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"The effect of endurance training on gait fall risk variables among community-dwelling older adults"

Master Thesis in Clinical Health Science
Applied Clinical Research

Trondheim, May 2018

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Abstract

Background: Gait is an essential part of human mobility and an important feature of quality of life. One third of people above 65 years fall each year and most falls among older adults happen during walking. Some gait characteristics are associated with a higher risk of falling and have even been able to distinguish a faller from a non-faller. Studies have shown that exercise focusing on balance and muscle strength can improve gait and reduce the risk of falls among older adults with an already established risk of falling.

Purpose: The aim of this study is to investigate if regular cardiovascular exercise can prevent a deterioration of gait characteristics associated with an increased risk of falls among healthy community dwelling older adults compared to controls.

Material and method: 1567 community dwelling older adults (72.5 ± 2.1 years) were randomized to either a control group (CON) or a high intensity training (HIT) or moderate intensity training (MIT) group. The participants where tested with a computerized walkway at baseline (GAITRite) and after three years intervention (Zeno).

Results: Overall there was a deterioration in most gait characteristics, but HIT had significant better scores for gait speed, step length and stance time for both fast and preferred condition when compared to CON, and in preferred condition when compared to MIT.

Conclusion: It seems as high intensity training can prevent a deterioration of certain mean gait characteristics related to fall risk among community dwelling older adults, while endurance exercise had no effect on gait variability measures. This study has confirmed that training has to be more specific to maintain most gait variables and therefore reduce the risk of falls.

Relevance

Falls are a major expense within health care, and those who fall experience injuries, loss of mobility, fear and reduced quality of life. An increased knowledge about how to prevent falls among healthy older adults is important. If we could prevent or delay the first fall this will reduce the burden on the health care services and maintain quality of life among older adults.

Acknowledgements

First of all I would like to express my great appreciation and thanks to my supervisor Jorunn Helbostad. You have given me valuable support, encouragement and guidance through the work with my master's thesis. Thank you for letting me into the warmth of the research group GeMS. Thank you for sharing your time and knowledge so generously. And thank you for showing me understanding when needed. You insipre me to do more research.

Next I would like to thank all the participants who participated in Generation 100. Without you this thesis would not excist. And NeXt Move for the use of the core facilities in testing the participants.

Further I would like to thank Xiangchun Tan for invaluable help with Matlab and reorganising the data. I am sure you have saved me weeks of troublesome work! For help with the statistics I would like to thank Turid Follestad. You are a great teacher who are able to make the numbers understandable. I would like to thank Per Bendik Wik for help in the lab and many bad jokes to lift the mood throughout the process. A great thanks go out to all of my coworkers in GeMS who have been there for big and small questions and for company during lunch.

At last a big thanks to my family and my dear soon to be husband for all your support! This would not have been possible without you takeing care of the children and letting me sleep through the morning after a difficult night. I would also like to thank my two little girls Ylva and Thyra for dragging me out to play and making me remember that flies and trampolines also are very important and interesting things in this world.

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1.0 Background

The demographics in Norway, along with the rest of the world, demonstrates an increase of the proportion of elderly residents [1, 2]. A number of challenges may rise with this development, such as a decreased number of active working persons per older person (<67 years) and an increased need for health care services.

Falls account for the largest proportion of both fatal and non-fatal injuries among older adults above 65 years [3]. One third of people above 65 years fall each year [4] and by the time they reach 70 this number has increased to almost one half [5]. Almost 70% of falls among the elderly result in injuries, where 9% are major injuries like fractures [4, 5]. In addition to injuries falls can lead to important consequences such as decline of the motility, loss of confidence, limitation in daily life activities, decrease of functional capacities and an increased risk of being sent to a nursing home [6, 7]. Average costs for treatment, care and rehabilitation the first year after a hip fracture for home dwelling older people above 70 years in Norway are about 60.000 Euro [8] and in 2000 in the US the costs of fatal and non-fatal falls among older adults above 65 years was almost 20 billion dollars [9]. This together with an increasing proportion of older people in the society [10] leads to substantial economic costs in health care, and to be able to decrease the incidence of falls is therefore important.

Most falls happen during walking [11, 12]. Gait performance, especially gait speed is an indicator of general health status [13] and a strong predictor of risk for falls [14] and institutionalization [15] among older adults. Older persons with gait speed slower than 1 m/s should be considered at high risk of adverse health outcomes [15] and measuring gait characteristics can provide an earlier detection of individuals at higher risk of major health-related events like falls. An early identification and appropriate intervention may prevent dysfunction, falls and loss of independence.

Several studies show that exercise can improve gait and reduce the risk of falls [16-19]. The Norwegian directorate of health recommend that older persons should do at least 150 minutes of physical activity with moderate intensity or 75 minutes with high intensity per week. Older adults with reduced mobility and/or unsteadiness is recommended to do additional balance and strength exercise at least three times a week [20]. Older populations are generally less active than young adults and the activities that are most popular among older adults are consistently of lower intensity (walking, gardening) compared to younger adults [21]. Exercise is an inexpensive, accessible and available treatment with few negative side effects.

Most studies have investigated persons with an already established risk of falling [16, 22]. Few studies have looked at relatively healthy older persons that may not yet have experienced a fall. To prevent the first incidence of a fall it is important to also put the focus on groups of people that are more able-bodied. Among this group we do not have knowledge of what is most effective to prevent falls, and it might be that more general interventions than for those who already have impaired balance and strength are needed.

The aim of this study is to investigate if regular cardiovascular exercise can prevent a deterioration of gait characteristics associated with an increased risk of falls compared to controls.

2.0 Introduction

2.1 Gait

Gait is an essential part of human mobility and an important feature of quality of life. On the question “What makes your life good” elderly people over 65 years answered having and retaining independence, having the mobility to be able to do what you want and to go out without depending on others [23].

To obtain normal gait several systems and functions are required to be intact, such as locomotor function, balance, postural reflexes, sensory function, sensorimotor integration, motor control, the musculoskeletal apparatus and cardiopulmonary functions [24]. Ageing is associated with a decline in gait speed and step length, and a greater stride width and stance time, whereas cadence remains relatively stable [25]. In addition, an increase in energy consumption while walking is seen with ageing. Older adults require more attention for motor control when moving around [25]. Gait, especially gait speed, can be a predictor of mobility disability, cognitive decline, future falls, institutionalization and death [15, 26, 27]. The prevalence of abnormal gait or gait disorders among community dwelling older adults is over 30% and the incidence increases with advancing age [14, 28].

Early identification of gait impairments and appropriate intervention may possibly prevent decline in gait function, prevention of falls and loss of independence. In daily life you usually do other things while walking, you carry the dishes, talk with someone, your avoid obstacles or keep track of traffic amongst other things. This makes most gait dual tasking. Unstable gait can be partly compensated be cognitive strategies, this may result in cognitive resources being allocated to walking and are no longer available for other activities while walking [29-31]. A consequence of this is that older adults often have larger problems than younger ones to walk and concurrently engage in other activities, dual tasking [29, 31]. Walking in a dual-task condition could provide important information as it can be more sensitive to reveal underlying gait disorders than single-task condition [32].

2.1.1 Association between gait speed and other gait variables

It is shown that several gait characteristics relate to gait speed. One study showed that both cadence and step length are associated with gait speed [33]. While anothers have shown an association between gait speed and mediolateral trunk acceleration and step width [34].

Helbostad and Moe-Nilssen [34] suggests that controlling speed-dependent gait variables for the effect of gait speed may increase the sensitivity of gait analysis.

2.2 Gait characteristics and falls

In most studies a faller is identified as elderly people who have experienced at least one fall during the previous 12 months. There are several risk factors for falls among older persons. Common intrinsic risk factors such are high age, being female, some diseases and impairments of gait, balance, vision, and cognition. Extrinsic risk factors include medications, environment and footwear [6, 35]. Falls are associated with a decrease in functioning [4] and problems with gait and balance are among the strongest risk factors for falls [35]. When you add that most falls happen during walking [11] gait seems to be a good place to start to prevent falls.

Some gait variables have shown to be associated with a higher risk of falling and even been able to distinguish a faller from a non-faller. The research is not consistent, but a recent review concludes that spatial and temporal variables that are most able to predict who is going to fall are gait speed, step length and stance time [36]. Gait variability, stride-to-stride fluctuations, has also shown to be useful in predicting who is going to fall [35, 37, 38]. One study shows that poorer performance on clinical gait assessment appeared to be associated with fear of falling, but not with falling [39]. Gait variability on the other hand could predict future falls in the same study and one could think that variability measures add valuable information about gait and falls.

It has been shown that changes in gait performance whilst dual tasking are associated with an increased risk for falling amongst older adults [40, 41] and that changes in step width and step length during walking while counting backwards appear to be related to the risk of falling [42]. As dual tasking might reveal gait deficits that are otherwise compensated by cognitive strategies, this gait condition could reveal more than just single task.

