NTNU
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MASTER´S THESIS IN HUMAN MOVEMENT SCIENCE

The effect of endurance training on lower extremity strength in older persons

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Abstract

Background and aim: The world's population in general lives longer and are healthier than earlier. Still, there are many neuromuscular changes that occur with increasing age. Age – related decline in muscle mass, muscle cross sectional area and muscle force are typical changes that can affect the ability to live an independent life and to function optimally in the daily life at older age. Many studies document the positive effect of strength training on lower extremity strength but there are only few studies that have been investigating if endurance training can have a positive effect as well. The main aim of this present study will therefor be to see if there is any effect of different types of endurance training on maximum leg force and maximum rate of force development among older persons.

Methods and materials: 387 men and women (born between 1936 – 1942) that participated in the three – year testing of the larger Generation 100 study, were included to this present study. The participants belonged to moderate intensity, high intensity or control groups and performed endurance training with different intensity in a three – year period. Effect of endurance training on peak force and peak RFD was tested by performing an isometric leg press, and further investigated using 4-way repeated measures MANOVA.

Results: At baseline women reported a higher activity level than men, but men reported a bit better self – perceived health than women. A larger amount of women was physically active for 30 minutes each day compared to men. There was no significant interaction between Time and Group, with indicates that the endurance training intervention has no significant effect on leg strength among the three groups. There was a significant interaction between Time and Gender, which indicated a smaller decline in peak force and peak RFD among women compared to men. There was also a significant interaction between Time and Side, which indicates that there were a larger decline in peak force and peak RFD in the right leg than the left leg from baseline to year three. The men had a larger difference in peak RFD values in right and left leg compared with women. It was neither any three – way or four – way interactions that was significant.

Conclusion: All participants had in average a significant decrease in lower extremity strength from baseline to year three. There was no significant effect based on what group in the intervention the participants belonged to. This indicates that endurance training has no effect on leg strength in older persons.

Sammendrag

Bakgrunn for studien: På verdensbasis lever menneskene i dagens samfunn lengre og er friskere enn før. Likevel er det mange endringer som følger med aldringsprosessen. Det skjer en reduksjon i muskelmasse, muskeltverrsnitt og muskelstyrke, noe som er typiske faktorer som påvirker evnen til å leve et selvstendig liv og ha en god fysisk funksjon til å klare seg selv gjennom dagliglivet. Flere studier har funnet ut at styrketrening har en positiv effekt på beinstyrke blant eldre, mens det er få studier som har funnet noen positiv effekt av utholdenhetstrening på beinstyrke. Hovedmålet i denne studien er derfor å undersøke om ulike intensiteter på utholdenhetstrening har noen effekt på maksimal isometrisk beinstyrke og evnen til å utvikle kraft hurtig blant frisk eldre personer.

Metode og materiale: 387 menn og kvinner (f. 1936 – 1942) som var en del av den større studien Generasjon 100 ble inkludert i denne studien, i forbindelse med 3-års testing. Deltakerne tilhørte enten moderat intensitet, høy intensitet eller kontrollgruppe og gjennomførte foreskrevet trening med ulik intensitet gjennom en tre års periode. Effekten av utholdenhetstrening på maksimal styrke og maksimal evne til hurtig kraftutvikling ble testet I en isometrisk beinpressmaskin og resultatene ble undersøkt med en fireveis MANOVA for repeterte målinger.

Resultater: Kvinner rapporterte et høyere aktivitetsnivå enn menn, mens menn rapporterte bedre selvopplevd helse enn kvinner i studien. Flere kvinner var fysisk aktive i 30 minutter daglig enn menn. Det var ingen interaksjon mellom test og gruppetilhørighet, noe som indikerer at ulik intensitet på utholdenhetstreningen ikke har noen forskjellig effekt på beinstyrke. Det var en signifikant interaksjon mellom test og kjønn, som indikerer en mindre reduksjon i maksimal kraft og maksimal evne til hurtig kraftutvikling blant kvinner sammenlignet med menn fra første testing til år tre. Det var også en signifikant interaksjon mellom test og hvilket bein som var sterkest, noe som indikerer en større reduksjon i maksimal kraft og maksimal evne til kraftutvikling i høyre bein, sammenlignet med venstre bein fra første testing til år tre. Menn hadde en større forskjell i maksimal evne til kraftutvikling i høyre og venstre ben sammenlignet med kvinner. Det var ingen signifikante tre – eller fireveis interaksjoner mellom kjønn, bein, testtidspunkt og gruppetilhørighet.

Konklusjon: Alle deltakerne hadde en signifikant gjennomsnittlig reduksjon i beinstyrke fra første års testing til år tre. Det var ingen signifikant effekt på beinstyrke basert på hvilken gruppe deltakerne tilhørte. Dette indikerer at utholdenhetstrening ikke har noen effekt på beinstyrke blant eldre.

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Every journey comes to an end, and this master´s thesis marks the final destination of my 18 years as a student. I have learned a lot through this process, got a lot of scientific experience, knowledge about physical activity in older persons and last but not least I have learned important and new things about my self as a person along the way that I would not have without taking part in this process. To get me through the way, I owe a lot of person's huge thanks!

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1.0 Introduction

The proportion of older persons living in the world is steadily increasing. According to The World Health Organization approximately 22 % of the worlds population will be defined as older people in 2050, compared with 11 % in 2000. The World Health Organization defines older people as those that are 60 years and older (WHO, 2014, Van Roie et al., 2013). With increasing age, several changes occur in the body´s physiology and functioning. Many organs in the body show a gradual decline in functional capacity, and the body's ability to retain homeostasis is gradually reduced (Matteson et al., 1996, Koopman and van Loon, 2009). After turning 50 years old a typical decrease in muscular cross sectional area occurs of 1 % every year (Iolascon et al., 2014). Others have been estimating that after around 50 years of age a muscle loss of 8 % per decade will occur, increasing to 15 % per decade after one has turned 70 years old (Grimby and Saltin, 1983). This is a normal process that is closely related to ageing. The alterations in the neuromuscular system with age affect the ability to develop force, and the rate of force development is also decreasing (Gurjao et.al, 2012). With the loss of muscle mass and decrease in rate of force development occurs also the possibility of a decrease in physical function. Together, these changes can cause an increasing risk of hospitalization (Cawthon et al., 2009), and reduce the level of well being among older people (Kunzmann et al., 2000). Equally important is the reduction in level of independence related to physical function. Maintaining a good physical function is highly valued among older people because of its transferability to daily living and coping with the challenges in the everyday life (Manini and Pahor, 2009).

An additional clinical problem for older persons can be the disease sarcopenia, which is an age-related loss of skeletal muscle mass as well as muscle function (Iolascon et al., 2014). Sarcopenia differs from the typical normal loss of muscle mass by affecting the physical function at a larger scale as well as possibly causing disability. The disease can affect the function of the body in a larger scale, and often causes loss of independence, higher risk of falls and reduced quality of life (Montero-Fernandez and Serra-Rexach, 2013). The importance of doing physical activity to maintain strength and good physical health is well documented, and a higher degree of physical activity can be a preventing factor for many of the negative effects aging has on physical function (WHO, 1998, Misic et al., 2009). For example, strength training has been shown to be an effective way to improve the function of the neuromuscular system in elderly (Latham et al., 2004). Research done in nonagenarians living in nursing homes indicates that high resistance weight training leads to an increase in muscle size, muscle strength and muscle function (Fiatarone et al., 1990). This leads to a better ability to function in daily life and a higher level of independence. The effect of strength training has been investigated and related to rate of force development, and findings show that strength training has a significant positive effect on rate of force development (Gurjao et al., 2012).

Although several studies indicate that resistance training has a positive effect on muscle function and muscle strength, it is unclear whether aerobic physical activity as well can affect lower extremity muscle strength in older persons. The main focus of this thesis will be to investigate how different types of endurance training may affect peak force and peak rate of force development in the lower extremities of older persons.

1.1 Theoretical background

1.1.1 Physical activity in older persons

Older persons all around the world tend to have a decreasing level of physical activity. By way of example, Americans are the least active according to the American College of Sports Medicine and the American Heart Association, (Nelson et al., 2007). A few studies on elderly living in Norway are conducted, but studies on persons in the same age group are included for comparing and discussion in this present study. The American College of Sports Medicine and the American Heart Association have developed recommendations for physical activity for older adults aiming to promote health and prevent disease. The physical activity recommendations are created to fit into the daily life of peers with age over 65 years. This physical activity is meant to be in addition to other daily activities such as shopping, housekeeping and walking short distances and consists of a minimum of 30 minutes moderate-intensity aerobic physical activity for five days per week or vigorous-intensity aerobic physical activity for a minimum of 20 minutes on three days per week (Nelson et al., 2007).

Walking has been shown to be the most popular form of physical activity among older adults living in Australia (Scott et al., 2009). For ageing and elderly people, walking is an ideal way to start exercising more because it is the most natural form of movement for a human being (WHO, 1998). As earlier mentioned, physical activity has many benefits and starting to walk regularly, for example, can quickly improve muscle strength in elderly (Fiatarone et al., 1990). An increased amount of walking activities can actually cause a decrease in mortality caused by cardio vascular disease (Hakim et al., 1999) and all-cause mortality (Bijnen et al., 1998). According to Hakim et al. (1999) the mortality risk is twice as high among healthy men (aged 71 – 93 years) walking < 1 mile per day compared with men from the same group walking > 2 miles per day. A significant reduction in 10 – year total mortality also occurred among physically capable men (aged 64 – 84 years) that walk or cycle 20 minutes three times per week compared with those did not (Bijnen et al., 1998).

1.1.2 Effects of ageing on the neuromuscular system

Many different physical changes can occur when a person gets older. Aging is a natural part of life and the way people grow older depends on genetic factors as well as environmental and lifestyle factors (WHO, 1998). As the population of older persons is growing the interest and focus on independence and life quality increases as well. Significant changes in the neuromuscular system are present in the aging process of the human body. Loss of both muscle mass, strength and power could decrease the ability to live an independent life as an old person (Gurjao et al., 2012). Observational studies have indicated that muscle mass and force reach their peaks somewhere between 20 and 40 years of age, and then slowly decrease every following year (Lauretani et al., 2003). The study mentioned above used both subjective and objective measurements of the physical variables, measuring lower extremity strength by performing a single leg extension movement (Lauretani et al., 2003). The loss of strength in all the limbs of the body can cause a decrease in daily functioning, and the loss of leg strength can specifically result in an elevated risk of falling (Schlicht et al., 2001).

1.1.3 Rate of force development and physical activity in older persons

Rate of force development (RFD) is often defined as a person's ability to produce muscle force as fast as possible (Gurjao et al., 2012). RFD affects the acceleration a person can generate in one certain move, and it also influences the velocity of a movement (Aagaard et al., 2002, Caserotti et al., 2008, Kraemer and Newton, 2000). The RFD also plays an important role in developing maximal muscle power, and according to Aagaard et al. (2002) and Kraemer and Newton (2000), the ability of developing force also correlates with maintaining postural control. RFD can also be a predictor of the number of falling events among older persons. When a person is activating the muscular system of the body to prevent a fall, the development of force needs to occur in 0 – 200 ms (Aagaard et al., 2002, Kraemer and Newton, 2000). This leads to the assumption that RFD is a more important function than muscle strength itself among older persons in particular and in fall preventive situations in general (Aagaard et al., 2002). According to Thompson et al. (2014), aging affects the rate of muscle activation and rapid force characteristics of the plantar flexors, which was investigated in young, middle-aged and older men (Thompson et al., 2014). In this study, the test results showed that all values describing the rate of force development were larger in the groups of young and middle-aged compared with the group of older men (Thompson et al., 2014).

