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Overlooked issues in cardiovascular research designs:

The impact of reactivity and accuracy in physical activity measurement

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CONTENT

LIST OF ABBREVIATIONS

BP	Blood pressure
CVD	Cardiovascular disease
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung (engl.: German Centre for Cardiovascular Research)
GAP	"Closing the Gap between Self-reported and Accelerometer-based Physical Activity", a randomized controlled trial
HbA1c	Glycated hemoglobin
HDL	High-density lipoprotein
IBEKO	"In Bewegung kommen, in Bewegung bleiben", a feasibility study
IPAQ	International Physical Activity Questionnaire
IPAQ-SF	International Physical Activity Questionnaire – Short Form
MET	Metabolic equivalent of task
MVPA	Moderate-to-vigorous physical activity
PA	Physical activity
$PA_{leisure}$	Leisure-time physical activity
$PA_{transport}$	Transport-related physical activity
RCT	Randomized controlled trial
ST	Sedentary time
WHO	World Health Organization

SUMMARY

Background: Physical inactivity is one of the main risk factors for cardiovascular disease, which remains a major cause of death in Germany and around the globe. Thus, investigating prevalences, population trends, high-risk groups, and intervention effects of physical activity (PA) and sedentary time (ST) is highly relevant to public health. To receive reliable data, a key issue in research is to apply an appropriate study design including the carefully considered use of assessments. Otherwise, bias to PA and ST data may be introduced. The present thesis investigates three often overlooked issues related to the impact of measurement on PA and ST research data. The first aim was to examine whether mere measurement alters PA and ST over the course of twelve months (study 1). The second aim was to identify potential socio-demographic and cardiometabolic moderators of the mere-measurement effect (study 2). The third aim was to present design, protocol, and preliminary results of an interim analysis of a randomized controlled trial (RCT) aiming to test whether a video demonstration of PA intensity levels reduces the lack of agreement between self-reported and objectively measured PA (study 3).

Methods: Studies 1 and 2 were based on data of a trial to test the feasibility of a brief tailored letter intervention to increase PA and to reduce ST during leisure time. Among a sample of subjects with no history of myocardial infarction, stroke, or vascular interventions, a number of 175 individuals aged 40 to 65 years participated in the study. At baseline, participants received standardized measurement of blood pressure and waist circumference, blood sample taking, and seven-day accelerometry. At baseline and after one, six, and twelve months, participants completed the International Physical Activity Questionnaire (IPAQ). A random subsample received a brief tailored letter intervention at months one, three, and four. A number of 153 participants were included in study 1 using all available data across 12 months. Changes in PA and ST were analyzed using latent growth modeling. For study 2, baseline and one-month follow-up data of 175 participants were used. Dependence of one-month changes in PA and ST on socio-demographic and cardiometabolic variables was analyzed using linear regression models. In study 3, individuals aged between 40 and 75 years were recruited at a shopping mall in Greifswald, Germany. Participants received seven-day accelerometry and were invited to the cardiovascular examination center of the University Medicine Greifswald. After random allocation to experimental and control group, they completed the self-administered IPAQ – Short Form via tablet-computer. The experimental group additionally received a video demonstration of PA intensity levels before answering the questionnaire. A number of 131 participants were analyzed to receive preliminary results of an interim analysis in order to verify the presumptions made for the a priori power calculation and to decide on early stopping of the study. The difference between the study groups in the agreement between self-reported and accelerometer-based PA was analyzed using a two-sample t-test.

Results: In study 1, results revealed no change in leisure-time PA, an increase in transport-related PA ($p = .023$), and a tendency towards a reduction of ST ($p = .060$) between baseline and one-month assessment. Further, ST decreased between six and twelve months ($p = .037$). Time trends of the intervention group did not differ significantly from those of the assessment-only group. Results of study 2 revealed that men increased transport-related PA more than women ($p = .031$) and men with higher triglycerides increased transport-related PA less than men with lower triglycerides ($p = .043$). Men with higher systolic blood pressure reduced ST more than those with lower systolic blood pressure ($p = .028$). However, this linear association ceased to exist at a level of approximately 145 mmHg. A similar relationship was found for glycated hemoglobin and ST in men. In study 3, preliminary results of the interim analysis revealed a lower formal mean difference in the video group ($M = 21.8$ min/day, $SD = 108.9$) compared to the control group ($M = 41.0$ min/day, $SD = 117.4$, $t(129) = 0.97$, $p = .166$). The p-value lay between the significance ($p < .010$) and futility ($p > .269$) boundaries of the test simulations.

Conclusions: Results of the present thesis have three implications for considering the impact of PA and ST assessments in cardiovascular research. First, mere-measurement effects within a feasibility trial were found in transport-related PA and ST suggesting to interfere with potential intervention effects. Thus, measurement effects should be considered when planning studies and interventions and when interpreting outcomes. Second, male sex and more favorable triglycerides levels in men were associated with a higher increase of transport-related PA whereas worse health in men was associated with a higher reduction of ST. Thus, using the mere-measurement effect for prevention purposes may require researchers and practitioners to tailor PA and ST intervention components to individuals' health condition. Third, the design and protocol of the RCT seems appropriate to test the effect of a novel video on the gap between self-reported and accelerometer-based PA. Preliminary results point to the efficacy of the video.

ZUSAMMENFASSUNG

Hintergrund: Bewegungsmangel ist einer der wichtigsten Risikofaktoren für Herz-Kreislauf-Erkrankungen. Diese zählen zu den häufigsten Todesursachen in Deutschland sowie weltweit. Dementsprechend sind die Bestimmung von Prävalenzen, die Identifikation von Risikogruppen sowie die Wirksamkeitsprüfung verhaltensbezogener Interventionen im Hinblick auf körperliche Aktivität und langen Sitzzeiten von hoher Bedeutung. Ein wesentlicher Kernpunkt der Forschung zu körperlicher Aktivität und Sitzzeiten betrifft deren korrekte Erfassung. Eine sorgfältige Abwägung dahingehend, welche Erhebungsinstrumente zu welchem Zeitpunkt und mit welcher Frequenz eingesetzt werden, ist unumgänglich, um systematische Verzerrungen der Daten und somit das Risiko fehlerhafter Schlussfolgerungen zu minimieren. In der vorliegenden Arbeit wurden drei methodische Aspekte der Erfassung von körperlicher Aktivität und Sitzzeiten untersucht. Studie 1 beinhaltete die Frage, ob sich Aktivität und Sitzzeiten über einen Zeitraum von zwölf Monaten durch die reine Messung dieser Verhaltensweisen mittels Fragebogen verändern. In Studie 2 sollten potenzielle sozio-demografische und kardiometabolische Moderatoren des reinen Messeffekts analysiert werden. In Studie 3 sollten das Studiendesign und vorläufige Ergebnisse einer Interimsanalyse einer randomisierten Kontrollgruppenstudie (RCT) präsentiert werden. Ziel der Studie war es, die Wirksamkeit eines Videos über Intensitäten von Bewegung auf die fehlende Übereinstimmung zwischen selbstberichteter und objektiv gemessener körperlicher Aktivität zu prüfen.

Methode: Die Studien 1 und 2 basierten auf Daten einer Machbarkeitsstudie zur Untersuchung einer computergestützten Kurzintervention zur Steigerung von körperlicher Aktivität und Reduktion von Sitzzeiten während der Freizeit. Aus einer Zufallsstichprobe aus 40- bis 65-jährigen wiederbefragungsbereiten Teilnehmenden einer früheren Querschnittstudie zum Thema Herz-Kreislauf-Gesundheit nahmen 175 Personen teil. Die Baseline-Untersuchung umfasste die standardisierte Messung von Blutdruck, Taille und Hüfte sowie Blutentnahme, eine siebentägige Bewegungsaufzeichnung per Akzelerometer und die Erfassung körperlicher Aktivität und Sitzzeiten durch den International Physical Activity Questionnaire (IPAQ). Die Beantwortung des Fragebogens wurde nach Monat 1, 6 und 12 wiederholt. Eine zufällig ausgewählte Gruppe von Teilnehmenden erhielt zudem bis zu dreimal ein automatisiert generiertes schriftliches Feedback, beginnend nach Monat 1. In Studie 1 gingen die Daten von 153 Teilnehmenden über alle Messzeitpunkte ein. Die Veränderungen in Aktivität und Sitzzeiten wurden mittels latenter Wachstumskurvenmodelle

analysiert. In Studie 2 wurden die Daten von 175 Teilnehmenden zu den Zeitpunkten Baseline und Monat 1 analysiert. Anhand linearer Regressionsmodelle wurde die Abhängigkeit der Veränderung körperlicher Aktivität und Sitzzeiten von sozio-demografischen und kardiovaskulären Faktoren untersucht. Für Studie 3 wurden Personen zwischen 40 und 75 Jahren in einem Greifswalder Einkaufszentrum durch persönliche Ansprache rekrutiert. Diese nahmen an einer siebentägigen Bewegungsaufzeichnung per Akzelerometrie und im Anschluss an einem Tablet-PC gestützten Assessment im DZHK-Untersuchungszentrum der Universitätsmedizin Greifswald teil. Nach der randomisierten Zuordnung zu Video- und Kontrollgruppe wurde die IPAQ-Kurzform am Tablet-PC ausgefüllt. Die Videogruppe erhielt die Videodemonstration über Intensitäten körperlicher Aktivität vor Beantwortung des IPAQ. Anhand der Daten aller Teilnehmenden, die das Studienprotokoll bis zu diesem Zeitpunkt durchlaufen hatten (n = 131), erfolgte eine Interimsanalyse. Ziel war es, die Annahmen der a priori Poweranalyse zu prüfen und anhand des Ergebnisses über die Fortsetzung der Studie zu entscheiden. Der Unterschied zwischen den Studiengruppen bezüglich der Übereinstimmung zwischen selbstberichteter und per Akzelerometrie gemessener körperlicher Aktivität wurde mittels t-Test für unabhängige Stichproben geprüft.

Ergebnisse: Studie 1 ergab, dass Teilnehmende innerhalb des ersten Monats nach Baseline ihre körperliche Aktivität zu Beförderungszwecken erhöhten (p = .023), zu einer Reduktion ihrer Sitzzeiten tendierten (p = .060), jedoch ihre Aktivität während der Freizeit nicht veränderten. Weiterhin reduzierten sie ihre Sitzzeiten zwischen Monat 6 und 12 (p = .037). Die Veränderungen über die Zeit in der Feedbackgruppe unterschied sich nicht von denen der Gruppe ohne Feedback. Daten aus Studie 2 zeigten, dass Männer ihre Aktivität zu Beförderungszwecken stärker erhöhten, verglichen mit Frauen (p = .031). Männer mit höheren Werten auf dem Laborparameter Triglyceride steigerten ihre Aktivität zu Beförderungszwecken in geringerem Umfang, verglichen mit Männern mit niedrigerem Triglyceridwert (p = .043). Männer mit einem höheren systolischen Blutdruck reduzierten Sitzzeiten stärker als Männer mit einem niedrigeren systolischen Blutdruck (p = .028). Jedoch zeigte sich dieser lineare Zusammenhang nicht über den gesamten Bereich der gemessenen Blutdruckwerte. Ebenfalls für Männer wurde eine ähnliche Assoziation zwischen dem Glukoseparameter HbA1c und Sitzzeiten gefunden. Die vorläufigen Ergebnisse der Interimsanalyse aus Studie 3 zeigten eine geringere mittlere Differenz in der Videogruppe (M = 21.8 Minuten/Tag, SD = 108.9) verglichen mit der Kontrollgruppe (M = 41.0 Minuten/Tag, SD = 117.4, t(129) = 0.97). Der p-Wert (p = .166) lag innerhalb der Grenzen der Testsimulation ($p < .010$ und $p > .269$).

Schlussfolgerung: Die Ergebnisse der vorliegenden Arbeit beinhalten drei wesentliche Implikationen, die bei der Planung von Studien und der Erhebung von Daten zu körperlicher Aktivität und Sitzzeiten in der Herz-Kreislauf-Forschung berücksichtigt werden sollten. (1) Allein der Einsatz von Fragebögen zur Erfassung von Bewegung hat, unabhängig von Rückmeldungen, einen Effekt auf Teilbereiche körperlicher Aktivität, wie z. B. auf Aktivitäten zur Beförderung und auf Sitzzeiten. Dies bedeutet, dass potenzielle Effekte von Interventionen durch Effekte der reinen Messung verzerrt sein können. Messeffekte sollten daher bei der Planung von Studien und Interventionen und bei der Interpretation der Ergebnisse berücksichtigt werden. (2) Männliches Geschlecht und günstigere Triglyceridwerte bei Männern waren mit einer größeren Steigerung von körperlicher Aktivität zur Beförderung assoziiert, während schlechtere kardiometabolische Werte bei Männern mit einer höheren Reduktion von Sitzzeiten verbunden war. Soll der Messeffekt, z. B. eines Fragebogens, als Intervention nutzbar gemacht werden, sind Gesundheitsparameter des Adressaten zu berücksichtigen. (3) Das Studiendesign des RCTs scheint angemessen zur Testung des Effekts eines neu entwickelten Videos auf die fehlende Übereinstimmung zwischen selbstberichteter und per Akzelerometrie gemessener körperlicher Aktivität. Vorläufige Ergebnisse deuten auf die intendierte Wirksamkeit des Videos hin.

1 INTRODUCTION

1.1 Physical activity and cardiovascular health

Insufficient physical activity (PA) is a key risk factor for cardiovascular disease (CVD), which remains a major cause of death worldwide. In 2015, there were 422.7 million estimated CVD cases and 17.9 million deaths with coronary heart disease being the leading cause of CVD health lost (110.5 million cases and 8.9 million deaths, 156.7 million years of life lost, and 7.3 million years lived with disability) [1]. In Germany, CVD accounted for 37.2% (n = 338,687) of all deaths in 2016 [2] with 13.4% solely caused by coronary heart disease [3].

Beneficial associations between regular PA and cardiovascular health are well-established [4, 5]. For example, leisure-time PA has been shown to be associated with lower risk of all-cause mortality [6, 7] and CVD mortality [7]. In recent years, evidence for adverse associations between prolonged sedentary time (ST) and risk of all-cause and CVD mortality, independent of PA [8, 9], has grown. Thus, sedentary time is increasingly discussed as a distinct cardiovascular risk factor [8, 10].

To account for the public health problem of insufficient PA, the World Health Organization (WHO) and the American Heart Association have established global health guidelines for use in research, public, and practice. For adults aged between 18 and 64 years, it is recommended to engage in at least 150 minutes of moderate-intensity activity or 75 minutes of vigorous activity per week, or a combination of both [11, 12]. Recently, the American Heart Association has updated their guidelines by adding the general advice to spend less time sitting in order to account for potentially independent detrimental effects of prolonged ST.

Despite this knowledge, a large proportion of the world's population remains physically inactive [13]. In 2016, 42.2% of all adults in Germany did not meet the WHO recommendations on PA [14]. Nevertheless, prevalence data on both PA and ST are inconsistent as they vary largely depending on the measurement method applied [15, 16]. Finding strategies to improve health at the population level by increasing PA and reducing ST includes the development of feasible and effective behavior change interventions, which represents an ongoing challenge in prevention research.

1.2 Pitfalls in physical activity and sedentary time measurement

All statistics stated above rely greatly on the accurate measurement of PA and ST, whether monitoring population trends, understanding prevalences and high-risk groups, identifying correlates, determinants, and CVD risk estimates, or testing intervention effects. [17]. A key issue in research is to employ an appropriate study design including the well-considered use of assessments in terms of the amount and suitability of measures and time points. If failed to do so, study outcomes may be biased. The present thesis addressed three issues related to the use of assessments in PA and ST research studies. First, assessment may change the behavior that is aimed to be investigated. This may lead to biased data within longitudinal monitoring studies as well as within behavior change intervention trials. Second, a favorable effect of assessments on behavior change could be used as an intervention itself. Both aspects were investigated in a PA and ST feasibility trial. Last, there is a lack of agreement between self-reported and objectively measured PA, which may lead to ambiguous prevalence data, inappropriate recommendations, and flawed treatment of participants in interventions. A randomized controlled trial (RCT) to test the effect of a tool that might help to overcome this issue is presented.

1.3 Does mere measurement change physical activity and sedentary time?

Many challenges in the design and conduction of behavior change trials have been well described and addressed accordingly in renowned risk of bias frameworks as well as practice and reporting guidelines [18-21]. One important issue not incorporated in such guidelines to date is that measurement can affect the people being measured [22]. Evidence from systematic reviews shows that being asked about a behavior can result in changes of that behavior [23-25]. In a broader sense of research participation effects, this phenomenon has been known for decades as ‘Hawthorne effect’ and found great attention in the field of psychology [26]. In health research, the terms ‘mere-measurement effect’, ‘question-behavior effect’, or ‘measurement reactivity’ have been established [27]. Altering behavior might occur because answering questions for research assessment purposes might stimulate re-thinking about a behavior. This new thinking might, then, initiate action [22]. If participants of intervention trials change their behavior as a reaction to baseline assessments, the investigated intervention outcomes may be biased [27-29]. On the one hand, intervention effects may be underestimated if both participants in the intervention group and in the control group improve their behavior. On the other hand, baseline assessments might increase receptiveness to an intervention resulting in an overestimation of intervention effects [30, 31]. There is evidence that measuring PA by questionnaire [32-34] or measuring PA related cognitions [35] changes self-reported PA. However, measurement reactivity is not a problem inherent to self-report measures but has also been shown to be present when using objective devices such as pedometers [36] or accelerometers [37]. Studies on the mere-measurement effect mostly use relatively short follow-up periods, ranging from seven days to six months [32-35, 38], which limits the meaningfulness of results. Overall, evidence in the context of PA intervention trials is scarce and to date there are no studies investigating the mere-measurement effect on ST.

1.4 The mere-measurement effect as a chance for behavior change?

As described above, the mere-measurement effect can pose a problem in behavior change intervention trials if it is not accounted for in the study design. In contrast, the effect might be used as an easy-to-administer and cost-effective minimal intervention to enhance health behavior among populations [35, 39-41]. Thus, it has to be ensured that the potential benefit of the effect is not systematically attenuated among subgroups with respect to individual characteristics such as socio-demographic or health related factors. However, there is a lack of evidence about sex, age, and socio-economic status as moderators of the mere-measurement effect. A study on various health behaviors aimed at investigating whether the effect differed across socio-economic groups, as this would potentially lead to an increase in health inequalities, but the study failed to produce conclusive results [42].

Given the adverse relationships between insufficient PA and prolonged ST and cardiovascular health, it seems particularly interesting to investigate whether the mere-measurement effect differs between individuals with respect to their cardiometabolic risk profile including factors like blood pressure (BP) or waist circumference. If altering PA and ST result from an increased awareness of discrepancies between desired and actual behavior [25, 43], individuals with a less favorable risk profile may be more receptive to the mere-measurement effect than individuals with a more favorable risk profile. In contrast, if general benefits from the effect are less pronounced among those with a less favorable risk profile, health promotion using mere measurement may fail to reach those with the higher need.

1.5 How to reduce the gap between self-reported and accelerometer-based physical activity?

Assessment of PA is commonly realized using questionnaires because they are inexpensive and easy to administer. As reflected in global health recommendations [11, 12], it is well established that health benefits from engaging in regular PA depend on the intensity of the performed activities. Thus, many questionnaires inquire frequency and time spent in light, moderate, and vigorous PA offering examples of respective activities [44-49]. However, responses may be inaccurate due to individually different understanding of PA intensity levels [50]. Further, respondents may not be able to correctly recall their activities or calculate the inquired time spent in different PA domains and intensity levels [50, 51]. As direct measures on the other hand (e.g., accelerometers) overcome some of these problems, they have increasingly been used in recent years as the supposedly superior method [17]. Nevertheless, they are comparatively time-consuming and cost-intensive and possess limited validity due to reactivity bias [36, 37], selection bias [52], and the lack of ability to accurately capture certain activities, for example, cycling [8]. Also, to date, there is no standardized method for cleaning, analyzing, and reporting accelerometer data [53]. Thus, there are specific advantages and disadvantages inherent to both measures.