Gait variability, the stride-to-stride fluctuations in walking, is a quantifiable feature of walking that is altered in for example falling and frailty. Older adults adopt a more conservative basic gait pattern with reduced gait speed but with increased variability compared to younger adults [43, 44]. Increased stride-to-stride variability in stride length, gait speed, double support and stride width are shown to be associated with falling and is reported with increasing age [39].

Recent research suggests that gait variability may provide a more discriminative measure of gait performance than routine spatial and temporal measures such as average gait speed or step time. In order to evaluate variability a minimum of three consecutive gait cycles for both left and right sides, a total of six gait cycles, are recommended [45]. Lower values of standard deviation (SD) reflect a more consistent gait. Low SD indicates that gait is consistent for parameters associated with rhythmicity and progression, such as step time and step length, while high SD is more likely to indicate a consistent gait for parameters that reflect postural control such as step width [46]. Excessive or reduced step width variability reflects an inability to adapt postural control and as such are harbingers of falls [47].

2.4 Measurements of gait and balance

There is no consensus on the ideal testing procedure for gait assessment. Both test protocols and equipment used in measuring gait vary widely. The distances walked during testing wary from 3 to 100 meters, and often the gait protocols chosen based on available space and convenience. One study has found that the 4-meterwalk test and the 10-meter walk test both have excellent reliability, but that they cannot be used interchangeably [48]. Another study found that participants walked faster when starting with a walking start compared to a standing start (with and without an acceleration and deceleration zone), and that the participants walked slower on a computerized walkway than on the ground [49]. These findings show that making comparisons across studies can be difficult.

Gait characteristics like step length, stride width and stance time are difficult to measure without an electronic walkway. Bridenbaugh implies that changes in gait parameters are often very small and could not be identified without a device such as an electronic walkway mat [30]. When you take into consideration that a meaningful change is 0.1 m/s for gait speed [50], 0.01 s for stance time variability and 0.25 cm for step length variability [51], the importance of using an electronic walkway becomes apparent. Kressig and Beauchet have made guidelines for clinical application of spatio-temporal gait analysis using electronic gait mats in older adults to enhance reproducibility of gait measures and for better comparability of outcomes [45].

2.5 Effects of exercise

Although physical activity cannot stop the biological aging process, there is evidence that regular exercise can minimize the physiological, psychological and cognitive effects of an otherwise sedentary lifestyle [21, 52]. Physical activity significantly reduces risk for chronic diseases associated with advancing age, preserves functional capacity, and improves bone health, muscular power, muscle quality and flexibility [21]. It has been shown that physical activity is beneficial for both previously active and previously inactive older adults [21]. According to the American College of Sports Medicine some physical activity is better than none, but for most health outcomes additional benefits occur as the amount of physical activity increases through higher intensity, greater frequency and/or longer duration [21].

There have been done several studies on the effect of exercise on the risk of falls and gait. The results show that exercise focusing on muscle strength and balance can reduce the both risk of falls and improve gait [16-19]. A meta-analysis concludes that therapeutic exercise in general improves habitual gait speed, but not fast gait speed in community-dwelling older people [19]. Most studies look at only the gait speed variable, but some studies have shown that exercise can improve step length, stride length, step width, stride time and double support time [53-56]. Some studies also show that exercise can improve gait variables in dual task condition, dual task costs and gait variability [54, 55, 57]. In most studies that have been done this far the exercise interventions consist of multiple components such as strength, endurance and balance training, but there are some studies that have looked at endurance exercise alone. Brown and Holloszy [53] showed that 12 months of moderate intensity endurance exercise consisting of walking and jogging improved step length, stride length, gait speed and step width for 60-72 year olds, and Brach et al [58] showed that 12 weeks of endurance training on a treadmill improved distance walked during 6min walk test. Buchner et al [22] showed that endurance training on a stationary bicycle had no effect on gait performance. One would think that to improve gait substantially the exercise should be more specific and involve activities in standing position and preferable walking or running. One study implies this by showing that walking as exercise gave more sustained improvement on balance and gait than cycling and aerobic movement, and that walking may be more useful for fall prevention than cycling and aerobic movement [59]. Further analysis of the habitual gait speed data in the meta-analysis revealed that only high intensity and high dosage exercise training produced significant effects [19]. This implies that high intensity exercise might prove better than moderate intensity exercise in improving gait characteristics.

2.5 Aim

The aim of this study is to investigate if regular cardiovascular exercise can prevent a deterioration of gait characteristics associated with an increased risk of falls compared to controls. It will also be investigated if the intensity of the exercise have any effect.

The gait variables that will be investigated are gait speed, stride length, step width and stance time in three different walking conditions; preferred walk, fast walk and dual-task. These have been chosen because they have been shown to be related to the risk of falling. Both the mean scores and variability for each variable will be investigated. It is hypothesized that both moderate and high intensity exercise will prevent a deterioration of gait speed, but not necessary the gait control variables because this might require more specific training that challenges balance more.

Mean gait values that is considered an improvement are longer stride length, faster gait speed, narrower step width and shortened stance time [39]. For the variability measures greater values of gait speed, stance time and step length, and lower values of step width are believed to be better [51].

2.0 Method

2.1 Study design

This study is a part of the larger Generation 100 (Gen100) study which is a randomized controlled trial with a primary aim to determine the effects of regular cardiovascular exercise training over a 5-year period on overall mortality in elderly people. The inclusion was from August 2012 to June 2013. The participants have been tested at baseline, after one year and three years, and they are in the progress of the 5-year testing. In the current study only data from baseline and the three-year follow-up will be used.

The participants were randomized 1:1, stratified by sex, into two groups: an exercise group and a control group. The exercise group was then randomized 1:1 to either a high intensity or a moderate intensity exercise group. Couples living together were randomized into the same group. The Unit for Applied Clinical Research at NTNU developed a web based randomization procedure to ensure impartial assignments.

2.2 Participants

All men and women born between January 1, 1936 and December 31, 1942 with a permanent address in Trondheim municipality were invited to participate. Invitations were sent via the postal services to all persons in the appropriate age group. See appendix for the information letter and consent (in Norwegian). The inclusion criteria were to be able to walk at least 1 km continuously, and be in good enough health, assessed by the researchers at Gen100. The exclusion criteria was disease or disabilities that limits the ability to exercise or to participate in the study, uncontrolled hypertension, symptomatic cardiac valve defects, hypertrophic cardiomyopathy, unstable angina, pulmonary hypertension, heart failure, severe cardiac arrhythmias, diagnosed dementia, cancer that makes participation impossible or where exercise is contraindicated, test results that indicates that further participation is not safe, persons with chronic infectious diseases and participation in other studies that was not compatible with this study.

2.3 Procedure

All testing, both baseline and follow-up, happened at laboratories at St. Olavs University Hospital in Trondheim. All personnel were trained to perform the testing. The participants started with blood samples, blood pressure and weighing amongst other things before they did the gait, balance and strength testing. After this they did the cognitive test Mocca (only at follow-up) and VO_2 max tests followed by another blood sample. They finished with a meeting with a tester where they got a summary of what they had done, information about the project, and at baseline they were randomized.

2.3.1 Gait

Gait was measured using an electronic walkway (Figure 1) following the guidelines made by Kressig and Beauchet [45]. At baseline the GAITRite walkway and software was used during data collection, at follow-up the Zeno walkway and PKMAS software was used. The gait mats have identical hardware and the validity and reliability is well established [51, 60-62]. A study by Egerton, Thingstad and Helbostad concluded that the outcome measures from both GAITRite and PKMAS can be used interchangeably for most of the spatial temporal variables [63]. The variables that stand out are step width and step length variability with intraclass correlations of 0.86 and 0.84. It is also indicated that there is a systematic difference in the step width values where GAITRite values are approximately 1.6 cm, or about 17%, lower than PKMAS values, which is due to different ways of calculating this variable between the softwares.

The walkway was 6.46 meters long in total with an active area of 5.49 meters. The total gait length was 8.7 meters, with an acceleration- and reacceleration zone of 1.16 meters at both ends of the mat to exclude the effects of gait initiation and deceleration on the measurements. Participants wore their own shoes and were encouraged to wear comfortable shoes without heels. The participants were asked to walk back and forth the walkway four times, ending in eight walking trials (no warming up trials). For the first two walks they were instructed to walk at preferred walking speed, what felt natural for them. Then were they asked to walk slowly, as if they were strolling around. Next, they walked as fast as they could without running. For the two last walks they were instructed to walk at preferred speed while they were counting backwards, first from 80, then from 100, subtracting three and three (80, 77 and so on, 100, 97 and so on).

