FACULTY OF MEDICINE AND HEALTH SCIENCES

The association between occupational physical activity and cardiorespiratory fitness

BMI as confounder and moderator

Word count: 7839

Lauri Lievens
Student number: 02103385

Supervisor: Prof. Dr. Els Clays
Cosupervisor: Drs. Margo Ketels

A dissertation submitted to Ghent University in partial fulfilment of the requirements for the degree of Master of Science in Health Promotion

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LIST OF ABBREVIATIONS

Abbreviation	Meaning
BFA	Beroepsmatige fysieke activiteit
BMI	Body mass index
CRF	Cardiorespiratory fitness
CVD	Cardiovascular disease
DV	Dependent variable
FAVT	Fysieke activiteit in de vrije tijd
FEPA	Flemish Employees' Physical Activity
HST	Harvard step test
IV	Independent variable
LFA	Lage intensiteit fysieke activiteit
LPA	Low intensity physical activity
LTPA	Leisure-time physical activity
MKFA	Matige tot krachtige fysieke activiteit
MVPA	Moderate to vigorous physical activity
OPA	Occupational physical activity
PA	Physical activity
PFI	Physical fitness index
VO_2max	Maximal oxygen consumption
WHO	World Health Organization

PREFACE

During a very enriching academic year I researched the association between occupational physical activity and cardiorespiratory fitness. In addition, I also investigated the influence of BMI as a confounder and moderator in this association. The results of this research came about thanks to the support of a number of people. Therefore, I would like to thank these people who supported me during this study.

First of all, I would like to thank my promotor, professor Els Clays, and co-promotor, doctorandus Margo Ketels, for giving me the opportunity to conduct this research. In their busy schedules they always made time to guide me. I would also like to thank them for their expert guidance, critical feedback and valuable insights. This support and guidance were key to accomplish this research.

I would also like to express my gratitude to my family and friends for their unconditional support and encouragement. I thank my parents for their support during this thesis and throughout my studies. They have always supported and encouraged me to chase my dreams and strive for the best result. Without their wise advice, patience and optimism, it would not have been possible to achieve this. I want to thank them for their constant presence, even when I was busy and unable to spend much time with them. Their support and understanding were invaluable and I will always be grateful for their efforts.

I also want to thank my friends. Thanks to them I could count on a listening ear and we supported each other during sometimes very stressful moments. Their confidence in me and my abilities was a source of inspiration and motivation.

Finally, I would like to take a moment to think about my guardian angels, aunt Anneke and my grandparents. You taught me to go for my dreams and never give up.

ABSTRACT

Dutch version

Literatuur: Beroepsmatige fysieke activiteit (BFA) heeft niet dezelfde gunstige gezondheidseffecten als fysieke activiteit in de vrije tijd (FAVT). Dit kan mogelijk verklaard worden door differentiële effecten van de domeinen van fysieke activiteit op cardiorespiratoire fitheid (CRF). Literatuur toont aan dat Body Mass Index (BMI) sterk geassocieerd is met BFA en CRF en deze associatie kan beïnvloeden. Het doel van deze studie is om de rol van BMI als confounder en moderator in de associatie tussen BFA en CRF te onderzoeken.
Methode: Deze cross-sectionele studie onderzocht de associatie tussen de verschillende types van BFA en CRF. Daarnaast werd ook de invloed van BMI als confounder en moderator in de associatie tussen BFA en CRF onderzocht. De fysieke activiteit van 332 participanten met een fysiek zware job werd gemeten met behulp van twee accelerometers. De gemeten BFA werd onderverdeeld in matige tot krachtige fysieke activiteit (MKFA) en lage intensiteit fysieke activiteit (LFA). CRF werd bepaald door de Harvard Step Test.
Resultaten: Hoge BFA niveaus worden geassocieerd met lage CRF-niveaus. BMI is een significante confounder van de associatie tussen BFA en CRF. BMI is geen significante moderator van de associatie.
Conclusie: Toekomstig onderzoek dient de associatie tussen BFA en CRF te bestuderen via een longitudinaal design. Het modererende effect van BMI dient onderzocht te worden in een grotere steekproefomvang en bij mensen met overgewicht en obesitas. Deze studieresultaten benadrukken de nood aan richtlijnen die rekening houden met het nadelige effect van BFA op CRF, bij mensen met een fysiek zware job.

Aantal woorden artikel: 7839 (exclusief woord vooraf, inhoudstafel, abstract, bijlagen, tabellen en referentielijst)

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English version

Literature: Occupational physical activity (OPA) does not have similar beneficial health effects as leisure time physical activity (LTPA). This may be explained by differential effects of both domains of physical activity on cardiorespiratory fitness (CRF). Literature shows that both OPA and CRF are associated with BMI. BMI can influence the association. Therefore, the aim of this study is to investigate the role of BMI as a confounder and moderator in the association.
Methods: This cross-sectional study examined the association between different types of OPA and CRF. Research was also carried out to investigate the influence of BMI as a confounder and moderator in the association between OPA and CRF. Physical behaviors were assessed by two accelerometers among 332 workers with a physically demanding job. OPA was divided into moderate-to-vigorous physical activity (MVPA) and low intensity physical activity (LPA). CRF was assessed by the Harvard Step Test.
Results: High OPA levels are associated with low CRF levels. BMI is a significant confounder in the association between OPA and CRF. BMI is not a significant moderator in the association between OPA and CRF.
Conclusion: Future research should study the association between OPA and CRF in a longitudinal design. The moderating effect of BMI should be investigated in a larger sample size and in overweight or obese people. Our study results highlight the need for recommendations to take into account the adverse effect of OPA on CRF, in people with a physically demanding job.

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LITERATURE REVIEW

1. Physical activity

1.1 Definition and guidelines

Physical activity (PA) is defined as any bodily movement by skeletal muscles that requires energy expenditure (World Health Organization, 2020). Energy expenditure is the amount of energy a body uses to perform essential physical functions including breathing, digestion, blood circulation and all the movements someone performs (MacPherson, 2022). PA is crucial for health, it has a positive influence on both physical and mental health. Furthermore, PA plays an important factor in the prevention of non-communicable diseases and premature mortality (Zeiher et al., 2020).

The World Health Organization (WHO) advises adults, between 18 and 64 years, to have at least 150-300 minutes of moderate-to-vigorous physical activity (MVPA) and 75-150 minutes of vigorous-intensity physical activity, or a combination of both types of PA for at least 150 minutes per week in order to improve health (World Health Organization, 2022). Following these guidelines results in a decrease of the risk for non-communicable diseases, such as cardiovascular disease (CVD). CVD is one of the main causes of death worldwide. In Belgium, 38.000 people die of CVD every year (Vlaams Instituut Gezond Leven, n.d.; World Health Organization, 2022).

1.2 Context of physical activity

PA consists of four domains of activities, such as leisure-time physical activity (LTPA), occupational physical activity (OPA), transportation PA and household PA (Hu et al., 2005; Ketels et al., 2020; Singer et al., 2016). This study will mainly focus on OPA and LTPA. LTPA takes place outside the job setting and contains sports and recreational PA such as walking, cycling, dancing, swimming and other sports (Hu et al., 2005; Ketels et al., 2020; Singer et al., 2016). OPA is considered as activities performed at work and contains different movements such as sitting office work, standing, walking, lifting and heavy manual labor (Hu et al., 2005; Ketels et al., 2020; Singer et al., 2016).

Jobs with high OPA levels are often called physically demanding jobs. These jobs are characterized by heavy physical or back-strenuous activities, extreme hot or cold conditions and a heavy work regime. In addition, mentally taxing professions such as care-related professions are also regarded as physically demanding jobs (van de Vyver, 2018). In literature the term blue-collar worker often refers to people with a physically demanding job (van de Vyver, 2018).

The different domains of PA are not included in the WHO PA-guidelines, suggesting that all the PA domains have comparable health effects and benefits (Cillekens et al., 2020, 2022; Stenholm et al., 2021). Despite the lack of nuance regarding the context of PA in the WHO guidelines, research shows that it is important to differentiate the domains of PA and take the context into account (Cillekens et al., 2020, 2022; Stenholm et al., 2021). Studies show that LTPA and OPA have different effects on cardiovascular health and all-cause mortality (Cillekens et al., 2020, 2022; Ketels et al., 2020; Stenholm et al., 2021). These effects are referred to in the literature as the physical activity health paradox.

2. Physical activity health paradox

2.1 General information about the physical activity health paradox

The PA health paradox describes the influence of LTPA and OPA on cardiovascular health and all-cause mortality. This paradox assumes that LTPA at a moderate-to-vigorous intensity combined with regular recovery time, will conserve or improve cardiovascular health (Cillekens et al., 2020, 2022; Ketels et al., 2020; Stenholm et al., 2021). This is however not the case for OPA. Specifically, OPA including heavy lifting, long periods of standing and uncomfortable body movements, might have a negative effect on cardiovascular health and contribute to a higher risk for CVD (Cillekens et al., 2020, 2022; Ketels et al., 2020; Stenholm et al., 2021).

The PA health paradox can be explained by the characteristics of LTPA and OPA (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). LTPA and OPA differ in duration, intensity and the amount of recovery breaks. Due to these characteristics, both domains of PA have a reverse impact on the cardiovascular system and cardiorespiratory fitness (CRF). CRF (mlO_2/min/kg) is the ability of the circulatory and respiratory systems to supply oxygen to the skeletal muscles, during physical activities (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). A low CRF corresponds to a low rate at which the body transports oxygen to the tissues. Which in turn can lead to a higher risk for CVD and all-cause mortality (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). The standard for assessing this parameter is the maximal oxygen consumption (VO_2 max) (Farooque & Hussain, 2017).

2.2 The influence of OPA and LTPA on CRF

OPA is characterized by prolonged exposure to static or anaerobic movement, during many hours a day. Another important characteristic is an insufficient amount of recovery breaks. The low intensity, long duration and limited recovery breaks result in a prolonged elevation of heart rate and blood pressure. This can result in erosion of the endothelium (Grootenboer, 2021; Zeiher et al., 2020). Due to vascular damage, the heart has to work harder to transport oxygen to the tissues. A low oxygen transportation rate is associated with a low CRF and a higher risk for CVD and CVD mortality (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021).

LTPA is, in contrast to OPA, characterized by short-term high intensity movements of large muscle groups and sufficient recovery breaks (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021; Zeiher et al., 2020). These characteristics have opposite effects on the cardiovascular system, compared to OPA. The heart rate and blood pressure will not be constantly elevated, which prevents the blood vessels from being damaged (Clays et al., 2012; Grootenboer, 2021; Zeiher et al., 2020). The absence of blood vessel damage results in a high CRF, which indicates a good cardiovascular health and a reduced risk for CVD and CVD mortality (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021).

In conclusion, the PA health paradox shows that OPA has a negative effect on cardiovascular and general health. LTPA has a positive effect on cardiovascular and general health (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). Literature shows that BMI is associated to both OPA and CRF. Therefore, it can be suspected that BMI could influence the association between OPA and CRF (Duffy et al., 2012; Salinas et al., 2016; van den Berge et al., 2022).

3. Influence of BMI in the association between OPA and CRF

3.1 Definition and guidelines

BMI (kg/m²) is an estimate of body fat that is based on weight and height (Bailey & Chandrasekaran, 2022; National health service, 2019). It is calculated by dividing a person's weight in kilograms by the square of height in meters. BMI is used to determine whether someone is underweight, at a healthy weight, overweight or obese (Bailey & Chandrasekaran, 2022; National health service, 2019). Table 1 shows the determination of weight status based on BMI. BMI is the most frequently used parameter for estimating weight and body fat. It is convenient, inexpensive and can be used routinely (Bailey & Chandrasekaran, 2022; National health service, 2019).

Overweight and obesity are associated with a higher risk for developing certain health problems such as CVD, high blood pressure, cancer, type 2 diabetes, sleep apnea, high cholesterol and other diseases (Bailey & Chandrasekaran, 2022).