Numerous studies showed that the association between self-reported and accelerometer-based PA is low to moderate [54-56]. Most findings indicate that persons report more time spent in higher-intensity PA compared to what was directly measured. This poses a problem for the reliability of data and the comparability between studies, as epidemiological data, associations of PA with health, and intervention outcomes may vary according to the measurement method used. For example, there is evidence that associations between PA and the metabolic syndrome differ according to whether PA was self-reported or measured by accelerometry [57]. Further, self-report assessments are often used to tailor behavior change interventions. However, if respondents overestimate their PA levels, and thus, seem to meet health recommendations, they will be encouraged to maintain their behavior when they actually ought to change it.

A video as part of a computer-assisted self-completed questionnaire might help to reduce the gap between the two measurement methods by increasing the accuracy of self-reported time spent in different PA intensity levels. Whereas questionnaires rely on written descriptions, which can be misleading, a video demonstration provides an opportunity to visualize PA intensity levels. Respondents receive a clear frame of reference they may compare their performance levels with, which might reduce ambiguity. Thus, misclassification of light, moderate, and vigorous PA may be reduced. Up to now, videos to support assessments exist in the context of mobility and physical functioning validated for older adults [58-61]. There are no video-supported assessments that provide a reference for light, moderate, and vigorous PA.

1.6 Aims

The present thesis comprises three studies that have investigated different aspects of assessment methods relevant to PA and ST research and practice.

The aim of study 1 was to identify potential mere-measurement effects of a cardiovascular examination program on PA and ST indicated by significant changes in leisure-time PA ($PA_{leisure}$), transport-related PA ($PA_{transport}$), and ST between baseline assessment and twelve-month follow-up in a sample of apparently healthy adults aged between 40 and 65 years. Further, it was intended to explore whether measurement effects may bias intervention outcomes by investigating whether a brief tailored letter intervention may have an additional effect indicated by differences over time in a respective subsample. These questions were examined in:

> Voigt L, Baumann S, Ullrich A, Weymar F, John U, Ulbricht S: The effect of mere measurement from a cardiovascular examination program on physical activity and sedentary time in an adult population. *BMC Sports Science, Medicine and Rehabilitation* 2018, 10(1).

The aim of study 2 was to identify potential moderators of the mere-measurement effect by exploring associations between socio-demographic variables (sex, age, and employment) as well as cardiometabolic risk factors (systolic BP, waist circumference, glycated hemoglobin [HbA1c], total cholesterol, high-density lipoprotein [HDL], and triglycerides) and changes in $PA_{leisure}$, $PA_{transport}$, and ST. This was investigated in:

> Voigt L, Ullrich A, Baumann S, Dörr M, John U, Ulbricht S: Do sociodemographic variables and cardiometabolic risk factors moderate the mere-measurement effect on physical activity and sedentary time? *BMC Cardiovascular Disorders* submitted.

The aim of study 3 was to present the design of an RCT that was conducted to test the effect of a novel video on the gap between self-reported and accelerometer-based moderate-to-vigorous PA. In order to insightfully demonstrate the methods used, a journal was chosen that provided the opportunity to visualize the whole procedure via video. This was addressed in:

> Voigt L, Ullrich A, Siewert-Markus U, Dörr M, John U, Ulbricht S: Visualization of intensity levels to reduce the gap between self-reported and directly measured physical activity. *Journal of Visualized Experiments* 2019, 145, e58997.

2 METHODS

The underlying three studies were based on two different datasets. All studies [62-64] were funded by the German Centre for Cardiovascular Research (DZHK). The author's contribution to the scientific studies is summarized in Table 3 (Appendix). Data were analyzed using Stata/SE version 14.2 [65].

2.1 Studies 1 and 2

Study design

The first two studies were based on data of the feasibility trial "In Bewegung kommen, in Bewegung bleiben" (IBEKO, ClinicalTrials.gov: NCT02990039). The study was developed to assess the feasibility of a brief tailored letter intervention to increase PA and to reduce ST during leisure time. The study was approved by the clinical ethical committee of the University Medicine Greifswald (protocol number BB 002/15a) and was conducted between February 2015 and August 2016.

Participants of this study were originally approached between June 2012 and December 2013 at eleven general practices, two job centers, and via one statutory health insurance company in Northeastern Germany. They were invited to participate in a stepwise cardiovascular examination program, which is described more detailed elsewhere [66]. Among individuals who agreed to be contacted again for future studies, a random sample of persons aged between 40 and 65 years was drawn. Residents in the study area predefined by zip-code who had no history of cardiovascular events (myocardial infarction or stroke), no previous vascular interventions, and a self-reported body mass index ≤ 35 kg/m² were eligible and were offered to participate in the IBEKO study.

All persons who gave written informed consent were invited via letter to the cardiovascular examination center of the University Medicine Greifswald for baseline assessment. The invitation also contained a self-administered paper-pencil questionnaire on PA, ST, and socio-demographic variables, which participants completed at home and returned at the appointed day at the examination center. Participants received blood sample taking and standardized measurement of BP, waist circumference, height, and body weight. Starting the day after the examination, an accelerometer was worn for seven consecutive days. After baseline assessment, participants were randomly allocated to an assessment-only group and an intervention group. The assessment-only group received follow-up assessments on PA and ST using self-administered paper-pencil questionnaires sent via letter mail at one, three, four, six, and twelve months after baseline. The intervention group additionally received up to three counseling letters tailored to their self-reported PA and ST at months one, three, and four.

Samples

Among 1,165 individuals who agreed to be contacted again, a number of 513 were randomly selected and met the inclusion criteria stated above. Due to time restrictions, only 401 individuals were contacted and invited to participate in the IBEKO study. A number of 175 agreed to participate and took part in the baseline assessment. Of those, 85 individuals were randomly allocated to assessment-only group and 90 persons were assigned to the intervention group. A detailed description of the participant flow from baseline to twelve-month follow-up can be found in the methods section of the corresponding publication (study 1).

For study 1, data of the baseline assessment and the follow-up assessments at one, six, and twelve months after baseline were analyzed. A number of 22 were excluded because they severely exceeded the given time frame of two weeks to respond to the assessments. Thus, the final sample comprised 153 individuals. For study 2, the data of baseline and one-month follow-up (in the corresponding manuscript referred to as ‘five-week follow-up’) were analyzed (n = 175).

Measures

PA and ST were assessed using the International Physical Activity Questionnaire (IPAQ) [44]. Comprising 27 items, the IPAQ measures frequency, duration, and intensity of PA during the last seven days in four domains of life including leisure time and transportation. $PA_{leisure}$ comprises walking, PA on a moderate-intensity level, and PA on a vigorous-intensity level. $PA_{transport}$ includes walking and cycling. To sum time spent in each domain, each of these activities is multiplied by its metabolic equivalent of task value (MET) to account for the specific intensity. Time spent sedentarily during the last seven days is assessed separately for weekdays and weekend days using one question each.

Socio-demographic variables were obtained via self-administrative paper-pencil questionnaire at baseline including sex, age (years), school education (< 10, 10, > 10 years), and employment (yes, no).

Standardized measurement of BP was conducted by trained and certificated medical staff at the cardiovascular examination center using a digital BP monitor (705IT, Omron Corporation, Tokyo, Japan). BP was measured three times with five minutes rest prior to the first measurement and three minutes each before second and third measurement. For data analysis, the means of second and third measurements of systolic and diastolic BP (mmHg) were used. Antihypertensive medication prescribed within the last twelve months (yes, no) was assessed via questionnaire. Waist circumference (cm) was measured midway between lowest rib and iliac crest using an inelastic tape. Non-fasting blood samples were taken and HbA1c (mmol/mol), plasma total cholesterol (mmol/L), HDL (mmol/L), and triglycerides (mmol/L) were determined by standard methodology at the Institute for Clinical Chemistry and Laboratory Medicine of the University Medicine Greifswald.

Statistical analysis

Study 1

Latent growth models [67] were used to examine changes in $PA_{leisure}$, $PA_{transport}$, and ST over a period of twelve months. Measurement effects were indicated by significant changes between baseline and one-month assessment, that is, before the intervention started, and by significant changes over the remaining eleven months in the assessment-only group. To account for non-linear associations between the outcomes and time, a piecewise model approach was used. Thus, time was divided into intervals at months one and six, allowing each trajectory to have three distinct slopes. Interaction terms of study group and time were included to capture differences in trajectories between assessment-only group and intervention group. Likelihood ratio tests were used to test whether random intercepts or random slopes (i.e., between-person variability around the average growth curve) are required. To approximate normality, skewed $PA_{leisure}$ and $PA_{transport}$ data were modeled as negative-binomial variables and ST data were square root transformed. Incidence rate ratios (*IRR*s) were reported for both PA outcomes. A maximum likelihood estimator was used. Models were estimated under a missing at random assumption using all available data. In addition to sex and age, education was included as a covariate as multiple logistic regression analyses had revealed that lower education was predictive for dropout. *P*-values below .05 were considered statistically significant.

Study 2

Three outcomes were investigated: One-month changes of $PA_{leisure}$, $PA_{transport}$, and ST (calculated as follow-up value minus baseline value, respectively). Linear regression analyses were calculated to estimate associations between the outcomes and socio-demographics and cardiometabolic risk factors. Robust standard errors were used to account for potential estimation bias. To account for missing data, multiple imputation using chained equations was performed [68]. The approach of this method is to use the distribution of the observed data to estimate a set of plausible values for the missing data. A number of 80 imputed data sets were used. The imputation model was built using the outcomes, predictors, and covariates of the main analysis models as well as seven auxiliary variables (e.g., diastolic BP). To account for skewed continuous variables, the predictive mean matching method was used.

First, associations between sex, age, and employment and the outcomes were investigated in one model for each outcome. Employment but not school education was investigated as an indicator for socio-economic status because non-participation in this study was associated with lower education and the number of individuals with < 10 years of school education was low (*n* = 12). Second, because sex differences were found, all analyses were stratified by sex. Third, each cardiometabolic risk factor was tested in a separate model. All models were adjusted for age, employment, duration between baseline and follow-up, and baseline $PA_{leisure}$, $PA_{transport}$, or ST, respectively. Associations between systolic BP and the outcomes were additionally adjusted for BP lowering medication. In all analyses, likelihood ratio tests were used to decide whether to add quadratic terms of age or cardiometabolic risk factors to improve model fit. *P*-values < .05 were considered statistically significant.

2.2 Study 3

Study design

The third study is based on study design and protocol of the RCT "Closing the Gap between Self-reported and Accelerometer-based Physical Activity" (GAP, ClinicalTrials.gov: NCT03539237). The study was developed to assess the effect of a video demonstration of PA intensity levels on the difference between self-reported and accelerometer-based PA. The study was approved by the clinical ethical committee of the University Medicine Greifswald (protocol number BB 076/18) and was conducted between May and November 2018. Prior to recruitment of participants, a power calculation was performed including an interim analysis to verify the underlying presumptions and to decide on early stopping of the study. Assuming a drop-out rate of about 10%, it was planned to recruit 350 persons.

Participants were proactively recruited at a shopping mall in Greifswald, Germany. Persons aged between 40 and 75 years with the ability to walk independently (e.g., no permanent use of a wheelchair) and with the physical and cognitive capability to complete a self-report questionnaire were eligible. All participants gave written informed consent. Starting the next day, participants wore an accelerometer for seven consecutive days. After the wearing period, they returned the accelerometer at the examination center of the University Medicine Greifswald. Afterwards, they were randomly allocated to experimental group and control group. Both groups completed a self-administered computer-based survey on self-reported PA, socio-demographics, and health variables. The experimental group additionally received a video demonstration of PA intensity levels before answering the PA questionnaire. After completing the survey, both groups received standardized measurement of height, body weight, and waist and hip circumference. The total procedure of the study can be viewed online (https://www.jove.com/video/58997).

Experimental condition: Video demonstration of physical activity intensity levels

The experimental group received a three-minute video demonstration via tablet computer directly before answering the PA questionnaire. The video shows an approximately fifty-year-old, normal-weight male in good physical shape standing on a treadmill in a fitness center. After giving a general introduction, he describes the terms ‘light’, ‘moderate’, and ‘vigorous PA’ and explains differences in heart rate, breathing frequency, and capability to talk normally. He simultaneously demonstrates those symptoms while walking/running on a treadmill at the according pace. Further, he gives examples of daily-life activities and emphasizes individual differences in the evaluation of PA intensity levels. The video was produced in German language based on a video clip from the Centers for Disease Control and Prevention [69] and can be viewed online (http://www2.medizin.uni-greifswald.de/prevention/forschung/video-visualisierung-koerperlicher-aktivitaet). Figure 1 illustrates the main content of the video.

Figure 1: Illustration of the main video content.

Sample

Study 3 focused on the design and the methods of the GAP study. An interim analysis was conducted to verify the underlying assumptions and to decide on early stopping of the study. Thus, data of a preliminary sample were analyzed including all participants who completed the study protocol up to this point (n = 142, July 2018). Participants who exceeded the aimed age range (n = 1) or who did not wear the accelerometer for at least ten hours per day on at least six days (n = 10) were excluded from the analysis. Thus, data analysis was carried out using a sample of 131 participants.

Measures

Objectively measured PA was assessed using three-axial ActiGraph Model GT3X+ accelerometers (Pensacola, FL, USA). Participants were instructed to wear the device on the right hip for seven consecutive days and to remove it before going to bed and for any water-based activities. Accelerometers were initialized using a sampling rate of 30 Hz [70] and an epoch length of 10 seconds. Data from the vertical axis were used. ActiGraph accelerometers assess acceleration using counts as the output metric enabling to select cut points in order to determine non-wear time and to differentiate between PA intensity levels [71, 72]. Accelerometer wear time (min/day) was determined by removing non-wear time defined as at least 60 minutes of consecutive zero counts, allowing for ≤ 2 minutes of counts between 0 and 100 [71]. Values between 100 and 2019 counts per minute were classified as light PA.

Moderate-to-vigorous PA (MVPA) was defined by values of 2020 counts per minute or more [71].

Self-reported PA was assessed using a modified version of the International Physical Activity Questionnaire – Short Form (IPAQ-SF) [44], German version [73]. Two items each address number of days and respective time spent in moderate and vigorous PA during the last seven days. The original items on walking were replaced with questions on light PA as walking may be performed on different intensity levels [74] and walking is not equivalent to light PA measured by accelerometry.

Socio-demographics were obtained via self-administrative computer-based questionnaire including sex, age (years), school education (< 10, 10, > 10 years), and current smoking (yes, no).

Assessment of body composition comprised standardized measurement of height, body weight, and waist and hip circumference. Height (cm) and body weight (kg) were measured using digital scales (MZ 10020, ADE GmbH & Co., Hamburg, Germany and SOEHNLE 7720, Soehnle Industrial Solutions GmbH, Backnang, Germany, respectively). Using an inelastic tape, waist circumference (cm) was measured midway between lowest rib and iliac crest and hip circumference (cm) was measured about two inches below iliac crest.

Statistical analysis

An interim analysis using a preliminary sample was carried out including 131 participants to examine assumptions underlying the a priori power calculation and to decide on early stopping of the study. The main outcome was a difference score (delta, Δ), calculated as self-reported minus accelerometer-derived minutes of MVPA. A two-sample t-test was used to determine the difference between the deltas of the control group and the experimental group. Based on a comparable sample [37], the assumed mean delta between questionnaire and accelerometer data in the control group was 90 minutes per day of MVPA. The assumed mean delta in the experimental group was 60 minutes per day (*SD* in both groups = 100 min/day). As it had been hypothesized that the integration of the video reduced the gap between the two measures, a one-sided significance level of $p = .05$ was chosen (power = .80).

3 RESULTS

3.1 Study 1

Sample characteristics

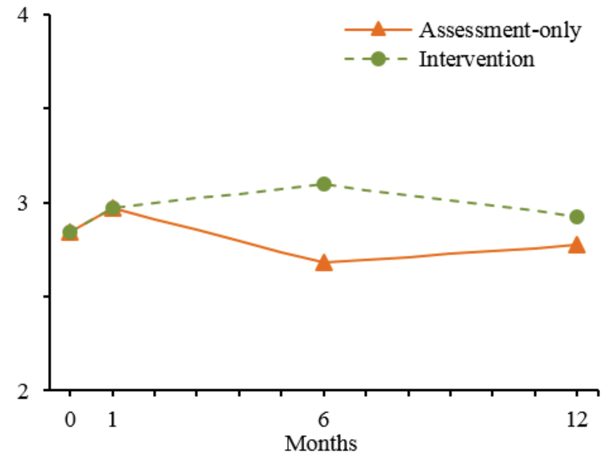
The sample comprised 98 women (64%) and 55 men (36%) with a mean age of 54.5 years (*SD* = 6.2). The majority of the participants had 10 years of school education (*n* = 102, 68%), 36 (24%) had more than 10 years, and 12 (8%) had less than 10 years of school education. A number of 31 persons (21%) were not employed. At baseline, median PA during leisure time was 15.6 MET-hours per week (*IQR*: 3.3-33.1) and 13.1 MET-hours per week (*IQR*: 2.2-26.2) during transport. Median ST was 40 hours per week (*IQR*: 28.5-56.0).

Twelve-month changes of physical activity and sedentary time after a cardiovascular examination

Results of latent growth modeling are depicted in Figure 2. One-month changes after baseline refer to the whole sample as the intervention started after one-month assessment. Participants increased $PA_{transport}$ by 0.31 log MET-hours per week (*IRR* = 1.37, *p* = .023) and tended to decrease ST by 1.96 sqrt minutes per week (*p* = .060). Changes in $PA_{leisure}$ were not significant (b = 0.13 log MET-h/week, *IRR* = 1.13, *p* = .432). Time trends after one-month assessment were analyzed separately for the study groups. In the assessment-only group, persons significantly reduced ST between six and twelve months by 0.52 sqrt minutes per week (*p* = .037). All other time trends were not statistically significant. Interactions between time and study group revealed that there was no difference between the intervention group and the assessment-only group over eleven months in any outcome.