1.1.4 The effect of strength training on lower extremity strength in older persons

Several studies have shown that strength training has a positive effect on lower extremity strength in older persons. Different studies have been done investigating the difference between high and low external resistance training. A Belgian study with 50 participants over 60 years investigated the effects of strength training on muscle volume, muscle strength and force-velocity characteristics (Van Roie et al., 2013). The participants were randomly placed into one of three groups; HIGH, LOW and LOW + that did leg press and leg extension in different amounts of sets and repetitions. The HIGH group did heavy weights and few repetitions; the LOW group did light weights and many repetitions while the LOW+ did combined some lightweights and many repetitions with medium heavy weights in 10 – 20 repetitions. The results from this randomized controlled trial showed that the HIGH and LOW+ group achieved a larger improvement in 1 RM than the LOW group did. High resistance exercises had a trend towards larger increase in maximal strength in elderly than low resistance exercise did (Van Roie et al., 2013). Another randomized controlled trial mentioned above included 61-87 year old men and women, who performed an eight-week intense strength-training program (Schlicht et al., 2001). The aim of the study was to see whether eight weeks of strength training three times per week could improve functional ability, more accurate the muscle velocity and postural control specifically related to the risk of falling. After comparing test results from prior, mid and post intervention Schlicht et al., (2001) found that the intervention group had an increase in leg strength and a decrease in risk of falling, compared to the control group that continued their normal physical activity level.

Several other studies have also examined the effect of different types of resistance training on muscular strength. One study showed that progressive resistance training could produce a significant increase in knee extensor strength in older women aged 76 – 93 years old (Skelton et al., 1995). The women tested in this study served as either controls or as a part of an exercise groups, and had a twelve-week intervention period. After three strength training sessions each week, the exercise group had a significant 27 % mean change in knee extensor strength, and 18 % mean change in leg extension power (Skelton et al., 1995). Granacher et al., (2009) performed a study that included strength tests on 40 older persons before and after three sessions per week of thirteen weeks of strength training. The participants were split into a control group and a training group and similar findings were also reported here as in the abovementioned study. The training group increased their maximal isometric leg extension force as well as the explosive force while the control group did not (Granacher et al., 2009).

Another study compared the effect of strength training and balance training on different physical variables. One of the variables was maximal isometric force production that was measured by looking at the force production in the leg extensors (Beurskens et al., 2015). In this study they also compared older persons (> 65 years) with younger people (20 – 30 years), to see if there was any difference in effect after 13 weeks of training. According to Beurskens et al. (2015) the leg extensor strength increased in both training groups and the older persons had the same effect as the younger ones.

1.1.5 The effect of endurance training on lower extremity strength in older persons

As described above there has been a lot of research on how systematic resistance training affects older peoples lower extremity strength. There is evidence that indicates that strength training leads to the best effects on lower extremity strength in elderly. Some studies are also conducted on endurance training and its effect on lower extremity strength, and some of these will be described in detail in the following part of this chapter. A study performed in Austria on 42 participants examined the effect of systematic endurance and resistance training on muscle strength and endurance performance (Strasser et al., 2009). To measure the effect on the outcome variables all the participants performed maximum aerobic power tests and three different 1 RM strength tests. They found no significant effect of endurance training on maximum strength in the bench press and the leg press exercise, but an increase in the bench pull exercise after 6 months of endurance training. In contrast, they found positive effects of strength training on muscle mass and muscle strength. In the post intervention maximum workload test, the endurance training group showed improved maximum workload with 31 %, compared with 6 % in the resistance training group (Strasser et al., 2009).

Little is still known on what type of physical training is the best for elderly to maintain function and well – being. A study that was done on 118 Norwegians (mean age: 74.8) investigated how three different types of training effected variables such as muscle strength, physical function, body composition and well – being (Solberg et al., 2011). The participants were randomized into traditional strength training, functional strength training, endurance training, and control group. Results indicated that only the strength training groups increased muscle strength. In contrast, an Italian intervention study found some results that could indicate that endurance training had a positive effect on muscle strength. Of the three groups in the intervention, the two groups that performed either arm cranking (ARM) or leg cycling (CYC) had a significant increase in strength variables at the post intervention test compared with the control group (C) (Pogliaghi et al., 2006). Compared with this study, two other studies that examined the different effects of intensive strength and endurance training on variables such as muscle mass, muscle strength and fiber characteristics, only found increase in muscle strength in the strength-training group in the intervention compared with no increase in the same variables in the endurance training groups (Izquierdo et al., 2004, Sipila et al., 1997).

Another study done by Sipila et al., (1996) did findings after a 18 week intervention program that indicates that in older women (76 – 78 years) the effects on leg muscle strength occurs after both endurance and resistance training (Sipila et al., 1996). This result occurred in the endurance – trained group after 9 weeks of intervention compared with the controls that did not, and remained also after 18 weeks of training. The increase in the knee extensions tendency of the force to turn or twist and the walking speed also occurred in the strength training groups (Sipila et al., 1996).

1.2 The purpose of this present study

Effective interventions are needed to prevent decrease in muscle mass and in physical function in elderly (Van Roie et al., 2013). It exists a certain importance of characterizing what kind of exercise training is most effective and affect the decrease in older peoples function in a positive way (Misic et al., 2009). By looking at the effect of different types of training and different combinations of training it would make it easier to recommend training for older people as well as maintaining better health longer for older people. Muscular strength is an important function at high age, and should be maintained as long as possible. It is done a lot of research that confirms the positive effect of strength training on leg strength. Several studies on endurance training and its effect on health in general and for example cardiovascular disease are also performed. There are only done a few studies on endurance training and the effect on leg strength among older people. The studies that are done show conflicting results, and does not come out with clear and similar results.

The intervention periods of the studies that are done on endurance training and leg strength are not long lasting, and studies with longer intervention period would probably give more accurate results for this age group. The purpose of this present study will therefore be to investigate whether endurance training has an effect on lower extremity strength after a three-year intervention period and whether specific types of endurance training can be recommended over others.

2.0 Materials and Methods

The current study is a population-based cross sectional study that examines whether there is an effect of different intensity levels of endurance training on lower extremity muscle strength and rate of force development in elderly. This study is a part of the larger randomized controlled study called Generation 100 that is conducted by The Cardiac Exercise Research Group (CERG) as a collaboration between the Norwegian University of Science and Technology and St. Olavs Hospital in Trondheim. The primary aim of the Generation 100 project is to evaluate the effect of five years of exercise training on mortality and morbidity in an elderly population.

2.1 Participants

The Generation 100 invited all inhabitants in the region of Trondheim that were born between 1936 and 1942 (n=6966). The potential participants were identified through the National Population Register. Attached to the invitation letter (see Appendix A) was information about the study, a questionnaire regarding personal health status and a response sheet that all invited individuals was asked to fill in and return. After returning the response sheet, they were screened for inclusion. The inclusion criteria were that they were born between 1936 and 1942 and that they were able to complete the exercise program that was prescribed to the group they were randomized into. There were three different groups: 1) two session per week with high intensity training, based on 10 minutes warm up and 4*4 minutes of intervals at 90 % of maximal heart rate: 2) two sessions per week with moderate – intensity training, based on 50 minutes of continuous endurance training at 70 % of maximal heart rate. The last group: 3) served as a control group, and was asked to follow the national physical activity recommendations. The exclusion criteria involved any type of illness, heart disease, dementia or other conditions that reduced ability to exercise or hindered completion of the study. After screening the interested participants, 1567 people, 777 men and 790 women were included in the study that started baseline measurements in August 2012. These participants were also invited to the one year follow up and three year follow-up. The last round of data collection is planned in 2017/2018, as a five-year follow-up. The current study includes about half the number of remaining participants that attended at baseline; 1- and 3 year follow up. The participants (n = 387) performing valid physical tests of interest between August and December 2015 at the three – year follow-up are included in this study.

Table 1. Descriptive characteristics of the participants (n = 387) included in this thesis.

Variable	Control (*n* = 197)		Moderate (*n* = 88)		High (*n* = 102)	
	Female (*n*= 105)	Male (*n* = 92)	Female (*n* = 48)	Male (*n* = 40)	Female(*n* = 44)	Male (*n* = 58)
Age (years)	71.8 ± 1.3	72.04 ± 1.35	71.85 ± 1.4	71.85 ± 1.27	72.05 ± 1.43	71.53 ± 1.42
Height (cm)	163.78 ± 5.41	177.53 ± 5.54	163.63 ± 5.67	176.47 ± 5.68	164.70 ± 4.78	176.07 ± 5.55
Weight (kg)	66.34 ± 9.87	81.13 ± 9.85	69.61 ± 11.41	81.94 ± 11.05	64.51 ± 8.69	83.33 ± 11.56
Fat (%)	33.53 ± 6.71	24.05 ± 5.95	34.72 ± 7.1	24.19 ± 6.24	32.34 ± 6.06	25.48 ± 6.69
Muscle mass(kg)	23.54 ± 2.57	33.85 ± 3.85	24.28 ± 2.6	34.35 ± 3.55	23.34 ± 2.18	34.21 ± 3.46
Waist (cm)	88.86 ± 9.63	97.24 ± 8.87	90.86 ± 11.11	97.40 ± 0.20	85.48 ± 7.73	98.93 ± 9.83

Note. Data presented as mean ± SD values, presented per group and gender measured at baseline.

2.2 Equipment

To collect the data material for the current study many different machines were used to test the participant's physical and mental health. The test stations were placed on different places at the laboratory, the treadmills and the leg press machine was in the same room. The equipment to perform the gait test, handgrip measurement as well as the blood samples and the cognitive test was placed in other rooms. Only the equipment that was used to investigate this specific area of interest measured the lower extremity strength and rate of force development, and will be described in more detailed.

2.2.1 HUR leg press

The HUR leg press machine was used to perform a maximal isometric strength test. Isometric muscle strength in the lower extremities was measured by using FCM 5540 Leg Press Rehab Standard, Helsinki University of Research (HUR), Finland. The HUR leg press machine is specially designed for people in rehabilitation, with long-term physical impairments as well as seniors in general. The construction of the machine is such that participants can get easily in and out of the chair. The chair has a belt to be fastened around the hips during the exercise, to get isolated leg activation during the leg press test. Two separate plates record the amount of force that is developed by each foot separately. The power cells are recording the maximum force, minimum force, force velocity as well as the rate of force development during five seconds. The computer software program Performance Recorder was used together with the HUR machine to register the results from each trial. To find the right angle in the knee joint (110 °) a plastic goniometer was used to measure the participant´s actual knee angle, so that the back of the chair could be adjusted back or forward if necessary.

2.2.2 Performance Recorder PR1

The Performance Recorder (HUR labs OY. Åkerlundinkatu, Tampere) is an additional device to the HUR leg press machine. It is a portable general-purpose device that is recording strength. The Performance Recorder consists of an industrial grade strength sensor that measures all force produced between 0 and 500 at 100 Hz. The Performance Recorder is easily connected to the HUR machine, by plug-ins on each force cell located on the front side of the chair. Together with the Performance Recorder there is also a software, HUR Labs Performance Recorder. This is a computer based program that is connected to the Performance Recorder and the HUR leg press, which shows the results from the strength and force measurements.

2.3 Procedure

All testing took place in the training unit at the acute – heart – lung center at St. Olavs Hospital. The tests were located at three different places, divided into three stations. Post 1 was the first station the participants came to, where they took blood samples, measured body composition and measured lung capacity. Post 2 was the second station, and was performed the week after the first station. This station consisted of physical tests such as maximal oxygen consumption test, isometric leg press, gait, grip strength, cognition, balance and functional leg strength. The third and last station gave feedback from the questionnaires and physical tests, as well as results from the blood samples, body composition test and the other indicators for the health status. After the conversation and feedback was given, the participant was done with the testing and aloud to leave the location. The tests that are relevant for the present study are described in more detail below.

2.3.1 HUR leg press procedure

To measure the lower extremity strength the participants took place on the chair of the HUR leg press machine (illustrated in Figure 1). The test leader then used a plastic goniometer to make sure the knee joint angle was right, prescribed in the protocol to be around 110 °. A belt was then fastened around the participants' hips, to avoid movement at the chair and to isolate the power from the legs. The participants were instructed to place their arms crossed over the chest during the test. A total of six trials were performed, measuring three trials on each leg separately starting with the left leg. After three trials the participants got a short break, when the computer device was manually changed from measuring the left leg to measuring the right leg. Prior to each trial, the test leader counted down from three to one, and gave a signal for the participant to push as fast and hard as they could. The participant was then asked to hold the force for about three seconds before they were told to relax rapidly. Before and after the maximal force development the participants were instructed not to lean against the plates with the force cells, to make the force development start from close to zero Nm. The measurement data was then saved on the computer under the participants ID-number.

Figure 1. Seated position in HUR isometric leg press. Arms are crossed over the chest, knee angle is 110 °, and the belt around the hips is fastened (picture used with permission).