Table 1: Determination of weight status based on BMI (Bailey & Chandrasekaran, 2022)

BMI	Weight status
<18,5 kg/m²	Underweight
18,5 - 24,9 kg/m²	Healthy weight
25 - 29,9 kg/m²	Overweight
>30 kg/m²	Obese

In 2021, more than two billion adults worldwide were overweight. Of those two billion adults, 650 million adults were obese (World Health Organization, 2022). Research shows that the prevalence of overweight and obese people continues to increase worldwide (Akil & Ahmad, 2011; World Health Organization, 2022).

3.2 BMI as a confounder in the association between OPA and CRF

In several studies that examine the association between OPA and CRF, BMI is included as a confounder (Duffy et al., 2012; Salinas et al., 2016; van den Berge et al., 2022). A confounder is a factor that is strongly related to the dependent (DV) and independent (IV) variables. It can reinforce or mask the association between DV and IV, which can lead to a bias and misinterpretation of the association between both (Rockwood & Hayes, 2020). Literature shows that BMI is strongly related to both OPA and CRF (Duffy et al., 2012; Salinas et al., 2016; van den Berge et al., 2022). These strong associations suggest that BMI might be a confounder in the association.

3.2.1 The association between OPA and BMI

Research shows that there is a statistically significant positive association between OPA and BMI. People with a physically demanding job have a higher risk for being overweight or obese compared to people with a sedentary job, also known as white-collar workers (Duffy et al., 2012; Salinas et al., 2016; van den Berge et al., 2022). This finding is counterintuitive. People with a physically demanding job are physically active during working hours. Due to this active work style, it would be expected that they have a lower risk for being overweight, compared to white-collar workers. However, the opposite is shown, blue-collar workers have higher risks for being overweight, poorer health and higher mortality rates (Duffy et al., 2012; Salinas et al., 2016; van den Berge et al., 2022).

The higher risk for being overweight and poorer health can be explained by different factors, such as work-related characteristics and lifestyle characteristics (Duffy et al., 2012; van den Berge et al., 2022). The work-related characteristics are: working in disadvantaged environments, performing several hours of physically demanding activities per day, having insufficient time to recover and working long and irregular shifts (Duffy et al., 2012; van den Berge et al., 2022). Due to the combination of these work-related characteristics, blue-collar workers often do not have the energy to do physical activity in their leisure time (Duffy et al., 2012; van den Berge et al., 2022). This can result in high OPA and low LTPA levels (Petersen et al., 2012; Proper et al., 2020; Singer et al., 2016; Van den Berge et al., 2022). The leisure-time physical inactivity can lead to a higher risk for being overweight or obese, which in turn can result in a higher risk for low cardiorespiratory health (Proper et al., 2020; Singer et al., 2016; Van den Berge et al., 2022).

Lifestyle characteristics can also influence the risk for being overweight or obese. Research shows that blue collar-workers tend to have a lower socio-economic status and educational level compared to white-collar workers. A low socio-economic status is significantly associated with less healthy lifestyle characteristics (Duffy et al., 2012; Salinas et al., 2016).

Duffy et al. (2012) show that blue-collar workers consume significantly more fried food and less fruit and vegetables, compared to white-collar workers, which is significantly associated with a higher risk for being overweight. The increased intake of these unhealthy products can be declared by a low nutrition education (Duffy et al., 2012). Salinas et al. (2016) show that blue-collar workers tend to have a low nutrition education, which results in a higher chance of making unhealthy food choices. Duffy et al. (2012) show that blue-collar workers consume more alcohol compared to white-collar workers. Alcohol consumption is positively associated with the risk for being overweight and cardiac events. The excessive use of alcohol can also be explained by an insufficient knowledge about the risks of alcohol consumption (Duffy et al., 2012; Salinas et al., 2016). In conclusion, blue-collar workers tend to have insufficient knowledge about the negative effects of unhealthy lifestyle characteristics, which can lead to a higher risk for being overweight or obese (Duffy et al., 2012; Salinas et al., 2016).

3.2.2 The association between CRF and BMI

Several studies, including the study of Bonney et al. (2018), show a statistically significant negative association between BMI and CRF. Blue-collar workers with a high BMI, have low CRF levels (Ku et al., 2019; Ortega et al., 2016; Proper et al., 2020; Singer et al., 2016). This can be explained by work-related characteristics, lifestyle characteristics and lower LTPA levels due to high OPA levels. These studies show that work-related and lifestyle characteristics in people with a physically demanding job can cause a higher risk for being overweight or obese. The presence of these characteristics and the risk for being overweight or obese can negatively affect the cardiovascular structure and function. A loss of function leads to a low CRF and a higher risk for developing CVD and CVD mortality (Ku et al., 2019; Mäkinen et al., 2010; Morassaei & Smith, 2011; Ortega et al., 2016; Proper et al., 2020).

4. Limitations of other studies

The existing studies have a number of limitations that should be taken into account in future studies. Firstly, objective measurements of OPA and CRF should be an important focus for future studies. The number of studies using objective measurement of OPA (e.g., accelerometers) is rather limited compared to the vast majority of studies using subjective measures (e.g., self-reported OPA questionnaires) (Hallman et al., 2017; Holtermann et al., 2016). This while recent research shows that subjective measurements significantly differ from objective measurements. Kuster et al. (2021) find no significant association between OPA and CRF when subjective measurements were performed. However, a significant association is found when using objective measurements. Subjective measurements are often prone to bias, which can lead to a misinterpretation of the parameters under investigation (Korshøj et al., 2022; Kuster et al., 2021).Therefore, this study will use objective measurements of OPA and CRF.

Secondly, BMI is often included as a confounder in the analysis of the association between OPA and CRF. Studies describe the association between BMI and the exposure variable (OPA) and the association between BMI and the outcome variable (CRF) (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021; Singer et al., 2016; van den Berge et al., 2022). Based on these associations, it can be suspected that BMI is a confounder in the association between OPA and CRF. However, none of these studies examined how strongly BMI can influence the association between OPA and CRF.

Thirdly, literature suggests that BMI may also be a moderator in the association between OPA and CRF (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021; Singer et al., 2016). Given the strong association between OPA and BMI on the one hand and CRF and BMI on the other hand, it can be suspected that BMI may enhance the negative association. To the best of our knowledge, most available literature focuses on the association between BMI and the exposure and outcome variables. There are no studies available that examined the influence of BMI as a moderator in the association between OPA and CRF.

5. Problem statement and research question

This research aims to gain more insight into the influence of physically demanding work on cardiovascular health. A physically demanding job can have a negative impact on health. In 2020, 53% of employees in Belgium were absent due to physical complaints caused by physical overload during work (Beroepsverenging voor ergonomie, 2020). People with a physically demanding job have high OPA levels which can have a negative impact on CRF and the risk for CVD mortality (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). By examining the physical activity pattern of people with a physically demanding job, health risks could be identified and interventions could be developed to improve the health of the employees. By mapping the physical load of certain tasks, employers could adjust work processes to reduce the physical load and improve working conditions.

Literature suggests that BMI could influence the association between OPA and CRF (Duffy et al., 2012; Ku et al., 2019; Mäkinen et al., 2010; Morassaei & Smith, 2011; Proper et al., 2020; Salinas et al., 2016; van den Berge et al., 2022). Given the strong association between BMI and OPA on one hand and BMI and CRF on the other hand, several studies include BMI as a confounder in the analysis of the association between OPA on CRF. However, none of these studies examined how strongly BMI can influence the association between OPA and CRF (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021; Singer et al., 2016; van den Berge et al., 2022). Therefore, the aim of this research is to examine whether BMI can lead to an underestimation or overestimation of the association between OPA and CRF. In addition, the extent to which BMI distorts the association between OPA and CRF will also be examined.

Literature also suggests that BMI could be a moderator and could influence the strength and direction of the association between OPA and CRF (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021; Singer et al., 2016; van den Berge et al., 2022). People with a physically demanding job can have a lower socio-economic status and lower health education. The possible lack of health education can lead to unhealthy lifestyle characteristics. This can in turn lead to a higher risk for being overweight or obese. Literature shows that people with a physically demanding job can also have a higher risk for being overweight or obese because of work-related determinants. People with a physically demanding job have high OPA levels, what can lead to more physical inactivity during leisure time. A high OPA and low LPTA can negatively affect BMI and CRF (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021) To the best of our knowledge there are no studies that describe the influence of BMI as a moderator in the association between OPA and CRF. Therefore, this study will also examine the impact of BMI on the strength and direction of the association between OPA and CRF. If BMI influences the association between OPA and CRF, it is important to develop different health promotion intervention components for the different BMI categories.

The research question and research hypotheses that were formulated from the literature review are presented in Table 2.

Table 2: Research question and hypotheses

Research question
What is the association between occupation physical activity and cardiorespiratory fitness, with BMI as a confounder/ moderator?
Research hypothesis
BMI is a significant confounder in the negative association between OPA and CRF. If BMI is not included as a confounder, the association will be underestimated. BMI is a significant moderator in the negative association between OPA and CRF. BMI has a synergetic effect in the association between OPA and CRF. The negative association will be stronger in overweight or obese people.

METHOD

1. Study population and design

1.1 General information

The data in this study were collected as part of the larger Flemish Employees' Physical Activity (FEPA) study (Ketels et al., 2019, 2020). The protocol of this study was described by Ketels et al. (2019). The participants were recruited by convenience sampling across seven different companies within the service and production sector in Flanders, Belgium. The measurements were carried out in the period from February 2017 to June 2018. This cross-sectional study examined the effect of BMI in the association between OPA and CRF in the study participants.

The inclusion criteria were: non-pregnant, Dutch speaking, employed for at least 50% and aged between 18 and 65 years. People who worked exclusive nightshifts were not included in the study population (Ketels et al., 2019).

2. Measurements

2.1 General procedure

The procedure included a self-reported questionnaire, a medical screening and objective measurement of OPA and CRF (Ketels et al., 2019, 2020). Participants who wanted to participate in the research were provided an appointment for a medical screening, which took place at the worksite during the working hours, and a questionnaire. Participants could choose if they wanted to fill in the questionnaire on paper or to fill it in online. The different items of this questionnaire were described in the FEPA study protocol (Ketels et al., 2019). Not all the items that were prompted in the questionnaire of the FEPA study protocol were used in this study. In this study the information about age, sex, educational level and smoking status was used for the statistical analyses. During the baseline medical screening participants received information about the study and the procedure. Before starting the examinations, the participants were also asked to sign an informed consent (Ketels et al., 2019, 2020).

A researcher conducted baseline measurements including height, weight, waist circumference and blood pressure. An estimation of the CRF was determined by the Harvard Step test (HST). After medical screening the researcher attached two accelerometers on the skin of the participants. The accelerometers provided objective measurement of PA. (Ketels et al., 2019, 2020).

2.2 Exposure variable: OPA

Two tri-axial Activity AX3 accelerometers were used to measure OPA and LTPA (Ketels et al., 2019; Skotte et al., 2014; Stemland et al., 2015). One accelerometer was worn on the back and the other on the right thigh. The accelerometers were orientated with the x-axis pointing downwards, y-axis horizontally to the left and z-axis horizontally forward (Ketels et al., 2019).

Participants wore the accelerometers for three to four consecutive working days. Participants also had to keep a diary, in which they reported the beginning and the end of their working day, their time of going to and getting out of bed, the moments they took the accelerometers off (e.g., while taking a bath or going swimming) and the time of a reference measurement. The reference measurement was used to calibrate the accelerometers. Participants had to stand straight and still for fifteen seconds per day to perform the calibration (Ketels et al., 2019, 2020; Skotte et al., 2014; Stemland et al., 2015).

The accelerometer data were downloaded using Axivity software (AX3-GUI, Omgui Software) and analyzed using a custom-made MATLAB software called Acti 4 (The National Research Centre for the Working Environment, Copenhagen, Denmark and Federal Institute for Occupational Safety and Health, Berlin, Germany). This software was able to identify different domains of PA and postures such as lying, walking, running, sitting, standing, moving, rowing, cycling and walking on stairs. The domains of PA were identified with a high sensitivity and specificity. The accelerometers have a sensitivity and specificity of respectively 98.2% and 98.3%. The interobserver reliability is more than 90% (Ketels et al., 2019, 2020; Skotte et al., 2014; Stemland et al., 2015).

