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Original research

## Exercise more or sit less? A randomized trial assessing the feasibility of two advice-based interventions in obese inactive adults

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### ABSTRACT

**Objectives:** The risk of metabolic and cardiovascular disease may be reduced by a healthy pattern of daily physical activity. We investigated the feasibility and preliminary effectiveness of advice-based interventions aiming at either increasing moderate-to-vigorous intensity physical activity (MVPA) or reducing sedentary time (ST) in obese volunteers.

**Design:** Randomized non-blinded two-armed trial.

**Method:** Inactive, obese adults were randomly assigned to reduce sedentary behavior (SitLess) ( $n = 30$ ) or increase MVPA (ExMore) ( $n = 29$ ) for 4 weeks. Participants wore ActivPAL (AP) and ActiGraph (AG) devices for 7 consecutive days at baseline and during the final week of the intervention period. Cardiometabolic risk factors (waist circumference, BMI, percent body fat, blood pressure,  $\text{VO}_2\text{max}$  and blood markers) were measured at baseline and at follow-up. Trial was set in Midtjylland Denmark from 2012 to 2014.

**Results:** The interventions were completed by 77% (SitLess) and 69% (ExMore) of the participants. The SitLess group reduced sedentary time by 53 min/day (95% CI 10; 96;  $P < 0.05$ ) while ExMore increased MVPA by 16 min/day (95% CI 5; 27;  $P < 0.05$ ). SitLess and ExMore both improved  $\text{VO}_2\text{max}$  by 8% and 11%, respectively ( $P < 0.05$ ). None of the other measured cardiometabolic risk factors changed over the 4 weeks of intervention.

**Conclusions:** This trial showed that completion of 4-week, advice-based interventions led to reduced ST or increased MVPA in obese adults. Furthermore, both interventions led to small significant increases in  $\text{VO}_2\text{max}$ . Studies of longer duration are needed to determine if these behavioral changes can be maintained, and to quantify possible longterm effects of reduced ST or increased MVPA on cardiometabolic risk factors.

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### 1. Introduction

The daily pattern of physical activity is an important health determinant, influencing development of prevalent non-communicable diseases such as type 2 diabetes (T2DM) and cardiovascular disease.<sup>1</sup> Thus, lack of physical activity at moderate-to-vigorous intensity (MVPA) is recognized as a risk factor for development of cardiovascular disease, metabolic syndrome and T2DM and for all-cause mortality.<sup>1,2</sup> In keeping with this, intervention studies have shown that scheduled exercise at moderate-to-vigorous intensity elicits positive effects on cardiometabolic risk markers.<sup>3,4</sup>

Accumulation of sedentary behavior has also been associated with cardiovascular disease, metabolic syndrome,<sup>5,6</sup> all-cause mortality and T2DM.<sup>7,8</sup> Recently, epidemiological data using isotemporal substitution has shown that replacing sedentary time with either MVPA, light PA or sleep might lead to improved health outcomes,<sup>9,10</sup> and short term interventions that replace physical activity with sedentary behaviour have demonstrated acute effects on metabolic health variables.<sup>11,12</sup> Recent intervention studies have shown that it is possible to reduce daily sedentary behaviour among overweight individuals with sedentary jobs,<sup>13–15</sup> although intervention studies of longer durations (6–12 months) have failed to find such changes in behavior.<sup>16,17</sup>

Despite well established recommendations on MVPA, it is often difficult to induce and maintain changes in MVPA among sedentary adults.<sup>18</sup> One explanation could be that incorporating daily MVPA is difficult for individuals who are used to an inactive lifestyle, particularly for obese inactive adults.<sup>19</sup> In contrast, reducing seden-

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tary behavior by substituting sitting time (ST) with light physical activity may be easier to implement for individuals in sedentary populations. It would, therefore be beneficial to gain greater experimental evidence of which activity category is most readily altered in order to inform future interventions aiming to induce health benefits in a sedentary population at risk for developing T2DM. So far, only few studies have directly compared the feasibility of reducing ST with increasing MVPA. Thus, in obese participants, Kozey-Keadle et al.<sup>14</sup> found that approximately 80% complied with different interventions aimed at increasing MVPA, reducing ST, or both. In this study, it was found that groups increasing MVPA with or without reduced ST were more effective in improving health related outcomes compared with a group reducing ST only. Notably, the MVPA intervention, in the study by Kozey-Keadle et al.,<sup>14</sup> consisted of scheduled supervised exercise, while the ST reduction intervention was purely advice-based. Furthermore, Kerr et al.<sup>20</sup> reported that it was possible to either reduce total sedentary time or increase sit-to-stand transitions through interventions specifically focused on these elements. Interestingly, so far, no studies have compared the feasibility of purely advice-based interventions aiming to increase MVPA or decrease SB in obese inactive adults.

With this study, we aimed to examine the feasibility of two 4 week, advice-based interventions aiming to (1) increase physical activity of moderate to vigorous intensity, or (2) decrease sedentary time in inactive obese men and women. In addition, we investigated the short-term (i.e., 4 weeks) effects of these distinct interventions on metabolic and cardiovascular risk factors.

