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A randomized, controlled, supervised, exercise trial in young overweight men and women: The Midwest Exercise Trial II (MET2)

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ABSTRACT

We evaluated weight loss response to 16 months of supervised exercise (45 min/day, 5 days/ week, 75% heart-rate-reserve) in sedentary, overweight/obese participants without energy restriction in the Midwest Exercise Trial (MET1). Results indicated men lost weight, women did not. The gender differences were associated with differences in the energy expenditure of exercise (EEEx) (men = 667 ± 116 ; women = 439 ± 88 kcal/session) when exercise was prescribed by frequency, intensity and duration. MET2 is a randomized control trial designed and powered to examine differences in weight loss and gender in response to EEEx for men and women of 400 or 600 kcal/session, 5 days/week, for 10 months without energy restriction. One hundred forty-one participants will be randomized to 1 of 2 exercise groups or a nonexercise control. EEEx will be verified by indirect calorimetry monthly during the intervention. This study will evaluate: (1) the weight change response to two levels of EEEx versus nonexercise control; (2) gender differences in weight response to two levels of EEEx; (3) potential compensatory changes in energy intake and/or daily physical activity that may explain the observed weight changes. Results from this study may impact how exercise is prescribed for weight loss and prevention of weight regain and may clarify if men and women differ in response to exercise.

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1. Introduction

The prevalence of overweight (BMI>25.0) and obesity (BMI>30.0) among US adults is ~68% and 34%, respectively [1]. Overweight and obesity contribute to heart disease,

hypertension, diabetes, and some cancers as well as psychosocial and economic difficulties [2–5]. The cost of treatment for weight reduction is now estimated to exceed 147 billion annually [6].

Exercise is recommended by virtually every public health organization for weight loss and prevention of weight regain [7–13]. However, the role of exercise is generally considered secondary to energy restriction [14–16]. Indeed, an argument can be made that exercise is ineffective for weight loss. Wing [17] reviewed the literature on the role of exercise on weight loss and concluded that exercise alone results in a minimal weight loss of 2 kg compared to control conditions. The American College of Sports Medicine Position Stand on "Appropriate Physical Activity Intervention Strategies for Weight loss and Prevention of Weight



Abbreviations: BMI, Body Mass Index; DLW, doubly-labeled water; DXA, dual-energy X-ray absorptiometry; EEEx, energy expenditure of exercise; EI, energy intake; HR, heart rate;Kcal, kilocalories; Kg, kilograms; MET1, Midwest Exercise Trial 1; MET2, Midwest Exercise Trial 2; MJ, Megajoules;PAEE, physical activity energy expenditure; TDEE, total daily energy expenditure.

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Regain for Adults," suggested that 150–250 min/week of moderate intensity exercise does not result in clinically significant weight loss [12].

The literature on the effects of exercise for weight loss is influenced by the absence of studies that prescribe exercise with equivalent levels of exercise energy expenditure (EEEx) across individuals and genders, as well as the lack of verification that the exercise was competed at the prescribed level of EEEx. Verification of exercise completion is critical as self-reported exercise is frequently over-estimated [18]. Previously, Donnelly et al. [19] reported results from the Midwest Exercise Trial (MET1) where exercise was prescribed to previously sedentary overweight/obese men and women by frequency, intensity and duration for 16 months without energy restriction. EEEx was measured at 3-month intervals and was higher in men (667 ± 116 kcal/session) than women $(439\pm88 \text{ kcal/session})$, which is expected due to gender differences in body weight. The gender differences in EEEx (228 kcal/session) resulted in a mean weight loss for men of 5.2 ± 4.7 kg and a small weight gain for women of 0.6 ± 3.8 kg. The gender differences in EEEx diminished our ability to conclude that differences in the weight response to exercise were due to gender.

The Midwest Exercise Trial II (MET2) study was designed to evaluate gender differences in weight response to exercise prescribed at the same level of EEEx without diet restriction. Overweight and obese men and women will be randomly assigned to 10 months of supervised exercise 5 days/week with a verified EEEx of 400 kcal/session or 600 kcal/session (2000 or 3000 kcal/week) or a non-exercise control group. This study will evaluate: (1) the weight change response to two levels of EEEx versus non-exercise control; (2) gender differences in weight response to two levels of EEEx; (3) potential compensatory changes in energy intake and/or daily physical activity that may explain the observed weight changes.