The data of the diary were used to identify leisure time, work time and time spent in bed. Work time (OPA) was defined as the hours spent at the job setting. Leisure time was defined as the time away from work, not including sleep. Only participants with measurements for work and leisure time for at least one day were included in further analyses. Moments where the participants did not wear the accelerometers were excluded (Ketels et al., 2019, 2020).

Sedentary behavior was defined as time spent sitting or lying down. Time spent moving and walking slowly (<100 steps per minute) was combined to estimate the time spent on LPA. Moving was defined as a standing position with small movements but without regular walking. MVPA was defined as the time spent running, walking on stairs and fast walking (>100 steps per minute). The mean time spent on these three activities was calculated for work and leisure time (Ketels et al., 2019, 2020). This study focused on the association between OPA and CRF. Sedentary behavior and time spent standing were not directly related to PA during work. Therefore, only LPA and MVPA during work were included in further analyses.

2.3 Outcome variable: CRF

The standard for assessing CRF is the maximal incremental cycle ergometer test, also known as the cycling test or VO_2 max test (Farooque & Hussain, 2017). The company setting in which the tests were conducted did not allow the cycling test to be performed. In this research the CRF was objectively measured by using the Harvard Step Test (HST). The HST is a single-stage test used to determine the physical fitness index (PFI). PFI is an estimation of the CRF (Ketels et al., 2019, 2020).

During the HST participants were asked to step up and down a bench for five minutes. The bench was 33 cm for women and 40 cm for men. The rhythm at which the participants had to step up and down was indicated by a metronome with a stepping rate of 22.5 steps per minute. Before doing the test, the participants had a one minute practice session to become familiar with the protocol. Participants were allowed to stop before the end of five minutes, if they felt exhausted or when the stepping rate was not maintained for longer than fifteen seconds (Ketels et al., 2019, 2020).

After the test, participants were asked to sit down. During the recovery time, heart rate was measured. Three recovery heart rates were measured by using a polar device (Polar A300 HR, Kempele, Finland) with a one minute interval. The three recovery heart rates were used to calculate the PFI, which was determined by the following equation: PFI% = (duration of exercise in seconds x 100)/(2 x (recovery heart rate 1 + 2 + 3)). The PFI rating is shown in Table 3 (Fox et al., 1973; Ketels et al., 2019, 2020).

Table 3: PFI rating index (Fox et al., 1973)

PFI rating	Physical fitness index	
	Male	**Female**
Excellent	>115	>91
Good	103-115	84-91
Fair	91-102	77-83
Poor	<91	<77

2.4 Baseline characteristics and confounding variables

Baseline characteristics were assessed by a questionnaire and baseline clinical measurements. The questionnaire included socio-demographic data such as, age, sex, educational level and smoking status. Sex was classified as 'man' or 'woman'. Smoking status was classified as 'non-smoker' or 'current smoker'. Educational level was categorized in three levels. Education until primary school was classified as 'low', secondary school and/ or one or two years of specialization was coded as 'medium' and university or college was classified as 'high' (Ketels et al., 2019, 2020).

Participants' length and weight were measured with a Seca 704 column scale (SECA Medical Measuring Systems and Scales, Birmingham, UK; scales 701/704). Before standing on the scale participants were asked to remove heavy clothes and shoes. Height was measured while the participants were standing straight and not wearing shoes. Based on these measurements the corresponding BMI (kg/m²) was calculated. In line with the WHO international standards, overweight and obesity were defined. BMI was classified as 'underweight' (<18.5 kg/m²), 'normal weight' (18.5-24.9 kg/m²), 'overweight (25-30 kg/m²) and 'obese' (>30 kg/m²) (Ketels et al., 2019, 2020).

3. Statistical analyses

Before further analyses were conducted, the distribution of all parameters was checked. Histograms were requested to detect any outliers. The associations between the different types of OPA (MVPA during work and LPA during work) and CRF were investigated by means of linear regression analyses. The analyses were gradually corrected for confounding variables (age, sex, smoking status, BMI, educational level and percentage MVPA during leisure time). In addition, the role of BMI as a possible moderator was investigated by means of moderation analyses. All analyzes were performed using the SPSS software (version 28.0.1.1, SPSS Inc., Chicago, Illinois). The level of significance for the multiple linear regressions was set at $p<0.05$ (5%). The level of significance for the moderation analyses was set at $p<0.10$ (10%).

RESULTS

All analyses are performed on part of the data of the study by Ketels et al. (2020). The analyses are performed on the data of 332 people with a physically demanding job.

1. Descriptive statistics

Information regarding demographics, accelerometers-assessed information and accelerometers-assessed physical behaviors are provided in Table 4. The mean age is 38.78 (±11.17) years, 57.20% of the participants are women. Almost half of the participants graduate from university or university college (49.10%). The participants have a mean BMI of 24.86 (±4.21) kg/m². More than half of the participants have a healthy weight (56.00%), 31.90% of the participants are overweight and 10.50% are obese. A quarter of the participants (24.10%) smoke. The mean fitness score for men is 102.95 (±28.03). A third (33.10%) of men with a physically demanding job have a poor fitness score, while 26.80% have an excellent fitness score. The mean fitness score for women is 91.24 (±26.83). Of all women with a physically demanding job 44.70% have a poor fitness score, while 13.70% have an excellent fitness score. On average, workers provide 3.0 (±0.90) valid accelerometer-assessed working days, with an average of 7 hours 54 minutes (± 1 hour 13 minutes) working hours and 7 hours 46 minutes (±1 hour 40 minutes) leisure time hours.

Table 4: Descriptive characteristics of the study population (N=332). (Flemish Employees Physical Activity study, Flanders, Belgium, 2017-2018) (Ketels et al., 2019, 2020)

Demographic characteristics	N (%)	Mean (SD)
Age		38.78 (±11.17)
Sex		
Female	190 (57.20)	
Male	142 (42.80)	
Educational level		
Low (until primary school)	59 (17.80)	
Medium (secondary school and/ or 1 to 2 years of specialization)	110 (33.10)	
High (university or university college)	163 (49.10)	
BMI (kg/m²)		
BMI general (kg/m²)		24.86 (±4.21)
Underweight (<18.5 kg/m²)	1.20	
Healthy weight (18.5 – 24.9 kg/m²)	56.00	
Overweight (25-29.9 kg/m²)	31.90	
Obese (>30 kg/m²)	10.50	
Current smoker	80 (24.10)	
Physically active job	332 (100)	
Fitness score (CRF) men		102.95 (±28.03)
Poor (<91)	33.10	
Fair (91-102)	17.60	
Good (103-115)	21.20	
Excellent (>115)	26.80	
Fitness score (CRF) women		91.24 (±26.83)
Poor (<91)	44.70	

Fair (91-102)	24.70	
Good (103-115)	13.70	
Excellent (>115)	13.70	
Accelerometer-assessed information	**N (%)**	**Mean (SD)**
Valid accelerometer wear-days		3.0 (±0.90)
Mean total work time (min/day)		474 (±73.20)
Mean total leisure time (min/day)		466 (±100)
Accelerometer-assessed behaviors	**N (%)**	**Mean (SD)**
Mean total work time (min/day)		474 (±73.20)
Percentage MVPA during work		14.44 (7.35)
Percentage LPA during work		53.92 (±19.15)
Mean total leisure time (min/day)		466 (±100)
Percentage MVPA during leisure time		9.57 (5.01)
Percentage LPA during leisure time		30.44 (±12.66)

2. Main analyses

2.1 Linear regression analyses: the influence of BMI as confounder in the association between different types of OPA and CRF

Table 5 shows the results of the multiple linear regression analyses of the association between percentage MVPA during work/ percentage LPA during work and CRF. The unadjusted model shows the association between the independent variables (percentage MVPA during work or percentage LPA during work) and CRF. The following models are gradually corrected for the confounders BMI, age, sex, educational level, smoking level and percentage MVPA during leisure time. Model 1 shows the association between the different types of OPA and CRF, controlled for BMI. Model 2 shows the association, controlled for BMI, age, sex and educational level. Model 3 shows the association, controlled for the confounders included in model 2, smoking level and percentage MVPA during leisure time.

Table 5: Linear regression analyses between the different types of occupational physical activity (MVPA and LPA) and CRF. Results from multiple linear regression analyses in 332 workers (Flemish Employees' Physical Activity Study, Flanders, Belgium, 2017-2018).

Linear regression analysis of percentage MVPA during work and CRF				
	β	**SE**	**t-value**	**P**
Unadjusted model	-0.339	0.210	-1.615	0.107
Model 1	-0.418	0.191	-2.189	0.029
Model 2	-0.516	0.195	-2.652	0.008
Model 3	-0.699	0.186	-3.758	<0.001
Linear regression analysis of percentage LPA during work and CRF				
	β	**SE**	**t-value**	**P**
Unadjusted model	-0.272	0.080	-3.403	<0.001
Model 1	-0.265	0.073	-3.651	<0.001
Model 2	-0.165	0.075	-2.207	0.028
Model 3	-0.150	0.073	-2.047	0.041

The level of significance is set at p<0.05 (5%).
Unadjusted model: The association between independent variables (percentage MPVA during work or percentage LPA during work) and dependent variable (CRF).
Model 1: Unadjusted model with BMI added as a confounder.
Model 2: Model 1 with age, sex and educational level added as confounders.
Model 3: Model 2 with smoking level and percentage MVPA during leisure time added as confounders.

The unadjusted model shows no statistically significant association between percentage MVPA during work and CRF. However, the association becomes statistically significant when controlled for confounders. There is a statistically significant negative association (β=-0.418 and p=0.029) between percentage MVPA during work and CRF, adjusted for BMI. An increase of percentage MVPA during work results in a decrease of cardiorespiratory fitness score.

The research question focuses on the influence of BMI as a confounder in the association between percentage MVPA during work and CRF. Upon comparison of the effect sizes between the unadjusted model (β=-0.339) and model 1 (β=-0.418), it can be seen that the effect sizes differ more than 10%. This means that BMI is rightly included as a confounder. If BMI is not controlled for, the association can be misinterpreted. The association between percentage MVPA during work and CRF stays statistically significant when gradually corrected for age, sex, educational level, percentage MVPA during leisure time and smoking level (shown in Table 5, model 2 and model 3).

The unadjusted model shows a statically significant negative association between percentage LPA during work and CRF. The association remains significant after adding BMI as a confounder (Table 5, model 1). There is a statistically significant negative association between percentage LPA during work and CRF, adjusted for BMI (β=-0.265 and p=<0.001). An increase of percentage LPA during work results in a decrease of cardiorespiratory fitness score. Upon comparison of the unadjusted model (β=-0.272) and model 1 (β=-0.265), it can be seen that the effect sizes do not differ more than 10%. This means that BMI does not need to be included as a confounder. This can be explained by a less strong association between LPA and BMI compared to the association between percentage MVPA during work and BMI. The association between percentage LPA during work and CRF stays statistically significant when gradually corrected for age, sex, educational level, percentage MVPA during leisure time and smoking level (shown in Table 5, model 2 and model 3).

2.2 Moderation analyses: the influence of BMI as a moderator in the association between different types of OPA and CRF

Table 6 displays the main effects of percentage MVPA during work/percentage LPA during work and BMI on CRF, as well as their interaction effects. The moderation analyses are performed with the centralized variables of percentage MPVA during work, percentage LPA during work, BMI and CRF.

Table 6: Moderation analyses between the different types of occupational physical activity (MVPA and LPA) and CRF with BMI as a moderator. Results from moderation analyses in 332 workers (Flemish Employees' Physical Activity Study, Flanders, Belgium, 2017-2018).

