DISSERTATION FROM THE NORWEGIAN SCHOOL OF SPORT SCIENCES 2019

Ingirid Geirsdatter Heald Kjær

## Health-related physical fitness

Status of body composition, musculoskeletal- and neuromotor fitness, and the effect of a tailored, telephone and email based exercise intervention on body composition and physical fitness



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#### **SAMMENDRAG**

#### Bakgrunn

Den økende prevalensen av fedme og fysisk inaktivitet er to alvorlig folkehelseutfordring i verden. Effekten av disse trendene på ulike aspekter ved helserelatert fysisk form er uklar ettersom målemetodene som oftest er selvrapporterte og enklere objektive mål. Nyere data på fedme prevalens og muskelskjelett- og nevromotorisk form målt ved veletablerte og objektive metoder mangler. I tillegg er behovet for intervensjoner som har som mål å redusere både prevalensen av fedme og fysisk inaktivitet, blitt fremhevet. Skreddersydde fysiske aktivitetsintervensjoner levert med bruk av alternative teknologiske verktøy har vist seg å være effektive i å fremme økt fysisk aktivitetsnivå blant voksne, men effekten av slike intervensjoner på objektive aspekter av helserelatert fysisk form blant fysisk inaktive voksne mangler.

#### Hensikt

Den overordnede hensikten med denne avhandlingen var å undersøke status på ulike aspekter ved helserelatert fysisk form og å undersøke effekten av en seks måneders telefon og epostbasert treningsintervensjon på ulike aspekter ved helserelatert fysisk form.

#### Metoder

Resultatene som er presentert i denne avhandlingen er basert på to separate studier; en nasjonal tverrsnitts studie på norske voksne (20-65 år) (*PAPER I* og *II*) og eldre (65-85 år)(*PAPER I*) og en randomisert kontrollert studie av en seks måneders treningsintervensjon blant fysisk inaktive voksne (40-55 år)(*PAPER III* og *IV*).

#### Hovedresultater

Hovedresultatene i *PAPER I* viste at fedme prevalensen varierte fra 12.7% basert på KMI til 30.9% basert på midje omkrets. Sensitiviteten og spesifisiteten til de ulike målemetodene for å estimere overvekt og fedme, varierte henholdsvis fra 77.0% til 86.9% og fra 60.6% til 82.3%. Hovedresultatene fra *PAPER II* var en presentasjon av de normative verdiene på muskelskjelett og nevromotorisk form, som viser klare kjønns- (p<0.001) og aldersforskjeller (p $\leq$ 0.044). Kvinner hadde signifikant høyere test score på muskulær utholdenhet i ryggekstensorene og på fleksibilitetstestene (p<0.001), mens menn hadde signifikant høyere test score på muskulær styrke, muskulær dynamisk utholdenhet og evne til å stabilisere overkroppen, samt eksplosiv power (p<0.001). Videre hadde yngre deltakere høyere test score på alle muskelskjelett og nevromotorisk form testene, sammenliknet med eldre deltakere (Kvinner; Beta:-0.06-(-0.92), p  $\leq$  0.044, Menn; Beta:-0.15-(0.91), p  $\leq$  0.006). I tillegg var midjeomkrets inverst relatert til

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mange aspekter ved muskelskjelett og nevromotorisk form (p<0.001). Hovedfunnene fra *PAPER III* og *PAPER IV* var signifikante forbedringer i test score på maksimalt oksygenopptak (VO<sub>2</sub>max, ml/kg/min) (ES:0.12, p=0.002), muskulær utholdenhet av ryggekstensorene (ES:0.21, p<0.001), fleksibilitet i hamstrings muskulatur (ES:0.12, p=0.006), eksplosiv power (ES:0.09, p=0.022) fra pre- til posttest i intervensjonsgruppen sammenliknet med kontrollgruppen, justert for pretest score. Videre medførte intervensjonen en større reduksjon på alle kroppssammensetningsmål i intervensjonsgruppen sammenliknet med kontrollgruppen (p<0.043) justert for pretest score, med unntak av KMI. I tillegg, var det en signifikant høyere andel av deltakerne i intervensjonsgruppen (64.1%) som oppnådde en klinisk signifikant reduksjon i fettprosent sammenliknet med deltakerne i kontrollgruppen (36.2%, p=0.018).

#### Konklusjon

Overensstemmelsen mellom ulike objektive mål på fedme var rimelig til god, men variasjonen i fedme prevalens mellom de ulike målemetodene var oppsiktsvekkende. Videre viste status på muskelskjelett og nevromotor form klare kjønnsforskjeller og et inverst forhold mellom muskelskjelett- og nevromotor form og alder og midjeomkrets. Den seks måneder lange telefonog epostbaserte treningsintervensjonen som hadde som mål å øke kardiorespiratorisk form og muskelskjelett- og nevromororisk form, samt en reduksjon i kroppssammensetning, viste lovende resultater. Dermed bør denne typen intervensjon undersøkes videre for å evaluere om det er enkelte elementer av intervensjons designet som er mer effektive enn andre, om noen elementer burde legges til for å øke effekten av- og deltakelsen i liknende intervensjon, i tillegg til å undersøke langtidseffekten av intervensjoner som har som mål å fremme helse-relatert fysisk from blant fysisk inaktive voksne.

#### **SUMMARY**

#### **Background**

The increasing obesity prevalence rates in addition to the increasing physical inactivity rates present serious public health challenges worldwide. The effect of these trends on aspects of health-related physical fitness is unclear as these trends are most commonly assessed by self-report or simpler objective measures. Up-to-date research on obesity prevalence rates and musculoskeletal- and neuromotor fitness by various well established and objectively measures is lacking. Additionally, the need interventions aiming at reducing both the prevalence of physical inactivity in addition to the prevalence of obesity has been highlighted. Tailored physical activity interventions delivered in alternative technological modes have proven effective in enhancing physical activity levels in adults, however the effect of such interventions on objectively measured aspects of health-related physical fitness among physically inactive adults is lacking.

#### **Purpose**

The overall purpose of this thesis was to investigate the status of various aspects of health-related physical fitness and to assess the effect of a six-month tailored telephone- and email based exercise intervention on various aspects of health-related physical fitness.

#### Methods

The results presented in this thesis are based on two separate studies; a national cross-sectional study of Norwegian adults (20-65 years) (*PAPERS I* and *II*) and elderly (65-85 years) (PAPER I) in addition to a randomized controlled trial of a six-month tailored exercise intervention in physically inactive adults (40-55 years) (*Papers III* and *IV*).

#### Main results

The main results from *PAPER* I revealed that obesity prevalence rates ranging from 12.7% based on BMI measures to 30.9% based on waist circumference. The sensitivity and specificity of the different measuring methods for estimating overweight and obesity, varied from 77.0% to 86.9% and from 60.6% to 82.3%, respectively. The main results from *PAPER II* were the normative data on musculoskeletal- and neuromotor fitness, displaying clear gender (p<0.001) and age related (p $\leq$ 0.044) differences. Females displayed significantly higher scores on muscular endurance of the back extensors and on the flexibility tests (p < 0.001), while males displayed significantly higher scores on muscular strength, muscular dynamic endurance and ability to stabilize the upper body, as well as explosive power (p < 0.001). Additionally, younger

participants displayed higher test scores on all musculoskeletal- and neuromotor fitness tests, compared to older participants (Females; Beta:-0.06-(-0.92), p  $\leq 0.044$ , Males; Beta:-0.15-(0.91), p  $\leq 0.006$ ). Furthermore, waist circumference was inversely related to many aspects of musculoskeletal- and neuromotor fitness (p < 0.001). The main findings from *PAPER III* and *PAPER IV* revealed significant improvements in test scores on maximal oxygen consumption (VO<sub>2</sub>max, ml/kg/min) (ES:0.12, p=0.002), muscular endurance of the back extensors (ES:0.21, p<0.001), flexibility of the hamstrings muscles (ES:0.12, p=0.006) and explosive power (ES:0.09, p=0.022) from baseline to posttest in the intervention group, compared to the control group, when adjusting for baseline test scores. Furthermore, the intervention induced a larger reduction on all body compositional measures in the intervention group compared to the control group (p<0.043) when controlling for baseline test scores, except for BMI. Additionally, a significantly higher percentage of the participants in the intervention group (64.1%) accomplished a clinically significant reduction in fat percentage by skinfolds compared to participants in the control group (36.2%, p=0.018).

#### Conclusion

The agreement between various objective measures of obesity was fair to good, however, the variation in obesity prevalence rates between the different assessments methods was striking. Additionally, the status of musculoskeletal- and neuromotor fitness reveal clear gender differences and an inverse relationship between musculoskeletal- and neuromotor fitness and age and waist circumference. The six-month tailored telephone- and email based exercise intervention aiming at increasing cardiorespiratory fitness and musculoskeletal- and neuromotor fitness, in addition to reducing various body compositional measures, revealed promising results. Thus, this type of intervention should be further investigated as to elaborate on whether or not any of the components of the intervention are more effective than others, whether or not further elements should be implemented to enhance the effect size of- and adherence to similar interventions, and to assess the long term follow-up of interventions promoting aspects of health-related physical fitness in physically inactive adults.

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Ingirid Geirsdatter Heald Kjær

Kristiansand, 2018

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### **LIST OF PAPERS**

The present dissertation is based on the following four papers, which are referred to by their roman numerals;

Paper I

Kjaer IG, Kolle E, Hansen BH, Anderssen SA, Torstveit MK: **Obesity prevalence in Norwegian** adults assessed by body mass index, waist circumference and fat mass percentage. *Clinical obesity* 2015, **5**(4):211-218.

Paper II

Kjær IGH, Torstveit MK, Kolle E, Hansen BH, Anderssen SA: **Normative values for musculoskeletal- and neuromotor fitness in apparently healthy Norwegian adults and the association with obesity: a cross-sectional study**. *BMC Sports Science, Medicine and Rehabilitation* 2016.

Paper III

Kjaer IG, Anderssen SA, Torstveit MK: **A tailored telephone and email based exercise intervention increased physical fitness in physically inactive adults: A RCT.** *Submitted BMC Public Health*, 30.10.17

Paper IV

Kjaer IG, Anderssen SA, Torstveit MK: **The effect of a tailored telephone and email based exercise intervention on various measures of body composition in physically inactive adults: a randomized controlled trial.** *Submitted Preventive Medicine Reports*, 04.12.17, manuscript number: PMEDR-17-227

#### THESIS AT GLANCE

**Main findings** 

#### Clinical implications

#### PAPER I

Obesity prevalence rates varied depending on assessment method, where the body mass index predicted prevalence rates of obesity of 12.7% were lower compared with those of waist circumference and fat percentage was estimated based on both waist by skinfolds of 30.8% and 29.1%, respectively. Additionally, there was fair to good agreement between the ability of selected measuring methods to categorize obesity.

The the inconsistency in obesity prevalence rates reported, questions the validity of established cut-off scores, as the estimated prevalence rate of obesity, based on body mass index, was markedly lower than what circumference and fat percentage, despite the agreement between selected measuring methods being fair to good.

PAPER II

The data provide normative values of musculoskeltal and neuromotor fitness for adults based on age and gender, and support an inverse relationship of musculoskeltal and neuromotor fitness indicate the need to enhance MSMF in to age and waist circumference.

The present study makes it possible for others to compare results from various field based MSMF tests to normative data based on age and gender. Furthermore, the results population subgroups in higher ages and with higher WC, in order to secure an independent daily lifestyle.

### and IV

PAPER III A six-month tailored telephone and email based exercise intervention had significant positive effects on maximal oxygen consumption, muscular endurance of the back extensors, flexibility of the hamstrings muscles, and explosive power in addition to inducing significant reductions weight, waist circumference and fat percentage more effective or important than others. by skinfoldsin physically inactive adults. Additionally, a significantly higher percentage of the intervention group achieved a clinically significant reduction in fat percentage, compared to the control group.

The presented intervention could be implemented in a real-life setting, such as relevant sectors aiming at promoting physical activity, as a promising public health measure to promote physical fitness in physically inactive adults. However, the study design should be further investigated as to elaborate on what components of the intervention are

#### **DEFINITION OF CONCEPTS**

The following are definitions of some central concepts of the thesis, given in alphabetical order.

#### **Balance**

Balance is a component of physical fitness that relates to the maintenance of equilibrium while stationary or moving <sup>1</sup>.

#### **Body composition**

Body composition has been defined as a health-related component of physical fitness that relates to the relative amounts of muscle, fat, bone and other vital parts of the body  $^1$ .

#### Cardiorespiratory endurance

Cardiorespiratory endurance has been defined as a health-related component of physical fitness that relates to the ability of the circulatory system to supply fuel during sustained physical activity and to eliminate fatigue products after supplying fuel <sup>1</sup>. In this thesis the concept of cardiorespiratory fitness (CRF) is mainly used. This concept is defined by the ACSM <sup>2</sup> as being related to the ability to perform large muscle, dynamic, moderate-to-high intensity exercise for prolonged periods.

#### Health related physical fitness

Health-related physical fitness are the health-related components of physical fitness that have a relation to health <sup>3</sup>, and have commonly been referred to as cardiorespiratory endurance, muscular endurance, muscular strength, body composition, and flexibility <sup>1</sup>. According to Ruiz et al <sup>3</sup>, the musculoskeletal components of health-related fitness include power, strength, endurance and flexibility. Additionally, Ruiz et al <sup>3</sup> outline the inclusion of agility, balance, coordination and speed of movement in the motor component of health-related physical fitness.

#### **Exercise**

Exercise is defined as *planned*, *structured*, and repetitive bodily movement done to improve or maintain one or more components of physical fitness <sup>1</sup>.

#### **Flexibility**

Flexibility is defined at a component of health related physical fitness *that relates to the range of motion available at a joint* <sup>1</sup>.

#### Muscular endurance

Muscular endurance is defined as a health related component of physical fitness that relates to the ability of muscle groups to exert external force for many repetitions or excessive exertions <sup>1</sup>.

#### Muscular power

Muscular power is defined as a component of physical fitness *that relates to the rate at which one can perform work* <sup>1</sup>.

#### Muscular strength

The term of muscular strength has been defined as a *health related component of physical fitness* that relates to the amount of external force that a muscle can exert <sup>1</sup>.

#### Musculoskeletal fitness

The musculoskeletal components of physical fitness relate to muscle strength, muscular endurance and explosive strength (power) <sup>3</sup>.

#### **Neuromotor fitness**

Neuromotor fitness relates to those components of physical fitness which relates to *motor skills* such as balance, coordination, gait, and agility, and proprioceptive training <sup>4</sup>.

#### Obesity

Obesity is defined as abnormal or excessive fat accumulation that may impair health  $^5$ .

#### Physical activity

Physical activity is defined as *any bodily movement produced by skeletal muscles that results in energy expenditure* <sup>1</sup> *above resting (basal) levels* <sup>6</sup>.

#### Physical fitness

Physical fitness is defined as a set of attributes that people have or achieve that relate to the ability to perform physical activity  $^{1}$ .

### **ABBREVIATIONS**

The following abbreviations are given in alphabetical order.

ACSM American College of Sports Medicine
AISN the Active in Southern Norway Study

AUC Area Under the Curve
BMI Body Mass Index
BSC Back Scratch test
CG Control Group

**CRF** Cardiorespiratory Fitness

**EPP** Explosive Power on a Power Platform test

FPskf Fat percentage by skinfolds
HGS Hand Grip Strength test

ICC Intraclass correlation coefficient

IG Intervention GroupKMI Kroppsmasse IndeksMPU Modified Push-Ups test

MPUK Modified Push-Ups on knees test

**MSMF** Musculoskeletal and Neuromotor Fitness

NPASS the Norwegian Physical Activity Surveillance Study

**OLS** One Leg Standing test

PA Physical Activity

RCT Randomized Controlled Trial
RER Respiratory Exchange Rate

**ROC** Receiver Operating Characteristics

SBE Static Back Extension test

SR Sit and Reach test
VJ Vertical Jump test

VO<sub>2</sub>max Maximal Oxygen Consumption

WC Waist Circumference

WHO World health Organization

Yrs. Years

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### 1.0 INTRODUCTION

In the early 20th century, the increase in mechanization, urbanization, motorization and computerization lead to changes in daily energy expenditure caused by a drastic decrease in physical activity levels <sup>7</sup>. The rising physical inactivity was at the time most possibly accompanied by a decrease in energy intake, which kept the energy balance at the time. In the 1960, the decrease in energy expenditure, was accompanied by a so-called energy balance flipping point when environmental push factors such as increasingly available-, cheap, tasty and highly promoted obesogenic foods gave a rise in energy intake <sup>7</sup>. The rise in energy intake in combination with the increasing physical inactivity leading to a decreased energy expenditure, has been claimed to be the *main* reason for the change in body composition, causing the rising prevalence of obesity <sup>7</sup>. Though, the causes of obesity worldwide are claimed to be exceedingly complex <sup>7,8</sup>.

Today, physical inactivity is highly widespread, estimated to be prevalent in a total of 31% of the adult population worldwide, though data is scarce  $^9$ . In Norway, the prevalence of adults not meeting the national guidelines of  $\geq$ 150 minutes of weekly physical activity of an intensity that equals moderate to vigorous, is 69%  $^{10}$ .

Physical inactivity is estimated to be the fourth leading risk of death <sup>11</sup> and is one of the largest contributors to cardiovascular disease and morbidity and mortality worldwide <sup>12</sup>. In fact, Lee et al <sup>13</sup> estimated physical inactivity to cause more than 9.3% of all deaths worldwide in 2008. Additionally, physical inactivity is estimated to be a great economic burden, both due to the burden to health care systems, physical inactivity related deaths, productivity losses and the large accountability of physical inactivity to disability-adjusted life-years <sup>14</sup>.

Health-related physical fitness has been characterized by an ability to perform daily activities with vigor, and by traits and capacities that are associated with a low risk for the development of chronic diseases and premature death. <sup>3</sup>. Physical activity is strongly related to physical fitness <sup>4</sup>, hence a reduction in physical activity will possibly reduce many components of physical fitness, including the components of physical fitness which relate to health. Thus, the rising trends reported in recent years of increasing physical inactivity and obesity prevalence rates, and the associated effects on overall health-related physical fitness, are worrying.

In regards to this, there are several possible effects of this development, which need to be addressed. First and foremost, there is a need to track health-related physical fitness trends in Norway and to address the results of decreasing physical activity levels and rising obesity

prevalence rates on various objective measures of health-related physical fitness. Secondly, there is a need to develop, implement and adequately report the results of effective interventions, aiming at influencing major determinants for obesity, thereby also increasing physical activity levels. This thesis addresses the status of obesity and musculoskeletal and neuromotor fitness by various, objective measures of health-related physical fitness, which are easily administered, in addition to investigating the implementation of a possible low-cost, technology-based exercise intervention on various components of health-related physical fitness.

#### 2.0 BACKGROUND

#### 2.1 OVERWEIGTH AND OBESITY

Obesity is one of the components of health-related physical fitness, relating to body composition, which has increasingly been recognized to be rising rapidly in prevalence rates <sup>15,16</sup>, reaching epidemic proportions <sup>17</sup>, with subsequent health risks that have become a major public health challenge <sup>16</sup>. The association between obesity and comorbidities/mortality is considered to be strong and causal <sup>17-19</sup>. The health-related effects of excessive fat mass, brings forth abnormalities and alterations in the pathophysiology of amongst other things cardiomyopathy, which in turn increases the risk of incidents of cardiovascular disease and cardiovascular mortality <sup>18</sup>. Individuals categorized as overweight or obese are at increased risk of coronary heart disease, stroke, respiratory disease mortality, diabetes mellitus and certain types of cancers <sup>20,21</sup>. Furthermore, obese individuals are at higher risk of all-cause mortality <sup>20,21</sup>. Recent data from the Global Burden of Diseases, Injuries, and Risk Factors Study <sup>22</sup> indicate that high body mass index (BMI) was estimated to account for 3.96 million deaths in 2015 in addition to 120.13 million disability -life years in 2015.

Although total body fat mass is associated with elevated health risks, abdominal fat mass has proven to be an independent risk factor for the development of comorbidities such as stroke, coronary heart disease, type II diabetes, sleep apnea, insulin resistance, hypertension, dyslipidemia, inflammation and cancer <sup>23,24</sup>. Abdominal obesity orchestrates important interactions with vital organs and tissues such as the brain <sup>25</sup>, liver <sup>24,25</sup>, skeletal muscles (including the heart) <sup>24,25</sup>, blood vessels <sup>25</sup>, pancreas <sup>24</sup> and renal sinus <sup>24</sup> influencing overall health. In fact, excess adipose fat mass is considered to be one of the largest risk factors for chronic disease morbidity and mortality <sup>20</sup>. Thus, indicating the large impact this form of excess adiposity may have on public health and hence, the importance of addressing adipose fat mass in addition to overall fat mass.

#### 2.1.1 ASSESSING OBESITY

The World Health Organization (WHO) clearly state that health assessment is needed in order to illustrate the dimensions of the obesity epidemic in addition to tracking the trends <sup>17</sup>. Tracking trends is crucial in order to quantify health risks in the population and to govern actions <sup>16</sup>. Even though Magnetic Resonance Imaging and Computed Tomography are considered to be the most valid methods for measuring adiposity, these are costly <sup>26</sup> and are therefore regarded as less suitable for use in large-scale epidemiological and cross sectional surveillance studies. There is a

clear need for robust, although less expensive and more readily available tools and methods for assessing obesity prevalence <sup>16</sup>. Together with skinfolds, BMI and waist circumference (WC) are considered to be simpler methods for estimating excess fat mass compared to more detailed methods such as under water weighing and Magnetic Resonance Imaging. This is in addition to being considered less expensive methods for assessing body composition <sup>27</sup>, especially in large population based studies <sup>28</sup>.

The most commonly ustilized <sup>15,16,29-31</sup> and possibly the most useful, though crude method for assessment of excess adiposity, is BMI <sup>27,31</sup>. Especially in large scale epidemiological studies, where population level measures are of interest <sup>15,16,27</sup>. However, a potential for misclassification exists when using BMI as a measure for estimating body composition in studying adiposity and health <sup>27,31-35</sup>. This limitation is mostly due to the weight-based index's restricted ability to distinguish between fatty tissue and greater-than-average muscularity or skeletal tissue <sup>27,32</sup>. BMI has not been found eligible to accurately distinguish between various types of body mass <sup>31,36</sup>, and should not be used as a predictive measure of metabolic impairments and clinical outcomes <sup>31</sup>. Additionally, large scale studies often base their analysis on self-reported height and weight values to calculate BMI <sup>35</sup>, and the potential for misclassification is especially prominent when height and weight are self-reported <sup>16,17</sup>.

Skinfold measures are an indirect estimation of subcutaneous fat <sup>37</sup>, and are used to estimate body density, which again can be used to estimate a fat percentage by any one of numerous prediction equations <sup>38-40</sup>. Assessing fat percentage by skinfold measurements is considered a widely used method of assessing body composition. It is easy to administer, low in cost and is suitable for large population based studies <sup>37</sup>. However, the precision of skinfold measurements are highly dependent on various methodological quality's such as technician skill, caliper quality, individual differences in the person(s) being measured and the choice or use of prediction equation <sup>37,41</sup>. The error of estimating fat percentage by skinfolds compared to a laboratory based method (such as densitometry) is 3-5 % and is said to be dependent on age, gender and body fatness <sup>42</sup>. In order to increase the reliability of the skinfold measures and limit the risk of bias, instructions have been forwarded <sup>43</sup>, which should be followed.

Measures of abdominal fat mass have shown to be highly correlated with coronary heart disease <sup>30,44</sup>, but the rate of correlation is dependent on the measuring methods used and the chosen predictive equation <sup>30</sup>. WC is considered to be a feasible method for estimating abdominal fat mass, when correlated with the more detailed methods, Computed Tomography <sup>29</sup>. WC as a measure of abdominal fat mass has gained support in the latter years and is becoming a

frequently used way of assessing abdominal fat mass <sup>44,45</sup>. However, the validity of WC in estimating abdominal fat mass has been questioned as Browning et al <sup>46</sup> found that WC did not seem to provide valid estimates of visceral fat mass compared to Magnetic Resonance Imaging. However, given the strong association between abdominal obesity and health <sup>20,23-25,30,44</sup>, the need for using both WC and BMI in assessing health consequences associated with obesity has been highlighted <sup>34,47</sup>, as BMI as a single measure may be underestimating the health risks <sup>47</sup>.

To sum up, the robust nature of BMI measurements together with the widespread use of BMI as outcome measure in large clinical and epidemiological, population level surveys, underlines the importance of BMI as a primary information source  $^{27,34}$ . However, it is of importance to acknowledge more selective measures of adiposity, such as skinfold thickness measurements, and WC as important additional information  $^{27}$ .

#### 2.1.2 OBESITY PREVALENCE

Pooled analysis of trends in BMI from 1975 to 2014 <sup>15</sup>, indicate that there has been an increase in global age-standardized mean BMI values from 1975 to 2014 for males and females, from 21.7kg/m² to 24.2kg/m² and from 22.1kg/m² to 24.4kg/m², respectively. The associated increase in global obesity prevalence rates increased from 3.2% to 10.8% in males and from 6.4% to 14.9% in females from 1975 to 2014 (table 1) <sup>15</sup>. The World Health Organization's annual health statistics report approximates that as many as 20.4% of European males and 23.1% of European females above 20 years are obese <sup>48</sup>. Data from the US are amongst the highest prevalence rates of obesity worldwide, with recently reported obesity prevalence rates of 31.7% for males and 33.9% for females (table 1) <sup>15,16,49</sup>.

**Table 1** The prevalence of obesity globally and in selected developed countries worldwide <sup>15,49-53</sup>, given by percentage, based on waist circumference (WC) and body mass index (BMI), stratified by gender.

	Abdominal obesity by WC (%)				Obese by BMI (%)			
Country	n	Females	n	Males	n	Females	n	Males
Global prevalence rates (2014) 15 *					9.3 mill.	24.4	9.9 mill.	24.2
<i>US</i> (2007-2010) <sup>50 N</sup> *	5591	62.6	5554	42.7				
<i>US</i> (2013-2014) <sup>49 N</sup> *					2817	40.4	2638	35.0
United Kingdom (2008) <sup>51 UN</sup>						25.2		24.4
Denmark (2005-2008) <sup>52 N</sup>					1179	11.0	1070	12.3
<i>Norway</i> (2006-2008) <sup>53 R</sup> *	27171	55.9	22658	31.9	27171	23.1	22658	22.1

The date in years marks the time frame of data collection

Since the 1970s the number of people categorized as overweight or obese in Norway has increased immensely across all ages and socioeconomic groups,  $^{51,54,55}$ . Obesity prevalence rates nearly increased by four times from the time period between 1972-1976  $^{54}$ , to 2013  $^{16}$  in males and nearly doubled in the same time period for females (figure 1) . However, the available data are mainly based on samples from specific regions  $^{51,55}$  and/or use BMI measures solely as a marker for obesity  $^{16,53,54}$ . Thus, the validity and possible generalizability of the reported prevalence rates are questioned.

 $<sup>^{15}</sup>$  all population based studies having measured height and weight in adults (>18 years), unknown whether regional or national

<sup>\*</sup>based on measured height/weight/WC values

N based on national data

R based on regional data

<sup>&</sup>lt;sup>∪N</sup> unknown sample/source

**Table 2** The prevalence of obesity in Norway  $^{16,51,53-55}$  given by percentage, based on waist circumference (WC) and body mass index (BMI), stratified by gender.

	Abdominal obesity by WC (%)				Obese by BMI (%)			
•	n	Females	n	Males	n	Females	n	Males
1972-1976 <sup>54</sup> *					21835	9.9	40328	4.8
1977-1980 <sup>54</sup> *					9690	7.6	9981	5.8
1981-1985 <sup>54</sup> *					3991	7.3	4217	6.7
1986-1990 <sup>54</sup> *					81993	7.7	79561	7.4
1991-1994 <sup>54</sup> *					75973	8.4	69672	8.7
1994-1995 <sup>55</sup> *	3448	35.0	3364	20.8				
1995-2002 <sup>54</sup> *					12654	13.3	10690	15.4
2000-2009 <sup>51 UN</sup>						17.9		21.6
2007-2008 <sup>55</sup> *	6672	54.0	5821	36.5				
2007-2010 <sup>53</sup> * <sup>R</sup>	27171	55.9	22658	31.9	27171	23.1	22658	22.1
$2013^{16\mathrm{UN}}$						18.0		19.1

The date in years marks the time frame of data collection

 $<sup>^{54}</sup>$  all population studies during 1972–2002 involving the Norwegian Institute of Public Health/National Health Screening Service unknown whether regional or national

<sup>\*</sup>based on measured height/weight/WC values

 $<sup>^{\</sup>rm R}\,{\rm based}$  on regional data

UN unknown sample/source

## 2.2 CARDIORESPIRATORY-, MUSCULOSKELETAL AND NEUROMOTOR FITNESS

Cardiorespiratory-, musculoskeletal- and neuromotor fitness are a set of attributes related to the ability to perform physical activity, which again are related to physical fitness, and subsequent health 1,3. As physical fitness is strongly related to physical activity 4, the increasing rise in prevalence rates of physical inactivity will affect the overall physical fitness in the general population and subsequent health 56. Furthermore, a recent review of musculoskeletal health, based on a report by the WHO on ageing and health 57, clearly highlights the tremendous burden of the increasing prevalence of musculoskeletal disease and the effects on health, which by far exceeds that of other non-communicable diseases. Briggs et al <sup>57</sup> point out the strong relationship that has been found between painful musculoskeletal disease and reduced physical fitness, which in turn leads to functional decline, frailty, reduced well-being and the loss of independence. A position-stand by the American College of Sports Medicine (ACSM) on the Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults 4 argue that the evidence is indisputable when it comes to the beneficial effects of exercise. Maintaining or improving cardiorespiratory fitness, muscular strength, flexibility and neuromotor fitness has been found to be essential in preventing disease, in addition to enhancing health, and quality of life 4.58. Furthermore, cardiorespiratory fitness and muscular strength have both been found to provide unique and significant benefits in the prevention and treatment of cardiovascular disease and mortality in addition to several other health and fitness variables 58,59. Neuromuscular exercise has shown to reduce the risk and fear of falls and when combined with muscular strength exercise, neuromuscular exercise has also shown to improve physical function, which in trun relates to the ability to carry out physical activities of daily living 4. Maintaining or improving muscular fitness, flexibility and balance has also been found to be essential for remaining independent during the aging process 4.

Artero et al. <sup>59</sup> further argue the positive effects of muscle mass on adiposity as muscular strength has been found to improve resting metabolic rate, blood glucose levels, basal insulin levels, insulin response and insulin sensitivity, in addition to improved blood pressure and decreased incidence of glycohemoglobin (HbA1c) in diabetics <sup>59,60</sup>. In overweight and obese subjects, greater cardiorespiratory fitness and muscular strength have been found to some degree to counteract an adverse cardiovascular profile <sup>59,61,62</sup>, this in addition to lowering the risk of developing hypertension and chronic inflammation <sup>59</sup>. Muscle strengthening exercises has also been found to have a preventive effect on the increase in fat mass and the attenuation of

intra-abdominal fat in overweight and obese adult females <sup>63</sup>. Furthermore, a recent metaanalysis by Berry et al <sup>64</sup> concluded that unfit subjects had double the risk of mortality, compared to fit subjects, regardless of BMI. Being both obese and inactive or unfit, seems to be associated with the highest risk of mortality and morbidity <sup>62</sup>.

## 2.2.1 ASSESSING CARDIORESPIRATORY-, MUSCULOSKELETAL AND NEUROMOTOR FITNESS

The effects of the rising physical inactivity trends are usually based on measures of physical activity, and often based on self-report 14. Self-reported measures of physical activity may be biased by the overestimation of physical activity rates 14. As physical activity and fitness are closely related <sup>4</sup>, an increase in physical activity may provide benefits in health and fitness outcomes. However, it is of importance to recognize that an increase in physical activity may not induce positive changes in all components of physical fitness 1. Therefore, even though measures of physical activity level may provide information on prevalence of people fulfilling national and/or international recommendations of physical activity for health, these measures cannot give valid estimations or measures of cardiovascular-, musculoskeletal and neuromotor fitness. Suni et al 65 clearly state the importance of assessing and monitoring both physical activity levels and health related fitness as an important public health measure in order to intervene with intent to increase population levels of physical activity and physical fitness in addition to monitor different aspects of physical activity and fitness. Up to date research is therefore crucial for creating data on physical fitness, in order to continue the work of health promotion, for provision of a representative base for comparison nationally and internationally, and to create reference values 66,67.

Recent years, there has been a marked change in the way of thinking about physical fitness and the assessment of aspects related to physical fitness <sup>68</sup>. There has been an increased recognition of the concept of physical fitness as multidimentional, comprizing several abilities <sup>68</sup>. Simultaneously, former methods of assessing physical fitness have been developed throughout several decades and largely reflect the development within this field of research and the subsequent recognition for the concept of physical fitness and also health-related physical fitness <sup>68</sup>. Comprehensive and well-established assessment methods for surveillance is fundamental in the work of physical activity and public health, especially in order to track trends and guide policy and practice <sup>11,69</sup>. However, both the development and implementation of comprehensive assessment methods for tracking and monitoring trends, is dependent on capacity and recourses <sup>11</sup>. The ACSM <sup>2</sup> clearly state that the ideal health-related physical fitness assessment methods are *reliable*, *valid*, *relatively inexpensive and easy to administer* <sup>2, p. 61</sup>.

Furthermore, the ACSM <sup>2</sup> state that the tests should be applicable for comparison to normative values, they should be able to be indicative for the status of health-related physical fitness and be able to reflect a change in health-related physical fitness induced by interventions. The number of different field-based methods for assessing physical fitness seems to be large and the standardization of assessment methods is assumed to be of importance as it allows for the comparison of results in addition to allowing for tracking of trends. As a result in the recent years development and the increasing scientific knowledge of the importance of physical fitness as an important indicator of a person's health, Suni et al 70 developed the ALPHA-FIT test battery. The ALPHA-FIT test battery consists of evidence based instruments for assessing physical fitness in a comparable way within the European Union. The ALPHA-FIT test battery was developed based on thorough literature review by an expert panel and the aim was to create a reliable, valid and easily applicable assessment battery for assessing and monitoring health-related physical fitness. The implication of evidence based assessment methods that are valid, reliable and easily applicable, such as the ALPHA-FIT Test Battery for Adults is crucial for monitoring trends at population level and for governing actions in addition to allowing for comparison to normative values 70.

## 2.2.2 TRACKING CARDIORESPIRATORY-, MUSCULOSKELETAL- AND NEUROMOTOR FITNESS

Due to the highly increased health and mortality risks associated with reduced physical activity 11-13, and the strong relation between physical activity and physical fitness 4, the subsequent consequences of the increasing physical inactivity rates on physical fitness are questioned. Reference values for cardiorespiratory fitness in Norway have been published recently 72. However, information on the status of muscular endurance, muscular strength and flexibility is scarce. Most of the existing literature has assessed almost solely hand-grip strength 73-78. The latest published Scandinavian data on musculoskeletal and neuromotor fitness are two Norwegian regional studies of 566 adults and elderly (20-94 yrs.) <sup>76</sup> and 370 adults and elderly (18-90 yrs.) <sup>79</sup> in addition to a national Danish study of 3471 males and females (19-72yr) <sup>73</sup>. However, these Scandinavian studies cover only four aspects of musculoskeletal and neuromotor fitness (pinch grip, hand-grip strength, flexibility and lower limb extension power). The latest published normative data on field based musculoskeletal and neuromotor fitness tests covering various elements are those of Rikli and Jones 80 studying older adults aged 60-94 years (N=7183), and data published by the ACSM 81, based on Canadian normative values published in 2000 82. Additionally, Suni et al 70 published reference values for adult on balance, power, and muscular endurance, based on data derived from two unknown Finnish population studies, conducted by the UKK institute in addition to muscular strength based on data derived from the

text book of Eurofit for adults, in where the sample is unknown. Thereby, normative data on various measures of musculoskeletal and neuromotor fitness is lacking. Furthermore, most of the published normative data are presented by various centiles <sup>70,83,84</sup> or as differently ranked values <sup>70,83</sup> making comparisons difficult.

## 2.2.3 MUSCULOSKELETAL- AND NEUROMOTOR FITNESS AND IT'S RELATION TO AGE AND GENDER

Physical fitness decreases with increasing age, but at varying rates 73,76,77,85-88, and is dependent on lifestyle and physical health earlier in life 89. Muscular strength seems to decrease from between the age of 40-50 years 73,76,77,86 and muscular endurance seems to decrease from between the age of 20-30 years 88. Bø & Hagen 85 further claim musculoskeletal fitness in the form of flexibility, balance and dynamic muscular endurance to decrease markedly after the age of 51 years. Furthermore, in muscular strength, muscular endurance, balance, flexibility and explosive power, clear gender differences have been reported. The main literature indicates that males display significantly higher mean scores on muscle strength 73,86 and balance 85, compared to females and that females generally display higher scores on flexibility compared to males 80,81,90. However, inconsistencies in gender differences on muscular endurance of the back 88 and flexibility of the shoulder 85,90,91 have been reported, which renders some uncertainty as to how clear possible gender differences in musculoskeletal and neuromotor fitness really are.

#### 2.2.4 MUSCULOSKELETAL- AND NEUROMOTOR FITNESS AND OBESITY

Studies that have investigated the relationship between musculoskeletal- and neuromotor fitness and obesity are limited. Most studies reported an inverse relationship between various aspects of musculoskeletal and neuromotor fitness and obesity measured by BMI or WC <sup>73,92-94</sup>, where scores on musculoskeletal and neuromotor fitness declined with increasing BMI or WC or were higher in the obese categories. Some studies have, however, found positive correlations between handgrip strength and BMI <sup>92,93</sup>. Hence, the association between various aspects of musculoskeletal and neuromotor fitness and selected measures of obesity is unclear.

#### 2.3 EXERCISE INTERVENTIONS

The WHO global action plan for non-communicable diseases 2013-2020 <sup>95</sup>, addresses both obesity and physical inactivity as priority global targets, aiming at reducing the prevalence of insufficient physical activity by 10% and aiming at halting the rise in obesity prevalence rates. Effective strategies for promoting physical activity are needed <sup>11</sup> and it is stated that countries must effectively intervene on major determinants of obesity which may be problematic in an already obesogenic environment, in order to counter the increasing adverse health effects of the rising overweight and obesity trends <sup>16,52</sup>. Strong evidence shows that physical activity interventions are capable of increasing physical activity levels to where significant health benefits are achieved <sup>96,99</sup>. The need to further build a solid evidence base for effective programs and promotion strategies for increasing physical activity is key in addressing the increasing physical inactivity rates <sup>11</sup>. The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines <sup>100</sup> further highlight the need to study effective lifestyle interventions delivered by remote, technological modes such as the internet, telephone, DVD or possibly a combination of these, which induce clinically significant changes in body composition.