2.3.2 Signal processing

To define the variables used in this study other studies was used to find a valid measurement. In another study by Thompson et al., (2014) they used the highest measured 0.25 second force during a total of 3-4 second MVC in the plantar flexor muscles (Thompson et al., 2014). The peak rate of force development was determined from the peak value of the first derivate of the force signal. RFD was quantified from the linear slope of the force-time curve at time intervals of 0-50 and 100-200 ms (Thompson et al., 2014). Based on this literature and some thoughts regarding how to define the peak values of the two main variables, the peak force value was defined by calculating the mean peak value of all included trials per leg separately. The peak RFD value was also calculated by finding the mean value of the included trials per leg.

2.4 Analyses of the outcome measurements

The analysis of the participants force data was done in multiple stages and in different programs. The data was first transcribed into MATLAB R2015b is a computer mathematic program that are using a fourth – generation programming language. The programming language allows the user to plot functions, algorithms and other implementations written in a script that are programmed with combinations of different computer language. The MATLAB program can produce three-dimensional graphics using certain functions. Through MATLAB the data went through several processes regarding inclusion/exclusion, peak values and mean values. The data was then further analyzed in IBM SPSS Statistics. The analyses will be described more detailed below.

2.4.1 Visualizing the force curves from the HUR – measurements

All the 387 participants performed as earlier mentioned a total of six isometric leg presses, three per foot. After the recording of the data, the data file was transformed into an excel file for further analysis. The trials had to fill a number of criteria's to be defined as valid trial to include in the final analyzes (see Figure 2.). The force signal was not valid if the force began over a level of 5 kilograms. The force curve should also have a certain preferable shape, to be included in the analysis. The force curve should both start and end at zero kilograms so that the curve had a clear beginning and end, and was not included if the force curve did not end before the end of the time window on five seconds. The last criteria for the force curve was that it should have a box formed shape, so that force curves with multiple tops as a result of pedaling was also excluded. To define a RFD signal as valid, there was one criteria that had to be fulfilled, that peak RFD occurred in prior of the peak force (see Figure 3.). When manually looking at every force curve, the curves got a score of either 0 (not accepted) or 1 (accepted). This was coded in one specific excel sheet so that it later could be used in combination with a custom made MATLAB script that excluded the 0 – coded trials. The included trials were later calculated to a mean value of peak RFD and peak force, for each foot. From the total of 401 participants that were tested in the data collection period, 2406 trials were performed in the HUR leg press machine. Of these trials, 12.3 % of force measurements were excluded due to the exclusion criteria. Of the RFD – measurements, 11.7 % of the trials were excluded due to the exclusion criteria, and a total of 388 participants remained.

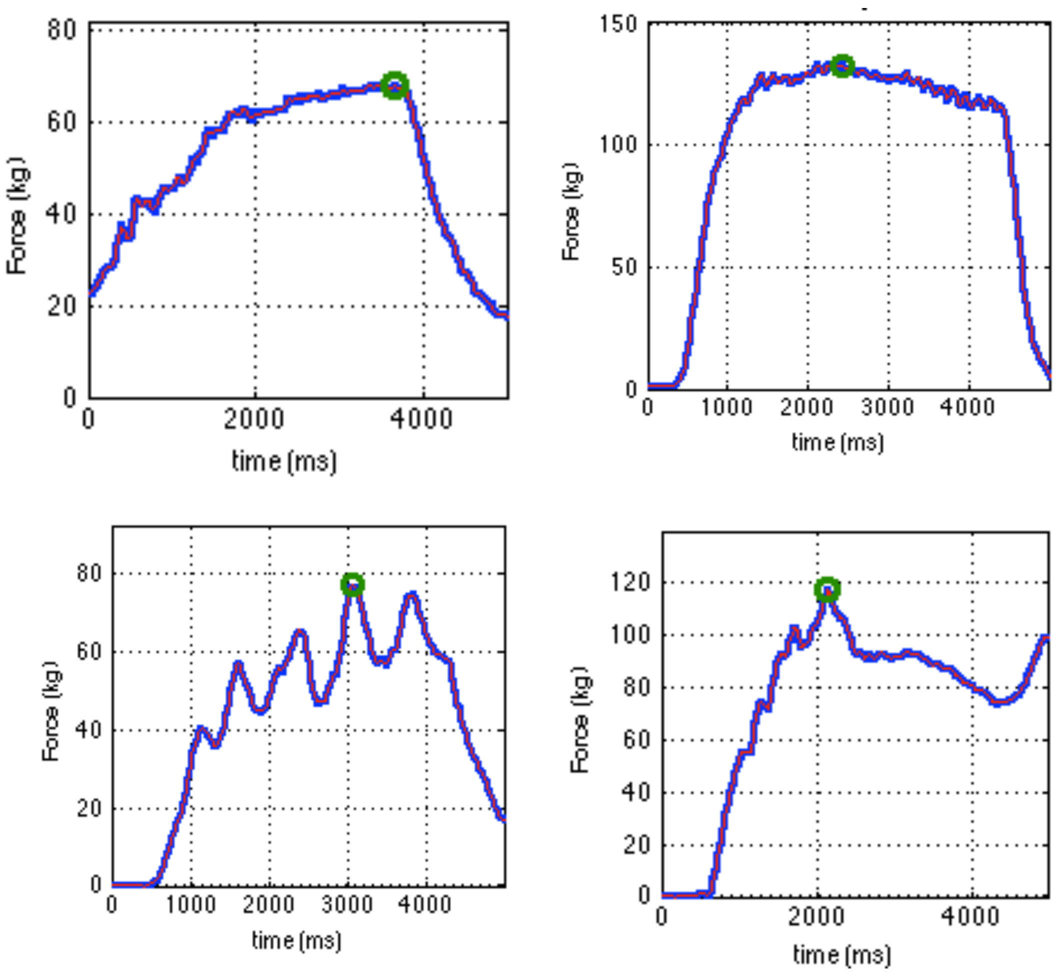

Figure 2. The figure illustrates a randomized selection of trials from the HUR leg press machine, and shows four different force curves from MATLAB where only the top right curve is defined as an accepted and included trial. The peak force value is marked in each curve with a green circle. Top left curve = Starts the force signal over 5 kilograms, and is not included. Top right curve = Has a box shape with a clear start and end within the time window as well as a plateau, and is included to further analysis. Bottom left curve = Contains a force signal with pedaling and several top points, and is not included. Bottom right curve = Does not have a clear end, and the force signal seems to increase after the 5 second window, the first marked peak could possibly not be the peak force value since there is no clear end. This trial is not included.

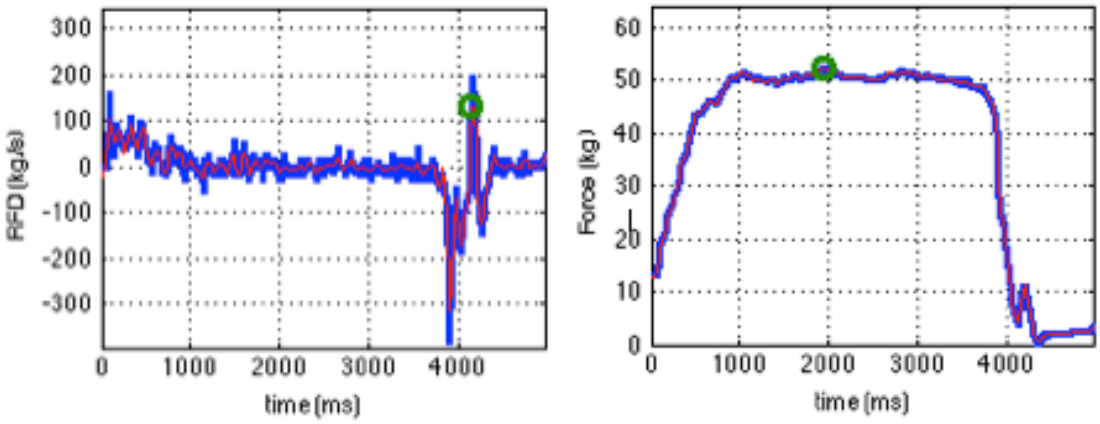

Figure 3. The figure shows one random selected trial, and illustrates the peak RFD to the left and the peak force on the right. The peak values are marked with a green circle in both curved. As illustrated on the RFD signal to the left, the peak measurement occurred after the peak force occurred. This indicates that the peak RFD occurred at the little peak in the force curve to the right on the signal.

2.5 Statistical analyses

All data was analyzed in IBM SPSS Statistics version 23. Descriptive analysis was used to present mean and standard deviations (SD) of the variables, as well as the difference from the strength tests from baseline data compared with the data from the three-year follow – up. All data were checked for normal distributions by looking at QQ – plots, histograms and significant levels. Chi-square test were used to check if the participant were equally distributed in each of the three groups. A 4-way repeated measures multivariate analysis of variance (rMANOVA) was used to investigate the effects of the different exercise groups, gender and body side on both mean peak force variables and mean peak RFD variables.

2.6 Ethics

The Generation 100 study was approved by the Regional Ethical Committee in Health Region IV (REK). As a part of the Generation 100 study, this present study also was approved. The participants in the study could at any time choose not to be a part of the study anymore, and all types of physical testing, training and other concerns regarding the project were voluntary (see Appendix B and C).

3.0 Results

This chapter presents baseline characteristics, changes in leg strength from baseline to year three and effects of different types of training on leg strength changes.

3.1 Background characteristics of participants

The total sample analyzed consisted of 387 participants, 197 women and 190 men. Table 2 presents the baseline characteristics from the questionnaire in percentages. The baseline characteristics include living situation, education level, health status, smoking habits, daily activity level and history of disease. The characteristics are presented per group and split by gender and show that more men have a higher education compared to women, men report better self-perceived health than women, there are more smokers, diabetics, and cardiovascular diseases among men than women, but a larger amount of women are reporting osteoporosis compared to men. Table 2 also shows that women are more frequently living alone than men. A chi-square test of all variables indicated that there were no statistically significant differences in percentages between the training groups. This indicates that males and females are successfully randomized into the three intervention groups.

Table 2. Background characteristics of participants at baseline according to group and gender.

	Control (n = 197)		**Moderate (n = 89)**		**High (n = 102)**	
	F (n = 105)	M (n = 92)	F (n = 48)	M (n = 40)	F (n = 44)	M (n = 58)
Living situation (%)						
Alone	40.6	13	40.8	10	29.5	12.1
Cohabitant/spouse	57.5	87	59.2	90	70.5	87.9
Others	1.9	0	0	0	0	0
Education level (%)						
Lower education	50	35.2	48	30	52.2	43
Higher education	50	64.9	52	70	47.7	57
Health Status (%)						
Very good	23.6	27.5	20.8	28.2	15.9	31.6
Good	66	68.1	70.8	64.1	72.7	63.2
Not that good	10.4	4.4	8.3	7.7	9.1	5.3
Bad	0	0	0	0	2.3	0
Smoking habits (%)						
Never	100	96.7	95.9	97.4	95.5	93.1
Former	0	2.2	0	2.6	0	5.2
Current	0	1.1	0	0	0	1.7
Missing*			4.1		4.5	0
Daily activity level (%)						
> 30 minutes daily	78.6	68.5	83	75	86.4	82.1
Prevalent diseases (%)						
CVD						
NO	95.2	92.4	93.8	87.5	97.7	91.4
YES	4.8	7.6	6.3	12.5	2.3	8.6
Diabetes						
NO	99.1	89.1	100	97.5	100	91.4
YES	0.9	10.9	0	2.5	0	8.6
Osteoporosis						
NO	89.5	97.8	87	100	90.5	100
YES	10.5	2.2	13	0	9.5	0

Note. All data presented in percentage.

3.2 Change in maximal force from baseline to year three

Figure 4 shows mean changes in mean peak force values on strength tests from baseline to three year follow up. As shown in the figure all groups have a reduction in mean peak force levels from baseline to three-year follow-up. For females the reduction in mean peak force seem smaller in the high intensity group, followed by the moderate group and the control group has the largest decrease in mean peak force. The results from the men show that for the force values, the high intensity group has the largest reduction, with moderate intensity as second and the control groups has the smallest reduction. However, variability between participants in each group is very large.