Moderation regression analysis of percentage MVPA during work and CRF with BMI as moderator					
	β	**SE**	**t-value**	**P**	**95% CI β**
Interaction effect (MVPAw.BMI)	-0.019	0.055	-0.347	0.728	-0.127;0.089
Percentage MVPAw	-0.429	0.194	-2.214	0.028	-0.810;-0.048
BMI	-3.002	0.365	-8.150	<0.001	-3.721;-2.283
Moderation regression analysis of percentage LPA during work and CRF with BMI as moderator					
	β	**SE**	**t-value**	**P**	**95% CI β**
Interaction effect (LPAw.BMI)	-0.004	0.019	-0.237	0.813	-0.041;0.032
Percentage LPAw	-0.264	0.073	-3.602	<0.001	-0.408;-0.120
BMI	-2.910	0.368	-7.917	<0.001	-3.634;-2.187

The level of significance is set at p<0.10 (10%). The interaction effects were calculated with the centralized variables, percentage MVPA during work, percentage LPA during work and BMI. The main effects were calculated with the centralized variables.

There is no statistically significant interaction effect in both moderation regression analyses. The association between percentage MVPA during work and CRF is not statistically significant different by BMI (p=0.728). The association between percentage LPA during work and CRF is not statistically significant different by BMI (p=0.813). However, there is a statistically significant negative main effect between percentage MVPA during work and CRF (p=0.028) and between percentage LPA during work and CRF (p<0.001). The results of the moderation analyses confirm the results of the multiple linear regression analyses. The multiple linear regression analyses show statistically significant negative associations between percentage MVPA during work/percentage LPA during work and CRF, corrected for BMI.

DISCUSSION

1. The association between OPA and CRF

This study examines the influence of OPA on CRF in people with a physically demanding job. This target population was chosen because research has shown that continuous physical activity and insufficient recovery time at work result in a higher risk for developing CVD (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). CRF was used to determine the capacity of the cardiovascular system and the risk for developing CVD. This parameter is measured in a company setting by means of the Harvard Step Test. A low CRF corresponds to a low rate at which the body transports oxygen to the tissues. The slower the oxygen is transported to the tissues, the more difficult it is to perform physical tasks and the greater the risk for developing blood vessel damage and CVD (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021).

This study shows a statistically significant negative association between the different types of OPA (MVPA and LPA) and CRF. More physical activity at work is associated with a lower CRF. These findings are in line with literature (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). Studies have already shown that OPA is, in contrast to LTPA, characterized by a long-term and moderate intense load and insufficient recovery time. These characteristics have a negative effect on the cardiovascular health (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). This research shows that it is important to take into account the setting in which the physical activity is performed, when drawing up future PA guidelines.

2. The Influence of BMI as a confounder in the association between OPA and CRF

This study investigates the role of BMI as a confounder in the association between the different types of OPA and CRF. The multiple linear regression analysis between percentage MVPA during work and CRF shows that BMI is a statistically significant confounder. If the analysis is not corrected for BMI, the regression coefficient of the association is underestimated by more than 10%. The multiple linear regression analysis between percentage LPA during work and CRF shows that BMI is not a statistically significant confounder. This can be explained by a less strong association between LPA and BMI (Cillekens et al., 2020; Ketels et al., 2020; Stenholm et al., 2021). Although BMI is not a significant confounder in the association between LPA and CRF, it is recommended to include BMI as a confounder when investigating the association between OPA and CRF. If BMI is not included, the association between OPA and CRF is misinterpreted. The confounding influence of BMI could be explained by the strong association between BMI and OPA on one hand and between BMI and CRF on the other hand (Duffy et al., 2012; Proper et al., 2020; Salinas et al., 2016; Singer et al., 2016; Van den Berge et al., 2022).

3. The influence of BMI as a moderator in the association between OPA and CRF

This study also examines the role of BMI as a moderator in the association between the different types of OPA and CRF. The moderation analyses show that no statistically significant moderation effects are present. The association between percentage of MVPA during work/ percentage LPA during work and CRF is not significantly different according to BMI. To conclude, our results show that BMI does not statistically significantly influence the strength and direction of the association OPA and CRF. Due to a lack of literature the results of this study cannot be compared to previous studies. More general studies have already shown that there are three reasons that could explain a non-significant moderation effect: small sample size, the actual absence of a moderation effect and the setting (Kraemer et al., 2006; Livingston & Haardörfer, 2019; Rockwood & Hayes, 2020). Firstly, a small sample could make moderation effects unobservable. It could be that the amount of people with a physically demanding job and overweight or obesity is too small to find a moderation effect. Significant moderation effects can be found in sample sizes larger than 200-300 participants (Kraemer et al., 2006; Livingston & Haardörfer, 2019). In this study 141 participants with a physically demanding job are overweight or obese. This could be too small to detect a significant moderation effect. Another explanation is the actual absence of a moderation effect. The literature does not describe a moderating influence of BMI in the association between OPA and CRF. A lack of literature could confirm the absence of a significant moderation effect (Kraemer et al., 2006; Livingston & Haardörfer, 2019; Rockwood & Hayes, 2020). Non-significant results are often not published in scientific literature. A third explanation is the setting. There could be an insufficient variance in the setting and sample. The population of this study is rather homogeneous, with more than half of the participants having a healthy weight. More than half of the participants have a medium and high educational level. The homogeneous sample could result in not finding a significant moderation effect. If the setting is more heterogeneous, BMI could be a statistically significant moderator (Rockwood & Hayes, 2020).

4. Strengths, limitations and recommendations for future research

4.1 Strengths

To the best of our knowledge, this is the first study that examined the influence of BMI as a moderator in the association between OPA and CRF. This study adds evidence to the very limited literature available on this topic. The research also has several general strengths. Firstly, this study, in contrast to most available studies in literature, distinguishes between the different types of OPA (Hall et al., 2019; Korshøj et al., 2022; Stenholm et al., 2021). This distinction makes it possible to investigate which type of OPA has a stronger positive or negative influence on CRF (Ketels et al., 2020, 2022). Future policy makers should take the strength of these associations into account. In order to develop correct exercise guidelines, it is necessary to investigate the most optimal ratio between the different types of OPA and sitting breaks. This optimal ratio is called the sweet spot hypothesis. However, few studies have investigated this sweet spot hypothesis in people with a physically demanding job. Further research is needed to be able to draw up correct exercise guidelines. These studies need to distinguish between the different types of OPA and LTPA (Holtermann et al., 2021). Secondly, the setting is also a strength of this study. The study is conducted in people with a physically demanding job. This target group has a higher risk for developing problems such as cardiovascular diseases. By examining the physical activity of this target group, health risks can be identified, and interventions can be developed to improve the health of the employees (Cillekens et al., 2020; Kang et al., 2015; Ketels et al., 2020). Another strength of this study is the use of objective measures of physical activity through accelerometers. Research has shown that subjective measurements often lead to an underestimation of the actual movement pattern (Korshøj et al., 2022; Kuster et al., 2021). Two accelerometers were used for the objective measurement of physical activity. Using multiple accelerometers results in more accurate identification of the different body movements (Korshøj et al., 2022; Kuster et al., 2021).

4.2 Limitations and recommendations for future research

The study has a number of general limitations. Firstly, two accelerometers were used to objectively measure OPA. As a result, it is not possible to measure forward bending of the back and repetitive movements of the arms above the head. However, these movements are common during work hours and are associated with lower levels of CRF (Dencker-Larsen et al., 2019). The use of more accelerometers, preferably four, is required for a more comprehensive assessment of specific postures (Dencker-Larsen et al., 2019; Ketels et al., 2020). A second limitation of this study is the use of the Harvard step test to measure CRF in a large sample. The HST is not the most valid method for assessing VO_2max. The literature has shown that the maximal incremental cycle ergometer test is the most valid method to assess VO_2max and cardiorespiratory health (Ekblom-Bak et al., 2014; Ketels et al., 2020).

However, it is not possible to perform this test in an occupational context, therefore the Harvard step test can be used and gives an estimation of the VO_2max. The Harvard step test has the disadvantage that the workload increases with body weight. This makes the step test easy to perform for healthy people in good physical condition, while it requires almost maximum effort for less fit people (Ketels et al., 2019, 2020). Another limitation is the use of BMI as a parameter to determine the body composition of individuals. Recent studies have shown that there are other parameters such as body fat percentage and waist circumference that provide a more accurate measurement of body composition (Lutoslawska et al., 2014; Nimptsch et al., 2019). However, in this study BMI was chosen because it is a widely used and inexpensive parameter with which body composition can be determined in an occupational context. It may be appropriate in future studies to measure body composition using bioelectric impedance analysis, instead of BMI (Lutoslawska et al., 2014; Nimptsch et al., 2019). Another shortcoming of this research is the design. A cross-sectional study does not allow to draw conclusions about causality. Thus, it cannot be concluded with certainty that a change in OPA is the cause of a change in CRF. It is also not possible to study changes in variables over time. It is recommended to conduct longitudinal studies in the future, to be able to formulate statements about causal relationships (Ketels et al., 2020; Van den Berge et al., 2022; Zeiher et al., 2020). The last restriction of this study is the convenience sampling that is used to recruit participants. This can lead to a sample that is only partially representative of the target population. Voluntary participation can also lead to selection bias. It cannot be ruled out that participants were younger and fitter than their non-participating colleagues. In addition, only the fit employees will perform a physically demanding job for a long time. There is also a selection bias at the company level. It may be that only companies with more resources chose to participate in the study (Ketels et al., 2020). Due to the lack of literature on the influence of BMI as a moderator in the association between OPA and CRF, it is not possible to compare the results of this study with previous studies. A lack of literature can lead to shortcomings in methodology and a limited theoretical base (Livingston & Haardörfer, 2019; Rockwood & Hayes, 2020). Future studies should use a larger sample size. The composition of this sample is also important. It is possible that a moderation effect can be observed in overweight or obese people (Kraemer et al., 2006; Livingston & Haardörfer, 2019). The number of participants with a low educational level is also too small. It could be that the higher educational level results in healthier lifestyle characteristics and higher CRF levels. However, in this study the amount of overweight or obese participants is too small to find a statistically significant moderation effect (Kraemer et al., 2006; Livingston & Haardörfer, 2019).

CONCLUSION

This study shows that there is a statistically significant negative association between OPA and CRF. More physical activity at work is related to a decrease in CRF. This is in line with the available literature. This study examines the influence of BMI as a confounder and a moderator in the association between OPA and CRF. The analyses show that BMI is a significant confounder in the association between OPA and CRF. Failure to control for BMI when studying the association between OPA and CRF will lead to a misinterpretation of the association. This finding is in line with the literature and research hypothesis. The confounding effect can be explained by the strong relationship between BMI and OPA on one hand and BMI and CRF on the other. In addition, the moderation analyses show that BMI is not a statistically significant moderator of the association between OPA and CRF. The association between OPA and CRF is not significantly different according to BMI. This finding is not in line with the research hypothesis. Based on the strong between BMI and OPA on one hand and BMI and CRF on the other hand, it was suspected that BMI was a moderator of the association between OPA and CRF. The discrepancy between the observed results and expectations can be explained by a too small sample size, an insufficient heterogenous sample or the actual absence of a moderation effect. Due to lack of literature in which the moderating effect of BMI is described, it is not possible to compare the results of this study with previous studies. The moderating role needs further investigation in a larger and more heterogenous sample size.

This study shows that an increase in the amount of OPA is associated with a decrease in CRF in people with a physically demanding job. Physical work does not have the same positive effects on cardiovascular health, compared to physical activity during leisure time. Despite the evidence on the opposite health effects of OPA and LTPA on CRF, the WHO PA-guidelines do not take the different domains of PA into account. In the future, policymakers should take these different domains into account when drawing up new exercise guidelines. To establish correct guidelines, future research should investigate the causality of the association between OPA and CRF through a longitudinal design with four accelerometers. It is also necessary to determine the most favorable movement ratio (sweet spot hypothesis) for people with a physically demanding job. Based on this information, guidelines can be drawn up regarding the number of breaks that people with a physically demanding job should take.