#### 2.3.1 INTERVENTIONS BY VARIOUS TECHNOLOGICAL MODES

The implementation of modern technology has generated effective modes of enhancing health behavior change such as physical activity, healthy diets and weight reduction <sup>13,98,99,101-106</sup>. These modern technological modes, including online chat rooms, text messaging or e-mail, self-monitoring with smartphone/mobile device, and Web-based modes are less comprehensive and less resource demanding compared to more traditional modes <sup>101</sup>. Additionally, several recently conducted systematic reviews and/or meta-analyses <sup>101-103</sup> conclude that technology assisted interventions, may indeed induce significant weight loss, in overweight and obese adults, in addition to potentially yielding positive effects on physical activity level <sup>13,98,99</sup>. However, Reis et al <sup>107</sup> emphasize the need for "more rigorous" real-world physical activity interventions as an approach in getting people more physically active. Recently published guidelines to manage obesity by the Obesity Society and American College of Cardiology/American Heart Association task force on practice guidelines <sup>100</sup> clearly state that remote lifestyle interventions using the telephone, mobile, internet or similar modes of delivery, need to be evaluated in terms of efficacy to clarify whether or not interventions with such modes of delivery are capable of achieving clinically meaningful weight loss.

Recently published reviews of interventions aiming at increasing physical activity levels, using various modes of delivery, report several methodological limitations <sup>96,97,99,108,109</sup>. Many previous

interventions have been reported to have low study quality, in the sense that they usually use a treatment control group and thereby lack a no-intervention control group, display high attrition-rate, lack in sufficient reporting of study components and the prevalence of studies with an intervention duration of six months or more is low <sup>96,97,99,109</sup>. Furthermore, remote lifestyle interventions using the telephone and mobile have been encouraged <sup>100</sup>, and have been found to yield effective results in weight loss <sup>96,98,101</sup>. However, most mobile health interventions have used SMS as a mode of delivery <sup>98</sup>, and few were found to have included personal contact <sup>98,99</sup>. Personal contact has been suggested to be a crucial component of effective interventions aiming at increasing physical activity, in addition to tailored interventions <sup>96,97</sup>, and including these components to an intervention design is thereby considered to be of importance.

## 2.3.2 EFFECTS OF TECHNOLOGY BASED EXERCISE INTERVENTIONS ON CARDIORESPIRATORY, MUSCULOSKELETAL- AND NEUROMOTOR FITNESS

Several studies have investigated the effect of a physical activity intervention by mobile  $^{98}$  and/or electronic modes  $^{99}$ , though primary outcome was either objectively assessed or self-reported physical activity level. Only three previous studies  $^{110\cdot112}$  were found having used newer, supposedly less expensive modes of delivering interventions investigating the effect on components of physical fitness. However, only two aspects of physical fitness were studied in these studies, namely, hand grip strength  $^{111}$  and cardiorespiratory fitness (CRF) by  $VO_2$ max  $^{110,112}$ . Thus, studies reporting effects of interventions on musculoskeletal- and neuromotor fitness and are scarce.

#### 2.3.3 EFFECTS OF TECHNOLOGY BASED EXERCISE INTERVENTIONS ON OBESITY

Even though previous studies using alternative modes of reach have proven to be capable strategies for reducing weight <sup>101-103,113</sup>, there is a need for further high-quality research into in this field <sup>101-104,113,114</sup>. There are several reasons for this. Firstly, conclusions are difficult to draw, due to the wide variation in intervention components, such as study design <sup>103</sup>, the use of self-reported measures of primary outcome (including self-reported weight loss) <sup>103,114</sup>, small sample sizes <sup>101-103</sup>, inconsistency in the reported effectiveness of different interventions <sup>114</sup> and partly also due to poor study quality (including poor reporting) <sup>103,104,113,114</sup>. Moreover, some of the emphasized limitations regarding previous studies was due to the lack of information on the quality related components of the different interventions, such as allocation, blinding, randomization, intervention components, and bias <sup>103,114</sup>. Additionally, the majority of previous studies report only weight change, weight, or BMI as primary weight outcomes <sup>102,113</sup>. Liu et al <sup>102</sup> and Allen et al <sup>101</sup> have both clearly addressed the need to better understand the effect of mobile based weight loss/weight management interventions on WC and body fat percentage. Ortega et

al  $^{115}$  emphasize the importance of focusing on CRF, rather than merely on weight/fat loss, as CRF has been found to attenuate the adverse health related consequences of obesity. However, the changes induced by CRF may not provide the same metabolic stress with following changes in body composition and thereby the same changes in health status as resistance training does  $^{116,117}$ . Thus, the importance of combining resistance training with CRF as part of the exercise program for fat or obese individuals  $^{115-117}$ , rather than focusing merely on CRF or on creating energy imbalance, has been highlighted  $^{117}$ .

#### 2.4 KNOWLEDGE GAPS

The WHO's global action plan for non-communicable diseases 2013-2020 95, address both obesity and physical inactivity as priority global targets. A 10% reduction in insufficient physical activity and halting the rise in obesity prevalence rates, have been highlighted as being two separate, but important voluntary global targets in WHO's action plan 95.

Therefore, given the above, there is a need for objectively measured data on various measures of body composition, assessed using robust measuring methods, in order to evaluate the progress in the obesity trends in Norway. Additionally, the necessity of assessing the status of musculoskeletal and neuromotor fitness in the Norwegian population is important, both in order to ensure progression in the global target set forth by the WHO, in addition to quantify the possible health risks in the population and to govern actions.

The need for effective, public health measures in order to address rising obesity and physical inactivity rates is crucial in reaching objectives of the WHO's global action plan for non-communicable diseases 2013-2020 95. The main limitation of existing interventions aiming at increasing physical activity levels/physical fitness and reducing obesity is the lack in study quality 96,97,99,101-104,108,109,113,114. Hence, there is a further need for adequately reported randomized controlled trials, investigating the effect of a possibly low-cost exercise interventions delivered by alternative technological modes on various objective measures of body composition, musculoskeletal- and neuromotor fitness and CRF.

#### **3.0 AIMS**

The overall purpose of this thesis was to investigate the status of various aspects of health-related physical fitness and to assess the effect of a six-month tailored telephone- and email based exercise intervention on various aspects of health-related physical fitness.

The aims of the separate papers were as follows:

#### PAPER I

The primary aim of the paper I was to describe the sensitivity of BMI, WC and fat mass percentage derived from skinfolds in the classification of overweight and obesity. The secondary aim was to describe the prevalence of overweight and obesity using different measurement methods in a national sample of Norwegian adults and elderly.

#### PAPER II

The aims for paper II were to a) establish normative values of musculoskeletal and neuromotor fitness by age and gender covering a wide range of musculoskeletal and neuromotor fitness, and b) to assess how much of the variance in musculoskeletal and neuromotor fitness can be explained by obesity in a sample of adult Norwegian males and females aged 20–65 years.

#### PAPER III

The aim of paper III was to assess the effect of a six-month tailored telephone and email based exercise intervention on cardiorespiratory-, musculoskeletal and neuromotor fitness in a sample of initially physically inactive adults.

#### PAPER IV

The aim of paper IV was to assess the effect of a tailored telephone and email based exercise intervention on various measures of body composition in a sample of apparently healthy and initially physically inactive adults.

### 4.0 MATERIALS AND METHODS

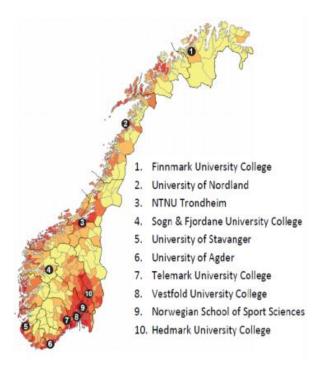
The present thesis is based upon two studies, a national cross-sectional study (*PAPERS I and II*) and a parallel group randomized controlled trial (*PAPERS III and IV*). As these studies are separate and considered to differ largely in methodology and design, the studies will be described and presented separately.

# 4.1 PAPER I AND II – THE NORWEGIAN PHYSICAL ACTIVITY SURVEILLANCE STUDY

PAPER I and II are based on the national multicentered cross-sectional study the Norwegian Physical Activity Surveillance Study (NPASS) 72,118, which assessed physical activity level and correlates for physical activity in addition to physical fitness in a sample of Norwegian adults and older people (20–85 years). The NPASS study was initiated and funded by the Norwegian Directorate of Health and lead by the Norwegian School of Sport Sciences. It was approved by the Regional Committees for Medical and Health Research Ethics South East B (REK Sør-Øst B, S-08046b) in addition to the Norwegian Social Science Data Services (**Appendix 1**). Written consent was obtained from all volunteering participants prior to assessment (**Appendix 2**).

#### 4.1.1 DESIGN

The NPASS study consisted of two data collecting phases. Phase I was conducted in 2008-09 and included the objective assessment of physical activity level using the ActiGraph GT1M accelerometer (ActiGraph, LLC) and the collection of correlates for physical activity through a questionnaire  $^{118}$ . Phase II was conducted in 2009 and assessed various aspects of physical fitness, including  $VO_2$ max, musculoskeletal and neuromotor fitness, blood pressure, lung capacity and body composition  $^{72,119,120}$ . A total of ten test centers across Norway were involved in the data collection in phase I and all test centers, except one, were involved in phase II (figure 1).



**Figure 1** A map presenting the geographical areas in which the test centers, involved in phase I in the NPASS study, were located. Test center 8. Vestfold University College was not involved in phase II of the NPASS study.

## **4.1.2 SAMPLE**

The Norwegian national population registry randomly selected a representative sample of 11515 men and women ranging in age from 20 to 85 years, covering 126 municipalities from the geographical areas surrounding the test centers involved (figure 1). Of these, a total of 3800 volunteered and a total of 3465 were assessed and found valid for inclusion in analysis in phase I (table 3). A random sample of 1930 individuals who took part in phase I, were invited by letter to take part in phase II. Of these, we obtained telephone contact with 1368 in which 1030 accepted the invitation and 904 predominantly Caucasian 72 participants showed up for assessment in phase II. In *PAPER I*, all 904 participants were included in the analysis. In *PAPER II*, only the adults, ranging in age from 20.0 - 64.9 years were included in the analysis, which equaled a sample size of 726 (table 3). An extensive non-response analysis was conducted for phase I invitees. This analysis displayed a selection bias with respect to educational status, where responders displayed a higher educational status compared to non-responders <sup>118</sup>.

**Table 3** The recruitment process for *PAPER I* and *II*.

Enrollment	11 515 adults were drawn from the norwegian national population registry
Phase I	3 464 were included in phase I
	11 248 were invited (adress available)
	3 800 volunteered
Phase II	Included in phase II (n=904)
	1 930 were invited to take part in Phase II
	1 368 we obtained contact with
	1 030 accepted the invitation
	f DADED I

Included in analysis for	PAPER I	PAPER II
	904 adults and elderly (aged 20.0-85.0 yrs.)	726 adults (aged 20.0-64.9 yrs.)
	Females 441 Males 463	Females 350 Males 376

## 4.1.3 PROCEDURES AND MEASURES

All objective measures in phase II of the NPASS study, were conducted at the test centers involved in the data collection (figure 1) in the period from April 2009 to January 2010.

## PAPER I

The main outcome measures in *PAPER I* were body weight, height, WC and skinfold measures. BMI, body density and fat percentage (FP<sup>Skf</sup>) were calculated based on the recorded body compositional measures. All body compositional measures were conducted by trained investigators following a detailed test protocol and all measuring instruments were calibrated prior to testing.

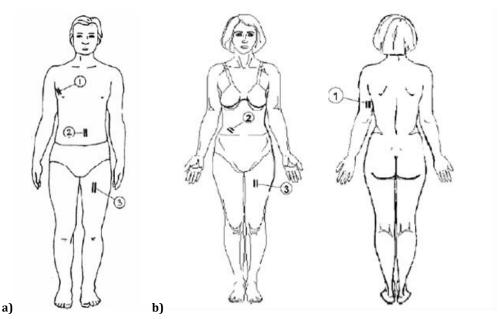
**Table 4** The measuring instruments used to assess body composition in the NPASS study, given by type (brand) and number of participants undergoing the measures (n).

## **Measuring instrument**

Height	n	Weight	n	Skinfolds	n
KaWe (KIRCHNER & WILHELM GmbH + Co. KG, Germany)	566	Seca 770 (Seca, Germany)	391	Harpenden caliper (Baty Intervnational, UK)	273
Measuring band on wall	160	Inbody 720 (Biospace Inc)	101	Lange caliper (Beta Technology Inc., USA)	250
Seca 222 (Seca, Germany)	100	Terrallion (UK)	100		
Seca stadiometer (Seca, Germany)	78	Point digital weight scale	81		
		Tanita TBF 521 (USA)	81		
		Bosch (Bosch, Germany)	79		
		A&D UC321 (A & D Instruments Ltd., Germany)	71		

Body weight was recorded by one of seven weight scales (table ), to the nearest 0.1 kg, with the 4participant wearing underwear and a t-shirt. Height was assessed to the nearest centimeter using one of four stadiometers (table 4). The participants were instructed to stand upright with a straight body facing forward, with their heels touching the wall and without shoes. BMI was calculated by weight (kilogram)/ height (meters)<sup>2</sup> <sup>121</sup>. The BMI values were categorized based on cut-off values developed by the WHO $^{27}$ . Thereby, participants with BMI values of < 18.5 kg/m $^{2}$ were categorized as underweight, 18.5-24.9 kg/m<sup>2</sup> as normal weight, 25.0-29.9 kg/m<sup>2</sup> as overweight and those registered with BMI values  $\geq 30.0 \text{ kg/m}^2$  were categorized as obese  $^{27}$ . Furthermore, participants with BMI values of 30–34.9, 35–39.9 and ≥40.0 kg/m<sup>2</sup> were categorized in obesity class I, class II and class III, respectively 27. WC was recorded at the midpoint between the upper most lateral part of the iliac crest and the lowest most lateral point of the ribcage, following a protocol developed by the WHO<sup>122</sup>. Using a measuring band, two measures were conducted at the end of expiration. The mean of these two measures were recorded to the nearest half centimeter. Based on cut-off values presented by the WHO 27, men and women with WC values of ≥94 cm and ≥80 cm, respectively, were categorized as abdominally overweight and men and women with WC values ≥ 102 cm and ≥88 cm, respectively, were categorized as abdominally obese. Skinfolds were either measured using a Harpenden caliper (Baty International, UK) or Lange caliper (Beta Technology Inc., USA), depending on availability (table 4). The following three skinfold sites were measured in men

(figure 2a): chest, abdomen and thigh. For women (figure 2b), the triceps, suprailiac and thigh were assessed for skinfolds. Each site was measured twice and the mean of two measures were recorded to the nearest millimeter and the summation of skinfold values were used to calculate body density <sup>38,39</sup>. Based on the calculated estimates for body density, the Siri equation<sup>123</sup> was used to calculate fat percentage by skinfolds. As the equations for body density have only been developed for men aged 18-61 years and for women aged 18-55 years, the fat percentages by skinfolds were only calculated for men 20-60 years and women 20-55 years. Hence, in PAPER I, slightly fewer participants were registered with estimates of fat percentage by skinfolds compared with number of participants registered with WC and BMI. Additionally, in order to define obesity based on fat percentage by skinfolds, cut-off values developed by Lohman et al 124 were used. As the equations for body density were only developed for women and men aged 20-55 and 20-60 years respectively, fat percentage by skinfolds was only calculated for these age groups. This way, men with fat percentage by skinfolds values >22% at the age of 18-34 years, >25% at the age of 35–55 years, and >23% at the age of >55 years, were defined as obese. The equivalent fat percentage by skinfolds values for women were >35% at the age of 18-34 years and >38% at the age of 35-55 years.



**Figure 2a and b** The three skinfold sites measured on males: a): chest (1), abdomen (2) and thigh (3), and females: b) the triceps (1), suprailiac (2) and thigh (3).

Covariates for *PAPER I* were age, gender, educational level and income level, which were assessed by questionnaire, developed for the NPASS study. Participants aged 20 to 64.9 years were defined as adults and participants aged 65 to 85 were defined as older people <sup>125</sup>. Educational level was divided into four categories: completed less than High School, completed High School, completed three years or less of College/University and completed four years or more at College/University.

PAPER II The selection of field based measuring methods for assessing musculoskeletal and neuromotor fitness in the NPASS study was based on the ALPHA-FIT test battery developed by Suni et al <sup>70</sup>. Therefore, the main outcome measures in *PAPER II* were nine tests which were carried out in the following order (table 5); Muscular endurance of the upper body was measured by the static back extension test (SBE)<sup>126</sup>. Grip strength was recorded by the Handgrip strength test (HGS)<sup>127,128</sup>. Neuromuscular fitness was measured as balance, using the one leg standing test (OLS)<sup>126</sup>. Muscular dynamic endurance and ability to stabilize the upper body was assessed using the modified push-ups test (MPU)<sup>126</sup>. If the participants were not able to complete the modified push-ups test, the modified push-ups test was carried out on the knees (MPUK). Flexibility of the hamstrings musculature and the shoulder joint, were assessed by the sit-and-reach test (SR)<sup>129</sup> and the back-scratch test (BSC)<sup>130</sup>, respectively. The mean of the back-scratch test for the left and the right arm resulted in a mean back-scratch test variable, which is the only back-scratch test variable used in this thesis. Explosive power in the lower extremities was measured by the vertical jump test (VJ)<sup>126</sup> and on a power platform test (EPP) (HurLabs Force platform). Data on VO<sub>2</sub>max from the NPASS study are published elsewhere <sup>72</sup>.

**Table 5** Measuring methods used to assess musculoskeletal and neuromotor fitness.

#### Muscular endurance

Muscular endurance was measured by the static back extension (SBE) test (Suni, 2000). The participants lay face down on a 15 centimeter (cm) tall, 18 cm broad and 135 cm long bench with their spina iliaca anterior superior lined with the bench's short side, leaving the upper body in a horizontal position for a s long as they could and the time the participants managed to hold a horizontal position was recorded (min 0 seconds (sec), max 240 sec.).

Muscular dynamic endurance and ability to stabilize the upper body was measured by *the modified push-ups (MPU) test* (Suni, 2000). The participants lay face down on the floor, with their arms alongside their body. The test was initiated by the participants touching the side of their hips, followed by an ordinary push-up with the body held straight. All push-ups where the participants placed the one hand over the other while the albows were extended were counted. Those participants who were not able to perform the MPU with a straight body, performed the test on their knees (MPUK). The number of repetitions completed in 40 sec. were recorded. MPU and MPUK test scores were recorded separately.



#### Muscular strength

Muscular strength was measured by handgrip strength (HGS) test (Al Snih et al, 2002; Sasaki et al, 2007) using a hydraulic dynamometer (Chattanooga, Hixon, USA). The participants were to stand up straight with their arms hanging down alongside their body, about 10 cm out from the body. The dominant hand held the dynamometer. The best of three attempts was recorded to the nearest 1



The vertical jump (VJ) test (Suni, 2000) measured explosive power in the lower extremities. The participants were to stand with a foot of choice alongside the wall. With a piece of chalk, the participants reached up the wall, as high as possible, setting a mark on the wall. The participants then stood one foot away from the wall and were instructed to jump as high as possible, setting a mark on the wall with the chalk at peak height of the jump. The distance between the chalk mark set at standing height and that set at peak jumping height was recorded to the nearest cm.

The explosive power (EPP) test measured on a power platform (HurLabs Forceplatform), registered explosive power in the lower extremity. The participants were instructed to stand on the middle of the power platform, the feet placed with a shoulder width distance apart and hands on the hips. The arms were to stay on the hips throughout the jump. The participants were instructed to jump as high as possible. The best of three results was recorded in cm.





## Flexibility

Flexibility of the hamstring musculature was measured by *the sit and reach (SR) test* (Presidents council on Physical Fitness and Sports, 2008). A specially designed box was placed to a wall and the participants sat on the floor with their knees and upper body straight, and their heels against the box. The participants leant as far along the measuring tape on top of the box as possible, with one hand on top of the other and the back and legs straight. The furthest the participants managed to stretch their hands along the measuring tape and hold for two seconds, was recorded to the nearest half cm. Point zero, the point where the feet met the box was set at 23 cm from the box's edge, and the recorded result was 23 cm plus or minus the distance from point zero.

The back scratch (BSC) test (Rikli and Jones, 1999) measured flexibility in the shoulder joint. The participants were standing upright, placing one hand on the lower back, moving it up the participants spine toward their head. The opposite hand was placed on the participants neck, moving it down the spine, aiming to place the long finger of each hand as near each other as possible or to overlap. The procedure was repeated with opposite hands. The gap between the fingertips of the long finger of both hands was measured to the nearest half centimeter. The results were recorded to the nearest half cm, as positive numbers as long as the fingers overlapped and with negative numbers if the fingers did not meet or overlap.



# No.



## Balance

Balance was recorded by means of *the one leg standing (OLS) test* (Suni, 2000). The participants were instructed to stand on one optional leg, facing a mark at eye height on a wall three meters away. The non-balancing legs heel was to be placed in the knee joint of the supporting leg and the knee was to be rotated externally. The participants arms hung alongside their body. The total time the participants managed to hold the initial balancing position was recorded in sec. If the participants managed to hold the position for 60 sec, the same test procedure was repeated, only blinded. Both test times were recorded separately and summed.

Covariates for *PAPER II* were: age, gender, educational level, height, body weight and WC, as described under measuring methods for *PAPER I*. Based on the assessed body compositional measures, BMI was calculated (kg/m²). The BMI and WC values were further grouped based on cut-off points developed by the WHO<sup>27</sup> as previously described. Age was used as a continuous variable in addition to being used as a categorical variable dividing the sample into ten-year age groups.

A health risk assessment, aiming to eliminate participants potentially at health risk, was conducted prior the physical fitness assessments in order to assure the safety of the participant in conjunction with the physical testing. The assessment consisted of a questionnaire comprising elements of general health status. None of the participants were considered to be at risk. All participants went through a test of CRF (by VO<sub>2</sub>max, described under methods for *PAPER III*) before the musculoskeletal and neuromotor fitness tests were conducted. All measures were conducted by trained instructors following a detailed test protocol and all measuring instruments were calibrated prior to assessment.

## 4.4.4 ANALYSIS

Data for *PAPER I* was analyzed using IBM SPSS Statistics 19 (IBM Corporation, Route, Somers, NY, USA) and data for *PAPER II* was analyzed using IBM SPSS Statistics 22 (IBM Corporation, Route, Somers, NY, USA). A statistical significance value of probability was set to p < 0.05 for all analyses for both *PAPER I* and *II*. Sample characteristics are displayed by number (n), mean and standard deviation (SD), split by gender. To assess possible gender differences in the continuous variables, an independent samples *t*-test was used. For categorical variables, a chi² test was used. Based on BMI scores, six participants were classified as underweight and the lowest BMI score was  $17.4 \text{ kg/m}^2$ . As the lowest BMI score was only  $1.1 \text{kg/m}^2$  lower than the cut-off for normal weight, the underweight participants were grouped in the normal weight category for all analyses in both papers.

PAPER I Both prevalence results and results on the sensitivity and specificity are given in percentage. To assess the sensitivity and specificity of the different body compositional assessment methods, the overweight categories for BMI and WC were added to the obesity categories for BMI and WC respectively, before a cross-tabulation test was run. Furthermore, a receiver operating characteristic curve (ROC) was created where obesity defined by fat percentage by skinfolds, was used as the state variable. Area under the curve (AUC) was given by AUC value and 95% confidence interval (95% CI).

**PAPER II** All musculoskeletal and neuromotor fitness test results were normally distributed, except for the results from the balance test by one-leg-standing, which had a ceiling effect. The normative values for musculoskeletal and neuromotor fitness were given by mean ± standard deviation (SD), displayed by gender and 10-year age groups. An independent samples t-test was used to analyze for possible gender differences on all musculoskeletal and neuromotor fitness tests, except for the one-leg-standing summed variable where a Mann Whitney U test was used. Furthermore, a standard multiple regression analysis was used to analyze how much of the variance in musculoskeletal and neuromotor fitness could possibly be explained by age and obesity by WC (see *PAPER II*).

## 4.2 PAPER III AND IV - THE ACTIVE IN SOUTHERN NORWAY STUDY

PAPER III and IV were based on the regional parallel group randomized controlled trial Active in Southern Norway study (AISN) which investigated the effects of a six-month tailored exercise intervention on physical fitness and body composition among initially physically inactive adults, aged 40-55 years. The AISN study was initiated and lead by the University of Agder and approved by the Regional Committees for Medical and Health Research Ethics South East D (REK Sør-Øst, D, ref. no. 2010/2371-1) (**Appendix III**), in addition to being registered in ClinicalTrials.gov (NCT03164239) and the Norwegian Social Science Data Services (project no. 28023, 2011). All participants signed a written consent prior to intervention commencement, to sign up for the study (**Appendix IV**).

## **4.2.1 DESIGN**

The AISN study randomly assigned participants to one of the following two groups; an intervention group and a no-information control group, by random allocation numbering in SPSS, stratified by gender. This random allocation was conducted by a third party who did not have any further involvement in the study. The study administrators (coordinator, project manager), and data collectors were blinded for group allocation. The person counselling the participants in the intervention group, was solely responsible for delivering information on group allocation and for delivering the intervention to the intervention group, including being responsible for the counselling sessions.

The intervention commenced in April, 2011 and was ended in October, 2011. It consisted of a) tailored exercise programs for self-administration, developed based on national- and international recommendations for physical activity <sup>131</sup> and a national Norwegian report on physical inactivity <sup>132</sup> (table 7), and b) fortnightly counseling sessions based on motivational interviewing <sup>133</sup> alternately by telephone or email, all given by a trained person with a master's degree in sport sciences, who had no further involvement in data collection and/or group allocation (table 6).

**Table 6** The design synopsis for the Active in Southern Norway study.

	INTERVENTION DESIGN	
	Intervention group	Control group
Baseline	All volunteered participants went through a health-related physical fitness assess assessing VO $_2$ max, musculoskeletal- and neuromotor fitness, body composition and a questionnain physical activity (see measuring methods)	
At intervention start	Intervention package I was distributed and consisted of  1. A letter containing information on group allocation, individual results on health-related physical fitness assessment at baseline, information on reccommendations for physical activity, prompts and reminders (i.e. taking the stairs instead of the elevator, walk/cycle to work).  2. A leaflet on national dietary recommendations  3. One of three tailored exercise programs.	Received information or group allocation
1 <sup>st</sup> month	Self-administered exercise based on the 1 <sup>st</sup> intervention package. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email. An instruction form based on MI containing predefined questions and topics was used in these councelling sessions.	NF
2 <sup>nd</sup> month	<b>Self-administrered excersise</b> based on the 1 <sup>st</sup> intervention package. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email.	NF
3 <sup>rd</sup> month	Intervention package II was distributed and consisted of  1. A letter containing information on the second intervention package, what this intervention package added compared to the first intervention package in addition to providing information on the further progress of the intervention  2. A tailored exercise program based on the exercise program from the first intervention package, aiming at ensuring progression.  3. Self-administrered exercise based on the 2 <sup>nd</sup> intervention package.  4. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email.	NF
4 <sup>th</sup> month	$\label{eq:Self-administrered excersise} \textbf{ Based on the 2}^{nd} \textbf{ intervention package}.$ Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email.	NF
5 <sup>th</sup> month	Intervention package III was distributed and consisted of  1. A letter containing information on the third intervention package, what this intervention package added in addition to the information given in the previous two intervention packages.  2. A tailored exercise program based on the exercise program from the first and second intervention packages, aiming at ensuring progression.	NF
6 <sup>th</sup> month	<b>Self-administrered exercise</b> based on the $3^{\rm rd}$ intervention package. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email.	NF

NF received no follow-up

To facilitate tailoring of the self-administered intervention, ensure progress, enhance motivation and prevent the high drop-out rates previously experienced in some electronic and mobile health interventions <sup>98,99</sup>, three intervention packages were distributed to the intervention group every two months by email or post (table 6). Intervention package I was distributed at intervention start and consisted of: written individual feedback on baseline health-related physical fitness (i.e. body composition, CRF and musculoskeletal and neuromotor fitness), a letter informing the participants of national and international recommendations for physical activity and its associated health benefits, a leaflet on national dietary recommendations <sup>134</sup>, prompts and reminders, and one of three tailored exercise programs (table 7). Furthermore, the

physical activity (see measuring methods)

participants were recommended to increase their daily physical activity level, advised on how to obtain exercise equipment (either by utilizing household or otherwise comparable equipment or by purchasing equipment). Additionally, they were informed of possible natural variations in physical activity level, especially declines in physical activity level due to chance or unforeseen events, in order to prevent the perception of failure due to probable variations in physical activity level. The second and third intervention packages were distributed two and four months into the intervention period (table 6), respectively, to accompany the progression in physical activity level, to ensure variation and progression in types of exercise if desirable, and to enhance motivation.

Three different exercise programs (table 7) were designed based on the total amount of days per week the participants reported being physically active at baseline. This way the participants were categorized into one of three predefined physical activity frequency levels. The participants were thereby recommended to engage in either two, three, or four physical activity sessions a week during the first two months, amounting in a one day increase in physical activity level from baseline reporting's. Participants in the intervention group who reported not engaging in physical activity at baseline, were recommended to increase their physical activity level with two days. In both intervention package II and III a further one and two day increase in physical activity level per week from baseline was recommended. All exercise programs recommended participants to engage in both musculoskeletal- and neuromotor exercises and cardiorespiratory exercise. For each exercise program, seven different strength-training programs were developed for different arenas of exercise and for the utility of different types of equipment using EXORLive <sup>135</sup>. The seven different strength training programs had the following strength training focus arenas: at home, at work, at the gym, outdoors, in water, strength training with a large exercise ball and strength training with a resistance band. Additionally, participants in the intervention group were further recommended to engage in 20-60 minutes CRF exercise of choise, and after two months, the possibility of engaging in interval training was introduced (see table 7). Numerous examples of cardiorespiratory exercise were given for different arenas of exercise, such as walk/run, Nordic walking (with rods), cycling/spinning, dance/aerobic, swimming/water gymnastics, ball games, rowing, skiing/skating, housework, gardening, active games/play, step/ellipse, tennis/badminton/squash, golf or other cardiorespiratory exercises (table 7). This was done to meet individual preferences in interests and physical function (table 7), and together with the individual councelling on the recommended exercise, this was part of the tailoring to individual needs and preferences. Additionally, the participants were given prompts and reminders.. The control group did not

receive any follow-up during the intervention period. However, they received similar follow-up as the intervention group after completing post-test.

**Table 7** A schematic overview of the tailored exercise programs.

			Tailored exercise program	*
		1	2	3
	Amount of exercise sessions	2	3	4
1 <sup>st</sup> intervention	Cardiorespiratory exercise	1 session Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	2 sessions Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.
package	Strength, balance and flexibility exercise	1 session Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	1 session Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	2 sessions Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.
	Amount of exercise sessions	3	4	5
2 <sup>nd</sup> intervention package	Cardiorespiratory exercise	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training
	Strength, balance and flexibility exercise	1 session Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.
	Amount of exercise sessions	4	5	6 (1 session of choise)
3 <sup>rd</sup> intervention package	Cardiorespiratory exercise	2 sessions Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training
	Strength, balance and flexibility exercise  2 sessions  Program of choice STT Sets: 2 Reps: 8-12 Intensity: exhaustion aft 8-12 reps.		<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	2 sessions Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.

<sup>\* 1:</sup> those who reported being physically active *none or one day a week* at baseline, 2: those who reported being physically active *two days a week* at baseline, 3: those who reported being physically active *three days a week* at baseline.

<sup>\*\*</sup> Sessions can vary in duration between 20-60 minutes, depending on intensity. Higher or lower intensity equals durations closer to 20 or 60 minutes respectively.

STT Types of strength training exercise: at the office, at the gym, outdoors, in water, with a large exercise ball, and with an elastic band TCRF Types of cardiorespiratory exercise: walk/run, nordic walking (with rods), sycling/spinning, dance/aerobic, swimming/water gymnastics, ball games, rowing, skiing/skating, housework, gardening, games/play, step/elipse, tennis/badmington/squash, golf or other cardiorespiratory exercises.

#### **4.2.2 SAMPLE**

A power analysis was conducted prior to the study commencement, where the main outcome measures were  $VO_2$ max and body fat percentage. Based on a meta-analysis of randomized controlled trials examining the effects of aerobic exercise on C-reactive protein, body composition, and  $VO_2$ max in adults by Kelley and Kelley  $^{136}$ , we estimated an effect size of 0,69 mL kg -1 min-1 (3.3 mL kg -1 min-1 /4,8) for  $VO_2$  max and an effect size for fat percentage of -0.36% (-1,4%/3,9)  $^{136}$ . The measuring instrument for predicting fat mass (InBody 720) displayed an intra-class correlation coefficient (ICC) of 0.995 (p= 0.05)  $^{136}$ . Given a power of 90%, and an alpha value of 0.05, the estimated number of participants needed in each group to detect differences of these sizes, was 44 participants. A predicted drop-out rate of <20% previously reported  $^{137}$ , was calculated into the sample size estimation. The target sample size was thereby intended to be n=110.

Between January and March, 2011 the project coordinator enrolled participants to the AISN study through four different recruitment procedures; 1) participants lining in the two Agder counties who took part in a the NPASS study<sup>72</sup> were invited by letter (n = 37, 40-55 yrs.), 2) a randomly selected additional sample from the NPASS study 72, living in the Agder counties (n=200, 43-48 yrs.), were invited by letter, 3) advertisements in local newspapers and radio station, and 4) employees at the University of Agder and Kristiansand community were invited to take part through advertisements on the intranet. The following inclusion criteria were set; the participants had to a) be physically inactive, thereby *not* fulfill the national recommendations of 30 minutes of daily physical activity set by the Norwegian Directorate of Public Health (2010), assessed by the International Physical Activity Questionnaire- short form (IPAQ-SF) 138, b) initially be within the age range 40 – 55 years, which was assessed by telephone interview/screening and questionnaire c) live in one of the two Agder counties, assessed by telephone interview/screening and d) be healthy enough to be able to undergo the baseline assessment (a health related physical fitness assessment), which was assessed by questionnaire and e) be within stage two or three of the five stages of change in the transtheoretical model stages of change 139, assessed by questionnaire. If there was doubt whether the participants fulfilled the inclusion criteria of being physically inactive based on IPAQ-SF, the results from the baseline  $VO_2$ max test were compared to normative  $VO_2$ max values published by Shvartz and Reibold<sup>140</sup>. Participants who scored above or equal to average on the baseline VO<sub>2</sub>max test by gender and age group, where excluded from the study (table 8). A total of 125 females (n=81) and males (n=44) volunteered to take part in the AISN study. Of these, 14 (7 females) were found to be too physically active, as in fulfilling the national recommendations of 30 minutes of daily physical activity set by the Norwegian Directorate of Public Health (2010), and/or scoring

at or above average on the  $VO_2$ max test and were thereby excluded from further participation in the study. A total of 111 participants were randomly allocated to the intervention group (n=55) or the control group (n=56). Of these, 19.8% dropped out, rendering complete baseline and posttest assessment of outcome from 39 participants in the intervention group and 50 in the control group (table 8).

Table 8 A flow chart for the AISN study.

Table of the well are not the most state								
Enrollment								
125 volunteered								
Baseline Health-related physical fitness assessment (n=125)								
	ts were assessed at baseline n: not physically inactive							
Random	nized (n=111)							
111 participant we	ere randomly assigned							
All	location							
Allocated to intervention group (n=56)	Allocated to control group (n=55)							
Lost to follow-up (n=17)	Lost to follow-up (n=5)							
Reasons	Reasons							
5 Unknown	2 Unknown							
5 Lost to follow-up	1 Lost to follow-up							
2 Disease	1 Disease							
1 Lack of time	1 Dissatisfied							
2 Dissatisfied								
2 Unmotivated								
Follow-up: Posttest Health realted physical fitness assessment (n=89)								
Intervention group (n=39)	Control group (n=50)							
Analysis								
A	ini yo io							

## 4.2.3 PROCEDURES AND MEASURES

The baseline and post-test measures for the AISN study were conducted in a test laboratory at the University of Agder, Norway. All objective tests were carried out and lead by the project coordinator. Additional data collectors were qualified master-degree students and a physiotherapist. These had no further involvement in or knowledge about group allocation or were involved in delivering the intervention. In the time-frame from mid-March 2011, to mid-

April 2011 baseline measures were assessed and from mid-October throughout November 2011, post-test measures were assessed. The methods used to assess baseline and post-test measures in the AISN study were the same as those used in the NPASS study <sup>72</sup>, and thereby the same as the measuring methods described under *PAPER I* and *PAPER II* in the methods section. The primary outcomes were CRF and musculoskeletal and neuromotor fitness (*PAPER III*) in addition to body composition (*PAPER IV*). Fixed factors were age, gender and educational level which were assessed by the same questionnaire as used in the NPASS study (*PAPER I and II*). For *PAPER III* body weight, height, and BMI were additional covariates. Adherence to the counseling sessions, was recorded through registration of completed counselling sessions, by the counselor.

*CRF* was assessed on a Woodway treadmill (Woodway ELG 55, Weil am Rhein, Germany) using a modified Balke protocol  $^{141}$ . With each participant wearing a two-way breathing mask (2700 series, Hans Rudolph, Inc), in addition to utilizing the Oxycon Pro Breathing System (Oxycon, Jaeger BeNeLux Bv, Breda, Netherlands) gas exchange averaged over 30 seconds was registered throughout the test. A calibrating routing was completed after every fourth or fifth test to ensure reliable measures. Perceived exhaustion was continuously registered during the test and at test completion, using the Borg scale  $^{142}$ . Additionally, and within one minute after completing the test, the lactate content in a capillary blood sample was measured (LactatePro LT-1710, Arkay KDK, Japan). All CRF tests where the respiratory exchange ratio (RER) was  $\geq 1.10$  or the Borg rate of perceived exertion  $^{143}$  was  $\geq 17$  merconsidered valid.

The following musculoskeletal and neuromotor fitness tests were included in the AISN study and carried out in the following order both at baseline and posttest; the static back-extension test (SBE) <sup>126</sup> recorded muscular endurance of the back extensors, handgrip strength was measured by the hand-grip strength test (HGS) <sup>127,128</sup>, the one-leg-standing test (OLS) registered neuromotor fitness, the modified push-ups test (MPU) <sup>126</sup>assessed muscular dynamic endurance of and the ability to stabilize the upper body. The sit and reach test (SR) <sup>129</sup> recorded flexibility of the hamstring musculature, the back-scratch test (BSC) <sup>130</sup> recorded flexibility in the shoulder joint to the nearest half centimeter, and explosive power in the lower extremities was recorded using the vertical jump test (VJ)<sup>126</sup>. For further description of the assessment methods for musculoskeletal and neuromotor fitness tests, see table 4 and/or *PAPER II* and *IV*.