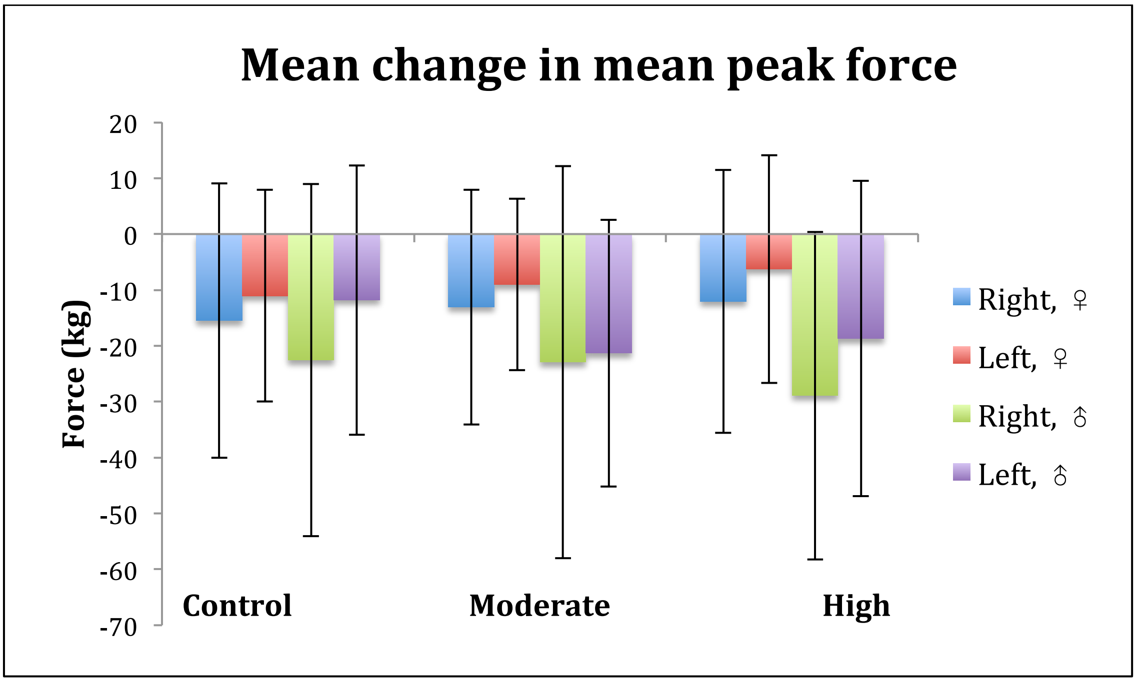

Figure 4. Change in mean peak force from baseline to three-year follow-up. Data are presented as mean ± SD values, and are divided into group, gender and left and right leg.

3.3 Effect of endurance training on leg strength

A 4–way repeated measures MANOVA was conducted to determine the effects of gender, intervention group, pre- and post-test and left/right leg on mean peak force and mean peak rate of force development on all the participants (n=387). Below, the effects of endurance training on mean peak force are presented first. Results regarding rate of force development are presented in section 3.4 and 3.5.

As shown in Table 3, there was a statistically significant main effect of Time on the mean peak force value ($p < .0001$), indicating that strength at 3-years was lower than at baseline. Side is also statistically significant ($p < .0001$), with the right side overall being significantly stronger than the left side. There was a statistically significant Time * Gender interaction on mean peak force value, reflecting that men had a larger reduction in peak force than women from baseline to three-year testing (see Figure 5). Men had a 25.6 % mean reduction in peak

force, while women had a mean reduction of 18.2 % in peak force from baseline to year three. There was a significant Time * Side interaction in mean peak force as well, reflecting that the peak force in the right leg decreased slightly more than in the left leg (see Figure 6). The right leg had a mean decrease in peak force of 20.5 % while the left leg decreased 17.3 % from baseline to year three. None of the other 2-way interactions were significant (all p´s > .3)
None of the 3-way interactions Time * Group * Gender, Side * Group * Gender, Time * Side * Group and Time * Side * Gender was statistically significant, neither was the 4-way interactions between all factors (all p´s >.1)

Table 3. Results from the 4-way repeated measures MANOVA. Group (3) by Time (2) by Gender (2) by Side (2) on mean peak force.

Effect	**F**	**p - value**	**Effect size**
Group	.795	.452	.005
Time	168.95	< .0001	.327
Gender	229.009	< .0001	.398
Side	211.452	< .0001	.379
*Group * Gender*	.962	.383	.006
Group Time*	.453	.636	.003
*Time * Gender*	14.907	< .0001	.041
*Time * Side*	21.908	< .0001	.059
*Side * Gender*	.316	.574	.001
*Side * Group*	.520	.595	.003
*Group * Time * Gender*	2.171	.116	.012
*Group * Gender * Side*	0.506	.603	.003
*Group * Time * Side*	.948	.389	.005
*Time * Gender * Side*	2.092	.149	.006
*Group * Time * Gender * Side*	1.326	.267	.008

Note. Time refers to the two measurements at baseline and year three. Group refers to the three groups in the intervention, that is control, moderate intensity and high intensity group. Side refers to the isometric strength tests performed by the participants on left and right leg. Gender is defined as either female or male. The data are presented as F – value, p – value and effect size.

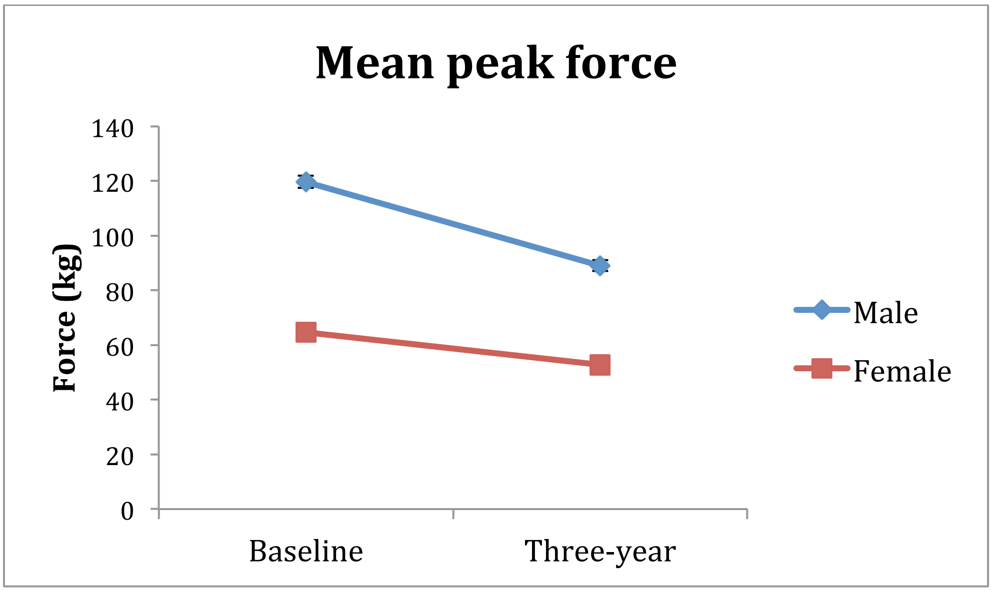

Figure. 5. Mean peak force (kg) with standard error bars from baseline to three years for males and females separately, showing the statistically significant two-way interaction between time and gender.

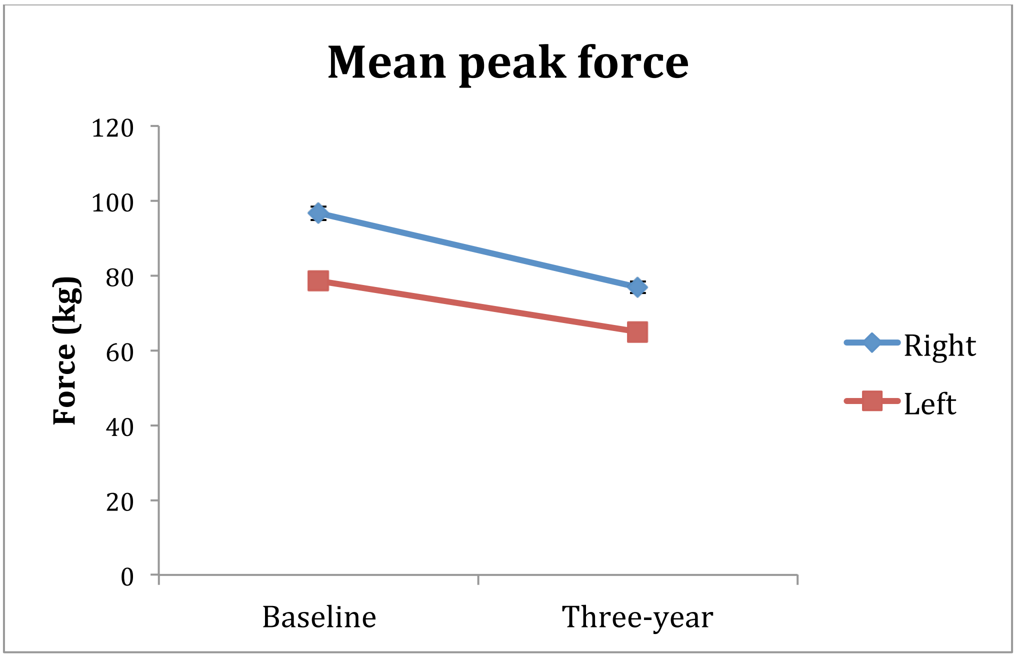

Figure 6. Mean peak force (kg) with standard error bars from baseline to three years for right and left side separately, showing the statistically significant two-way interaction between time and side.

3.4 Change in rate of force development from baseline to year three

Figure 7 shows mean changes in mean peak rate of force development values in isometric strength tests from baseline to three year follow up. As shown in the Figure 7 all groups have a reduction in mean peak RFD levels. For females the reduction in mean peak RFD are smallest in the high intensity group, followed by the moderate group and the control group. The results from the men show that for the mean peak RFD values the moderate intensity training group has the largest reduction, followed by the high intensity group and the control group.

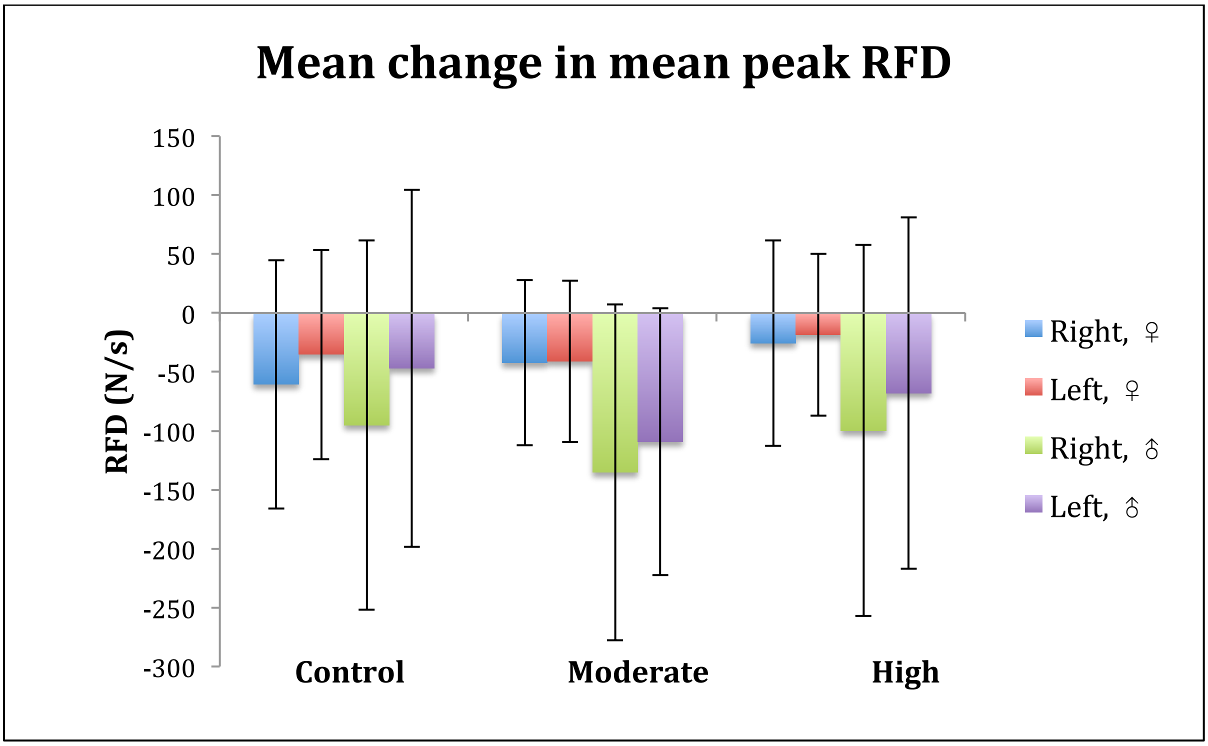

Figure 7. Change in mean peak RFD. Data are presented as mean ± SD and are divided into group, gender and right and left leg.

