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Long-term effects of a weight loss intervention with or without exercise component in postmenopausal women: A randomized trial

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ABSTRACT

The aim of this study was to determine the long-term effects of a weight loss intervention with or without an exercise component on body weight and physical activity.

Women were randomized to diet ($n = 97$) or exercise ($N = 98$) for 16 weeks. During the intervention, both groups had achieved the set goal of 5–6 kg weight loss. All women were re-contacted twelve months after study cessation for follow-up where body weight and physical activity were measured (PASE questionnaire and ActiGraph accelerometer).

At follow-up, body weight and physical activity (measured by the PASE questionnaire and accelerometer) were measured again. At follow-up, both mainly exercise (−4.3 kg, $p < 0.001$) and diet (−3.4 kg, $p < 0.001$) showed significantly reduced body weight compared to baseline. Both the mainly exercise and diet group were significantly more physically active at one year follow-up compared to baseline (PASE: +33%, $p < 0.001$ and +12%, $p = 0.040$, respectively; ActiGraph: +16%, $p = 0.012$. and +2.2%, $p = 0.695$ moderate-to-vigorous activity, respectively). Moreover, the increase in physical activity was statistically significantly when comparing exercise to diet (+0.6%, $p = 0.035$). ActiGraph data also showed significantly less sedentary time in mainly exercise group compared to baseline (−2.1%, $p = 0.018$) and when comparing exercise to diet (−1.8%, $p = 0.023$). No significant within group differences were found for the diet group.

This study shows largely sustained weight loss one year after completing a weight loss program with and without exercise in overweight postmenopausal women. Although the mainly exercise group maintained more physically active compared to the diet group, maintenance of weight loss did not differ between groups.

1. Introduction

Obesity and a sedentary lifestyle are an increasing worldwide health problem (Ogden et al., 2014). The World Health Organization (WHO) reports that worldwide 39% of adults are overweight of which 13% are obese (Mendis et al., 2015). The prevalence of overweight and obesity is proportionally higher in postmenopausal women, compared to premenopausal women (Lambrinoudaki et al., 2010). It has been shown for obese postmenopausal women to have an increased risk for developing coronary heart diseases, stroke, venous thrombosis, osteoporosis, stroke, type 2 diabetes, and certain types of cancers, some of the leading causes of preventable death (Mendis et al., 2015; Lambrinoudaki et al., 2010; Wiseman, 2008). It is well known, aside from contributing factors as increasing age, lower energy expenditure due to a sedentary lifestyle and increased caloric intake, that menopause affects the body composition on hormonal levels, fat distribution and insulin resistance causing central obesity (Lambrinoudaki et al., 2010; Neilson et al., 2009). Since both physical inactivity and obesity increase with age and are affected by menopause, this postmenopausal group is a relevant population to study lifestyle interventions (Centers for Disease Control and Prevention, 2011; Lynch et al., 2011). It has been shown that taking part in an exercise intervention or weight loss program is a successful method to lose body weight and to become more physically active over the short-term (Ryan et al., 2012; Wu et al., 2009; Franz et al., 2007). As shown by Baker et al. interventions taking up to 1 year have shown to be successful but those interventions did not include a follow-up measurement after completing the supervised intervention period (Baker et al., 2016). Wu et al. did study sustainability of weight loss interventions in their meta-analysis, however, the included studies nor the results were aimed at postmenopausal women (Wu et al., 2009).

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So, there is a lack of knowledge on the long-term effects of a short-term weight loss intervention in postmenopausal women specifically. Therefore, the aim of this study is to determine sustainability of effects of a weight loss intervention with or without an exercise component on body weight and physical activity in postmenopausal women. Furthermore, we aimed to investigate whether effects are different when weight loss is induced by a hypocaloric diet or mainly by exercise.

2. Methods

This study is a post-intervention study in women who participated in the Sex Hormones And Physical Exercise (SHAPE)-2 study; a three-armed randomized controlled trial conducted from February 2012 to May 2013 in eight municipalities in and around Utrecht and Enschede in the Netherlands. The primary goal of the SHAPE-2 trial was to study the effects of 5–6 kg weight loss induced by a hypocaloric diet or mainly by exercise on postmenopausal serum sex hormone levels, associated with breast cancer risk(van Gemert et al., 2015; van Gemert et al., 2013). The mainly exercise intervention was combined with a small caloric intake restriction to ensure the intended weight loss in this short time-frame. However, the emphasis was on exercise and for clarity reasons, we refer to this group as 'exercise group' throughout the paper. The SHAPE-2 main results showed that weight loss in both intervention groups resulted in favourable effects on sex hormones. Weight loss induced mainly by exercise additionally resulted in maintenance of lean mass, greater fitness, greater fat loss and a larger effect on (some) sex hormones. Details of the study design are reported elsewhere (van Gemert et al., 2013). The study was approved by the ethical committee of the University Medical Center of Utrecht. All participants provided informed consent.