The following outcome measures for *body composition* were assessed in the AISN study: body weight, height, WC and skinfold thickness. Additionally, BMI, body density and fat percentage by skinfolds (FP<sup>Skf</sup>) were calculated. The bioimpendance instrument InBody 720 (Biospace, Korea) was used to assess various body compositional measures both at baseline and post-test.

However, as inconsistencies in the instruments reliability and validity in predicting body composition have been reported <sup>144</sup>, the body composition results from InBody 720 were not reported in the papers, except for body weight.

Body weight, height, BMI, and WC were measured as described under the methods section for PAPER I. Body weight was measured using InBody 720 (Biospace, Korea) and height was measured using a Seca 222 stadiometer (Seca, Germany). Skinfold thickness was measured using a Lange skinfold caliper (Beta Technology Inc.), as described in the methods section for PAPER I. The following three sights were measured in males; chest, abdomen and thigh (see figure 2a) and in females, the following three sites were measured: triceps, suprailiac and thigh (se figure 2b). All skinfolds were measured twice, and recorded to the nearest millimeter (mm), before a mean value was calculated. Body density was thereby calculated using the sum of the mean skinfold values 38,39,145. In order to calculate a fat percentage based on the estimated body density, the Siri equation 123 was used (see PAPER I and III). All body compositional measures both at baseline and posttest were completed by the same trained, ISAK certified investigator. The BMI and WC values were categorized based on WHO developed cut-off values <sup>27,146</sup>, as described in the methods section in *PAPER I* and *II*. In order to define participants as obese based on fat percentage by skinfolds, cut-off values developed by Lohman et al. 124 were used, where females and males with fat percentage by skinfold values > 35% and > 25% (35-55 yr. age group), respectively, were defined as obese. In order to assess the effectiveness of interventions aiming at inducing weight loss, across investigations and programs, Williamson et al 147 state that a 5% criterion appears to be well justified. Therefore, a calculation was made in order to evaluate many participants achieved a 5% clinical significant reduction on all body compositional measures.

The following covariate measures were assessed by questionnaire: age, gender and educational level. Four categories of educational level were created based on an eight-answering option question. The four categories were: completed less than High School, completed High School, completed three years or less of College/University and completed four years or more at College/University (see *all PAPERS*).

## 4.2.4 ANALYSIS

Data for *PAPER III* and *IV* was analyzed by per-protocol using the Statistical Program for Social Sciences (SPSS 21.0). This way, all participants who had completed both baseline and post-test were included all analysis for both *PAPER III* and *IV* (n=89). Additionally, a significance level of probability was set to p< 0.05 for both *PAPER III* and *IV*. Sample characteristics are presented by

number (n), mean and standard deviation, split by intervention group (intervention group or control group). To analyze for possible group differences in sample characteristics between those who completed the study and those who dropped-out, an independent samples t-test and a chi² test were used for continuous covariate variables and categorical fixed factors, respectively.

**PAPER III** To analyze the main outcome for *PAPER III*, between-group differences in posttest values on CRF and MSMF, an ANCOVA was used, adjusted for baseline scores and fully adjusted by baseline scores, age, gender, weight, body mass index and educational level. The OLS test was not considered to be normally distributed, hence this variable was presented by median and percentiles. A Mann-Whitney test was thereby used to check for possible between group differences on the one-leg-standing test, using delta values (Δ=posttest scores – baseline scores).

**PAPER IV** In *PAPER IV*, an ANCOVA was used to analyze for between-group differences in posttest scores on all body compositional measures, adjusted for baseline scores and fully adjusted by baselinescores, age, gender, weight, body mass index and educational level. Additionally, a chi² test was run to check for between-group differences in how many participants achieved a 5% clinical significant reduction on all body compositional measures <sup>147</sup>. Effect size by Cohen's d for *PAPER III* and *IV* was calculated using a formula by Cohen <sup>148</sup>, presented by DeCoster <sup>149</sup>.

## 4.3 ETHICAL CONSIDERATIONS

Ethical norms are purposeful in scientific research and the reasons for this are many <sup>150</sup>. Ethical norms promote objectives of the research (knowledge, truth and avoidance of error), the values that are essential to collaborate work (trust, accountability, mutual respect and fairness), ensure that the researchers can be held accountable to the public, help to build public support for research, and promote other important moral and social values (social responsibility, human rights, animal welfare compliance with the law, and health and safety). All these ethical norms have been taken into consideration in planning and conducting both in the NPASS study and in the AISN study, through various measures, some of which are mentioned above and throughout the methods section.

Both the NPASS study and the AISN study were designed and conducted in accordance with the Helsinki declaration and the general requirements of the Regional Committees for Medical and Health Research Ethics South East. All volunteering participants consented in writing and were informed of the right to withdraw from the studies at any time, without requiring further explanation. According to the American College of Sports Medicine, the following steps are essential in ensuring the participants informed consent 83; a) explaining the purpose of the assessment and describing the procedures to be used, b) describing risks and discomforts associated with the assessment, in addition to the benefits possible to obtain from taking part in the assessment, c) if alternatives exist, describe this to the participant, d) describing responsibilities required of the client, e) encouraging the client to ask questions at any time, f)explaining how data will be handled (in respect to confidentiality) and inform the participant of the right to withdraw his or her consent from the study at any time and thereby stop the assessment of this participant. The guidelines presented by the ACSM were followed in both studies. Additionally, all volunteering participants were asked to answer a prescreening questionnaire assessing health risks prior to the physical assessments, aimed at ensuring the health and safety for each participant (for further description of the health risk assessment on page 40 in the methods section).

## **5.0 SUMMARY OF RESULTS**

The following section is a summary of selected main results from *PAPERS I-IV*. For further results from the work in which this thesis is based upon, see PAPERS I-IV.

## **5.1 STATUS HEALTH-RELATED PHYSICAL FITNESS**

A total of 904 females and males, aged 20-85 years met at the laboratory in the NPASS study's phase II, and of these 91 women and 87 men were categorized as elderly (table 3). Table 9 displays the sample characteristics for adults and elderly (PAPER I) in addition to sample characteristics for adults only (PAPER II). Males displayed significantly higher scores on all body compositional measures compared with females (p <0.001), except for fat percentage by skinfolds, where women displayed significantly higher scores than men (p <0.001).

**Table 9** Sample characteristics for participants in the NPASS study, for both PAPER I (adults and elderly) and PAPER II (adults).

Characteristic	F	emales		Males	Gender differences
	n	mean ± SD	n	mean ± SD	p-value
PAPER I - Adults and Elderly (20-85 yr	rs.)				
Age (years)	441	51.1 ± 15.1	463	51.1 ± 14.6	0.642
Educational level (%)					
<high school<="" td=""><td></td><td>12.4%</td><td></td><td>10.4%</td><td></td></high>		12.4%		10.4%	
High school		32.3%		38.1%	0.440
<4 yr University		24.8%		24.0%	0.440
≥4 yr University		30.5%		27.5%	
Height (cm)	441	16.1 ± 6.4	463	179.2 ± 6.6	<0.001
Body mass index (kg/m²)	441	$25.3 \pm 4.3$	463	$26.3 \pm 3.4$	<0.001
Waist circumference (cm)	437	85.4 ± 11.5	460	94.7 ± 10.3	<0.001
Fat percentage by skinfolds (%)*	235	31.2 ± 7.1	288	21.8 ± 7.1	<0.001
PAPER II Adults (20-64 yrs)					
Age (years)	350	46.0 ± 11.5	376	46.3 ± 11.7	0.709
Educational level (%)					
<high school<="" td=""><td></td><td>8.4%</td><td></td><td>6.8%</td><td></td></high>		8.4%		6.8%	
High school		30.3%		38.4%	0.195
<4 yr University		27.1%		24.0%	0.195
≥4 yr University		34.3%		30.8%	
Height (cm)	350	167.2 ± 6.1	376	179.9 ± 6.5	<0.001
Body mass index (kg/m²)	350	25.2 ± 4.4	376	$26.3 \pm 3.4$	<0.001
Waist circumference (cm)	347	84.7 ± 11.3	373	94.0 ± 10.4	<0.001
Fat percentage by skinfolds (%)*	235**	31.2 ± 7.1	288	21.8 ± 7.1	<0.001

<sup>\*</sup>  $FP^{\rm Skf}$  was only calulated for the adult part of the sample

<sup>\*\*</sup>only female participants aged  $\leq 55$  years are included.

## 5.1.1 OBESITY IN NORWEGIAN ADULTS AND ELDERLY - PAPER I

A total of 39.9% of the adult and elderly sample from the NPASS study were classified as overweight and 12.7% as obese, based on BMI calculations. Additionally, according to the recorded WC measures, 27.8% were abdominally overweight and 30.9% were abdominally obese. Furthermore, 29.1% of the adult sample was categorized as obese based on fat percentage by skinfolds.

The sensitivity and specificity of the overweight/obesity prevalence estimates varied from 77.0% to 86.9% and from 60.6% to 82.3%, respectively (table 10). Additionally, the ability of BMI and WC to predict fat mass by skinfolds displayed an area under the curve of 0.837 (95% confidence interval [CI]: 0.801-0.872) and 0.811 (95% CI: 0.770-0.852), respectively.

**Table 10** The sensitivity and specificity of the obesity prevalence estimates by body mass index, waist circumference and fat mass percentage by skinfolds, given by percentage.

		Fat percentage by skin	folds
		Obese	Normal
Waist	Overweight and obese	23.0	28.0
circumference	Normal weight	5.9	43.1
		Sensitivity 79.6%	Specificity 60.6%
		Fat percentage by skin	folds
		Obese	Normal
Body mass	Overweight and obese	25.2	24.1
index	Normal weight	3.8	46.8
		Sensitivity 86.9%	Specificity 66.0%
		Waist circumference	
		Overweight and obese	Normal
Body mass	Overweight and obese	45.2	7.3
index	Normal weight	13.5	34.0
		Sensitivity 77.0%	Specificity 82.3%

# 5.1.2 MUSCULOSKELETAL AND NEUROMOTOR FITNESS IN NORWEGIAN ADULTS - PAPER II

Normative values for musculoskeletal and neuromotor fitness were developed based on the results from the adult NPASS sample (table 11). With the exception of the balance test by OLSsum, clear gender differences were found on all musculoskeletal and neuromotor fitness tests (p < 0.001) (table 11). Females scored significantly higher compared to males on muscular endurance of the upper body by static back extension, flexibility of the hamstrings by sit and reach and flexibility of the shoulder joint by back scratch (p < 0.001). Males scored significantly higher test scores on muscular strength of the hand by hand grip strength, muscular dynamic endurance and ability to stabilize the upper body by modified push-ups, muscular power in the lower extremities by both explosive power tests (p < 0.001). Additionally, an inverse relationship was found between all musculoskeletal and neuromotor fitness tests and age for both females (p < 0.044) and males (p < 0.006). Furthermore, WC was found to be inversely associated with scores on muscular endurance, muscular dynamic endurance, balance, flexibility and explosive power (see PAPER II).

**Table 11** Normative values for various musculoskeletal and neuromotor tests, by test, gender, ten-year age groups, number (n), mean ± standard deviation (SD).

			Females		Males	
Test	Age group (years)	n	Mean ± SD	n	Mean ± SD	
ш	20.0 - 29.9	36	101.1 ± 41.9	39	86.0 ±37.0	
Static back extension SBE (sec)	30.0 - 39.9	73	110.6 ± 49.3	78	84.5 ± 30.9**	
ıtic ba nsion (sec)	40.0 - 49.9	101	83.4 ± 42.7	96	$76.0 \pm 41.4$	
Stat sten (	50.0 - 59.9	85	82.8 ± 54.7	94	66.6 ± 33.6*	
8	60.0 - 64.9	43	82.3 ± 51.3	53.0	61.1 ± 45.0*	
S	20.0 - 29.9	36	33.4 ± 6.0	40	58.0 ± 10.3**	
Handgrip strength HGS (kg)	30.0 - 39.9	73	$33.8 \pm 6.0$	78	58.8 ± 9.6**	
Handgrip rength HC (kg)	40.0 - 49.9	104	33.1 ± 5.6	100	55.8 ± 8.1**	
Ha tren	50.0 - 59.9	89	30.7 ± 6.1	102	53.4 ± 7.8**	
S	60.0 - 64.9	45	28.8 ± 5.2	55	47.9 ± 9.8**	
ng um	20.0 - 29.9	33	77.6 ± 18.4	35	70.0 ± 8.8	
One leg standing summed OLSsum (max 120 sec)	30.0 - 39.9	63	73.4 ± 13.1	66	71.2 ± 11.3	
3 sta d O 120	40.0 - 49.9	74	67.8 ± 7.3	79	69.5 ± 10.7	
e leg ıme ıax	50.0 - 59.9	48	67.2 ± 6.2	60	65.6 ± 5.3*	
One leg standing summed OLSsum (max 120 sec)	60.0 - 64.9	19	64.8 ± 2.7	16	65.7 ± 3.5	
Ė	20.0 - 29.9	23	10.3 ± 4.2	39	14.2 ± 3.2**	
Modified push- ups MPU (no/40 sec)	30.0 - 39.9	44	9.5 ± 4.4	75	14.3 ± 5.0**	
odified pus ups MPU (no/40 sec)	40.0 - 49.9	47	7.7 ± 3.9	96	12.6 ± 4.7**	
odifi ups no/	50.0 - 59.9	25	7.8 ± 4.5	90	10.5 ± 4.0*	
M C	60.0 - 64.9	11	5.1 ± 3.0	42	8.4 ± 3.4*	
L	20.0 - 29.9	14	6.6 ± 5.2	_	_	
ush lees ec)	30.0 - 39.9	32	8.9 ± 4.2		_	
Modified pushups on knees MPUK (no/40 sec)	40.0 - 49.9	56	9.0 ± 4.9	_	_	
difi to so M)	50.0 - 59.9	61	$7.3 \pm 4.0$	_	_	
oM qu	60.0 - 64.9	33	6.7 ± 3.6	_	_	
~				40	20.0 . 11.0	
h Si	20.0 - 29.9	37	24.4 ± 14.8	40	20.8 ± 11.0	
ıd reac (cm)	30.0 - 39.9	73	29.0 ± 14.3	78	21.1 ± 12.2**	
i puu	40.0 - 49.9	103	22.3 ± 13.1	100	20.2 ± 12.6	
Sit and reach SR (cm)	50.0 - 59.9	88	23.8 ± 10.6	100	16.5 ± 11.8**	
	60.0 - 64.9	47	22.1 ± 13.1	55	16.8 ± 10.9*	
BS	20.0 - 29.9	37	1.1 ± 7.8	40	$-0.2 \pm 8.9$	
atch n)	30.0 - 39.9	71	$1.8 \pm 8.0$	77	-3.1 ± 10.0**	
scratc (cm)	40.0 - 49.9	101	-2.2 ± 8.7	98	-7.7 ± 10.2**	
Back scratch BSC (cm)	50.0 - 59.9	87	-5.2 ± 7.2	99	-11.0 ± 10.0**	
	60.0 - 64.9	47	$-5.8 \pm 8.0$	52	-16.6 ± 10.9**	
[V c	20.0 - 29.9	16	29.8 ± 5.8	25	44.7 ± 9.1**	
lum (t	30.0 - 39.9	50	29.8 ± 6.4	51	43.1 ± 7.4**	
cal jur (cm)	40.0 - 49.9	84	$25.8 \pm 6.1$	69	38.6 ± 7.5**	
Vertical jump VJ (cm)	50.0 - 59.9	57	$20.7 \pm 5.6$	69	35.9 ± 6.1**	
Σ	60.0 - 64.9	30	18.6 ± 5.3	33	28.4 ± 5.4**	
wer	20.0 - 29.9	23	$24.2 \pm 3.7$	24	36.2 ± 4.8**	
e por atfor	30.0 - 39.9	39	22.1 ± 4.7	37	34.3 ± 5.8**	
sive j on erplat EPP	40.0 - 49.9	55	19.7 ± 4.1	51	29.5 ± 6.2**	
Explosive power on on powerplatform EPP	50.0 - 59.9	50	17.1 ± 3.8	52	26.3 ± 5.7**	
E3	60.0 - 64.9	30	18.6 ± 5.3	27 ** p<0.001 for	21.8 ± 4.3**	

too few cases for further analysis (n for all ages=21), \*p<0.05 for gender differences, \*\*p<0.001 for gender differences \*\* Vertical jump and explosive power on a power platform were only conducted at selected test-centers due to avaiability of resourses and equipment

# 5.2 EFFECTS OF A TAILORED TELEPHONE AND EMAIL BASED EXERCISE INTERVENTION ON HEALTH-RELATED PHYSICAL FITNESS

A total of 111 participants were enrolled in the AISN study and 89 participants completed both baseline and post-test. All participants in the intervention group, adhered to the counselling sessions given by email or telephone. Table 12 displays the sample characteristics where all 89 participants were either overweight or obese on one or more of the body compositional measures. No statistically significant differences were found in sample characteristics between those who completed the study compared to those who were lost to follow-up on any of the baseline characteristics, except for those who dropped out of the intervention group, who were 3.4 years younger than the completers in the intervention group (p=0.01).

**Table 12** Sample characteristics for participants in the AISN study, for both PAPER III and PAPER IV.

Characteristic	Interve	ention group	Control group		
_	n	mean ± SD	n	mean ± SD	
Age (years)	39	48.4 ± 4.6	50	47.3 ± 4.5	
Gender % female	39	66.7%	50	68.0%	
Body mass index (BMI) (kg/m <sup>2</sup> )	39	28.9 ± 4.4	50	29.0 ± 5.9	
% overweight	39	35.9%	50	30.0%	
% obese	39	41.0%	50	46.0%	
Waist circumference (WC) (%)	39	96.3 ± 14.2	50	96.0 ± 15.2	
% abdominally overweight	39	28.2%	50	14.0%	
% abdominally obese	39	59.0%	50	60.0%	
Fat percentage by skinfolds (FP <sup>Skf</sup> )	39	39.1 ± 7.9	49	$38.8 \pm 9.9$	
% obese	39	87.2%	49	77.6%	
Educational level (%)					
<high school<="" td=""><td></td><td>2.6%</td><td></td><td>6.3%</td></high>		2.6%		6.3%	
High school	39	35.9%	48	35.4%	
<4 yr university	39	17.9%	48	29.2%	
≥4 yr university		43.6%		29.2%	

# 5.2.1 EFFECTS ON CARDIORESPIRATORY-, MUSCULOSKELETAL AND NEUROMOTOR FITNESS - PAPER III

Results from the AISN study revealed that the intervention group had an increase in cardiorespiratory fitness measured by  $VO_2$ max (ml/kg/min and l/min), muscular endurance of the upper body by static back extension, flexibility of the shoulder joint by back-scratch and explosive power in the lower extremities by vertical jump, which was differed significantly from that achieved by the control group, when controlling for baseline scores (p<0.022) (table 12). The largest effect size was found in the SBE test (ES: 0.210, p<0.001) and the lowest effect size was found in VJ (ES: 0.089, p=0.022).

 
 Table 13 Illustrating mean test scores (±standard deviation) for the intervention group and the control
 group on all musculoskeletal and neuromotor fitness test scores, cardiorespiratory fitness, and all body compositional measures both at baseline and posttest.

			Intervention	on group			Control g	group		Between group	Effect size	
		n	Pretest Mean (±SD)	Posttest Mean (±SD)	Δ %	n	Pretest Mean (±SD)	Posttest Mean (±SD)	Δ %	differences* (p-value)	(partial eta squared)	Cohen's d
	VO <sub>2</sub> max (ml/kg/min)	36	29.7 ± 4.8	31.8 ± 5.7	7.1	45	30.6 ± 6.1	30.7 ± 6.3	0.3	0.002	0.12	0.74
	VO <sub>2</sub> max (l/min)	36	2.6 ± 0.7	2.7 ± 0.8	3.8	45	2.6 ± 0.6	2.6 ± 0.6	0.0	0.008	0.12	0.74
	SBE (seconds)	36	50.4 ± 22.7	51.8 ± 24.1	2.7	45	50.9 ±28.8	47.5 ±25.8	-7.2	<0.001	0.210	1.03
	HGS (kilograms)	39	40.7 ± 15.2	39.5 ± 14.7	-3.0	48	39.6 ± 13.3	38.5 ± 13.7	-2.9	0.883	0.003	0.11
SR III	MPU (no. reps.)	14	9.0 ± 2.8	9.5 ± 3.4	5.3	18	10.3 ± 3.0	10.9 ± 3.5	5.5	0.885	0.011	0.21
PAPER II	MPUK (no. reps.)	17	8.6 ± 1.9	10.2 ± 2.0	15.7	18	8.2 ±2.9	10.6 ± 3.6	22.6	0.013	0.238	1.12
	OLS# (seconds)	39	57 (26.0-64.0)	41.0 (18.0-63.1)	NC	48	33.5 (15.8-62.3)	27.4 (16.3-58.6)	NC	0.354	NC	NC
	BSC (centimeters)	39	-11.6 ± 11.1	-8.6 ± 9.3	-34.9	48	-8.3 ± 2.9	-7.4 ± 3.6	-12.2	0.183	0.040	0.41
	SR (centimeters)	39	19.0 ± 10.0	22.0 ± 10.4	13.6	48	20.6 ± 9.2	21.0 ± 10.2	1.9	0.006	0.116	0.73
	VJ (centimeters)	39	26.0 ± 9.4	26.1 ± 9.0	0.4	46	25.2 ± 8.2	24.7 ± 8.1	-2.0	0.022	0.089	0.63
	Weight (kg)	39	87.5 (18.9)	84.7 (17.8)	3.3%	47	86.5 (19.9)	85.5 (20.3)	0.1%	0.046	0.047	0.44
ER IV	BMI (kg/m <sup>2</sup> )	39	28.9 (4.4)	28.0 (4.2)	3.1%	42	29.0 (5.6)	28.6 (5.5)	1.4%	0.120	0.031	0.36
PAPER IV	WC (cm)	39	96.3 (14.2)	92.7 (13.3)	2.7%	48	95.2 (15.1)	93.6 (14.8)	1.8%	0.045	0.047	0.44
	FP <sup>skf</sup> (%)	39	39.1 (7.9)	35.7 (8.8)	8.7%	47	38.7 (9.9)	36.9 (10.3)	4.7%	0.025	0.059	0.50

NC: not calculated as the data are have non parametric characteristics.

"For the balance test (OLS) median (25-75 percentiles) is displayed.

Abbrevations: Static back extension (SBE), Handgrip strength (HGS), Modified push-ups (MPU), Modified push-ups onknees (MPUK), One leg standing (OLS), Back scratch (BSC), Sit and reach (SR), Vertical jump (VJ), maximal ventilatory oxygen consumption (VO2max)

## 5.2.2 EFFECTS ON BODY COMPOSITION - PAPER IV

Significantly larger reductions in weight, WC and fat percentage by skinfolds were found in the intervention group, compared to the observed scores in the control group participants, when compared to baseline scores (table 13). Additionally, a total of 64.1% of the intervention group achieved a clinically significant reduction in fat percentage by skinfolds of >5%, which was significantly larger compared to that achieved by the control group (36.2%) (p<0.018).

## 6.0 DISCUSSION

This thesis presents results on the status of various objectively measured aspects of health-related physical fitness in Norway, through a national cross sectional observational study. It also presents results on the effects of a six-month tailored telephone and email based exercise intervention on various measures of objectively assessed health related physical fitness in a sample of initially physically inactive adults. The following discussion will focus on a general discussion addressing the main results, in addition to a methods discussion, addressing the study design in addition to strengths and limitations of the NPASS study and the AISN study. Finally, practical implications and future research are put forward.

## **6.1 GENERAL DISCUSSION**

## 6.1.1 STATUS HEALTH RELATED PHYSICAL FITNESS

The results from the NPASS study display an agreement between selected methods for assessing obesity to be fair to good, based on ROC analysis. The sensitivity levels of the different assessment methods varied from 77.0% to 86.9% and specificity levels varied from 60.6% to 82.3%. However, the estimated prevalence rate of obesity in Norway, based on BMI measures was markedly lower (12.7%) than what was estimated based on both WC (30.9%) and fat percentage by skinfolds (29.1%). Furthermore, the NPASS study brings forth normative values for musculoskeletal and neuromotor fitness. Clear gender differences were found on nearly all musculoskeletal and neuromotor fitness tests, where males scores significantly higher on handgrip strength, muscular dynamic endurance and ability to stabilize the upper body, and muscular power. Females, however scored significantly higher on muscular endurance of the upper body, and flexibility. Furthermore, musculoskeletal and neuromotor fitness was found to be inversely associated with age and partly by obesity.

## Overweight and obesity

The discrepancies in obesity prevalence rates by BMI and WC as measuring methods reported in *PAPER I*, were also reported in the study by Midthjell et al <sup>51</sup>. This is noteworthy. There clearly exists a potential of misclassification when using BMI, WC and skinfolds as measures for estimating body composition <sup>32,36,41,151,152</sup>. BMI is said to underestimate the health-risks associated with obesity, when used as the only indicator of obesity <sup>36,47</sup>. The association between WC and cardiometabolic risk is dependent on the anatomical reference point used for measurement <sup>152</sup>. Furthermore, WC increases with increasing age even in the absence of weight

gain  $^{153}$ . The need for age specific cut-off scores for WC  $^{100,153}$  in addition to internationally accepted cut-off scores for fat percentage has been highlighted, as a mean to obtain better tools in the process of tracking obesity prevalence rates and subsequent evaluation of elevated health risk  $^{100}$ . Hence, the reported obesity prevalence rate in the older part of the studied population in *PAPER I* may be biased by the existing reference values for BMI and WC being developed based on literature mainly studying adults  $^{154}$ .

Predicting fat mass by skinfolds has revealed rather large discrepancies in inter-rater reliability (~3% - 9%) <sup>41</sup>. However, the validity of two-compartment methods for estimating fat mass by body density such as the Siri equation <sup>123</sup>, are said to be reasonable provided that the rules or assumptions of the equations are fulfilled <sup>37</sup>. One of the main challenges in linking skinfold measured fat mass to associated health-risks, is the lack in internationally accepted cut-off scores, linking fat mass percentage to health-risks <sup>124,155</sup>. These possible sources or error imply that the validity of the skinfold-based estimations of obesity reported in *PAPER I* may be questioned. Considering the findings from *PAPER I*, it is of great importance to be critical towards various assessment methods and the adjacent cut-off scores ability to classify individuals as obese and/or at certain health risk, as one would expect the obesity prevalence rates to be more similar, if they were highly valid. Furthermore, based on the possible limitations of the utilized assessment methods ability to estimate excess fat mass and the discrepancies in obesity prevalence rates reported, it would be natural to assume, that the number of people in Norway who are classified as obese by BMI measures may be underestimated.

The obesity prevalence rates by BMI reported in *PAPER I*, collected in 2009, are markedly lower compared to the most recently reported prevalence rates in Norway, collected between 2000 and 2010, which are within the range of 17.9-23.1% (Table 2) <sup>16,51,53</sup>. Additionally, the most recently reported WC based obesity prevalence rates for Norwegian females and males, collected between 2007-2010 (Females: 54% and 55.9, Males: 36.5% and 31.9%, see table 2) <sup>51,55</sup>, are also markedly higher compared to the findings reported in *PAPER I* (Females: 37.8%, Males: 24.3%). In fact, the BMI based obesity prevalence rates reported in *PAPER I* are closer in numbers to BMI based prevalence rates, collected in the timeframe from 1995 to 2002, reported by Anderssen et al <sup>54</sup>. Additionally, the WC based prevalence rates reported in *PAPER I* are closer to the WC based obesity prevalence rates based on a regional study from northern Norway, which were collected in the timeframe of 1994-1995, reported by Jacobsen & Aars <sup>55</sup>. These comparisons seem to indicate a reduction in obesity prevalence rates in Norway occurring during the past years. However, there is a need to consider the possible influence of other

factors that may have affected the variance in reported obesity prevalence rates, such as differences in study population (including the use of national/regional samples) and other possible methodological differences.

The BMI based obesity prevalence rates reported by Anderssen et al <sup>54</sup>, Midthjell et al <sup>51</sup> and Jacobsen and Aars <sup>55</sup> are the only BMI based obesity prevalence rates in Norway, which we know to be based on measured height for weight values. The anatomical reference site for the measurements of WC used in the study of Midthjell et al <sup>51</sup> and the study by Jacobsen & Aar <sup>55</sup>, were somewhat different from the anatomical reference point used in the NPASS study. However, the large difference in WC based obesity prevalence rates between *PAPER I* and the values reported by Midthjell et al <sup>51</sup> and Jacobsen & Aars <sup>55</sup> are not considered to be solely explained by methodological differences. Similar trends were found for both BMI and WC based obesity prevalence rates. Therefore, the observed differences are considered to be real, thus possibly rather reflecting other methodological aspects of these measures and the adjacent cutoff scores, highlighted earlier in this discussion.

Socio-economic status has been inversely related to obesity prevalence <sup>156</sup>. A higher socio-economic status was found for the NPASS sample, compared to the sample by Midthjell et al <sup>51</sup> and seemingly similar discrepancies in socio-economic status were found between the sample in the NPASS study and the sample by Jacobsen and Aar <sup>55</sup>. The discrepancies in socio-economic status may be an explainable factor for the observed differences in obesity prevalence rates. Thus, possibly indicating an overestimation of obesity prevalence in the studies by Midthjell et al <sup>51</sup> and Jacobsen and Aars <sup>55</sup>, while the present study may have underestimated the obesity prevalence rates. However, these implications are merely speculative, though the need to further track obesity trends with emphasis larger sample sizes and as representative samples as possible, with regards to socioeconomic status, is needed.

Compared to global BMI based obesity prevalence rates and not least the high objectively measured BMI based obesity prevalence rates reported by Flegal et al <sup>49</sup> for the US population, the reported prevalence rates in *PAPER I* are markedly lower. When comparing obesity prevalence rates from Norway and other Scandinavian countries, published by the WHO <sup>53</sup> and Ng et al <sup>16</sup>, which are based on both self-reported and measured values for BMI, BMI based obesity prevalence rates seem fairly similar across Scandinavian countries. When comparing the results from *PAPER I* to that of other countries and to other recently reported obesity prevalence rates in Norway, our findings may seem promising regarding the increasing obesity prevalence rates worldwide. In fact, there seems to have been a halting or even a reduction in obesity

prevalence rates, when comparing the results from PAPER I, to previously reported obesity prevalence rates in Norway. However, the large prevalence of abdominally obesity in Norway, reported in *PAPER I* is concerning, especially considering the increased awareness of the huge impact this may have on chronic disease morbidity and mortality <sup>20</sup>.

The NPASS study found markedly more females (37.8%) to be abdominally obese by WC measures, compared to males (24.3%) (see *PAPER I*) <sup>119</sup>. Similar gender differences were, however, also reposted by Midthjell at al <sup>51</sup> (F:55.9%, M:31.9%) and Jacobsen and Aars <sup>55</sup> (F: 54.0%, M: 36.5%). However, the NPASS study also reported markedly more males (36.5%) to be obese assessed by fat percentage by skinfolds, compared to females (20.0%) Whether or not this difference in WC based prevalence rates indicates an increased metabolic health-risk for the female population solely, is unclear, especially regarding the opposite gender differences found in the fat percentage by skinfolds based obesity rates. There is a further need to investigate possible gender differences in obesity prevalence rates by various assessment methods. Furthermore, there is a clear need to address established cut-off scores' ability to estimate health-risk based on body composition.

## Musculoskeletal and neuromotor fitness

*PAPER II* brings forth sought-for normative values for musculoskeletal and neuromotor fitness in Norwegian adults. Comparable data is scarce; however, some partly comparable studies have been found. The most recent Norwegian data on musculoskeletal- and neuromotor fitness was that of a regional study by Nilsen et al <sup>76</sup>. Nilsen et al <sup>76</sup> reported normative values of hand-grip strength in a random sample (20-94 yrs., N=566) of Norwegians recruited at different geographical, public settings in Oslo, Norway. The results by Nilsen et al <sup>76</sup>, were primarily similar to the results in *PAPER II* by ten-year age groups. Though, males in their 50s displayed markedly lower scores on hand-grip strength in the study by Nilsen et al <sup>76</sup>, compared to the results from *PAPER II*. The reason for these differences in hand-grip strength test scores are unclear, however, they may reflect regional differences, differences in recruitment procedures or differences in sample characteristics in this specific age group. Another Norwegian study of musculoskeletal- and neuromotor fitness by Bø & Hagen <sup>85</sup> studied a wider range of musculoskeletal and neuromotor fitness aspects. However, no normative or reference values were displayed and therefore the results were not comparable to the NPASS study.

A national Danish study of 3471 females and males (19-72yr)  $^{73}$ , displayed mean hand-grip strength scores which were similar to those found in *PAPER II*. Another regional Danish study by Danneskiold-Samsoe et al  $^{86}$  established normative values on maximal concentric isokinetic

strength and maximal isometric strength from major muscle groups. However, the results are not applicable for comparison to the normative data from PAPER II, as musculoskeletal- and neuromotor fitness was not assessed by field based tests. Compared to two regional Brazilian studies 74,77, Brazilian adults and elderly score markedly lower on hand-grip strength compared to the results from PAPER II and other Scandinavian findings 73,76. Whether or not these findings suggest differences in muscular strength between geographical regions, or between different ethnic groups, or whether the differed results may be due to methodological issues within the study design and recruitment procedures, is uncertain and may only be prone to speculation. When comparing the normative values for hand-grip strength from PAPER II, with normative values for hand-grip strength published by the ACSM 81, the results from PAPER II were within or above the cut-off for average in all age groups. The study upon which the normative values by ACSM are based, recorded hand-grip strength as the average of the measures of the right and left hand, whereas the NPASS study recorded the highest hand-grip strength score for one optional hand. A peak score is expected to be higher compared to an average score. Therefore, the scores published by the ACSM would be expected to be lower compared to the ones reported in PAPER II. Following this, the comparison may reflect slightly lower musculoskeletal fitness in the sample from the NPASS study, compared to the data published by the ACSM. Therefore, the scores from the NPASS study may be poorer than what is indicated in the comparison to the values published by the ACSM 83.

The European working group on sarcopenia in older people <sup>157</sup> put forward hand-grip strength cut-off values for the diagnosis of sarcopenia, which refers to a condition characterized by loss of skeletal muscle mass and function <sup>158</sup>. Among the different measures believed to be indicators of sarcopenia, was hand-grip strength and the cut-off values indicating sarcopenia, where < 30.0 kg for males and < 20.0 kg for females <sup>157</sup>. The mean hand-grip strength score for males reported in *PAPER II* were not below 30.0 kg, but when looking at the range of scores for the participants in their 60s, outlying scores down to 27.0 kg were observed. For females, none of the mean hand-grip strength scores by ten-year age groups were below the 20.0 kg sarcopenic cut-off, but for participants in their 40s, 50s, and 60s, individual scores down to 15.0 kg, 19.0 kg, and 18.0 kg, respectively were found. This indicates that the studied population in general do not seem to be sarcopenic based on hand-grip strength alone, but some of the older adult male and female participants show disturbingly low hand-grip strength scores.

The ACSM <sup>81</sup> have also published normative values for hamstrings flexibility by the sit-and-reach test, where mean scores on the sit-and-reach test reported in *PAPER II* were within the ACSM category of *needs improvement* and *fair*. Again, the assessment methods used for collecting the

data published by the ACSM differ slightly between that used in the NPASS study. The measuring protocol used to assess sit-and-reach for the ACSM allowed for flexion of the neck when leaning forward toward the measuring band. The protocol used in the NPASS study, instructed the participants to keep a straight back. Whether this difference in assessment method may give an advantage on the sit-and-reach test in favor of the participants in the study reported by the ACSM, is merely speculative. Furthermore, the data in which the normative values reported by the ACSM <sup>81</sup> are based on, was a study on a representative sample Canadian adults (N=571, 15-65yr) dated prior to 2000 <sup>82</sup>. The time gap between when the Canadian study by Payne et al <sup>82</sup> conducted the assessment and when the NPASS study conducted their assessment, may question the comparability between the reported normative scores. However, the association between various musculoskeletal and neuromotor fitness measures and health outcomes investigated by Payne et al <sup>82</sup>, is believed to be relevant. Thus, flexibility is an aspect of the measured musculoskeletal and neuromotor fitness that seems to need improvement. No further studies were considered comparable in design, methods or sample in regard to normative values for musculoskeletal- and neuromotor fitness.

The association between increasing age and adjacent decreasing test scores on musculoskeletal and neuromotor fitness reported in *PAPER II*, has been reported previously, especially for muscular strength across major joints in the body <sup>73,76,77,86</sup> in addition to flexibility, muscular endurance and explosive power <sup>73,85,88</sup>. However, age-dependent decline in muscular strength is said to vary from movement to movement, though most studies report an increasing decline in muscular strength from 40 to 50 years of age <sup>73,76,77,86</sup>. It is, however, of major importance to point out that the data presented in *PAPER II* are based on cross-sectional data and cannot imply age-related changes in musculoskeletal and neuromotor fitness <sup>159</sup>.

An inverse association was found between obesity by WC and the following aspects of musculoskeletal and neuromotor fitness: muscular endurance of the upper body, balance, flexibility of the shoulders, and explosive power of the lower extremities for both males and females, in addition to between muscular dynamic endurance of and the ability to stabilize the upper body and flexibility of the hamstrings musculature, for males. This inverse association between increased scores on WC and lower scores on musculoskeletal and neuromotor fitness has been reported previously 73,92-94. The association between increased WC scores and decreased scores on flexibility of the shoulder joint for both genders and for the hamstrings muscle for males, may be explained by the increased fat mass located in a way that it reduces the ability to achieve a larger range of motion. The association between WC and flexibility of the hamstrings muscle seen in males only, may possibly reflect gender specific differences in

females' smaller WC. The inverse association between WC and muscular endurance of the upper body, muscular dynamic endurance of and the ability to stabilize the upper body and explosive power, is thought to be explained by the weight bearing characteristics of those aspects of musculoskeletal and neuromotor fitness. Hence, heavier participants are assumed to have to exert and/or endure higher muscular strength forces to accomplish the mentioned aspects of musculoskeletal and neuromotor fitness, compared to lighter participants. The findings in *PAPER II* are supported by Fogelholm et al 92 who found the functional muscle fitness to be impaired in individuals with abdominal obesity. Fogelholm et al 92 further concluded that the deterioration in musculoskeletal and neuromotor fitness should be given increased attention.