3.5 Effect of endurance training on rate of force development

As shown in Table 4 below, the 4-way MANOVA indicated that there was a statistically significant main effect of Time on mean peak RFD value ($p < .0001$), reflecting that RFD at 3-years was lower than at baseline. Side had statistically significant main effect of mean peak RFD as well ($p < .0001$), with the right side generally building up force faster than the left side. There was a statistically significant Time * Gender interaction for mean peak RFD that indicated that men had a significantly larger reduction in peak RFD than women, with 25.5 %

compared to womens 22.3 % (see Figure 8). There was a statistically significant Side * Gender interaction for mean peak RFD, indicating that there was a larger difference between right and left leg for men than there is for women (see Figure 9.). There was also a statistically significant Time * Side interaction for mean peak RFD as well, showing that the right leg had a larger reduction in mean peak RFD than the left leg from baseline to year three (see Figure 10). The right leg had a 14.1 % reduction compared with 6.4 % reduction in the left leg. The other 2-way interactions were not statistically significant for mean peak RFD (both p´s >.2). The 3-way and 4-way interactions were not statistically significant (all p´s > .055). In sum, there were no statistically significant main effect or interactions of the Group factor, indicating that the intervention groups and control group did not differ on the strength measurements.

Table 4. Results from the 4-way repeated measures MANOVA. Group (3) by (2) by Time (2) by Gender (2) by Side (2) on mean peak RFD.

Effect	**F**	**p - value**	**Effect size**
Group	.239	.788	.001
Time	113.619	< .0001	.247
Gender	232.853	< .0001	.402
Side	43.467	< .0001	.109
*Group * Gender*	.752	.472	.004
*Group * Time*	1.555	.213	.009
*Time * Gender*	20.607	< .0001	.056
*Time * Side*	18.852	< .0001	.052
*Side * Gender*	3.953	.048	.011
*Side * Group*	.152	.859	.001
*Group * Time * Gender*	2.544	.080	.014
*Group * Gender * Side*	0.717	.489	.004
*Group * Time * Side*	.750	.473	.004
*Time * Gender * Side*	3.716	.055	.011
*Group * Time * Gender * Side*	.321	.726	.002

Note. Time is defined as the variance between results from the two tests performed by the same person, from baseline to year three. Group is defined as the variance between the participants in the three groups in the intervention; control, moderate and high intensity group. Side is defined as the variance of tests done by the same participant on respectively left and right leg. Gender is defined as either female or male. The data are presented in F – value, p – value and effect size.

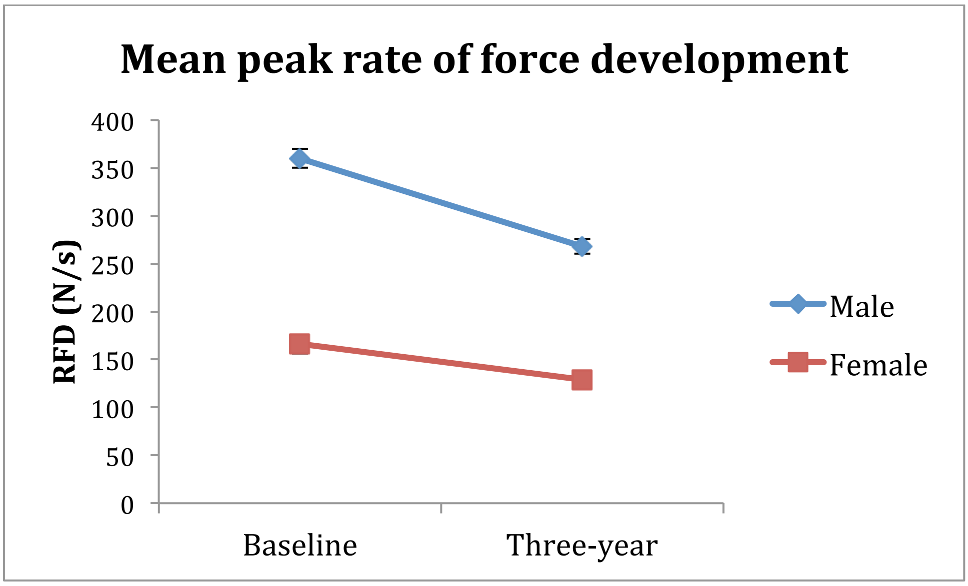

Figure 8. Mean peak rate of force development (N/s) with standard error bars from baseline to three years for males and females separately, illustrating the statistically significant 2-way interaction between time and gender.

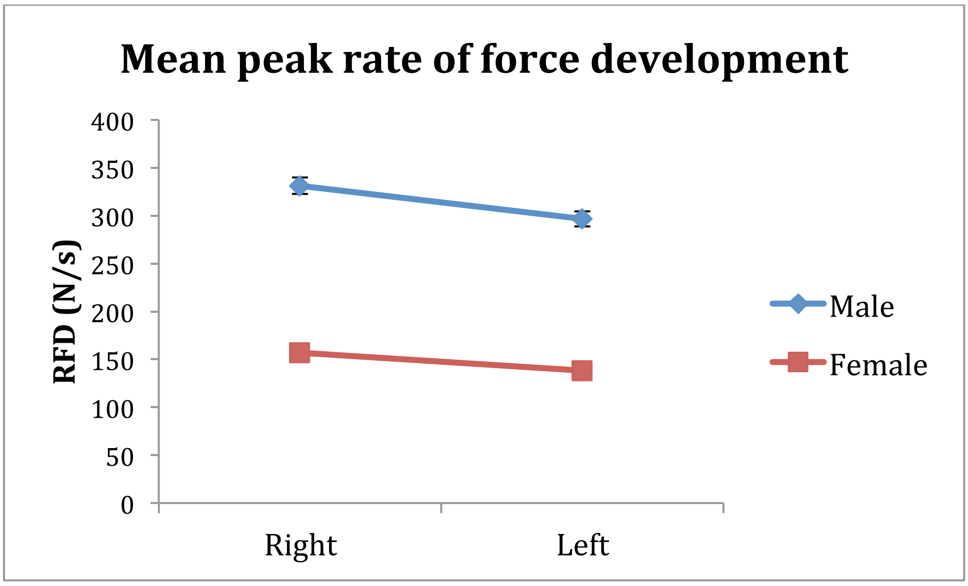

Figure 9. Mean peak rate of force development (N/s) with standard error bars for right and left side separately presented for males and females separately, illustrating the statistically significant 2-way interaction between side and gender.

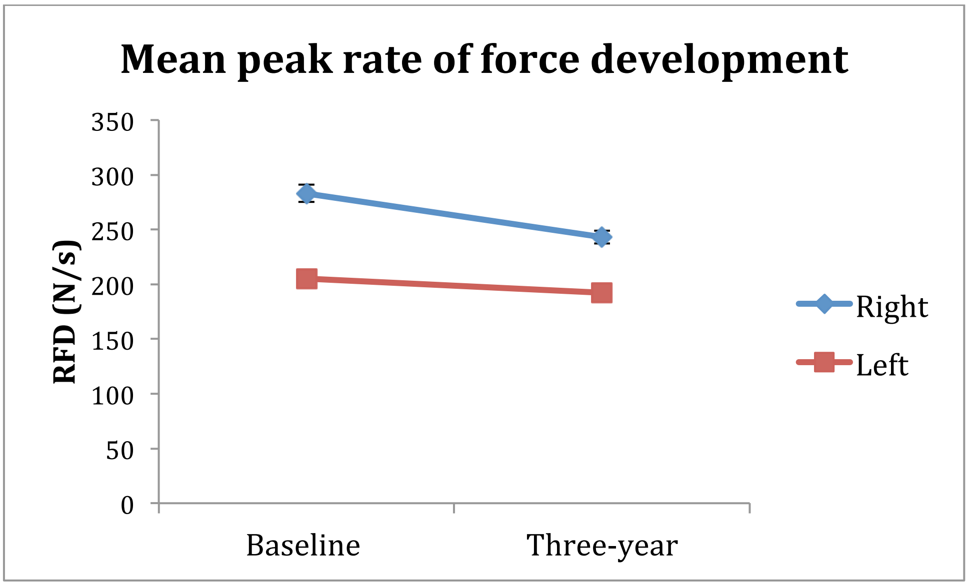

Figure 10. Mean peak rate of force development (N/s) with standard error bars from baseline to three years for right and left side separately, illustrating the statistically significant 2-way interaction between time and side.

4.0 Discussion

The main aim of this present study was to investigate the effect of different intensities of endurance training compared to a control group on lower extremity strength in older persons. More specifically, the aim was to see whether three different groups of the intervention had different effects on peak force and peak rate of force development over a three-year period. Since men in general are stronger than women and may have a different body composition, the data were analyzed separately for each gender. Furthermore, the present study investigated whether effects differed on the two legs. Lower extremity strength was expressed as mean peak force and mean peak rate of force development as measured using an isometric leg press machine.

4.1 Main findings

The main finding of this study was that there was no effect of the different types of endurance training compared to the control group on lower extremity leg strength in older persons. Furthermore, none of the interactions involving group was statistically significant, indicating that all three groups responded equally during the follow up period. However, there was a small trend for women in the high intensity training group had a smaller decrease in maximum legs strength and RFD from baseline to year three compared to the moderate intensity group and the control group. But the effect size is very small. Although there were no significant interactions between Group and Time, there were several significant interactions for Gender, Side and Test that are interesting to highlight. Women in all groups had a smaller decrease in maximal leg strength and maximum rate of force development than men. In both men and women, the right leg was strongest and had the highest RFD values. The women in this study were also reporting a higher level of activity than men in the questionnaire. Furthermore, at baseline a larger amount of the participants in the high intensity group reported physical activities over 30 minutes every day than in the moderate and the control group that are the least active.

4.2 The effect of physical activity on lower extremity strength

In the following two chapters, the findings from the present study will be discussed against existing literature and earlier research done on the topic.

4.2.1 The effect of endurance training on force

The present study found no statistically significant effect of endurance training on lower extremity strength among the elderly participants in any intervention groups. There were interactions that indicated both significant gender differences and leg side differences of the training. Despite few studies, similarities and differences can be seen and compared with existing literature.

For example, Buchner et.al. (1997) found an improvement in leg strength between three different endurance training group consisting of 68 – 85 year old persons with reduced balance control after a six months long intervention. These participants were divided into three different groups; cycling, walking and aerobic exercises. Even if an improvement in peak force was found in these participants, the peak value was calculated from several peak torque values, not directly measured (Buchner et al., 1997). The peak force value in this present study was measured accurate and will therefor be much more valid than the results presented in Buchner et al. (1997). The participants in the abovementioned study only had three months with supervised training, followed by three months of individual training. The intervention period was short compared to this present study, and results could possibly be caused by coincidences, the participants training level in prior of the intervention and weaknesses associated with the formula that gives the peak force value.

Several studies in the field of endurance training and muscular strength in older persons have come to similar conclusions. However, these earlier studies often combined different types of training, for example the effect of endurance training and strength training on both cardiovascular fitness and strength measures (Solberg et al., 2011, Izquierdo et al., 2004, Sipila et al., 1997). In all three studies only the strength training groups had significant effects on the strength variables in the study. The endurance training groups had no significant effects on strength variable in the post intervention tests.