In conclusion, this study shows that BMI needs to be included as a confounder in future studies when investigating the association between OPA and CRF. Failure to control for BMI will lead to misinterpretation of the results. This study also shows that BMI is not a moderator in the association between OPA and CRF. To the best of our knowledge this study was the first to examen the moderating effect of BMI. Therefore, this study contributes to the lack of available literature. Given the limited literature and possible methodological limitations, it is necessary that future studies examine the moderating effect to confirm the results of this study. Future research should use a longitudinal design with a larger and heterogeneous sample size. If these studies can show that the association between OPA and CRF is stronger in overweight or obese people, BMI should be taken into account when developing health promotion interventions. The intervention components for overweight or obese people should not only focus on promoting healthy physical activity at work, but also on lowering BMI.

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ATTACHMENTS

1. Attachment 1: Social outreach

Is fysieke arbeid gezond? Hebben mensen met een fysiek zware job en overgewicht een slechtere hart- en vaatgezondheid?

Bewegen is goed voor de gezondheid, maar niet als het gaat over lang aangehouden fysieke arbeid. Verschillende werk gerelateerde inspanningen, zoals lasten tillen of regelmatig met de armen boven schouderhoogte werken, hebben een negatieve invloed op de hart- en vaatgezondheid. Onderzoek toont aan dat dit soort arbeid, in tegenstelling tot sporten, het hart op een slechte manier belast. Tijdens het sporten worden het hart en de bloedvaten gedurende een korte periode sterk belast. Het hart krijgt na deze inspanning de tijd om te herstellen, waardoor het sterker wordt. Fysieke arbeid heeft tegenovergestelde effecten op het hart. Het hart en de bloedvaten worden continue belast en krijgen onvoldoende tijd om te herstellen, dit kan aanleiding geven tot beschadiging van deze organen en dus een verhoogd risico op hart- en vaatziekten. Onderzoek toont aan dat mensen met een fysieke zware job meer kans hebben op een slechte hartgezondheid. Er is dus een negatief verband tussen fysieke arbeid en hartgezondheid.

Onderzoek stelt dat dit negatief verband kan beïnvloed worden door de Body Mass Index (BMI). BMI kan een verstorende of een modererende variabele zijn. Een verstorende variabele heeft een sterk verband met de variabelen waartussen je een relatie wil onderzoeken. Dit wil zeggen dat BMI een sterk verband heeft met fysieke arbeid en hartgezondheid. Als er tijdens het bestuderen van het verband tussen fysieke arbeid en hartgezondheid geen rekening wordt gehouden met BMI, zorgt dit voor een verkeerde interpretatie van het verband. De eigen studie bevestigd dat BMI een verstorende variabele is. BMI zou niet alleen een verstorende variabele maar ook een moderator kunnen zijn. Een moderator is een variabele die de sterkte en de richting van het verband kan beïnvloeden. Eigen onderzoek kon niet aantonen dat BMI een moderator is. Het verband tussen fysieke arbeid en hartgezondheid is niet verschillend naargelang de BMI-categorie. Mensen met een fysiek zware job en overgewicht hebben geen slechtere hartgezondheid in vergelijking met mensen met een gezonde BMI. Er is echter weinig literatuur beschikbaar over dit onderwerp. Verder onderzoek bij een grotere steekproef en bij mensen met overgewicht is noodzakelijk om deze resultaten te bevestigen.

In tegenstelling tot de gangbare veronderstellingen heeft fysieke arbeid een overwegend negatieve impact op de gezondheid. Meer fysieke activiteit op het werk zorgt voor een slechtere hartgezondheid. Toekomstig onderzoek moet BMI opnemen als een verstorende variabele. De rol van BMI als moderator moet verder onderzocht worden. Als BMI een moderator zou zijn van dit verband dan is het belangrijk om hiermee rekening te houden bij het ontwikkelen van gezondheid bevorderende programma's.

2. Attachment 2: consent Ethics Committee

Afzender : Commissie voor medische ethiek

Prof. Dr. Els Clays

Alhier

contact	telefoon	e-mail
Commissie voor medische ethiek	+32 (0)9 332 33 36	Ethisch.comite@uzgent.be
Aanvrager	**datum**	**pagina**
Lauri Lievens	30/05/2022	1/6
Onze referentie:	**EudraCT-nr:**	**Belg. Regnr:**
BC-09453 E03		B6702022000226

Betreft:
"Kan fysiek zwaar werk ook gezond zijn? Welk bewegingspatroon tijdens het werk zorgt voor een verbeterde fitheid en gezondheid?"
"Can physically demanding work also be healthy? What movement pattern during work ensures improved fitness and health?"

Positief advies conform de wet van 7 mei 2004 betreffende experimenten op de menselijke persoon

Beste collega

De Commissie Medische Ethiek (CME) verbonden aan de Universiteit Gent (Ugent) en het Universitair Ziekenhuis Gent (UZ Gent) heeft het bovenvermelde dossier onderzocht.

Na raadpleging van de bijkomende informatie en/of aangepaste documenten met betrekking tot dit dossier, is de CME van oordeel dat de voorgestelde studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is.
EC geeft daarom op 18/05/2022 een gunstig advies over deze studie.

Ingediende documenten: zie bijlage 1
Ledenlijst: zie Bijlage 2
Aandachtspunten: zie Bijlage 3a

Met vriendelijke groeten,

Prof. dr. Philippe Deron
Voorzitter
Commissie voor Medische Ethiek U(Z) Gent

ALGEMENE DIRECTIE
Commissie voor Medische Ethiek

VOORZITTER:
Prof.dr. P. Deron

SECRETARIS
Prof.dr. R. Paleman

INGANG 75
ROUTE 7522

UZ GENT
UNIVERSITEIT GENT

Universitair Ziekenhuis Gent
C. Heymanslaan 10 | B 9000 Gent
www.uzgent.be

CC: FAGG
Cc: HIRUZ CTU (Clinical Trial Center UZ Gent)

Unofficial translation in English:

Positive advice in accordance with the law of 7 May 2004 on experiments on the human person

The Ethics committee (EC) of University Ghent (Ugent) and Ghent University Hospital (UZ Gent) has examined the above mentioned dossier.

EC therefore gives on 17/05/2022 a favourable opinion on this study.

Submitted documents: see Annex 1
List of members: see appendix 2
Points of concern: see appendix 3b

Bijlage 1: Documenten

Categorie: CV
- CV student Lauri Lievens

Categorie: Diverse
- Informatiebrief voor de deelnemers, versie 2 dd. 20/01/2021

Categorie: Opmerkingsbrief CME U(Z) Gent
- Opmerkingsbrief CME - 13/05/2022, dd. 13/05/2022

Bijlage 2: Overzicht leden CME U(Z) Gent

voorzitter: Prof. dr. P. Deron
Secretaris: Prof. Dr. R. Peleman

Effectief lid	Plaatsvervangend lid
Dr. G. VAN LANCKER (UZ GENT – klinisch farmacoloog, ♀)	Prof. dr. S. ROTTEY (UZ GENT – klinisch farmacoloog, ♀)
Prof.dr. D. DE BACQUER (UGENT - statisticus, ♂)	Prof. dr. P. COOREVITS (UGENT - statisticus, ♂)
Dr. J. VAN ELSEN (huisarts, ♂)	Dr. M. COSYNS (huisarts, ♂)
Prof. dr. K. DE GROOTE (UZ GENT – kindercardioloog, ♀)	Prof. dr. P. SCHELSTRAETE (UZ GENT – kinderpneumoloog/infectioloog, ♀)
Prof. dr. W. NOTEBAERT (UGENT – psycholoog, ♂)	Mr. W. SCHRAUWEN (UZ GENT – psycholoog, ♂)
Mevr. M. FOUQUET (UZ GENT – verpleegkundige, ♀)	Mevr. I. VLERICK (UZ GENT – verpleegkundige, ♀)
Dhr. C. DEMEESTERE (UZ GENT – verpleegkundige, lic. Medisch sociale wetenschappen, ♂)	Dhr. G. DE SMET (UZ GENT – verpleegkundige, - lic. Medisch sociale wetenschappen ♂)
Mevr. K. KINT (UZ GENT – apotheker, ♀)	Mevr. L. HUYS (UZ GENT – apotheker, ♀)
Dhr. B. VANDERHAEGEN (UZ GENT - moraaltheoloog, ♂)	Prof. dr. S. STERCKX (UGENT - moraalfilosoof, ♀)
Prof. dr. mr. T. BALTHAZAR (UGENT - jurist, ♂)	Prof. Dr. T. GOFFIN (UGENT - jurist, ♂)
Mevr. C. VANCAENEGHEM (patiëntvertegenwoordiger, ♀)	Mevr. S. DE GROOTE (patiëntvertegenwoordiger, ♀)
Prof. dr. P. DERON (UZ GENT – chirurg, ♂)	Prof. dr. W. CEELEN (UZ GENT – chirurg, ♂)
Prof. dr. R. PELEMAN (UZ GENT - internist/pneumoloog, ♂)	Prof. dr. H. VERSTRAELEN (UZ GENT – Vulva-arts, ♂)
Prof. dr. J. DECRUYENAERE (UZ GENT – internist/intensivist, ♂)	Dr. N. PETERS (UZ GENT – fertiliteitsarts, ♀)
Prof. dr. R. RUBENS (UZ GENT – internist/endocrinoloog, ♂)	Prof. dr. W. VAN BIESEN (UZ GENT – nefroloog, ♂)
Prof. dr. M. De MUYNCK (UZ GENT – arts fysische geneeskunde en revalidatie, ♀)	Prof. dr. S. JANSSENS (UZ GENT – geneticus, ♀)
Prof. dr. K. DHONDT (UZ GENT – (kinder)psychiater, ♀)	Dr. L. GOOSSENS (UZ GENT – neonatoloog, ♀)

Appendix 3a: Aandachtspunten (indien van toepassing)

De CME benadrukt de verantwoordelijkheid van de PI/promotor van dit onderzoek ten aanzien van de privacy van de persoons-/patiëntgegevens in contacten met patiënten, of bij het inzien van patiëntgegevens, inclusief de juiste uitvoering daarvan door collega's en studenten. De PI/promotor is verantwoordelijk voor de uitvoering van het projectvoorstel in overeenstemming met de toepasselijke wet- en regelgeving waaronder, maar niet beperkt tot, de EU-verordening 2016/679 (Algemene Verordening Gegevensbescherming), de Belgische Wet op de patiëntenrechten van 22/ 8/2002, en het beleid van de instelling waar het onderzoek wordt uitgevoerd.

De CME verwijst op haar website naar de ICH/GCP-richtlijnen en bevestigt dat van elke onderzoeker een GCP-training vereist is. Het is de verantwoordelijkheid van de hoofdonderzoeker dat elk lid van het onderzoeksteam een geldig GCP-certificaat heeft. De conformiteit van vertaalde documenten ten opzichte van de Nederlandse documenten is de verantwoordelijkheid van de opdrachtgever.

Wij vestigen uw aandacht op het feit dat de CME verwacht dat haar eerste opmerkingen ab initio in aanmerking worden genomen bij de volgende indiening door dezelfde sponsor.

Mits er een Clinical Trial Agreement is, kan de studie pas starten wanneer de Clinical Trial Agreement werd goedgekeurd en ondertekend door de CEO van het UZ Gent (en/of door een gemachtigde vertegenwoordiger van de UGent).

Studies met geneesmiddelen voor onderzoek en bepaalde studies met "medical devices" dienen door de klant (PI of sponsor) te worden ingediend bij het FAGG (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten).

Studies met geneesmiddelen voor onderzoek mogen enkel uitgevoerd worden op voorwaarde dat de minister (FAGG) geen bezwaar maakt binnen de wettelijke termijnen zoals beschreven in art. 13 van de Belgische wet van 7/5/2004 betreffende experimenten op de menselijke persoon en in art. 21 van de Belgische wet van 7/05/2017 betreffende klinische proeven met geneesmiddelen voor menselijk gebruik.