There is a clear need to achieve and retain a high musculoskeletal and neuromotor fitness and to reduce fat mass to prevent future functional limitations among adults <sup>4,58,92,93</sup>. The overall results from *PAPER I* and *II* indicate that various aspects of health-related fitness in the Norwegian population should be addressed. Special focus should be directed to those in the older adult age groups, as this may be a time when health-related fitness aspects such as musculoskeletal and neuromotor fitness seem to decline most, and the increase in body compositional measures, such as WC and fat mass most, probably increase most.

# 6.1.2 EFFECTS OF A TAILORED TELEPHONE AND EMAIL BASED EXERCISE INTERVENTION ON HEALTH-RELATED PHYSICAL FITNESS

The AISN study is to our knowledge the first randomized controlled study on the effect of an exercise intervention by the presented modes, which measures muscular fitness *and* CRF outcomes objectively. Additionally, it is one of the first randomized controlled studies that also measures fat percentage in assessing changes in body composition. The effects of the AISN study displayed significant improvements in test scores on CRF, muscular endurance of the back extensors, flexibility of the hamstrings, and muscular power of the lower extremities in the intervention group, from baseline to posttest compared to the control group. Additionally, the AISN study induced significantly larger reductions on all body compositional measures in the intervention group compared to the control group, when adjusting for baseline scores, except for BMI. The associated Cohens'd <sup>148</sup> effect sizes for the effect of the trial on physical fitness, ranged from between medium and large on the flexibility of the hamstrings muscle, explosive power and CRF to large effect sizes on muscular endurance of the back extensors, and muscular dynamic endurance of the upper body. Additionally, the effect sizes for the effect of the study on body composition ranged from between small to medium on weight and WC, to medium on fat percentage by skinfolds. Furthermore, a significantly higher prevalence of individuals in the

intervention group achieved a clinical significant reduction ( $\geq$ 5%) in fat percentage (64.1%), compared to the control group (36.2%).

## The effects of AISN on musculoskeletal- and neuromotor fitness and CRF

Only three previous studies 110-112 were found to be both similar in modality to the AISN study in addition to reporting objective measures of physical fitness. The oldest study is by King, Haskell, Taylor, Kraemer, DeBusk 112. This study is the most similar in study design to the AISN study. They compared both high- and low intensity home-based endurance exercise prescribed three and five days a week, respectively, accompanied by telephone contact, to a face-to-face mode. Additionally, they used a no-intervention control group. King et al 112 reported that both highand low intensity homebased endurance exercises were capable of significantly increasing CRF levels (VO<sub>2</sub>max), with results comparable to that of a face-to-face mode 112. The increase in test scores on VO<sub>2</sub>max (ml/kg/min) reported for the intervention group in PAPER III (+2.1 ml/kg/min) exceeds the reported increase in test scores on VO<sub>2</sub>max in the study by King et al 112 at both six and 12 month follow-up. The study by King et al 112 differed slightly in design from the AISN study. They had a one-year intervention duration design, assessed CRF as the only measure of physical fitness and recruited slightly older participants compared to the AISN study. A more recently published study by Andersen et al  $^{110}$  investigated the effect of a 10-week emailbased intervention, aiming at encouraging their participants to do workplace stair-walks, on CRF. They reported a similar increase in VO<sub>2</sub> max (ml/kg/min) in their intervention group (approximately 6%) as the AISN study reported for their intervention group (7.1%), and which differed significantly from that achieved by the control group. However, comparisons are difficult to make, and the comparability is questioned as the sample in the study by Andersen et al 110 was more initially fit, displayed lower mean BMI values and were younger individuals, compared to the sample from the AISN trial. The most recent study by Muntaner-Mas et al  $^{111}$ investigated the effect of a whatsapp-delivered physical activity intervention to enhance healthrelated physical fitness components and cardiovascular disease risk factors. They found a significant increase in hand-grip strength for the intervention group receiving exercise sessions through whatsapp, from baseline to posttest, though no between-group differences in hand-grip strength were found. Two additional studies were found having measured primary outcome by objective measures of physical fitness, though they were based on face-to-face interventions, either in elderly <sup>160</sup> or in a small sample young adults <sup>161</sup>. These studies are therefore not considered to be comparable to findings from the present study.

To our knowledge, no further studies have applied similar intervention methods as was utilized in the AISN study, where the effect was measured by objective measures of several physical

fitness parameters. However, quite a few studies have reported the effect of similar physical activity interventions on physical activity level. A recently published systematic review on the effectiveness of electronic- and mobile health interventions (i.e. internet, mobile phones, and other wireless devices) <sup>99</sup>, and a recently published systematic review and meta-analysis on RCT's primarily using mobile health technologies <sup>98</sup>, report that these modes of delivery and communication were effective in promoting physical activity levels and healthy diets. However, the use of no-intervention control groups should be strived for, as Direito et al <sup>98</sup> question the widespread use of so-called "active" comparator groups to be a possible factor limiting larger effect sizes to be reported.

#### The effects of AISN on various measures of body composition

The AISN study induced significant reductions on various body compositional measures (see PAPER IV). No previous studies were found having conducted the same type of intervention as the AISN trial and the variation in study design for interventions aiming at reducing body compositional measures is enormous. However, results from three recently published reviews of self-directed interventions to promote weight loss 103, motivational physical activity interventions to promote reductions in body compositional measures 113 and mobile phone interventions to promote weight loss in overweight and obese individuals 102 reveal that such interventions are capable of promoting significant weight loss 102,103,113, reductions in BMI 102,113 and declines in WC measures 103. The reductions in body compositional measures and the associated effect sizes/standardized mean differences reported by Tang et al 103, Conn et al 113 and Liu et al <sup>102</sup> were slightly lower compared to the reported reductions in the AISN study, except for the weight reduction reported by Tang et al 103, which were similar. Whether the comparison of effects between the mentioned reviews and the AISN study reflects a superior effect of the AISN study design, compared to many other similar studies aiming at reducing body compositional measures estimating excess body fat, is uncertain. Several previous reviews on interventions promoting physical activity and weight loss 103,104,113,114 clearly state that there is a lack of high quality interventions. Furthermore, the variation in delivery mode and study design is large 101,103,113, making comparisons and possible adjacent conclusions difficult to draw.

BMI was the only body compositional measure that was not significantly different between the intervention group and the control group from baseline to posttest, when controlling for baseline values (see *PAPER IV*). This has also been reported previously <sup>103</sup>, and may be explained by the BMI measures reduced ability to distinguish between fatty tissue and greater-than-average muscularity or skeletal tissue <sup>162</sup>. Therefore, improvements related to increased resistance training, the adjacent increase in muscle mass and the subsequent relationship to

health, may not be reflected in changes in BMI or BMI classifications <sup>116</sup>. This supports the importance of applying objective measures of body composition beyond that of weight and BMI, to enhance better quality in reporting of interventions possible effect on health-related excess fat mass. The need to also measure WC in assessing health consequences of obesity has been highlighted previously <sup>27,34,47</sup>. Furthermore, skinfold measures have been considered to be a suitable way of investigating changes in subcutaneous fat during a period of weight loss or increase of physical activity level <sup>37</sup>. Following this, adding skinfold measures as an indication of changes in fat mass in addition to assessing WC may give additional and important information.

## 6.2 METHODS DISCUSSION

In cross-sectional surveillance studies and randomized controlled trials, one strives to obtain large and representative samples of the target population. This comes in addition to ensuring a good study design and the best methods for assessing outcome measures, in order to get as valid and reliable estimates of outcomes as possible. However, there are many potential sources of bias, which may affect the validity and reliability of the study. This discussion of methodological considerations will be focused both on the observational cross-sectional design of the NPASS study as well as on the experimental design of the randomized controlled trail AISN.

#### 6.2.1 THE NORWEGIAN PHYSICAL ACTIVITY SURVEILLANCE STUDY

#### Study design, selection bias and generalization

The NPASS study was an observational cross-sectional study based on a national sample of randomly selected adults and elderly Norwegians from different geographical regions in Norway. The data for *PAPER I* and *PAPER II* were based on the data collected in phase II of NPASS. The cross-sectional design allows for the reporting of observations made at one timepoint, often being used to obtain reference values. This kind of study design cannot be used to describe causation or predict changes over time <sup>159</sup>. One of the main challenges with crosssectional studies is the study population <sup>159</sup>. Although one strives to obtain an ideally representative sample through random selection from the target population, these ideally representative samples are extremely hard to obtain, and will often introduce uncertainty with respect to representativeness<sup>159</sup>. Thereby, even though the sample is chosen to be as similar as possible to the target population, this description of the participating sample is of great importance for the interpretation of the results <sup>159</sup>. The NPASS attained a participation rate of 32% of the initially invited sample to participating in phase I.<sup>118</sup>. Statistics Norway performed a drop-out analysis, and revealed higher socio-economic background and higher income for completing participants in phase I compared to the non-participating invitees. The sample in phase II of the NPASS study, consisted of approximately one in four of the phase I participants. The samples from the two phases reveal similar educational level, hence it is natural to assume that the drop-out analysis by Statistics Norway is also relevant for phase II participants. Thereby it is likely that the completing participants in phase II have a higher socio-economic background and a higher income compared to the non-participating invitees. PAPER I revealed that participants with higher educational level had a significantly lower prevalence of overweight and/or obesity by BMI, WC and fat percentage by skinfolds, compared to participants with a lower educational level. Furthermoe, Shishehbor et al 163 report higher socio-economic status such as educational level, personal income, employment status, and ability to pay for basic needs, as being inversely related to impaired physical fitness. The drop-out analysis completed

by Statistics Norway may therefore indicate that the reported status of health-related physical fitness presented in *PAPER I* and *PAPER II* may overestimate the health-related physical fitness in the Norwegian population, which might impede the generalizability of the results <sup>118</sup>. Furthermore, the low representation of participants with ethnically non-Norwegian background in the NPASS study, leaves little room for generalizing these findings to that specific subgroups.

## Strengths

The primary strength of the NPASS study is that it includes a national sample of randomly selected adults and older people across Norway (*PAPER I* and *PAPER II*). Secondly, objective measuring methods for recording health related physical fitness were used, and all elements of musculoskeletal- and neuromotor fitness and CRF in addition to obesity were measured by established measuring procedures (*PAPER I* and *PAPER II*). Thirdly, a detailed test protocol was distributed and thorough on-site training in measuring procedures was given, to minimize intertester variability (*PAPER I* and *PAPER II*).

### Limitations

The NPASS study is primarily limited by a possible selection bias observed in the participants both in phase I and phase II of the study, indicating a higher socio-economic status of the participating sample. This might impede the generalizability of the results 118 (PAPER I and PAPER II) and it may indicate that PAPER I and PAPER II underestimate the prevalence of overweight and obesity and underestimate the status of musculoskeletal and neuromotor fitness. Secondly, the study is limited by the lack of data on inter-tester and inter-caliper reliability. The prediction equations for body density used in PAPER I 38,39, were developed based on a sample of Caucasian males and females (M:18-61yr, F:18-55yr), where the range of fat percentage by hydrodensitrometry was slightly lower compared to the range of fat mass by skinfolds estimated in the present study. Since the range of fat percentage from the present study to some extent exceeds that of Jackson and Pollock's sample 38,39, there may have been some individuals for whom the equations used to convert sum of skinfolds into fat percentage by skinfolds, were not valid. However, the estimated inter-caliper variation ( $\sim$ 1.5% predicted fat mass) is considered to be of little significant importance for the results reported in PAPER I. The possible effect of the inter-tester variability (3-9% predicted fat mass) might represent a larger source of error. However, thorough staff training was performed, and detailed test protocols were distributed to limit such inter-tester variability (PAPER I). Furthermore, the one leg standing test was summed with the one-leg standing blinded test into a one-leg standing summed variable for analyzing and presenting the normative data in PAPER II. This fusion of test scores was meant to prevent the clustering of maximum scores observed in the one-leg standing

test and create more normally distributed test scores. The high percentage managing to endure the one-leg standing test combined with the high percentage ending the one-leg standing blinded test within the first 15 seconds, leaves the question of whether the one-leg standing test, both blinded and not blinded, are valid measures of balance, as a neuromotor function.

#### 6.2.2 THE ACTIVE IN SOUTHERN NORWAY STUDY

# Study design, selection bias and generalization

The AISN study was an experimental randomized controlled trial assessing the effects of a sixmonth tailored telephone and email based exercise intervention in a two-parallel-group design. The use of an experimental RCT design reduces the risk of selection bias. A total of 111 apparently healthy and physically inactive adults were mainly recruited by advertisements, and recruitment was thereby based on active volunteering, where participants had to actively sign up for participation, through signed consent. Though we aimed at reaching as many physically inactive adults in the age range between 40 and 55 years from the Agder counties as possible, one may question the method of reaching the target population and to what degree the participants in the AISN study were homogenous or not. Enwald &Houtari <sup>164</sup> found volunteering participants tend to have a higher educational level and the effect of a higher educational level on success rate has been under enquiry, as this has been considered to be a possible bias in intervention studies <sup>164</sup>. Compared to data from the NPASS study, the participants in the AISN study were similarly educated. Therefore, based on the analysis conducted by Statistics Norway in the sample from the NPASS study, the sample from the AISN study seem to be slightly higher educated, compared to the general Norwegian population.

In an experimental study design it is vital to have a control group which does not undergo the experimental procedure <sup>159</sup>. A no-intervention control group was included in the AISN study, however, the subsequent behavior of the participants in the control group was not tracked, which renders uncertainty whether they complied with the study protocol, of retaining current lifestyle habits. Measuring physical activity parameters in studies have been found to have a positive effect on physical activity behavior, possibly due to raised awareness about the participants own physical activity level <sup>165</sup>. Additionally, in what degree the participants themselves were unaware of each other, is unknown and communication between participants across groups (intervention group and control group) may have occurred, thereby possibly weakening the effect of the no-intervention control group. However, these are confounding elements of any experimental study design possibly affecting selection bias, which would be difficult to eliminate completely.

The study design was preventive, targeting healthy, but not sufficiently physically active adults. To what degree the described study design would have similar effects in other populations is not certain. Therefore any generalizability beyond that of the target sample may only be speculative. However, the effects the intervention induced are promising.

#### Strengths

The main strengths of the AISN study were the use of objective measures for primary outcomes of various health-related physical fitness, the inclusion of a no-intervention control group, the use of a blinded RCT design, as well as the intervention duration. Most previous studies have investigated the effect of electronic and mobile health interventions on self-reported physical activity level, and not objective measures of physical activity 98,99 or physical fitness. The use of various objective measures of physical fitness and the inclusion of sought for 101-103,114 objective and more diverse measures for assessing body composition, including both WC and fat percentage by skinfolds, in addition to the more commonly used weight and BMI measures, are considered to be quality enhancers. The additional inclusion of a no-intervention control group reduces the risk of bias in the study and the reported results as well as possibly allowing for the pooling of results, in order to conduct meta-analysis 99. Ensuring that the project coordinator, data collectors, outcome adjudicators and data analysts were blinded for group allocation further reduces the risk of bias, which could possibly be associated with awareness of group allocation and thereby affect study outcome. Additionally, the intervention duration was six months, which exceeds the average duration of previously conducted electronic and mobile health-based physical activity interventions 98,109. Williams et al 166. It can be further emphasizes that lifestyle intervention durations of more than six months may not be necessary, as weight loss seems to plateau around this period in time. However, a follow-up period should be conducted, to investigate the long-term effects of the reported effective intervention 102,103,167. The need for studies with even longer duration in order to better understand the effect of different and individual intervention components has been emphasized 96, and the possible challenges associated with the transition from being part of an intervention to returning to a life in an obesogenic environment at intervention end should be addressed 25.

Secondly, many of the behavior-change strategies and intervention components applied in the AISN study have previously been highlighted as promising individual and/or combined components in interventions designs. Even though the AISN study has not investigated the effect of individual components of the study design, incorporating the following components is sought to be strengths of the study design: goal-setting 101,103,113,168, self-monitoring 101,113,168, feedback 101,103,168, prompts and reminders 113,167, focus on maintaining routines (making habits) 169,

information on perceived improvements (including disappointment of experiencing failure to achieve set goals) 169, linking for gym-based activities 169, range of different types of physical activities (arranging for various exercise in variable settings) 169, progression and periodization <sup>116,170</sup>, the use of the transtheoretical model <sup>113</sup>, individualized and personalized service (including tailoring) 116,167,169,170, including a minimum of five contacts during the intervention period <sup>171</sup>, the use of person-centered and autonomy supportive communication methods such as motivational interviewing 168 and the use of personal support and supervision from providers including coaching 101,103,167-169. Applying some form of personal contact through telephone as a medium to give feedback and to encourage increase in physical activity level, has been reported as especially promising as an effective tool to enhance adherence and positive effects <sup>96,97</sup>. Furthermore, Goode et al <sup>172</sup> support the use of broad-reach modalities, mainly the telephone, as an effective delivery mode for lifestyle interventions. However, the effectiveness of different delivery modes of tailored physical activity interventions, have been found to differ among older adults (>50yr) 173, where a higher participation rate was found in a print delivered tailored physical activity intervention, compared to the same web delivered intervention 173. However, Peels et al <sup>173</sup> highlight the possibility of reaching high risk populations, such as people with lower intentions for physical activity and higher BMI, through web-based interventions. This may indicate the need for facilitating both print and web-based delivery modes, to increase attrition and reach, supporting the AISN study design.

Finally, the AISN study aimed at increasing overall health-related physical fitness, and hence, included both CRF and musculoskeletal and neuromotor fitness in the exercise programs. Clark <sup>170</sup> recently published meta-analysis of interventions aiming at enhancing health body compositional changes, and found larger effect sizes in interventions implementing resistance training or the combination of resistance training and CRF, which in turn creates larger metabolic stress and thereby creates weight loss promotion and better health status in overweight and obese individuals.

#### Limitations

The main limitation of the AISN study was a fairly low sample size (N=89) and a drop-out rate of 19.9% (IG: 30.4%, CG:9.1%). Compared to other studies investigating physical activity interventions with similar intervention design, the number of participants is reported to vary from 20-69219 participants <sup>98,99</sup>. A power analysis was conducted prior to recruitment, with an additional calculation of a presumed drop-out rate of 20%, previously reported <sup>137</sup>. The drop-out rate experienced in the AISN study is just within the quality enhancing inclusion criteria of <20% drop-out put forward by Richards et al <sup>137</sup>. The superior attrition rate observed in the

intervention group is questionable, as we have no certain explanation as to why. This may have affected outcome measures reported and the power of the analysis's ability to detect effects. Additionally, the higher attrition rate in the intervention group may reflect natural drop-outs, and/or it may reflect possible limitations of the study design. The latter is difficult to further speculate about, as only 35% of the participants who dropped-out reported any reason for dropping out. However, based on the reasons given for dropping-out, and feedback from the counsellor conducting the counselling sessions, one may speculate whether certain elements of the intervention were perceived to be too demanding. These elements may especially concern the counselling sessions, every fortnight, where the participants had to register progress, personal effort, goals and motivation. Nonetheless, emphasis should be made on recruiting larger sample sizes, both to be able to do further sub-group analysis of outcome measures, and to further elaborate on different intervention components in addition to being able to generalize findings, if possible.

Secondly, adherence to the counselling sessions was registered by the counsellor, but no objective registration of adherence to the recommended exercise prescribed was registered. Thereby, in what degree the participants adhered to the study design is not fully known. Additionally, baseline and posttest assessment were conducted within <2-3 weeks prior to-intervention commencement and after intervention end, which may have affected the association between the outcome measures and the actual results of the intervention.

Furthermore, several elements that were not included in the AISN study design, but which later have been reported to be positively associated with success in similar interventions, could have been included in the present study to enhance effects. These elements include encouraging/enhancing external support from family members and peer support 103,169, facilitate off-peak scheduling for individuals using the gym, but who do not want to exercise together with many people 169, on-going professional support after the main intervention had ended 169, feedback regarding progress in health behavior change 167, and monthly prompts with accompanied feedback in addition to prompts with specific accompanied strategies 167.

#### 6.3 PRACTICAL IMPLICATIONS AND FUTURE RESEARCH

Based on the general discussion, the following practical implications and future research are put forward.

#### 6.3.1 PRACTICAL IMPLICATIONS

- The results from *PAPER I* may contribute to the understanding of obesity as a still current public health challenge.
- The normative values put forward in PAPER II may be of use in clinical or practical settings, making it possible for others to compare results from various field based musculoskeletal- and neuromotor fitness tests to normative data based on age and gender.
- The results from PAPER II indicates a need to enhance musculoskeletal- and neuromotor
  fitness in population subgroups, such as older and obese individuals, in order to prevent
  disease and mortality in addition to secure an independent daily lifestyle.
- Given the increasing trends of obesity and physical inactivity, in addition to the results
  from the NPASS study on health-related physical fitness, the need for actions to increase
  physical activity levels and subsequent physical fitness in addition to reducing obesity
  prevalence rates, is crucial.
- The AISN study showed positive effects and could therefore be considered implemented in practical settings as a mean of action, to achieve the goals put forward by the WHO global action plan for non-communicable diseases 2013-2020 95.

## 6.3.2 FUTURE RESEARCH

- The results from *PAPER I* highlight the importance of continuing to track obesity prevalence rates, with emphasis on collecting data from large representative study samples, in order to govern actions and implications for public health measures.
- BMI should be used with caution when assessing excess fat mass.
- Future research should review already established cut-off scores for BMI and WC, pursue
  the establishment of age specific cut-off scores for WC, and pursue the establishment of
  internationally accepted cut-off scores for fat percentage.
- In light of the increasing prevalence of physical inactivity, there is a need to continuously
  track the status in physical fitness in order to survey the effects of physical inactivity on
  health-related physical fitness outcomes.
- The AISN study design should be further investigated in order to elaborate on what components of the intervention are more effective or important than others, whether or

- not further elements should be implemented to enhance effect and adherence, and to assess long term follow-up.
- There is a need to incorporate larger sample sizes and longer durations to investigate the long-term effect of effective interventions in addition to incorporating objective measures of physical fitness.
- It is of importance to use the CONSORT statement <sup>174</sup> in reporting effects of interventions, in order to enhance the quality of reporting.
- There is a need to assess effective ways of managing the transition from completing an
  effective intervention program to returning to a life in an obesogenic and sedentary
  environment at the end of an intervention. Therefore, long term follow-up studies should
  assess means to overcome the possible challenges of the transition between being part of
  an intervention/receiving support, to continuing the transitioned lifestyle.

# 7.0 CONCLUSIONS

Based on the presented results from PAPERS I-IV, the following conclusions are drawn;

**PAPER I** The estimated prevalence rate of obesity in Norway, based on BMI measures were markedly lower compared to obesity estimates based on both waist circumference and fat percentage by skinfolds. The agreement between selected methods for assessing obesity was fair to good though, the inconsistency in obesity prevalence rates reported, questions the validity of established cut-off scores.

**PAPER II** The present study offers warranted normative data on MSMF based on a national sample primarily Caucasian adult Norwegians. Furthermore, the results displayed clear gender differences and a clear decrease in musculoskeletal and neuromotor fitness test scores with increasing age and with increasing fat mass estimated by WC.

**PAPER III and IV** A six-month tailored telephone and email based exercise intervention induced significant effects on various measures of musculoskeletal and neuromotor fitness and cardiorespiratory fitness in addition to on various measures of body composition in a sample of initially physically inactive adults.

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# PAPER I

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#### Review

# Obesity prevalence in Norwegian adults assessed by body mass index, waist circumference and fat mass percentage

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#### What is already known about this subject?

- Obesity is a large public health challenge worldwide, with increasing prevalence rates in many Western countries including Norway.
- Worldwide prevalence estimates of obesity are commonly based on standardized body mass index cut-offs.

#### What does this study add?

- The estimated prevalence rate of obesity in Norway, based on body mass index measures, is markedly lower than what is estimated based on both waist circumference and fat percentage by skinfolds.
- The agreement between selected methods for assessing obesity was fair to good, although the inconsistency in obesity prevalence rates reported questions the validity of established cut-off scores.

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#### **Summary**

The prevalence of obesity presents serious public health challenges worldwide and is most commonly estimated by the categorization of body mass index (BMI). The purpose of this study was (i) to describe the sensitivity of BMI, waist circumference (WC) and fat mass percentage in the classification of overweight and obesity and (ii) to describe the prevalence of overweight and obesity using different measurement methods in a national sample of Norwegians. A total of 904 Norwegians (20-85 years) were randomly enrolled. Body weight, height, WC and skinfold thickness were measured; BMI and fat mass percentage (FPskf) were calculated. The sensitivity and specificity varied from 77.0% to 86.9% and from 60.6% to 82.3%, respectively. Area under the curve was 0.837 (95% confidence interval [CI]: 0.801-0.872) for the ability of BMI to predict obesity by FPskf and 0.811 (95% CI: 0.770-0.852) for WC. A total of 12.7% (male: 12.1%, female: 13.4%) were obese based on BMI classifications, 29.1% (male: 36.5%, female: 20.0%) of the sample were obese based on FPskf and 24.3% of men and 37.8% of women were abdominally obese by WC. The agreement between selected measuring methods was fair to good, although the variation in obesity prevalence rates between the different assessments methods varied markedly.

**Keywords:** Assessment methods, elderly, obesity, prevalence.

# Introduction

The prevalence of obesity has tripled over the past two decades and the World Health Organization states that it has reached epidemic proportions (1). In the European region, overweight and obesity represent serious public health challenges (1,2) and the World Health Organization's annual health statistics report approximates that as

many as 20.4% of European males and 23.1% of European females above 20 years old are obese (3). Obesity is estimated to be responsible for up to 80% of the type II diabetes cases, 35% of the ischaemic heart disease cases and 55% of hypertension cases in the adult European population (2). Furthermore, obesity is said to cause up to 1 million deaths and 12 million life years of reduced health every year (2) and is thereby estimated to be accountable for up to 6% of national health care costs in the World Health Organization European region (1).

The association between obesity, defined by various assessment methods, and comorbidities/mortality is considered to be strong and causal (4,5). Even though total body fat mass is associated with an increased health risk. abdominal fat mass has proved to be an independent risk factor for the development of comorbidities such as stroke. coronary heart disease, type II diabetes, sleep apnoea, insulin resistance, hypertension, dyslipidaemia, inflammation and cancer (5,6). Furthermore, abdominal obesity has gained increased recognition for its relation to undesired lipid accumulation in the heart, liver, pancreas, skeletal muscle and renal sinus (5). Body mass index (BMI) is one of the most commonly used methods for the assessment of nutritional status and measurement of excess adiposity. especially in large-scale epidemiological studies (7). However, BMI has been found to yield sensitivity for detecting adiposity of 0.5 (8). This limitation is mostly due to the restricted ability of the weight based index to distinguish between fatty tissue and greater-than-average muscularity or skeletal tissue (7). The American Heart Association's statement of 2012 (9) points out that BMI should be used as part of the primary assessment tool for assessing individuals for excess fat mass due to its correlation with body fat mass on a population level. Additionally, the American Heart Association clearly address the importance of adding waist circumference (WC) as part of the primary assessment tool in addition to BMI in assessing the obesity epidemic (9), given the strong association between abdominal obesity and metabolic disorders. Together with skinfolds, BMI and WC are considered simpler, inexpensive methods for assessing body composition and the three compartment models such as that of Siri (10) have been used increasingly as they are not based on assumptions of standard hydration or fat-free mass density for its validity.

Since the 1970s the amount of people categorized as overweight or obese in Norway has increased across all ages and socioeconomic groups (11,12). However, the available data are mainly based on samples from specific regions (12-14) and/or use solely BMI measures as a marker for obesity (11,13,14). Thus, the primary objective of the study was to describe the sensitivity of BMI, WC and fat mass percentage derived from skinfolds in the classification of overweight and obesity. The secondary objective was to describe the prevalence of overweight and obesity

using different measurement methods in a national sample of Norwegian adults and elderly.

#### Materials and methods

The present study was part of a national multicentre study assessing physical activity and physical fitness in a sample of Norwegian adults and older people (20-85 years) (15,16). The study was approved by the Regional Committee for Medical Ethics (REK Sør-Øst B, S-08046b) and the Norwegian Social Science Data Services. Written consent forms were obtained from all participants.

#### Study design and sample

The study was conducted in 2008-2009 and consisted of two separate data collection phases nationwide. A total of nine regional test centres across Norway participated in the data collection in both phases. Phase I included objective assessment of physical activity level using the ActiGraph GT1M accelerometer (ActiGraph, LLC) and the collection of correlates for physical activity through a questionnaire (16). Phase II consisted of an assessment of physical fitness, including assessment of maximal oxygen consumption, musculoskeletal and motor fitness, blood pressure, lung capacity and body composition (15).

A random and representative sample was drawn from the Norwegian National Population Registry. The initial sample consisted of 11 515 men and women, ranging in age from 20 to 85 years, covering 126 communities. A total of 3800 individuals agreed to take part in the initial phase of the study, where data from 3464 were found valid and thereby included. For the second phase of the study, 1930 individuals who participated in phase I were randomly selected and invited by letter to take part. Of the 1368 whom we obtained telephone contact with, a total of 1030 accepted the invitation and 904 participants showed up for the data collection for phase II. A comprehensive nonresponse analysis was conducted for the phase II invitees and displayed a selection bias as educational status concerns, where the responders displayed a higher educational status compared with the non-responders (15).

#### Measuring methods

The following anthropometrical measures were conducted: body weight, height, WC and skinfold thickness. BMI, body density and fat mass percentage (FPSkf) were calculated based on the recorded anthropometrical measures. All anthropometric measures were conducted by trained investigators following a detailed test protocol and all measuring instruments were calibrated.

Body weight was recorded to the nearest 0.1 kg using a weight scale (Table 1), with the participant wearing

Table 1 The measuring instruments used in assessing height, weight and skinfolds given by type (brand) and number of participants undergoing the measures (n)

Measuring instrument Height	n	Measuring instrument Weight	п	Measuring methods Skinfolds	n
KaWe (Kirchner & Wilhelm GmbH+Co. KG, Asperg, Germany)	566	Seca 770 (Seca)	391	Harpenden caliper (Baty International, UK)	273
Measuring band on wall	160	Inbody 720 (Biospace Inc)	101	Lange caliper (Beta Technology Inc., USA)	250
Seca 222 (Seca, Germany)	100	Terraillon (UK)	100		
Seca stadiometer (Seca)	78	Point digital weight scale	81		
		Tanita TBF 521 (USA)	81		
		Bosch (Bosch, Germany)	79		
		A&D UC321 (A & D Instruments Ltd.,	71		
		Germany)			

underwear and a t-shirt. Height was measured to the nearest centimetre using a stadiometer (Table 1). The participants were instructed to stand upright without shoes, with the heels touching the wall and with a straight body facing forward. BMI was calculated by weight(kilogram)/ height(metres) (2).

WC was recorded following a protocol developed by the World Health Organization (17). The mid-point between the upper most lateral part of the iliac crest and the lowest most lateral point of the ribcage was located and used as the marker of the recorded WC values. Using a measuring band, two measures were conducted at the end of the participants' expiration and the mean of these two measures were recorded to the nearest half centimetre. WC has shown acceptable inter rater reliability (technical error of measurement: 2.35-2.50%) (18) in addition to good correlation with dual-energy X-ray absorptiometry measures of trunk fat mass percentage (partial Pearson's correlations r = 0.76 - 0.86, P < 0.05 (19).

Skinfolds were measured using a Harpenden caliper (Baty International, UK) or Lange skinfold caliper (Beta Technology Inc., USA), depending on availability (Table 1). For men, the following three sites were measured: chest, abdomen and thigh. For women, sites on the triceps, suprailiac and thigh were measured. The mean of two measures were recorded to the nearest millimetre and the summed skinfold values were used to calculate body density (20,21). The Siri equation (10) was used to calculate FPSkf based on the calculated body density estimates. Due to the body density equations being developed for men aged 18-61 years and women 18-55 years, the FPSkf has only been calculated for men 20-60 years and women 20-55 years in the present study. Thereby, a slightly lower number of participants were registered with FPSkf values compared with WC and BMI. Measures by the Harpenden caliper have been found to be smaller compared with measures by the Lange caliper (22), accounting for ~1.5% of the variation in fat percentage (23), depending on technician (24). Additionally, the inter rater reliability of skinfold

measures have been found to vary from 3% to 9% in fat percentage (24). In order to minimize the bias of inter rater reliability and instrument, the present study implemented thorough technician training, in addition to developing a detailed test protocol.

The BMI and WC values were categorized based on World Health Organization cut-off values (25). Individuals with BMI values < 18.5 kg m<sup>-2</sup> were categorized as underweight, 18.5-24.9 kg m<sup>-2</sup> as normal weight, 25.0-29.9 kg m<sup>-2</sup> as overweight and those with BMI values ≥ 30.0 kg m<sup>-2</sup> were categorized as obese. Furthermore, participants with BMI values of 30-34.9, 35-39.9 and ≥40.0 kg m<sup>-2</sup> were categorized into obesity class I, class II and class III, respectively. Additionally, men and women with WC values of ≥94 cm and ≥80 cm, respectively, were categorized as abdominally overweight and men and women with WC values ≥ 102 cm and ≥88 cm, respectively, were categorized as abdominally obese.

We used cut-off values developed by Lohman et al. (26) in order to define obesity based on FPSkf. Men with FPSkf values >22% at the age of 18-34 years, >25% at the age of 35-55 years and >23% at the age of >55 years were defined as obese. Moreover, women with FPSkf values >35% at the age of 18-34 years and >38% at the age of 35-55 years were defined as obese.

#### Statistical analysis

Data were analysed using IBM SPSS Statistics 19 (IBM Corporation, Route, Somers, NY, USA). The continuous variables are displayed using means and standard deviations, primarily stratified by gender and age groups. Participants in the age group of 20 to 64.9 years were defined as adults and the participants between the age of 65 and 85 were defined as older people (27). As only six female participants were classified as underweight and the lowest BMI score was 17.4 kg m<sup>-2</sup> and thereby close to the cut-off for normal weight, the underweight participants were grouped in the normal weight category for all analyses. Independent samples *t*-tests were used to examine gender differences in all continuous variables and to detect differences in mean BMI and WC values between adults and elderly. In order to assess sensitivity and specificity of the different assessment methods, a cross-tabulation test was run where the overweight categories for WC and BMI were added to the obesity categories. Additionally, a receiver operating characteristic curve (ROC) was run where FPskf defined obesity was used as the state variable. Area under the curve (AUC) was given by AUC value and 95% confidence interval (95% CI). Statistical significance level was set to  $P \le 0.05$ .

#### Results

A total of 904 predominantly Caucasian (15) females (n = 441) and males (n = 463) took part in this study, where 91 women and 87 men were categorized as older people. All 904 participants were registered with valid BMI values, 897 participants were registered with WC measures and 523 of the total sample were registered with FP<sup>Skf</sup> (Table 2).

The sensitivity of the prevalence estimates varied from 77.0% to 86.9% and the specificity of the prevalence estimates varied from 60.6% to 82.3% (Table 3). The ability of BMI to estimate fat mass estimated by FPskf given by AUC was 0.837 (95% CI 0.801–0.872) (Fig. 1). The

age-related AUC values for BMI were 0.832 (95% CI: 0.753–0.912) for those between 20.0 and 34.9 years of age, 0.871 (95% CI: 0.827–0.916) for those between 35.0 and 49.9 years of age and 0.772 (95% CI: 0.694–0.851) for those aged 50.0 to 64.9 years. The AUC value for WC's ability to distinguish obesity by FPskf estimated fat mass was 0.811 (95% CI 0.770–0.852) (Fig. 1). The adjacent age-related AUC values were 0.782 (95% CI: 0.680–0.884) for those aged 20.0 to 34.9 years, 0.825 (95% CI: 0.765–0.884) for those between the age of 35.0 and 49.9 years and 0.771 (95% CI: 0.961–0.851) for those between the ages of 50.0 and 64.9 years.

According to the BMI values, a total of 39.9% of the sample were classified as overweight and 12.7% as obese. Among those who were categorized as obese, a total of 82.0% were categorized in obesity class I, in addition to 13.0% and 5.0% in obesity class II and III, respectively. The recorded WC measures indicate that 27.8% were abdominally overweight and 30.9% were abdominally obese. Based on the FPskf, 29.1% of the adult sample was categorized as obese. Prevalence rates varied significantly according to gender, age groups, geographical regions and education level ( $P \le 0.048$ ), but not for income level (Table 4). For all body compositional markers, men displayed significantly higher values compared with women (P < 0.001), with the exception of skinfolds and FPskf, where women displayed significantly higher scores than

Table 2 The descriptive statistics for the anthropometrical data by adults and elderly in addition to gender

Test	Age group	Females	Females			Gender differences	
		n	Mean ± SD	n	Mean ± SD	P-value	
Weight	All ages	441	69.8 ± 12.7	463	84.5 ± 12.0	<0.001	
	Adults	350	70.5 ± 13.2	376	85.2 ± 12.0	< 0.001	
	Elderly	91	67.1 ± 10.3	87	81.7 ± 11.9	< 0.001	
Height (cm)	All ages	441	166.1 ± 6.4	463	179.2 ± 6.6	< 0.001	
	Adults	350	167.2 ± 6.1	376	$179.9 \pm 6.5$	< 0.001	
	Elderly	91	161.7 ± 5.9	87	$176.4 \pm 6.5$	< 0.001	
Body mass index (kg m <sup>-2</sup> )	All ages	441	$25.3 \pm 4.3$	463	$26.3 \pm 3.4$	< 0.001	
	Adults	350	$25.2 \pm 4.4$	376	$26.3 \pm 3.4$	< 0.001	
	Elderly	91	$25.7 \pm 3.9$	87	$26.2 \pm 3.1$	< 0.001	
Waist circumference (cm)	All ages	437	85.4 ± 11.5	460	94.7 ± 10.3	< 0.001	
	Adults	347	$84.7 \pm 11.3$	373	$94.0 \pm 10.4$	< 0.001	
	Elderly	90	88.2 ± 11.7	87	$97.7 \pm 9.2$	< 0.001	
Sum of skinfolds (mm)	All ages	401	$81.8 \pm 24.4$	417	$70.5 \pm 25.4$	< 0.001	
	Adults	319	82.1 ± 24.9	336	$70.5 \pm 26.2$	< 0.001	
	Elderly	82	$80.7 \pm 22.2$	81	$70.4 \pm 21.6$	0.003	
FP <sup>skf</sup> (%)	All ages	*					
	Adults	235†	$31.2 \pm 7.1$	288	$21.8 \pm 7.1$	< 0.001	
	Elderly	*					

<sup>\*</sup>FPSkf was only calculated for the adult part of the sample.