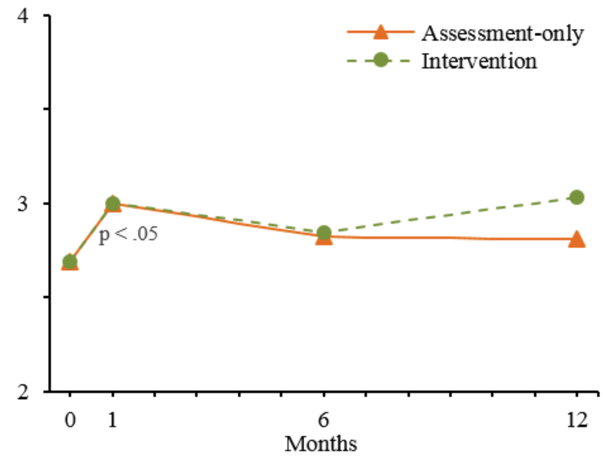
(a) Leisure-time physical activity (log MET-h/week; *n* = 145)

	Est. (SE)
Fixed effects	
Intercept	2.84 (0.16)
Slope (0-1 months)	0.13 (0.16)
Slope (1-6 months)	-0.06 (0.04)
Slope (6-12 months)	0.02 (0.04)
Slope (1-6 months*study group)	0.08 (0.05)
Slope (6-12 months*study group)	-0.04 (0.05)
Random effects	
Intercept	0.90 (0.16)
Slope	-



(b) Transport-related physical activity (log MET-h/week; *n* = 146)

	Est. (SE)
Fixed effects	
Intercept	2.69 (0.14)
Slope (0-1 months)	0.31 (0.14)
Slope (1-6 months)	-0.04 (0.04)
Slope (6-12 months)	-0.00 (0.03)
Slope (1-6 months*study group)	0.00 (0.05)
Slope (6-12 months*study group)	0.03 (0.05)
Random effects	
Intercept	0.85 (0.15)
Slope	-



(c) Sedentary time (sqrt min/week [table]; h/week [graph]; *n* = 150)

	Est. (SE)
Fixed effects	
Intercept	49.36 (1.19)
Slope (0-1 months)	-1.96 (1.04)
Slope (1-6 months)	0.06 (0.28)
Slope (6-12 months)	-0.52 (0.25)
Slope (1-6 months*study group)	-0.23 (0.35)
Slope (6-12 months*study group)	0.56 (0.35)
Random effects	
Intercept	7.89 (0.62)
Slope	-

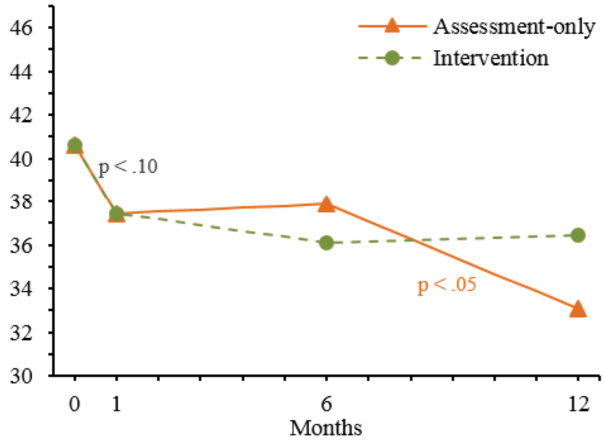


Figure 2: Results of latent growth modeling for leisure-time physical activity (a), transport-related physical activity (b), and sedentary time (c).

Notes. *MET*: metabolic equivalent of task; *Est.*: estimate: mean (fixed effects), standard deviation (random effects); *SE*: standard error; − fixed at zero as indicated by likelihood ratio test. All slopes are linear. Models were adjusted for time-invariant covariates: sex, age, and education. For graphical display, the outcome of sedentary time was re-calculated into hours per week.

3.2 Study 2

Sample characteristics

The sample consisted of 112 women (64%) and 63 men (36%) with a mean age of 54.4 years (*SD* = 6.2). A number of 139 participants (81%) were employed. The mean difference between baseline and follow-up was *M* = 4.3 MET-hours per week (*SD* = 29.0) in $PA_{leisure}$, *M* = 6.5 MET-hours per week (*SD* = 20.3) in $PA_{transport}$, and *M* = -163.2 minutes per week (*SD* = 1039.5) in ST. The mean duration between baseline and follow-up was 39.2 days (*SD* = 8.9). Descriptive statistics of cardiometabolic risk factors can be found in Table 1 of the corresponding manuscript.

Associations between socio-demographics and cardiometabolic risk factors and changes in physical activity and sedentary time

Men increased $PA_{transport}$ significantly more than women (*b* = 9.3 MET-h/week, *p* = .031) and older individuals tended to increase $PA_{transport}$ more than younger individuals (*b* = 0.5 MET-h/week, *p* = .065, data presented in supplementary table S1 of the corresponding manuscript). After stratification by sex, the association between $PA_{transport}$ and age disappeared. No associations between employment and the outcomes were found.

In men, results indicated a U-shaped association between systolic BP and the reduction of ST (linear term: *b* = -35.7 min/week, *p* = .028; quadratic term: *b* = 1.0, *p* = .080; Table 1, Figure 3a). In men, a U-shaped association between HbA1c and the reduction of ST (linear term: -93.0 min/week, *p* = .003; quadratic term: *b* = 6.2, *p* = .064, Figure 3b) was found. Men with higher triglycerides increased $PA_{transport}$ less than men with lower triglycerides (*b* = -5.6 MET-h/week, *p* = .043) and women with higher HDL tended to increase $PA_{transport}$ more than women with lower HDL (*b* = 10.6 MET-h/week, *p* = .077). No associations between waist circumference or total cholesterol and the outcomes were found. Sensitivity analyses using complete cases yielded similar results, which are presented in supplementary tables S2, S3, and S4 of the corresponding manuscript.

Table 1. Associations between cardiometabolic risk factors and changes in physical activity and sedentary time in women (n = 112) and men (n = 63)

	$PA_{leisure}$ Δ (MET-h/week)	**$PA_{transport}$ Δ (MET-h/week)**	**Sedentary time Δ (min/week)**
	b [95% CI]	*b* [95% CI]	*b* [95% CI] [a]
Women			
SBP, mmHg [c]	0.2 [-0.2; 0.7]	0.0 [-0.3; 0.3]	-7.4 [-21.5; 6.7]
SBP*SBP [b, c]	0.0 [-0.0; 0.0]$^{+}$	-	-
Waist circumference, cm	-0.1 [-0.6; 0.5]	0.0 [-0.3; 0.3]	0.7 [-16.1; 17.4]
HbA1c, mmol/mol	0.6 [-0.4; 1.5]	-1.1 [-0.6; 0.4]	-16.2 [-58.9; 26.5]
Total cholesterol, mmol/L	2.6 [-2.9; 8.1]	1.0 [-2.5; 4.4]	-70.8 [-259.8; 118.2]
HDL, mmol/L	3.9 [-9.7; 17.5]	10.6 [-1.2; 22.4]$^{+}$	-18.8 [-565.2; 527.6]
Triglycerides, mmol/L	-2.1 [-7.8; 3.6]	-1.6 [-5.0; 1.7]	-12.9 [-224.8; 199.0]
Men			
SBP, mmHg [c]	0.0 [-0.5; 0.5]	0.3 [-0.4; 1.0]	-35.7 [-67.3; -4.0]*
SBP*SBP [b, c]	-	-	1.0 [-0.1; 2.1]$^{+}$
Waist circumference, cm	0.3 [-0.5; 1.1]	0.4 [-0.3; 1.1]	-11.7 [-36.9; 13.4]
HbA1c, mmol/mol	1.2 [-0.6; 3.1]	0.7 [-1.0; 2.4]	-93.0 [-152.6; -33.4]**
HbA1c*HbA1c [b]	-	-	6.2 [-0.4; 12.9]$^{+}$
Total cholesterol, mmol/L	-0.6 [-13.4; 12.1]	-5.2 [-13.6; 3.2]	-24.8 [-413.9; 364.2]
HDL, mmol/L	-4.2 [-31.8; 23.4]	3.2 [-20.5; 26.8]	-562.8 [-1590.4; 464.9]
HDL*HDL [b]	-	-	-1928.3 [-3912.8; 56.2]$^{+}$
Triglycerides, mmol/L	-1.0 [-8.8; 6.8]	-5.6 [-11.1; -0.2]*	-35.6 [-326.6; 255.4]

Notes. *PA*: physical activity; Δ*:* delta, one-month change; *MET*: metabolic equivalent of task; *b*: unstandardized regression coefficient; *CI*: confidence interval; *SBP*: systolic blood pressure; *HbA1c*: glycated hemoglobin; *HDL*: high-density lipoprotein; - not included. Models were adjusted for age, employment, duration to follow-up, and baseline value of $PA_{leisure}$, $PA_{transport}$, or sedentary time, respectively. [a] additionally adjusted for age*age representing the quadratic term of age. [b] the quadratic term was added because it was shown to improve model fit. [c] additionally adjusted for blood pressure lowering medication. $^{+}p < .10$, $^{*}p < .05$, $^{**}p < .01$

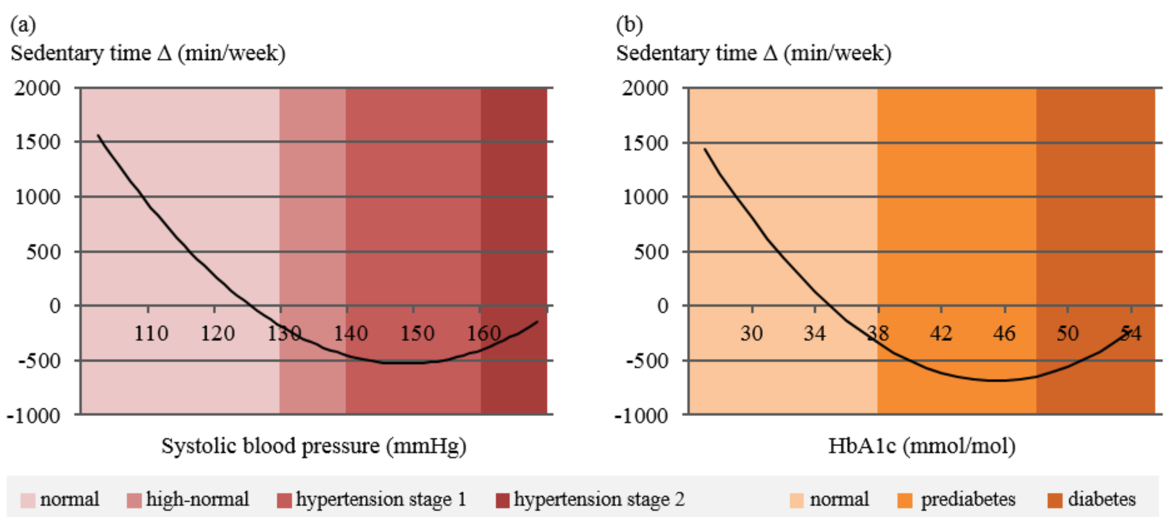


Figure 3: One-month changes of sedentary time in men (n = 63) dependent on systolic blood pressure (a) and HbA1c (*glycated hemoglobin*, b).

Notes. Models were adjusted for age, employment, duration to follow-up, and baseline value of sedentary time. (a) was additionally adjusted for blood pressure lowering medication.

3.3 Study 3

Sample characteristics

The analysis sample comprised 131 participants. Descriptive statistics separately for control group (n = 63, 48%) and video group (n = 68, 52%) are displayed in Table 2.

Table 2. Sample characteristics (n = 131)

	Control group	**Video group**
Sex, women	46 (73%)	39 (57%)
Age, years	58.1 ± 9.6	61.9 ± 7.9
School education		
< 10 years	12 (19%)	8 (12%)
= 10 years	27 (44%)	37 (56%)
> 10 years	23 (37%)	21 (32%)
Not specified (n = 3)		
Current smoker, yes	12 (19%)	10 (15%)
Body mass index		
< 25 kg/m^2	23 (37%)	11 (16%)
≥ 25 kg/m^2 and < 30 kg/m^2	22 (35%)	33 (49%)
≥ 30 kg/m^2	18 (29%)	24 (35%)
Accelerometer-based MVPA, min/day	44.1 ± 24.3	46.2 ± 30.7
Self-reported MVPA, min/day	85.2 ± 119.0	68.0 ± 115.8

Notes. *MVPA*: moderate-to-vigorous physical activity. Data are presented as $M \pm SD$ for continuous variables and as n (%) for categorical variables. Body mass index was calculated from objectively measured height and weight.

Difference between study group deltas of self-reported and accelerometer-based moderate-to-vigorous physical activity

Preliminary results of the interim analysis revealed a lower formal mean delta in the video group (M = 21.8, SD = 108.9) compared to the control group (M = 41.0, SD = 117.4, $t(129)$ = 0.97, p = .166). The p-value lay between the significance ($p < .010$) and futility ($p > .269$) boundaries of the test simulations. A graphical display of the results is depicted in Figure 4.

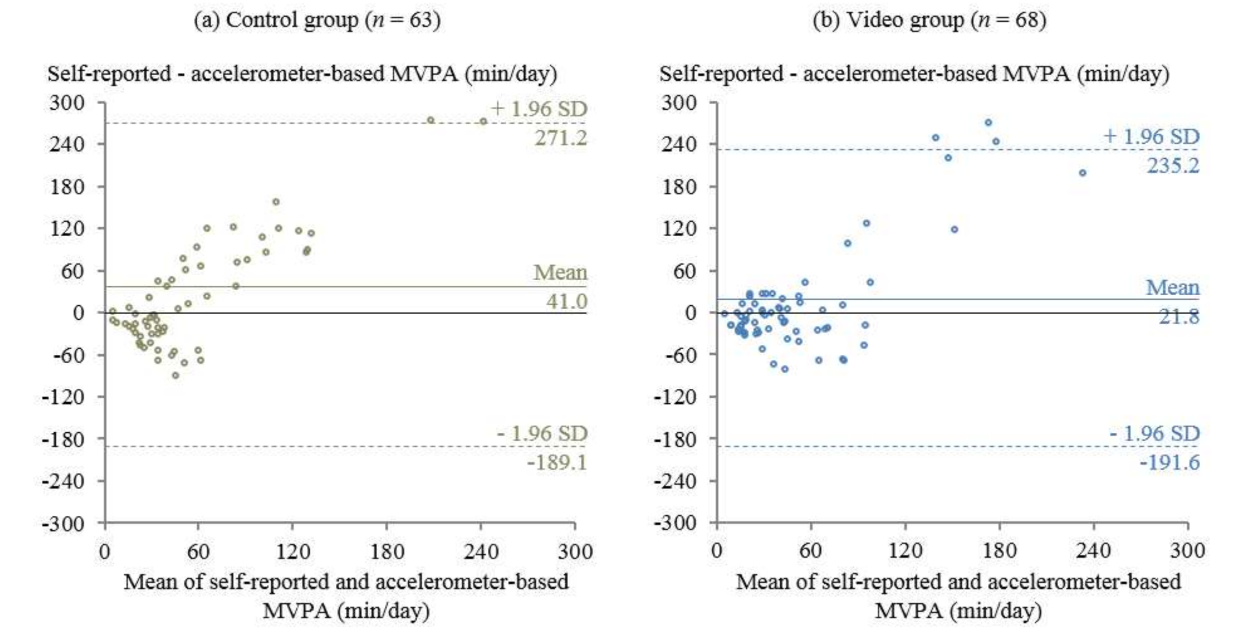


Figure 4: Bland Altman plots of the relationship between self-reported and accelerometer-based moderate-to-vigorous physical activity in the control group (a) and in the video group (b).

Notes. *MVPA*: moderate-to-vigorous physical activity; *SD*: standard deviation. The solid horizontal line represents the mean difference of the measures whereas the dotted lines represent the 95% limits of agreement. Differences were calculated as self-reported minus accelerometer-based min of MVPA. A perfect agreement between the measures would be present if all observations (dots) lied on a horizontal line at the value 0 of the y-axis (black line).

4 DISCUSSION

The aim of this thesis was to investigate overlooked issues of assessment methods relevant to PA and ST research. The data revealed three main findings. First, mere-measurement effects were found for $PA_{transport}$ and ST whereas a brief tailored letter intervention did not have an additional effect. Second, measurement effects on $PA_{transport}$ were associated with male sex and with lower triglycerides in men. Further, there were U-shaped associations between measurement effects on ST and systolic BP as well as HbA1c in men. Third, the applied RCT seemed appropriate to generate data eligible for testing the effect of a video demonstration on the gap between self-reported and accelerometer-based PA. Preliminary results of the interim analysis pointed to a reduction of the gap caused by the video.

4.1 General discussion

The mere-measurement effect on physical activity and sedentary time

The results of study 1 indicate the presence of mere-measurement effects in $PA_{transport}$ and ST, but not in $PA_{leisure}$ within a feasibility trial. Similar to previous research, results were inconsistent across investigated PA outcomes. For example, in a sample of Dutch adults [32] evidence for measurement effects was found on meeting PA recommendations (30 min of at least moderate-intensity PA on $\geq$ 5 days a week), but not on other outcomes such as categorized MVPA minutes per week. Thus, it seems to be important to consider various outcome variables when concluding on the extent of measurement effects. Further, results may differ according to the questionnaire used to evaluate domain-specific PA levels. For example, Godin and others found evidence for measurement effects on leisure-time PA in a sample of overweight and obese adults [35]. In contrast to the IPAQ used in the present study, yard, household, and transport-related activities were not explicitly excluded from leisure-time PA. That is, respondents may categorize activities differently depending on the specific questionnaire used. The IPAQ leisure-time domain is conceptually more narrowly defined and, thus, provides fewer options to be altered.

The present study was the first to investigate potential effects of mere measurement on ST. Marginally significant changes during the first month and significant changes between six and twelve months in the assessment-only group may imply measurement effects. It has been suggested that asking in detail about a behavior may raise awareness about its true magnitude across several domains of daily living and thus, motivate people to become more active [32, 75]. This may especially apply to ST as thinking about duration and frequency of ST independent of PA may be novel to respondents [76].

Starting from one-month assessment, a random subsample of participants received a brief tailored letter intervention. Changes over time did not significantly differ from those observed in the assessment-only group in any of the three outcomes. Thus, the intervention did not have an effect in addition to mere measurement. These findings are consistent with the presumption of intervention effects being difficult to detect if mere-measurement effects are present in an intervention trial [31].

Moderators of the mere-measurement effect on physical activity and sedentary time

The results of study 2 indicate that mere-measurement effects on $PA_{transport}$ depend on sex and age as well as triglycerides in men and that measurement effects on ST in men depend on systolic BP and HbA1c. In the present sample, men seem to have a worse health condition than women indicated by less favorable values of systolic BP, HDL, and triglycerides (data presented in Table 1 of the corresponding manuscript). In line with the suggested mechanisms underlying the mere-measurement effect [23, 27], men may have increased $PA_{transport}$ as their awareness of the relationship between behavior and health increased in response to reflecting on activity levels when completing a detailed 27-item-questionnaire followed by the assessment of cardiometabolic risk factors. Further, there is evidence that active transport depends on environmental conditions such as neighborhood walkability [77, 78]. That is, changing $PA_{transport}$ may not be achievable for everyone, for example, due to long distances between home and work.

Despite the fact that the age range in the present sample was restricted to 40 to 65 years, it was found that older participants tended to increase $PA_{transport}$ more than younger participants. This may be contrary to results of prior meta-analyses comparing student samples with non-student samples including older adults that might suggest a larger measurement effect among younger adults compared to older adults [23, 25]. Not surprisingly, however, older participants in this sample seem to have a worse health condition indicated by higher levels of HbA1c, total cholesterol, and triglycerides (data not shown). Thus, they may have been more motivated to increase PA.

Findings on systolic BP and HbA1c in men indicate that those with less favorable cardiometabolic risk factors improved ST more than those with more favorable risk factors. In contrast, results on triglycerides in men (and on HDL in women) revealed that those with more favorable values improved (or tended to improve) $PA_{transport}$ more than those with less favorable values. Thinking about weekly ST independent of PA levels may have motivated men with less favorable risk factors to alter inactivity on a lower threshold. In contrast, individuals in good health may have more resources to alter their behavior and to engage in regular PA. Compared to men, women in the present sample had more favorable cardiometabolic risk factors, which might explain why these factors did not moderate changes of PA and ST in women.