Figure 1: The Zeno walkway set up in the test facility. The participants were instructed to walk in the broad field to the right and not cross the red line.

2.3.2 Intervention

High intensity group (HIT)

The participants were asked to exercise at high intensity for about 40 minutes twice a week. In the course of one month after baseline the subjects were invited to a meeting were they got information about the principle of the exercise and how they were going to give feedback to the project staff about their exercise. The 4x4 interval training model was introduced, were each exercise session should start with 10 minutes warm-up followed by four intervals with high intensity workouts lasting for four minutes, with a three minutes active break between each interval. The intensity of the intervals should be 85-95% of the participants' maximal heart rate. They were instructed to use a Borg 6-20 scale of perceived exertion, where 85-95% of maximal heart rate is equivalent to 16 on Borg's scale [64]. This makes the intensity of the intervals 16 and the active pauses around 12 on Borg's scale. Three times a week there was arranged supervised exercise sessions on different locations, both indoors and outdoors, several places around Trondheim. The participants were offered different types of exercise, which varied from week to week, like walking, running, spinning, dancing and aerobics. These sessions were voluntary, and the participants were free to exercise individually instead of, or in addition to group sessions. To ensure that the participants exercised at the recommended intensity, they met every sixth week for a supervised spinning session where they exercised with a heart rate monitor.

Moderate intensity group (MIT)

In this group the participants were asked to complete 50 minutes of continuous exercise at moderate intensity, equivalent to 13 on Borg's scale. This is experienced as a talking pace. A meeting with information about the training principles, how they were going to give feedback about their exercise and information about the exercise sessions that were offered was arranged in the same manner as for the high intensity group.

Control group (CON)

In this group the participants were asked to follow the current recommendations for physical activity in Norway which at the time was 30 minutes of moderate physical activity every day [65]. No further supervision was given.

2.3.3 Adherence

The participants in the exercise groups were asked to fill in exercise logs immediately after each exercise session with information of the intensity and duration, and type of exercise. The logs could be sent monthly in prepaid envelopes or by using the internet-based forms (LimeSurvey: Training logs Generation 100. https://survey.medisin.ntnu.no/limesurvey/index.php?sid=54583)

2.4 Outcome measures

2.4.1 Variables

The outcome variables of interest in this study are gait speed (cm/sec), step length (cm), stance time (sec) and step with (cm). The variables will be studied at three different walking conditions; preferred walk, fast walk and dual-task. Slow walking was not included as it can be difficult to interpret whether people walked as slow as possible or a little slower than usual. To include as high number of steps as possible for each walking condition, the mean of each gait variable of two walks (back and forth the mat) at each walking condition will be used in the analysis [45]. Variability calculated as standard deviation (SD) between consecutive steps for each walk of the selected gait variables. The standard deviation from left and right steps was calculated separately. They were then combined by taking the square root of the mean variance of the left and right steps. By using this method variation originating from asymmetry between left and right will not be calculated as a part of the step-to-step variability [66]. The mean variability of two walks were used in the analysis.

$$SD_{Left} \,\&\, SD_{Right} = \sqrt{\frac{(n_1 - 1) \times V_1 + (n_2 - 1) \times V_2}{(n_1 + n_2 - 2)}}$$

$$n_1 = number\ of\ left\ steps, n_2 = number\ of\ right\ steps$$

$$V_1 = Variance_{Left}, V_2 = Variance_{Right}$$

Table 1: List of outcome variables

Variables						Measured in
Preferred walk		Fast walk		Dual-task		
Mean	SD	Mean	SD	Mean	SD	
Gait speed	Gait speed	Gait speed	Gait speed	Gait speed	Gait speed	cm/sec
Step length	Step length	Step length	Step length	Step length	Step length	cm
Stance time	Stance time	Stance time	Stance time	Stance time	Stance time	sec
Stride width	Stride width	Stride width	Stride width	Stride width	Stride width	cm

2.4.2 Demographics and covariates

Together with the invitation to participate, everyone received a questionnaire which contained questions regarding background information, civil status, education, physical activity and general health. Everyone was asked to send an answer were they told if they wanted to participate, and those who did not want to participate could give their approval to use their data from the questionnaire. Those who participated in the study also received another questionnaire that they handed in when they came in for the first testing. This contained more in depth questions about physical activity, mobility and general health. Some of the background characteristics are presented with pooled categories: Education has been pooled into two categories where one is education up to finished high school and the other education above high school. Physical activity has been pooled into three categories where the first is less than once a week, the second is one to three times a week and the third is almost every day.

2.5 Data processing statistical analysis

2.5.1 Data processing

In order to avoid differences between softwares when calculating gait variables, the recorded and stored gait data from both the Gait rite (baseline) and Zeno (three years) walkways were opened and processed in the PKMAS software, where the footprints for the walks were presented visually on the screen. Each walk was inspected, and each footprint was marked as either left or right. Footprints that were partially outside the active measurement area were deleted (figure 2). The exception was footprints that was on the left or right line where only small parts off the lateral side of the foot was missing and the start and end was intact (figure 3).

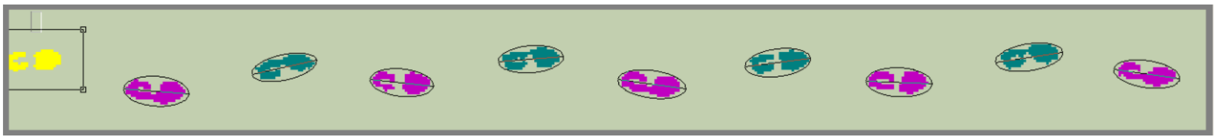

Figure 2: End footprint deleted

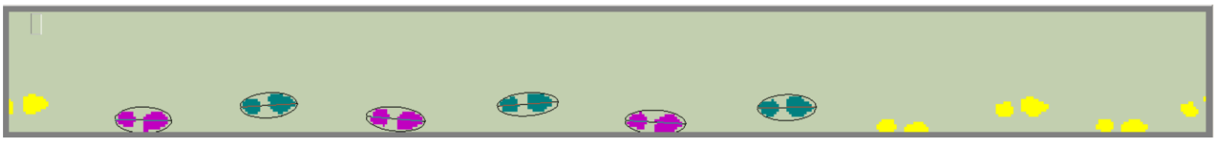

Figure 3: Right step 1 and 3 are kept, right step 4 is deleted

The PKMAS software produces text files with the exported gait data. The values for the gait variables was transferred to Excel and reorganized to make a data matrix for all subjects, gait conditions and gait variables. A custom made Matlab script was used for the reorganization of the text files to form a matrix suitable for further data analysis. For statistical analysis the data was concerted to an SPSS-format.

Before the analysis checks to identify processing errors were carried out and outliers were checked. In addition, all walks with negative step width values were checked. Most outliers were true outliers. For about half of the walks with a negative step width the left and right footprints had been switched. When processing errors were found the data was reprocessed, exported to new text files and reorganized.

2.5.2 Statistical analysis

The statistical analysis were done using IBM SPSS Statistics 24. Sample descriptive data are presented as means and standard deviations (SD). The statistical significance was set at p less than 0.05. Visual inspections of QQ-plots and Saphiro-Wilk tests were used to determine normality distribution of the variables. All mean values for the gait variables were normally distributed. The variability measurements were not normal distributed. These data were therefore log transformed and checked for normality again. The log transformed data were considered normal distributed.

To assess between-group changes and within group changes over time, Linear mixed models analysis were used. This analysis includes all available data and can be used to perform intention-to-treat (ITT) analysis [67]. An ITT analysis includes every subject who is randomized according to randomized treatment assignment regardless of withdrawal and adherence. An ITT analysis maintains the prognostic balance generated from the original random treatment allocation [68]. This means the results of our analysis answer if the intervention works for the whole sample. The opposite, a per-protocol analysis, would answer if the intervention works for only those who actually participated in the intervention. The model used was a constrained longitudinal data analysis which means that baseline means are constrained to be equal between the randomized groups. When missing data occur and mixed-effect models are used, constrained longitudinal analysis models are the optimal choice for providing the most precise estimate of treatment differenced under a reasonable assumption that missing data are related to observable characteristics [69]. According to the aim of this study the between-group comparisons were done pairwise, comparing change between two and two groups. There was an uncertainty about normal distribution of the mean vales for stance time. We therefore also performed a non-parametric Kruskall-Wallis test on these data. These results ended with the same conclusions as the Linear Mixed models, and we therefore only present the results from the Linear Mixed model analysis.

We performed all the analyses once more, where we controlled for gait speed, age and gender to see if any of the covariates had any impact on the results. These results are only presented in written form.