 $<sup>^{\</sup>dagger}$ Only female participants aged  $\leq$  55 years are included.

SD, standard deviation.

Table 3 The sensitivity and specificity of the body mass index (BMI), waist circumference (WC) and fat mass percentage by skinfolds (FPskf) ability to estimate overweight and obesity given by percentage

		Fat percentage		
		Obese	Normal	
WC	Overweight and obese (n = 266)	23.0	28.0	
	Normal weight (n = 256)	5.9	43.1	
	( 200)	Sensitivity 79.6%	Specificity 60.6%	
		Fat percentage		
		Obese	Normal	
BMI	Overweight and obese (n = 258)	25.2	24.1	
	Normal weight (n = 265)	3.8	46.8	
	(// 200)	Sensitivity 86.9%	Specificity 66.0%	
		WC		
		Overweight and obese	Normal	
BMI	Overweight and obese (n = 470)	45.2	7.3	
	Normal weight (n = 426)	13.5	34.0	
	(11 – 420)	Sensitivity 77.0%	Specificity 82.3%	

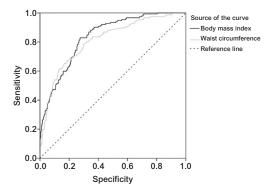


Figure 1 Illustration of the sensitivity and specificity of body mass index and waist circumference scores by fat mass percentage by skinfolds (FPskf) measured obesity in a receiver operating characteristic curve

men ( $P \le 0.003$ ) (Table 2). Mean BMI values did not differ between adults and elderly, but mean WC values were significantly higher in the elderly compared with the adult participants (P = 0.001).

#### Discussion

The main findings from the present study reveal sensitivity levels varying from 77.0% to 86.9% and specificity levels varying from 60.6% to 82.3%. Additional ROC analysis indicates a fair to good agreement between selected measures, although obesity prevalence rates varied. A total of 12.7% of Norwegians were obese based on BMI, 30.9% were abdominally obese based on WC and a total of 29.1% were estimated to be obese based on

A review of the current literature on the BMI-based obesity prevalence in Norway (11,12) reveals inconsistency in prevalence rates. A regional study from the west of Norway (12) revealed higher obesity prevalence rates (23.1%) compared with the present study, even by region (Western region: 13.8%). The difference in socioeconomic status reported between the studied samples may be the main explanatory factor for the observed differences in prevalence rates between Midthjell et al.'s (12) study and the present study. Socioeconomic status has been inversely related to obesity prevalence (28), hence the numbers from Midthjell et al.'s (12) study, reporting lower socioeconomic status, may have overestimated obesity prevalence, while the present study may have underestimated prevalence rates. Whether or not these findings imply that the true obesity prevalence rate lies somewhere between that reported in the present study and the study by Midthjell et al. (12) is unclear and further investigation with a sample more representative with regard to socioeconomic status is needed.

Compared with BMI-based obesity prevalence rates reported by Anderssen et al. (11) from the time frame of 1995-2002 (15.4%), the development of obesity trends in Norway may seem to have reversed or stagnated, although uncertainty exists, especially, regarding the higher prevalence rates reported by Midthjell et al. Compared with a national Danish study (29), the BMI-based obesity prevalence rates (female: 11.0%, male: 12.2%) are similar to those reported in the present study, supposedly indicating similarities in obesity prevalence rates between Scandinavian countries.

The WC prevalence rates of abdominal obesity reported by Midthjell et al. (12) are also markedly higher (female: 55.9%, male: 31.9%) compared with the present findings, although socioeconomic differences between participants in the two studies is sought to be the most obvious explanatory factor for the observed differences in prevalence rates as previously mentioned. The anatomical reference site for the WC measurement used in the study of Midthjell et al. (12) differed from that used in the present study; the large difference in WC based prevalence rates is not considered to be solely explainable by technical or instrumental differences. As similar trends were found for BMI-measured

Variable	BMI		WC			FP <sup>Skf</sup>	
	Overweight		Obese	Abdominally overweight	Abdominally obese		Obese
Gender							
Females	29.9		13.4	28.7		37.8	20.0
Males	49.5		12.1	27.0		24.3	36.5
P-value		< 0.001			< 0.001		< 0.001
Age group							
20.0-34.9 years	28.6		11.4	25.0		15.0	25.4
35.0-49.9 years	33.8		14.0	22.5		26.6	23.8
50.0-64.9 years	46.1		14.0	33.6		36.0	43.2
65.0+ years	48.9		9.6	29.4		42.4	-
P-value		< 0.001			< 0.001		< 0.001
Regional area							
North	36.8		14.6	25.6		27.4	36.8
South	40.8		13.4	25.0		33.0	37.6
East	40.1		11.0	29.8		35.2	27.1
West	41.9		13.8	28.9		22.0	5.8
P-value		NS			0.014		< 0.001
Education level							
<high school<="" td=""><td>46.6</td><td></td><td>12.9</td><td>34.3</td><td></td><td>38.4</td><td>37.9</td></high>	46.6		12.9	34.3		38.4	37.9
High school	43.3		18.5	29.0		36.1	34.6
<4 years university	42.4		10.6	27.3		31.0	27.6
>4 years university	31.8		8.1	24.1		22.6	22.3
P-value		< 0.001			< 0.001		0.048
Income level (NOK)							
0-200 000	29.3		12.2	29.3		34.1	21.7
201 000-400 000	36.8		11.1	25.1		33.3	26.1
401 000-700 000	41.2		14.2	28.3		33.1	29.0
>700.000	41.7		12.3	26.7		27.0	29.4
P-value		NS			NS		NS

**Table 4** The prevalence of overweight and obesity based on body mass index (BMI), waist circumference (WC) and fat mass percentage by skinfolds (FP<sup>SkI</sup>) cut-off values by gender, 15-year age groups, geographical regions, education level and income level

All results are given in percentage (%).

NS, non-significant.

obesity prevalence rates, the observed differences in WC-based prevalence rates are considered to be reliable.

The different assessment methods for body composition used in the present study and the categorization into groups associated with health risks displayed a fair to good agreement, although they yielded different prevalence rates, which is noteworthy. Similar differences in prevalence rates between BMI and WC were also reported in the study by Midthjell et al (12). The ability of BMI and WC to estimate obesity by FPskf was largest for the middle-aged group (35.0-49.9 years) and weakest for the oldest age group (50.0-64.9 years). There clearly exists a potential of misclassification when using BMI, WC and skinfolds as a measure for estimating body composition (7,8,24,30,31). BMI has been found to underestimate the health risks associated with adiposity when used as a single indicator for obesity (8,32). The association of WC to cardiometabolic risk has been found to be dependent on the anatomical site of measurement (31). Furthermore, as WC increases with age, even in the absence of weight gain (33), the necessity of age-specific WC cut-off points in order to assess the risk of metabolic complications has been highlighted (33). Thereby, the obesity prevalence assessment of the older population in the present study may be biased by the existing reference values for BMI and WC being developed based on literature predominantly studying adults (34). Additionally, rather large discrepancies in inter rater reliability have been found in predicted fat mass based on skinfold (~3-9%) (24). The validity of two-compartment methods for converting body density into FPskf such as the Siri equation (10) are claimed to be reasonable as long as the rules or assumptions of the equations are fulfilled (35), although no internationally accepted cut-off scores linking fat mass percentage to health risks have been developed (26,36). Thus, the validity of the FPSkf categorization of obesity in the present study may be questioned. These highlighted issues bring forth important issues to take into account when interpreting the results. However, even though magnetic resonance imaging and computed tomography are considered to be the most valid methods for measuring adipose tissue and the choice of reference method when validating field-based methods, magnetic

resonance imaging and computed tomography are costly (37). These methods are therefore regarded as not suitable for use in large epidemiological studies. Both WC and BMI have shown good correlation to the estimations of total abdominal adipose tissue made by magnetic resonance imaging. Hence, these simpler methods may be advantageous in large population-based studies (38). The results from the present study imply that it is of great importance to be critical towards the various assessment methods established cut-of scores ability to classify individuals as being at a certain health risk, as one would expect them to correlate more in prevalence rates if they were highly valid. Furthermore, based on the possible limitations of the ability of the utilized assessment methods to estimate excess fat mass, it is justified to assume that the number of people in Norway who are classified as obese by BMI measures might be underestimated.

The age-specific cut-off scores for WC and internationally accepted cut-off scores for fat percentage are highly needed and should be pursued in future research. Furthermore, the surveillance of population obesity prevalence should continue and the use of objective measuring methods should be stressed. The present study brings forth prevalence rates for obesity based on a randomly selected sample Norwegians from diverse regional areas, which hopefully may contribute to the understanding of obesity as a public health challenge and to the continuous observation of prevalence rates and the advancement in implications for public health measures.

#### Strengths and limitations

The primary strength of the present study is that it includes a national sample of randomly selected adults and older people across Norway. Secondly, different objective measuring methods for recording obesity were used. Thirdly, a detailed test protocol was distributed and thorough on-site training in measuring procedures was given in order to minimize inter-tester variability. The study is primarily limited by a possible selection bias observed both in the participants in the first phase of the study and in the participants in the second phase of the study indicating a higher socioeconomic status of the participating sample, which might impede the generalizability of the results (16). Additionally, the study is limited by the lack of data on inter-tester and inter-caliper reliability. The estimated intercaliper variation (~1.5% predicted fat mass) is considered to be of little significance for the results of the present study. The possible effect of the inter-tester variability (3-9% predicted fat mass) might represent a larger source of error. However, thorough staff training was performed and detailed test protocols were distributed to limit intertester variability.

The results from the present study reveal sensitivity values ranging from 77.0% to 86.9% with adjacent AUC values indicating fair to good agreement between the ability of selected measuring methods to categorize obesity. However, obesity prevalence rates varied depending on assessment method, where the BMI predicted prevalence rates of obesity of 12.7% were lower compared with those of WC and FP<sup>Skf</sup> of 30.8% and 29.1%, respectively.

#### Conflict of interest statement

No conflict of interest was declared.

#### **Acknowledgements**

IGHK took part in the data collection, completed the data analysis, took part in data interpretation and the generation of figures and in drafting the manuscript. EK and BHH took part in coordinating and planning the study, collecting the data, data interpretation and in reviewing the manuscript. SAA was the project manager for the study, contributed to planning the study, the study design and contributed to the data interpretation and in reviewing the manuscript. MKT contributed to the data interpretation and in reviewing the manuscript. All authors had final approval of the submitted manuscript.

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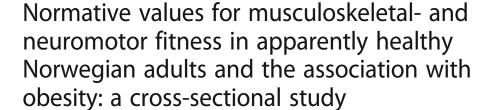
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# **PAPER II**

#### RESEARCH ARTICLE

Open Access





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#### **Abstract**

**Background:** Up-to-date research on musculoskeletal- and neuromotor fitness (MSMF) is lacking. The aims of the present paper were to a) establish normative values of MSMF by gender and age, and b) to assess how much of the variance in MSMF can be explained by obesity in adults.

**Methods:** A random selection of 726 Norwegians (20–65 years) participated in a national cross-sectional study. Muscular endurance, muscular strength, explosive power, flexibility and balance were assessed in addition to waist circumference (WC).

**Results:** Females displayed significantly higher scores compared to males on muscular endurance of the back extensors and on the flexibility tests (p < 0.001). Males displayed significantly higher scores than females (p < 0.001) on handgrip strength, modified push-ups, and explosive power. An inverse association was found between age and all MSMF scores for females (Beta:-0.06-(-0.92),  $p \le 0.044$ ) and males (Beta:-0.15-(0.91),  $p \le 0.006$ ), where younger participants displayed higher test scores on all MSMF tests, compared to older participants. Furthermore, participants showing higher scores on WC displayed lower scores on the following MSMF tests for both females and males: muscular endurance of the back extensors, balance, flexibility of the shoulder, and explosive power (p < 0.001). Additionally, male participants with higher WC scores showed lower scores on muscular endurance of the upper body and flexibility of the hamstrings compared to males with lower WC scores (p < 0.001).

**Conclusions:** The data provide normative values of MSMF for adults based on age and gender, and support an inverse relationship of MSMF to age and WC.

**Keywords:** Physical fitness, Mobility, Neuromuscular fitness, Muscular fitness, Muscular power, Reference values, Public health, Fatness

#### **Background**

Cardiorespiratory fitness and muscular strength seem to provide unique and important benefits to the prevention and treatment of cardiovascular disease and mortality in addition to several other health and fitness variables [1, 2]. Both the American College of Sports Medicine (ACSM)

position stand on the Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculo-skeletal, and neuromuscular fitness in apparently healthy adults [3] and recently published Nordic nutrition recommendations integrating nutrition and physical activity [2] emphasize the importance of combining cardiorespiratory exercise with muscular strength, flexibility and neuromotor exercise (e.g. balance, coordination, agility and gait) as essential in preventing disease, in addition to improving health, and quality of life.

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Physical fitness decreases with increasing age at varying rates, depending on lifestyle and physical health earlier in life [3–5]. Additionally, clear gender differences have been reported not only in muscular strength, but also in muscular endurance, balance, flexibility and explosive power, though some of the results are inconsistent. The literature indicate that males display significantly higher mean scores on muscle strength [6, 7] and balance [8]. Females seem to generally display higher scores on flexibility compared to males [9–11]. Inconsistency has been found for gender differences in muscular endurance of the back [12] and for flexibility of the shoulder [8, 11, 13].

Few studies have investigated the relationship between musculoskeletal- and neuromotor fitness (MSMF) and obesity. Most studies have reported an inverse relationship between various aspects of MSMF and obesity assessed by body mass index (BMI) or waist circumference (WC) [6, 14–16], where scores on MSMF decline with increasing BMI or WC values or categories, while some studies have found positive relationships between handgrip strength and BMI [14, 15].

There is a clear lack in up-to-date normative data on field based MSMF assessing muscular strength, muscular endurance, explosive power, flexibility and balance. Most of the present studies have assessed almost solely hand grip strength [6, 17-21]. The latest published Scandinavian data on MSMF are a Norwegian regional study of 566 adults and elderly (20-94 years) [19] and a national Danish study of 3471 males and females (19-72 years) [6]. However, these Scandinavian studies cover only three aspects of MSMF (pinch grip, hand grip strength and lower limb extension power). The latest published normative data on field based MSMF tests covering various elements are those of Rikli and Jones [10] studying older adults aged 60-94 years (N = 7183), and data published by the ACSM [9], based on Canadian normative values published in 2000 [22].

Based on the previously highlighted issues, the aims for this study were to a) establish normative values of MSMF by age and gender covering a wide range of MSMF, and b) to assess how much of the variance in MSMF can be explained by obesity in a sample of adult Norwegian males and females aged 20–65 years.

#### Methods

#### Study design and sample

The present study is part of a national, multicenter crosssectional study [23], and has been approved by the Regional Committee for Medical Ethics (REK Sør-Øst B, S-08046b) and the Norwegian Social Science Data Services. In order to sign up for participation, all participants signed and returned a written consent form.

A total of nine regional test centers nationwide in Norway participated in the two separate data collecting

phases of the study. The initial phase was conducted in 2008 and assessed physical activity level using the Acti-Graph GT1M accelerometer (ActiGraph, LLC), as well as demography, educational level, nutritional status, tobacco use, physical activity level and correlates for physical activity amongst other things through a questionnaire [24]. Initially, a random representative sample of 11,515 individuals, aged 20-85 years was drawn from the Norwegian National Population Registry and invited to participate. A total of 3800 agreed to participate in the initial data collection phase, where valid data from 3464 males (n = 1614) and females (n = 1850) were included. The second phase was conducted in 2009 and assessed physical fitness, including assessment of maximal oxygen consumption (VO<sub>2max</sub>), musculoskeletal- and motor fitness, blood pressure, lung capacity, and body composition [23]. A random selection of 1930 participants from the initial phase, were invited to take part in the second phase, where 463 males and 441females participated. For this paper, only the adult participants, aged 20.0–64.9 years were included (N = 726, F:350, M:376).

#### Methods and procedures

The following MSMF tests were included in this study and carried out in the following order; Muscular endurance of the upper body was measured by the static back extension test (SBE) [25]. The handgrip strength test (HGS) [26, 27] recorded muscular strength of the hand. Neuromuscular fitness was measured by the one leg standing test (OLS). The modified push-ups test (MPU) [25] assessed muscular dynamic endurance and ability to stabilize the upper body. Alternately, if the participants could not complete the ordinary MPU test, the MPU test was carried out on the knees (MPUK). The sit and reach test (SR) [28] recorded the flexibility of the hamstring musculature, and the back scratch test (BSC) [29] measured flexibility in the shoulder joint. In addition, explosive power in the lower extremities was measured by the vertical jump test (VJ) [25] and the explosive power on a power platform test (EPP) (HurLabs Force platform). Data on VO<sub>2max</sub> are published elsewhere [23]. For further elaboration on the tests used to assess MSMF, see Additional file 1: Appendix.

A health risk assessment was conducted prior to all physical fitness assessments and consisted of a question-naire comprising elements of general health status. The health risk assessment was conducted in order to eliminate potential participants at risk, though none were considered to be at risk. All participants went through a 10–15 min warm-up before the MSMF tests were conducted. For all tests, the instructor demonstrated the test-procedure before the participants conducted the test. All measures were conducted by trained instructors following a detailed test protocol and all measuring instruments were calibrated.

#### Measures of adiposity

Height was measured to the nearest centimeter (cm) using a stadiometer while the participant was standing upright with the heels touching the wall, without shoes. Body weight was measured to the nearest 0.1 kilogram (kg) with minimal clothing, using Seca weight scales. BMI was calculated (kg/m<sup>2</sup>). The BMI values were further grouped based on cut-off points developed by the World Health Organization (WHO) [30], where those with BMI values < 18.5 kg/m<sup>2</sup> were categorized as underweight, between 18.5 and 24.9 kg/m<sup>2</sup> were categorized as normal weight, between 25.0 and 29.9 kg/m<sup>2</sup> were categorized as overweight and those with BMI values ≥ 30 kg/m<sup>2</sup> were categorized as obese. WC was measured at the mid-point between the upper most lateral part of the iliac crest and the lowest most lateral point of the ribcage using a measuring band, where the mean of two measures was recorded to the nearest half centimeter. The WC values were grouped based on cutoff values developed by the WHO [30]. Males and females with WC values of  $\geq 94$  cm and  $\geq 80$  cm, respectively, were categorized as abdominally overweight and males and females with WC values ≥ 102 cm and ≥ 88 cm, respectively, were categorized as abdominally obese.

The collected data were analyzed using IBM SPSS Statistics 22 (IBM Corporation, Route, Somers, NY, USA). The mean of the two BSC tests for left and right arm resulted in a mean BSC variable, which is the only BSC variable used in this study. Furthermore, the OLS test and the OLS blinded test were summed and the OLSsum variable was created which is the only OLS variable used in this study. As only six female participants were classified as underweight, and the lowest BMI score among these was 18.0 kg/m<sup>2</sup>, the underweight participants were grouped in the normal weight category in the analyses. All the MSMF tests were considered normally distributed based on histogram distribution, except for the OLSsum test which peaked markedly at 60 s.

The normative values were given by mean ± standard deviation (SD), and quartile 1 (Q1) to quartile 3 (Q3), displayed by gender and 10-year age groups. An independent samples t-test was used to detect gender differences on all MSMF tests, with the exception of the OLSsum tests where a Mann Whitney U test was used. A regression analysis was run in order to analyze how much of the variance in MSMF could be explained by age and obesity. As WC and BMI correlated significantly (Pearson r = 0.796, p = 0.001), and as BMI has been more closely related to muscle mass and WC more closely related to fat mass [14], we chose WC as the main indicator for obesity in the standard multiple regression analysis. The results from the regression analyses between age and

MSMF, and between WC and MSMF, were thereby given by Beta and beta of the z-score (Beta Z) in brackets, p-value and 95 % confidence interval (95 % CI), displayed by gender. A statistical significance value of probability was set to  $p \le 0.05$ .

#### Results

Sample characteristics are presented in Table 1. A total of 58 % (F:61.4 %, M:54.8 %) of the sample had completed higher education (College/University). Furthermore, based on BMI, a total of 37.7 % (F:27.1 %, M:46.6 %) of the sample were classified as overweight and 13.5 % (F:14.3 %, M:12.8 %) as obese. In addition, based on WC, 27.4 % (F:28.0 %, M:26.8 %) were abdominally overweight and 28.1 % (F:35.5 %, M:21.1 %) were abdominally obese (Table 1).

#### MSMF-status and normative values

Normative values on all the MSMF tests are displayed in Table 2. The total sample displayed significant gender differences on all MSMF tests (p < 0.001), except for the OLSsum (Table 2). Males displayed significantly higher scores on HGS (F:32.1 kg, M:58.8 kg, p < 0.001), MPU (F:8.5 rep, M:12.1 rep, p < 0.001), VJ (F:24.7 cm, M:38.0 cm, p < 0.001) and EPP (F:19.5 cm, M:29.3 cm, p < 0.001), while females displayed significantly higher scores on SBE (F:90.9 s, M:74.3 s, p < 0.001), SR (F:24.3 cm, M:18.9 cm, p < 0.001) and BSC (F: -2.3 cm, M: -8.1 cm, p < 0.001).

Table 1 Sample characteristics

Characteristic	Fema	iles	Male	ŝ
	n	Mean ± SD	n	Mean ± SD
Age (years)	350	46.0 ± 11.5	376	46.3 ± 11.7
Weight (kg)	350	70.5 ± 13.2**	376	85.2 ± 12.0**
Height (m)	350	$1.67 \pm 0.06**$	376	1.80 ± 0.06**
BMI (kg/m²)	350	25.2 ± 4.4**	376	26.3 ± 3.4**
Overweight	95	27.1 %*	179	47.6 %*
Obese	50	14.3 %*	48	12.8 %*
WC (cm)	347	84.7 ± 11.3**	373	94.0 ± 10.4**
Abdominally overweight	97	28.0 %*	100	26.8 %*
Abdominally obese	123	35.5 %*	79	21.1 %*
Educational level				
< High school	29	8.4 %	25	6.8 %
High school	105	30.3 %	141	38.4 %
< 4 years university	94	27.1 %	88	24.0 %
≥ 4 years university	119	34.3 %	113	30.8 %

Sample characteristics given as number (n) and mean  $\pm$  standard deviation (SD), displayed by gender. Weight groups (BMI and WC) and educational level given as percentage, displayed by gender Abbrevations: NS Non-significant

<sup>\*</sup>p < 0.001 for gender differences in prevalence distribution between

weight categories
\*\*gender difference p < 0.001

Table 2 MSMF-status and normative values

Test	Age group	Number	Females		Number	Males		Gender dif
	(years)		Mean ± SD	ean ± SD Q1–Q3		Mean ± SD Q1–Q3		<i>p</i> -value
Static back extension SBE	All ages	338	90.9 ± 49.5	58.0-120.0	360	74.3 ± 38.3**	52.0-96.8	**
(sec)	20.0-29.9	36	101.1 ± 41.9	63.8-124.8	39	$86.0 \pm 37.0$	58.0-120.0	NS
	30.0-39.9	73	110.6 ± 49.3	68.5-142.5	78	84.5 ± 30.9**	60.8-107.0	**
	40.0-49.9	101	$83.4 \pm 42.7$	57.5-110.0	96	$76.0 \pm 41.4$	50.3-90.0	NS
	50.0-59.9	85	$82.8 \pm 54.7$	43.9-111.5	94	66.6 ± 33.6*	48.0-80.5	*
	60.0-64.9	43	82.3 ± 51.3	45.0-110.0	53.0	61.1 ± 45.0*	32.5-77.5	*
Handgrip strength HGS	All ages	347	$32.1 \pm 6.0$	28.0-36.0	375	54.8 ± 9.5**	48.0-60.0	**
kg)	20.0-29.9	36	$33.4 \pm 6.0$	29.3-39.0	40	58.0 ± 10.3**	51.0-64.0	**
	30.0-39.9	73	$33.8 \pm 6.0$	30.0-38.0	78	58.8 ± 9.6**	52.0-64.0	**
	40.0-49.9	104	$33.1 \pm 5.6$	30.0-36.0	100	55.8 ± 8.1**	50.0-61.0	**
	50.0-59.9	89	$30.7 \pm 6.1$	27.0-34.0	102	53.4 ± 7.8**	48.0-59.0	**
	60.0-64.9	45	$28.8 \pm 5.2$	25.0-32.0	55	47.9 ± 9.8**	42.0-55.0	**
One leg standing	All ages	349	57.4 ± 22.7	44.5-68.0	374	55.7 ± 22.9	42.0-67.0	NS
summed OLSsum max 120 s)	20.0-29.9	37	$72.7 \pm 23.4$	63.5-76.5	40	$66.4 \pm 13.4$	62.3-74.5	NS
,	30.0-39.9	73	67.5 ± 19.7	64.0-74.0	78	66.6 ± 16.2	63.0-72.53	NS
	40.0-49.9	103	58.9 ± 17.2	55.0-68.0	100	$60.2 \pm 21.5$	62.0-68.8	NS
	50.0-59.9	89	$50.7 \pm 21.7$	34.0-66.0	101	50.3 ± 21.2	34.0-64.0	NS
	60.0-64.9	47	39.5 ± 23.2	15.0-63.5	55	$33.8 \pm 24.2$	11.0-63.0	NS
Modified push-ups MPU	All ages	150	$8.5 \pm 4.3$	6.0-11.3	342	12.1 ± 4.7**	9.0-15.0	**
no/40 s)	20.0-29.9	23	$10.3 \pm 4.2$	7.0-13.0	39	14.2 ± 3.2**	12.0-16.0	**
	30.0-39.9	44	$9.5 \pm 4.4$	7.0-13.0	75	14.3 ± 5.0**	11.0-17.0	**
	40.0-49.9	47	$7.7 \pm 3.9$	6.0-10.0	96	12.6 ± 4.7**	9.0-16.0	**
	50.0-59.9	25	$7.8 \pm 4.5$	5.0-10.5	90	10.5 ± 4.0*	8.0-13.0	*
	60.0-64.9	11	$5.1 \pm 3.0$	2.0-7.0	42	8.4 ± 3.4*	6.0-10.0	*
Modified push-ups	All ages	196	$7.9 \pm 4.4$	5.0-11.0	-	-	-	-
on knees MPUK no/40 s)	20.0-29.9	14	$6.6 \pm 5.2$	0.0-11.5	-	-	-	-
110, 10 3,	30.0-39.9	32	$8.9 \pm 4.2$	6.3-11.8	-	-	-	-
	40.0-49.9	56	$9.0 \pm 4.9$	6.0-12.0	-	-	-	-
	50.0-59.9	61	$7.3 \pm 4.0$	5.0-10.0	-	-	-	-
	60.0-64.9	33	$6.8 \pm 3.6$	4.0-9.0	-	-	-	-
it and reach SR	All ages	348	24.3 ± 13.2	17.3-33.9	373	18.9 ± 12.0**	11.0-28.0	**
cm)	20.0-29.9	37	$24.4 \pm 14.8$	19.0-33.8	40	20.8 ± 11.0	15.0-28.4	NS
	30.0-39.9	73	29.0 ± 14.3	22.0-38.5	78	21.1 ± 12.2**	13.0-31.6	**
	40.0-49.9	103	22.3 ± 13.1	15.0-31.5	100	20.2 ± 12.6	10.6-30.4	NS
	50.0-59.9	88	$23.8 \pm 10.6$	16.0-30.9	100	16.5 ± 11.8**	8.0-25.5	**
	60.0-64.9	47	22.1 ± 13.1	14.5-32.0	55	16.8 ± 10.9*	9.0-25.0	*
Back scratch BSC	All ages	343	$-2.3 \pm 8.5$	-7.5-4.3	366	$-8.1 \pm 11.2**$	-15-5-0.0	**
cm)	20.0-29.9	37	$1.1 \pm 7.8$	-3.9-6.4	40	$-0.2 \pm 8.9$	-3.9-4.8	NS
	30.0-39.9	71	$1.8 \pm 8.0$	-1.5-7.0	77	$-3.1 \pm 10.0**$	-8.5-3.7	**
	40.0-49.9	101	$-2.2 \pm 8.7$	-7.8-3.9	98	-7.7 ± 10.2**	-15.1-(-0.5)	**
	50.0-59.9	87	$-5.2 \pm 7.2$	-9.0-0.0	99	$-11.0 \pm 10.0**$	-18.5-(-4.5)	**
	60.0-64.9	47	$-5.8 \pm 8.0$	-11.0-0.0	52	-16.6 ± 10.9**	-23.0-(-9.8)	**
/ertical jump VJ (cm)^	All ages	237	24.7 ± 7.1	20.0-29.2	247	38.0 ± 8.5**	32.0-45.0	**

**Table 2** MSMF-status and normative values (Continued)

	20.0-29.9	16	29.8 ± 5.8	25.5-32.8	25	44.7 ± 9.1**	40.8-49.5	**
	30.0-39.9	50	$29.8 \pm 6.4$	26.0-34.0	51	43.1 ± 7.4**	38.5-48.0	**
	40.0-49.9	84	$25.8 \pm 6.1$	22.0-29.5	69	38.6 ± 7.5**	34.8-43.5	**
	50.0-59.9	57	$20.7 \pm 5.6$	16.5-24.3	69	$35.9 \pm 6.1**$	31.5-39.0	**
	60.0-64.9	30	$18.6 \pm 5.3$	15.6-23.3	33	28.4 ± 5.4**	24.3-31.5	**
Explosive power on	All ages	191	$19.5 \pm 5.1$	15.9-23.0	191	29.3 ± 7.2**	24.1-34.4	**
power platform EPP (cm)^	20.0-29.9	23	$24.2 \pm 3.7$	21.8-26.4	24	$36.2 \pm 4.8**$	33.6-39.3	**
	30.0-39.9	39	$22.1 \pm 4.7$	19.9-24.8	37	34.3 ± 5.8**	30.6-38.3	**
	40.0-49.9	55	$19.7 \pm 4.1$	17.4-22.7	51	29.5 ± 6.2**	23.8-32.6	**
	50.0-59.9	50	$17.1 \pm 3.8$	14.1-20.1	52	26.3 ± 5.7**	22.6-30.1	**
	60.0-64.9	24	$15.4 \pm 5.4$	11.0-17.4	27	$21.8 \pm 4.3**$	18.1-24.7	**

Normative values for all the MSMF scores displayed by test, age group, number (n), mean  $\pm$  standard deviation (SD), quartile 1 (Q1) and quartile 3 (Q3) - too few cases for further analysis (n for all ages = 21), \*p < 0.05 for gender differences, \*\*p < 0.001 for gender differences, NS Not statistically significant ^ Vertical jump and explosive power on a power platform were only conducted at selected test-centers due to availability of resources and equipment

All MSMF tests were inversely associated with age for both females ( $p \le 0.044$ ) and males ( $p \le 0.006$ ), where younger participants scored significantly higher on all MSMF tests, compared to older participants (Table 3). The largest reduction in MSMF test scores related to age for females was found in the OLSsum (Beta Z = -0.04), where test scores declined with 0.91 s for every 1 year increase in age (p < 0.001). HGS, MPUK and SR tests displayed the least reduction in test scores related to age in females (Beta Z for HGS, MPUK and SR = -0.01). For males, the largest decline in test scores for MSMF associated with age was found in the EPP test (Beta Z = -0.05). A 1 year increase in age was associated with a reduction in EPP test scores of 0.40 cm (p < 0.001). The SR scores declined least in relation to age (Beta Z = -0.01) for males.

## MSMF in relation to WC

WC was found to be inversely associated with scores on SBE (Beta = F: -1.75, M: -1.37,), OLS (Beta = F: -0.58,

M: -0.55), BSC (Beta = F: -0.37, M: -0.52), and both explosive power tests, VJ (Beta = F: -0.19, M: -0.26) and EPP (Beta = F: -0.14, M: -0.34) for both genders (p < 0.001), where higher WC scores were associated with lower MSMF test scores. Additionally, higher WC scores were related to lower scores on MPU (Beta = -0.19) and SR (Beta = -0.29) in males (p < 0.001) (Table 4). For females, the largest change in MSMF by each one cm increase in WC, was found for SBE (Beta Z = -0.04). SBE decreased by -1.75 s per one cm increase in WC in females (p < 0.001). The equivalent for males was found for BSC (Beta Z = -0.05), which decreased by -0.52 cm per one cm increase in WC (p < 0.001).

## Discussion

Our results display clear gender differences on all MSMF tests, except for the OLSsum and MPUK tests. Increasing age was associated with lower MSMF test scores for both genders. Furthermore, higher WC scores

**Table 3** MSMF in relation to age (years)

	Females			Males			
	Beta (Beta Z)	P-value	95 % CI	Beta (Beta Z)	P-value	95 % CI	
Static back extension SBE (sec)	-0.91 (-0.02)	< 0.001	-1.36-(-0.46)	-0.72 (-0.02)	< 0.001	-1.05-(-0.39)	
Handgrip strength HGS (kg)	-0.14 (-0.01)	< 0.001	-0.19-(-0.08)	-0.28 (-0.02)	< 0.001	-0.36-(-0.20)	
One leg standing summed OLSsum (max 120 s)	-0.91 (-0.04)	< 0.001	-1.10-(-0.73)	-0.91 (-0.04)	< 0.001	-1.08-(-0.73)	
Modified push-ups MPU (no/40 s)	-0.13 (-0.03)	< 0.001	-0.18-(-0.07)	-0.16 (-0.03)	< 0.001	-0.20-(-0.12)	
Modified push-ups on knees MPUK (no/40 s)	-0.06 (-0.01)	0.044	-0.11-(-0.00)	-	-	-	
Sit and reach SR (cm)	-0.13 (-0.01)	0.036	-0.25-(-0.01)	-0.15 (-0.01)	0.006	-0.25-(-0.04)	
Back scratch BSC (cm)	-0.26 (-0.03)	< 0.001	-0.33-(-0.18)	-0.42 (-0.04)	< 0.001	-0.51-(-0.33)	
Explosive power on a power platform EPP (cm)	-0.24 (-0.03)	< 0.001	-0.29-(0.19)	-0.40 (-0.05)	< 0.001	-0.47-(-0.54)	
Vertical jump VJ (cm)	-0.35 (-0.03)	< 0.001	-0.42-(-0.29)	-0.39 (-0.04)	< 0.001	-0.47-(-0.31)	

A regression analysis for all the MSMF tests against age (years), given by Beta (Beta Z), p-value and 95 % Cl, displayed by gender, where Beta Z is the beta of the z-score of each MSMF test

<sup>-</sup> not analyzed due to low sample size (n = 21)

Table 4 MSMF in relation to WC

	Females			Males			
	Beta (Beta Z)	P-value	95 % CI	Beta (Beta Z)	P-value	95 % CI	
Static back extension SBE (sec)	-1.75 (-0.04)	< 0.001	-2.19-(-1.32)	-1.37 (-0.03)	<0.001	-1.73-(-1.02)	
Handgrip strength HGS (kg)	0.04 (0.00)	0.156	-0.02-0.10	-0.01 (0.00)	0.849	-0.10-0.08	
One leg standing summed OLSsum (max 120 s)	-0.58 (-0.03)	< 0.001	-0.78-(-0.37)	-0.55 (-0.02)	< 0.001	-0.77-(-0.33)	
Modified push-ups MPU (no/40 s)	-0.05 (-0.01)	0.148	-0.11-0.02	-0.19 (-0.04)	< 0.001	-0.23-(-0.14)	
Modified push-ups on knees MPUK (no/40 s)	-0.04 (-0.01)	0.125	-0.10-(0.01)	-	-	-	
Sit and reach SR (cm)	-0.10 (-0.01)	0.117	-0.22-0.03	-0.29 (-0.02)	< 0.001	-0.40-(-0.18)	
Back scratch BSC (cm)	-0.37 (-0.04)	< 0.001	-0.44-(-0.30)	-0.52 (-0.05)	< 0.001	-0.62-(-0.42)	
Explosive power on a power platform EPP (cm)	-0.14 (-0.02)	< 0.001	-0.20-(-0.08)	-0.34 (-0.04)	< 0.001	-0.43-(-0.26)	
Vertical jump VJ (cm)	-0.19 (-0.02)	< 0.001	-0.26-(-0.11)	-0.26 (-0.03)	< 0.001	-0.35-(-0.16)	

A regression analysis for all the MSMF tests against waist circumference (WC), given by Beta (Beta Z), p-value and 95 % CI, displayed by gender, where Beta Z is the beta of the z-score of each MSMF test

were associated with lower scores on SBE, OLS, BSC and both explosive power tests for females and males, in addition to MPU and SR for males.

#### MSMF status

A national Danish study of 3471 females and males (19-72 years) [6], displayed mean HGS scores which were similar to those found in the present study. Compared to a regional Norwegian study of 566 adults and elderly (20-94 years) [19], the present study found mean HGS scores by 10 year age groups which were primarily similar, except for males in the age group of 50.0-59.9 years. Males in their 50s displayed markedly lower scores on HGS in the study by Nilsen et al. [19], compared to our study. Whether or not the difference in HGS test scores reflect regional differences, differences in recruitment procedures or differences in sample characteristics in this specific age group is therefore unclear, though they should be considered as possible explanatory factors as the differences in this specific age group for males are noteworthy. The study by Aadahl, Beyer, Linneberg, Thuesen, and Jorgensen [6], however displayed mean HGS scores which were similar to those found in the present study.

Compared to normative values for HGS published by the ACSM [9], the mean HGS scores from our study were within or above the cut-off for *average* in all age groups. The normative HGS scores presented by the ACSM are based on the sum of the average measures from both the right and the left hand grip, whereas our study recorded the highest HGS score for one hand. As an average score would be expected to be lower compared to a peak score, the ACSM scores would be expected to be lower compared to the ones reported in this study. Hence, the difference in assessment protocol may imply an overestimation of the HGS status in our study.

The ACSM [9] also published age based normative values for hamstrings flexibility by SR, where mean SR values from the present study reveal scores within the category of needs improvement and fair. The assessment protocol for SR recommended by the ACSM, differs slightly from that used in our study in that they allow for flexion of the neck when leaning forward toward the measuring band, while our study's protocol instruct the participants to keep a straight back. Whether this difference in assessment method may be a significant explanatory factor for the observed differences between the present study and the normative values by the ACSM is unknown, thus prone for speculation. Furthermore, the reference data published by the ACSM [9] is based on a study on a representative sample Canadian adults (N = 571, 15-65 years) dated prior to 2000 [22]. The time difference in the studies data collection may question the comparability of the categorization of test scores, though the link between various MSMF measures and health outcomes investigated in the study by Payne, Gledhill, Katzmarzyk, Jamnik, and Ferguson [22] is believed to remain unchanged. For the remaining tests, we found no further studies we considered comparable in design, methods or sample.