A video to reduce the gap between self-reported and accelerometer-based physical activity

In study 3, design and protocol of an RCT to test the effect of a novel video on the gap between self-reported and accelerometer-based PA were presented. Preliminary results showed that the completion of the protocol was feasible and that data eligible for analyses were collected. Critical steps were realized as intended including the 1:1 randomization of participants, the correct initialization of accelerometers, and the participants' adherence to the scheduled appointment at the examination center for answering the PA questionnaire. 69.5% of participants attended the assessment one day after seven-day accelerometry and 28.2% attended two days after. Thus, for the vast majority of participants, accelerometer wearing and seven-day recall refer to the exact or nearly exact time period, respectively. In addition, to rule out bias due to the lack of accordance between wearing and recall period, it was decided to apply more conservative cut-off values for sufficient accelerometer wear time across the week. Whereas most studies on correlations between accelerometry and PA questionnaire data request a wear time of ≥ 10 hours per day on ≥ 4 days per week [79], in the present study, it was decided to exclude participants from the analysis who did not wear the accelerometer for ≥ 10 hours per day on ≥ 6 days. As reported in the sample section, a number of 10 (7.0%) were excluded. Thus, the applied exclusion criterion seems to be justifiable considering the feasibility of the trial.

Preliminary results of the interim analysis revealed a reduced gap between measurement methods in the video group compared to the control group pointing to the expected video effect. As the *p*-value lay between the significance and futility boundaries of the test simulations, it was concluded that the study may proceed as planned until the total sample size was reached. Finally, the recruitment of participants was completed in a suitable time frame in November 2018.

4.2 Limitations

There are four limitations of the underlying studies that should be considered. First, systematic changes in PA and ST observed in studies 1 and 2 do not necessarily imply mere-measurement effects as they were lacking a control condition. To reduce potential confounding, adjustments were made for variables related to individuals' characteristics and data collection. However, data on other potentially important confounders such as neighborhood walkability were not collected. Second, the findings on mere-measurement effects and moderators may suffer from a lack of power to detect differences, as the feasibility study was not particularly designed to investigate these research questions. Third, generalizability of findings may be compromised due to selection bias. The proportion of individuals who declined participation was high (53%) and non-participation was associated with smoking, lower education, and female sex. A selection of highly motivated individuals is likely. Last, in study 3, there were considerably more women in the sample than men. Thus, results may be less representative for men than for women.

4.3 Implications and future directions

PA and ST as important cardiovascular health behaviors need to be investigated in terms of population trends, prevalences, high-risk groups, and intervention effects. Their accurate assessment, however, can be challenging. In the context of monitoring studies and behavior change intervention trials, potential bias induced by mere-measurement effects need to be considered when planning studies and interpreting outcomes. Especially in brief interventions, expected effects are small to moderate and, thus, may be hard to detect. Further, it should be considered that intervention effects refer not alone to intervention components, but in fact to the combined impact of both intervention and assessments because assessments, including participant contact, are part of the intervention. Potential solutions like applying a Solomon four-group design [29] or extending device wearing periods in order to receive PA and ST levels less affected by reactivity bias [36, 37] may not be feasible primarily due to higher costs [22], especially in large-scale studies. More practical solutions are required and, thus, future research is needed to further investigate the mere-measurement effect and find out circumstances under which bias can be minimized, possibly by using specific measures, sub-groups, or number and size of assessments [22, 80].

Researchers and practitioners may use the mere-measurement effect to promote behavior change. For example, a questionnaire on PA or ST can easily be administered while waiting in a physician's practice inducing a patient to reflect on the behavior. If cardiometabolic risk factors are assessed such as BP or blood lipids, a deeper awareness of the relationship between inactivity and health risks might be raised. In the course of this, individual characteristics of patients should be considered. For example, men with a worse cardiometabolic health profile may be more responsive to answering a questionnaire on ST rather than PA. Altering inactivity on this lower threshold should be encouraged as some activity is better than none [12] and overcoming low motivation for change may be triggered [10]. Future research with larger sample sizes is needed to verify the moderators found in the present exploratory study and to investigate long-term effects on behavior and health outcomes.

It should be acknowledged that PA can vary largely according to whether data was self-reported or measured by device. Finding ways to increase the validity of each method may be an option to enhance comparability between studies. A video demonstration aimed at the reduction of over-reporting by targeting participants' understanding of PA intensity levels could easily be integrated into computer-assisted self-report assessments of PA. Given the rapid advances in handheld computer technology, the use of tablets provides a user-friendly, cost-effective opportunity for data collection in large-scale studies. Future research could investigate subgroups or apply cognitive interviews to identify the underlying mechanisms responsible for potential benefits of the video demonstration. Consequently, video components could be adjusted for the use among other target groups such as in prediabetic or cardiac patients. The RCT presented here seems eligible and feasible to test the effect of any experimental manipulation on the gap between the two measurement methods. Future research could apply similar trials to target, for example, recall bias or accelerometer reactivity bias. In contrast to those approaches, it has been suggested that the lack of agreement between the two methods is in fact not a sign for flawed data but rather a pattern emerging because the instruments are not equivalent but measure different aspects of the same construct [15, 17, 81]; hence, researchers should either choose the method that seems more suitable for the study aim or apply a parallel use to complementarily collect more comprehensive information on PA [17, 79, 82]. In line with that, the American Heart Association has published a decision matrix for selecting PA assessment instruments [83] and calls for standardized approaches for analyzing accelerometer data have been made [84]. Thus, future research should put efforts into finding a consensus on what exactly is measured by each method and whether direct comparability between the corresponding data is worth striving for.

4.4 Conclusion

To conclude, this thesis may elucidate often overlooked issues in cardiovascular research on the impact of PA measurement. First, the potential presence of measurement effects on PA and ST should be considered when planning studies, developing interventions, and interpreting outcomes. Second, researchers and practitioners using the mere-measurement effect for prevention purposes may address PA and ST depending on individual differences in responsiveness to assessments such as sex or health status. Third, the gap between self-reported and accelerometer-based PA may be reduced by a video demonstration of PA intensity levels. Further investigations on these issues are needed in order to reduce bias in cardiovascular research studies and to increase benefits from behavior change trials.

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APPENDIX

Scientific studies

The author’s contribution to the scientific studies

Eidesstattliche Erklärung

List of publications

Dank

Scientific studies

Voigt L, Baumann S, Ullrich A, Weymar F, John U, Ulbricht S: The effect of mere measurement from a cardiovascular examination program on physical activity and sedentary time in an adult population. *BMC Sports Science, Medicine and Rehabilitation* 2018, 10(1).

Voigt L, Ullrich A, Baumann S, Dörr M, John U, Ulbricht S: Do sociodemographic variables and cardiometabolic risk factors moderate the mere-measurement effect on physical activity and sedentary time? *BMC Cardiovascular Disorders* submitted.

Voigt L, Ullrich A, Siewert-Markus U, Dörr M, John U, Ulbricht S: Visualization of intensity levels to reduce the gap between self-reported and directly measured physical activity. *Journal of Visualized Experiments* 2019, 145, e58997.

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BMC Sports Science, Medicine and Rehabilitation

RESEARCH ARTICLE Open Access

The effect of mere measurement from a cardiovascular examination program on physical activity and sedentary time in an adult population

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Abstract

Background: Measuring physical activity (PA) and sedentary time (ST) by self-report or device as well as assessing related health factors may alter those behaviors. Thus, in intervention trials assessments may bias intervention effects. The aim of our study was to examine whether leisure-time PA, transport-related PA, and overall ST measured via self-report vary after assessments and whether a brief tailored letter intervention has an additional effect.

Methods: Among a sample of subjects with no history of myocardial infarction, stroke, or vascular intervention, a number of 175 individuals participated in a study comprising multiple repeated assessments. Of those, 153 were analyzed (mean age 54.5 years, standard deviation = 6.2; 64% women). At baseline, participants attended a cardiovascular examination (standardized measurement of blood pressure and waist circumference, blood sample taking) and wore an accelerometer for seven days. At baseline and after 1, 6, and 12 months, participants completed the International Physical Activity Questionnaire. A random subsample received a tailored counseling letter intervention at month 1, 3, and 4. Changes in PA and ST from baseline to 12-month follow-up were analyzed using random-effects modelling.

Results: From baseline to 1-month assessment, leisure-time PA did not change (Incidence rate ratio = 1.13, $p = .432$), transport-related PA increased (Incidence rate ratio = 1.45, $p = .023$), and overall ST tended to decrease ($b = -1.96$, $p = .060$). Further, overall ST decreased from month 6 to month 12 ($b = -0.52$, $p = .037$). Time trends of the intervention group did not differ significantly from those of the assessment-only group.

Conclusions: Results suggest an effect of measurements on PA and ST. Data of random-effects modelling results revealed an increase of transport-related PA after baseline to 1-month assessment. Decreases in overall ST may result from repeated assessments. A brief tailored letter intervention seemed to have no additional effect. Thus, measurement effects should be considered when planning intervention studies and interpreting intervention effects.

Trial registration: ClinicalTrials.gov NCT02990039. Registered 7 December 2016. Retrospectively registered.

Keywords: Question-behavior effect, Measurement reactivity, Research participation, Brief intervention, Random-effects modelling

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Background

Assessments are essential in order to determine the initial level of outcome-related variables, to monitor the progress over the course of the study, and to collect the outcome measures [1]. In trials aimed to increase physical activity (PA) or to reduce sedentary time (ST), measurements may comprise (i) self-reported frequency and duration of PA and ST as well as related cognitions, (ii) objectively measured PA and ST using technical devices, e.g., accelerometer, and (iii) physical examinations, e.g., standardized measurement of blood pressure or waist circumference. However, assessing past behavior, intentions, or other related cognitions may change the behavior that is investigated. This phenomenon is known as mere-measurement effect (MME) [2]. Altering behavior as a result of MME may occur because (i) attitudes towards the behavior are more accessible, (ii) cognitive dissonance is raised when realizing a desirable behavior is not performed, or (iii) the behavior is simulated in the mind which increases likelihood of performance at the next opportunity [3, 4]. If participants of intervention trials change their behavior as a reaction to baseline assessments this may introduce bias to the investigated intervention outcomes [2, 5, 6]. Both participants in the intervention and in the control group may alter their behavior in a way similar to the behavior change that is intended by an intervention, thus, intervention effects may be underestimated. It was also suggested that baseline assessments may increase receptiveness to an intervention. This could yield some kind of synergetic effect which may result in an overestimation of intervention effects [7, 8].

There is evidence that measuring PA by self-report or device as well as measuring related constructs changes various PA outcomes assessed by self-report [9, 10] or device [11, 12]. Two recent meta-analyses [4, 13] found small effect sizes for MME, nevertheless, both suggested that estimates were inflated due to publication bias. Moreover, it was found that several studies showed considerable risk of bias indicating further overestimation of the small effect size [13, 14]. Thus, evidence on MME remains inconclusive.

Although MME poses a problem in intervention trials [2], researchers usually do not examine whether changes in the target behavior occurred under absence of any intervention components, that is, due to MME. Further, studies investigating MME mostly assess outcomes after a short period of time, for example, 6 weeks [15–17] without an extended follow-up. Finally, we are not aware of studies investigating MME on ST.

The aim of our study was (i) to identify potential MME of a cardiovascular examination program on PA and ST indicated by significant differences in leisure-time PA, transport-related PA, and overall ST between baseline assessment and 12-month follow-up measured via self-report in a sample of apparently healthy adults and (ii) to investigate whether a brief tailored letter intervention may have an additional effect indicated by differences over time in a respective subsample.

Methods

Study sample

As described elsewhere [18], persons aged between 40 and 75 years were recruited for a prior study between June 2012 and December 2013 in general practices, job centers, and via one statutory health insurance. A random sample of 513 people was drawn from individuals who agreed to be contacted again ($n = 1165$, 95%) and fulfilled the following eligibility criteria: age between 40 and 65 years, no history of cardiovascular event (myocardial infarction or stroke) or vascular intervention, self-reported body mass index ≤ 35 kg/m^2, and resident in a pre-defined zip-code area. Among them, 401 persons were contacted and invited to participate in a study aimed to assess the feasibility of a tailored counselling letter intervention to increase PA and to reduce ST during leisure time. A number of 175 agreed to participate and gave written informed consent. For analyses, 22 cases were excluded because they severely exceeded the given time frame of 2 weeks to respond to assessments. Thus, the final sample comprised 153 individuals (Fig. 1).

Procedure

The current study was conducted between February 2015 and August 2016. All participants were invited to the cardiovascular examination center of the University Medicine Greifswald, where they received blood sample taking and standardized measurement of blood pressure, waist circumference, body height, and body weight. Afterwards, they wore an accelerometer for 7 days. Prior to the examination, participants completed a paper-pencil questionnaire on PA and ST. After baseline assessments, participants were randomized into an assessment-only group ($n = 85$) and an intervention group ($n = 90$). Self-administered assessments regarding PA and ST were conducted at month 1, 3, 4, 6, and 12. In addition, at 12-month follow-up, participants underwent the same procedure and assessments as at baseline. Only individuals of the intervention group received up to three tailored letters to their self-reported PA and ST at month 1, 3, and 4 (Fig. 1).

The study was approved by the clinical ethical committee of the University Medicine Greifswald (protocol number BB 002/15a).

Measures

Physical activity and sedentary time

To assess PA and ST at baseline and at month 1, 6, and 12, the International Physical Activity Questionnaire

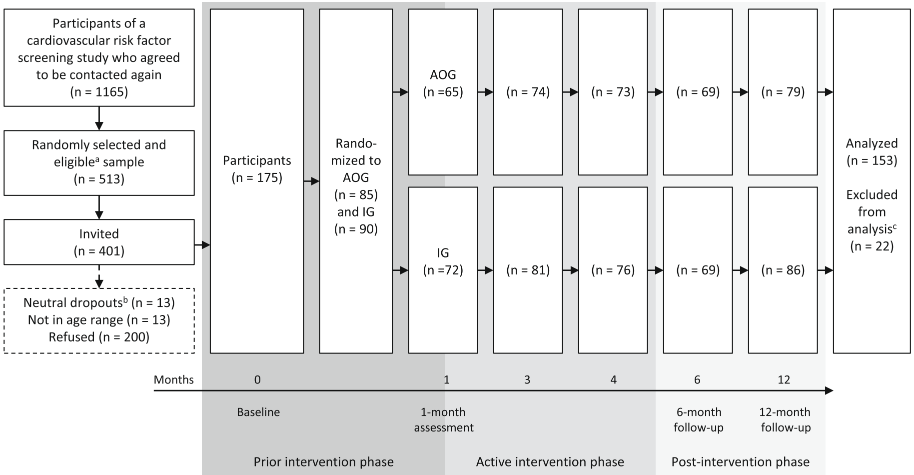

Fig. 1 Flow of participation and study design. AOG = Assessment-only group. IG = Intervention group. Assessments at baseline and at 12 months included: paper-pencil questionnaires on socio-demographics, physical activity, and sedentary time as well as physical examination (standardized measurement of blood pressure, body height, body weight, and waist- and hip-circumference, blood sample taking) and 7-day-accelerometry. Assessments at months 1, 3, 4, and 6 included: paper-pencil questionnaires on physical activity and sedentary time. [a] Eligibility criteria: age ≥ 40 and ≤ 65 years, no history of cardiovascular event (myocardial infarction or stroke) or vascular intervention, self-reported body mass index ≤ 35 kg/m^2, resident in a pre-defined zip-code area. [b] had died, had a cardiovascular event or intervention, were too ill to participate, or moved away. [c] due to late response

(IPAQ) was used [19]. The IPAQ measures frequency, duration, and intensity of PA during the last 7 days in various domains of life as well as overall time spent sedentarily during weekdays and weekends. The leisure-time domain includes walking, PA on a moderate-intensity level, and PA on a vigorous-intensity level. The transportation domain includes walking and cycling. In order to sum time spent in PA within one domain, amounts of time spent in one activity are multiplied by their metabolic equivalent of task (MET) values which account for the intensity of the activity. Leisure-time and transport-related PA in MET-hours per week and overall ST in hours per week were calculated according to the IPAQ protocol [20].

Socio-demographic, health, and context variables

Several socio-demographic, health, and context variables were collected and considered as covariates for analyses: Socio-demographics were obtained by a self-administrative questionnaire at baseline including sex, age (in years), educational level (< 10, 10, > 10 years), employment status (full-time or part-time, irregularly, not employed), and current partnership (yes, no). Body mass index (< 25 kg/m^2, ≥ 25 kg/m^2 and < 30 kg/m^2, ≥ 30 kg/m^2) was calculated from body height (using digital scales MZ 10020, ADE GmbH & Co., Hamburg, Germany) and weight (using digital scales SOEHNLE 7720, Soehnle Industrial Solutions GmbH, Backnang, Germany). Context variables included season at baseline data collection (winter, spring, summer) and setting of initial recruitment (general practices, job centers, statutory health insurance).

Statistical analyses

Latent growth models [21] were used to examine changes in leisure-time PA, transport-related PA, and overall ST over a period of 12 months. MME was indicated by significant differences of those outcomes between baseline and 1-month assessment, that is, before the intervention started and by significant changes between month 1 and 12 in the assessment-only group. *P*-values below .05 were considered statistically significant. Using latent growth models enables to model complex non-linear outcome growth curves, to capture individual differences, and to properly estimate models with missing data [22]. To account for non-linear associations between the outcomes and time, a piecewise model approach was used. Thus, time was divided into intervals at months 1 and 6, allowing each trajectory to have three distinct slopes. Interaction terms of study group and time were included starting from 1-month assessment to capture differences in trajectories between assessment-only group and intervention group. Likelihood ratio tests were used to test whether random intercepts or random slopes (i.e., between-person variability around the average growth curve) are required. Leisure-time PA and transport-related PA were modelled as negative-binomial variables due to strongly right-skewed distributions. Incidence rate ratios (IRRs) were reported for both PA outcomes. Overall ST was square root transformed to account for its slightly right-skewed distribution and then modelled as a continuous variable. A maximum likelihood estimator was used. Models were estimated under a missing at random assumption using all available data from participants with responses on the outcome variable on at least one time point and with complete responses on covariates. In addition to sex and age, results were adjusted for socio-demographic, health, and context variables that were distributed differently between follow-up responders and non-responders. Thus, education was included as a covariate as multiple logistic regression analyses had revealed that lower education was predictive for dropout ($p < .05$). Data were analyzed using Stata/SE version 14.2 [23].

Results

Sample characteristics

There were 98 women (64%) and 55 men (36%) with a mean age of 54.5 years (standard deviation = 6.2; Table 1). At baseline, participants were physically active for 15.6 MET-hours per week during leisure time (Median; Interquartile range [IQR]: 3.3–33.1), for 13.1 MET-hours per week during transport (Median; IQR: 2.2–26.2), and spent 40 h per week sedentarily (Median; IQR: 28.5–56.0).

Changes between baseline and 1-month assessment

Because the intervention started after the 1-month assessment, study groups were not analyzed separately between baseline and month 1. Time spent in PA during leisure time increased over the first month by 0.13 log MET-hours per week, but the effect was not significant (IRR = 1.13, $p = .432$). Time spent in PA for transport increased significantly by 0.31 log MET-hours per week (IRR = 1.37, $p = .023$). Overall ST decreased by 1.96 square root minutes per week, but the effect was not significant ($p = .060$; Table 2, Fig. 2).