The results will be presented with the estimates from the linear mixed model analysis and not the calculated mean values. The reason for this is that the empirical mean does not take the missing data into consideration. The empirical mean and the estimates for the baseline values are the same because there are no missing data at baseline, but after three years there is a small difference between the estimate and the empirical mean. As log transformed data is difficult to interpret, the results from the gait variability analysis will be presented with the empirical median and interquartile range together with the estimate of change and p-values from the analysis done with the log transformed data. For presentation for the results with log transformed values, see attachment.

For the Gen100 study, overall mortality was selected as the primary outcome for the sample size calculation. With a power of 90%, about 600 participants are needed in each group to detect a 50% reduction in mortality [65]. No additional power estimation has been done for this gait study.

2.6 Ethical considerations

Participation was voluntary and all participants signed an informed consent prior to any testing. They were free to withdraw their consent and leave the study at any time. The larger study Gen100 has been approved by the Regional Committee for Medical Research Ethics in Southern Norway (REK). This sub study was submitted and approved separately (REK: 2015/2300). This study did not involve any new data collection other than what already existed in Gen100.

3.0 Results

3.1 Sample characteristics

Subjects were invited to participate between August 2012 and June 2013. A total of 1790 subjects were assessed for eligibility, of whom 1567 (790 women) subjects were randomized; N=780 in the control group, n=387 in the moderate intensity group, and n=400 in the high intensity group. The most common reason for ineligibility was that the subjects did not want to participate (174). Of those who were included there were missing gait data on 33 subjects at baseline, so a sample of 1534 was included in the analysis. There was a loss to follow up for a total of 563 subjects, leaving a sample with gait data for 1004 persons after three years. A flow chart of the participants throughout the study is presented in figure X.

Baseline characteristics of the subjects are presented in Table 1. Chi Square tests for categorical data and Kruskal-Wallis tests for continuous data show that there are no significant differences between the three groups (all *p*'s > 0.127).

Table 2: Baseline characteristics

		HIT (N=395)	MIT (N=375)	CON (N=764)
Age; years		72.5 (2.1)	72.4 (2.0)	72.4 (2.1)
Sex (female); n (%)		190 (48%)	199 (51%)	401 (51%)
BMI; kg/m^2		26.0 (3.7)	25.9 (3.7)	25.9 (3.4)
Persons with education above high school; n (%)		199 (51%)	194 (52%)	372 (49%)
Gait speed: cm/s		131.0 (20.5)	132.1 (19.6)	131.0 (20.0)
Physical activity; n (%)	< 1 x pr week	34 (9%)	27 (7%)	70 (9%)
	1-3 x pr week	271 (70%)	262 (70%)	528 (70%)
	almost every day	84 (22%)	88 (23%)	161 (21%)
Number of prescribed medications: Mean (SD)		2.1 (1.9)	2.2 (1.9)	2.0 (1.8)
Persons who have experienced a fall during the last 12 months; n (%)		115 (30%)	123 (35%)	228 (30%)

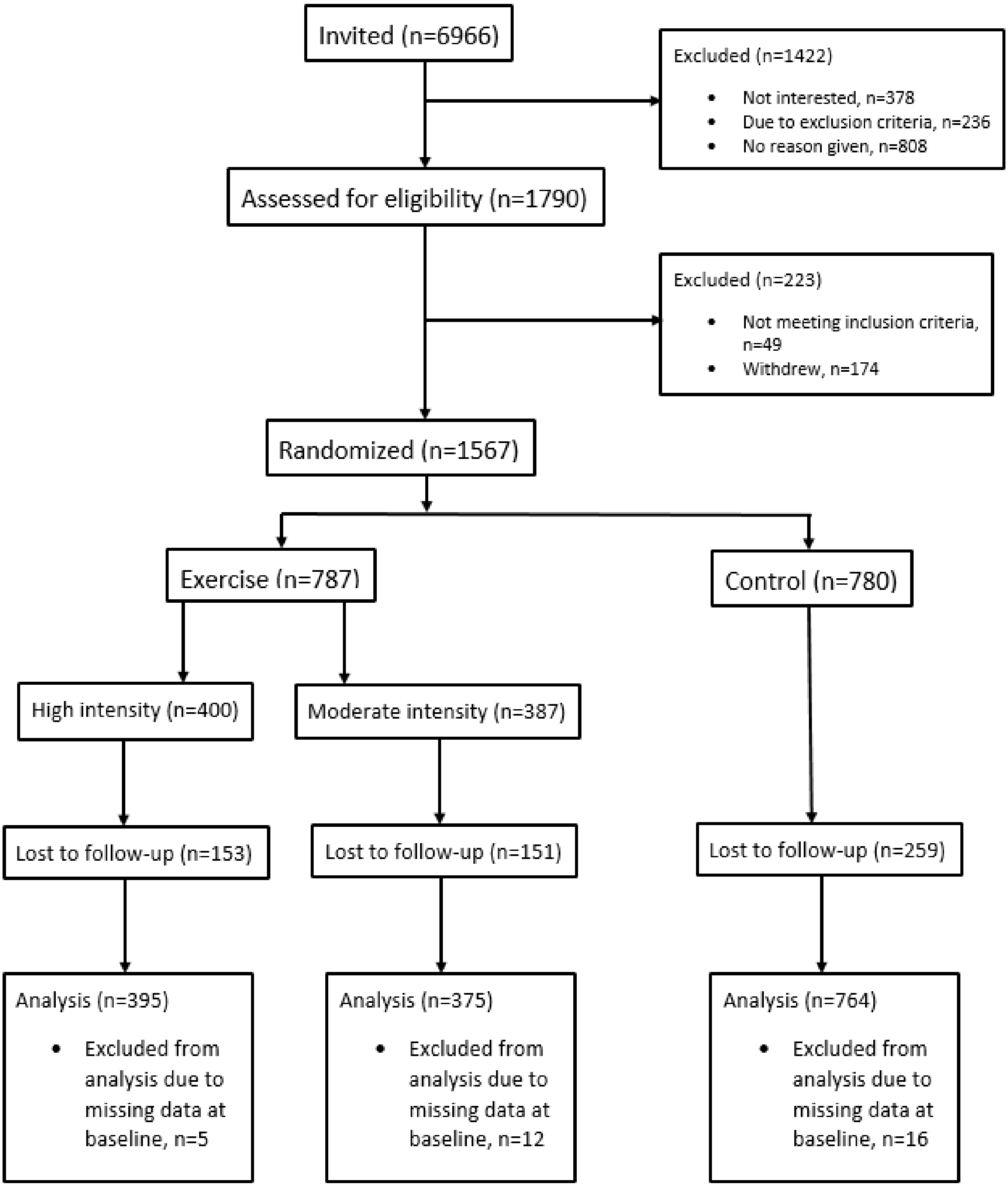

Figure 4: Flowchart

3.2 Mean gait values

3.2.2 Change over time

Table 3 shows the mean scores of the gait characteristics at baseline and after three years exercise. At baseline there is one collective score for all three groups because baseline means are constrained to be equal between the randomized groups. We found a small deterioration in gait for most variables for preferred speed after three years. The stance time increased and step length decreased for all three groups, and the changes are significant. For gait speed, both MIT and CON had a significant decrease in gait speed of 3.53 cm/s and 2.67 cm/s respectively, while HIT remained stable. Stride width remained stable for all three groups over the three years.

For the fast condition gait speed increased with 3.53 cm/s for HIT and decreased with 1.90 cm/s for CON, while MIT remained stable after three years. All three groups had a significant decrease in step length, were HIT had the smallest decline. Stance time remained stable for HIT and MIT and had a small increase of 0.02 s for CON. Stride width remained stable for all three groups over the three years.

For the dual task condition all three groups showed approximately the same changes after three years: Gait speed increased significantly for HIT and CON, where HIT has the largest improvement estimated to be 6.19 cm/s. Step length and stance time decreased, and stride width remained stable.

3.2.1 Group differences

As seen in Table 4 there are significant differences in change between HIT and CON for gait speed, mean step length and mean stance time for both preferred and fast condition after three years. There are also significant differences in change between HIT and MIT after three years for gait speed, mean step length and mean stance time, but only for the preferred speed gait condition. There are no significant differences between MIT and CON for any of the gait variables, and no significant differences between any of the groups for dual task condition.

