et al., 1981). Although PA was measured in both groups during intervention, the PA metrics are not directly comparable. However, this was one of the assumptions for the hypothesis, we were interested in testing; it was expected that the PAI metric would lead to more favourable changes in CRF than the step metric, because it accounts for intensity. Although the study have some limitations, it still gives indications of the effects of the different interventions, and provides data that might be used for sample size estimations and comparisons in future randomized controlled trials.

5.4 Future perspectives

There is a need for a validation of the Mio slice. Since the PAI algorithm rely on continuous streams of HR data, accurate measurements become important. As mentioned, previous studies have drawn different conclusions whether or not wrist worn activity trackers give reliable outputs. Furthermore, these studies have been conducted in laboratory studies. It would be beneficial to validate the Mio slice in free living activities as well, to ensure that future clinical trials involving PAI is not disturbed by incorrect HR measurements. In addition, technical difficulties with the synchronization between the app and the Mio slice should be investigated and improved.

The primary aim of the study was not to investigate body composition, however, future studies could preferably control for changes in body composition with a dietary plan. Alternatively, if energy expenditure measurements on activity trackers is found to be valid in future studies, the energy expenditure from PA could be accounted for by activity trackers.

This study was performed with a relative small sample size. Future controlled clinical trials should be performed, and data obtained from our study could be helpful in sample size estimation. The recommended amendments proposed here could improve study design of future studies to better evaluate the effectiveness of the PAI algorithm.

It should be noted that the findings from this study is specific to inactive overweight and obese middle-aged men and woman, and not necessarily representable for the general population. The generalizability of the PAI algorithm in other populations with varying CVD risk should also be investigated.

6. Conclusion

Participants in both groups improved PA from pre- to post-intervention. Neither of the groups increased median absolute VO_{2max} significantly, and there was no statistically significant evidence that either of the interventions was superior. Median VO_{2max} relative to body weight increased significantly (p=0.009) in the step group and non-significantly (p=0.051) in the PAI group. These changes probably reflect changes in body weight as the step group reduced their median body weight significantly (p=0.047) and the PAI group saw a non-significant median reduction in body weight. However, a trend towards a large mean increase in CRF was observed in the PAI group. Future randomized controlled clinical trials may use data obtained in this study for sample size estimations.

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Appendix

- Appendix 1 Adjusted and unadjusted means and variability from ANCOVA
- Appendix 2 Written consent agreement
- Appendix 3 Recruitment Poster

	Group		Unadjusted		Adjusted	
		Ν	М	SD	М	SE
VO _{2max} (L·min ⁻¹)	PAI	9	3.96	1.28	3.80	0.09
	Step	10	3.57	1.02	3.73	0.08
VO _{2max} (mL·kg ⁻¹ ·min ⁻¹)	PAI	9	44.62	8.98	41.92	0.87
	Step	10	39.19	8.14	41.62	0.82
Systolic BP (mmHg)	PAI	9	128.89	10.18	129.30	2.73
	Step	10	126.30	13.19	125.93	2.59
Diastolic BP (mmHg)	PAI	9	81.78	5.97	82.23	1.42
	Step	10	81.70	7.01	81.29	1.35
Body weight (kg)	PAI	9	87.23	14.08	89.20	0.65
	Step	10	90.54	15.26	88.77	0.61
FFM (kg)	PAI	9	60.60	14.09	60.28	0.61
	Step	10	58.99	13.42	59.28	0.58
BF (%)	PAI	9	30.99	7.09	32.55	0.69
	Step	10	34.88	10.30	33.48	0.65
BMI (kg/m ²)	PAI	9	28.83	1.80	29.82	0.24
	Step	10	30.63	4.56	29.74	0.23

Appendix 1 Adjusted and unadjusted means and variability from ANCOVA

N, Number of participants; M, Mean; SD, Standard Deviation; SE, Standard Error. BF, Body Fat; FFM, Fat Free Mass; BMI, Body Mass Index; BP, Blood Pressure; VO₂, oxygen uptake;