The spread in scores on the flexibility tests (BSC and SR) and the muscular endurance tests (MPU, MPUK and SBE) were large, not only for the mean of the entire sample (20.0–64.9 years), but also within each 10-year age group and for both genders. Whether or not this observed variation in test scores is attributable to measuring methods or a naturally large population variation on these specific MSMF properties, is uncertain, though the reported variability in test scores should be taken into consideration when interpreting and applying the normative values. Further research is needed in order to address variability in MSMF.

<sup>-</sup> not analyzed due to low sample size (n = 21)

#### MSMF and gender

Although inconsistencies in gender differences have been found in previous studies, clear gender differences were found within the different MSMF scores in our study. In accordance with the present findings, other studies have also reported male superiority in muscular strength [7, 17, 19, 20]. Even though our findings display female superiority on the SBE test, muscular endurance by SBE seems to be a measure of musculoskeletal fitness in which gender differences are not as clear as other aspects of musculoskeletal fitness [12]. Haizlip, Harrison, and Leinwand [31] clearly state that muscular endurance is a measure of muscular fitness in which females are superior to males, due to the larger number of type I muscle fibers characterized by slow oxidative metabolism. However, males showed significantly higher mean scores on muscular endurance by the MPU test in the present study. Furthermore, markedly more males (n = 342), than females (n = 150) completed the MPU test, whereas markedly more females (n = 196), than males (n = 21) completed the MPUK test. Whether or not the observed inequalities between genders concerning choice of test is related to the registered male superiority in muscular endurance of the upper body, or other factors is unclear, though noteworthy for future testing of and research on muscular endurance. With the exception of Bø and Hagen's [8] findings of male superiority on flexibility of the shoulder, the remaining literature on flexibility of the shoulder seem to indicate female supremacy in flexibility [11, 13], which is in accordance with our findings, though data is sparse. Manire, Kipp, Spencer and Swank [32] mention the possibility of females' longer m. hamstrings muscle length, as a possible explanatory factor related to females superiority in m. hamstring flexibility, though they clearly state that more research is needed in order to elaborate the mechanisms underlying the difference in flexibility between genders. No difference in score on the OLS test was found in this study, however in previous studies, males have shown better scores on balance compared to their female peers [8, 10]. The lack of data in this field and the lack of agreement in the studied literature, give little room for resolution.

#### MSMF and age

An increase in age was associated with lower test scores on all MSMF aspects. Muscular strength across the major joints in the body has previously been shown to decrease with increasing age [6, 7, 19, 20]. The age dependency has been shown to vary from movement to movement, though most studies report increasing decline in muscular strength from 40 to 50 years of age [6, 7, 19, 20]. Furthermore, the age related declines in flexibility, muscular endurance and explosive power found in our study are supported by previous findings [6, 8, 12].

The present study, however, is cross sectional and cannot imply age related changes in MSMF, or the subsequent cause of differences in scores on the various MSMF tests observed between age groups.

#### MSMF and obesity

Increased WC values were found to be associated with decreased scores on SBE, OLS, BSC, EPP and VJ for both genders, in addition to MPU and SR for males. According to the Beta of the z-scores (Beta Z) females decreased most in test score on the SBE and BSC tests per one cm increase in WC and least on both explosive power tests. Males decreased most in test score on the BSC test and least on the OLSsum, SR and VJ per one cm increase in WC. The increased WC scores associated with decreased test scores on BSC for both genders and on SR for males, may be explained by the increased fat mass located such that it hinders the range of motion, possibly reflecting females smaller WC. Furthermore, the high contribution of WC to SBE, MPU and both the explosive power tests, is thought to be explained by the weight bearing characteristics of those MSMF tests. The inverse association between increased scores on BMI, WC and body fat percentage and lower scores on MSMF have been reported in previously published studies [6, 14-16]. Fogelholm, Malmberg, Suni, Santtila, Kyrolainen and Mantysaari [14]. clearly state that the functional muscle fitness is impaired in individuals with abdominal obesity, and that the decline in MSMF should be given increased attention.

Muscular strength has previously been found to provide unique and important benefits to the prevention and treatment of cardiovascular disease and mortality in addition to several other health and fitness variables, including the prevention of adiposity gains [1]. Maintaining or improving muscular fitness together with flexibility and balance can be crucial for remaining independent [3]. Thus, there is a clear need to achieve and retain a high MSMF level and to reduce fat mass in order to prevent future functional limitations among adults [2, 3, 14, 15].

#### Strengths and limitations

The primary strength of our study is that the studied population is based on a nationally random sample of Norwegians from regions across the entire country. Secondly, objective measuring methods for recording MSMF and obesity were used, and all elements of MSMF and obesity were measured by established measuring procedures.

The present study's primary limitation is the relatively low participation rate with 32 % of the initially invited sample participating in the initial phase (phase I) of this larger survey [24]. Statistics Norway performed a drop-out

analysis, and revealed higher socioeconomic background for those participating in phase I of this study, compared to the non-participating invitees. Comparing educational level between the participants of phase I and phase II of this study reveals similar educational level between participants. As higher socioeconomic status (i.e., educational level, personal income, employment status, and ability to pay for basic needs) has been inversely related to impaired physical fitness [33], the drop-out analysis may indicate that the normative values put forward through this paper possibly overestimates the MSMF in the Norwegian population. Furthermore, summing the OLS test with the OLS blinded test into an OLSsum variable, was meant to prevent the clustering of maximum scores observed in the OLS test and create more normally distributed test scores. The high percentage managing to endure the OLS test in addition to the high percentage ending the OLS blind test within the first 15 s, renders the question of whether or not the OLS or the OLSsum are valid measures of balance as a neuromotor function.

Not adjusting for confounding variables in the regression analysis was done with the intent of displaying crude descriptive data, though this may be a bias to the presentation and interpretation of the results. Moreover, some of the normative values should be interpreted with caution as the presentation of normative values by gender and 10 year age groups, rendered few cases (n < 20) in three of the female age groups.

#### **Conclusions**

The present study offers warranted normative data on MSMF based on a national sample primarily Caucasian adult Norwegians, making it possible for others to compare results from various field based MSMF tests to normative data based on age and gender. Furthermore, the results displayed a clear decrease in MSMF test scores with increasing age and with increasing WC. This indicates the need to enhance MSMF in population subgroups with these characteristics, in order to prevent disease and mortality in addition to secure an independent daily lifestyle.

#### **Additional files**

**Additional file 1: Appendix 1.** Measuring procedures for MSMF. The measuring procedures of the musculoskeletal and motor fitness (MSMF) tests used in the present study. (PDF 194 kb)

**Additional file 2:** Availability of data. The available data generated or analyzed for this research article. (XLSX 247 kb)

#### Abbreviations

BSC: Back scratch test; EPP: Explosive power on a power platform test; HGS: Hand grip strength test; MPU: Modified push-ups test; MPUK: Modified push-ups on knees test; MSMF: Musculoskeletal- and neuromotor fitness; OLS: One leg standing test; SBE: Static back extension test; SR: Sit and reach test; VJ: Vertical jump test; WC: Waist circumference

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#### Availability of data and materials

Data generated or analyzed for this research article are included in the article and its Additional file 2.

#### Author's contributions

IGHK took part in the data collection, completed the data analysis, data interpretation and the generation of figures and drafting the manuscript, EK and BHH took part in coordinating and planning the study, collecting the data, data interpretation and in reviewing the manuscript, SAA was project manager for the study, contributed to planning the study, the study design and contributed to the data interpretation and in reviewing the manuscript, MKT contributed to the data interpretation and reviewing the manuscript. All authors had final approval of the submitted manuscript.

#### Competing interests

The authors declare that they have no competing interests

#### Consent for publication

Not applicable

#### Ethics approval and consent to participate

The present study has been approved by the Regional Committee for Medical Ethics (REK Sør-Øst B, 5-08046b) and the Norwegian Social Science Data Services. In order to sign up for participation, all participants signed and returned a written consent form.

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## PAPER III

# A tailored telephone and email based exercise intervention increased physical fitness in physically inactive adults:

## A RCT

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#### **Abstract**

**Background** Tailored physical activity (PA) interventions have proven effective in enhancing PA levels in adults, however the effect of such interventions on objectively measured physical fitness among physically inactive adults is lacking. The purpose of this parallel group randomized controlled trial was to assess the effect of a six-month tailored telephone and email based exercise intervention on cardiorespiratory fitness (CRF) and musculoskeletal- and neuromotor fitness (MSMF), in apparently healthy but physically inactive adults.

*Methods* A total of 111 physically inactive adults (40-55yr) from the Agder counties, Norway volunteered for the study and were randomly assigned to an intervention group (IG;n=56) or a no-intervention control group (CG;n=55), using random allocation numbering, stratified by gender. The IG received tailored exercise recommendations, every two months by email or mail (print) and supporting motivational follow-ups every fortnight, alternatively by email and telephone. The CG received no follow-up during the intervention period. Outcome measures were objective measures of physical fitness (CRF and MSMF), which were assessed at baseline and post-intervention (IG:n=39, CG:n=50). All personnel involved in the intervention and both assessments were blinded for group allocation.

**Results** The IG showed significant improvements in maximal oxygen consumption by  $VO_2$ max, in ml/kg/min (ES:0.12, p=0.002) and  $VO_2$ max in l/min (ES:0.12, p=0.008), in muscular endurance of the back extensors (ES:0.21, p<0.001), flexibility of the hamstrings muscles (ES:0.12, p=0.006), and explosive power (ES:0.09, p=0.022), from pre- to posttest compared to the CG, when adjusting for baseline scores. When fully adjusted, the IG showed significantly higher improvements in maximal oxygen consumption by  $VO_2$ max in ml/kg/min (ES:0.17, p=0.002) and  $VO_2$ max in l/min (ES:0.13, p=0.008), compared to the CG.

**Conclusion** A six-month tailored telephone and email based exercise intervention had significant positive effects on several aspects of CRF and MSMF in physically inactive adults, and may be a possible effective tool in promoting physical fitness in physically inactive adults.

Trial registration ClinicalTrials.gov (NCT03164239)

**Keywords:** mixed delivery modes, phone, mobility, muscular strength, randomized controlled trial, RCT, exercise intervention

## **Background**

A rich body of evidence underlines the importance of reducing physical inactivity by regular physical activity (PA) as vital for the health of adults <sup>1,2</sup>. Garber et al. <sup>1</sup> further argue that the necessity for healthy adults to engage in cardiorespiratory-, resistance-, flexibility- and neuromotor exercise, beyond activities of daily living, is essential for maintaining or improving physical fitness and health. Both increased levels of cardiorespiratory fitness (CRF) and muscular strength have been found to produce better cardiovascular and survival prognosis, in addition to several physical- and mental health related benefits <sup>1,3</sup>.

Strong evidence implies that PA interventions are capable of increasing PA levels to where meaningful health benefits are achieved <sup>4,5</sup>. The implementation of modern technological modes of delivering interventions such as phones, internet, tablets, tracking devices and other similar devices, has generated more comprehensive, interactive and responsive modes of enhancing PA levels and they have shown to aid and improve public health practice <sup>6</sup>. Interventions delivered through these rapidly growing information and communication technologies have also shown potential to yield positive effects on PA level <sup>6,7</sup>.

Most interventions including mobile phones as a mode of delivery used SMS <sup>6</sup>, and few mobile phone based studies have included some form of personal contact <sup>6,7</sup>. Together with tailoring of interventions <sup>4,5</sup>, personal contact has been suggested to be an essential component of effective interventions aiming at increasing PA level <sup>6,7</sup>. Additionally, recent reviews of interventions aiming at increasing PA levels, using various modes of delivery such as phones, internet, email and wireless devices, report several methodological limitations <sup>4,5,7,8</sup>. Many interventions are biased as they use a treatment control group and thereby lack a no-intervention control group, have high attrition-rate, lack sufficient reporting of study components and there seems to be a lower prevalence of interventions with a duration of six months or more <sup>4,5,7,8</sup>.

The primary outcome of several studies having investigated the effect of a PA intervention by mobile <sup>6</sup> and/or electronic modes <sup>7</sup>, was either objectively assessed- or self-reported PA level. Only three previous studies <sup>9-11</sup> were found having used newer, supposedly less expensive modes of delivering interventions where primary outcomes were components of physical fitness. However, only two aspects of physical fitness were studied in these studies,

namely, hand grip strength <sup>10</sup> and cardiorespiratory fitness (CRF) by VO<sub>2</sub>max <sup>9,11</sup>. Thus, data on the effects of such interventions on CRF and musculoskeletal- and neuromotor fitness (MSMF) is scarce.

The main aim of the present study was to assess the effect of a six-month tailored telephone and email based exercise intervention on CRF and MSMF in a sample of initially physically inactive adults. We hypothesized that a six-month tailored telephone and email based exercise intervention will induce an increase in MSMF and CRF in a sample of initially physically inactive adults

## Materials and methods

This paper is based on a parallel group randomized controlled trial where the project coordinator, data collectors, outcome adjudicators and data analysts were blinded for group allocation. The study was approved by the Regional Committees for Medical and Health Research Ethics (REC) South East D (ref. no. 2010/2371-1) and registered in ClinicalTrials.gov (NCT03164239). The project coordinator enrolled participants for the study and thereby obtained written consent from all participants prior to inclusion. The intervention duration was set to six months.

#### Sample

A power analysis was conducted prior to commencing the study in which this paper is based upon. Maximal oxygen consumption (VO<sub>2</sub>max) and body composition were main outcome measures, though only the results from the VO<sub>2</sub>max measures are presented in this paper. Power and significance level were set to 90% and p≤0.05, respectively. Based on an estimated effect size for the difference in change in VO<sub>2</sub>max of 0.69 (3.3 mL kg -1 min-1 /4,8) and an estimated effect size for the difference in change in fat percentage of 0.36% (-1,4%/3,9)<sup>12</sup>, the target sample size per group was 44 participants. Additionally, an assumed drop-out rate of <20% reported by Richards et al. <sup>13</sup> was added to the target sample size calculation, leaving a total target sample of N= 110. In order to assess eligibility for participation, the following inclusion criteria were set; the participants must a) be physically inactive, *not* fulfilling the national recommendations of 30 minutes of daily PA set by the Norwegian Directorate of Public Health (2010), assessed by The International Physical Activity Questionnaire short form (IPAQ-SF) <sup>14</sup>, b) be within the age range of 40 – 55 years, assessed by telephone

interview/screening and questionnaire c) live in one of the two Agder counties, assessed by telephone interview/screening d) be healthy enough to take part in the assessment and intervention, assessed by a screening tool used in a national surveillance study <sup>15-17</sup> and e) be within stage two or three of the five stages of change in the transtheoretical model stages of change (TTM SOC) <sup>18</sup>, assessed by questionnaire. In cases where there was doubt whether the participant was physically inactive based on the IPAQ-SF, the results from the VO<sub>2</sub>max test at pretest were compared to normative VO<sub>2</sub>max values <sup>19</sup> based on gender and age group. Those scoring below average for their age group were included in the study.

Three months prior to intervention commencement, participants were recruited by one of four recruitment procedures; 1) a sample of participants who took part in a national cross sectional study (the KAN study) <sup>15</sup> were invited to participate (n= 37, 40-55 yr), 2) a randomly selected additional sample for the KAN study <sup>15</sup> (n=200, 43-48 yr) who did not take part in the KAN study, were invited to participate, 3) advertisements in local papers and radio, and 4) employees at the University of Agder and in Kristiansand municipality were invited by advertisements on the workplace's intranet.

A total of 125 people in total volunteered to participate in the study, of which 81 were females and 44 males. A total of 14 (50% females) were excluded after pretest resulting in 111 included participants in the study, whereof 89 participants completed both pre- and post-test (figure 1). A third party who did not have any further involvement in the study, randomly assigned participants to either an intervention group (IG) or a no-intervention control group (CG). Group assignment was conducted by random allocation numbering in SPSS, stratified by gender.

## Intervention

The intervention consisted of a) tailored exercise programs for self-administration, developed based on national- and international recommendations for PA <sup>20</sup> and a national Norwegian report on physical inactivity <sup>21</sup>, (figure 3), and b) counseling sessions based on motivational interviewing (MI) <sup>22</sup> alternately by telephone or email, completed every two weeks (figure 2), all given by a trained person with a master's degree in sport sciences with experience within behavior change techniques (including MI), who had no further involvement in assessment and/or allocation. A total of three intervention packages were distributed to the IG every two months in order to facilitate the self-administered intervention, ensure progress, enhance

motivation and prevent the high drop-out rates previously experienced in some electronic and mobile health interventions <sup>6,7</sup> (figure 2). The first intervention package, distributed at intervention start, consisted of individual feedback on baseline health related physical fitness (body composition, CRF and MSMF), a letter with information on national and international recommendations for PA and the associated health benefits possibly achieved through following PA recommendations (figure 2), a leaflet on national dietary recommendations <sup>23</sup>, prompts and reminders and one of three tailored exercise programs. (figure 2). Additionally, the participants were encouraged to increase their daily PA, advised on how to obtain exercise equipment (either by buying or by utilizing household equipment) and they were informed of possible natural variations, especially declines in PA level due to chance or unforeseen events. The three different exercise programs (figure 3) were designed based on the total amount of days per week the participants reported being physically active at baseline, categorizing the participants into one of four predefined PA frequency levels. Thereby, the participants were recommended to engage in either two, three, or four PA sessions a week during the first intervention phase (first two months), increasing the amount of PA with one day from baseline reporting's. Those reporting not engaging in PA at baseline were recommended to increase their PA to two days. The second and third intervention packages recommended a further one and two-day increase in PA per week from baseline, respectively. However, through individual counselling, alterations in exercise recommendations and preferences were made, to ensure individual progression. All exercise programs included recommendations on musculoskeletal- and neuro motor exercises and cardiorespiratory exercise. For each exercise program, seven different strength training programs were developed using EXORLive 24 and numerous different examples of cardiorespiratory exercise were given for different arenas of exercise in order to meet individual preferences in interests and physical function (figure 3). The CG received no follow-up during the intervention period. However, after completing posttest, they received similar follow-up as the IG. The person counselling the participants in the IG was responsible for further delivering both information on group allocation and delivering the intervention.

#### Measuring methods

The study was based in the Agder counties, Norway, and baseline and posttest measures were conducted in a test laboratory at the University of Agder. Baseline assessments were carried out between mid-March, 2011 to mid-April, 2011 and posttest assessment was conducted between mid-October throughout November, 2011. The methods used to assess the outcomes

for the present study were the same as those used in a national multicenter study assessing PA and physical fitness in a sample of Norwegian adults and older people (20–85 years) <sup>15</sup>. The primary outcomes were CRF and MSMF. Age, gender, educational level and physical activity level were assessed by questionnaire as fixed factors. Four categories of educational level were created: completed less than High School, completed High School, completed three years or less of College/University and completed four years or more at College/University. Additionally, PA level was assessed by The International Physical Activity Questionnaire short form (IPAQ-SF), where metabolic equivalent of task values inn minutes (MET minutes) were calculated <sup>25</sup>. Baseline IPAQ-SF measures were subtracted from the posttest IPAQ-SF measures in order to create a difference/delta value for PA level. A total of 50 (IG: 24, CG: 26) of 89 cases were found valid for analysis by the IPAQ-SF. Other covariates were body weight, height, and body mass index (BMI), which were measured objectively. All objective tests were carried out and lead by the project coordinator. Additional test personnel were qualified master students and a physiotherapist, none of whom had any involvement in or knowledge about group allocation or were involved in any way in delivering the intervention. Furthermore, adherence to the counselling sessions was tracked by the person conducting the counseling, by registering each responsive and interactive counselling session. All those involved in assessment of outcome, were taken through thorough instructions and training prior to study commencement.

CRF was assessed by treadmill (Woodway ELG 55, Weil am Rhein, Tyskland) using a modified Balke protocol  $^{26}$ . With a two-way breathing mask (2700 series), an Oxycon Pro Breathing System (Oxycon, Jaeger BeNeLux Bv, Breda, Netherlands) registered gas exchange averaged over 30 seconds. The equipment was calibrated after every fourth or fifth test to ensure reliable measures. Perceived exhaustion was also continuously registered by Borg scale  $^{27}$  throughout the test duration and at test termination. Within one minute after terminating the test, the lactate content in a capillary blood sample was measured (LactatePro LT-1710, Arkay KDK, Japan). A CRF test was considered valid as long as the respiratory exchange ratio (RER) was  $\geq 1.10$  or the Borg rate of perceived exertion  $^{28}$  was  $\geq 17$   $^{15}$ .

The following MSMF tests were included and carried out in the following order both at baseline and posttest; The static back extension test (SBE) <sup>29</sup> recorded muscular endurance of the back extensors, where the duration of which the subjects managed to sustain a static horizontal position, with their lower body supported by a bench (max 240 sec) was recorded.

Handgrip strength was measured by the Hand grip strength test (HGS) <sup>30,31</sup> to the nearest 1 kilogram (kg) using a hydraulic dynamometer (Chattanooga, Hixon, USA). The one leg standing test (OLS) registered neuromotor fitness, where the duration each subject managed to hold the initial balancing position was recorded in seconds (max 60 seconds). The subjects who managed to endure a 60 second OLS were put through the same test again, only blinded (OLSblind). The added sum in seconds of the OLS and OLSblind test were used to create the final OLSsum variable. The modified push-ups test (MPU) <sup>29</sup>assessed muscular dynamic endurance of and the ability to stabilize the upper body, and the amount of correctly performed repetitions completed in 40 seconds, was recorded. Participants who were not able to perform a correct MPU, were given the option of completing the same test, on knees (MPUK). Using a specially designed box, the sit and reach test (SR) <sup>32</sup> recorded flexibility of the hamstring musculature. The back-scratch test (BSC) <sup>33</sup>recorded flexibility in the shoulder joint to the nearest half centimeter, and the mean registered flexibility score of both shoulders was recorded. Explosive power in the lower extremities was recorded using the vertical jump test (VJ)<sup>29</sup>. The subjects were instructed to jump as high as possible, and the outcomes were recorded in centimeters. For further description of the musculoskeletal- and neuromotor fitness tests, see appendix 1.

Body height and weight were recorded to the nearest 0.5 centimeter (cm) and 0.1 kg, respectively, with the participant wearing light clothes and no shoes. BMI was calculated by the following formula: weight/height<sup>2</sup>  $(kg/m^2)$  <sup>34</sup> and the recorded BMI values were categorized based on WHO cut-off values <sup>35</sup>.

#### Statistical analysis

The data was analyzed by per-protocol using the Statistical Program for Social Sciences (SPSS 21.0), where all participants who had completed both baseline and posttest were included (n=89). This analysis method was chosen as no further points of measurement existed, and as we considered the imputation of presumed posttest results or possibly forwarding baseline results to be a larger bias, compared to analyzing by per-protocol. The main analysis, for between group differences in posttest CRF and MSMF scores, was conducted by an ANCOVA, adjusted for baseline scores and fully adjusted by baseline scores, gender, age, educational level, BMI and PA level. The scores from the OLS test did not show any signs of being normally distributed, hence this variable is presented by median and percentiles. To address possible between group differences on the OLS test, a Mann-Whitney

test was used for delta values (baseline scores – pretest scores). A significance level of .05 was set.

## **Results**

#### Characteristics

No statistical differences in baseline characteristics were found between the completers in the IG and the CG (table 1), except for the participants in the IG who displayed a significantly higher PA level at baseline compared to participants in the CG (p=0.014). Mean age at baseline was 47.8 (±4.6) years and a total of 35.6% of the participants had completed four years or more of college and/or university education (table 1). Furthermore, a total of 32.6% of the sample were overweight and 43.8% were obese. There were no statistically significant differences in mean test scores on any of the CRF or MSMF tests between the IG and the CG. The participants in the CG who dropped out of the study displayed a significantly lower PA level at baseline (median: 0 MET min.), compared to the participants in the CG who completed the study (median: 358 MET min., p=0.017). Those who dropped out of the IG were 3.4 years younger compared to the completers in the IG (p=0.01). No other statistically significant differences in sample characteristics were found between those who completed the study compared to those who were lost to follow-up on any of the baseline characteristics. All participants in the IG, who completed posttest measures, adhered to the counselling sessions given by email or telephone.

Table 1 Sample characteristics at baseline for the intervention group (IG) and the control group (CG).

	Intervention group	Control group
	n=39	n=50
Age (years), mean (SD)	48.4 (4.6)	47.3 (3.9)
Gender, female%	66.7 %	68.0 %
Weight (kg), mean (SD)	87.5 (18.9)	88.2 (20.7)
BMI (kg/m <sup>2</sup> ), mean (SD)	28.9 (4.4)	29.0 (5.9)
Overweight	35.9 %	30.0 %
Obese	41.0 %	46.0 %
Education level		
< high school	2.6 %	6.3 %
High school	35.9 %	35.4 %
College/university <4yr	17.9 %	29.2 %
College/university ≥4yr	43.9%	29.2 %

Abbreviations: number (N/n), standard deviation (SD), kilograms (kg), squared meters (m<sup>2</sup>), years (yr)

#### Intervention effects

Both the IG and the CG had a significant increase in PA level from baseline to posttest. The median change in PA level for the IG (1239.5 METmin) was significantly larger compared to the median change achieved by the CG (194.3 METmin) (p=0.014). After adjusting for pretest scores, statistically significant between-group differences in posttest scores were found for the VO<sub>2</sub>max ml/kg/min test (ES: 0.12, p=0.002), the VO<sub>2</sub>max l/min test (ES: 0.12, p=0.008), in addition to the SBE test (ES: 0.21, p<0.001), the SR test (ES: 0.12, p=0.006), and the VJ test (ES: 0.09, p=0.022) in favor of the IG (table 2). Additionally, a statistically significant between group difference was found on the MPUK test (ES: 0.24, p=0.013) in favor of the CG. When fully adjusted, statistically significant between-group differences were found for the VO<sub>2</sub>max ml/kg/min (ES: 0.17, p=0.002) and VO<sub>2</sub>max l/min tests (ES: 0.13, p=0.008) in favor of the IG.

<sup>&</sup>quot;Indicated position of table 2"

#### Discussion

To our knowledge, this is the first RCT study on the effect of an exercise intervention by the presented modes, which measures CRF and MSMF outcomes objectively. The main findings from the present study are that the IG had statistically significant improvements in test scores on CRF, muscular endurance of the back extensors, flexibility of the hamstrings, and muscular power of the lower extremities from baseline to posttest compared to the CG. The associated between group effect sizes by partial eta squared, ranged from 0.09 on explosive power performance to 0.21 on the performance on muscular endurance of the back extensors, which in turn equals between medium to large, and large effect sizes, respectively. When fully adjusted, the IG showed improvements in CRF that were significantly higher compared to the CG. The adjacent effect sizes on VO<sub>2</sub>max by ml/kg/min was 0.13 and for VO<sub>2</sub>max by l/min was 0.17, which equals medium to large, and large effect sizes, respectively.

#### Discussion of results

Only three previous studies 9-11 were identified as both similar in modality as the present study as well as reporting objective measures of physical fitness. The study by King, Haskell, Taylor, Kraemer, DeBusk <sup>11</sup> is the oldest, though most similar in study design to our study, comparing both high intensity and low intensity home based endurance exercise prescribed three and five days a week, respectively, accompanied by telephone contact to a face-to-face mode and a no-intervention control group. They reported that both high intensity and low intensity homebased endurance exercise were capable of significantly increasing CRF levels (VO<sub>2</sub>max), with results comparable to a face-to-face mode <sup>11</sup>. The increase in test scores on VO<sub>2</sub>max (ml/kg/min) reported in the present study (+2.1 ml/kg/min) exceeds the reported increase in test scores at both six and 12 month follow-up in the study by King et al 11. The study by King et al 11 used a one year intervention duration design, assessed CRF as the only measure of physical fitness and recruited slightly older participants compared to the present study. The study by Andersen et al <sup>9</sup> investigated the effect of a 10-week email-based encouragement to do workplace stair-walks on CRF. They reported a similar increase in VO<sub>2</sub> max (ml/kg/min) in their IG as the present study, which differed significantly from that achieved by the CG. However, the sample in the study by Andersen et al 9 were more fit initially, had lower mean BMI values and were younger, compared to our sample. Thereby, the outlined differences in baseline sample characteristics, between the studies question the comparability of the results. The study by Muntaner-Mas et al 10 reported a significant

increase in hand grip strength for the IG receiving exercise sessions through a mobile app, though no between-group differences in hand grip strength were found.

To our knowledge, no further studies have applied similar exercise intervention as us, where the effect was measured by objective measures of several physical fitness parameters. Quite a few studies have however reported the effect of similar interventions on PA level. A recently published systematic review on the effectiveness of electronic- (eHealth) and mobile health (mHealth) interventions (i.e. internet, mobile phones, and other wireless devices) <sup>7</sup>, and a recently published systematic review and meta-analysis on RCT's primarily using mHealth technologies <sup>6</sup>, report that these modes of delivery and communication were effective in promoting PA levels and healthy diets. However, the use of no- intervention control groups should be emphasized, as Direito et al <sup>6</sup> question the widespread use of "active" comparator groups to be a possible factor restraining larger effect sizes to be reported.

In our study an ANCOVA analysis showed a significant difference in posttest scores on muscular dynamic endurance of the upper body by the MPUK test in favor of the CG. However only half of the participants in the study completed the MPUK test and the CG had no statistically significant increase on any of the other measures of CRF or MSMF, which is believed to indicate that the CG did not increase their overall physical fitness during the intervention period in a larger extent than the IG. Furthermore, *not* including the CG in pretest assessment in order to eliminate this form of bias, is inevitable.

#### Strengths and limitations

The main strength of the present study was the use of objective measures for primary outcomes. Secondly, the use of a single blinded RCT design where the project coordinator, data collectors, outcome adjudicators and data analysts were unaware of group allocation are all considered to be strengths in the present study as this reduces the risk of bias associated with awareness of group allocation effecting study outcome. Additionally, the use of a RCT design reduces the risk of selection bias and when using a no intervention control group, the risk of bias in the study and the reported results may further be reduced as well as possibly allowing for the pooling of results in order to conduct meta-analysis <sup>7</sup>. The intervention duration was six months, which exceeds the average duration of previously conducted e- and mHealth based PA interventions <sup>6,8</sup>, and is considered to be a strength of the study. However,

Foster et al. <sup>4</sup> emphasize the need for studies with even longer duration in order to better understand the effect of different and individual intervention components.

Furthermore, even though the AISN study has not investigated the effect of individual components of the study design, many of the intervention components applied in this study have previously been highlighted as promising individual and/or combined components. Firstly, tailoring interventions to individual needs and presenting various physical activities have been highlighted as components that enhances adherence and effectiveness of study interventions <sup>4,5,36</sup> <sup>4</sup>. Furthermore, intervention designs incorporating additional communication strategies, strategic feedback and prompts have been found more likely to report significant positive outcomes, compared to intervention designs that do not incorporate these intervention components <sup>8,37</sup>. Applying some form of personal contact through telephone as a medium to give feedback and to encourage increase in PA level, has been reported as especially promising as an effective tool to enhance adherence and positive effects <sup>4,5</sup>. Goode et al <sup>38</sup> support the use of broad-reach modalities, mainly the telephone, as delivery mode of lifestyle interventions. However, the effectiveness of diverse delivery modes of tailored PA interventions, have been found to differ among older adults (>50yr) <sup>39</sup>. For this age group, a higher participation rate was found for a print delivered tailored PA intervention, compared to the same web delivered PA intervention <sup>39</sup>. However, Peels et al <sup>39</sup> highlight the possibility of reaching high risk populations, such as people with lower intentions for PA and higher BMI, through web-based interventions. This may indicate the need for facilitating both print and web-based delivery modes, in order to reduce attrition and increase reach supporting the present studies design. Finally, the use of the transtheoretical model stages of change has shown to increase exercise duration and frequency <sup>40</sup>, and additionally motivational interviewing in counseling sessions have previously been shown to enhance adherence in exercise and diet modification programs<sup>41</sup>.

The main limitation of the present study was low sample size (N=89). Compared to other studies investigating PA interventions with similar intervention design, the number of participants varies from 20-69219 participants  $^{6,7}$ . However, a power analysis was conducted prior to recruitment, with an additional calculation of a presumed drop-out rate of 20%. The loss to follow-up in the present study of 19.8% is just within the quality enhancing inclusion criteria of <20% drop-out put forward by Richards et al  $^{13}$ . However, emphasis should be made on larger sample sizes, both to be able to do further sub-group analysis of outcome

measures and to further elaborate on different intervention components in addition to being able to generalize findings, if possible. The high attrition rate observed in the IG is questionable, as we have no certain explanation as to why. However, based on the reasons given for drop out, it is believed that certain elements of the intervention were perceived to be too demanding, especially the counselling sessions, every fortnight, where the participants had to register progress, personal effort, goals and motivation. The high attrition rate observed in the IG may also reflect non-adherence in the IG, as all the included participants in the IG adhered to the counselling sessions. The subsequent behavior of the participants who were enrolled to the CG was not tracked, which renders uncertainty whether they complied with the study protocol of retaining current lifestyle habits. Finally, the data on PA level were based on self-report and only 50 of 89 cases were found valid for analysis by the IPAQ-SF, and thereby the data and the adjacent analysis may be biased.

#### **Conclusions**

The results from the present study revealed that this six-month tailored telephone and email based exercise intervention had positive effects on several aspects of physical fitness in a high-risk group of initially physically inactive adults. However, there still is a need to further investigate this type of intervention, in order to elaborate on whether or not any of the components of the intervention are more effective than others, whether or not further elements should be incorporated, and to assess the long-term follow-up of interventions promoting aspects of health-related physical fitness in physically inactive adults.

#### List of abbreviations

MSMF musculoskeletal and neuromotor fitness

CRF cardiorespiratory fitness

SBE static back extension test

HGS hand grip strength test

OLS one leg standing test

MPU modified push-ups test

MPUK modified push-ups on knees test

SR sit and reach test

BSC back scratch test

VJ vertical jump test

EPP explosive power on a power platform test

VO2 max maximal oxygen consumption

RER respiratory exchange rate

BMI body mass index

WC waist circumference

PA Physical activity

IG Intervention group

CG Control group

## **Declarations**

Ethics approval and consent to participate

This study was approved by the Regional Committees for Medical and Health Research Ethics (REC) South East D (ref. no. 2010/2371-1) and written consent forms were obtained from all participants prior to enrollment.

Consent for publication

Not applicable

Availability of data and materials

Data will be made freely available to any scientist wishing to use them for non-commercial purposes, without breaching participant confidentiality.

Competing interests

Not applicable.

Funding

The University of Agder initiated and funded this study through Centre for Care Research in addition to leading and coordinating the study.

Authors' contributions

IGHK planned and coordinated the study, enrolled participants, took part in the data collection, completed the data analysis, data interpretation and the generation of figures and drafting the manuscript, MKT lead the study, was involved in planning the study and supervising the study in addition to reviewing the manuscript, SAA was involved in planning

the study and reviewed the manuscript. All authors had final approval of the submitted manuscript.

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## **Conflict of interest**

There are no conflicts of interest.

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Table 2 Mean test scores (±standard deviation) for the intervention group and the control group on both CRF and all MSMF test scores, both at baseline and posttest. For the non-parametric OLS test median (25-75)percentiles) is displayed.

	Intervention group			Control group			Between group	Effect size	Between group	Effect size		
	n	Pretest Mean (±SD)	Posttest Mean (±SD)	Δ%	n	Pretest Mean (±SD)	Posttest Mean (±SD)	Δ%	differences* (p-value)	(partial eta squared)	differences (p-value)**	(partial eta s quared)
VO <sub>2</sub> max (ml/kg/min)	36	29.7 ± 4.8	31.8 ± 5.7	7.1	45	30.6 ± 6.1	30.7 ± 6.3	0.3	0.002	0.12	0.002	0.17
VO <sub>2</sub> max (l/min)	36	2.6 ± 0.7	2.7 ± 0.8	3.8	45	2.6 ± 0.6	2.6 ± 0.6	0.0	0.008	0.12	0.008	0.13
SBE (seconds)	36	50.4 ± 22.7	51.8 ± 24.1	2.7	45	50.9 ±28.8	47.5 ±25.8	-7.2	<0.001	0.21	0.597	0.01
HGS (kilograms)	39	40.7 ± 15.2	39.5 ± 14.7	-3.0	48	39.6 ± 13.3	38.5 ± 13.7	-2.9	0.883	0.00	0.438	0.01
MPU (no. reps.)	14	9.0 ± 2.8	9.5 ± 3.4	5.3	18	10.3 ± 3.0	10.9 ± 3.5	5.5	0.885	0.01	0.819	0.00
MPUK (no. reps.)	17	8.6 ± 1.9	10.2 ± 2.0	15.7	18	8.2 ±2.9	10.6 ± 3.6	22.6	0.013	0.24	0.260	0.07
OLS (seconds)	39	57 (26.0-64.0)	41.0 (18.0-63.1)	NC	48	33.5 (15.8-62.3)	27.4 (16.3-58.6)	NC	0.354	NC	NC	NC
BSC (centimeters)	39	-11.6 ± 11.1	-8.6 ± 9.3	-34.9	48	-8.3 ± 2.9	-7.4 ± 3.6	-12.2	0.183	0.04	0.138	0.04
SR (centimeters)	39	19.0 ± 10.0	22.0 ± 10.4	13.6	48	20.6 ± 9.2	21.0 ± 10.2	1.9	0.006	0.12	0.115	0.05
VJ (centimeters)	39	26.0 ± 9.4	26.1 ± 9.0	0.4	46	25.2 ± 8.2	24.7 ± 8.1	-2.0	0.022	0.09	0.081	0.06

<sup>\*</sup> Differences between groups (IG/CG) in posttest scores, adjusted for baseline scores

NC: not calculated as the data have non parametric characteristics. Abbrevations: Maximal ventilatory oxygen consumption ( $VO_2$ max), Static back extension (SBE), Handgrip strength (HGS), Modified push-ups (MPU), Modified push-ups on knees (MPUK), One leg standing (OLS), Back scratch (BSC), Sit and reach (SR) and Vertical jump (VJ)

<sup>\*\*</sup> Fully adjusted model, adjusted by baseline scores, gender, age, educational level, body mass index and physical activity level

**Figure 1** The flow of participants throughout the intervention period, including information on those lost to follow-up with subsequent associated reasons.

#### Enrollment

125 volunteered

## Baseline Health-related physical fitness assessment (n=125)

125 potential participants were assessed at baseline **14 excluded** Reason: not physically inactive

## $Randomized \, (n=111)$

111 participant were randomly assigned

#### Allocation

Allocated to intervention group (n=56) Allocated to control group (n=55)

Lost to follow-up (n=17) Lost to follow-up (n=5)

ReasonsReasons5 Unknown2 Unknown5 Lost to follow-up1 Lost to follow-up

2 Disease 1 Disease 1 Lack of time 1 Dissatisfied

2 Dissatisfied2 Unmotivated

## Follow-up: Posttest Health realted physical fitness assessment (n=89)

Intervention group (n=39) Control group (n=50)

## Analysis

Included in analysis (n=39) Included in analysis (n=50)

Figure 2 The intervention design, illustrated by time-period.