Table 3

Mean gait measures: Baseline and 3 years results with change scores for each group presented with estimates

		Baseline (N=1534)	HIT 3y (N=521)			MIT 3y (N=236)			CON 3y (N=247)		
		Estimate (95%CI)	Estimate (95%CI)	Change from baseline (95%CI)	p-value	Estimate (95%CI)	Change from baseline (95%CI)	p-value	Estimate (95%CI)	Change from baseline (95%CI)	p-value
Gait speed cm/s	Pref	131.29 (130.26-132.31)	132.06 (130.06-134.06)	0.77 (-1.14 to 2.68)	0.428	127.75 (125.71-129.79)	-3.53 (-5.49 to 1.58)	<0.001	128.61 (127.15-130.08)	-2.67 (-4.01 to 1.34)	<0.001
	Fast	188.59 (187.15-190.04)	192.11 (189.49-194.76)	3.53 (1.09 to 5.97)	0.005	188.88 (186.21-191.55)	0.29 (-2.19 to 2.76)	0.820	186.69 (184.71-188.66)	-1.90 (-3.60 to 0.21)	0.028
	Dual	100.33 (98.79-101.95)	106.52 (102.94-110.10)	6.19 (2.63 to 9.75)	0.001	103.12 (99.44-106.79)	2.79 (-0.87 to 6.45)	0.135	105.79 (103.26-108.32)	5.47 (2.96 to 7.97)	<0.001
Step length cm	Pref	70.28 (69.87-70.69)	69.35 (68.66-70.05)	-0.93 (-1.54 to 0.32)	0.003	68.32 (67.61-69.02)	-1.96 (-2.59 to 1.34)	<0.001	68.55 (68.02-69.09)	-1.73 (-2.16 to 1.30)	<0.001
	Fast	83.12 (82.60-83.64)	82.01 (81.20-82.83)	-1.10 (-1.80 to 0.41)	0.002	81.11 (80.28-81.94)	-2.01 (-2.71 to 1.30)	<0.001	80.90 (80.25-81.24)	-2.22 (-2.70 to 1.74)	<0.001
	Dual	65.31 (64.75-65-88)	64.38 (63.30-65.46)	-0.93 (-1.95-0.08)	0.072	63.71 (62.61-64.82)	-1.60 (-2.65 to 0.55)	0.003	64.37 (63.57-65.16)	-0.95 (-1.65 to 0.24)	0.009
Stride width cm	Pref	7.35 (7.20-7.50)	7.29 (7.03-7.55)	-0.06 (-0.29 to 0.18)	0.641	7.19 (6.92-7.45)	-0.16 (-0.40 to 0.08)	0.198	7.21 (7.01-7.40)	-0.14 (-0.30 to 0.03)	0.101
	Fast	7.59 (7.43-7.73)	7.35 (7.07-7.63)	-0.23 (-0.48 to 0.02)	0.076	7.36 (7.08-7.65)	-0.21 (-0.47 to 0.04)	0.104	7.48 (7.27-7.69)	-0.19 (-0.28 to 0.08)	0.268
	Dual	7.18 (7.01-7.35)	7.22 (6.91-7.54)	0.04 (-0.25 to 0.33)	0.783	7.35 (7.02-7.67)	0.17 (-0.13 to 0.47)	0.279	7.15 (6.91-7.38)	-0.03 (-0.24 to 0.17)	0.753
Stance time sec	Pref	0.68 (0.68-0.68)	0.69 (0.68-0.70)	0.01 (0.00 to 0.02)	0.006	0.71 (0.70-0.71)	0.03 (0.02 to 0.04)	<0.001	0.70 (0.69-0.71)	0.02 (0.02 to 0.03)	<0.001
	Fast	0.54 (0.53-0.54)	0.53 (0.53-0.54)	-0.00 (-0.01 to 0.00)	0.139	0.54 (0.53-0.54)	0.00 (-0.00 to 0.01)	0.344	0.54 (0.54-0.55)	0.01 (0.00 to 0.01)	<0.001
	Dual	0.91 (0.90-0.93)	0.86 (0.83-0.90)	-0.05 (-0.08 to 0.02)	0.002	0.90 (0.86-0.93)	-0.05 (-0.05 to 0.01)	0.261	0.86 (0.84-0.88)	-0.05 (-0.08 to 0.03)	<0.001

HIT: High intensity training, MIT: Moderate intensity training, CON: Control group

Table 4

Between group differences from baseline to three years for preferred, fast and dual task gait conditions – Mean gait measures

Preferred		Estimate	CI	p-value	Fast		Estimate	CI	p-value	Dual		Estimate	CI	p-value
HIT vs CON	Gait speed	3.45	1.62 to 6.70	0.003	HIT vs CON	Gait speed	5.43	2.51 to 8.35	<0.001	HIT vs CON	Gait speed	0.73	-3.49 to 4.94	0.736
	Step length	0.80	0.06 to 1.54	0.034		Step length	1.12	0.28 to 1.95	0.009		Step length	0.01	-1.20 to 1.23	0.984
	Stride width	0.08	-0.20 to 0.37	0.572		Stride width	-0.13	-0.44 to 0.18	0.403		Stride width	0.07	-0.28 to 0.42	0.680
	Stance time	-0.01	-0.02 to 0.00	0.007		Stance time	-0.01	-0.02 to 0.01	0.001		Stance time	0.01	-0.03 to 0.04	0.779
HIT vs MIT	Gait speed	4.31	1.16 to 5.74	0.002	HIT vs MIT	Gait speed	3.24	-0.19 to 6.68	0.064	HIT vs MIT	Gait speed	3.40	-1.59 to 8.39	0.181
	Step length	1.03	0.16 to 1.91	0.020		Step length	0.90	-0.08 to 1.89	0.072		Step length	0.66	-0.78 to 2.11	0.366
	Stride width	0.10	-0.23 to 0.44	0.548		Stride width	-0.02	-0.38 to 0.34	0.930		Stride width	-0.13	-0.54 to 0.29	0.554
	Stance time	-0.02	-0.03 to 0.01	<0.001		Stance time	-0.01	-0.01 to 0.00	0.082		Stance time	-0.03	-0.07 to 0.01	0.165
MIT vs CON	Gait speed	-0.86	-3.18 to 1.46	0.467	MIT vs CON	Gait speed	2.19	-0.77 to 5.14	0.146	MIT vs CON	Gait speed	-2.68	-6.97 to 1.62	0.222
	Step length	-0.23	-0.98 to 0.52	0.542		Step length	0.21	-0.63 to 1.06	0.620		Step length	-0.65	-1.89 to 0.59	0.303
	Stride width	0.02	-0.31 to 0.27	0.888		Stride width	-0.11	-0.42 to 0.19	0.468		Stride width	0.20	-0.16 to 0.56	0.276
	Stance time	0.01	-0.00 to 0.02	0.160		Stance time	-0.01	-0.01 to 0.00	0.154		Stance time	0.04	-0.00 to 0.07	0.059

HIT: High intensity training, MIT: Moderate intensity training, CON: Control group

3.3 Variability of gait measures

3.3.1 Change over time

As seen in Table 5 there is an overall increase in gait speed variability, step length variability and stance time variability from baseline to three years for all three groups. These changes are significant for all variables in preferred and fast gait conditions. For the dual task condition only increase in gait speed variability and step length variability is significant. Stride width remains relatively stable for all three groups for all three gait conditions.

3.3.2 Group differences

As seen in Table 6 there are few differences in the variability measures between the three groups after three years, and the differences we see do not seem to have any clear pattern. But we could highlight that HIT has significantly higher variability for gait speed and step length in dual task condition when compared to CON after three years.

Table 5

Gait variability measures (SD):
Presented with empirical medians and Interquartile ranges (IQR).
The analyses are done with log transformed data, the estimate of change and *p*-values are based on this data