Changes between 1-month assessment and 12-month follow-up

Assessment-only group

Participants in the assessment-only group did not significantly change leisure-time PA between 1 and

Table 1 Baseline characteristics of the study sample (*n* = 153)

		n	Mean (SD) or median (IQR) or n (%)
Sex	Women	153	98 (64.1%)
Age (years)		153	54.5 (SD 6.2)
Education (years)		150	
	< 10		12 (8.0%)
	= 10		102 (68.0%)
	> 10		36 (24.0%)
Employment		150	
	Full-time or part-time		103 (68.7%)
	Not regularly		16 (10.7%)
	Not employed		31 (20.7%)
Current partnership	yes	153	108 (70.6%)
Body mass index (kg/m^2)		152	
	< 25		42 (27.6%)
	≥ 25 and < 30		58 (38.2%)
	≥ 30		52 (34.2%)
Season		153	
	winter		17 (11.1%)
	spring		127 (83.0%)
	summer		9 (5.9%)
Recruitment		153	
	General practices		56 (36.6%)
	Job centers		34 (22.2%)
	Health insurance		63 (41.2%)
Leisure-time physical activity (MET-hours/week)		122	15.6 (IQR 3.3; 33.1)
Transport-related physical activity (MET-hours/week)		131	13.1 (IQR 2.2; 26.2)
Overall sedentary time (hours/week)		138	40.0 (IQR 28.5; 56.0)

Notes: *n* number of subjects, *SD* standard deviation, *IQR* interquartile range, *MET* metabolic equivalent of task

Table 2 Parameter estimates for latent growth models of leisure-time physical activity ($n = 145$), transport-related physical activity ($n = 146$), and overall sedentary time ($n = 150$)

	Leisure-time physical activity (log MET-hours/week)			Transport-related physical activity (log MET-hours/week)			Overall sedentary time (sqrt min/week)		
	Est.	(SE)	*p*-value	Est.	(SE)	*p*-value	Est.	(SE)	*p*-value
Fixed effects									
Intercept	2.84	(0.16)	<.001	2.69	(0.14)	<.001	49.36	(1.19)	<.001
Slope (0 to 1 month)	0.13	(0.16)	.432	0.31	(0.14)	.023	−1.96	(1.04)	.060
Slope (1 to 6 months)	−0.06	(0.04)	.156	−0.04	(0.04)	.334	0.06	(0.28)	.842
Slope (6 to 12 months)	0.02	(0.04)	.673	−0.00	(0.03)	.951	− 0.52	(0.25)	.037
Slope (1 to 6 months × study group)	0.08	(0.05)	.111	0.00	(0.05)	.912	−0.23	(0.35)	.521
Slope (6 to 12 months × study group)	−0.04	(0.05)	.401	0.03	(0.05)	.467	0.56	(0.35)	.109
Random effects									
Intercept	0.90	(0.16)		0.85	(0.15)		7.89	(0.62)	
Slope	–			–			–		

Notes: *MET* metabolic equivalent of task, *Est.* estimate: mean (fixed effects), standard deviation (random effects: intercept, slope), *SE* standard error, × interaction term, – fixed at zero as indicated by likelihood ratio test
All slopes are linear. Models were adjusted for time-invariant covariates: sex, age, and education

6 months (IRR = 0.94, $p = .156$) or between 6 and 12 months (IRR = 1.02, $p = .673$). Transport-related PA did not significantly change between 1 and 6 months (IRR = 0.96, $p = .334$) or between 6 and 12 months (IRR = 1.00, $p = .951$). Overall ST did not change between 1 and 6 months ($p = .842$). Between 6 and 12 months, overall ST decreased significantly by 0.52 square root minutes per week ($p = .037$; Table 2, Fig. 2).

Intervention group

Time × study group interactions revealed that in the intervention group time trends of leisure-time PA, transport-related PA, and overall ST did not differ significantly from those in the assessment-only group both between 1 and 6 months and between 6 and 12 months (Table 2, Fig. 2).

Discussion

There are two main findings of our study. First, participants increased self-reported transport-related PA, tended to decrease overall ST, and did not change leisure-time PA, after baseline assessment prior to the intervention period. Further, participants in the assessment-only group decreased overall ST between 6 and 12 months. These findings indicate the presence of MME. Second, in the intervention group changes over time on any of the three behaviors did not significantly differ from those observed in the assessment-only group. This indicates that the intervention did not have an effect in addition to MME.

Similar to previous findings on PA, MME was significant for one investigated PA outcome whereas comparisons on another outcome were not significant. For example, van Sluijs et al. [10] found evidence for MME on meeting recommendations on PA (30 min of at least moderate-intensity PA on at least 5 days a week), but not on other PA outcome measures, such as a categorical variable of minutes per week of moderate-to-vigorous-intensity PA. Thus, it seems to be important to consider the specific outcome measure of PA when evaluating MME.

To our knowledge, this is the first study that explicitly investigated potential effects of MME on ST. Changes during the first month after baseline were marginally significant in the expected direction indicating that MME may have altered levels of overall ST. Further, overall ST decreased after 6-month follow-up in the assessment-only group. As Ogden [24] suggested, completing a questionnaire may create new cognitions on a behavior, particularly if the behavior is novel or unfamiliar.

Starting from 1-month assessment, a random subsample of participants received a brief tailored counseling letter intervention. At 6-month follow-up, that is, shortly after the intervention period, participants in the intervention group reported an increase in leisure-time PA, whereas participants in the assessment-only group reported a reduction. Nevertheless, this difference was not statistically significant. Subsequent time trends did not indicate distinct levels of leisure-time PA between study groups after 12 months. Similar, results for transport-related PA suggest that study groups did not differ between 1 and 12 months. Whereas levels of overall ST in both groups appeared relatively constant over the course of the intervention period, time trends between 6 and 12 months suggest a less favorable development in the intervention group than in the assessment-only group. Thus, it seems that the brief tailored letter intervention did not give additional benefit over differences due to MME for all investigated

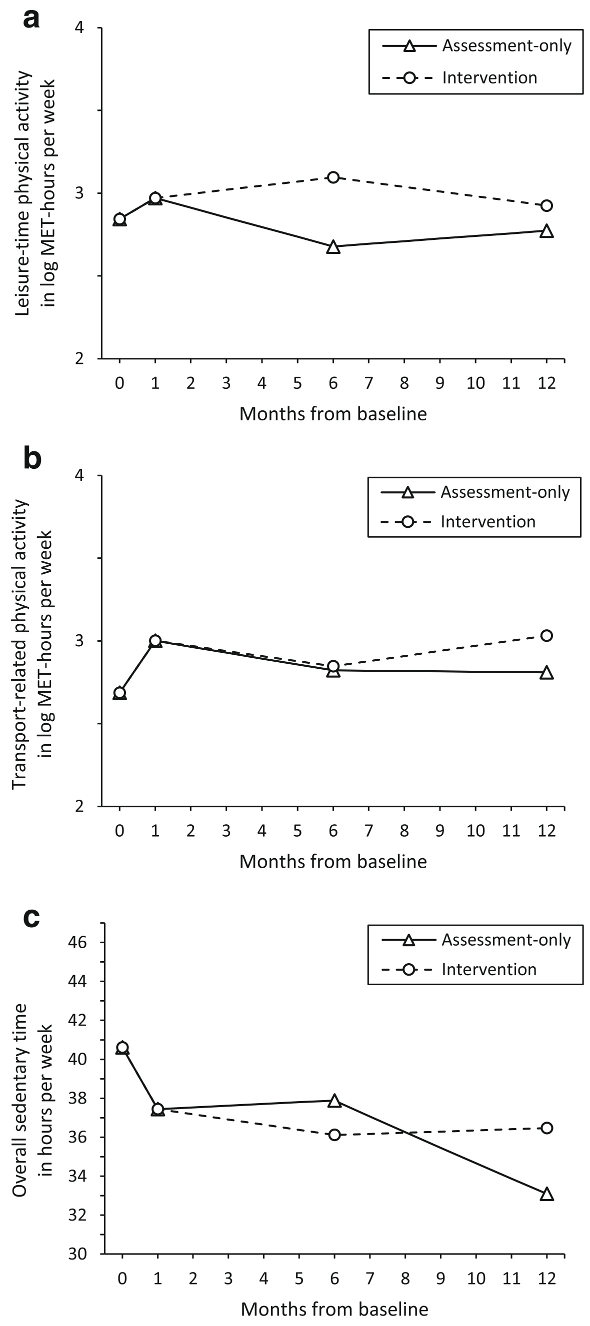

Fig. 2 Estimated average linear growth curves for log MET-hours per week of leisure-time physical activity (**a**), log MET-hours per week of transport-related physical activity (**b**), and hours per week of overall sedentary time (**c**) separately for assessment-only group and intervention group. MET = Metabolic equivalent of task. Results were adjusted for sex, age, and education. Slope variances fixed to zero as indicated by likelihood ratio tests. To raise intuitive understanding, the outcome of sedentary time was re-calculated into hours per week

outcomes. This would be consistent with the presumption of intervention effects being difficult to detect if MMEs are present in an intervention trial [8].

Three limitations of this study should be acknowledged. First, we cannot conclude which part of the research process induced MME. Baseline measurement comprised several assessments, such as self-report questionnaires on behaviors and cognitions, standardized measurement of blood pressure and waist circumference, and wearing an accelerometer. Nevertheless, previous research suggests no dose-response relationships for MME on health behaviors [13] and participants may even alter their behavior as a response to necessities like signing a consent form [8]. Second, conclusions on the presence or absence of measurement and intervention effects on any of the three behaviors should be treated with caution because our findings may suffer from a lack of power to detect differences. Third, generalizability of our findings may be compromised due to selection bias. The proportion of individuals who declined participation was high (53%) and non-participation was associated with smoking, lower education, and female sex.

Future research evaluating effects in PA and ST intervention trials should take into account that results can be biased due to MME. First, participants may change PA and ST as a reaction to baseline assessment. Therefore, an intervention may not have an effect in addition to MME. Especially in the context of brief interventions where interventions consist of short feedback letters rather than comprehensive exercise training, expected intervention effects are modest and therefore may be difficult to detect. Second, it should be considered that effects refer not alone to intervention components, but in fact to the combined impact of both intervention and assessments. Specifically in brief interventions, it should be acknowledged that assessments are part of the intervention. It may be more reasonable to compare the intervention group with controls that did not receive any assessments. Third, our findings of long-term effects of MME on ST should be verified, as it has been suggested that measurement itself could be a feasible and cost-effective public-health intervention [13].

Conclusion

In conclusion, study results suggest the presence of measurement effects within a PA and ST intervention trial on transport-related PA and overall ST, but not on leisure-time PA. A brief tailored letter intervention did not produce effects in addition to MME. Future studies may need to consider the potential influence of MME by choosing an appropriate study design or cautious interpretation of intervention outcomes.

Abbreviations

IPAQ: International Physical Activity Questionnaire; IQR: Interquartile range; IRR: Incidence rate ratio; MET: Metabolic equivalent of task; MME: Mere-measurement effect; PA: Physical activity; ST: Sedentary time

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Availability of data and materials
The data that support the findings of this study are available from the corresponding author on reasonable request. Researchers requesting the data will be required to sign a contract ensuring data usage in compliance with the statement given in the informed consent procedure and with the German data protection law, that the data will not be transferred to others, and that the data will be deleted after the intended analysis has been completed. The data are not publicly available due to potential privacy restrictions. To comply with the statement given in the informed consent procedure, the use of the data is restricted to medical research purposes. We cannot ensure to prevent use for other purposes when uploading the data for public access.

Authors' contributions
LV performed data analyses and drafted the work. FW, UJ, and SU designed the study. AU, FW, and SU were involved in collection and preparation of data. SB, AU, FW, UJ, and SU were involved in interpretation of data and in revising the work critically for important intellectual content. All authors approved the final version of the manuscript.

Ethics approval and consent to participate
The ethics committee of the University Medicine Greifswald approved the study (BB 002/15a). All participants provided informed written consent prior to participation.

Consent for publication
All participants provided written consent that was based on study information sheet which included the statement that all scientific publications will not include personal data (e.g., name, birth date, and address).

Competing interests
The authors declare that they have no competing interests.

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Do Sociodemographic Variables and Cardiometabolic Risk Factors Moderate the Mere-Measurement Effect on Physical Activity and Sedentary Time?

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Abstract

Background: Participation in an assessment may change health behavior. This "mere-measurement effect" may be used for prevention purposes. However, little is known about whether individuals' characteristics moderate the effect. The objective was to explore whether changes of physical activity (PA) and sedentary time (ST) after a cardiovascular assessment depend on sociodemographic variables and cardiometabolic risk factors.

Methods: A sample of 175 adults aged 40 to 65 years received self-administered assessment of PA and ST, standardized measurement of blood pressure, waist circumference, and blood parameters, and seven-day accelerometry. After five weeks, participants again reported PA and ST without any prior treatment or intervention. Dependence of five-week changes in PA and ST on sociodemographic and cardiometabolic variables was analyzed using linear regression models.

Results: Men increased transport-related PA more than women (b = 9.3 MET-hours/week, P = .031). Men with higher triglycerides increased transport-related PA less than men with lower triglycerides (b = -5.6 MET-hours/week, P = .043). Men with higher systolic blood pressure reduced ST more than those with lower systolic blood pressure (b = -35.7 minutes/week, P = .028). However, this linear association ceased to exist at a level of approximately 145 mmHg (b of squared association = 1.0, P = .080). A similar relationship was found for glycated hemoglobin and ST.

Conclusions: The findings suggest that sex and cardiometabolic risk factors moderate mere-measurement effects on PA and ST. Researchers and practitioners using mere measurement for prevention purposes may address PA and ST according to those individual differences.

Keywords: mere-measurement effect, question-behavior effect, reactivity, cardiometabolic risk factors, physical activity, sedentary time

Introduction

Participation in an assessment may change the behavior that is aimed to be investigated [1,2]. In health behavior research, such effects have been called "mere-measurement effect", "assessment reactivity", or "question-behavior effect" [3,4]. A meta-analysis found small but significant effect sizes for measurement of physical activity (PA) [4]. Altering PA can occur as a result of wearing a device [5,6] or filling out a questionnaire on past behavior or on cognitions related to PA [7,8]. Several mechanisms underlying the mere-measurement effect have been discussed. Participants may change their behavior, for example, as a result of reflecting on their attitudes or on discrepancies between beliefs and actual behavior [9].

It has been suggested that the mere-measurement effect could be used as a simple and cost-effective intervention to improve health behavior among populations [8,10-12]. Thus, it needs to be verified that the potential benefit of the effect is not systematically attenuated among groups of individuals according to sociodemographic and health related characteristics. However, there is a lack of evidence about sex, age, and socioeconomic status as moderators of the mere-measurement effect. A recent study on several health behaviors could not conclusively demonstrate a difference in the effect across socioeconomic groups which would potentially lead to increased health inequalities [13].

Associations between regular PA and cardiovascular health are well established [14-16]. Evidence for increased health risks of prolonged sedentary time (ST) have become more consolidated [17,18]. Thus, it seems of particular interest whether the mere-measurement effect on PA and ST differentially affects individuals with various cardiometabolic risk factors. If improvements of PA and ST result from an increased awareness of discrepancies between desired and actual behavior, individuals with a less favorable cardiometabolic risk profile may be more likely to respond to the mere-measurement effect than individuals with a more favorable risk profile. In contrast, if general benefits from the effect are less pronounced among those with a less favorable cardiometabolic risk profile, it may lead to detrimental effects of health promotion using mere measurement.

In a previous study, it was found that participants of a cardiovascular examination program subsequently increased PA for transport and tended to decrease ST without any formal treatment, referral, or intervention [19]. As little research has been conducted on individual characteristics of the participants, the objective of the present study was to explore whether the mere-measurement effect on leisure-time PA ($PA_{leisure}$), transport-related PA ($PA_{transport}$), and ST after attending a cardiovascular examination is moderated by sociodemographic variables (sex, age, and employment) and cardiometabolic risk factors (systolic blood pressure [SBP], waist circumference, glycated hemoglobin [HbA1c], total cholesterol, high-density lipoprotein [HDL], and triglycerides).

Methods

Study Sample

Participants of this study were recruited for a cardiovascular risk factor screening study at general practices, job centers, and via one statutory health insurance company in Northeastern Germany between June 2012 and December 2013. The study is described more detailed elsewhere [20]. Among individuals who agreed to be contacted again (n = 1165, 95%) 513 persons were randomly selected who fulfilled the following eligibility criteria: age ≥ 40 and ≤ 65 years, no history of cardiovascular event (myocardial infarction or stroke) or vascular intervention, self-reported body mass index ≤ 35 kg/m², and residency in a pre-defined zip-code area. Of those, 401 individuals were offered participation in a study aimed to assess the feasibility of a tailored counselling letter intervention to increase PA and to reduce ST during leisure time. A number of 175 agreed and gave written informed consent for participation. The study was conducted between February 2015 and August 2016. The present study exploring the mere-measurement effect comprised baseline assessment and the first follow-up assessment. At follow-up, five weeks after baseline, 78% still participated (Figure 1).

- Figure 1 -

Procedure

All participants were invited via letter to the cardiovascular examination center of the University Medicine Greifswald for a baseline assessment of cardiometabolic risk factors. Prior to the examination, they completed a self-administered paper-pencil questionnaire on PA, ST, and sociodemographic variables. The questionnaire was sent to respondents via letter mail and was returned at the appointed day at the examination center. Participants received blood sample taking and standardized measurement of blood pressure, waist circumference, body height, and body weight. Starting the day after the examination, they wore an accelerometer for seven consecutive days. The follow-up assessment was realized five weeks after baseline using a self-administered paper-pencil questionnaire on PA and ST sent via letter mail. The study was approved by the clinical ethical committee of the University Medicine Greifswald (protocol number BB 002/15a).

Measures

Physical Activity and Sedentary Time

To assess PA and ST at baseline and follow-up, the International Physical Activity Questionnaire (IPAQ) was used [21]. The IPAQ measures frequency, duration, and intensity of PA during the last seven days in four domains of life including leisure time and transportation. $PA_{leisure}$ comprises walking, PA on a moderate-intensity level, and PA on a vigorous-intensity level. $PA_{transport}$ includes walking and cycling. In order to sum time spent in each domain, time spent in one activity is multiplied by its metabolic equivalent of task (MET) value, which accounts for the intensity of the activity. ST is reported separately for weekdays and weekend days independent of the domain. $PA_{leisure}$ and $PA_{transport}$ in MET-hours per week and ST in minutes per week were calculated according to the IPAQ protocol [22].

Sociodemographics

Sex, age (years), employment (yes/no), and current living together with a partner (yes/no) was assessed at baseline by a self-administered questionnaire.

Cardiometabolic Risk Factors

Blood pressure was assessed at the cardiovascular examination center in a seating position via standardized measurement using a digital blood pressure monitor (705IT, Omron Corporation, Tokyo, Japan). After a five-minute resting period, blood pressure was measured three times with three minutes rest between each measurement. Assessments were conducted by trained and certificated medical staff. For data analysis, the means of second and third measurements of systolic and diastolic blood pressure (mmHg) were used. Antihypertensive medication prescribed within the last 12 months (yes/no) was assessed by questionnaire. Waist circumference (cm) was measured midway between lowest rib and iliac crest using an inelastic tape. Non-fasting blood samples were taken and HbA1c (mmol/mol), plasma total cholesterol (mmol/L), HDL (mmol/L), and triglycerides (mmol/L) were determined by standard methodology at the Institute for Clinical Chemistry and Laboratory Medicine of the University Medicine Greifswald.

Statistical Analysis

Data were analyzed with Stata/SE version 14.2 [23]. Multiple imputation using chained equations was performed to account for missing data. The approach of this method is to use the distribution of the observed data to estimate a set of plausible values for the missing data. 80 imputed data sets were used, which were combined to obtain the overall estimates, variances, and confidence intervals for linear regression models of $PA_{leisure}$, $PA_{transport}$, and ST. The imputation model was built using the outcomes, predictors, and covariates of the main analysis models. In addition, a number of seven auxiliary variables (e.g., current partnership, diastolic blood pressure) were included to improve the imputation model. To account for skewed continuous variables, the predictive mean matching method was used [24].