This present study did not include strength training in the training program. Nevertheless, participants in the study could have done strength training on their own. By looking at the results it seems like if any of the participants did so, it did not affect the results. A large number of participants give room for many different kinds of interests, and some could enjoy strength training better than endurance training and choose to go to the gym lifting weights or doing strength training activity instead of doing endurance training. On the other hand, the present study shows that both men and women on average actually decreased in strength with 25.6 % for men and 18.2 % for women in all groups. This suggests that even if some of the participants chose to do strength training combined with the recommended endurance training, it did not lead to increased leg strength. Since the studies mentioned above had durations of 6 months follow up and post intervention testing, which is longer than many other studies, this strengthens the findings in the present study that endurance training does not increase leg strength. However, an important point here is that there is no data that gives information about whether the participants did strength training or not. An intervention that includes a large amount of endurance training could potentially result in a reduction in other activities that the participants usually performed, for example strength training.

However, findings from two studies indicated a positive effect of endurance training on leg strength. The study by Strasser et al., (2009) found a significant effect of endurance training on one specific strength variable, the bench pull exercise (Strasser et al., 2009). Another similar study by Pogliaghi et al., (2006) found positive effects of arm cranking and leg cycling on strength variables. The findings from earlier research are not consistent with the findings from the present study, which found no effect from the endurance training intervention. What could be the underlying reasons for these differences?

The significant findings in this present study indicated that men had a larger reduction in mean peak force than women from baseline to three years testing. Even if women had a lower start value than men, they got test results with force values that showed less decrease than men. The start value at baseline testing among men was on average higher, and it will be natural that men have a larger decrease than women in percent. As earlier mentioned older persons tend to have an average decrease in muscle mass about 15 % per decade after turned 70 years (Grimby and Saltin, 1983). The decrease strength in both men and women in this present study are larger than what earlier literature shows, and larger among men than women. A Japanese study among men and women aged over 65 years old, found a steeper decrease in strength among women than men – which is the opposite than what is found in this present study (Yanagawa et al., 2015). This study did two different tests with one year between, and did not include any training. The reason for these opposite findings can be that the study by Yanagawa et al. (2015) did not include any training between the two tests.

Another possible explanation could be that the baseline value for women in this present study was quite low compared with men, and a steeper decrease in strength among women would end up with a low force value.

There was a larger decrease in the right leg compare to the left leg from baseline to year three. This could also be related to the fact that the force value at baseline was higher in the right leg compared to the left. Both legs are most likely to have the same neuromuscular changes, and it is also natural that one leg is stronger than the other. The difference between left and right leg are further discussed in the chapter about methodological considerations.

One important aspect may be the physical shape the participants were in prior to the different intervention programs. In the Generation 100 study, the physical condition was investigated at the baseline testing in 2012, and it seems that the most healthy and well-educated elderly are participating in the study. This could mean that the participant were in quite good shape in the beginning of the study, and they would therefore not have such effect as less fit persons would. A less fit group could potentially gain more strength than a more trained group, or at least have a smaller decrease from baseline to year three, because they could potentially get a general effect of physical activity. Some of the participants could also be former athletes compared with others that might have been living a more sedentary life that could affect how they responded to exercise. Even with these outlying participants, this large sample size and a group of participants that seems to be quite homogeneous such differences should be evened out and should not have a large effect on the results.

4.2.2 The effect of endurance training on rate of force development

The evaluation of rate of force development as part of a muscular voluntary contraction relates to explosive strength and is important to evaluate in active athletes, older persons and hospitalized patients in rehabilitation (Maffiuletti et al., 2016). In older person it is relevant to focus on explosive force production when it comes to improving the physical function and reduce risk of falling and following injuries (Gurjao et al., 2012). Maintaining a good RFD is important to be able to do rapid movements and changes in for example walking, running and other activities. This is getting more important with age, mainly because of the ability to avoid and prevent falling events. All participants were tested for their ability to generate force rapidly in the HUR leg press machine. However, the results showed that there was no significant interaction between training group and the tests performed prior and after a three year long intervention program, indicating that neither the endurance training in the moderate or the high intensity group had an effect on RFD, nor had the prescribed physical activity in the control group.

Similar findings have also been reported earlier. For example, (Vila-Cha et al., 2010) report on a study that had three groups, strength training, endurance training and control. The endurance-training group did six weeks of training on ergometer bicycle, but did not have a change in RFD values or muscle activation measured as EMG amplitude. This is consistent with the findings in this present study, even if the study population in the abovementioned study was younger, fewer and had a much shorter intervention period.

Results from previous research suggest that explosive exercise is the best method to increase RFD values. A study by Tillin and Folland (2014) investigated whether there was an effect of short time maximal strength training compared to explosive training and found markedly larger gains in RFD values in the explosive strength training group (Tillin and Folland, 2014). The effect of strength training on strength seems to be present in all studies where strength interventions are used. Even in the study mentioned earlier by Caserotti et al. (2008) there was an increased RFD in women aged 60 – 80 years after a twelve-week period consisting of heavy explosive resistance training. As there were no strength training as a part of the intervention in the Generation 100 study, this might explain why there was no effect of endurance training on RFD.

Findings from this present study indicated that there was a significant gender difference in peak RFD. The results showed that men had steeper average decrease in peak RFD than women, and men also had a larger difference between right and left leg with the right leg decreasing more than the left leg. As mentioned earlier in the force chapter this steeper decline in RFD among men could be related to the fact that their start value is higher than women. RFD plays an important role regarding the ability to develop maximal muscle power (Aagaard et al., 2002), which indicates that the participants with greater peak force values also has a greater RFD value. Men are stronger than women, and could therefor have a better ability to develop force faster than women.

The RFD measurements in the present study were done as a part of a maximal isometric leg press. To get a good RFD measurement it is important to give clear instructions to the participants that are doing the contractions, as several studies have found differences in RFD results depending on what instructions the participants were given. Both Bemben et al. (1990) and Sahaly et al. (2001) compared force – time characteristics in different contractions after giving two different vocal instructions on how to reach peak RFD. Both studies investigated the difference between the instructions "hard and fast" and "fast" on RFD and force values. In the present study the participants were told to press as "hard and fast" as possible. According to Sahaly et al. (2001) and Bemben et al. (1990), this was the instruction that resulted in a lower RFD value, compared with the "fast" instruction. The participants actually achieved a 20 – 46 % improvement in peak RFD when they were instructed to push as "fast" as they could compared with as "hard and fast" as they could (Sahaly et al., 2001). This might mean that the peak RFD values in this present study could be better. However, the HUR leg press might be more easily recognized by the participants to be a maximal strength test than an explosive strength test. Therefore, many of the participants could have focused on pushing more hard than fast at the beginning of the pushing phase, even they were told and explained to do both. The test does also have a quite long duration, with a push lasting for about three seconds. This could potentially be one reason for that the RFD are not significantly affected by the training intervention because the participants might have focused more on only developing maximal force than doing it as fast as they could.

Another interesting point regarding peak RFD value is how many of the three trials per leg were approved for further analysis. Many of the trials had a peak RFD value that occurred after the peak force value, and were therefore excluded from the analysis. On the other hand less than 12 % of the trials were excluded, which is less than one trial per participant on average.

4.3 Methodical considerations

In the following chapters the strengths and limitations of the present study are presented. The equipment, procedures, test personel, interventions and different criteria regarding the data analyzing process are discussed as well.

4.3.1 Strengths

This study is a part of a larger randomized controlled trial, which is seen as the gold standard in science. The participants were randomized 1:1 into a training and a control group. The training group was then further divided into two groups with different intensity training.

The study had a long follow up period, which makes the study more reliable and the results could be more polite since the participants get the opportunity to get used to the training over a long period of time.

The number of participants included in this present study was 401, of which 387 were analyzed. This is a good sample size that should give a reliable picture of the entire group of participants. To collect high quality data in a large study such as Generation 100 requires that the test procedures are valid and reliable, and that the test leaders follow the protocols strictly. All test leaders went through pilot testing and training to learn and perform the protocols correctly. This is an important aspect regarding the quality of the test results, and also very important to make sure that all participants are being tested in the same way.

Since all participants did three tests on each leg, the mean value was calculated for each leg separately. If any of the measurements failed or did not fulfill the inclusion criteria, there were still two more trials that could be used for further calculations. As earlier mentioned there was a strict and concrete set of rules that was followed when working with the data material. The rules for inclusion and exclusion were easy to follow, and several persons could be a part of the inclusion process. If any of the trials was difficult to consider as accepted or not, the trial was discussed with a colleague.

4.3.2 Limitations

One of the limitations that could have affected the results of this study is that all physical activity was self – reported. The participants were sending in their physical activity diaries every month of the year, which they filled in with respect to duration, frequency, and intensity of each session with physical activity. The compliance to this self – reporting is very relevant in this study, since it is based on different types of training plans. Many of the participants did follow the instructions regarding the diary, while others did not send in the diaries every month. The physical activities from the diaries were logged into a database, and could be used to see if the different groups of the intervention actually did follow the physical activity instructions as they should. Another limitation is that the training is observed only once every six weeks, and this is not mandatory. While observed, the participants can follow a trainer to perform the workout at the intensity that belongs to each group in the intervention. During the supervised outdoor workout sessions, there is no intensity control to make sure the participants are following the given guidelines.

Another aspect to mention as a possible limitation of the study is to what extent the participants in the three groups adhere to their training or control schedules. Some of the participants in the control group are likely motivated to do more than the 30 minutes of daily moderate intensity physical activity, whereas some of the participants in the high intensity group might want to exercise less than the two high intensity sessions according to the guidelines. The combination of self – reported physical activity and motivation to do the training as they were instructed to do, gives room to consider how valid the results are based on the actual attendance, intensity levels and how the physical activity comes out from the activity diaries.

One last factor that could limit the quality of the test results is that the oral instruction and explaining of test routines can be different form one test person to anther. Even if the test persons were given a manuscript that they were supposed to follow, small changes in the instructions can occur and be different in the beginning of the test period, for example, compared to the period of the ending of the data collection.

The HUR leg press machine is supposed to be custom made for rehabilitation purposes and for older persons. Although the machine provides a standard way to measure maximal isometric leg strength, there are some aspects with the machine itself and the leg press procedure that are important to include in this discussion. First of all it is worth to mention the possibilities to adjust the distance between the participant´s back and the force plate, to get the correct knee angle for each participant. For shorter persons it was not possible to make the chair fit perfectly, and the participant could end up with a larger knee angle than instructed. This could possibly affect the ability to produce force, and the knee angle differs from the protocol. With a larger or smaller knee angle than 110 ° the participant would get a longer or shorter lever that also would reduce the ability to produce maximal force. This could also be a disturbing factor regarding the analysis and comparing from baseline to year three. One participant could have different knee angle the first round of testing compared to the third year that could possibly affect the results. Another important aspect of the chair is the fabric and the friction that could occur in the participant's lower back area. For the strongest participants, this was seen as disruptive and inhibitory for pushing maximally without ending up with lower back pain or at least the feeling that damage could occur. This could affect the results of the tests of the participants with potentially high force values, and could turn out much lower. Older persons often have more fragile skin and could feel pain also even if they were not the ones performing most force. A better ergonomic designed backrest could perhaps reduce these affections on the results, and would allow every participant to push as hard as they could without feeling any pain.

4.4 Future research

This study has been investigating a large group of older people, and found results that shows the physical condition of this group and the affection of different types of endurance training. Anyhow, more research is required to find out what is the best type of exercise to recommend to people in this age group. For this present study, it would be interesting to see more deeply into the training diaries to see how active the three different groups actually was during the intervention period. It would also be useful to use accelerometers over a longer period, and compare these data with the reported activity in the diaries. By investigating this data it could be easier to say more accurate how the different endurance training intensities affects physical function, in terms of the amount of training the participants actually does. This could also show if the activity level differed in the three groups, especially between the two endurance-training groups. Since previous research shows significant effects of the combination of endurance training and strength training, this could be an interesting thing to implement in this intervention. This could possibly result in less decrease in strength and the participants could maintain a better level of physical function longer in life.

5.0 Conclusion

This present study investigated the effect of different types of endurance training on lower extremity strength in older persons. The results indicated that there is no effect of endurance training on leg strength and all participants had a decrease in strength values in a three year period. These findings are consistent with previous literature that mainly indicates that strength training leads to a positive effect on leg strength while endurance training does not have any significant effect. The results showed that there was a very small difference between the effect on the high intensity group, with a little less decrease in strength values among women compared with the other two groups. Women had a smaller reduction in both peak force and peak RFD from baseline to year three compared with men. On the other hand, the women had much lower start values – and this would also affect how much they could decrease in three years also when including the age related decline in the consideration. It seems like strength training is the most effective and important training method to maintain leg strength in older age.