#### INTERVENTION DESIGN Intervention group Control group $assessing\ \textit{VO}\ \textit{2}\ \textit{max},\ \textit{musculoskeletal-}\ \textit{and}\ \textit{neuromotor}\ \textit{fitness},\ \textit{body}\ \textit{composition}\ \textit{and}\ \textit{a}\ \textit{questionnaire}\ \textit{assessing}\ \textit{correlates}\ \textit{of}\ \textit{max},\ \textit{fitness}\ \textit{fi$ Baseline physical activity (see measuring methods) Intervention package I was distributed and consisted of 1. A letter containing information on group allocation, individual results on health-related physical fitness assessment at baseline, information on reccommendations for physical activity, Received information on intervention group allocation prompts and reminders (i.e. taking the stairs instead of the elevator, walk/cycle to work). start 2. A leaflet on national dietary recommendations 3. One of three tailored exercise programs. Self-administered exercise based on the 1st intervention package. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email. An NF 1st month instruction form based on MI containing predefined questions and topics was used in these councelling sessions. **Self-administrered excersise** based on the 1<sup>st</sup> intervention package. 2<sup>nd</sup> month NF Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email. Intervention package II was distributed and consisted of 1. A letter containing information on the second intervention package, what this intervention package added compared to the first intervention package in addition to providing information on the further progress of the intervention $3^{rd}\,month$ NF $2.\ A\ tailored\ exercise\ program\ based\ on\ the\ exercise\ program\ from\ the\ first\ intervention\ package,$ $aiming \ at \ ensuring \ progression.$ 3. Self-administrered exercise based on the $2^{\mbox{\scriptsize nd}}$ intervention package. 4. Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email. $\textbf{Self-administrered excersise} \text{ based on the } 2^{nd} \text{ intervention package}.$ 4<sup>th</sup> month NF Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email. Intervention package III was distributed and consisted of $1.\ A\ letter\ containing\ information\ on\ the\ third\ intervention\ package,\ what\ this\ intervention$ 5<sup>th</sup> month NF package added in addition to the information given in the previous two intervention packages. 2. A tailored exercise program based on the exercise program from the first and second intervention packages, aiming at ensuring progression. Self-administrered exercise based on the 3rd intervention package. NF 6<sup>th</sup> month Fortnightly councelling sessions, alternately by telephone (ex. 10-15 minutes) and email.

A total of 88 participants (IG: 39, CG: 50) went through a health-related physical fitness assessment, assessing  $VO_2$  max, musculoskeletal- and neuromotor fitness, body composition and a questionnaire assessing correlates of

physical activity (see measuring methods)

NF received no follow-up

Posttest

**Figure 3** A detailed description of the exercise recommended for the participants in the IG, based on PA level at baseline.

			Tailored exercise program	*
		1	2	3
	Amount of exercise sessions	2	3	4
1 st intervention	Cardiorespiratory exercise	1 session Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.
package	Strength, balance and flexibility exercise	1 session Program of choice STT Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	1 session Program of choice STT Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	2 sessions Program of choice STT Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.
	Amount of exercise sessions	3	4	5
2 <sup>nd</sup> intervention package	Cardiorespiratory exercise	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	2 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training
	Strength, balance and flexibility exercise	1 session Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	2 sessions Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.
	Amount of exercise sessions	4	5	6 (1 session of choise)
3 <sup>rd</sup> intervention package	Cardiorespiratory exercise	2 sessions Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training	3 sessions Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall training
	Strength, balance and flexibility exercise	2 sessions  Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	<b>2 sessions</b> Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.

<sup>\* 1:</sup> those who reported being physically active none or one day a week at baseline, 2: those who reported being physically active two days a week at baseline, 3: those who reported being physically active three days a week at baseline.

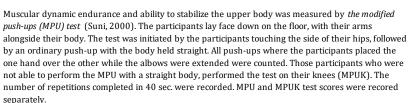
<sup>\*\*</sup> Sessions can vary in duration between 20-60 minutes, depending on intensity. Higher or lower intensity equals durations closer to 20 or 60 minutes respectively.

STT Types of strength training exercise: at the office, at the gym, outdoors, in water, with a large exercise ball, and with an elastic band TCRF Types of cardiorespiratory exercise: walk/run, nordic walking (with rods), sycling/spinning, dance/aerobic, swimming/water gymnastics, ball games, rowing skiing/skating, housework, gardening, games/play, step/elipse, tennis/badmington/squash, golf or other cardiorespiratory exercises.

#### MUS CULOS KELETAL AND NEUROMOTOR FITNESS

#### Muscular endurance

Muscular endurance was measured by the static back extension (SBE) test (Suni, 2000). The participants lay face down on a 15 centimeter (cm) tall, 18 cm broad and 135 cm long bench with their spina iliaca anterior superior lined with the bench's short side, leaving the upper body in a horizontal position for a s long as they could and the time the participants managed to hold a horizontal position was recorded (min 0 seconds (sec), max 240 sec.).





Muscular strength was measured by *handgrip strength (HGS) test* (Al Snih et al, 2002; Sasaki et al, 2007) using a hydraulic dynamometer (Chattanooga, Hixon, USA). The participants were to stand up straight with their arms hanging down alongside their body, about 10 cm out from the body. The dominant hand held the dynamometer. The best of three attempts was recorded to the nearest 1

#### Muscular power

The vertical jump (VJ) test (Suni, 2000) measured explosive power in the lower extremities. The participants were to stand with a foot of choice alongside the wall. With a piece of chalk, the participants reached up the wall, as high as possible, setting a mark on the wall. The participants then stood one foot away from the wall and were instructed to jump as high as possible, setting a mark on the wall with the chalk at peak height of the jump. The distance between the chalk mark set at standing height and that set at peak jumping height was recorded to the nearest cm.

The explosive power (EPP) test measured on a power platform (HurLabs Forceplatform), registered explosive power in the lower extremity. The participants were instructed to stand on the middle of the power platform, the feet placed with a shoulder width distance apart and hands on the hips. The arms were to stay on the hips throughout the jump. The participants were instructed to jump as high as possible. The best of three results was recorded in cm.

#### Flovihility

Flexibility of the hamstring musculature was measured by the sit and reach (SR) test (Presidents council on Physical Fitness and Sports, 2008). A specially designed box was placed to a wall and the participants sat on the floor with their knees and upper body straight, and their heels against the box. The participants leant as far along the measuring tape on top of the box as possible, with one hand on top of the other and the back and legs straight. The furthest the participants managed to stretch their hands along the measuring tape and hold for two seconds, was recorded to the nearest half cm. Point zero, the point where the feet met the box was set at 23 cm from the box's edge, and the recorded result was 23 cm plus or minus the distance from point zero.

The back scratch (BSC) test (Rikli and Jones, 1999) measured flexibility in the shoulder joint. The participants were standing upright, placing one hand on the lower back, moving it up the participants spine toward their head. The opposite hand was placed on the participants neck, moving it down the spine, aiming to place the long finger of each hand as near each other as possible or to overlap. The procedure was repeated with opposite hands. The gap between the fingertips of the long finger of both hands was measured to the nearest half centimeter. The results were recorded to the nearest half cm, as positive numbers as long as the fingers overlapped and with negative numbers if the fingers did not meet or overlap.

#### Balanc

Balance was recorded by means of *the one leg standing (OLS) test* (Suni, 2000). The participants were instructed to stand on one optional leg, facing a mark at eye height on a wall three meters away. The non-balancing legs heel was to be placed in the knee joint of the supporting leg and the knee was to be rotated externally. The participants arms hung alongside their body. The total time the participants managed to hold the initial balancing position was recorded in sec. If the participants managed to hold the position for 60 sec, the same test procedure was repeated, only blinded. Both test times were recorded separately and summed.

















## **PAPER IV**



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### A tailored telephone and email based exercise intervention induced reductions in various measures of body composition in physically inactive adults: A randomized controlled trial

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#### ARTICLE INFO

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#### ABSTRACT

Obesity prevalence has increased the past decades and has become a serious public health problem. The aim of this six-month assessor-blinded, parallel-group randomized controlled trial was to assess the effect of a tailored telephone and email-based exercise intervention on various measures of body composition in a sample of apparently healthy and physically inactive adults. A total of 111 volunteering adults (40-55 yr) in Southern Norway were randomly assigned to an intervention group (IG; n = 39) or a no-information control group (CG; n = 50), by random allocation numbering. The IG received feedback on their health-related physical fitness, information on guidelines and recommendations for physical activity, a leaflet on national dietary re-commendations, prompts and reminders in addition to three tailored exercise programs, one every two months, and fortnightly motivational counselling by email or telephone, alternately. The CG received no follow-up during the intervention period. The main outcome measures: weight, body mass index (BMI), waist circumference (WC) and fat percentage by skinfolds (FP<sup>skf</sup>) were assessed objectively at baseline and posttest. A one-way ANCOVA analysis, adjusted for baseline scores, gender, age, and educational level, revealed a larger reduction on all body compositional measures in the IG compared to the CG (p ≤ 0.043), except for BMI when adjusted for baseline scores. Additionally, a significantly higher percentage of the IG (64.1%) achieved a clinically significant reduction in  $FP^{skf}$  compared to the CG (36.2%, p = 0.018). This six-month tailored telephone and email-based exercise intervention induced significant reductions on several measures of body composition in physically inactive adults.

Trial registration: ClinicalTrials.gov (NCT03164239).

#### 1. Introduction

Worldwide, the prevalence of obesity has increased drastically the past few decades and has become a major public health challenge (Nget al., 2014). Ortega et al. (2017) emphasize the necessity of implementing lifestyle interventions as important measures for reducing the health challenges of obesity. The implementation of modern technology has generated effective modes of enhancing health behavior change (i.e. physical activity, healthy diets and weight reduction) (Allen et al., 2014; Direito et al., 2017; Liu et al., 2015; Tang et al., 2016; Vandelanotte et al., 2016), which are less extensive and less resource demanding compared to more traditional modes (Allen et al., 2014). Additionally, several recently conducted systematic reviews and/or meta-analysis (Allen et al., 2014; Liu et al., 2015; Tang et al.,

2016) conclude that technology assisted interventions, may indeed induce significant weight loss, in overweight and obese adults.

Even though previous studies using alternative modes of reach have shown to be promising strategies to reduce weight (Allen et al., 2014; Liu et al., 2015; Tang et al., 2016; Conn et al., 2014), the need for further high quality research in the area is warranted (Allen et al., 2014; Liu et al., 2015; Tang et al., 2016; Vandelanotte et al., 2016; Conn et al., 2014; Mastellos et al., 2014). This is partly due to the difficulty of drawing conclusions based on the wide variation in intervention components, such as study design (Tang et al., 2016), the use of self-reported measures of primary outcome (including self-reported weight loss) (Tang et al., 2016; Mastellos et al., 2014), small sample sizes (Allen et al., 2014; Liu et al., 2015; Tang et al., 2016), inconsistency in the reported effectiveness of different interventions

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Abbreviations: IG, Intervention Group; CG, Control Group; BMI, Body Mass Index; WC, Waist Circumference; FP<sup>skf</sup>, Fat Percentage by skinfolds; CRF, cardiorespiratory fitness \* Corresponding author at: Faculty of Health and Sports Science, The University of Agder, Postboks 422, 4604 Kristiansand, Norway.

(Mastellos et al., 2014) and partly due to poor study quality (including poor reporting) (Tang et al., 2016; Vandelanotte et al., 2016; Conn et al., 2014; Mastellos et al., 2014). Some of the highlighted limitations concerning previous studies is the lack of information on quality related intervention components (i.e. allocation, blinding, randomization, intervention components, and bias) (Tang et al., 2016; Mastellos et al., 2014). Furthermore, the majority of previous studies report only weight change (kilograms), weight (kilograms), or BMI as primary weight outcomes (Liu et al., 2015; Conn et al., 2014). Weight based indexes may be biased, mostly due to the reduced ability of such indexes to distinguish between fatty tissue and greater-than-average muscularity or skeletal tissue (Sardinha & Teixeira, 2005). Liu et al. (2015) and Allen et al. (2014) clearly emphasize the need to better understand the effect of mobile based weight loss/weight management interventions on waist circumference (WC) and body fat percentage. Additionally, Ortega et al. (2017) emphasize the importance of focusing on cardiorespiratory fitness (CRF), rather than solely on weight/fat loss, as CRF has been found to attenuate the adverse health related consequences of obesity. However, the changes induced by CRF may not provide the same metabolic stress, body compositional changes and thereby the same changes in health status as resistance training does (Clark & Goon, 2015; Clark, 2015). Therefore, rather than focusing on creating energy imbalance, the importance of implementing resistance training in addition to CRF (Ortega et al., 2017) as part of the total exercise program for overfat individuals (Clark & Goon, 2015; Clark, 2015)has been highlighted (Clark, 2015). Thereby, there is a need for adequately reported randomized controlled trials, investigating the effect of exercise as main intervention focus delivered by alternative modes on various objective measures of body composition.

The aim of the present study was to assess the effect of a tailored telephone and email-based exercise intervention on various measures of body composition in a sample of apparently healthy and initially physically inactive adults.

#### 2. Methods

The present study was a regional parallel-group randomized controlled trial (RCT), approved by the Regional Committees for Medical and Health Research Ethics (REC) South East D (ref. no. 2010/2371-1) and registered in clinical trials (NCT03164239). Written consent forms were obtained from all participants prior to enrollment and reporting of the trial adheres to the CONSORT statement (Moher et al., 2010) (Appendix A) and TiDieR (Hoffmann et al., 2014). The study was based at, and baseline and posttest outcomes were assessed in a test laboratory, at the University of Agder, Norway.

#### 2.1. Sample

Prior to commencing the intervention study in which this paper is based upon, a power analysis was conducted. The main outcome measures were ventilatory threshold (VO<sub>2</sub>max) and fat percentage, though only the results from the fat percentage measures are presented in this paper. The estimated effect size for VO<sub>2</sub> max was 0,69 mL kg $^{-1}$  min $^{-1}$  (3.3 mL kg $^{-1}$ min $^{-1}$ /4,8) (Kelley & Kelley, 2006) and the estimated effect size for fat percentage was -0.36% (-1,4%/3,9) (Kelley & Kelley, 2006), where the measuring instrument for fat mass (InBody 720) showed an intra-class correlation coefficient (ICC) of 0.995 (p = 0.05). Given a power of 90%, and an alpha value of 0.05, a total of 44 participants were estimated to be needed in each group to detect differences of these sizes. Additionally, a previously reported predicted drop-out rate of < 20% (Richards et al., 2013), was calculated in to the sample size estimation, rendering a target sample size of 110.

Participants were enrolled between January and March 2011 through four recruitment procedures; 1) participants from the two Agder counties who took part in a national cross sectional study (KAN

study) (Edvardsen et al., 2013) were invited by letter to participate (n = 37, 40-55 yr), 2) a random additional sample from the KAN study (Edvardsen et al., 2013), (n = 200, 43-48 yr), were invited by letter to participate, 3) advertisements in local papers and radio, and 4) employees at the University of Agder and Kristiansand community were invited via advertisements on the intranet. The following inclusion criteria were set; the participants had to a) be physically inactive, as in not fulfilling the national recommendations of 30 min of daily physical activity set by the Norwegian Directorate of Public Health (2010), assessed by the International Physical Activity Questionnaire- short form (IPAQ-SF) (Craig et al., 2003), b) be within the age range of 40-55 years, c) live in one of the two Agder counties and d) be healthy enough to be able to go through the health related physical fitness assessment. When in doubt whether the participants fulfilled the inclusion criteria of being physically inactive based on IPAQ-SF, the baseline results from the VO2max test were compared to normative VO2max values published by Shvartz and Reibold (Shvartz & Reibold, 1990). All participants who scored below average by gender and age group, where included in the study.

A total of 125 females (n = 81) and males (n = 44) volunteered to participate in the RCT, where 14 (7 females) were excluded due to them not fulfilling the criteria for being physically inactive. A third party with no further connection to the study randomly allocated all remaining 111 participants to either the intervention group (IG) or the control group (IG), by allocation numbering in SPSS, stratified by gender. A total of 39 participants in the IG and 50 in the CG completed the health-related physical fitness assessments both at baseline and post-intervention (Fig. 1), rendering a total drop-out rate of 19.8%. The project coordinator, data collectors, outcome adjudicators and data analysts were blinded for group allocation. This was ensured through delegating the coordination of practical aspects of the intervention to the counselor, who had no further involvement in the study.

#### 2.2. Study design

The intervention duration was set to six months based on financial-and time related aspects. Thereby, the intervention commenced in April 2011 and was ended in October 2011. The intervention received by the IG consisted of: 1) Tailored self-administered exercise recommendations which were developed based on national- and international recommendations for physical activity (Haskell et al., 2007) and a national Norwegian report on physical inactivity (Ommundsen & Aadland, 2009), and 2) Fortnightly counselling sessions, based on motivational interviewing (MI) (Miller & Rollnick, 2002) given alternately by telephone and/or email by a trained person with a master's degree in sport sciences (Fig. 2).

The tailored self-administered intervention consisted of three intervention packages which either were distributed by email or post every two months (Fig. 2), aiming at facilitating the self-administered intervention, ensuring periodization and progress, enhancing motivation and preventing the high drop-out rates previously experienced in some electronic and mobile health interventions (Direito et al., 2017). The first intervention package consisted of written feedback on the participants health related physical fitness (including baseline results on body compositional measures. CRF and musculoskeletal and neuromotor function), a letter containing information on national and international recommendations for- and health benefits of physical activity (Haskell et al., 2007), a leaflet on national dietary recommendations (The Norweigan Directorate of Health, 2011), prompts and reminders in addition to one of three exercise programs (Fig. 3). In addition, the IG was encouraged to increase their physical activity level, associated with daily living. Furthermore, they were given advise on how to acquire exercise equipment if needed (either by buying or by means of utilizing household equipment) and they were informed of possible anticipated variations in physical activity level due to chance or unforeseen events (such as periods of less involvement in

#### Enrollment

#### 125 volunteered

#### Baseline Health related physical fitness assessment (n=125)

125 potential participants were assessed in the pretest **14 excluded** Reason: not physically inactive

#### Randomized (n=111)

111 participant were randomly assigned

#### Allocation

Allocated to intervention group (n=56) Allocated to control group (n=55)

Lost to follow-up (n=17)

Lost to follow-up (n=5)

ReasonsReasons5 Unknown2 Unknown5 Lost to follow-up1 Lost to follow-up2 Disease1 Disease1 Lack of time1 Dissatisfied

2 Dissatisfied2 Unmotivated

#### Follow-up: Posttest Health realted physical fitness assessment (n=89)

Intervention group (n=39) Control group (n=50)

#### Analysis

Included in analysis (n=39) Included in analysis (n=50)

Fig. 1. The flow of participants throughout the intervention period (Agder, Norway, 2011).

physical activity, due to unpredictable reasons, i.e. sickness, lack of time and similar). The three different exercise programs were developed based on how many days per week the participants reported being physically active at baseline, aiming at ensuring tailoring to individual needs. This categorized the participants in one of three predefined physical activity levels: encouraging two, three or four bouts of exercise a week. Based on this categorization, the participants were recommended to increase their physical activity levels with one day from reported baseline physical activity level, except for those who reported not engaging in any form of physical activity, who were encouraged to increase their physical activity level with two days. The second and third intervention packages were distributed two and four months into the intervention period, respectively, and recommended a further oneday increase in physical activity level (Fig. 3), to accompany the progression in physical activity level. The exercise programs included recommendations of both cardiorespiratory-, musculoskeletal- and neuro motor exercises. Each exercise program consisted of various examples of cardiorespiratory exercise and seven different strength training exercise programs for different types and arenas of exercise, developed using EXORLive (EXORLive, 2016). The CG was only informed of the result of the random allocation, and received no follow-up during the intervention period. However, they received similar follow-up as the IG, after the completion of posttest assessment.

#### 2.3. Measuring methods

All objective tests were conducted, coordinated and lead by the project coordinator. Baseline and posttest assessments were conducted between mid-March 2011 to mid-April 2011 and between mid-October throughout November 2011, respectively. The main outcome measures for body composition in the present study were: body weight, height, WC and skinfold thickness. Additionally, BMI, body density and fat percentage by skinfolds (FP<sup>Skf</sup>) were calculated. Initially, InBody 720 (Biospace, Korea) was planned used to assess various body compositional measures. However, due to varying results of the instruments ability to give reliable and valid measures of body composition (Volgyi et al., 2008), the results from this test are not reported. All body compositional measures were completed by a trained, ISAK certified investigator, who completed both baseline and posttest assessment, to reduce possible inter-rater bias. Further test personnel were a physiotherapist and qualified master students, whom all had gone through thorough instructions prior to testing in addition to on-set follow-up

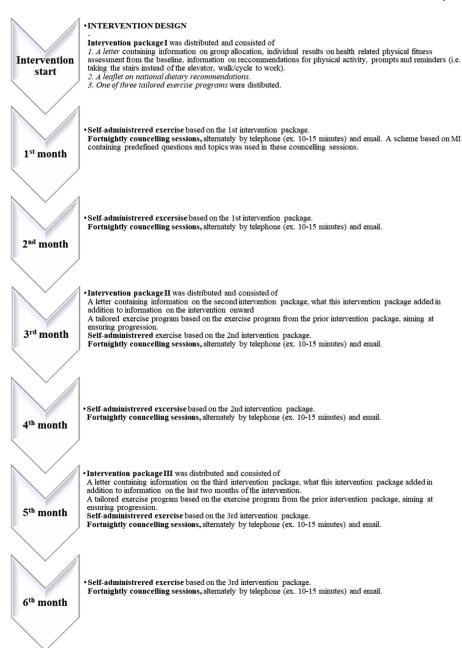


Fig. 2. Flow chart of the intervention (design synopsis) (Agder, Norway, 2011).

during testing. Additionally, none of them had any knowledge of or further involvement in group allocation. Measures were conducted using calibrated measuring devices and following a detailed test protocol.

Body weight was measured to the nearest 0.1 kg (kg) on InBody 720 (Biospace, Korea), with the participant wearing a t-shirt and underwear. Height was measured to the nearest centimeter (cm), using a Seca

stadiometer, while the participant was standing without shoes and with the heels touching the wall. BMI was calculated using the following formula: body weight/body height<sup>2</sup> (kg/m<sup>2</sup>).

WC was measured by a protocol developed by the WHO (World Health Organization, 2008), where the mid-point between the upper most lateral part of the iliac crest and the lowest most lateral point of the ribcage was set as the marking point for measuring WC values. Two

Intervention		Та	ilored exercise program	xercise program*		
package		1	2	3		
	Amount of exercise sessions	2	3	4		
		1 session	2 sessions	2 sessions		
1st intervention	Cardiorespiratory exercise	Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks.	Exercise of choice TCRF Duration: 20-60 minutes** Sessions can be divided into smaller >10 min, bolks.		
package		1 session	1 session	2 sessions		
	Strength, balance and flexibility exercise	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12 Intensity: exhaustion after		
		8-12 reps.	8-12 reps.	8-12 reps.		
	Amount of exercise sessions	3	4	5		
2nd intervention package		2 sessions	2 sessions	3 sessions		
		Exercise of choice <sup>TCRF</sup>	Exercise of choice <sup>TCRF</sup>	Exercise of choice <sup>TCRF</sup>		
	Cardiorespiratory exercise	Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall	Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall	Duration: 20-60 minutes** Sessions can be divided into smaller >10 min. bolks. Advised to try Intervall		
		training	training	training		
		1 session  Program of choice STT	2 sessions  Program of choice STT	2 sessions  Program of choice STT		
	Strength, balance and flexibility exercise	Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.	Sets: 2 Reps: 8-12 Intensity: exhaustion after 8-12 reps.		
	Amount of exercise sessions	4	5	<b>6</b> (1 session of choise)		
3rd intervention package		2 sessions	3 sessions	3 sessions		
	Cardiorespiratory exercise	Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes**	Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes**	Exercise of choice <sup>TCRF</sup> Duration: 20-60 minutes**		
		Sessions can be divided into smaller >10 min. bolks.	Sessions can be divided into smaller >10 min. bolks.	Sessions can be divided into smaller >10 min. bolks.		
		Advised to try Intervall training	Advised to try Intervall training	Advised to try Intervall training		
		2 sessions	2 sessions	2 sessions		
	Strength, balance and flexibility	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12	Program of choice <sup>STT</sup> Sets: 2 Reps: 8-12		
	exercise	Intensity: exhaustion after 8-12 reps.	Intensity: exhaustion after 8-12 reps.	Intensity: exhaustion after 8-12 reps.		

<sup>\* 1:</sup> those who reported being physically active none or one day a week at baseline, 2: those who reported being physically active two days a week at baseline, 3: those who reported being physically active three days a week at baseline.

STT Types of strength training exercise: at the office, at the gym, outdoors, in water, with a large exercise ball, and with an elastic band TCRF Types of cardiorespiratory exercise: walk/run, Nordic walking (with rods), sycling/spinning, dance/aerobic, swimming/water gymnastics, ball games, rowing, skiing/skating, housework, gardening, games/play, step/elpise, tennis/badmington/squash, golf or other cardiorespiratory exercises.

 $\textbf{Fig. 3.} \ \textbf{A} \ \textbf{schematic} \ \textbf{overview} \ \textbf{of the tailored} \ \textbf{exercise} \ \textbf{programs} \ \textbf{(Agder, Norway, 2011)}.$ 

<sup>\*\*</sup> Sessions can vary in duration between 20-60 minutes, depending on intensity. Higher or lower intensity equals durations closer to 20 or 60 minutes respectively.

**Table 1**Sample characteristics, by intervention group and control group (Agder, Norway, 2011).

	Intervention group	Control group
	n = 39	n = 50
Age (years), mean (SD)	48.4 (4.6)	47.3 (3.9)
Gender, female%	66.7%	68.0%
Education level		
< high school	2.6%	6.3%
High school	35.9%	35.4%
College/university < 4 yr	17.9%	29.2%
College/university ≥ 4 yr	43.9%	29.2%
Physical activity level (MET	505.5	358.0 (66.0-628.5)
min.), median(Q1-Q3)	(240.0-933.0)*	
Weight (kg), mean (SD)	87.5 (18.9)	88.2 (20.7)
BMI (kg/m <sup>2</sup> ), mean (SD)	28.9 (4.4)	29.0 (5.9)
Overweight	35.9%	30.0%
Obese	41.0%	46.0%
WC (cm), mean (SD)	96.3 (14.2)	96.0 (15.2)
Abdominally overweight	28.2%	14.0%
Abdominally obese	59.0%	60.0%
FPskf % obese	87.2%	77.6%

<sup>\*</sup> p for between-group differences < 0.005.

measures were recorded at the end of the participant's expiration using a measuring band and the mean of these two measures were recorded to the nearest half-centimeter.

Skinfold thickness was measured using a Lange skinfold caliper (Beta Technology Inc.). The following three sights were measured in males; chest, abdomen and thigh and the following three sites were measured in females: triceps, suprailiac and thigh. All sites were measured two times, and the mean of two measures was recorded to the nearest millimeter (mm) and body density was calculated using the summed skinfold value (Jackson & Pollock, 1978; Jackson et al., 1980; Nevill et al., 2008). The Siri equation (Siri, 1956) was further used to calculate fat percentage based on the body density estimates.

The BMI and WC values were categorized based on WHO developed cut-off values (World Health Organization, 2000; Han et al., 1995). BMI values of  $<18.5\,\mathrm{kg}\,\mathrm{m}^2$  were categorized as underweight,  $18.5-24.9\,\mathrm{kg}\,\mathrm{m}^2$  as normal weight,  $25.0-29.9\,\mathrm{kg}\,\mathrm{m}^2$  as overweight and BMI values of  $\geq 30.0\,\mathrm{kg}\,\mathrm{m}^2$  were categorized as obese. For WC, males and females were categorized as abdominally overweight when WC values were  $\geq 94\,\mathrm{cm}$  and  $\geq 80\,\mathrm{cm}$ , respectively, and as abdominally obese when WC values were  $\geq 102\,\mathrm{cm}$  and  $\geq 88\,\mathrm{cm}$ , respectively. As only one participant was categorized as underweight based on the BMI measures both pre (BMI =  $18.3\,\mathrm{kg/m}^2$ ) and post intervention (BMI =  $17.8\,\mathrm{kg/m}^2$ ), this participant was included in the normal weight group in all analyzes.

Cut-off values developed by Lohman et al. (1997) were used in order to define obesity based on FP<sup>Skf</sup>, where females and males with FP<sup>Skf</sup> values > 35% and \*25% (35–55 yr age group), respectively, were defined as obese

Age, gender and educational level were assessed through a questionnaire as secondary outcome measures. Four categories of educational level were created based on an eight-answering option question: completed less than High School, completed High School, completed three years or less at College/University and completed four years or more at College/University. Physical activity level was assessed by The International Physical Activity Questionnaire short form (IPAQ-SF), where metabolic equivalent of task values inn minutes (MET minutes) were calculated (IPAQ Research Committee, 2005). A difference value was created for the physical activity data, where baseline measures were subtracted from the posttest measures in order to create a delta value for physical activity. A total of 50 (IG: 24, CG: 26) of 89 cases were found valid for analysis by the IPAQ-SF. Additionally, adherence to the counselling sessions was recorded by the counselor.

#### 2.4. Statistical analysis

The main analysis was a per protocol analysis, applying a one-way ANCOVA, adjusted for baseline scores and adjusted for gender, age, and educational level. To detect between group differences in posttest values. In order to check for between group differences in baseline data, an independent samples t-test was applied for continuous variables, a chi2 test for categorical variables, and for continuous and non-normally distributed variables, a Man Whitney U test was run. A dependent samples t-test was run to investigate within group differences from baseline to posttest measures for both groups separately, and a Mcnemar analysis was run in order to detect within group changes for the categorical variables and non-normally distributed data. In order to check for between group differences in how many participants achieved a 5% clinical significant reduction on all body compositional measures (Williamson et al., 2015), a chi<sup>2</sup> test was applied. Additionally, to adjust for gender, age, educational level and baseline fat percentage, a logistic regression was applied. The data was processed using the Statistical Program for Social Sciences (SPSS Version 24.0. Armonk, NY: IBM Corp.). The significance level was set to 0.05.

#### 3. Results

A total of 89 participants completed both baseline and posttest and all participants in the IG adhered to the counselling sessions. All participants were either overweight or obese on one or more of the following body compositional measures: BMI, WC, and/or FPskf at pretest. The prevalence of overweight and/or obesity based on BMI, WC, and FPskf, ranged from 76.9% (BMI) to 87.2% (WC) in the IG and from 74.0% (WC) to 77.6% (FPskf) in the CG (Table 1). The participants in the IG were significantly more physically active at baseline compared to the participants in the CG (p = 0.014). The participants who dropped out from the CG were significantly less physically active at baseline (median: 0 MET min.), compared to the participants in the CG who completed the study (median: 358 MET min., p = 0.017). Furthermore, the participants in the IG who dropped-out of the IG were 3.4 years younger than the completers in the IG (p = 0.011).

Both the IG and the CG increased their physical activity level significantly from baseline to posttest. The median change in physical activity level for the IG (1239.5 METmin) was significantly higher, compared to that achieved by the CG (194.3 METmin) (p = 0.014). All mean body compositional test scores for the IG decreased significantly from pre- to post test (p < 0.001) (Table 2). The CG decreased significantly in mean scores on WC and FP $^{\rm skf}$  (p  $\leq$  0.013) (Table 2). When adjusted for pretest scores, the IG decreased significantly more on weight, WC and FP $^{\rm skf}$ , compared to the CG (p  $\leq$  0.046, Table 2), with effect sizes ranging from small to medium (Cohens'd = 0.044) on both the change in weight (p = 0.046) and the change in WC (p = 0.045), to medium (Cohens'd = 0.50) on the change in FP $^{\rm skf}$  (p = 0.010).

The percentage of participants achieving a reduction in body compositional measures during the intervention period varied from 71.8% (BMI) to 87.2% (FPskf) in the IG and from 59.6% (BMI) to 74.5% (FPskf) in the CG. The IG displayed a significantly higher percentage of participants achieving a clinically significant reduction in FPskf of  $\geq 5\%$ , compared to the CG (Table 3). The adjacent odds ratios for the between group difference in the percentage of participants who achieved a  $\geq 5\%$  reduction in FPskf, when adjusting for baseline FPskf and when adjusting for baseline FPskf, gender, age and educational level was 3.60 (p = 0.007) and 3.62 (p = 0.011) respectively.

#### 4. Discussion

The main findings from the present study revealed that a six-month tailored email- and telephone-based exercise intervention induced significantly larger reductions on all body compositional measures in the IG compared to the CG, when adjusting for pretest scores in addition to

1

control group on all body compositional test scores, both at baseline and posttest (Agder, Norway, 2011) group and the Table 2 Mean test scores (  $\pm$  standard deviation) for the intervention

	Inte	Intervention group		φ ν	Within group	Contr	Control group		φ ∇	Within group	Between group	Effect size	Cohen's d	Cohen's d Between group	Effect size
	п	n Pretest Posttest	Posttest		dinerences (p- value)	n l	Pretest Posttest	Posttest		unerences (p- value)	unerences (p- value)	(partain n )		umerences (p- value)**	(partial η )
		Mean ( ± SD) Mean ( ± SD	Mean (±SD)				Mean ( ± SD) Mean ( ± SD)	Mean ( ± SD)							
Weight	39	Neight 39 87.5 (18.9) 84.7 (17.8)	84.7 (17.8)	-3.3%	-3.3% < 0.001	47 8	47 86.5 (19.9)	85.5 (20.3)	-0.1% 0.128	0.128	0.046	0.047	0.44	0.040	0.053
BMI (kg/	39	BMI (kg/ 39 28.9 (4.4)	28.0 (4.2)	-3.1%	< 0.001	42	42 29.0 (5.6)	28.6 (5.5)	-1.4% 0.086	0.086	0.120	0.031	0.36	0.111	0.034
WC (cm) FP <sup>skf</sup> (%)	39	WC (cm) 39 96.3 (14.2) FP <sup>skf</sup> (%) 39 39.1 (7.9)	92.7 (13.3) 35.7 (8.8)	-2.7% -8.7%	< 0.001 < 0.001	48 9	95.2 (15.1) 38.7 (9.9)	93.6 (14.8) 36.9 (10.3)	-1.8% -4.7%	$\begin{array}{lll} -1.8\% & 0.013 \\ -4.7\% & < 0.001 \end{array}$	0.045 0.025	0.047	0.44 0.50	0.037 0.033	0.054

Differences between groups (IG/CG) in post test scores, adjusted for pretest scores Fully adjusted model, adjusted by age, gender and educational level

Table 3 Displaying the prevalence of participants achieving a clinically significant reduction in body compositional measures of ≥5% (Agder, Norway, 2011).

	Intervention group	Control group	p-Value
Weight	30.8%	12.8%	0.076
BMI	28.2%	16.7%	0.327
WC	28.2%	12.5%	0.117
FP <sup>skf</sup>	64.1%	36.2%	0.018

gender, age, and educational level, except for BMI, when adjusting for pretest scores only. The associated Cohens'd (Cohen, 1988) effect sizes ranged from between small and medium to medium.

No previous studies were found having conducted the same type of intervention. However, results from previous recent reviews of self-directed interventions to promote weight loss (Tang et al., 2016), motivational physical activity interventions to promote reductions in body compositional measures (Conn et al., 2014) and mobile phone interventions to promote weight loss in overweight and obese individuals (Liu et al., 2015) reveals that such interventions are capable of promoting significant weight loss (Liu et al., 2015; Tang et al., 2016; Conn et al., 2014), in addition to reductions in BMI (Liu et al., 2015; Conn et al., 2014) and WC measures (Tang et al., 2016). The reductions in body compositional measures and the associated effect sizes and/or standardized mean differences reported by Tang et al. (2016), Conn et al. (2014) and Liu et al. (2015)) were slightly lower compared to the reported reductions in the present study, except for the weight reduction reported by Tang et al. (2016), which was similar. The comparison of our results to that of previous studies with similar design may reflect a superior effect of the present study's design, however, this is uncertain. There is a lack of high quality interventions (Tang et al., 2016; Vandelanotte et al., 2016; Conn et al., 2014; Mastellos et al., 2014) and the variation in delivery mode and study design is large (Allen et al., 2014; Tang et al., 2016; Conn et al., 2014), so comparisons are therefore difficult to make, and possible conclusions are even more difficult to draw. However, the significantly higher prevalence of individuals in the IG achieving a clinical significant reduction (≥5%) in fat percentage (64.1%), compared to the CG (36.2%), supports the effectiveness of the presented study design.

As previously reported (Tang et al., 2016), BMI was the only body compositional measure that was not significantly different between our two groups, when adjusted for baseline BMI measures, only. This may be explained by the nature of the measure, and its reduced ability to distinguish between fatty tissue and greater-than-average muscularity or skeletal tissue (Sardinha & Teixeira, 2005). Thereby, improvements related to increased resistance training and the subsequent relation to health may not be reflected in changes in BMI classifications (Clark & Goon, 2015). Hence, the importance of applying objective measures of fat related body mass beyond that of weight and BMI, in order to enhance better quality in reporting, should be stressed.

#### 4.1. Study limitations and strengths

The main strength of the present study is the inclusion of sought for (Allen et al., 2014; Liu et al., 2015; Tang et al., 2016; Mastellos et al., 2014) objective and more diverse measures for assessing body composition, including both WC and FPskf in addition to the more commonly used weight and BMI measures. Although the anthropometric measures used may have measurement errors which must be considered when interpreting the results, all anthropometric measures were conducted by the same trained investigator, at both baseline and posttest.

Secondly, the current study incorporated behavior change strategies and elements that have previously been found to be effective in similar studies such as: goal-setting (Allen et al., 2014; Tang et al., 2016; Conn et al., 2014; Samdal et al., 2017), self-monitoring (Allen et al., 2014;

Conn et al., 2014; Samdal et al., 2017), feedback (Allen et al., 2014; Tang et al., 2016; Samdal et al., 2017), prompts and reminders (Conn et al., 2014; De Leon et al., 2014), focus on maintain routines (making habits) (Morgan et al., 2016), information on perceived improvements (including disappointment of experiencing failure to achieve set goals) (Morgan et al., 2016), linking for gym-based activities (Morgan et al., 2016), range of different types of physical activities (arranging for various exercise in variable settings) (Morgan et al., 2016), progression and periodization (Clark & Goon, 2015; Clark, 2016), the use of the transtheoretical model (TTM) (Conn et al., 2014), individualized and personalized service (including tailoring) (Clark & Goon, 2015; De Leon et al., 2014; Morgan et al., 2016; Clark, 2016), personal support and supervision from providers including coaching (Allen et al., 2014; Tang et al., 2016; Samdal et al., 2017; De Leon et al., 2014; Morgan et al., 2016), including a minimum of five contacts during the intervention period (Vandelanotte et al., 2007), and the use of person centered and autonomy supportive communication methods such as motivational interviewing (Samdal et al., 2017).