Three outcomes were investigated: five-week changes of self-reported $PA_{leisure}$, $PA_{transport}$, and ST (calculated as follow-up value minus baseline value). Linear regression analyses were calculated to estimate associations between sociodemographic characteristics as well as cardiometabolic risk factors and the outcomes. Robust standard errors were used to account for potential estimation bias. First, associations between sex, age, and employment and the outcomes were investigated in one model separately for each outcome. Employment but not school education as an indicator for socioeconomic status was investigated because non-participation in this study was associated with lower education and the number of individuals with < 10 years of school education was low (n = 12). Second, because sex differences were found (results presented in supplementary table S1), all analyses were stratified. Third, each cardiometabolic risk factor was tested in a separate model. All models were adjusted for age, employment, duration between baseline and follow-up, and baseline $PA_{leisure}$, $PA_{transport}$, or ST, respectively. Associations between SBP and the outcomes were additionally adjusted for blood pressure lowering medication. In all analyses, likelihood ratio tests were used to decide whether to include quadratic terms of age or cardiometabolic risk factors in the models. P-values < .05 were considered statistically significant. As the study was not powered for subgroup analyses, findings with P-values < .10 are reported additionally indicating trends towards moderation effects. In addition to the main analysis using multiply imputed data, a sensitivity analysis was conducted using complete cases.

Results

Sample Characteristics

There were 112 women (64.0%) and 63 men (36.0%) in the study sample. The mean age was 54.4 years (SD = 6.2) and 80.8% were employed. The mean difference of $PA_{leisure}$ between baseline and follow-up was M = 4.3 MET-hours per week (SD = 29.0) and, accordingly, M = 6.5 MET-hours per week (SD = 20.3) for $PA_{transport}$ and M = -163.2 minutes per week (SD = 1039.5) for ST. The mean duration between baseline and follow-up was 39.2 days (SD = 8.9). Descriptive statistics of cardiometabolic risk factors are shown in Table 1.

- Table 1 -

Associations between Sociodemographic Characteristics and Physical Activity and Sedentary Time

Men increased $PA_{transport}$ more than women (b = 9.3 MET-hours/week [95% CI: 0.9; 17.7], P = .031) and older individuals tended to increase $PA_{transport}$ more than younger individuals (b = 0.5 MET-hours/week [95% CI: -0.03; 1.1], P = .065, Table S1). After stratification by sex, the association between $PA_{transport}$ and age disappeared. There was a tendency towards a quadratic association between age and the reduction of ST in women (linear term: b = 0.8 minutes/week [95% CI: -34.0; 35.5] P = .965; quadratic term: b = -6.5 [95% CI: -13.4; 0.3], P = .061). No associations between employment and the outcomes were found (Table 2).

- Table 2 -

Associations between Cardiometabolic Risk Factors and Physical Activity and Sedentary Time

In men, results indicated a U-shaped association between SBP and the reduction of ST (linear term: b = -35.7 minutes/week [95% CI: -67.3; -4.0] P = .028; quadratic term: b = 1.0 [95% CI: -0.1; 2.1] P = .080; Table 3, Figure 2 A). In women, there was a trend towards a quadratic association between SBP and the increase of $PA_{leisure}$ (linear term: b = 0.2 MET-hours/week [95% CI: -0.2; 0.7] P = .306; quadratic term: b = 0.02 [95% CI: -0.003; 0.04], P = .093). In men, a U-shaped association between HbA1c and the reduction of ST (linear term: -93.0

minutes/week [95% CI: -152.6; -33.4] *P* = .003; quadratic term: *b* = 6.2 [95% CI: -0.4; 12.9] *P* = .064; Figure 2 B) was found.

In men, there was a trend towards a quadratic association between HDL and the reduction of ST (linear term: *b* = -562.8 minutes/week [95% CI: -1590.4; 464.9] *P* = .275; quadratic term: *b* = -1928.3 [95% CI: -3912.8; 56.2], *P* = .057). Women with higher HDL tended to increase $PA_{transport}$ more than women with lower HDL (*b* = 10.6 MET-hours/week [95% CI: -1.2; 22.4] *P* = .077). Men with higher triglycerides increased $PA_{transport}$ less than men with lower triglycerides (*b* = -5.6 MET-hours/week [95% CI: -11.1; -0.2] *P* = .043). No associations between waist circumference or total cholesterol and the outcomes were found. Sensitivity analyses using complete cases yielded similar results, which are presented in supplementary tables S2, S3, and S4.

- Table 3 and Figure 2 -

Discussion

This study aimed to explore moderators of the mere-measurement effect in adults as indicated by associations between sociodemographic variables and cardiometabolic risk factors and changes in PA and ST after attending a cardiovascular examination program. The data revealed two main findings. First, men increased $PA_{transport}$ more than women. Age tended to be associated with $PA_{transport}$. Second, among men, results revealed U-shaped associations both between SBP and HbA1c and the reduction of ST. And, men with higher triglycerides increased $PA_{transport}$ less than men with lower triglycerides.

In this sample, men might have increased $PA_{transport}$ more than women because of a possibly worse health condition as indicated by less favorable values of SBP, HDL, and triglycerides. In line with suggested mechanisms underlying the mere-measurement effect [3,9], men might have altered their behavior as their awareness of the relationship between behavior and health increased in response to reflecting on activity levels when completing a detailed 27-item-questionnaire followed by the assessment of cardiometabolic risk factors. Further, evidence suggests that the built environment is an important factor associated with active transport [25,26]. Changing $PA_{transport}$ may not be achievable to any individual due to long distances between home and work or other daily responsibilities that require transportation using motor vehicles.

Despite the fact that the present sample was restricted to 40- to 65-year olds, it was found that older participants tended to increase $PA_{transport}$ more than younger participants. This may be contrary to expectations as prior meta-analyses comparing student samples with non-student samples including older adults may hint at a larger measurement effect among young adults compared to older adults [9,27]. However, compared to younger participants, older participants in this sample had higher levels of HbA1c, total cholesterol, and triglycerides (data not shown). Thus, older participants may have a worse health condition and, therefore, may have been more motivated to increase PA.

Associations between SBP as well as HbA1c and ST in men indicate that those with less favorable risk factors improve more than those with more favorable risk factors. In contrast, results on PA point to the opposite direction. Associations between triglycerides and $PA_{transport}$ in men and between HDL and $PA_{transport}$ in women revealed that those with more favorable values improved their behavior more than those with less favorable values. Thinking about weekly ST independent of PA levels might have motivated men with a less favorable risk profile to alter inactivity on a lower threshold, in contrast to men in good health, who altered PA rather than ST. Compared to men, women in this sample had more favorable cardiometabolic risk factors which might explain why these factors did not moderate changes of PA and ST in women.

There are four limitations to consider. First, a selection of highly motivated individuals is likely. The proportion of individuals who declined participation was high (53%) and non-participation was associated with smoking, lower education, and female sex. Thus, the findings may not be generalizable to the general population. Second, systematic changes in PA and ST observed in this non-controlled study do not necessarily imply mere-measurement effects. To reduce potential confounding, adjustments were made for variables related to individuals' characteristics and data collection. Future research on transport-related PA should take additional context variables into account, e.g., the distance between home and work. Third, PA and ST were assessed using self-report measures. Due to social desirability bias [28,29], PA might have been over-reported and ST might have been under-reported in this study. Recent research revealed higher odds of having metabolic syndrome for men who did not meet PA guidelines according to accelerometry data than for men who met the guidelines [30]. However, this relationship disappeared when PA was measured via self-report, which might hint at an over-reporting of PA by men with metabolic syndrome. Similarly, in this sample, men with less favorable risk factors might have under-reported ST. Future studies could assess behavior change via direct measures, e.g. accelerometry, using wearing periods of at least two weeks since prior research suggested the presence of reactivity bias during the first week of measurement [5,6]. Finally, the findings may suffer from a lack of power to detect differences, as this study was not particularly designed to investigate moderators of the mere-measurement effect.

Conclusion

The findings of this study suggest that beneficial alterations of PA and ST after a cardiovascular examination program may be moderated by sex, age, and cardiometabolic risk factors. Researchers and practitioners using the mere-measurement effect to promote behavior change should consider these individual characteristics. For example, completing a questionnaire on PA or ST while waiting in a physician's practice may trigger new thinking about a behavior in a patient. If cardiometabolic risk factors are assessed, a deeper awareness of the relationship between inactivity and health risks may be raised. In the course of this, men with a less favorable risk profile, for example, may be more responsive to answering a questionnaire on ST instead of PA. Future research using larger sample sizes is needed to verify the moderators found in this exploratory study and to investigate long-term effects on behavior and health.

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Table 1. Characteristics of the study sample (*n* = 175)

Variables	Overall (*n* = 175)		Women (*n* = 112)		Men (*n* = 63)		
	n	**Values**	***n***	**Values**	***n***	**Values**	***p***
Sociodemographic variables							
Age (years)	175	54.4 ± 6.2	112	54.6 ± 6.2	63	54.0 ± 6.1	ns
Employment (yes)	172	139 (80.8%)	110	88 (80.0%)	62	51 (82.3%)	ns
Cardiometabolic risk factors							
Systolic blood pressure (mmHg)	172	126.8 ± 14.7	109	123.0 ± 13.9	63	133.4 ± 13.7	<.001
Diastolic blood pressure (mmHg)	172	76.6 ± 9.5	109	75.1 ± 9.0	63	79.1 ± 9.9	.009
Blood pressure lowering medication (yes)	167	67 (40.1%)	104	47 (45.2%)	63	20 (31.8%)	ns
Waist circumference (cm)	173	91.6 ± 12.5	110	87.9 ± 12.3	63	98.1 ± 10.0	<.001
HbA1c (mmol/mol)	170	39.1 ± 6.0	108	39.3 ± 6.5	62	38.9 ± 4.9	ns
Total cholesterol (mmol/L)	171	5.3 ± 1.0	109	5.4 ± 1.1	62	5.0 ± 0.9	.034
HDL (mmol/L)	168	1.4 ± 0.4	106	1.5 ± 0.4	62	1.2 ± 0.3	<.001
Triglycerides (mmol/L)	172	1.6 ± 1.0	111	1.5 ± 0.9	61	1.9 ± 1.1	.008
Context variables							
Duration from baseline to follow-up (days)	137	39.2 ± 8.9	90	38.6 ± 6.7	47	40.4 ± 12.1	ns
Physical activity and sedentary time							
Difference in leisure-time physical activity (MET-hours/week)	98	4.3 ± 29.0[a]	61	2.7 ± 25.4[a]	37	6.9 ± 34.3[a]	ns
Difference in transport-related physical activity (MET-hours/week)	110	6.5 ± 20.3[a]	72	2.0 ± 16.4[a]	38	15.0 ± 24.3[a]	.001
Difference in sedentary time (minutes/week)	120	-163.2 ± 1039.5[a]	79	-175.9 ± 929.4[a]	41	-138.7 ± 1236.8[a]	ns

HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; MET: metabolic equivalent of task; ns: not significant
Data are presented as mean ± standard deviation for continuous variables and as the number of participants (%) for categorical variables. Presented p-values for comparisons between women and men are based on t-test for continuous variables and chi-square test for categorical variables.
[a] Positive mean values indicate an increase from baseline to follow-up and negative values indicate a reduction.

Table 2. Results of linear regression analyses regarding associations between sociodemographic characteristics and changes in self-reported physical activity and sedentary time separately for women (*n* = 112) and men (*n* = 63)

	Leisure-time physical activity Δ (MET-hours per week)		Transport-related physical activity Δ (MET-hours per week)		Sedentary time Δ (minutes per week)	
	Women	Men	Women	Men	Women	Men
	b [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]
Age (years)	0.7 [-0.3; 1.7]	0.5 [-0.9; 1.8]	0.5 [-0.2; 1.2]	0.8 [-0.3; 1.9]	0.8 [-34.0; 35.5]	-10.8 [-68.1; 46.5]
Age squared	-	-	-	-	-6.5 [-13.4; 0.3]$^{+}$	-
Employment (Ref. yes)	3.8 [-12.5; 20.0]	13.6 [-18.8; 45.9]	1.7 [-9.7; 13.1]	-2.1 [-25.1; 20.8]	-81.6 [-583.6; 420.4]	421.2 [-374.6; 1217.1]

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval; - not included

Five-week changes are calculated as follow-up value minus baseline value. Results are based on multiply imputed data. Coefficients were adjusted for all other variables shown in the table, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. $^{+}P<.10$; based on robust standard errors.

Table 3. Results of linear regression analyses regarding associations between cardiometabolic risk factors and changes in self-reported physical activity and sedentary time separately for women (*n* = 112) and men (*n* = 63)

	Leisure-time physical activity Δ (MET-hours per week)		Transport-related physical activity Δ (MET-hours per week)		Sedentary time Δ (minutes per week)	
	Women	Men	Women	Men	Women	Men
	b [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI][a]	*b* [95% CI]
SBP (mmHg)[b]	0.2 [-0.2; 0.7]	0.01 [-0.5; 0.5]	0.04 [-0.3; 0.3]	0.3 [-0.4; 1.0]	-7.4 [-21.5; 6.7]	-35.7 [-67.3; -4.0]*
SBP squared[b]	0.02 [-0.003; 0.04][+]	-	-	-	-	1.0 [-0.1; 2.1][+]
Waist circumference (cm)	-0.1 [-0.6; 0.5]	0.3 [-0.5; 1.1]	0.003 [-0.3; 0.3]	0.4 [-0.3; 1.1]	0.7 [-16.1; 17.4]	-11.7 [-36.9; 13.4]
HbA1c (mmol/mol)	0.6 [-0.4; 1.5]	1.2 [-0.6; 3.1]	-1.1 [-0.6; 0.4]	0.7 [-1.0; 2.4]	-16.2 [-58.9; 26.5]	-93.0 [-152.6; -33.4]**
HbA1c squared	-	-	-	-	-	6.2 [-0.4; 12.9][+]
Total cholesterol (mmol/L)	2.6 [-2.9; 8.1]	-0.6 [-13.4; 12.1]	1.0 [-2.5; 4.4]	-5.2 [-13.6; 3.2]	-70.8 [-259.8; 118.2]	-24.8 [-413.9; 364.2]
HDL (mmol/L)	3.9 [-9.7; 17.5]	-4.2 [-31.8; 23.4]	10.6 [-1.2; 22.4][+]	3.2 [-20.5; 26.8]	-18.8 [-565.2; 527.6]	-562.8 [-1590.4; 464.9]
HDL squared	-	-	-	-	-	-1928.3 [-3912.8; 56.2][+]
Triglycerides (mmol/L)	-2.1 [-7.8; 3.6]	-1.0 [-8.8; 6.8]	-1.6 [-5.0; 1.7]	-5.6 [-11.1; -0.2]*	-12.9 [-224.8; 199.0]	-35.6 [-326.6; 255.4]

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval; SBP: systolic blood pressure; HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; - not included

Five-week changes are calculated as follow-up value minus baseline value. Results are based on multiply imputed data. Coefficients were adjusted for age, employment, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. [+]P<.10, *P<.05, **P<.01; based on robust standard errors. [a] Coefficients were additionally adjusted for age squared as indicated by likelihood ratio test. [b] Coefficients were additionally adjusted for blood pressure lowering medication.

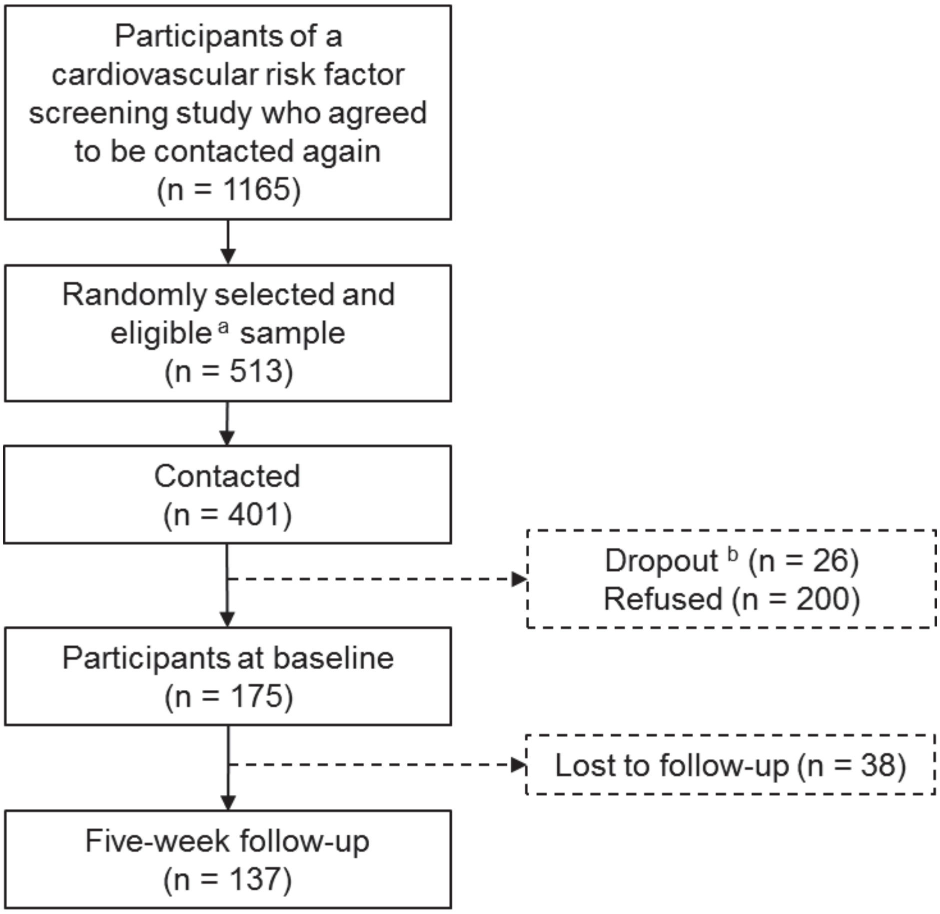

Figure 1. Flow of participation.