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Appendix A : Invitation to the Generation 100 study

Forespørsel om deltakelse i forskningsprosjektet *Generasjon 100*

Bakgrunn og hensikt
Dette er en forespørsel til alle som er født årene 1936-1942 og bosatt i Trondheim kommune om å delta i et forskningsprosjekt (Generasjon 100) hvor vi ønsker å undersøke hvordan regelmessig fysisk aktivitet påvirker sykelighet og dødelighet hos eldre. Andelen eldre øker sterkt i Norge, og i hele den vestlige verden. Denne utviklingen byr på utfordringer bl.a. i eldreomsorgen, fordi rekrutteringen av nye ansatte til denne yrkesgruppen ikke øker i samme grad. Bedre helse og evne til å klare seg selv, blir trukket fram som en av de viktigste løsningene på disse utfordringene. Generasjon 100 vil ventelig bidra til å avklare om trening, og eventuelt av ulik intensitet, har en effekt på flere av de store helseproblemene i den eldre befolkningen i Norge. Prosjektet blir ledet av "K.G. Jebsen – Senter for hjertetrening", Det medisinske fakultet, NTNU i Trondheim, og prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk (REK).

Hva innebærer deltakelse?
De som svarer ja til å delta i prosjektet, vil bli oppringt og innkalt til undersøkelse 1 (se under). Etter undersøkelse 1, blir deltakerne tilfeldig plassert i en treningsgruppe eller en kontrollgruppe. Treningsgruppa får tilbud om veiledet trening to ganger i uken i prosjektperioden. Du vil få både skriftlig og muntlig informasjon om hvordan trening skal utføres og registreres. Kontrollgruppa blir bedt om å følge helsemyndighetenes anbefaling om fysisk aktivitet. Ektefeller/samboere vil bli plassert i samme gruppe. Kliniske undersøkelser samt spørreundersøkelser vil bli gjennomført på alle deltagerne før oppstart, etter ett år og etter tre år. Prosjektet startet i 2012 og avsluttes i 2015. Dersom du *ikke* ønsker å delta i prosjektet, ønsker vi likevel at du sender inn utfylt spørreskjema og gir samtykke til at det kan brukes i forskning.

Husk at du kan fortsette akkurat som du har gjort før, både om du trener eller ikke, og det gjelder både de som blir trukket ut til å være i kontrollgruppa og de som blir trukket ut til treningsgruppa. Vi har et tilbud og et ønske om at de som blir trukket ut til treningsveiledning, trener minst to ganger i uken.

Hvem kan delta?
Personer med bostedsadresse i Trondheim kommune, i aldersgruppen 70-76 år (født årene 1936-1942).
Du kan dessverre IKKE delta i prosjektet dersom du:

- Har sykdommer eller funksjonshemninger som gjør at du ikke kan trene eller gjennomføre prosjektet
- Har ukontrollert hypertensjon (forhøyet blodtrykk) (over 200/110)
- Har symptomatisk klaffefeil, hypertrofisk kardiomyopati, ustabil angina, pulmonal hypertensjon, hjertesvikt og alvorlig rytmeforstyrrelser

- Har kreftsykdom som gjør deltakelse umulig eller trening kontraindisert. Vurderes individuelt i samråd med behandlende lege
- Har kroniske smittsomme infeksjonssykdommer
- Har testresultater som indikerer at deltakelse i prosjektet ikke er trygt
- Deltar i andre studier som ikke er forenelig med deltakelse i dette prosjektet

Undersøkelse 1
De som svarer ja til å delta i prosjektet vil bli oppringt og innkalt til undersøkelse 1 (se oppmøtested på side 4), hvor følgende undersøkelser vil bli gjort:

- Lungefunksjon
- Blodprøve
- Blodtrykk
- Hvilepuls
- Vekt, høyde og midjeomkrets
- Kroppssammensetning
- Gangtest
- Gripestyrketest
- Benstyrketest
- Maksimalt oksygenopptak
- Spørreskjema

Undersøkelsene gjennomføres over to dager, og vil ta omkring 2 timer hver gang. Alle metodene i forsøket er godt utprøvd på både friske personer og i ulike risikogrupper, og anses ikke som risikable eller å ha negative bivirkninger. Det vil være to leger knyttet til prosjektet som vil være tilgjengelig dersom uforutsette problemer skulle oppstå.

Når du kommer inn til Undersøkelse 1 skal du ikke ha drukket kaffe/te eller røkt/brukt snus. I tillegg skal du ikke ha spist de siste 2 timene før du kommer inn. Dersom du tar medisiner skal disse inntas som vanlig før du kommer til undersøkelsen. Til den andre oppmøtedagen bør du ha på deg/med deg lette klær og sko som er gode å gå/løpe i.

Mulige fordeler og ulemper
Det er gode holdepunkter for at regelmessig trening gir bedre helse enn om man ikke trener. I tillegg vil deltakerne få kunnskap om trening, fysisk aktivitet og helse. Deltakerne vil få utført en rekke helseundersøkelser og oppfølging som de ellers ikke ville fått (gjelder også kontrollgruppen).

Risikoen ved å trene anses som svært liten, men det må nevnes at under, og umiddelbart etter trening/testing er sjansen for komplikasjoner/død litt høyere. Allikevel er det vist at den helsemessige gevinsten av trening er så høy at det blir ansett som mindre skadelig å trene enn å være inaktiv. En sikkerhetskomite vil evaluere prosjektet underveis, i den forbindelse kan du få tilsendt et skjema hvor vi ber deg fylle ut om noe spesielt har hendt i løpet av den siste tiden.

Hva skjer med prøvene og informasjonen om deg?
Prøvene som tas av deg og informasjonen som registreres om deg skal kun brukes som beskrevet i dette skrivet. I prinsippet er alle data fra prosjektet identifiserbare, det vil si at de er knyttet til ditt 11-sifrede personnummer. Men personnummeret skal kun benyttes dersom det er helt nødvendig, og bare noen få personer vil ha tilgang til denne opprinnelige datafilen. Alle innsamlede data vil bli behandlet uten navn og fødselsnummer, eller andre direkte

gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Professor Ulrik Wisløff er ansvarlig for datamaterialet i denne perioden.

Frivillig deltakelse
Det er frivillig å delta i prosjektet. Du kan når som helst, og uten å oppgi noen grunn, trekke tilbake ditt samtykke og trekke deg fra prosjektet. Ved oppmøte på undersøkelse 1, skal alle deltakerne igjen gi skriftlig samtykke til at de ønsker å delta i prosjektet.

Tidsskjema
Prosjektet ble startet opp høsten 2012 med planlagt avslutning i 2015. Deltakerne samtykker i at de kan bli spurt om å delta i underprosjekter i løpet av prosjektperioden. Det er helt frivillig om man ønsker å være med på disse eller ikke, og det vil ikke få noen konsekvenser for deltakelse i hovedprosjektet om man ikke ønsker å være med på disse.

Deltakerne kan bli kontaktet igjen 5 år og 10 år etter prosjektslutt (altså i 2020 og 2025) med forespørsel om å gjøre basisundersøkelsene igjen. Det er helt frivillig om man ønsker å delta på disse oppfølgingsundersøkelsene.

Kobling til registre
Vi har i spørreundersøkelsene prøvd å utelate spørsmål om forhold som det allerede finnes opplysninger om i registre. Vi ønsker å koble data fra prosjektet til følgende registre: Dødsårsaksregisteret, PAS St.Olav (Pasient Administrativ System), Skaderegisteret, Kreftregisteret, Folkeregisteret, Gerica (bruk av kommunale pleie og omsorgstilbud), Reseptregisteret, Norsk pasientregister (NPR) og Statistisk sentralbyrå (SSB). Folkeregisteret er brukt som innkallingsgrunnlag til prosjektet. Vi ønsker å koble våre innsamlede data til de ulike registrene fram til 2035.

Dersom du samtykker til å delta i prosjektet, samtykker du samtidig til at medisinsk ansvarlig i «Generasjon 100» får tilgang til din journal.

Biobank
Prosjektet vil opprette en egen biobank for oppbevaring av blodprøvene. Denne vil være plassert ved HUNT, Levanger. Ulrik Wisløff vil være ansvarlig for biobanken. Deltakerne som underskriver samtykkeerklæringen gir også sitt samtykke til at det biologiske materialet som samles inn inngår i denne biobanken. Vi ønsker å oppbevare blod som senere eventuelt kan bli brukt til DNA-isolering. Disse prøvene vil bli brukt til å søke etter polymorfismer knyttet til livsstils-sykdommer og molekylære tilpasninger til trening. Det skal ikke gjøres genetiske undersøkelser som får diagnostiske eller behandlingsmessige konsekvenser for den enkelte deltaker, og informasjon vil derfor ikke bli tilbakeført til den enkelte deltaker. Opplysningene i biobanken er avidentifisert, og bare et fåtall autoriserte personer (4 stk) vil ha tilgang til koblingsnøkkelen som kobler sammen løpenummer og personidentitet. Etter 2025 vil vi søke REK om å flytte det resterende biologiske materialet til HUNT biobank i Levanger.

Vitenskapelig betydning
Prosjektet vil være unikt på flere måter. Det vil gi de største tverrsnittsdata, spesielt på kondisjon, kardiovaskulær helse og funksjonsnivå, på eldre i Norge. Det vil også være den største og lengste randomiserte studien som ser på effekten av trening på sykelighet og dødelighet. Med tanke på eldrebølgen som kommer, vil våre data forhåpentligvis bidra til bedre forståelse og gi eksempler på mulige løsninger for bedre helse til eldre.

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

Finansiering
Prosjektet vil i hovedsak være finansiert av K.G. Jebsen - Senter for hjertetrening. I tillegg er disse viktige bidragsytere: Helse Midt-Norge, Norges forskningsråd, Nasjonalforeningen for folkehelsa og NTNU.

Forsikring
Alle deltakerne er forsikret i henhold til Norsk Pasientskadeerstatning.

Informasjon til deltakerne
Dersom noen av dine prøveresultater er unormale vil du bli informert om dette. På undersøkelsesdagen vil du så langt mulig få muntlig informasjon om de testresultater som er tilgjengelige. Medisinsk ansvarlig for prosjektet er Asbjørn Støylen, MD, PhD ved NTNU.

Det vil være mye og oppdatert informasjon om prosjektet på forskningsgruppens internettside: www.ntnu.no/cerg/generasjon100

Ta kontakt dersom du har spørsmål om prosjektet:

Email: generasjon100@medisin.ntnu.no
Bookingtlf.: (+47) 72827343
Kontor: (+47) 72825070

Oppmøtested til undersøkelse 1:
St. Olavs hospital
Prinsesse Kristinas gate 3
Akutten-hjerte-lungesenteret (AHL-senteret)
1. etg, midtfløyen: Lunge poliklinikk

Appendix B – Application to the Regional Ethical Committee

Protokoll:

Motorisk og kognitiv funksjon som følge av kondisjonstrening- Delstudier av Generasjon 100 studien

Prosjektledelse Generasjon 100

Ulrik Wisløff, Professor ved Institutt for sirkulasjon og bildediagnostikk (ISB), NTNU

Dorthe Stensvold, PhD, post-doc, ISB, NTNU

Prosjektleder delstudiene på motorisk og kognitiv funksjon

Jorunn L Helbostad, Professor Institutt for nevromedisin, DMF, NTNU

Beatrix Vereijken, Professor Institutt for nevromedisin, DMF, NTNU

Sammendrag

Generasjon 100 er en populasjonsbasert klinisk kontrollert studie med personer mellom 70 og 76 år som tester effekten av høyintensiv og moderat intensiv trening på sykelighet, dødelighet og funksjon. Treningen foregår over 5 år. 1567 personer ble inkludert i studien. Testing foregår på baseline, etter 1 år, 3 og ved avsluttet trening etter 5 år. 3 års-undersøkelsene foregår høst 2015-vår 2016. Denne protokollen beskriver delstudier basert på data fra baseline og 3 års-undersøkelsen for motorisk funksjon og kognisjon. Studiene har som mål å undersøke effekt av trening på motorisk funksjon og assosiasjoner mellom motorisk og kognitiv funksjon. Delstudiene gjennomføres som masteroppgaver for studenter i Bevegelsesvitenskap og Exercise Physiology.