Furthermore, our study focused on increasing both musculoskeletal and neuromotor fitness in addition to CRF during the intervention period. A recently published meta-analysis of interventions aiming at enhancing health and body compositional changes (Clark, 2016) revealed that effect sizes were larger for interventions implementing resistance training or the combination of resistance training and CRF, especially early in the intervention period, which in turn creates larger metabolic stress and thereby creates weight loss promotion and better health status in overweight and obese individuals.

The main limitation in the present study was the drop-out rate. The study experienced a total drop-out rate of 19,9% (IG: 30.4%, CG:9.1%) during the intervention period. This may have affected the power of the analysis's ability to detect effects, additionally, it may reflect natural drop-outs, and/or it may reflect possible limitations of the study design. The latter is difficult to further elaborate on, as only 35% reported a reason for dropping out. It is possible that the difference in physical activity level between those in the CG who completed the study and those who dropped-out, may be of importance. However, the data on physical activity level were based on self-report and only 50 (IG:24, CG:26) of 89 cases were found valid for analysis by the IPAQ-SF, and thereby the data may be biased. However, based on the reasons given for dropping out, and feedback from the counselor conducting the counselling sessions, the excess work associated with self-monitoring registration of accumulated exercise, and goals prior to the counselling sessions, may have been perceived as too demanding.

Secondly, the duration of the intervention was six months which exceeds the minimum duration recommended for an intervention (Groeneveld et al., 2008). Williams et al. (2015) further emphasize that lifestyle intervention durations of more than six months may not be necessary as weight loss seems to plateau around this period in time. However, a follow-up period should be conducted, to investigate the long term effects of the reported effective intervention (Liu et al., 2015; Tang et al., 2016; De Leon et al., 2014). Adherence to the counselling sessions was registered, but there was no objective registration of adherence to the recommended exercise prescribed. Hence the degree to which the participants adhered to the study design is not known. Furthermore, baseline and posttest assessment were conducted within < 2-3 weeks prior to- and after intervention commencement and intervention end, respectively. Additionally, type of exercise in which the participants adopted was not tracked.

In conclusion, the studied intervention design showed promising results, displaying significantly larger reductions in weight, WC and  $FP^{skf}$  for participants following the intervention in addition to a larger prevalence of participants achieving clinically significant reductions in FP<sup>skf</sup> in the IG, compared to the CG. This study design contains various elements which are regarded as success criteria, both based on the results from the present study and based on previous findings. Thereby, this type of study design should be further investigated as to what

elements are more effective than others, whether or not elements could be implemented to enhance effect and adherence, and to assess maintenance effects in terms of long term follow-up assessment (De Leon et al., 2014). Additionally, implementing interventions that have shown to have positive effects in primary care settings is of major importance, as this may have large beneficiary consequences for underlying comorbidities associated with overweight and obesity (Kushner & Ryan,

Supplementary data to this article can be found online at https:// doi.org/10.1016/j.pmedr.2018.06.011

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Study materials, including materials used in the intervention (intervention packages) can be made accessible by contact with the corresponding author.

#### Acknowledgements

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## **APPENDIX I**

Approval letters from the Regional Committees for Medical and Health Research Ethics South East and the Norwegian Social Science Data Services for the Norwegian Physical Activity Surveillance Study (NPASS).



Professor Dr. scient Sigmund Alfred Anderssen Norges idrettshøgskole Pb. 4014 Ullevål Stadion 0806 Oslo

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst B (REK Sør-Øst B) Postboks 1130 Blindern NO-0318 Oslo

Dato: 29.04.08 Deres ref.:

Vår ref.: S-08046b

Telefon: 22 85 06 70 Telefaks: 22 85 05 90 E-post: juliannk@medisin.uio.no

Nettadresse: www.etikkom.no

S-08046b Kartlegging av fysisk aktivitetsnivå, helserelatert fysisk form og determinanter for fysisk aktivitet hos voksne og eldre i Norge [6.2008.142]

Vi viser til brev datert 18.03.08 vedlagt revidert informasjonsskriv og spørreskjema.

Komiteen tar revidert informasjonsskriv og spørreskjema til orientering.

Vi ønsker lykke til med prosjektet!

Med vennlig hilsen

Tor Norseth Leder

Julianne Krohn-Hansen

Sekretær

#### Norsk samfunnsvitenskapelig datatjeneste AS

NORWEGIAN SOCIAL SCIENCE DATA SERVICES



Harald Hårfagres gate 29 N-5007 Bergen Norway Tel: +47-55 58 21 17 Fax: +47-55 58 21 17 oxww.nsd.uib.no www.nsd.uib.no

Sigmund A. Anderssen Seksjon for idrettsmedisinske fag Norges idrettshøgskole Postboks 4014 Ullevål Stadion 0806 OSLO

Vår dato: 24.04.2008

Vår ref: 18886 / 2 / SF

Deres dato:

Deres ref:

#### TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 14.03.2008. Meldingen gjelder prosjektet:

18886

Kartlegging av fysisk aktivitetsnivå, helserelatert fysisk form og determinanter for fysisk

aktivitet hos voksne og eldre i Norge

Behandlingsansvarlig

Norges idrettshøgskole, ved institusjonens øverste leder

Daglig ansvarlig

Sigmund A. Anderssen

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, <a href="http://www.nsd.uib.no/personvern/forsk\_stud/skjema.html">http://www.nsd.uib.no/personvern/forsk\_stud/skjema.html</a>. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, <a href="http://www.nsd.uib.no/personvern/prosjektoversikt.jsp">http://www.nsd.uib.no/personvern/prosjektoversikt.jsp</a>.

Personvernombudet vil ved prosjektets avslutning, 31.12.2020, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Bjørn Henrichsen

Sølve Fauskevåg

Kontaktperson: Sølve Fauskevåg tlf: 55 58 25 83

Vedlegg: Prosjektvurdering

## Personvernombudet for forskning



#### Prosjektvurdering - Kommentar

18886

#### BAKGRUNN

Prosjektet er et samarbeid mellom institusjonene:

- Norges idrettshøgskole
- Høgskolene i Finnmark, Bodø, Sogn og Fjordane, Vestfold, Telemark og Hedmark
- Universitetene i Stavanger og Agder, samt NTNU

Norges idrettshøgskole (NIH) er koordinerende aktør og databehandlingsansvarlig for prosjektet. Prosjektleder, ved NIH, er daglig ansvarlig. Det inngås databehandleravtaler mellom samarbeidspartene i henhold til personopplysningsloven § 15.

#### FORMÅL

Formålet med undersøkelsen er å øke kunnskapen om fysisk aktivitetsnivå, fysiske aktivitetsvaner, samt determinanter for fysisk aktivitet i den voksne delen av den norske befolkningen.

Undersøkelsen iverksettes på initiativ fra Sosial- og helsedirektoratet. Det kan bli aktuelt å gjennomføre oppfølgingsundersøkelser om fem og/eller ti år, og det kan være aktuelt å utvide datagrunnlaget med registerdata. Eventuelle nye oppfølginger og/eller utvidelser meldes ombudet i god tid før iverksetting.

#### UTVALG, INFORMASJON OG SAMTYKKE

Utvalget er et tilfeldig utvalg av cirka 8000 personer. Utvalget trekkes fra Folkeregisteret og av EDB Business Partner basert på tillatelse fra Skattedirektoratet.

Utvalget sendes informasjonsskriv og kan samtykke skriftlig til deltakelse.

#### DATAMATERIALET

Datamaterialet innhentes ved hjelp av spørreskjema, aktivitetsmåler og fysiske tester og målinger. Datamaterialet inneholder blant annet navn, personnummer, kjønn, alder, etnisk bakgrunn, yrke, inntekt og utdanningsnivå, kommune, røyking og snus, medlemskap i idrettslag/foreninger, kosthold og bruk av TV og PC, fysisk form (balanse, styrke, bevegelighet og koordinasjon), høyde, vekt, livvidde, hoftevidde, kroppssammensetning, blodtrykk samt resultatene fra aktivitetsmåler (akselerometer) som utvalget skal gå med i syv dager.

#### REGISTRERING, OPPBEVARING OG UTLEVERING

Navn, fødselsår, adresse, fødekommune og fødeland, sivilstatus og antall barn trekkes fra Folkeregisteret. Informasjonsskriv sendes det trekte utvalget. Det kan gjøres en purring til personer som ikke har svart på første forespørsel.

Alle registrerte opplysninger tilknyttet den delen av utvalget som ikke samtykker, anonymiseres umiddelbart etter at svarfristen på purringen har utløpt.

Prosjektleder vil ha tilgang til hele datamaterialet. De lokale koordinatorene har tilgang til den delen av datamaterialet som de er ansvarlige for å samle inn. Prosjektets styringsgruppe vil ikke ha tilgang til datamaterialet.

Prosjektet forventes avsluttet med rapport 31.01.2009. Datamaterialet skal deretter oppbevares til 31.12.2020 med tanke på eventuelle oppfølgings- eller utvidede undersøkelser. Innen 31.12.2020 anonymiseres datamaterialet. Anonymisering innebærer at direkte og indirekte personidentifiserende opplysninger slettes eller omskrives (grovkategoriseres), samt at koblingsnøkkel slettes.

#### ANDRE TILLATELSER

Prosjektet er godkjent av Regional komité for medisinsk forskningsetikk Midt-Norge (REKs ref. S-08046b).

Skatteetaten har gitt tillatelse til å trekke utvalget inkludert noen bakgrunnsopplysninger fra Folkeregisteret (Skatteetatens ref. 2008/167522 /SKDRESF/GTE /341).

#### KOMMENTAR

Personvernombudet finner at prosjektet kan gjennomføres med hjemmel i personopplysningsloven (pol) §§ 8, første ledd og 9 a), samtykke.

Informasjonsskrivet per 23.04.2008 er godt utformet og redegjør for alle sider ved prosjektet forutsatt at dato for anonymisering av data tilføyes, jf. e-post samme dag.

Trekking og førstegangskontakt med utvalget kan hjemles i personopplysningsloven §§ 8 d) og 9 h). Det vises til at undersøkelsen er på oppdrag fra Sosial- og helsedirektoratet og tar sikte på å fremskaffe ny representativ kunnskap om aktivitet og helse. Trekking og kontakt med et representativt utvalg kan vanskelig gjøres på mer skånsom måte enn via Folkeregisteret. Ulempene for de registrerte er minimale da de informeres om trekkingen, og registrerte opplysninger anonymiseres umiddelbart for de som ikke samtykker innen svarfrist for purringen har utløpt.

## **APPENDIX II**

Informed consent for the Norwegian Physical Activity Surveillance Study (NPASS).





# Forespørsel om deltakelse i Kanı

 en kartleggingsundersøkelse av fysisk aktivitet og fysisk form blant voksne og eldre

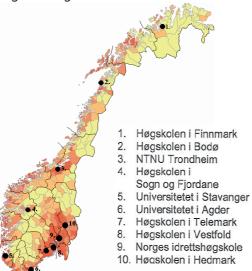






#### Hva er Kan1-undersøkelsen?

Kan1 er en landsomfattende kartlegging av befolkningens aktivitetsnivå og fysiske form. Vi har i dag ikke tilstrekkelig informasjon på dette feltet til å kunne beskrive utviklingstrekk i befolkningsgrupper og geografiske områder og forskjeller mellom dem. Denne undersøkelsen er ett ledd i Helsedirektoratets Handlingsplan for fysisk aktivitet, hvor et av hovedmålene er å etablere et system for kartlegging av det fysiske aktivitetsnivået i befolkningen. Undersøkelsen gjennomføres over hele landet i løpet av 2008 og 2009 og utføres av følgende høgskoler og universiteter:



## Hva innebærer deltakelse i undersøkelsen for deg?

Deltakelse i undersøkelsen innebærer at du svarer på et spørreskjema og går med en aktivitetsmåler i syv dager.
Aktivitetsmåleren er et lite og lett apparat som bæres i et elastisk belte rundt livet (se bilder neste side). Du går med måleren i 7 dager og returnerer den deretter sammen med spørreskjemaet i vedlagt returkonvolutt (Fase 1). I etterkant av Fase 1 vil om lag ¼ av deltakerne bli tilfeldig trukket ut og invitert til å gjennomføre en tilleggsundersøkelse av fysisk form (Fase

2). Du kan delta i den første delen av undersøkelsen, og si nei til videre deltakelse.

#### KAN du delta?

Velger du å delta i Kan1-undersøkelsen bidrar du med viktig og ny kunnskap om aktivitetsnivå og fysisk form i befolkningen.

Alle kan delta, uansett om man ser på seg selv som fysisk aktiv eller ikke.

Hensikten med undersøkelsen er å kartlegge et utvalg som representerer hele befolkningen, ikke bare den delen som er mest aktiv.

#### Fordeler og ulemper

Ved deltakelse i undersøkelsen vil du i etterkant motta en detaljert tilbakemelding på eget aktivitetsnivå. Du vil blant annet se hvorvidt du oppfyller Helsedirektoratets anbefalinger for fysisk aktivitet. Dersom du blir invitert til videre deltakelse i Fase 2, vil du få tilbakemelding på egen fysisk form. Test av fysisk form i Fase 2 kan påføre deltakere noe ubehag, da man skal utføre enkelte øvelser med høy intensitet.

#### Hva skjer med informasjonen om deg?

All informasjon som samles inn om deg, vil bli behandlet i henhold til gjeldende lover og forskrifter. Alle medarbeidere involvert i undersøkelsen har taushetsplikt, og opplysningene som samles inn, vil kun bli brukt til godkjente forskningsformål. Se avsnittet om personvern på neste side for mer informasjon.

#### Frivillig deltakelse

Det er frivillig å delta i undersøkelsen. Du kan når som helst trekke deg uten å oppgi noen grunn. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side.

#### Kriterier for deltakelse

Kriterier for deltakelse er at man er over 20 år, bor i Norge og er norsk statsborger.

#### **Tidsplan**

I perioden april til november 2008 sendes spørreskjema og aktivitetsmåler til deltakeren. Denne delen av undersøkelsen skjer kun per post og kalles Fase 1. Et tilfeldig utvalg av deltakerne i Fase 1 (omtrent ¼) vil bli invitert til en undersøkelse av fysisk form (Fase 2). Fase 2 vil finne sted to til seks måneder etter hovedundersøkelsen. Det er fullt mulig å si nei til deltakelse i Fase 2, selv om man har deltatt i Fase 1.

#### Mulige bivirkninger

Det er ingen kjente bivirkninger ved deltakelse i undersøkelsen. Test av fysisk form i Fase 2 kan påføre deltaker noe ubehag idet man skal utføre enkelte øvelser med høy intensitet. Eventuelle reiseutgifter for deltakere som blir invitert til deltakelse i Fase 2, vil bli dekket av undersøkelsen.

#### Personvern

Undersøkelsen er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk Helseregion Sør avdeling B, REK Sør B. Undersøkelsen er tilrådd av personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste A/S.

Opplysninger som registreres om deg, er personalia som alder, kjønn, sivil status og etnisitet, i tillegg til opplysninger om blant annet aktivitet, kosthold og helse. Du kan være trygg på at informasjonen du bidrar med til undersøkelsen, vil bli behandlet med respekt for personvern og privatliv, og i samsvar med lover og forskrifter.

Innsamlede opplysninger oppbevares slik at navn er erstattet med en kode som viser til en atskilt navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av undersøkelsen når disse publiseres.

# Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i undersøkelsen, 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 undersøkelsen, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Det kan bli aktuelt å innhente opplysninger om deg fra nasjonale helseregistre: Skade-, kreft-, dødsårsaks-, og reseptregisteret. Vi ber om din tillatelse til å innhente tilleggsinformasjon fra de nevnte registre. Alle innsamlede opplysninger anonymiseres senest innen 31.12.2020, med mindre vi innen da har kontaktet deg med forespørsel om noe annet.

#### **Økonomi og Helsedirektoratets rolle** Undersøkelsen er finansiert og initiert av Helsedirektoratet.





Bilde 1 og 2. Aktivitetsmåleren i bruk



#### Samtykke til deltakelse i undersøkelsen

Dette eksemplaret underskrives og returneres i vedlagt svarkonvolutt. Den returnerte samtykkeerklæringen vil bli oppbevart på ett nedlåst sted.

Jeg er villig til å delta i undersøkelsen

(skriv tydelig, helst med blokkbokstaver)
Fornavn:
Etternavn:
(Signer her)

Jeg bekrefter å ha gitt informasjon om undersøkelsen

Professor Sigmund Alfred Anderssen

Prosjektleder

Seksjon for idrettsmedisin Norges idrettshøgskole

kartlegging **aktivitet** Norge

2008

## **APPENDIX III**

Approval letters from the Regional Committees for Medical and Health Research Ethics South East for the Active in Southern Norway Study (AISN).



Førsteamanuensis Monica Klungland Torstveit Universitetet i Agder Fakultet for helse- og idrettsvitenskap Postboks 422 4604 Kristiansand Regional komité for medisinsk og helsefaglig forskningsetikk sør-øst D (REK sør-øst D) Postboks 1130 Blindern NO-0318 Oslo

Telefon: 22 85 05 93

Dato: 26.10.10 Deres ref.:

Vår ref.: 2010/2371-1

E-post: <a href="mailto:post@helseforskning.etikkom.no">post@helseforskning.etikkom.no</a>
Nettadresse: <a href="http://helseforskning.etikkom.no">http://helseforskning.etikkom.no</a>

#### Helserelatert fysisk form

Det vises til søknad av 02.09.10 for det ovenfor nevnte forskningsprosjekt. Søknaden ble behandlet i komiteens møte 30.09.10.

Prosjektleder er førsteamanuensis Monica Klungland Torstveit.

Komiteen forutsetter at forskningsansvarlig er Universitetet i Agder ved øverste admimnistrative ledelse. Det gjøres oppmerksom på at forskningsansvarlig etter helseforskningsloven § 4 e) er institusjon eller annen juridisk eller fysisk person som har det overordnede ansvaret for forskningsprosjektet, og som har de nødvendige forutsetningene for å kunne oppfylle den forskningsansvarliges plikter etter denne loven.

#### Prosjekttema:

I prosjektet skal man undersøke effekten av et skreddersydd program som formidles via telefon og e-post til et utvalg inaktive, overvektige voksne personer. Deltakerne randomiseres til en intervensjons- og en kontrollgruppe. Det skal inkluderes 100 personer fra Agderfylkene. Studien er del av et doktorgradsprosjekt.

Komiteen har vurdert søknaden og godkjenner prosjektet med hjemmel i helseforskningsloven § 10. Det knytter seg imidlertid vilkår til godkjenningen som må oppfylles før prosjektet kan settes i gang.

#### Godkjenningen omfatter:

• Tillatelse til å opprette forskningsprosjekt, helseforskningsloven § 10.

I tillegg til vilkår som fremgår av dette vedtaket er tillatelsen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, protokollen og de bestemmelser som følger av helseforskningsloven med forskrifter.

Ut fra det ovenfor nevnte setter komiteen følgende vilkår for prosjektet:

#### Forskningsetisk vurdering:

Komiteen tillater ikke at de forespurte kontaktes telefonisk for å bekrefte at de faktisk ikke ønsker å delta i prosjektet. Dette vurderes som utilbørlig press på den enkelte. Deres avholdenhet fra å svare skal respekteres. Eventuelt kan det sendes en purring per post.

## UNIVERSITETET I OSLO Det medisinske fakultet

#### Vilkår vedrørende informasjonsskrivet:

I informasjonsskrivet skal det gis opplysninger om hvorfor den forespurte er i målgruppen for prosjektet. Det skal gis informasjon om hvorfor de skal inkluderes og hvordan kartleggingen for inkludering foregår.

Da det ikke skal gjøres intervensjoner i prosjektet bes det om at dette begrepet byttes ut med ordet tiltak.

Da forsikring ikke er aktuelt i prosjektet bes det om at dette tas ut av informasjonsskrivet.

#### Vilkår vedrørende informasjonssikkerhet:

Komiteen forutsetter at data oppbevares i avidentifisert form. Det vil si at opplysningene oppbevares uten direkte personidentifiserbare parametre, men hvor man kan finne tilbake til den personen opplysningen stammer fra ved hjelp av en nøkkel eller kode.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren», <a href="http://www.norsk-helsenett.no/informasjonssikkerhet/bransjenormen/Personvern%20og%20informasjonssikkerhet%20i%20forskningsprosjekter%20v1.pdf">http://www.norsk-helsenett.no/informasjonssikkerhet/bransjenormen/Personvern%20og%20informasjonssikkerhet%20i%20forskningsprosjekter%20v1.pdf</a>

Tillatelsen gjelder til 31.12.2013. Av dokumentasjonshensyn skal opplysningene bevares til 31.12.2016. Opplysningene skal lagres avidentifisert i en nøkkel- og en opplysningsfil. De skal deretter anonymiseres eller slettes.

Prosjektet skal sende sluttmelding til REK Sør-Øst D, se helseforskningsloven § 12, senest 31.06.2014.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. forvaltningsloven 28 flg. En eventuell klage sendes til REK Sør-Øst D. Klagefristen er tre uker fra mottak av dette brevet.

Med vennlig hilsen

Stein A. Evensen (sign.) professor dr.med. leder

Just Q Vialletticu Ingrid Middelthon seniorrådgiver

Kopi:

Universitetet i Agder, ved øverste adm. ledelse

## **APPENDIX IV**

Informed consent for the Active in Southern Norway Study (AISN).







### Forespørsel om deltakelse i forskningsprosjektet Aktiv i Sør

## "Effekten av et telefon og (e)post basert tiltak for å øke aktivitetsnivået"

#### Bakgrunn og hensikt

I Norge og Europa i dag, er fysisk inaktivitet et økende problem og det fører til en rekke folkehelseutfordringer. Nylig forskning tyder på at så mange som 4 av 5 Nordmenn ikke oppfyller Helsedirektoratets anbefalinger for fysisk aktivitet. Det er derfor et økende behov for å kunne utvikle kostnadseffektive tiltak der målet er å øke det generelle fysiske aktivitetsnivået. Ved å bruke midler som telefonsamtaler og post eller e-post som kommunikasjonsmåte håper vi å kunne veilede en større andel mennesker til å bli mer fysisk aktive, på en måte som er mer tilpasset hver enkelts hverdag, sammenlignet med intervensjoner som krever personlig oppmøte. Vi mener det er viktig at aktiviteten som tilrådes er tilpasset den enkelte og at vi på den måten kan finne en måte å motivere hver enkelt til å bli mer fysisk aktiv.

Dette er et spørsmål til deg om å delta i forskningsprosjektet *Aktiv i Sør* der hensikten er å undersøke effekten av et skreddersydd telefon og (e)post basert fysisk aktivitets tiltak på fysisk form og kroppssammensetning blant lite aktive voksne i Agder fylkene. Vi leter etter voksne personer i alderen 40 - 55 år som er bosatt i Aust- eller Vest-Agder og som ikke oppfyller helsedirektoratets anbefalinger om 30 minutter daglig moderat fysisk aktivitet. Dersom du er i vår målgruppe, håper vi at du ønsker å delta i dette spennende prosjektet.

#### Hva innebærer prosjektet?

Aktiv i Sør prosjektet er det vi kaller en randomisert kontrollert studie, som betyr at deltakerne i prosjektet blir tilfeldig trukket til en av to grupper. Den ene gruppen vil motta treningsveiledning uten personlig oppmøte (tiltaksgruppe) og den andre gruppen vil være en kontrollgruppe (de skal kun være med på en helseundersøkelse i første omgang).

Alle deltakerne i prosjektet vil bli invitert til en helseundersøkelse (pretest) i februar/mars, 2011. Denne helseundersøkelsen vil innebære utfylling av et spørreskjema, samt registrering av helserelatert fysisk form. I etterkant av denne helseundersøkelsen vil deltakerne bli tilfeldig trukket til enten å delta i kontrollgruppen eller til å delta i tiltaksgruppen. Kontrollgruppen vil i etterkant av helseundersøkelsen motta et brev der det står litt informasjon om at de er trukket ut til å være i denne gruppen og at de vil bli kontaktet igjen når en ny helseundersøkelse (posttest) starter opp i oktober. Tiltaksgruppen vil derimot, innen 1. april, 2011 motta en pakke med informasjon om sine resultater fra helseundersøkelsen i februar/mars (pretesten) med referanseverdier (normalverdier/anbefalt verdier), et aktivitetsprogram skreddersydd etter informasjon fra helseundersøkelsen (pretesten), samt noe generell informasjon angående anbefalinger fra Helsedirektoratet. Under tiltaksperioden (1.april – 1.oktober, 2011) vil deltakerne i tiltaksgruppen motta i alt tre ulike aktivitetsprogram (justert etter behov og ønske fra deltakeren). I tillegg vil deltakerne i denne gruppen bli kontaktet via telefon eller post/epost omtrent hver 14. dag, for å følge opp hver enkelt deltaker med veiledning. Omtrent midtveis i tiltaksperioden vil deltakerne i tiltaksgruppen også få utdelt en aktivitetsmåler (likner en skritteller) for å registrere aktivitetsnivået.

Når tiltaket er avsluttet, vil alle deltakerne inviteres til å gjennomgå en ny helseundersøkelse (posttest) i oktober/november, 2011, som er helt lik den første helseundersøkelsen (pretesten). I etterkant av den

nye helseundersøkelsen (posttesten) vil *alle* deltakerne (både de i tiltaksgruppen og de i kontrollgruppen) motta sine resultater med referanseverdier (normalverdier/anbefalt verdier), et aktivitetsprogram skreddersydd etter informasjon fra den nye helseundersøkelsen (posttesten), samt noe generell informasjon angående anbefalinger fra Helsedirektoratet. Prosjektet avsluttes etter at posttesten er avsluttet og resultater pluss aktivitetsprogram er sendt ut til alle deltakerne. Øvrige detaljer om prosjektet følger i vedlegg A.

#### Mulige fordeler og ulemper

Som deltaker i Aktiv i Sør vil du kunne dra nytte av enkelte fordeler slik som; resultater fra helseundersøkelsene (pre- og posttestene), og aktivitetsprogram basert på resultater fra helseundersøkelsen i oktober 2011. Om du trekkes til å være med i tiltaksgruppen vil du i tillegg motta ytterligere 3 aktivitetsprogram basert på resultater fra helseundersøkelsen i februar/mars (pretesten), i perioden mellom 1. april 2011 og 1. oktober 2011, som del av tiltaket. Du vil da også få personlig oppfølging via telefon eller post/epost omtrent hver 14. dag.

Du må, imidlertid kunne ha mulighet til å være med på begge helseundersøkelsene (pre- og posttesten) som tar omtrent en til halvannen time hver og som vil gjennomføres på Universitetets kontorer/laboratorier på Spicheren treningssenter i Kristiansand. Om du blir trukket til å være med på tiltaket må du også kunne ha mulighet til å være med på denne. Tiltaket er planlagt slik at den gjennomføres på eget initiativ, på det sted og til den tid, du selv som deltaker måtte ønske, men med oppfølging og veiledning av aktivitetsprogrammet fra en av oss i prosjektgruppen.

#### Hva skjer med testresultatene og informasjonen om deg?

Resultatene fra helseundersøkelsene og annen informasjon som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og resultater gjennom en navneliste. Det er kun prosjektleder og prosjektansvarlig som har adgang til navnelisten (innelåst i safe) og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Prosjektet er godkjent av de Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK).

#### Frivillig deltakelse

Det er frivillig å delta i Aktiv i Sør prosjektet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, i prosjektet, bes du undertegne samtykkeerklæringen, på siste side i denne invitasjonen og returnere den i den vedlagte konvolutten. Porto er betalt og adressen er påskrevet konvolutten. Dersom invitasjonen er tilsendt deg per e-post, bes du følge påmeldingsmulighetene som er nevnt i e-post. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Ingirid Kjær (telefon 38 14 23 84 / 48 11 89 26 eller epost; ingirid.g.kjar@uia.no).

Ytterligere informasjon om studien finnes i kapittel A – utdypende forklaring av hva studien innebærer.

Ytterligere informasjon om biobank og personvern finnes i kapittel B – Personvern, biobank, og økonomi.

Samtykkeerklæring følger etter kapittel B.

### Kapittel A- utdypende forklaring av hva studien innebærer

#### · Kriterier for deltakelse

De personene som er i vår målgruppe for deltakelse i Aktiv i Sør prosjektet er mellom 40 og 55 år, bosatt i Agder og er lite fysisk aktiv (se under).

Rekruttering av deltakere til dette prosjektet har foregått på tre ulike måter; 1. Personer som tidligere har deltatt i Kartlegging Aktivitet Norge prosjektet (KAN1), 2. Personer i denne aldersgruppen fra Agder fylkene som er tilfeldig trukket av EDB Infobank, med utgangspunkt i Folkeregisteret, og 3. Andre via media eller bekjente.

Infobank, med utgangspunkt i Folkeregisteret, og 3. Andre via media eller bekjente. Ettersom rekrutteringen har foregått på denne måten, har vi informasjon om deres alder og bostedsadresse, men ingen informasjon om deres fysiske aktivitetsnivå. Denne henvendelsen gjelder de av dere som i en gjennomsnittlig uke, *ikke* er fysisk aktive i minst 30 minutter per dag, i 5 eller flere dager i uken, slik at du blir svett eller andpusten (der all aktivitet som varer over 10 minutter regnes med). Dersom du er usikker på om du er i vår målgruppe, ta gjerne kontakt.

#### • Bakgrunnsinformasjon om studien

I Norge og Europa i dag, er fysisk inaktivitet et økende problem og det fører til en rekke folkehelseutfordringer. Det er derfor et økende behov for å kunne utvikle kostnadseffektive tiltak der målet er å øke det generelle fysiske aktivitetsnivået. Ved å bruke midler som telefonsamtaler og post eller e-post som kommunikasjonsmåte håper vi å kunne veilede en større andel mennesker til å bli mer fysisk aktive, på en måte som er mer tilpasset hver enkelts hverdag, sammenlignet med tiltak som krever personlig oppmøte. Vi mener det er viktig at aktiviteten som tilrådes er tilpasset den enkelte og at vi på den måten kan finne en måte å motivere hver enkelt til å bli mer fysisk aktiv.

• Dersom du skulle ønske å trekke deg fra prosjektet underveis, vil du bli tildelt de resultatene vi har registrert på deg frem til den datoen du trekker deg.

#### • Testene (Helseundersøkslsen)

Et spørreskjema er utviklet som en del av helseundersøkelsen, med bakgrunn i et spørreskjema som er brukt i et nasjonalt prosjekt kalt Kartlegging Aktivitet Norge (KAN). Data som samles inn ved hjelp av dette spørreskjemaet er følgende; noe bakgrunnsinformasjon, fysisk aktivitet, motivasjon for fysisk aktivitet, foretrukne typer aktiviteter, stillesittende vaner, samt kostholdsvaner. I tillegg vil du motta et egenerklæringsskjema når du kommer til helseundersøkelsen, der din helsestatus (medikamentbruk, sykdommer, fysisk funksjon) registreres. Begge disse skjemaene tar omtrent 5-10 min hver å fylle ut.

I tillegg blir du bedt om å gjennomføre en registrering av helserelatert fysisk form. Denne delen av helseundersøkelsen er lik den registreringen av helserelatert fysisk form som deltakerne i KAN prosjektet (904 personer i alderen 20-85 år) gjennomførte (utenom en lungekapasitetstest). Denne helserelaterte fysiske form undersøkelsen vil gi oss data på antropometri (høyde, vekt, midjeomkrets og fettprosent), blodtrykk, utholdenhet (VO<sub>2</sub> maks), muskelstyrke, balanse, bevegelighet og spenst. Vi regner med at denne undersøkelsen vil ta omtrent 1 time, men setter av  $1^1/_2$  time til disposisjon per deltaker. Omtrent midtveis i tiltaksperioden vil deltakerne i tiltaksgruppen også få utdelt en aktivitetsmåler (likner en skritteller) for å registrere aktivitetsnivået.

#### • Tidsskjema – hva skjer og når skjer det?

Fra midten av februar til midten av mars, 2011 vil den første helseundersøkelsen utføres. I løpet av siste halvdel av mars vil du motta et brev der det enten står at du er blitt trukket til å være med i kontrollgruppen eller det vil stå at du er trukket til å være med i tiltaksgruppen. Er du med i kontrollgruppen vil du ikke få noe mer informasjon på dette tidspunktet. Er du derimot trukket til å være med i tiltaksgruppen vil du innen 1. april motta en konvolutt med informasion om dine resultater fra helseundersøkelsen i februar/mars (pretesten) med referanseverdier (normalverdier/anbefalt verdier), et aktivitetsprogram skreddersydd etter informasjon fra helseundersøkelsen (pretesten), samt noe generell informasjon angående anbefalinger fra Helsedirektoratet. De som blir trukket til å være med på tiltaket vil bli kontaktet omtrent hver 14. dag for oppfølging av aktivitetsprogrammet, i tillegg vil et oppdatert aktivitetsprogram sendes ut hver andre måned (totalt 3 programmer vil bli delt ut i løpet av hele tiltaksperioden). Ved tiltaksslutt (1. oktober) vil den andre helseundersøkelsen utføres. Denne skal også alle være med på (både kontrollgruppen og tiltaksgruppen). I etterkant av den andre og siste helseundersøkelsen, vil ALLE deltakerne motta sine resultater samt ett aktivitetsprogram tilpasset hver enkelts resultater.

#### • Mulige fordeler

I løpet av Aktiv i Sør prosjektet vil du være med på to helseundersøkelser. Resultatene fra begge disse vil du få tilsendt. De som blir trukket til å være med i kontrollgruppen vil få disse resultatene tilsendt når begge helseundersøkelsene er ferdige, altså i november, mens de som er med i tiltaksgruppen vil få disse resultatene fortløpende, altså et sett resultater i slutten av mars (etter pretesten) og ett sett resultater i november (etter posttesten).

Tiltaksgruppen vil i tillegg motta tre aktivitetsprogram i løpet av perioden 1. april til 1. oktober, i tillegg til ett i november. Kontrollgruppen vil motta et aktivitetsprogram utviklet med bakgrunn i resultatene fra den siste helseundersøkelsen (posttesten) i november.

#### • Mulige bivirkninger

Din deltakelse i Aktiv i Sør prosjektet bør ikke medføre bivirkninger.

#### • Mulige ubehag/ulemper

For oss som prosjektansvarlige er det veldig viktig at du som deltaker ikke føler noe ubehag eller føler at prosjektet er noen ulempe. Vi ønsker derfor å tilrettelegge din deltakelse i prosjektet på best mulig måte slik at du føler deg bekvem med å delta. Dersom det er enkelte deler av prosjektet du ikke ønsker å ta del i (som for eksempel enkelte deler av helseundersøkelsen) imøtekommer vi dine ønsker. Bare gjør oss oppmerksom på dette under helseundersøkelsen!

- Som deltaker i Aktiv i Sør prosjektet har du ingen ansvar, annet enn å ta del i prosjektet i form av helseundersøkelsene i februar/mars og oktober/november, samt å ta del i tiltaket, dersom du blir trukket til å være del av den gruppen.
- Du som deltaker vil bli orientert så raskt som mulig dersom ny informasjon blir tilgjengelig som kan påvirke din villighet til å delta i prosjektet.
- Du som deltaker skal opplyses om mulige beslutninger/situasjoner som gjør at din deltagelse i studien kan bli avsluttet tidligere enn planlagt

### Kapittel B - Personvern, biobank og økonomi

#### Personvern

Opplysninger som registreres (den informasjonen vi får inn gjennom helseundersøkelsen, se kapittel A –testene) om deg er avidentifiserte. Det vil si at resultatene dine registreres med et identitetsnummer. Koblingen mellom identitetsnummeret og ditt navn vil bli oppbevart separat på en minnepenn og i papirformat i en låst safe på Universitetet i Agder ved Fakultet for helse- og idrettsvitenskap sitt område. I etterkant av den siste helseundersøkelsen (posttesten), når alle resultater og aktivitetsprogram er tilsendt hver enkelt deltaker, vil denne koblingen bli slettet (innen 01.04.12). Ingen andre enn prosjektansvarlig og prosjektleder vil ha tilgang på koblingen mellom identitetsnummer og hver enkelt deltakers navn under prosjektperioden.

Eventuelle mastergradsstudenter som er delaktige i prosjektet vil få tilgang til å bruke enkelte data til sine mastergradsoppgaver. Dataene de da får tilgang til vil være anonyme, det vil si at det ikke vil være noen kobling mellom personidentifiserende opplysninger og øvrige resultater.

Universitetet i Agder, Fakultet for helse- og idrettsvitenskap, ved Fakultetsdirektør Veslemøy Rabe er databehandlingsansvarlig.

#### Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i Aktiv i Sør 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.

#### Økonomi, Universitetet i Agder og Norges Idrettshøgskole sin rolle

Aktiv i Sør er et doktorgradsprosjekt, det vil si at det er en stipendiat, ansatt ved Universitetet i Agder som følger doktorgradsprogrammet ved Norges Idrettshøgskole som skal levere deler av sin avhandling på bakgrunn av de dataene som samles inn i dette prosjektet. Driften av prosjektet er dermed sikret økonomisk gjennom stipendiatens lønn, som er tildelt Universitetet i Agder, gjennom Agderstipendet. Det er også blitt tildelt midler fra fakultet for helse- og idrettsvitenskap ved Universitetet i Agder, for å finansiere en tiltakskoordinator, som vil ha rollen som veileder for deltakerne i tiltaksgruppen. Utover dette er det per dags dato ikke delt ut øvrige midler til å drive prosjektet, men ettersom prosjektet i seg selv skal være økonomisk lite belastende, ser ikke prosjektledelsen dette som noen hindring.

#### Informasion om utfallet av studien

Det er viktig at du er klar over at du som deltaker har rett til å få informasjon om utfallet/resultatet av prosjektet. Dette er noe som vil bli opplyst om ved prosjektslutt (01.04.12).

## Samtykke til deltakelse i Aktiv i Sør prosjektet

Jeg er villig til å d	elta i studien
(Signert av prosjel	tdeltaker, dato)
leg hekrefter å ha	gitt informasjon om studien
•	
IMO	3.5.2011
(Signert av Ingirid	G.H. Kjær, prosjektleder for Aktiv i Sør, dato)