[a] Eligibility criteria: age ≥ 40 and ≤ 65 years, no history of cardiovascular event (myocardial infarction or stroke) or vascular intervention, self-reported body mass index ≤ 35 kg/m^2, resident in a pre-defined zip-code area

[b] not in age range, had died, had a cardiovascular event or intervention, were too ill to participate, or moved away

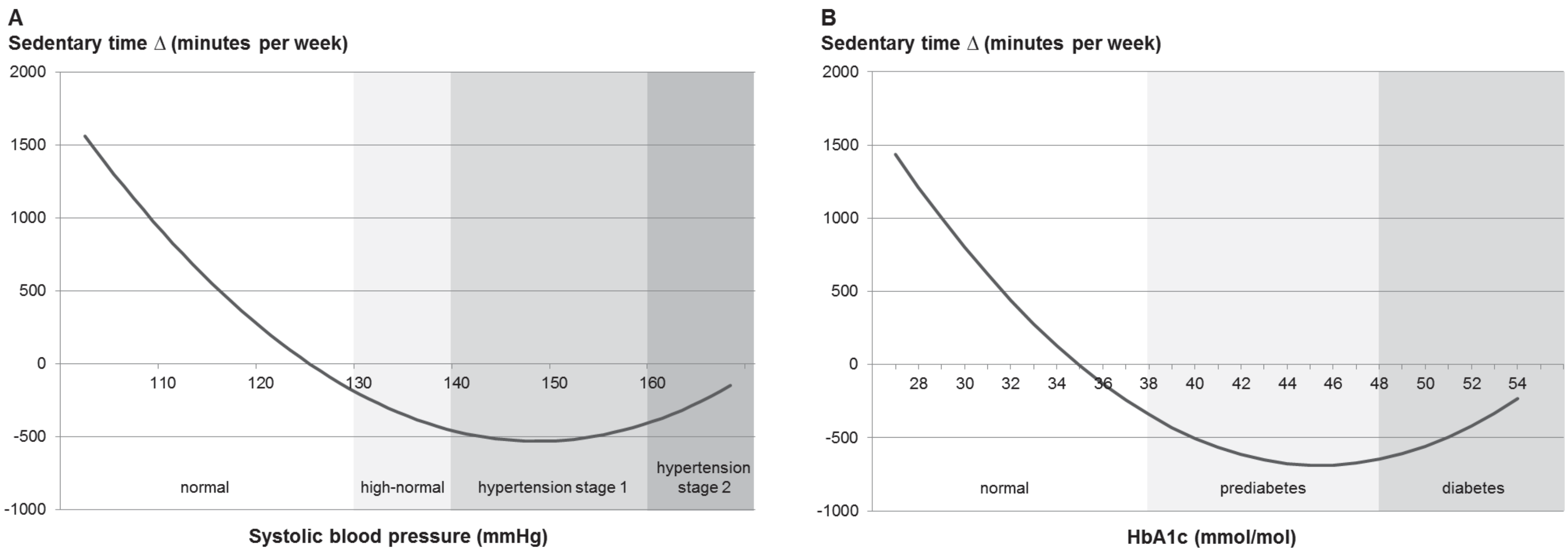

Figure 2. Five-week changes of sedentary time in men (n = 63) according to systolic blood pressure (A) and HbA1c (glycated hemoglobin, B).

Results were adjusted for age, employment, duration to follow-up, and baseline value of sedentary time. Coefficients of systolic blood pressure were additionally adjusted for blood pressure lowering medication.

Table S1. Results of linear regression analyses regarding associations between sociodemographic characteristics and changes in self-reported physical activity and sedentary time (*n* = 175)

	Leisure-time physical activity Δ (MET-hours per week)	Transport-related physical activity Δ (MET-hours per week)	Sedentary time Δ (minutes per week)
	b [95% CI]	*b* [95% CI]	*b* [95% CI]
Sex (Ref. women)	3.1 [-7.3; 13.5]	9.3 [0.9; 17.7]*	-16.3 [-386.5; 353.9]
Age (years)	0.6 [-0.2; 1.4]	0.5 [-0.0; 1.1]$^{+}$	-4.2 [-35.0; 26.7]
Employment (Ref. yes)	6.9 [-8.8; 22.5]	0.7 [-10.3; 11.7]	2.4 [-434.3; 439.0]

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval

Five-week changes are calculated as follow-up value minus baseline value. Results are based on multiply imputed data. Coefficients were adjusted for all other variables shown in the table, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. $^{+}$P<.10, *P<.05; based on robust standard errors.

Table S2. Results of linear regression analyses regarding associations between sociodemographic characteristics and changes in self-reported leisure-time physical activity (n = 98), transport-related physical activity (n = 110), and sedentary time (n = 119) using complete cases

	Leisure-time physical activity Δ (MET-hours per week)	Transport-related physical activity Δ (MET-hours per week)	Sedentary time Δ (minutes per week)
	b [95% CI]	*b* [95% CI]	*b* [95% CI]
Sex (Ref. women)	5.8 [-5.7; 17.2]	12.9 [3.8; 22.0]**	-82.1 [-462.9; 298.7]
Age (years)	0.5 [-0.5; 1.5]	0.3 [-0.3; 0.8]	-0.9 [-34.5; 32.8]
Age squared	-	-0.1 [-0.2; -0.0]**	-
Employment (Ref. yes)	5.5 [-14.7; 25.7]	2.5 [-9.5; 14.4]	125.8 [-206.7; 458.3]

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval; - not included

Five-week changes are calculated as follow-up value minus baseline value. Coefficients were adjusted for all other variables shown in the table, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. **P<.01; based on robust standard errors.

Table S3. Results of linear regression analyses regarding associations between sociodemographic characteristics and changes in self-reported leisure-time physical activity (*n* = 98), transport-related physical activity (*n* = 110), and overall sedentary time (*n* = 119) separately for women and men using complete cases

	Leisure-time physical activity Δ (MET-hours per week)		Transport-related physical activity Δ (MET-hours per week)		Sedentary time Δ (minutes per week)	
	Women	Men	Women	Men	Women	Men
	b [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]
Age (years)	0.4 [-1.0; 1.7]	0.5 [-0.8; 1.9]	0.3 [-0.3; 0.9]	0.8 [-0.4; 2.0]	11.9 [-22.3; 46.0]	-20.8 [-75.5; 34.0]
Age squared	-	-	-0.1 [-0.2; -0.0]*	-	-11.4 [-18.3; -4.5]**	-
Employment (Ref. yes)	-1.0 [-15.2; 13.3]	18.7 [-32.3; 69.7]	4.1 [-7.4; 15.7]	-10.3 [-34.9; 14.3]	35.6 [-329.2; 400.3]	824.5 [290.0; 1359.0]**

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval; - not included

Five-week changes are calculated as follow-up value minus baseline value. Coefficients were adjusted for all other variables shown in the table, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. *P<.05, **P<.01; based on robust standard errors.

Table S4. Results of linear regression analyses regarding associations between cardiometabolic risk factors and changes in self-reported leisure-time physical activity (*n* = 98), transport-related physical activity (*n* = 110), and sedentary time (*n* = 119) using complete cases

	Leisure-time physical activity Δ (MET-hours per week)		Transport-related physical activity Δ (MET-hours per week)		Sedentary time Δ (minutes per week)	
	Women	Men	Women	Men	Women	Men
	b [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI]	*b* [95% CI] [a]	*b* [95% CI]
SBP (mm Hg) [b]	-0.1 [-0.6; 0.5]	-0.1 [-0.7; 0.5]	0.0 [-0.3; 0.9]	0.4 [-0.5; 1.2]	-3.9 [-17.8; 9.9]	-43.5 [-77.8; -9.3]*
SBP squared [b]	-	-	-	-	-	1.2 [0.1; 2.3]*
Waist circumference (cm)	-0.2 [-0.9; 0.5]	0.3 [-0.5; 1.2]	-0.1 [-0.4; 0.2] [a]	0.3 [-0.4; 1.1]	3.3 [-12.4; 19.0]	-15.2 [-38.1; 7.6]
HbA1c (mmol/mol)	0.7 [0.3; 1.2]**	1.7 [-0.5; 3.8]	0.0 [-0.3; 0.4] [a]	0.8 [-1.2; 2.9]	-3.4 [-56.0; 49.1]	-56.5 [-114.4; 1.4]$^+$
HbA1c squared	-	-	-	-	-	13.6 [8.7; 18.4]***
Total cholesterol (mmol/L)	2.1 [-4.0; 8.2]	-2.2 [-21.4; 17.1]	0.9 [-2.5; 4.3]	-7.9 [-15.5; -0.3]*	-77.8 [-274.5; 119.0]	20.8 [-503.6; 545.3]
HDL (mmol/L)	3.9 [-9.1; 16.8]	-11.2 [-39.0; 16.6]	18.9 [5.4; 32.4]** [a]	-10.3 [-50.0; 29.3]	17.9 [-582.1; 617.9]	-576.9 [-1881.8; 727.9]
HDL squared	-	-	-	-	-	-2553.3 [-5038.7; -67.9]*
Triglycerides (mmol/L)	-4.0 [-10.3; 2.3]	-2.1 [-13.3; 9.0]	-2.1 [-5.2; 0.9] [a]	-9.9 [-17.2; 2.6]*	-21.2 [-212.5; 170.1]	-60.1 [-389.7; 269.6]

Δ Five-week change; MET: metabolic equivalent of task; b: unstandardized regression coefficient; CI: confidence interval; SBP: systolic blood pressure; HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; - not included

Five-week changes are calculated as follow-up value minus baseline value. Coefficients were adjusted for age, employment, duration to follow-up, and baseline value of leisure-time physical activity, transport-related physical activity, or sedentary time, respectively. $^+$P<.10, *P<.05, **P<.01, ***P<.001; based on robust standard errors. [a] coefficients were additionally adjusted for age squared as indicated by likelihood ratio test

[b] coefficients were additionally adjusted for blood pressure lowering medication.

Video Article

Visualization of Intensity Levels to Reduce the Gap Between Self-Reported and Directly Measured Physical Activity

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Abstract

Physical activity (PA) assessment needs tools that are inexpensive and easy to administer. Common questionnaires inquire time spent in light, moderate, and vigorous PA. However, inaccuracies may occur due to individually different understanding of PA intensity levels. Alternatively used direct measures (e.g., accelerometers) are susceptible to reactivity bias and may lack the ability to capture certain activities. Compared to accelerometer measurement, respondents report more time spent in higher-intensity PA. A video that visualizes PA intensity levels might help to overcome this problem. This report describes the design of a randomized controlled trial as a methodology to investigate the effect of a video on the difference between self-reported and directly measured PA. It is hypothesized that the video reduces the mean difference between the two measures. Individuals from the general population are recruited. Hip-worn accelerometers are used to collect directly measured PA data on seven consecutive days. Afterwards, participants are randomly allocated to the experimental and the control group. The experimental group receives a video demonstration on PA intensity levels and subsequent PA assessment via self-administered computer-assisted questionnaire. The control group receives PA assessment only. Thereafter, the data are processed to compare the difference between self-reported and accelerometer-based moderate-to-vigorous physical activity (MVPA) between the study groups using a two-sample t-test. This methodology is appropriate for investigating the effect of any existing or self-produced video on the difference between the two measurement methods. It can be used not only for persons from the general population, but for a variety of other populations and contexts as accurate measures are needed to evaluate PA levels.

Video Link

The video component of this article can be found at https://www.jove.com/video/58997/

Introduction

Assessment of physical activity (PA) is commonly done by questionnaires because they are inexpensive and easy to administer. As positive associations between amounts of higher-intensity PA and cardiovascular health are well established[1,2,3], many questionnaires inquire frequency and time spent in light, moderate, and vigorous PA presenting examples of respective activities[4,5,6,7,8]. However, they may be flawed by inaccuracy due to individually different understanding of PA intensity levels[9]. Further, specific activity examples may not hold true for individuals with different physical constitutions. For example, overweight or obese persons may feel more exerted than persons with normal weight when performing the exact same activity. Direct measures on the other hand (e.g., accelerometry) require considerable amounts of time and costs and possess limited validity due to reactivity bias[10,11], sample selection bias[12], and the lack of ability to accurately capture certain activities[13]. A broad range of studies showed only low to moderate agreements between self-reported and accelerometer-based PA[14,15,16]. Most findings indicate that respondents report more time spent in higher-intensity PA compared to directly measured data. Throughout the manuscript, the term "gap" is used to designate this lack of agreement between accelerometry and self-reported PA.

A video as part of a computer-assisted self-completed questionnaire might help to reconcile the two measures by increasing the accuracy of self-reports. A video demonstration provides an opportunity to show different intensity levels of PA that are hard to explain by written text only. Respondents receive a visual reference they may compare their performance levels with and thus, misclassification of light, moderate, and vigorous PA may be reduced. Up to now, videos to support assessments are available in the context of mobility and physical functioning validated for older adults[17,18,19]. To our knowledge, there are no video-supported assessments that provide a reference for light, moderate, and vigorous PA.

We developed a 3-minute video showing a middle-aged man on a treadmill in a fitness center who describes the terms light, moderate, and vigorous PA and simultaneously visualizes symptoms related to these intensity levels. The methodology described here is a randomized controlled trial to test the effect of the video demonstration on the gap between self-reported and accelerometer-based moderate-to-vigorous physical activity (MVPA). In addition, standardized assessment of somatometry (height, body weight, and waist and hip circumference) is conducted to investigate whether effects differ according to participants' physical constitution.

The methodology is appropriate to test the effect of any video demonstration that is meant to support computer-assisted PA questionnaire assessment with the aim of reducing the gap between self-reported and directly measured PA. The methodology can be used in various populations and contexts as accurate measures are needed to evaluate current and changing PA levels, efficacy of PA interventions, and associations between PA and health outcomes.

Protocol

This protocol was approved by the ethics committee of the University Medicine Greifswald (number BB 076/18; June 2018).

1. Video construction and experimental design

1. Select a publicly available or self-produced video based on the specific experimental question. The video should explain the terms used in the self-report questionnaire to support participants' understanding. The video used here contains explaining and visualizing symptoms as well as naming examples of light, moderate, and vigorous PA.
    1. In the video, have a person on a treadmill in a fitness center give a general introduction to the different intensity levels of PA.
    2. Have the person explain differences in heart rate, breathing frequency, and capability to talk normally in accordance with the intensity levels. Have the person simultaneously demonstrate those symptoms while walking/running on a treadmill at the according pace.
    3. Have the person give examples of daily-life activities and emphasize individual differences in the evaluation of PA intensity levels. NOTE: The video used here was produced in German based on a video clip from the Centers for Disease Control and Prevention (CDC)[20]. If participants are native English speakers, the original video may be used with emphasis on minutes 1:46 to 3:25. The person in the present video is an approximately fifty-year-old, normal-weight, white male in good physical shape. See **Figure 1** for a visual depiction of video structure and contents.

2. Integrate the video into a self-administered tablet-computer survey to be presented directly before the PA questionnaire and make sure participants cannot skip the video. Randomize presentation of the video 1:1.
    1. Integrate questions on sociodemographic and health related variables into the survey as desired for description of sample characteristics.
    2. In the present study, self-reported PA is assessed using a modified version of the International Physical Activity Questionnaire Short Form (IPAQ-SF)[4], German version[21], addressing the last seven days. Two items each address number of days and respective time spent in moderate and vigorous PA. The original items on walking are replaced with questions on light PA as walking may be performed on different intensity levels[22] and walking is not equivalent to light PA measured by accelerometry. Sociodemographic and health variables included in the survey are sex, age, school education, employment, current living together with a partner, current smoking, and self-rated general health.

Figure 1: Schematic structure of the video demonstration of different physical activity intensity levels. The main scenes of the video with according single shots, lengths, and summary of contents are depicted. The video was based on a video clip provided by the CDC[20]. Please click here to view a larger version of this figure.

2. Power calculation

1. Conduct a power analysis using respective software in order to define the sample size necessary to obtain statistically conclusive results. Include an interim analysis to verify underlying assumptions and early stopping of the study.
    1. Choose a statistical test appropriate for the research question.
    2. Based on the literature, set the assumed mean difference between questionnaire and accelerometer data in the control group, that is, the divergence between self-reported and directly measured PA without presentation of the video.
    3. Set the assumed mean difference between questionnaire and accelerometer data in the experimental group, that is, the divergence between self-reported and directly measured PA with inclusion of the video demonstration.
    4. Set the assumed standard deviation (SD) for both groups.
    5. Choose power and alpha-level as desired.

2. Based on the literature and considering the specific study design, decide on an assumed drop-out rate to retrieve the final number of participants to be recruited.
3. The power analysis of the present study is based on a two-sample t-test assuming equal variance. Based on a comparable sample[10], the assumed mean difference between questionnaire and accelerometer data in the control group is 90 min per day of MVPA. The assumed mean difference in the experimental group is 60 min per day (*SD* in both groups = 100 min per day). As it is hypothesized that the integration of the video reduces the gap between the two measures, a one-sided significance level of $p = .05$ is chosen (power = .80). Results of power calculation including interim analysis revealed that a total number of 314 participants is needed for demonstrating the experimental effect. Assuming a drop-out rate of about 10%, it is planned to recruit 350 participants (**Figure 2**).

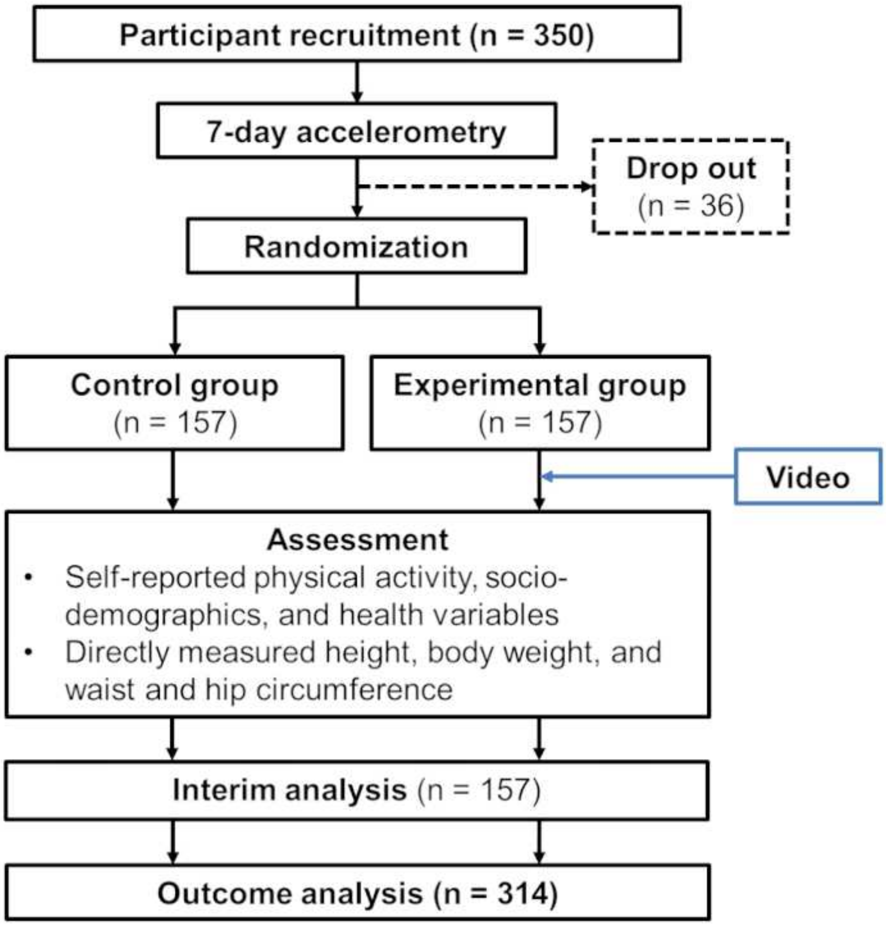

Figure 2: Schematic depiction of the calculated participation flow. *n* = number of participants. All n refer to results of the power calculation. Please click here to view a larger version of this figure.

3. Participant recruitment and preparation for data collection

1. Choose a recruitment setting that permits enough time to hand out the accelerometer and to prepare it for data collection (e.g., in a shopping mall or at the workplace) in order to keep efforts of participants low and to increase adherence to the study.
    1. Recruit participants who have the ability to walk independently (e.g., no permanent use of a wheelchair) and who are physically and cognitively capable of completing a self-report questionnaire. Be sure to recruit a similar number of male and female participants of all ages within the desired age range.
    2. As an incentive for participation, point out that participants are going to receive a feedback letter on directly measured PA and sedentary time after completing the study. Use monetary incentives as desired.
    3. Obtain written informed consent from each person prior to their participation.