Bepaalde onderzoeken met medische hulpmiddelen vallen ook onder wettelijke termijnen (KB van 17/3/2009). Raadpleeg de website van het FAGG voor meer informatie: www.fagg-afmps.be .

Onderzoek op embryo's in vitro valt onder de wet van 11 mei 2003. Alvorens het onderzoeksproject kan starten, vereist dergelijk onderzoek ook een positief advies van het Federaal Comité voor medisch en wetenschappelijk onderzoek op embryo's in vitro.

Gelieve rekening te houden met de reglementen van het ziekenhuis inzake weefselbeheer en de reglementen van de wet van 19 december 2008.

Dit gunstige advies van de CME houdt niet in dat zij de geplande studie op zich neemt. U blijft verantwoordelijk voor het onderzoek. Daarnaast dient u ervoor te zorgen dat uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid etc. die het resultaat zijn van dit onderzoek. U wordt eraan herinnerd dat met betrekking tot klinische onderzoeken elke waargenomen ernstige gebeurtenis onmiddellijk moet worden gemeld aan de sponsor en de ethische commissie, zelfs als het oorzakelijk verband met de studie onduidelijk is.

De CME-goedkeuring die voor een specifiek project wordt gegeven, is één jaar geldig. Wij verzoeken u ons te informeren als het onderzoek niet wordt gestart of als het onderzoek niet binnen 1 jaar na goedkeuring start.

De CME bevestigt dat - in geval van belangenverstrengeling - betrokken leden niet deelnemen aan de stemming over het onderzoek.

Indien het onderzoek niet binnen een jaar wordt beëindigd, eist de ICH-GCP dat jaarlijks een voortgangsrapportage aan de CME wordt verstrekt.

Tot slot verzoeken wij u de (voortijdige of geplande) beëindiging van het onderzoek binnen de wettelijke termijnen te melden en het Clinical Study Report (CSR) aan de CME te bezorgen.

Houd er in het geval van een klinische proef (EudraCT) rekening mee dat de resultaten moeten worden gepubliceerd in het European Clinical Trial Register. Het rapport van deze resultaten kan als CSR naar de EC worden gestuurd.

Appendix 3b: Points of concern (if applicable)

The EC emphasizes the responsibility of the PI/promotor of this study concerning the privacy of the person/patient data in contacts with patients, or when viewing patient data, including the correct implementation thereof by coworkers and students. The PI/promotor is responsible for the implementation of the project proposal in accordance with applicable laws and regulations including, but not limited to, the EU regulation 2016/679 (General Data Protection Regulation), the Belgian Law on patients' rights of 22/8/2002, and the policy of the institution where the research will be carried out.

The EC refers to the ICH/GCP guidelines on its website, and confirms that a GCP-training is required from each investigator. It is the responsibility of the principal investigator that each member of the study team has a valid GCP-certificate.

The conformity of translated documents compared to the Dutch documents, is the responsibility of the sponsor.
We would like to draw your attention to the fact that the EC expects her initial comments to be taken into account ab initio at the next submission by the same sponsor.

*Provided that there is a **Clinical Trial Agreement**, the study can only start when the Clinical Trial Agreement has been approved and signed by the CEO of UZ Gent (and/or by an authorized representative of UGent).*

Studies with investigational medicinal products and certain studies with "medical devices" should be submitted by the client (PI or sponsor) to the FAMHP (Federal Agency for Medicines and Health Products).
Studies with investigational medicinal products are only allowed to be conducted, provided that the minister (FAMHP) does not state objections within legal deadlines as described in art. 13 of the Belgian law of 7/5/2004 concerning experiments on the human person and art. 21 of the Belgian law of 7/5/2017 concerning clinical trials with medicines for human use.

Certain studies using medical devices are also covered by legal deadlines (KB of 17/3/2009). Please consult the FAMHP website for more information: www.fagg-afmps.be.

Research on embryos in vitro is covered by the law of May 11, 2003. Before the research project can start, such research also requires a positive advice of the Federal Committee for medical and scientific research on embryos in vitro.

Please take into account the regulations of the hospital concerning tissue management and the regulations of the law of December 19, 2008.

This favorable advice of the EC does not imply that it will assume responsibility for the planned study. You will remain responsible for the study. In addition, you should ensure that your opinion as an involved researcher is reproduced in publications, reports for the government, etc. which are the result of this study. You are reminded that concerning clinical studies, any observed serious event needs to be reported immediately to the sponsor and the ethics committee, even if the causal relationship with the study is unclear.

The EC approval given for a specific project, is valid for one year. We request you to inform us if the study will not be initiated or if the study does not start within 1 year after approval.

The EC confirms that - in case of conflict of interest - involved members do not take part in the vote concerning the study.

*If the study will not be terminated within a year, the ICH-GCP demands that an **annual progress report** will be provided to the EC.*

*Finally, we request you to report the termination (early or planned) of the study within the legal deadlines and provide the **Clinical Study Report** (CSR) to the EC.*

In case of a clinical trial (EudraCT), please be informed that the results must be published in the European Clinical Trial Register. The report of these results can be sent to the EC as the CSR.

3. Attachment 3: Log field work

UNIVERSITEIT GENT

FACULTEIT GENEESKUNDE EN GEZONDHEIDSWETENSCHAPPEN

Logboek veldwerk

Beschrijving veldwerk	Plaats (UGent of naam externe locatie)	Duur (X aantal uur of minuten)
• Meevolgen en uitvoeren van: - bloeddrukmetingen, - beenlengte, - buikomtrek, - heupomtrek, - gewicht, - lengte • meevolgen en helpen bij het aanbrengen van de hartslagmonitor en accelerometers. • Helpen bij het uitvoeren van de Harvard Step Test	Agristo Nazareth	9u00-14u30 (5u30)
• Installeren programma's data-verwerking • Invoeren van gegevens datacollectie Agristo Nazareth	UGent (UZ Gent)	14u30-16u15 (1u45)
• Meevolgen en uitvoeren van: - bloeddrukmetingen, - beenlengte, - buikomtrek, - heupomtrek, - gewicht, - lengte • meevolgen en helpen bij het aanbrengen van de hartslagmonitor en accelerometers. • Helpen bij het uitvoeren van de Harvard Step Test	Agristo Nazareth	8u30-11u00 (2u30)
• Installeren programma's data-verwerking + uitleg over het maken van feedbackrapport • Invoeren van gegevens datacollectie Agristo Nazareth	UGent (UZ Gent)	11u00-12u15 (1u15)

• **Maken van feedbackrapporten**	Thuiswerk	10u15-12u00 + 12u20-14u45 (4u10)
• **Maken van feedbackrapporten**	UGent (UZ Gent)	10u30-16u45 (6u15)
• **Maken van feedbackrapporten**	UGent (UZ Gent)	8u45-16u45 (8u)
• **Maken van feedbackrapporten**	Thuiswerk	8u45-14u00 (5u15)
• **Maken van feedbackrapporten**	UGent (UZ Gent)	8u45-15u45 (7u)
• **Maken van feedbackrapporten**	Ugent (UZ Gent)	12u30-15u30 (3u)
• **Maken van feedbackrapporten**	Thuiswerk	17u40-18u40 (1u)
• **Maken van feedbackrapporten**	Thuiswerk	18u00-19u30 (1u30)
• **Maken van feedbackrapporten**	Thuiswerk	18u50-21u30 (1u40)
• **Maken van feedbackrapporten**	Thuiswerk	16:00 – 16:45 (45min)
• **Maken van feedbackrapporten**	Thuiswerk	19:30-20:00 (30min)

Gelieve het logboek veldwerk op te laden in Sparta tegen de deadline voor het indienen van de masterproef.

4. Attachment 4: Receipt extra data

UNIVERSITEIT GENT

FACULTEIT GENEESKUNDE EN GEZONDHEIDSWETENSCHAPPEN

Ontvangstbewijs extra data

Ik, Els Clays, (co)promotor aan de Universiteit Gent, verklaart dat de student Laura Lievens uit de Master in de Gezondheidsbevordering de extra data met verplichte onderdelen heeft ingediend.

De 'extra data' dient drie verplichte onderdelen te bevatten:

- **deel 'Masterproef'**: Hieronder staat de integrale tekst van de masterproef, bijlagen inbegrepen (zowel in Word formaat als in pdf formaat) zoals deze wordt ingediend bij de examencommissie. De naam van het bestand is <familienaam_voornaam_jaar.doc>.
- **deel 'Andere documenten'**: Alle verzamelde documenten die niet in de masterproef opgenomen zijn, worden hieronder verzameld. Bvb: informatiebrochures, gebruikte vragenlijsten... kunnen in deze map worden opgenomen.
- **deel 'Data'**: Hierin staan alle onbewerkte data, alle bewerkte data en alle syntaxen.

Handtekening (co)promotor

Gelieve dit document op te laden in Sparta tegen de deadline voor het indienen van de masterproef

5. Attachment 5: Flyer FEPA study

GHENT UNIVERSITY

FACULTEIT GENEESKUNDE EN GEZONDHEIDSWETENSCHAPPEN

Studie:
Fysieke activiteit en gezondheid op het werk

Voor werknemers tussen de **18 en 67 jaar** oud
Meer dan **40% tewerkgesteld**

- Invullen van een **vragenlijst** (± 25 min)
- **Meten van lengte, gewicht, bloeddruk en fitheid** (tijdens de werkuren, ± 30 min)
- Dragen van 2 **bewegingsmeters** en 1 **hartslagmeter** gedurende 3 opeenvolgende werkdagen en 1 vrije dag

Meetperiode in onderling overleg
➡ Na de studie **gratis feedback** over uw beweegpatroon, hartslag en fysieke fitheid

Deelnemen?
Antwoordkaart invullen en afgeven aan uw leidinggevende of in de deponeerdoos werpen.

Voor vragen of meer informatie:
margo.ketels@ugent.be

6. Attachment 6: General information letter for participants

Informatiebrief voor de deelnemers

Titel van de studie: Onderzoek naar de fysieke activiteit en gezondheid op het werk.

Officiële titel: Onderzoek naar de invloed van verschillende risicofactoren op musculoskeletale en cardiovasculaire gezondheid en de mogelijke modererende rol van psychosociale hulpbronnen en fysieke fitheid bij werknemers met een fysiek zwaar beroep.

Beste,

U wordt uitgenodigd om deel te nemen aan een studie. Neem, voor u beslist deel te nemen aan deze studie, voldoende tijd om deze informatiebrief aandachtig te lezen en dit te bespreken met de onderzoeker of zijn/haar vertegenwoordiger. Neem ook de tijd om vragen te stellen indien er onduidelijkheden zijn of indien u bijkomende informatie wenst. Dit proces wordt 'informed consent' of 'geïnformeerde toestemming' genoemd. Eens u beslist heeft om deel te nemen aan de studie zal men u vragen om het toestemmingsformulier achteraan te ondertekenen.

1. Beschrijving en doel van de studie

Wij nodigen u graag uit om deel te nemen aan een wetenschappelijke studie van de vakgroep Volksgezondheid en Eerstelijnszorg van de Universiteit van Gent. De studie zal onderzoek voeren naar de fysieke activiteit en gezondheid van werknemers met een fysiek actief beroep. In deze studie willen we de fysieke activiteit en de hartslag van werknemers gedurende verschillende opeenvolgende dagen registreren alsook werk- en gezondheidsparameters via een vragenlijst in kaart brengen. Werknemers die meer dan 50% tewerkgesteld worden, niet zwanger zijn en de Nederlandse taal goed beheersen, zullen worden opgenomen in deze studie. Het doel van deze studie is om te weten welke factoren een negatieve maar ook positieve impact hebben op de gezondheid van werknemers. Met deze informatie kunnen we gerichte aanbevelingen opstellen om zowel uw mentale als fysieke gezondheid te verhogen.