## 2. Methods

Fifty-nine inactive and obese participants (Age:  $45.8 \pm 10.9$  years; BMI:  $32.9 \pm 4.9$ ) were recruited through local newspaper advertisements and flyers posted at educational institutions, public bulletin boards and health centers in two locations in Denmark (Aarhus and Nykøbing Mors). Volunteers were included based on the following inclusion criteria: (1) Age 20–65 years, (2) BMI  $>30$  or waist circumference  $>102$  cm (men) or  $>88$  cm (women), (3) Self-reported moderate-to-vigorous physical activity  $\leq 3$  bouts of 30 min per week, (4) Not taking medication for cardiovascular or metabolic disease, (5) no pain or other problems preventing physical activity, and (6) No allergic reaction to adhesive patches used to mount the accelerometers.

As shown in Fig. 1, 81 persons responded to the advertisements and were assessed for eligibility. Of these 59 were included and randomized in a 1:1 ratio to one of two interventions: reduction of sedentary time (SitLess) or increase in moderate to vigorous physical activity (ExMore). Randomization was performed by first author using publically available software (Minim: Allocation by minimization in clinical trials) with stratification for age and gender. The randomization was concealed until after the baseline measurements of physical activity. Following this, neither participants nor researchers were blinded to study condition. Enrollment and assignment was performed by KN and MKBL. All participants provided informed consent and the study was approved by the Regional Scientific Ethics Committee of Central Denmark (case nr. 1-10-72-131-12). The lab tests of the study were carried out in two locations in Denmark: Department of Public Health, University of Aarhus and Health Center Limfjorden, Nykøbing. The inclusion period was 2012–2014. Inclusion was stopped when the predetermined number of participants was reached. Final data analysis was performed in 2016.

The SitLess group was instructed to reduce sedentary behavior during the 4 week intervention period. For inspiration, a list of non-sedentary activities to replace sitting activities during time at home, at work, leisure or transport was presented and handed out. The ExMore-group was instructed to increase MVPA to at least

30 min per day (using activity types of their own choosing), corresponding to the recommendations for physical activity specified by the Danish health authorities. For both groups information about allocation and the requested behaviour change was given only once during the visit following measurement of baseline physical activity. Participants were not given self-monitoring devices or access to accelerometer data. However, participants were asked to keep a diary to record sleeping, waking and working hours as well as recordings of any exercise bouts for the ExMore group. For most participants the intervention period lasted 4 weeks, but in cases where it was impossible to schedule post-intervention measurements the intervention period was prolonged by 1–2 weeks.

The primary outcomes were sedentary time and time spent in MVPA, measured using objective activity recording devices (details below), during one week immediately prior to the intervention period (baseline) and during the last week of the intervention period.

To quantify sedentary time participants wore an inclinometer (ActivPAL<sup>3</sup>™, PAL Technologies, Glasgow, Scotland). The device was initialized with ActivPAL software (Version 6.4.1) to record for eight consecutive days using a sampling rate of 20 Hz (yielding data from 7 full 24 h days). The skin on the left anterior mid-thigh of the participants was cleaned with an alcohol swab before application of adhesive non-woven fabric (Fixomull) for protection of the skin. The device was mounted in a waterproof bag with tape on the Fixomull patch. Participants were given extra materials to remount the device in case it came loose, but were otherwise required to wear the device throughout the recording period. Quantifying sedentary time measured with ActivPAL has been validated in previous studies.<sup>15</sup>

MVPA was recorded with accelerometers (GT3X+, ActiGraph, Pensacola, FL USA). These devices were initialized to start recording on the test day and for the following eight days (yielding data from 7 full 24 h days). Data were sampled at 80 Hz. Data were summed in epochs, with duration of 10 s and MVPA cutoff was set at 1951 counts per min.<sup>21</sup>

The accelerometers were mounted in the same way as the ActivPAL devices, except that they were placed on the right hip (suprailiac). Actigraph recordings of MVPA have been validated previously.<sup>22</sup>

Days with missing, corrupted or incomplete recordings were discarded. Also, days reported as days spent sick in bed were discarded. Actigraph data from both pre and post intervention were obtained from a total of 39 participants and from these 529 of 546 possible days were included in the analysis. Likewise, ActivPAL data were obtained from 38 participants and 512 of 532 possible days were used in the analysis. Subjects were required to fill out a diary on sleeping/wake time during the measuring periods. Diary information together with the accelerometer recordings was used to define sleep time and wake time. Custom designed software (Actigraph Analyzer v. 1.6, Cuno Rasmussen) enabled the omission of sleep time from the recorded accelerometer data and thus, MVPA was quantified only during waking hours. The data on sedentary time from the ActivPAL devices provided sedentary time for each full 24 h day. Sleeping time could not be determined from ActivPAL recordings, since sitting and lying are both recorded as sedentary behaviour. Therefore, to obtain waking sedentary time, the sleeping time determined through analysis of diary and accelerometer data, was subtracted from the total sedentary time for each recording day.

Prior to baseline activity recordings and after completing the intervention participants underwent measurements of secondary outcomes:

Height, weight and waist circumference were measured while participants wore light clothing and no shoes. Waist circumference was measured midway between lower rib curvature and *crista ili-*

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