		Baseline (1534)	HIT 3y (N=521)			MIT 3y (N=236)			CON 3y (N=247)		
		Median (IQR)	Median (IQR)	Change from baseline (95%CI)	p-value	Median (IQR)	Change from baseline (95%CI)	p-value	Median (IQR)	Change from baseline (95%CI)	p-value
Gait speed	Pref	3.50 (1.77)	5.55 (2.30)	0.20 (0.17 to 0.22)	<0.001	5.79 (3.07)	0.21 (0.19 to 0.23)	<0.001	5.55 (2.59)	0.20 (0.19 to 0.22)	<0.001
cm/s	Fast	4.81 (2.92)	7.07 (3.74)	0.15 (0.13 to 0.18)	<0.001	6.87 (4.14)	0.16 (0.14 to 0.19)	<0.001	6.67 (3.76)	0.14 (0.12 to 0.16)	<0.001
	Dual	5.52 (3.87)	6.63 (4.35)	0.08 (0.05 to 0.10)	<0.001	6.34 (4.15)	0.06 (0.03 to 0.09)	<0.001	6.25 (3.96)	0.04 (0.02 to 0.06)	<0.001
Step length	Pref	1.87 (0.91)	2.54 (1.26)	0.15 (0.13 to 0.17)	<0.001	2.69 (1.23)	0.16 (0.14 to 0.18)	<0.001	2.72 (1.14)	0.16 (0.14 to 0.17)	<0.001
cm	Fast	2.09 (1.24)	2.74 (1.85)	0.12 (0.10 to 0.15)	<0.001	2.69 (1.63)	0.12 (0.10 to 0.15)	<0.001	2.74 (1.55)	0.13 (0.11 to 0.15)	<0.001
	Dual	2.74 (162)	3.16 (1.88)	0.07 (0.05 to 0.10)	<0.001	3.11 (1.67)	0.06 (0.04 to 0.09)	<0.001	3.06 (1.66)	0.04 (0.02 to 0.06)	<0.001
Stride width	Pref	2.05 (1.03)	2.06 (1.08)	0.02 (0.00 to 0.04)	0.042	2.06 (1.04)	0.01 (-0.01 to 0.01)	0.476	1.97 (0.92)	-0.01 (-0.02 to 0.01)	0.222
cm	Fast	2.10 (1.17)	2.22 (1.06)	0.02 (-0.01 to 0.04)	0.129	2.10 (1.04)	0.01 (-0.01 to 0.03)	0.449	2.19 (1.18)	0.02 (0.01 to 0.04)	0.011
	Dual	2.11 (2.21)	2.05 (1.18)	-0.01 (-0.03 to 0.01)	0.450	2.16 (1.61)	-0.01 (-0.03 to 0.02)	0.554	2.01 (0.97)	-0.02 (-0.04 to 0.00)	0.015
Stance time	Pref	0.02 (0.01)	0.03 (0.02)	0.15 (0.13 to 0.18)	<0.001	0.03 (0.02)	0.17 (0.15 to 0.20)	<0.001	0.03 (0.02)	0.17 (0.15 to 0.18)	<0.001
s	Fast	0.02 (0.01)	0.02 (0.02)	0.14 (0.11 to 0.16)	<0.001	0.02 (0.01)	0.16 (0.14 to 0.19)	<0.001	0.02 (0.01)	0.13 (0.12 to 0.15)	<0.001
	Dual	0.05 (0.08)	0.05 (0.07)	-0.00 (-0.05 to 0.04)	0.909	0.06 (0.08)	0.03 (-0.01 to 0.08)	0.163	0.05 (0.06)	-0.03 (-0.06 to 0.00)	0.069

HIT: High intensity training, MIT: Moderate intensity training, CON: Control group

Table 6

Between group differences after three years - Variability gait measures Results are from log transformed data														
Preferred					Fast					Dual				
		Estimate	CI	p-value			Estimate	CI	p-value			Estimate	CI	p-value
HIT vs CON	Gait speed	-0.01	-0.03 to 0.02	0.492	HIT vs CON	Gait speed	0.01	-0.02 to 0.04	0.380	HIT vs CON	Gait speed	0.03	0.00 to 0.07	0.043
	Step length	-0.01	-0.03 to 0.01	0.368		Step length	-0.00	-0.03 to 0.03	0.841		Step length	0.03	0.00 to 0.06	0.035
	Stride width	0.03	0.01 to 0.05	0.012		Stride width	-0.00	-0.03 to 0.02	0.743		Stride width	0.01	-0.02 to 0.04	0.383
	Stance time	-0.01	-0.04 to 0.02	0.371		Stance time	-0.03	-0.02 to 0.03	0.794		Stance time	0.03	-0.03 to 0.08	0.319
HIT vs MIT	Gait speed	-0.02	-0.05 to 0.01	0.255	HIT vs MIT	Gait speed	-0.01	-0.04 to 0.03	0.671	HIT vs MIT	Gait speed	0.02	-0.02 to 0.05	0.435
	Step length	-0.01	-0.04 to 0.02	0.487		Step length	0.00	-0.03 to 0.04	0.910		Step length	0.01	-0.03 to 0.04	0.637
	Stride width	0.01	-0.01 to 0.04	0.336		Stride width	0.01	-0.02 to 0.04	0.566		Stride width	-0.00	-0.03 to 0.03	0.912
	Stance time	-0.02	-0.05 to 0.01	0.247		Stance time	-0.03	-0.06 to 0.01	0.140		Stance time	-0.04	-0.10 to 0.03	0.267
MIT vs CON	Gait speed	0.01	-0.02 to 0.03	0.519	MIT vs CON	Gait speed	0.02	-0.01 to 0.05	0.172	MIT vs CON	Gait speed	0.02	-0.01 to 0.05	0.279
	Step length	-0.00	-0.03 to 0.02	0.935		Step length	-0.00	-0.03 to 0.02	0.741		Step length	0.02	-0.01 to 0.05	0.128
	Stride width	0.02	-0.01 to 0.04	0.170		Stride width	-0.01	-0.04 to 0.01	0.321		Stride width	0.01	-0.01 to 0.04	0.324
	Stance time	0.01	-0.02 to 0.03	0.646		Stance time	0.03	0.00 to 0.06	0.048		Stance time	0.06	0.01 to 0.12	0.024

HIT: High intensity training, MIT: Moderate intensity training, CON: Control group

3.4 Covariates

When controlling for age and gender in the analysis of between groups differences and within group change after three years group differences for change in mean step length, mean stride width and mean stance time were no longer significant apart from the mean value of stance time in preferred condition when comparing HIT and MIT.

4.0 Discussion

This study aimed to investigate if regular cardiovascular exercise can prevent a deterioration in gait characteristics associated with an increased risk of falls compared to controls. As hypothesized we found significant differences between HIT and CON for gait speed in both preferred and fast gait conditions, where HIT had the best mean values. More surprisingly we also found that HIT had significant better mean gait speed after three years than MIT and that there were no differences between MIT and CON. Also we found no pattern in the differences between the three groups for the gait variability measures, other than HIT having larger gait speed and step length variability in the dual task condition when compared to CON. Overall, we found that the mean measures and the variability measures of the gait variables had declined after three years. The exceptions was gait speed for all three walking conditions for HIT and gait speed and stance time for the dual task condition for all three groups.

4.1 Gait characteristics

When looking at the between group differences in change for the preferred condition we found that HIT had significant better scores for gait speed, step length and stance time than both MIT and CON. For the fast gait condition the scores were significantly better for HIT compared to CON and nearly significant better than for MIT (*p*'s 0.064 to 0.082). When looking at the change from baseline we found that HIT maintained the scores for mean step length and mean stance time better than MIT and CON. HIT did not show a decrease in preferred gait speed, and they even increased their fast gait speed. It seems as high intensity exercise is necessary to maintain or improve gait speed and some other gait characteristics as MIT and CON show about the same results. Lopopolo et al. have done a meta-analysis [19] on the effect of therapeutic exercise on gait speed in community-dwelling older adults. The therapeutic exercise consisted of various forms of strength, aerobic, flexibility, balance, gait, Tai Chi or relaxation training and the duration ranged from 2 to 52 weeks. This meta-analysis found that high intensity training had significant effects on gait speed, while moderate and low intensity had no effect. Wang et al. [56] also found that high intensity exercise have positive effects on gait speed, stride time and stride length among community-dwelling older adults.

The meta-analysis by Lopopolo et al. found a change of 0.01-0.02 m/s in habitual gait speed. In our study both MIT and CON had a reduction in gait speed while HIT remained stable. This is in agreement with a study by Brach et al. [58] who found that 12 weeks of walking endurance training on a treadmill did not improve gait speed. These participants did however have a subclinical gait dysfunction and a lower baseline gait speed (118 cm/s) than our participants. The meta-analysis by Lopopolo et al. did not find any change in fast gait speed, where we found a significant increase of 0.04 m/s in the HIT group. The study by Brach et al [58] did not measure fast gait speed, but they did however find an increase in gait endurance measured by 6 minute walk test. This might show that endurance exercise is not better than multi factor exercise in improving preferred gait speed, but could be more effective than therapeutic exercise in improving fast gait speed.

In the Gen100 study we do not know exactly what type of exercise the participants did as they could choose exercise sessions freely and they were free to exercise individually. This information could have been obtained through the exercise logs, but we did not have access to these details at this moment. Both HIT and MIT were offered similar types of exercises like walking, running, spinning, dancing and aerobics. So we could assume the two groups did the same things but the way they did it were different: High intensity intervals for 40 minutes versus moderate intensity for 50 continuous minutes, meaning that it is the intensity of the training that made the difference.

Gait speed is the most used outcome measure for gait, probably because it does not depend on equipment other than a stop watch. Few studies look at the effect of exercise on other gait variables than gait speed, but we have found some studies that do. Brown et al. found that endurance exercise (walking and jogging) improved step length and stride length, together with gait speed [53]. A study by Wang et al. showed that a combined exercise program consisting of resistance, balance and endurance training, improved stride time, stride length, stride time variability and stride length variability together with gait speed [56]. This intervention would be classified as high intensity and high dosage. Music-based multitask training with lower dosage than our intervention improved gait velocity, stride length, stride time variability and stride length variability for both single task and dual task conditions after 6 months [55]. The same study also showed that after 4 years the intervention group had unchanged gait variability measures while the control group had significant worsened gait variability [54]. These studies' participants were relatively healthy older adults with a mean age of 74.6 years comparable to our participants apart from that they were mostly female (98%).