2. Materials and methods

2.1. Eligibility/recruitment/randomization

Participant recruitment and randomization for MET2 has been completed. Participants were recruited from Lawrence, KS and surrounding communities and will be compensated for their participation. Approval for this study was obtained from the Human Subjects Committee at the University of Kansas-Lawrence. The following inclusion/exclusion criteria were used: age = 18-30 years, BMI = 25.0 to 39.9 kg/m², sedentary defined as <500 kcal/week in planned exercise as assessed by questionnaire [20]. Participants with a history of chronic disease (i.e., diabetes, heart disease, etc.), elevated blood pressure (\geq 140/90), lipids (cholesterol >6.72 mmol/L; triglycerides >5.65 mmol/L), or fasting glucose (>7.8 mmol/L) were excluded. Additionally, smokers, those taking medications that affect physical performance (i.e., beta blockers) or metabolism (i.e., thyroid, steroids), or those lacking the ability to perform laboratory tests or participate in moderate-tovigorous intensity exercise were excluded. Participants were randomized at a 2:2:1 ratio (~65% to the exercise groups and ~35% to the control group), stratified by gender under the supervision of the project statistician. The blinding of participants to group assignment is not possible with an exercise intervention. Investigators will be blinded at the level of outcome assessments, data entry and data analysis. A consort diagram describing recruitment and randomization is presented in Fig. 1.

One hundred forty-one participants were recruited, consented, and randomized into the 400 or 600 kcal/session exercise groups or non-exercise control. This slightly exceeded our targeted enrollment of 136 participants needed to meet power requirements. The sample is comprised of 55.3% women and 14.8% minorities. Sample baseline demographics by gender and group are presented in Table 1.

2.2. Exercise groups

Exercise will consist primarily of walking/jogging on motor-driven treadmills; however, alternate activities such as stationary biking, walking/jogging outside, or walking on stationary elliptical trainers will be allowed for 20% of the total exercise sessions (1 session/week). Exercise prescriptions will progress from 150 kcal/session at intervention onset to reach the target EEEx (400 or 600 kcal/session) at the end of month 4 and remain at target over the final 6 months of the study (Table 2). These levels for EEEx were selected based on recommendations from The American College of Sports Medicine Position Stand "Appropriate Physical Activity Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults," [21]. These levels of EEEx are also consistent with the recommendations for weight loss provided by Health and Human Services "2008 Physical Activity Guidelines for Americans" [22] and were associated with no weight change (~400 kcal/session) or clinically significant weight loss (>600 kcal/session) in MET1.

2.3. Energy expenditure of exercise

Changes in both body weight and aerobic fitness influence EEEx when performed at the same intensity. Therefore, EEEx will be assessed at baseline and monthly during the intervention to determine the duration of treadmill exercise required to achieve the EEEx goals (Table 2). EEEx will be assessed by indirect calorimetry (ParvoMedics TrueOne 2400 System, ParvoMedics Inc, Sandy, UT) at 1 min intervals. The Weir equation [23] will be used to calculate EEEx from measured oxygen consumption and carbon dioxide production. Prior to each EEEx assessment participants will perform a brief warmup (~2 min, 3–4 mph, 0% grade). At the baseline assessment, treadmill speed/grade will begin at 3 mph/0% grade and will be adjusted by increments of 0.5 mph/1% grade until the participant reaches 70% HR max \pm 4 beats/min. At the end of months 1 to 3, EEEx will be calculated at both 70% and 80% of heart rate (HR) maximum to accommodate personal preferences for walking or running. EEEx will be assessed at both 70% (15 min) and 80% HR max (15 min) with a 2 min interval between assessments to allow participants to remove the mouthpiece and obtain water if desired. Either speed or grade will be adjusted depending on participant preference. The average EEEx over a 15 min interval (kcal/min) will be used determine the duration of exercise sessions performed during the first month. For example: EEEx = 9.2 kcal/min, prescribed exercise = 400 kcal/session, exercise duration = 400/9.2 = 44 min/ Download English Version:

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