Deelname aan het onderzoek houdt een kort medisch onderzoek in waarbij we uw lengte, gewicht, bloeddruk, hartslag in rust en fysieke fitheid meten. De fysieke fitheid zal in kaart gebracht worden d.m.v. de Harvard steptest. De Harvard steptest is een submaximale test waarbij u gedurende 5 minuten op en af een verhoog (33 cm voor vrouwen, 40 cm voor mannen) dient te stappen. Na het beëindigen van de test dient u te gaan zitten en zal om de halve minuut uw hartslag gemeten worden. Voor deze test gelden er een paar extra exclusiecriteria: gewrichtsoperatie in de afgelopen maanden, werknemers met locomotorische of musculoskeletale aandoeningen, personen die bètablokkers moeten innemen, werknemers met een vastgestelde cardiovasculaire aandoening(en) of een recent vastgestelde bovenste luchtwegaandoening. Dit onderzoek vindt plaats tijdens de werkuren op uw werkplek en zal ongeveer een halfuur tijd in beslag nemen. Op het einde van het medisch onderzoek worden 3 kleine toestellen aangebracht die gedurende minstens 3 werkdagen en 1 vrije dag uw bewegingen en hartslag zullen registreren. U kunt tijdens deze metingen al uw gebruikelijke activiteiten blijven doen. Enkel tijdens het douchen of het zwemmen dient de hartslagmonitor verwijderd te worden om nadien terug aangebracht te worden. Na de meetperiode kunt u zelf de toestellen verwijderen, in de daar voorziene zak op te bergen en mee te nemen naar uw werk. Als laatste zult u verzocht worden om een vragenlijst in te vullen, schriftelijk of online, die peilt naar verschillende werk- en gezondheidsparameters en zal ongeveer 25 à 30 minuten duren. De vragenlijst mag u thuis invullen en nadien terug meenemen naar uw werk. Na afloop van de studie worden uw ziekteverzuim gegevens gedurende één jaar opgevolgd. De ziekteverzuim gegevens worden via de werkgever opgevraagd.

Sommige onder jullie zullen alreeds deelgenomen hebben aan een gelijkaardige studie in 2017-2018 van dezelfde onderzoeksgroep. Onderaan dit formulier vragen we daarvoor ook jullie toestemming om de alreeds verzamelde gegevens en verwerkte resultaten opnieuw te mogen gebruiken voor deze huidige studie.

Deze studie werd vooraf goedgekeurd door een onafhankelijke Commissie voor Medische Ethiek verbonden aan het Universitair Ziekenhuis van Gent en de Universiteit Gent. De studie wordt uitgevoerd volgens de richtlijnen voor de goede klinische praktijk (ICH/GCP) en de verklaring van Helsinki opgesteld ter bescherming van mensen deelnemend aan klinische studies. In geen geval dient u de goedkeuring door de Commissie voor Medische Ethiek te beschouwen als een aanzet tot deelname aan deze studie.

Deze verzameling van gegevens wordt uitgevoerd onder supervisie van Prof. Dr. Lutgart Braeckman. De opdrachtgever van de studie is UGent.

2. Hoeveel participanten zullen aan deze studie deelnemen en wat is de duur van de studie?

Er zullen in totaal een 500-tal werknemers aan deze studie deelnemen. Het invullen van de vragenlijst zal ongeveer een 25 tot 30 minuten van uw tijd in beslag nemen. Het medisch onderzoek inclusief meting van lengte, gewicht, bloeddruk en hartslag in rust en het uitvoeren van de Harvard Step test zal 30 minuten duren. Als laatste zal u gevraagd worden om gedurende een periode van minimum 3 werkdagen en 1 vrije dag 3 toestellen te dragen. Na het beëindigen van dit onderzoek zal er geen tijd meer van u gevraagd worden.

3. Toestemming en weigering

De deelname aan deze studie is volledig vrijwillig. U kunt weigeren om deel te nemen aan de medische screening (inclusief meting gewicht, lengte, buikomtrek en fysieke fitheid), het dragen van de meetinstrumenten voor opeenvolgende dagen, het invullen van de vragenlijst of het opvolgen van ziekteverzuim gedurende een jaar zonder dat u hiervoor een reden moet opgeven en zonder dat dit op enige wijze een invloed zal hebben op de verdere relatie met de onderzoeker of op uw werkrelaties. Dit zal ook geen negatieve invloed hebben op de kwaliteit van afnamen van de ambulante meting, medische screening, de vragenlijst en uw verdere feedback. Uw deelname aan deze studie zal beëindigd worden als de onderzoeker meent dat dit in uw beland is. U kan ook voortijdig uit de studie teruggetrokken worden door de onderzoeker als u de in deze informatiebrief beschreven procedures niet goed opvolgt of u de beschreven items niet respecteert. Indien u uit de studie gehaald wordt, zullen de reeds verzamelde gepseudonimiseerde gegevens in de databank blijven voor analyse, maar er zal geen nieuwe data toegevoegd worden.

4. Wat zijn de risico's bij deelname aan deze studie

Er zijn geen risico's of bijwerkingen verbonden aan dit onderzoek. Enkel geringe irritatie van de huid is in uitzonderlijke gevallen mogelijk bij het dragen van de hartslagmonitor of door de medische tape gebruikt om de activiteitsmeters te bevestigen aan de huid. Deze mogelijke irritatie verdwijnt echter binnen de eerste uren/dagen na het verwijderen van de toestellen en dus ook tape.

U hebt het recht op elk ogenblik vragen te stellen over de mogelijke en/of gekende risico's van deze studie. Als er in het verloop van de studie gegevens aan het licht komen die een invloed zouden kunnen hebben op uw bereidheid om te blijven deelnemen aan deze studie, zult u daarvan op de hoogte worden gebracht. Mocht u door uw deelname aan de studie toch enig nadeel ondervinden, zal u een gepaste behandeling krijgen.

5. Voordelen

Deelname aan deze studie brengt voor u waarschijnlijk geen medisch of ander voordeel met zich mee. Dit onderzoek biedt mogelijkheden om de oorzaken van deze problemen te bestuderen en zo specifieke richtlijnen op te stellen. Uw bijdrage aan de wetenschap is zeer waardevol en we appreciëren uw deelname ten zeerste. U ontvangt na afloop van de studie een uitgebreid geïndividualiseerd feedbackrapport over verschillende parameters zoals uw fysieke fitheid, bloeddruk, aantal stappen tijdens uw werkdag, aantal uur per dag dat u zit enzovoort. Voor u biedt dit onderzoek dus een unieke kans om meer te weten over uw gezondheid en fysiek activiteit zowel op het werk als tijdens uw vrije dagen.

6. Kosten

Uw deelname aan deze studie brengt geen extra kosten mee voor u, maar biedt ook geen financieel voordeel.

7. Vertrouwelijkheid

In overeenstemming met de Algemene Verordening Gegevensbescherming (of GDPR) (EU) 2016/679 van 27 april 2016 (die vanaf 25 mei 2018 in voege is) en de Belgische wet van 30 juli 2018, betreffende de bescherming van natuurlijke personen in verband met de verwerking van persoonsgegevens en betreffende het vrije verkeer van die gegevens, zal uw persoonlijke levenssfeer worden gerespecteerd en kan u toegang krijgen tot de verzamelde gegevens. Elk onjuist gegeven kan op uw verzoek verbeterd worden.

Uw toestemming om deel te nemen aan de studie betekent dat we gegevens van u verwerken voor het doel van de klinische studie. Deze verwerking van gegevens is wettelijk voorzien op basis van artikel 6, § 1, (b), (e) of (f) en artikel 9, § 2(j) van de Algemene Verordening Gegevensbescherming.

Alle informatie die tijdens deze studie verzameld wordt zal gepseudonimiseerd worden (hierbij kan men uw gegevens nog terug koppelen naar uw persoonlijk dossier). In het geval van pseudonimisering zal de sleutel tot deze codes enkel toegankelijk zijn voor de onderzoeker of de door hem/haar aangestelde vervanger. In deze studie kunnen ook gegevens verzameld worden via vragenlijst aan de deelnemer. Daartoe zal u gevraagd worden een persoonlijk email-adres te bezorgen waarop u deze vragenlijst wenst te ontvangen. Enkel de gepseudonimiseerde gegevens zullen gebruikt worden voor analyse van de gegevens en in alle documentatie, rapporten of publicaties (in medische tijdschriften of congressen) over de studie. Vertrouwelijkheid van uw gegevens wordt dus steeds gegarandeerd. Zowel persoonlijke gegevens als gegevens aangaande uw gezondheid zullen verwerkt en bewaard worden gedurende minstens 20 jaar. De verwerkingsverantwoordelijke van de gegevens is de instelling van de hoofdonderzoeker van de studie, Prof. Dr. Lutgart Braeckman (Universiteit Gent). Zijn/haar onderzoeksteam zal toegang krijgen tot uw persoonsgegevens.

In het kader van de gegevensbescherming zullen de gegevens verwerkt worden door personen behorend tot het onderzoeksteam en aangeduid door en onder de verantwoordelijkheid van de hoofdonderzoeker inclusief interne medewerkers met een niet-gezondheidszorgberoep.

De Data Protection Officer kan u desgewenst meer informatie verschaffen over de bescherming van uw persoonsgegevens. Contactgegevens: Hanne Elsen, privacy@ugent.be.

Vertegenwoordigers van de opdrachtgever, auditoren, de Commissie voor Medische Ethiek en de bevoegde overheden, allen gebonden door het beroepsgeheim, hebben rechtstreeks toegang tot uw medische dossiers om de procedures van de studie en/of de gegevens te

controleren, zonder de vertrouwelijkheid te schenden. Dit kan enkel binnen de grenzen die door de betreffende wetten zijn toegestaan. Door het toestemmingsformulier, na voorafgaande uitleg, te ondertekenen, stemt u in met deze toegang.

De Belgische toezichthoudende instantie die verantwoordelijk is voor het handhaven van de wetgeving inzake gegevensbescherming is bereikbaar via onderstaande contactgegevens:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

8. Verzekering

De opdrachtgever voorziet in een vergoeding en/of medische behandeling in het geval van schade en/of letsel ten gevolge van deelname aan deze klinische studie. Voor dit doeleinde is een verzekering afgesloten met foutloze aansprakelijkheid conform de wet inzake experimenten op de menselijke persoon van 7 mei 2004 (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; polisnummer BEL000862).

Indien de onderzoeker van mening is dat er verband met de studie mogelijk is, zal hij/zij de aangifteprocedure bij de verzekering starten. Op dat ogenblik kunnen uw gegevens doorgegeven worden aan de verzekeraar. In het geval van onenigheid met de onderzoeker of met de door de verzekeringsmaatschappij aangestelde expert, en steeds wanneer u dit nodig acht, kunnen u, of in dit geval van overlijden uw rechthebbende, de verzekeraar rechtstreeks in België dagvaarden (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: + 32 33 04 16 00).

9. Contact

Indien u wenst te registreren om deel te nemen, kunt u bijgevoegd antwoordformulier invullen en deponeren in de voorziene doos op uw werk. Daarna zullen we u contacteren om een eerste afspraak vast te leggen. Indien u meer informatie wenst of verdere vragen heeft, kan u ons altijd contacteren via e-mail (margo.ketels@ugent.be) of telefonisch (+32 9 332 83 31).

Met vriendelijke groet en alvast hartelijk dank voor uw medewerking!