For the dual task condition we found significant increases in gait speed after three years for all three groups. For dual task you might also think that the specificity of the exercise is important, but this does not explain why all three groups showed improvements. One explanation could be that the participants have a learning effect in the test situation, because they have done the backwards counting before. We as test personnel discussed the dual task condition several times because the participants found this task bothersome, especially if they had troubles with the counting. At the three-year follow up, many participants told us when we came to the dual task condition that they remembered the counting, and you one might think that some have practiced the counting in advance of the testing. The studies of Hars et al. [54] and Trombetti et al. [55] show the same tendency as both the intervention group and the control group improve their gait speed at dual task condition after six months, one year and four years. It could have been interesting controlling for cognition for the dual task condition, but we did not have any good measures of cognition at baseline.

The largest difference in gait speed was found when comparing HIT and CON at fast gait condition. The difference between the groups after three years was estimated to be 5.43 cm/s. For preferred speed the difference between the same groups were 3.45 cm/s. When comparing HIT and MIT, the difference between the groups were estimated to be 4.31 cm/s for preferred speed and 3.24 for fast speed, where the latter is only near significant (p=0.064). Perera suggests that a change of 5 cm/s in usual gait speed is a small meaningful change, and a change of 10 cm/s a substantial meaningful change. Difference between HIT and CON fast speed of 5 cm/s can therefore be categorized as a small meaningful change. But the literature has looked at preferred gait speed, so this might not be translatable to fast gait. The largest change in preferred gait speed is a decline of 4 cm/s after three years for the MIT group. The HIT group has an increase of 1 cm/s. None of these can be categorized as a meaningful changes.

Brach et al. [51] suggest that a change of 0.01 sec for stance time variability and 0.25 cm for step length variability are meaningful changes of gait variability. Step width variability is inconsistent where both too much and too little can be undesirable. There is a significant increase in stance time variability of about 0.01 sec for all three groups at preferred speed after three years. This can be seen as a clinical meaningful worsening of stance time variability. There are significant increases of 0.32 to 0.87 cm for step length variability for all three groups in all three conditions. The increase is highest for preferred speed and lowest for dual task. These changes can be seen as meaningful worsening of step length variability. We did not find any numbers for meaningful change in gait speed variability.

Overall we did not find any change in either mean scores of stride width or stride width variability apart from HIT which increased stride width variability by 0.01 cm in preferred condition and CON which increased 0.09 cm in fast condition and decreased 0.1 cm in dual task condition. The fact that it has been shown that both too much or too little stride width variability is associated with falls in older persons who walk at normal gait speed makes this variable difficult to interpret [47]. Stride width is also one of the least reliable variables when measured with an electronic walkway and Menz et al. say that the reliability for base of support (the distance between the heels when walking) may not be sufficiently high to be able to give a confident detection of small but clinically important differences over time in older people [61].

Controlling for gait speed made most of the group differences we found disappear. It was only the mean value of stance time in preferred condition that were significant when comparing HIT and MIT. This makes us wonder if the other gait variables do not tells us more than gait speed. If we look closer to our mean gait variables we see that the HIT group had a deterioration in step length and stance time after three years even though gait speed remained stable. We even found a small increase in preferred gait speed, but this was not significant. We saw the same tendency for the fast condition where gait speed had a significant increase and step length a significant decrease. This shows that even though the gait characteristics have a strong association they do not say exactly the same. To walk with a shorter step length and longer stance time when you walk faster could be considered as a strategy where you adapt a more conservative gait pattern to maintain control when you walk fast. This might mean that you do in fact not have better control or balance even though you walk faster. This is information you would lose if you only measured gait speed. At the same time you could also say that with limited time and resources, as it often is in a clinical setting, a measurement of only gait speed might give enough information to get an indicator of health or risk of falls.

4.2 Gait and falls

We found an overall worsening in all mean gait characteristics except gait speed for all three groups which makes them all have a higher risk of falling after three years. As Mortaza et al [36] found in their review that gait speed seems to be higher and step length longer in non-fallers when compared to fallers for both preferred and fast conditions.

For the variability gait measures the results are less consintant, but some findings show that an increased variability in step length, stance time and step width is found in fallers [36]. As mentioned the step width variable comes with some difficulties but Brach et al found that amongst personens with normal gait speed (>100 cm/s) higher step width variability was found among fallers [47]. As all of our participants have an overall increase in all variability measures this adds to the certainty that our participants have a higher risk of falling after three years and that the interventions have to counteracted this.

Still the HIT group had less worsening and even an increse in fast gait speed, and when comparing the groups after three years HIT had higher gait speed, longer step length and shorter stance time than both MIT and CON which had almost similar scores. This implies that HIT is less vunerable to experience falls than MIT and CON.

It has been found that increased dual task cost during gait assessment and a slower walking speed while counting backwards are associated with an increased fall risk [35, 38, 70]. All three groups had an increse in dual task gait speed after three years, at the same time all three groups had slower gait speed while dual tasking compared to single task. Beauchet et al [41] did a review where they found that the association between dual task related changes and fall incidence was only found in institutionalized frail populations and not community dwelling relatively healthy older adults. This might be why our findings are not consitent when it comes to dual task and association to falls.

4.3 Specificity of the exercise

Lopopolo's meta-analysis suggests that exercise type, intensity and dosage may be important in producing a change in gait [19]. A study by Bucher et al. showed that walking exercise improved usual gait speed while aerobic movement and stationary cycling did not. This shows that you get better at what you do and that the specificity of the exercise can be important.

The lack of between group differences on the variability measures might be because of the lack of specificity of the exercise. The lack of effect is shown by all three groups have significant worsened gait variability for gait speed, step length and stance time. You might think that walking, running and spinning probably is not specific enough to gain an effect in gait characteristics. A study by VanSwearingen et al. confirm this by showing that timing and coordination exercise resulted in greater improvements in energy cost of walking, clinical gait assessment with The modified Gait Abnormality Rating Scale (GARSM), gait speed and perceived confidence in walking compared with a program with walking, endurance, balance and strength exercise [71]. Lord et al. showed that 12 weeks endurance training on a treadmill did not improve preferred gait speed in older adults, while motor learning exercise did. It has also been shown that a music-based multitask training with lower dosage than our intervention improved gait velocity, stride length, stride time variability and stride length variability for both single task and dual task conditions after 6 months [55]. The same intervention also showed that after 4 years the intervention group had stable variability measures while the control group had significant worsened gait variability [54].

We found that HIT had significantly higher gait speed and step length variability after three years when compared to CON. The fact that those who did not receive any intervention other than a message to follow the national guidelines for activity actually had a smaller deterioration in gait variability adds to the certainty that our intervention was not specific enough to improve gait variability.

4.4 Duration of the intervention

Most studies have an intervention period of 3 to 12 months, while our study lasts for three years. The Gen 100 study will continue for 5 years and maybe even for 10 years. With an intervention period of some month it might be more likely to find a positive effect than after several years. Especially for older adults you would expect to find declines in gait characteristics after three years due to the effects of ageing. Another aspect is the adherence. Exercise two times a week for three years is a lot to demand. Still we did find an improvement in gait speed and a smaller deterioration of step length and stance time for the HIT group compared to MIT and CON. A study by Hars et al. [54] did a follow-up after four years of exercise intervention. The intervention was one hour of music-based multitask training per week for 45 weeks per year. After four years the control group had significant worsened the variability measures while the intervention group remained stable. These differences were not present after one year. It would be interesting to see if the group differences in our study increase after 5 and 10 years. Maybe the HIT group will continue to remain relatively stable in their gait characteristics while MIT and CON continue to worsen their gait.

4.5 The participants

The baseline characteristics show that our participants are quite active, as more than 90% exercised at least one time per week and more than 20% exercised almost evert day. Studenski et al. investigated 9 cohort studies with baseline gait data of older adults. A total of 34 485 community dwelling adults with a mean age of 73.5 years and 59.6% women were included. Mean gait speed in this study was 92 cm/s, while the mean gait speed at baseline in our study was approximately 131 cm/s. This suggest that our participants had a higher gait speed than average and are more fit than average. All cohorts in the study by Studenski et al. used instructions to walk at usual pace and from a standing start. This may explain some of the difference in mean gait speed as Sustakoski et al. found that the same participants walked 4 cm/s faster on a computerized walkway with a walking start than on the ground with a standing start [49], but still our participants have a higher gait speed. Studenski et al. [13] showed that a preferred gait speed above 100 cm/s suggests a better than average life expectancy, and that a gait speed above 120 cm/s suggests exceptional life expectancy. For people between 64 and 74 years a gait speed above 120 cm/s gives a 93% 5-year survival for men and 96% for women, and 75% 10-year survival for men and 83% for women. Our participants had a preferred gait speed above 120 cm/s both at baseline and after three years which means that many of our participants are expected to live well beyond 80 years.