Bakgrunn

Andelen eldre øker i Norge og hele den vestlige verden. Tall fra Helsedepartementet viser at fra år 2010 til 2040 vil det bli en dobling i antall eldre over 67 år. Levealderen øker, og mange de ekstra årene tas i dag ut med funksjonssvikt. Det er behov for tiltak som opprettholder funksjon i alderdommen og som gjør eldre i stand til å leve et aktivt og selvstendig liv lenger ut i alderdommen.

Trening er vist å ha svært mange positive effekter på helse og funksjon. Kondisjonstrening og intervalltrening i særdeleshet, har vist god effekt på kondisjon både for unge og eldre, og er også vist å redusere hjerte og kar-sykdom og tidig død (Blair, 1989; Paffenbarger, 1986; Lee, 2001; Lee, 2004; Wisløff, 2006, Swain, 2006; Tjønna, 2008). Det er imidlertid ikke utført populasjonsbaserte studier på eldre på dette feltet. Hvis slik trening skal ha effekt på selvstendighet i alderdommen, må treningen også bidra til å opprettholde funksjon i dagliglivet. Det finnes få studier som undersøker effekten av kardiovaskulær trening på for eksempel muskelstyrke, muskelmasse, mobilitet og balanse, og gangfunksjon over tid. Dette er viktige funksjoner for å opprettholde hverdagsaktivitet og funksjon og for å forebygge fall og fallskader hos eldre (Sherrington 2011).

Generasjon 100 er en populasjonsbasert studie med hjemmeboende eldre mellom 70 og 76 år som undersøker effekten av høyintensiv og moderat intensiv kondisjonstrening mot en kontrollgruppe som blir bedt om å følge nasjonale anbefalinger om fysisk aktivitet (Stensvold 2014). Denne protokollen beskriver delstudier som har til hensikt å

1) Undersøke effekt av høyintensiv og moderat intensiv trening på blodlipider, muskelstyrke, muskelmasse, daglig fysisk aktivitet, mobilitet og balanse, gangfunksjon og kognitiv funksjon.
2) Undersøke assosiasjoner mellom ulike aspekter av fysisk og kognitiv funksjon.

Data som benyttes er baselinedata og data fra 3-årsundersøkelsen som gjennomføres underveis i den 5 år lange intervensjonsperioden.

Metode og materiale

Utvalg

Personer hjemmeboende i Trondheim født mellom 1936 og 1942 ble invitert til å delta i Generasjon 100. Inklusjonskriterier er å være i stand til å gå en kilometer sammenhengende og ha god nok helse vurdert av prosjektmedarbeidere til å delta i studien. Eksklusjonskriterier er ukontrollert hypertensjon, ustabil hjertesykdom, diagnostisert demens, kreftsykdom hvor trening er kontraindisert, og smittsomme sykdommer.

Målgruppe for delstudiene er personer som er inkludert i Generasjon 100 og som fortsatt er med i studien 3 år etter inklusjon.

<u>Prosedyrer</u>

Inklusjon og baselineundersøkelser ble gjennomført i 2012-2013, og inkluderte fastende blodprøver, testing av VO2 max, gangtester, styrketester og registering av fysisk aktivitet vha aktivitetsmålere over en uke. I tillegg ble det gjennomført en survey for innhenting av bakgrunnsvariabler, hovedsakelig med spørsmål fra HUNT studiene. Treårsundersøkelense foregår høst 2015 og vår 2016, og inkluderer samme testbatteri som på baseline. I tillegg ble også kognitiv funksjon og mobilitet testet. Det er tidligere sendt inn endringsprotokoll på disse endringene til REK.

<u>Resultatmål</u>

De fleste resultatmål er beskrevet i detaljer i protokollartikkelen fra Generasjon 100 (Stensvold 2015). Dette gjelder ikke testing av kognitivt funksjon og mobilitet. Disse er derfor beskrevet med referanser i teksten under.

<u>Muskelstyrke</u> ble testet på ulike måter: 1) Isometrisk benstyrke ble testet sittende i en testrigg med 120 grader fleksjon i knærne, og hvor hvert ben ble testet med tre repeterte forsøk. Kraftceller måler resultat for hvert av benene separat. Data behandles så videre i Matlab for å finne tiden det tar å utvikle maksimal kraft (rate of force development) og maksimal styrke (kg). 2) Isometrisk håndgrepsstyrke ble testet med JAMAR dynamometer (kg). Deltakeren gjennomførte tre forsøk med dominant hånd. 3) Funksjonell benstyrke ble testet gjennom hurtig oppreising fra sittende til stående. En snelle på golvet festet til belte rundt livet på forsøkspersoner registrerer tid og hastighet under oppreising fra stol, og maks hastighet og gjennomsnittlig hastighet for hvert av 5 forsøk beregnes.

<u>Muskelmasse</u> ble undersøkt ved hjelp av bioimpedansmålinger (som måler kroppssammensetning), og uttrykt som muskelmasse og fettmasse målt i kilo og prosent av total kroppsmasse.

<u>Gangfunksjon</u> ble undersøkt ved hjelp av en elektronisk gangmatte og en sensor plassert bak på korsryggen. Den elektroniske gangmatten (GaitRite) måler fotavtrykk mot matten i tid og rom. Ganghastighet, gjennomsnitt og variabilitet av steglengde, stegbredde, stegtid, og tid in enkel og dobbel standfase ble beregnet vha tilhørende software. Sensoren på ryggen (Opal) måler akselerasjon og vinkelhastighet og benyttes for å måle balansekontroll under gange. Data fra sensoren blir trådløst

overført til PC og lest i software tilhørende sensorsystemet. Resultatvariabler er balansekontroll målt som root mean square av amplitude av akselerasjon eller som autokorrelasjon mellom akselerasjons-mønsteret mellom nabosteg og blir analysert i MatLab og Excel.

Fysisk aktivitet ble undersøkt med et treakset akselerometer (ActiGraph, GT3X) festet på hofta over en periode på 7 dager. Resultatvariabler inkluderer intensitet i aktivitet målt som tellinger (counts), tid i gående, og antall skritt og blir beregnet vha tilhørende software.

Mobilitet ble undersøkt med Short Physical Performance Battery på 3 års undersøkelsen. Dette er en klinisk test som undersøker 3 ferdigheter; 1) stående balanse, 2) oppreising fra stol, og 3) ganghastighet over 4 meter. Hver deltest skåres i sekunder, og skårene gjøres så om til en 0-4 skala, som total gir 12 mulige poeng på hele testen (Guralnik 1994).

Kognitiv funksjon ble testet med Montreal Cognitive Assessment (MoCA) på 3 års undersøkelsen. Dette er et screeninginstrument for lettere kognitive forstyrrelser som kartlegger oppmerksomhet og konsentrasjon, eksekutive funksjoner, hukommelse, språk, visuokonstruktive ferdigheter, abstrakt tenkning, regneferdigheter og orientering. Testen tar 10 minutter å gjennomføres og skåres på en skala fra 0-30 (Malek-Ahmadi 2015).

Blodprøver ble utført fastende på venøst blod fra armen. Serum triclycerider, glukose og lipoproteiner ble analysert ved hjelp av standard prosedyrer på St. Olavs hospital, hvor serum og EDTA behandlet plasma ble sentrifugert på 3000 rpm i 10 minutter og på 20 grader.

Dataanalyse

Data blir analysert i Excel og i SPPS for Windows. Undersøkelse av forskjell i effekt mellom og innen grupper fra baseline til 3 år gjøres ved hjelp av ANOVA, parete t-tester eller linear mixed model analyser. Bivariate assosiasjoner gjennomføres vha Pearson's korrelasjonskoeffisient for kontinuerlige data og Spearman for ordinale data. I tillegg vil multippel regresjon benyttes for å kontrollere for bakenforliggende faktorer som kan påvirke utkommet.

Etikk

Generasjon 100 er tidligere vurdert av REK. Hver ny delstudie skal søkes inn til REK separat. De delstudiene det her søkes om innebærer ingen ny datainnsamling ut over det som er standard tester i Generasjon 100. Studenter som deltar i studiene har allerede skrevet under en generell taushetserklæring. Data vil analyseres og rapporteres ut fra tidligere beskrevne prosedyrer som innebærer anonymitet av deltakere.

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Appendix C – Regional Ethical Committee Approval

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Marit Hovdal Moan	73597504	24.01.2016	2015/2300/REK midt
			Deres dato:	Deres referanse:
			08.12.2015	

Vår referanse må oppgis ved alle henvendelser

Jorunn Lægdheim Helbostad
NTNU

2015/2300 Motorisk og kognitiv funksjon som følge av kondisjonstrening

Forskningsansvarlig: NTNU
Prosjektleder: Jorunn Lægdheim Helbostad

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK midt) i møtet 08.01.2016. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Generasjon 100 er en populasjonsbasert klinisk kontrollert studie med personer mellom 70 og 76 år som tester effekten av høyintensiv og moderat intensiv trening på sykelighet, dødelighet og funksjon. Treningen foregår over 5 år. 1567 personer ble inkludert i studien. Testing foregår på baseline, etter 1 år, 3 og ved avsluttet trening etter 5 år. 3 års-undersøkelsene foregår høst 2015-vår 2016. Denne protokollen beskriver delstudier basert på data fra baseline og 3 års-undersøkelsen for motorisk funksjon og kognisjon. Studiene har som mål å undersøke effekt av trening på motorisk funksjon og assosiasjoner mellom motorisk og kognitiv funksjon.

Vurdering
Komiteens prosjektsammendrag
Formål med studien: Studien er en delstudie under den populasjonsbaserte studien «Generasjon100», der testing blir foretatt på baseline, etter 1år, 3 år og 5 år. Den aktuelle delstudien er en 3 års-undersøkelse, og har til hensikt å undersøke effekt av trening på motorisk funksjon og assosiasjoner mellom motorisk og kognitiv funksjon. Datakilder: Data er allerede samlet inn eller er under innsamling. I det aktuelle prosjektet hentes ut allerede analyserte verdier på triclycerider, glukose og lipoproteiner. Denne delstudien har ingen befatning med analyse av blod data. Utvalg: relativt friske, hjemmeboende eldre mellom 70 og 76 år som tester effekten av høyintensiv og moderat intensiv trening på sykelighet, dødelighet og funksjon over 5 år. Studien er samtykkebasert. Det er ingen fysisk risiko eller risiko med hensyn til personvern eller personlig integritet for deltakerne forbundet med prosjektet. Studien inngår som en del av en mastergrad.

Forsvarlighet
Komiteen har vurdert søknad, forskningsprotokoll, målsetting og plan for gjennomføring. Under forutsetning av at vilkårene nedenfor tas til følge, framstår prosjektet som forsvarlig og hensynet til deltakernes velferd og integritet er ivaretatt.

Vilkår for godkjenning

1. Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i

Besøksadresse:
Det medisinske fakultet
Medisinsk teknisk
forskningssenter 7489
Trondheim

Telefon: 73597511
E-post: rek-midt@medisin.ntnu.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK midt og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK midt, not to individual staff søknaden og protokollen. Prosjektet må også gjennomføres i henhold til REKs vilkår i saken og de bestemmelser som følger av helseforskningsloven (hfl.) med forskrifter.

2. Komiteen forutsetter at ingen personidentifiserbare opplysninger kan framkomme ved publisering eller annen offentliggjøring.
3. Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Av kontrollhensyn skal prosjektdata oppbevares i fem år etter sluttmelding er sendt REK. Data skal derfor oppbevares til denne datoen, for deretter å slettes eller anonymiseres, jf. hfl. § 38.
4. Prosjektleder skal sende sluttmelding til REK midt når forskningsprosjektet avsluttes. I sluttmeldingen skal resultatene presenteres på en objektiv og etterrettelig måte, som sikrer at både positive og negative funn fremgår, jf. hfl. § 12.

Vedtak
Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge godkjenner prosjektet med de vilkår som er gitt.

Komiteen var enstemmig i sin beslutning.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK midt på eget skjema senest 31.12.2019, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK midt dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

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

Med vennlig hilsen

Sven Erik Gisvold
Dr.med.
Leder, REK midt

Marit Hovdal Moan
Seniorrådgiver

Kopi til: rek-inm@medisin.ntnu.no