Mevr. Margo Ketels, onderzoeksmedewerker (Margo.Ketels@UGent.be)

Prof. dr. Els Clays, hoofdonderzoeker (Els.Clays@UGent.be)

Prof. dr. Lutgart Braeckman, hoofdonderzoeker (Lutgart.Braeckman@UGent.be)

7. Attachment 7: Practical information letter for participants

Informatie voor thuis

Studie fysieke activiteit en gezondheid op het werk

Meting: 4 opeenvolgende dagen: 3 werkdagen en 1 vrije dag (24u/dag)

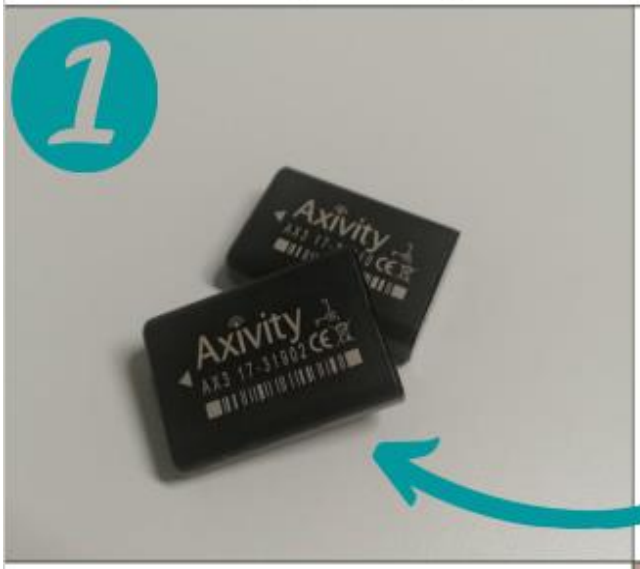
Belangrijk: dagboek invullen + referentiemeting

Na 4 dagen toestellen afdoen + alles van folie in de vuilnisbak

=> alle toestellen + kabels + dagboek + overig materiaal in blauwe zak en afgeven aan leidinggevende

Vragen: margo.ketels@ugent.be of 0473 12 11 09

1



Twee bewegingsmeters

Deze twee bewegingsmeters zijn **WATERBESTENDIG** => mogen dus **ALTIJD** aangehouden worden, ook tijdens het douchen.

Indien toch losgekomen: zie volgende pagina

Hartslagmeter

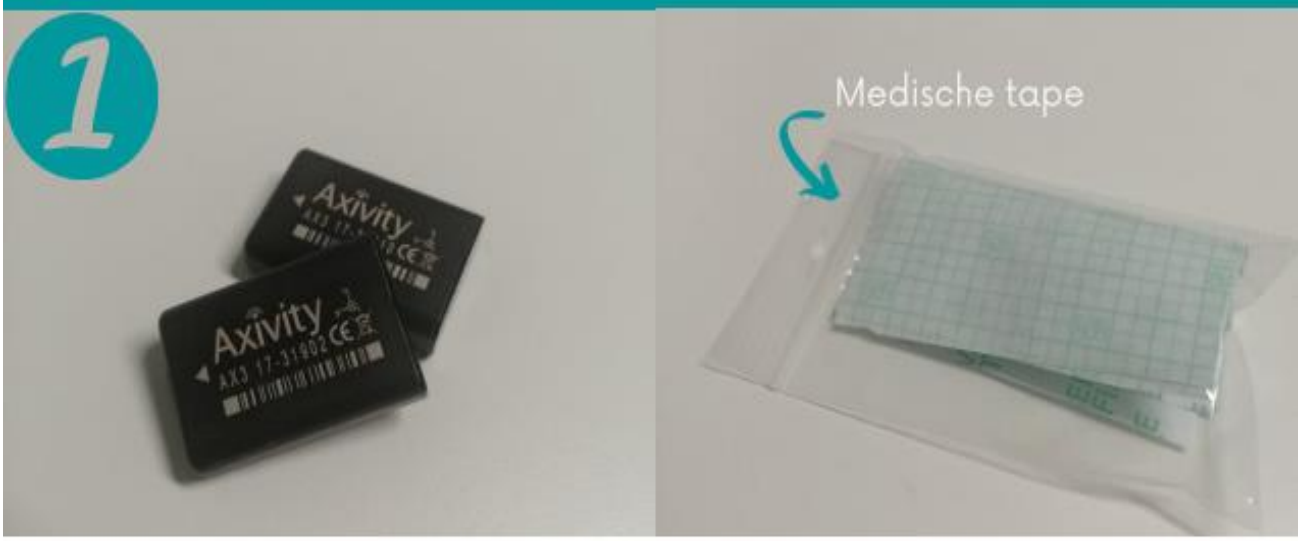
Hartslagmeter is **NIET WATERBESTENDIG** => dient dus **verwijderd** te worden tijdens het douchen, zwemmen...

Hoe verwijderen en terug aanbrengen: zie laatste pagina

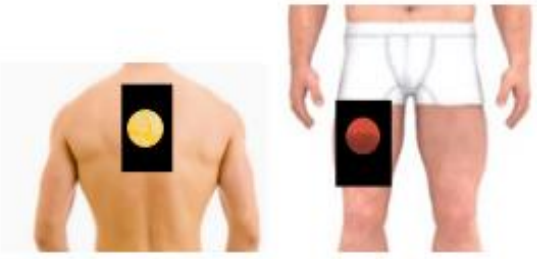
2

Twee bewegingsmeters

Wanneer de bewegingsmeters loskomen: zie hieronder



1) Doorzichtige medische tape die over de bewegingsmeter geplakt was, wegsmijten.
2) Folie rond de bewegingsmeter mag blijven (indien nog intact)
    a. Indien niet: klein beetje huishoudfolie rond toestel
3) Daarna toestel met **USB poort naar beneden** en bol naar boven (de bol moet je dus zien)
    - Gele bol = rug
    - Rode bol = rechter bovenbeen



4) Doe de medische tape aan één kant los, plaats dit op het toestel en doe de andere kant los = folie mooi over het toestel plakken
5) Eenmaal de toestellen aangebracht zijn, zijn ze terug klaar voor gebruik.

Geef op het dagboekje aan wanneer de toestellen zijn losgekomen. Indien 1 toestel losgekomen: vermeld kleur bol.

Hartslagmonitor

Wanneer men doucht, of in water gaat: zie hieronder

1) Eerst dient het toestel **UIT** gezet te worden: 4 seconden op de aan/uit knop drukken (knop in het midden)

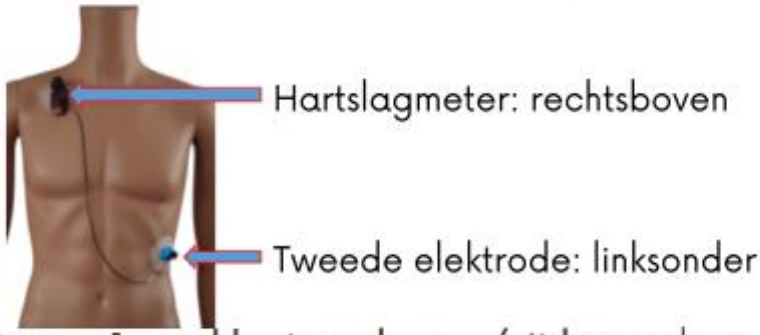
=> Eerst hoor je een korte pieptoon, gevolgd door 3 korte pieptonen

=> Ter controle: het groen lichtje van het toestel knippert NIET meer

2) Trek beide elektroden nu van het lichaam en verwijder van kabel

3) Nu kan u douchen of zwemmen = **Tijdsstip in dagboek noteren!**

4) **NIEUWE METING**: nieuwe elektroden nemen (zie zakje) en bevestigen aan kabeltje. Doe het wit plastiekje van de elektrode en plaats op dezelfde plaats (ontsmetten met doekje) als ervoor op het lichaam.



5) Duw nu **1 maal kort op de aan/uit knop**: de meting zal starten en het groen lichtje dient te knipperen.

8. Attachment 8: Informed consent participants

TOESTEMMINGSFORMULIER VOOR DE DEELNEMERS	
Referentienummer van de deelnemer voor deze studie	

Ik heb het document "**Informatiebrief voor de deelnemers**" pagina 1 tot en met 4 gelezen en begrepen en ik heb er een kopij van gekregen. Ik heb uitleg gekregen over de **aard**, het **doel** en de duur van de studie en over wat men van mij verwacht. Ik heb uitleg gekregen over de mogelijke **risico's** en voordele van de studie. Men heeft me de gelegenheid en voldoende tijd gegeven om **vragen** te stellen over de studie en ik heb op al mijn vragen een bevredigend antwoord gekregen, ook op medische vragen.
Ik begrijp dat deelname aan de studie **vrijwillig** is en dat ik mij op elk ogenblik uit de studie mag terugtrekken zonder een reden voor deze beslissing op te geven en zonder dat dit op enigerlei wijze een invloed zal hebben op mijn verdere relatie met de onderzoeker of op mijn werkrelaties.
Ik ben me ervan bewust dat deze studie werd goedgekeurd door een onafhankelijke **Commissie** voor **Medische Ethiek** verbonden aan het UZ Gent en de Universiteit Gent en dat deze studie zal uitgevoerd worden volgens de richtlijnen voor de goede klinische praktijk (ICH/GCP) en de verklaring van Helsinki, opgesteld ter bescherming van mensen deelnemend aan experimenten. Deze goedkeuring was in geen geval de aanzet om te beslissen om deel te nemen aan deze studie. Ik begrijp dat auditors, vertegenwoordigers van de opdrachtgever, de Commissie voor Medische Ethiek of bevoegde overheden, mijn gegevens mogelijks willen inspecteren om de verzamelde informatie te controleren. Bovendien ben ik op de hoogte dat bepaalde gegevens doorgegeven worden aan de opdrachtgever van de studie. Te allen tijde zal mijn privacy gerespecteerd worden.
Men heeft mij ingelicht dat zowel persoonlijke gegevens als gegevens aangaande mijn gezondheid worden verwerkt en **bewaard gedurende minstens 20 jaar**. Ik ben op de hoogte dat ik recht heb op toegang en op verbetering van deze gegevens. Aangezien deze gegevens verwerkt worden in het kader van medisch-wetenschappelijke doeleinden, begrijp ik dat de toegang tot mijn gegevens kan uitgesteld worden tot na beëindiging van het onderzoek. Indien ik toegang wil tot mijn gegevens, zal ik mij richten tot de onderzoeker die verantwoordelijk is voor de verwerking ervan.

Aankruisen door de deelnemer indien akkoord

Ik stem in om deel te nemen aan de volgende delen van de studie:

Ik stem ermee in om volledig **samen te werken met de onderzoeker**. Ik zal hem/haar op de hoogte brengen als ik onverwachte of ongebruikelijke symptomen ervaar.	
Ik stem ermee in dat mijn **ziekteverzuim** gegevens opgevraagd kunnen worden gedurende 12 maanden na de start van de studie.	
Ik stem ermee in deel te nemen aan de **medische screening**.	
Ik ben op de hoogte gebracht van de specifieke voorwaarden die verbonden zijn aan het uitvoeren van de **Harvard steptest**, en bevestig dat ik hieraan wens deel te nemen.	
Ik stem ermee in deel te nemen aan de **ambulante metingen (bewegingsmeters en hartslagmonitor)**.	
Ik stem ermee in de **vragenlijst** in te vullen.	
Ik stem ermee in dat mijn **e-mailadres** gebruikt wordt voor het versturen van vragenlijsten.	
Enkel van toepassing voor participanten die hebben deelgenomen aan de baseline studie in 2017-2018: Ik stem ermee in dat mijn **gegevens** van de **baseline studie** opnieuw gebruikt worden om de doelstellingen van de huidige studie te behalen.	

Naam en voornaam van de deelnemer	Handtekening	Datum
Naam en voornaam van de arts-onderzoeker*	Handtekening	Datum

2 kopieën dienen te worden vervolledigd. Het origineel wordt door de onderzoeker bewaard in het ziekenhuis gedurende 20 jaar, de kopie wordt aan de deelnemer gegeven.

* Aankruisen door de onderzoeker indien akkoord

Ik verklaar de benodigde informatie inzake deze studie (de aard, het doel, en de te voorziene effecten) mondeling te hebben verstrekt evenals een exemplaar van het informatiedocument aan de deelnemer te hebben verstrekt.	
Ik bevestig dat geen enkele druk op de deelnemer is uitgeoefend om hem/haar te doen toestemmen tot deelname aan de studie en ik ben bereid om op alle eventuele bijkomende vragen te antwoorden.	

LIST OF TABLES