Even though our participants seem to be quite fit they fall as much as other adults their same age. 24.1% of elderly Norwegians above 67 years living at home report having a fall during the last six months [12]. About 30% of our participants reported having a fall during the last 12 months. One explanation could be that they are active as most falls happen during some sort of locomotion. It could be interesting to investigate if our population has less falls per active hour than not as fit and active samples.

The lack of effects on gait speed and characteristics might be because of ceiling effects on the tasks that are tested, as this group is a relatively fit group of older adults. If strength and endurance capacities are adequate prior to exercise, further increases in capacity are not expected to alter basic tasks such as usual walking speed [22]. One study found that treatment effects were greatest in persons with higher energy cost of walking [71] and another study [72] found good effects with treadmill walking training on frail older adults. At the same time we found an effect where some of the HIT group’s gait characteristics remained more stable than for MIT and CON which shows that high intensity training can have an effect even though people are relatively fit to begin width.

4.6 Strength and limitations

This trial has methodological issues that should be considered.

The trial is a randomized controlled trial with blinded test personnel, which is considered to be the “gold standard” of clinical trials. The randomization ensures the the people in each group have a similar distribution of characteristics to make sure that the groups are comparable. In this way we eliminate the effect of most confunders. The blinding of the personell ensures that the participant's progress is measured independently of the treatment being received. This removes the potential for bias due to the test personell's perception of the treatments being compared. The large sample size is a strength and makes the results more reliable, and the long intervention period shows long-term effects on gait speed.

All testing happened at the same laboratory with trained personnel that had the opportunity to discuss unexpected challenges like how to handle interruptions of the testing or refusal to do certain tests on a daily basis. The electronic walkway gives objective measurements of the gait parameters. Studies have showed that both GAITRite and Zeno walkway produces excellent reliability for most spatio-temporal gait parameters in older subjects [46, 57-59].

Even though Kressig and Beauhet's guidelines say that a minimum of six steps are enough to evaluate gait variability other studies have shown that you need 25 or even hundreds of strides to get reliable results [46]. One study found that lowest measurement error was seen when gait variability were based on at least 40 steps [73]. With an acive area of 5.49 meters it is quite obvious that a number of 40 steps is difficult to obtain. We did not have the number of steps for each participant available for this thesis, but from my work with the processing we know that we have at least six steps for almost all participants. There was a few walks with fewer steps either because some steps could not be approved during the processing or because the active area was too short during fast walk where step length increased. But scince we had the mean of two walks even these subjects had more than six steps. Other studies that have showed a change in gait variability have also used electronic walkways with approximately the same length as ours (Hars and Trombetti 7.3m [54, 55] and Wang 5m [56]) so at least our results are comparable to those.

Limitations that should be mentioned are possible selection bias. Participants were included by invitations and one could imagine that the ones who say yes to participate in a study with exercise as intervention are people that are already active and relatively fit. Results from the protocol article for Gen100 shows that the participants in the study are more active, have higher education and better health compared with the non-participating group [65]. This means our results might not be generalizable to all older adults in Norway in the relevant age group. We do not know how our intervention would affect those with poorer health.

The long intervention period could offer limitations as well as being a strength. Loss to follow-up and adherence to the exercise over time could end up as bigger issues. Exercise two times a week for 3 years is a lot to demand from the participants. The adherence is measured, but we did not have access to this information available when this thesis was written. To ensure adherence to the intervention weekly exercise groups with different kinds of exercise were offered to both intervention groups.

5.0 Conclusion

In this study we investigated if regular cardiovascular exercise can prevent a deterioration of gait variables associated with an increased risk of falls compared to controls. We found as expected an overall deterioration in most gait variables, both mean gait measures and gait variability measures. The HIT group had less deterioration of their gait variables and even an improvement in their fast gait speed. HIT also had significant better gait characteristics for preferred and fast condition after three years when compared to MIT and CON. Interestingly we did not find any differences between MIT and CON. We did not find any differences with a clear pattern for the gait variability measures. It seems as high intensity training can prevent a deterioration of certain mean gait variables related to fall risk among community dwelling older adults. The fact that endurance exercise had no effect on gait variability measures suggests that more specific interventions are needed to reduce gait variability and reduce the risk of falls. Future studies should include more specific intervention.

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Appendix

Gait variability measures (SD): Presented with log transformed data											
		Baseline	HIT 3y (N=)			MIT 3y (N=)			CON 3y (N=)		
		Estimate (95%CI)	Estimate (95%CI)	Change from baseline (95%CI)	p-value	Estimate (95%CI)	Change from baseline (95%CI)	p-value	Estimate (95%CI)	Change from baseline (95%CI)	p-value
Gait speed	Pref	0.54 (0.53-0.55)	0.74 (0.72-0.76)	0.20 (0.17 to 0.22)	<0.001	0.75 (0.73-0.77)	0.21 (0.19 to 0.23)	<0.001	0.75 (0.73-0.76)	0.20 (0.19 to 0.22)	<0.001
cm/s	Fast	0.68 (0.67-0.69)	0.84 (0.81-0.86)	0.15 (0.13 to 0.18)	<0.001	0.84 (0.82-0.87)	0.16 (0.14 to 0.19)	<0.001	0.82 (0.81-0.84)	0.14 (0.12 to 0.16)	<0.001
	Dual	0.75 (0.73-0.76)	0.82 (0.79-0.85)	0.08 (0.05 to 0.10)	<0.001	0.80 (0.78-0.83)	0.06 (0.03 to 0.09)	<0.001	0.79 (0.77-0.80)	0.04 (0.02 to 0.06)	<0.001
Step length	Pref	0.277 (0.26-0.27)	0.41 (0.39-0.43)	0.15 (0.13 to 0.17)	<0.001	0.42 (0.40-0.44)	0.16 (0.14 to 0.18)	<0.001	0.43 (0.41-0.44)	0.16 (0.14 to 0.17)	<0.001
cm	Fast	0.32 (0.31-0.33)	0.44 (0.42-0.47)	0.12 (0.10 to 0.15)	<0.001	0.44 (0.42-0.47)	0.12 (0.10 to 0.15)	<0.001	0.45 (0.43-0.46)	0.13 (0.11 to 0.15)	<0.001
	Dual	0.43 (0.42-0.44)	0.50 (0.48-0.53)	0.07 (0.05 to 0.10)	<0.001	0.50 (0.47-0.52)	0.06 (0.04 to 0.09)	<0.001	0.47 (0.46-0.49)	0.04 (0.02 to 0.06)	0.000
Stride width	Pref	0.30 (0.30-0.31)	0.33 (0.31-0.35)	0.02 (0.00 to 0.04)	0.042	0.31 (0.29-0.33)	0.01 (-0.01 to 0.01)	0.476	0.29 (0.28-0.31)	-0.01 (-0.02 to 0.01)	0.222
cm	Fast	0.31 (0.30-0.32)	0.33 (0.31-0.35)	0.02 (-0.01 to 0.04)	0.129	0.32 (0.30-0.35)	0.01 (-0.01 to 0.03)	0.449	0.34 (0.32-0.35)	0.02 (0.01 to 0.04)	0.011
	Dual	0.32 (0.31-0.33)	0.31 (0.29-0.33)	-0.01 (-0.03 to 0.01)	0.450	0.31 (0.29-0.34)	-0.01 (-0.03 to 0.02)	0.554	0.30 (0.28-0.31)	-0.02 (-0.04 to 0.00)	0.015
Stance time	Pref	-1.69 (-1.70--1.68)	-1.53 (-1.55--1.51)	0.15 (0.13 to 0.18)	<0.001	-1.51 (-1.54--1.49)	0.17 (0.15 to 0.20)	<0.001	-1.52 (-1.54--1.50)	0.17 (0.15 to 0.18)	<0.001
s	Fast	-1-87 (-1.79--1.77)	-1.64 (-1.67--1.62)	0.14 (0.11 to 0.16)	<0.001	-1.62 (-1.64--1.59)	0.16 (0.14 to 0.19)	<0.001	-1.65 (-1.66--1.63)	0.13 (0.12 to 0.15)	<0.001
	Dual	-1.25 (-1.27--1.23)	-1.25 (-1.30--1.20)	-0.00 (-0.05 to 0.04)	0.909	-1.21 (-1.26--1.16)	0.03 (-0.01 to 0.08)	0.163	-1.28 (-1.31--1-24)	-0.03 (-0.06 to 0.00)	0.069

HIT: High intensity training, MIT: Moderate intensity training, CON: Control group