In short, women were eligible if they were aged 50–69 years, postmenopausal, overweight or obese (BMI 25–35 kg/m^2), and insufficiently physically active (<2 h/week of ≥4 metabolic equivalents (MET) activity). Women were included via mass mailings and media publicity. Women who responded were contacted by telephone by a study nurse to assess their eligibility criteria. Main exclusion criteria were smoking, use of exogenous (sex) hormones, diabetes, or ever diagnosed with breast cancer

Before the intervention started, all women started with a four to six-week run-in period during which a standardized diet was prescribed, (50–60% carbohydrates, 15–20% proteins, 20–35% fat, min. 25 g fiber, max. 1 alcoholic consumption/day), aiming to remain weight stable (van Gemert et al., 2013; Health council of the Netherlands, 2006). After baseline measurements, women were stratified for municipality randomized by computer. Postmenopausal women ($n = 243$) were randomized to either a 16-week diet-induced weight loss group ('diet group', $N = 97$), weight loss mainly induced by exercise ('mainly exercise group', $N = 98$), or stable weight control group ('control group', $N = 48$). Both weight loss interventions aimed for 5–6 kg weight loss and were delivered by physiotherapists and/or dieticians.

In the intervention phase, the diet group was prescribed a diet with a deficit of 3500 kcal/week. Women in the mainly exercise group followed an intensive four hour/week exercise program; two one-hour group sessions of combined strength and endurance training at the physiotherapy centre and two one-hour sessions of moderate-to-vigorous Nordic walking per week. The average energy expenditure by exercise was approximately 2530 kcal/week. These women were also prescribed a relatively small caloric intake restriction of 1750 kcal/week to ensure the 5–6 kg weight loss goal within 14 weeks. The total targeted weekly energy deficit was, therefore, approximately 4280 kcal/week. This was an a priori decision, to ensure the 5–6 kg weight loss goal within 14 weeks. The targeted total average weekly deficit for the mainly exercise group is larger than the diet group to compensate for the gain in muscle mass (i.e., body weight) by the combined endurance and strength exercise program (van Gemert et al., 2013).

2.1. One-year post-intervention (follow-up) study

2.1.1. Study population

In order to be eligible to participate in the follow-up study of SHAPE-2 trial, subjects had to have given informed consent at baseline to be re-contacted in the future for invitation for additional research. These subjects were contacted by telephone one year (±4 weeks) after completing the SHAPE-2 intervention study. If subjects could not be contacted by telephone, questionnaires were sent by mail including a letter of consent and a return envelope. Subjects that could not be contacted by telephone or e-mail did not receive the accelerometer at follow-up.

The control group was excluded for analyses of the follow-up data since control subjects received a weight loss intervention after the intervention period. Therefore, the natural course during follow up could not be studied.

2.1.2. Outcomes

Primary outcomes are body weight and physical activity levels at follow up (t2) compared to baseline (t0) and at end of study (t1).

At baseline and end of study body weight was measured using an identical balance scale. At follow-up, body weight was self-reported by the participants.

Physical activity was assessed through the Physical Activity Scale for the Elderly (PASE) and an accelerometer, the ActiGraph®. Both methods were used also in the SHAPE-2 trial. The PASE is a brief self-administered seven-day recall questionnaire to measure changes in physical activity over time (Liu et al., 2011). The PASE has shown to have excellent test-retest reliability (ICC 0.89) and reasonable validity (r_s 0.68) (Liu et al., 2011; Schuit et al., 1997). The PASE is evaluating the physical activity of the past 7 days in three life domains: recreational, household and work-related Subjects rate their weekly frequency and daily duration for the following recreational activities: walking outside the home, light, moderate and strenuous activities and muscle strengthening. Whether household activities (light and heavy housework, home repairs, lawn work/yard care, outdoor gardening and caring for others) were performed was captured by answering yes or no. Finally, working for pay or as a volunteer was assessed by recording the amount of hours per week and the type of work performed. For each activity, a score was obtained by multiplying an activity frequency value by a task-specific weight provided by the scoring manual. The questionnaire data results in a PASE total score and/categories ranging from very light activities to very vigorous activities. The PASE total score, which represents the overall physical activity level, is the sum of all activities together, and ranges between 0 and 400 or more (Bolszak et al., 2014). The results in all these categories will be count together forming a continuous "PASE" score. A higher PASE score means a person is more physically active.

The ActiGraph® is a waist-worn accelerometer which measures movements by a three-dimensional/axis acceleration sensor (Hanggi et al., 2013). In our study we used the ActiGraph® wGT3X. The activity monitor measures activity in activity counts, which were recorded in 10 s intervals and transformed into 1-minute epochs. The 1-min epochs were used to compute the time spent in the different activity intensities i.e. sedentary (<100 counts per minute), light (100–759 counts per minute), lifestyle (760–1951 counts per minute), moderate (1952–5274 counts per minute), vigorous (5725–9498 counts per minute) and very vigorous (≥9499 counts per minute) (Sasaki et al., 2011; Freedson et al., 1998). All days with a wear-time minimum of 10 h are included in the analyses. Thus, also days with a wear-time > 10 h are included. Days containing <10 h have been shown not to be representative for daily physical activity. The 10-hour day cut point is commonly used in literature. Data from the ActiGraph® was extracted using Actilife® 6.8.1. For analyses, three categories were defined: sedentary time, light activities (light and lifestyle activities) and moderate to vigorous activities (moderate and very vigorous activities) based on the Freedson cut off points (Freedson et al., 1998). A non-wear period was