2. For objective measurement, use a three-axial accelerometer to be worn on the right hip. Alternative devices can be used but should have the memory capacity for data collection on seven consecutive days. In order to most accurately capture daily PA, follow the instructions of the specific device used.
    1. Have accelerometers prepared with elastic belts of various sizes and select one that fits the participant comfortably.
    2. Give adequate information on how to handle the accelerometer according to instructions provided by the producer of the device. Instruct participants to start wearing the device on the next day. Ensure that participants wear the device during waking hours (i.e., every day after getting up until going to sleep).
    3. Initialize the accelerometer on a computer using the appropriate software. Make sure to set up the wearing period correctly. Select a sampling rate of 30 Hz[23]. If applicable, choose to fill in participant specific information as desired (e.g., body weight or date of birth for reasons of participant identification).
    4. Schedule each participant for an assessment session to obtain self-reported PA and somatometry. Ensure this session takes place one day after the last accelerometer wearing day. Hence, accelerometer and questionnaire data refer to the same period of time. If this is not possible for reasons of time, admit a maximum delay of two days.
    5. Dismiss the participant with encouragement to engage in normal daily activities and make sure the participant remembers to return the accelerometer when appearing for the session.
    NOTE: This study is conducted in Greifswald, a city in Western Pomerania, a rural area in northeastern Germany. Persons from the general population aged between 40 and 75 years are recruited proactively at a shopping mall. Accelerometer feedback letters

and shopping vouchers in the amount of 10 euros are used as incentives. Participants are instructed to wear the device for seven consecutive days and to remove it for any water-based activities (e.g., showering or swimming).

4. Participant assessment session

NOTE: Conduct this session within three days after the last accelerometer wearing day.

1. Collect the accelerometer from the participant.
2. Set up a new participant in the tablet-computer survey and type in the individual study identification number of the participant.
3. Hand over the tablet computer to the participant to answer the self-administrative questionnaire.
4. When the participant has completed the questionnaire, collect the tablet computer and continue with measurement of somatometry.
    1. Ask the participant to take off their shoes and to stand on calibrated scales for measurement of body weight. Type in the result into the tablet computer.
    2. Ask the participant to stand up straight in front of a mirror with toes at a mark on the ground for measurement of body height. Type in the result into the tablet computer.
    3. Ask the participant to remove upper layers of clothing for measurement of waist and hip circumference. Measure waist circumference midway between lowest rib and iliac crest. Measure hip circumference about two inches below iliac crest. Use the mirror to check accurate positioning of the tape. Type in the results into the tablet computer.
5. Thank and dismiss the participant.

5. Download of accelerometer data for processing and creation of feedback letters

1. Download the data from the device using the appropriate software.
    1. Select to use data from the vertical axis and choose an epoch length of 10 s.
    2. Export the data to an appropriate program for further processing. According to the output metric used, choose cut points to determine non-wear time and to differentiate between PA intensity levels[24,25].
        1. Define non-wear time as at least 60 min of consecutive zero counts, allowing for ≤2 min of counts between 0 and 100[24].
        2. In an adult sample (ages 18 or older), classify values <100 counts per min as sedentary time, values between 100 and 2019 counts per min as light PA, values between 2020 and 5998 as moderate PA and values of 5999 or more counts per min as vigorous PA[24].
2. Import all relevant variables into a computer program appropriate for creating a computerized feedback letter using an algorithm to automatically integrate the individual data into a general template. The letter may contain a number of graphs visualizing accelerometer-based PA outcomes as well as sedentary time as desired. Have each graph accompanied by a paragraph of three to five sentences explaining the content of the figures and providing respective health recommendations.
3. Deliver the feedback letter as soon as possible after the participant completed the study.
NOTE: Accelerometer feedback letters in the present study include three graphs. The first graph visualizes daily steps across the wearing period. The second graph shows amounts of time spent sedentary and in light, moderate, and vigorous PA on each wearing day. The third graph depicts all observed 10-min-bouts of sedentary time between 6 and 10 pm exemplified on a weekday and on a weekend day. Recommendations on PA are presented according to the PA guidelines of the World Health Organization for apparently healthy adults[2]. Recommendations on sedentary breaks are presented based on relevant studies[26,27,28].

6 Statistical analysis

1. Calculate descriptive statistics for all variables.
2. Define a cut-off value for daily accelerometer wear time to avoid bias in accelerometer data.
3. Create a variable that presents the gap between the two measures. Calculate the variable as self-reported minus accelerometer-derived min of moderate-to-vigorous PA which results in a difference score (delta, Δ). Use a two-sample t-test to determine the difference of deltas between experimental and control group.
4. Create a graph to visualize the results of the main analysis as desired.

Representative Results

The methods detailed above describe a randomized controlled trial to test whether a video demonstration of PA intensity levels reduces the gap between self-reported and accelerometer-based MVPA. An interim analysis (n = 157) was planned to evaluate whether the estimated sample size of 314 participants is sufficient to test our hypothesis. Up to this point, 142 participants completed the study protocol. Participants who were too old (n = 1) or who did not wear the accelerometer for ≥10 hours per day on ≥6 days (n = 10) were excluded from the analysis. Thus, data analysis was carried out using a sample of 131 participants to give an example of representative results among individuals from the general population aged between 40 and 75 years.

Table 1 presents descriptive statistics of the analysis sample (n = 131). Of this sample, 68 participants (52%) were randomized to the experimental group and 63 participants (48%) were randomized to the control group. The experimental group received a video demonstration before completing the PA questionnaire, whereas the control group received PA assessment only. It was hypothesized that the video demonstration reduces the gap between self-reported and accelerometer-based PA. Preliminary results of interim analysis revealed a lower formal mean difference in the video group (M = 21.8, SD = 108.9) compared to controls (M = 41.0, SD = 117.4, $t(129)$ = 0.97, p = .166, **Figure 3** and **Figure 4**). The p-value lies between the significance ($p < 0.010$) and futility ($p > 0.269$) boundaries of the test simulations. Thus, the study may continue as planned until the total sample size is reached.

	Total Sample	Control group	Video group
N	131	63 (48%)	68 (52%)
Sex, women	85 (65%)	46 (73%)	39 (57%)
Age, years	60.1 ± 8.9	58.1 ± 9.6	61.9 ± 7.9
Current living together with a partner, yes	102 (78%)	51 (81%)	51 (75%)
School education			
< 10 years	20 (16%)	12 (19%)	8 (12%)
10 years	64 (50%)	27 (44%)	37 (56%)
> 10 years	44 (34%)	23 (37%)	21 (32%)
Not specified (n = 3)			
Employment			
Full-time or part-time	55 (42%)	33 (52%)	22 (32%)
Irregularely	23 (18%)	8 (13%)	15 (22%)
Not employed or retired	53 (40%)	22 (35%)	31 (46%)
Current smoker, yes	22 (17%)	12 (19%)	10 (15%)
Body mass index			
< 25 kg/m^2	34 (26%)	23 (37%)	11 (16%)
≥ 25 kg/m^2 and < 30 kg/m^2	55 (42%)	22 (35%)	33 (49%)
≥ 30 kg/m^2	42 (32)	18 (29%)	24 (35%)
Self-reported general health	2.8 ± 0.7	2.8 ± 0.8	2.8 ± 0.6
Accelerometer wear time, min/day	883.0 ± 82.8	896.1 ± 74.4	870.8 ± 88.7
Accelerometer-based MVPA, min/day	45.2 ± 27.7	44.1 ± 24.3	46.2 ± 30.7
Self-reported MVPA, min/day	77.2 ± 117.2	85.2 ± 119.0	68.0 ± 115.8

Table 1: Sample characteristics of participants included in the preliminary interim analysis. *N* = number of participants. *MVPA* = moderate-to-vigorous physical activity. Data are presented as mean ± standard deviation for continuous variables and as the number of participants (%) for categorical variables. Body mass index was calculated from objectively measured height and body weight at the participant assessment session. Self-reported general health was measured on a 5-point scale from 1 "very good" to 5 "very bad". Self-reported and accelerometer-based MVPA as well as accelerometer wear time refer to average minutes per day across seven days.

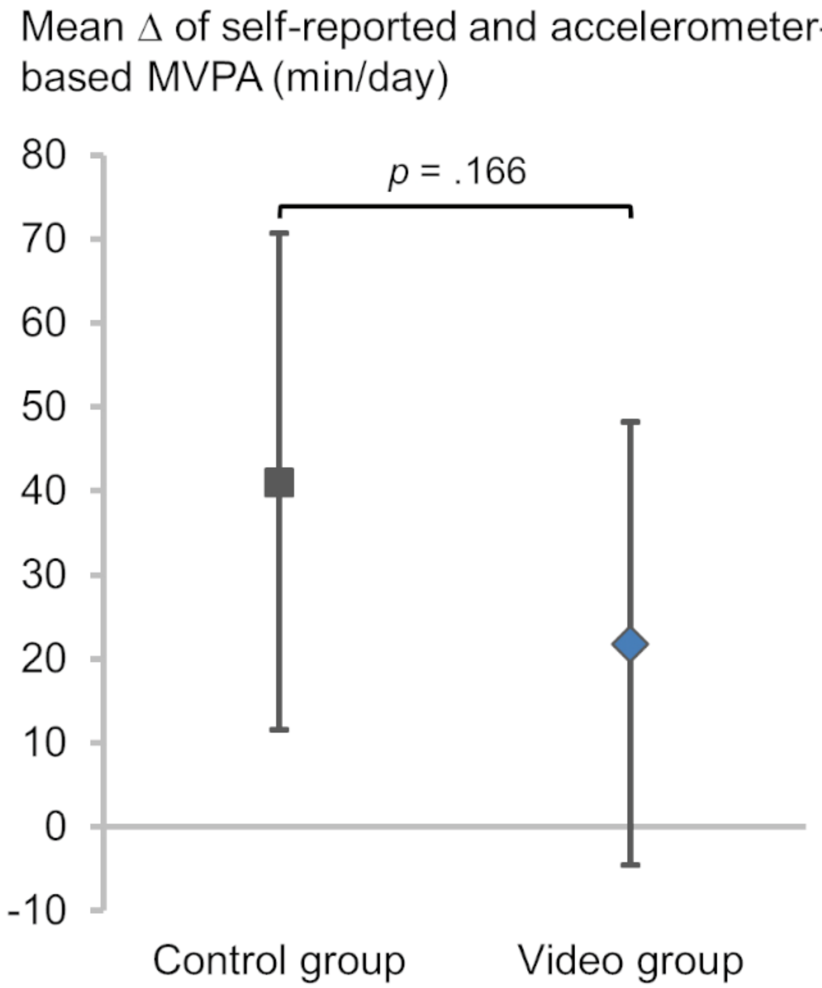

Figure 3: Mean difference between self-reported and accelerometer-based moderate-to-vigorous physical activity compared between study groups. *Δ* = delta. *MVPA* = moderate-to-vigorous physical activity. *min/day* = minutes per day. The mean differences with according 95% confidence intervals of the control group (grey square) and the video group (blue diamond) are depicted. Mean differences were calculated as self-reported minus accelerometer-derived min of MVPA. The data refer to preliminary results of interim analysis (n = 131). Please click here to view a larger version of this figure.

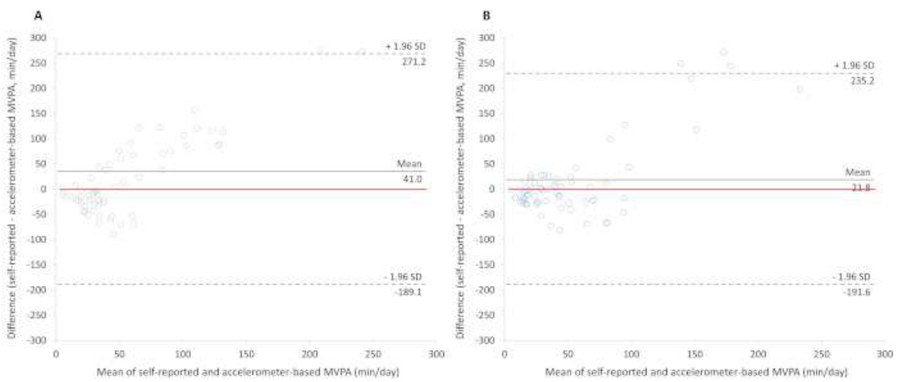

Figure 4: Bland Altman plots for visual depiction of the difference between self-reported and accelerometer-based moderate-to-vigorous physical activity in the control group (A) and in the video group (B). *MVPA* = moderate-to-vigorous physical activity. *min/day* = minutes per day. *SD* = standard deviation. Differences were calculated as self-reported minus accelerometer-derived min of MVPA. A perfect agreement between the measures would be present if all dots lied on a horizontal line at the value 0 of the y-axis (red line). The data refer to preliminary results of interim analysis (n = 131). Please click here to view a larger version of this figure.

Discussion

This report describes a methodology for testing the effect of a video demonstration on the gap between self-reported and accelerometer-based PA. If self-report assessment is preceded by a video demonstration of PA intensity levels, over-reporting of MVPA might be reduced. This protocol can be used to test the effect of any existing or self-produced information video on the gap between self-reported PA data derived from a computer-assisted assessment and directly measured PA.

The most important steps in the protocol include fundamental aspects of trial conduction that ensure the receipt of accurate data, such as correct accelerometer initialization and data download or making sure that the video may not be skipped by respondents. Further, there are more specific issues about the accelerometer wearing period and the daily wear time. First, the accelerometer wearing period and self-reported data should refer to the same time frame. To hand out accelerometers and agree on the date of the assessment session immediately after recruitment seems helpful to ensure participants' adherence to the scheduled appointment. Second, participants may not always comply with the instructions for accelerometer wearing. The device may be worn for less than seven days and/or only a few hours per day, whereas subsequent self-reports refer to the complete wearing period. Thus, over-reporting of MVPA may be bound to occur. Moreover, if wear time substantially differs between study groups, results may be compromised due to biased accelerometer-based MVPA data. Inspection of interim descriptive statistics may uncover insufficient amounts of wear time. For example, among the participants who completed the study protocol (n = 142), only 115 participants wore the device at least 10 hours on each of the seven days. There were three participants with a wear time of 0 minutes on one or more days. Excluding outliers seems necessary to ensure that the data are representative for an entire day as well as the total assessment period. Although most studies on correlations between accelerometry and PA questionnaire data request a wear time of ≥10 hours per day on ≥4 days per week[29], investigations on the gap between measures may require more conservative cut-off values. Thus, we decided to exclude participants from the analysis who did not wear the accelerometer for ≥10 hours per day on ≥6 days.

Further modifications of the protocol may be appropriate. Preliminary results of descriptive statistics shown in **Table 1** indicate an unbalanced proportion of men and women in our total sample and between study groups. If the video affects self-reports differentially in men and women, overall video effects may be biased. Thus, basic variables (e.g., sex and age) may need to be considered in the randomization algorithm. Moreover, the main analysis model may need to include sociodemographic and health related variables as potential confounders using a linear regression model instead of a t-test.

The methodology described here aims at reducing the gap between self-reported and accelerometer-derived PA by using a video to address comprehension of PA intensity levels. However, specific characteristics inherent to each measure remain to affect this gap. First, self-reported PA data is susceptible to recall bias[30] and may be affected by social desirability bias[31,32]. Second, bias in accelerometer data particularly origins in different motivation to wear the device. Third, hip-worn accelerometers may lack the ability to accurately capture cycling and swimming[13]. Finally, accelerometers capture absolute amounts of movement whereas self-reports account for relative physical exertion[33,34,35]. Considering these factors, the visualization of intensity levels may present only one of many options to reduce the gap between self-reported and directly measured PA.

Disclosures

The authors have nothing to disclose.

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Materials List for:

Visualization of Intensity Levels to Reduce the Gap Between Self-Reported and Directly Measured Physical Activity

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Materials

Name	Company	Catalog Number	Comments
Accelorometers	ActiGraph, LLC	ActiGraph Model GT3X+	This is the most common device on the market. Similar products are available from other vendors.
Access Software	Microsoft		The software ist used for creation of computerized feedback letters.
Actilife Software	ActiGraph, LLC		Software to prepare, initialize, download, and processing of data collected by the accelerometers.
Belts	ActiGraph, LLC	Elastic Belt	Elastic bands for accelerometer wearing on the hip.
Computational software	StataCorp		The software Stata ist used for statistical analysis.
Digital scales (height)	ADE GmbH & Co.	MZ 10020	The scales are used for measurement for body height.
Digital scales (weight)	Soehnle Industrial solutions GmbH	SOEHNLE 7720	The scales are used for measurement for body weight.
Excel Software	Microsoft		The software ist used for calculations on accelerometer-based data.
PASS Sample Size Software	NCSS	PASS Sample Size 16	The software is used for power calculations.
Tablet	Apple Inc.	iPad MC769FD/A	The tablet comupter ist used for the self-administered assessment.
USB cable	ActiGraph, LLC	USB cable	USB cable for device communication and charging of accelerometers.

The author’s contribution to the scientific studies

Table 3. The first author’s contribution to the scientific studies

	Study 1	Study 2	Study 3
Study conception and design	no	no	yes
Intervention development	yes	not applicable	yes
Data acquisition	no	no	yes
Data management and cleansing	yes	yes	yes
Data analysis	yes	yes	yes
Data interpretation	yes	yes	yes
Manuscript conception	yes	yes	yes
Writing draft and revision	yes	yes	yes

Greifswald, den __________________ __________________

Lisa Voigt

Eidesstattliche Erklärung

Hiermit erkläre ich, dass ich die vorliegende Dissertation selbständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe.

Die Dissertation ist bisher keiner anderen Fakultät, keiner anderen wissenschaftlichen Einrichtung vorgelegt worden.

Ich erkläre, dass ich bisher kein Promotionsverfahren erfolglos beendet habe und dass eine Aberkennung eines bereits erworbenen Doktorgrades nicht vorliegt.

Greifswald, den ________________ ________________

Lisa Voigt

List of publications

Peer reviewed publications

Baumann S, Groß S, Voigt L, Ullrich A, Weymar F, Schwaneberg T, Dörr M, Meyer C, John U, Ulbricht S: Pitfalls in accelerometer-based measurement of physical activity: The presence of reactivity in an adult population. *Scandinavian Journal of Medicine & Science in Sports* 2018, 28(3):1056-63.

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Submitted publications

Voigt L, Ullrich A, Baumann S, Dörr M, John U, Ulbricht S: Do sociodemographic variables and cardiometabolic risk factors moderate the mere-measurement effect on physical activity and sedentary time? *BMC Cardiovascular Disorders* submitted.

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Baumann S, Groß S, Voigt L, Ullrich A, Weymar F, Schwaneberg T, Dörr M, Meyer C, John U, Ulbricht S: Does accelerometer wearing bias physical activity data? Trending in time series of physical activity measured by accelerometry as an indicator of measurement reactivity. Oral presentation at the *7th European Society for Prevention Research (EUSPR) Conference*, Berlin, Germany, Oct 31 – Nov 2, 2016.

Siewert-Markus U, Ulbricht S, Voigt L, Ullrich A, Baumann S, Dörr M, John U, Freyer-Adam J:: Effects of an intensity level video demonstration on self-reported physical activity. Oral presentation at the *9th European Society for Prevention Research (EUSPR) Conference*, Lisbon, Portugal, Oct 24-26, 2018.

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Ullrich A, Voigt L, Baumann S, John U, Ulbricht S: Prospective changes in screen-based sedentary behaviour during leisure-time over 12 months among adults: Results of a brief intervention feasibility study. Poster presentation at the *8th European Society for Prevention Research (EUSPR) Conference*, Vienna, Austria, Sep 20-22, 2017.

Ullrich A, Voigt L, Baumann S, Weymar F, Gürtler D, Dörr M, John U, Ulbricht S: Determinants of non-participation in a behaviour change intervention study in apparently healthy individuals aged 42-65 years. Poster presentation at the *7th European Society for Prevention Research (EUSPR) Conference*, Berlin, Germany, Oct 31 – Nov 2, 2016.

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