Appendix 2: Written consent agreement

Personlig aktivitetesintelligens (PAI) versus skritteller og fysisk form

NTNU

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

PERSONLIG AKTIVITETSINTELLIGENS VERSUS SKRITTELLER OG FYSISK FORM

Dette er en forespørsel til deg om å delta i et forskningsprosjekt for å undersøke og sammenligne effekten av et nytt aktivitetsmål (personlig aktivitetsintelligens; PAI) og 10 000 skritt per dag. PAI er en målestokk for fysisk aktivitet som måler puls og gjør det om til et lettfattelig poengsystem hvor målet er å oppnå 100 PAI hver uke. Formålet med studien er å sammenligne effekten av minimum 100 PAI-poeng i uken med 10 000 skritt per dag og undersøke effekten av det på de fysiologiske parametere maksimalt oksygenopptak (VO_{2max}), blodtrykk og kroppssammensetning. Studien vil inkludere friske inaktive subjekter. Studien utføres i forbindelse med en masteroppgave, og ansvarlig institusjon er institutt for sirkulasjon og bildediagnostikk (ISB) ved fakultet for medisin og helsevitenskap (MH), NTNU.

HVA INNEBÆRER PROSJEKTET?

Ved studiestart vil det blir foretatt tester av din kroppssammensetning, blodtrykk og maksimalt oksygenopptak For å teste det maksimale oksygenopptak må du løpe på tredemølle med en maske foran munn og nese for å måle hvor mye oksygen og karbondioksid du puster inn og ut. Løpingen innebærer en økende intensitet til en relativt høy utmattelse. Du vil få utdelt utstyr for å måle PAI (Mio slice) og bedt om å installere applikasjonen Mio PAI 2.0 eller en gitt en skritteller. Opplæring i bruk av utstyret vil bli gitt. Du skal oppnå minimum 100 PAI i uken eller 10 000 skritt per dag over en periode på åtte uker. Etter åtte uker vil det igjen bli foretatt fysiologiske tester.

I prosjektet vil vi registrere opplysninger om deg. Kontaktopplysninger, kjønn, alder, og resultater av fysiologiske tester vil registreres.

MULIGE FORDELER OG ULEMPER

Det er forventet at økt fysisk aktivitet, som følger med deltakelse i studien, kan gi positive utslag for helsen. Du vil få informasjon om ditt maksimale oksygenopptak, blodtrykk og kroppssammensetning. Det kan følge det med en liten risiko for treningsrelaterte skader, som for eksempel overbelastning.

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. 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 Christoffer Børstad, tlf: 95428459 Mail: christoffer.borgstad@gmail.com eller Fredrik Hjulstad Bækkerud, tlf: 93062467 mail: fredrik.h.bakkerud@ntnu.no

HVA SKJER MED INFORMASJONEN OM DEG?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. 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.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte. Informasjon om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt.

FORSIKRING

Forsikring under pasientskadeloven gjelder.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk, 2017/1211). Personlig aktivitetesintelligens (PAI) versus skritteller og fysisk form

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver



Deltagere søkes til treningsstudie

"Personlig aktivitetsintelligens (PAI) versus 10 000 skritt og fysisk form"

En studie ved Fakultetet for medisin og helsevitenskap ved NTNU vil undersøke effekten av personlig aktivitetsintelligens (Mio Slice) i forhold til skritt-teller (Fitbit Zip) og 10 000 skritt om dagen på fysisk form.

PAI er en formel utviklet av Cardiac Exercise Research Goup (CERG) ved NTNU, basert på Helseundersøkelsen i Nord-Trøndelag. Et aktivitetsarmbånd og en app gir brukeren en poengsum utfra individuelle forutsetninger, og gir dermed et individuelt tilpasset mål for fysisk aktivitet. I denne studien vil det bli sett på sammenhengen mellom effekten av en PAI score på over 100 i uken i forhold til effekten av 10 000 skritt per dag på fysisk form.

Vi søker friske personer mellom 30 og 50 år med en body mass index (BMI) på 25-40 som ønsker å delta i en treningsstudie over 8 uker. Deltakere i studien vil bli tilfeldig fordelt i gruppen som skal oppnå PAI med en Mio slice og gruppen som skal telle skritt med fitbit zip. Det vil bli gjennomført målinger av blant annet kroppssammensetning (InBody analyse) og maksimalt oksygenopptak på St. Olavs Hospital (Trondheim) før oppstart og ved studiets slutt, og det vil være mulighet for veiledning underveis i studien.

Prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk, Midt-Norge.



For mer informasjon vedrørende studien, ta kontakt med: -Christoffer Børstad 95428459, epost: Christoffer.borstad@gmail.com