



## Comparative effectiveness of guided weight loss and physical activity monitoring for weight loss and metabolic risks: A pilot study

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### ABSTRACT

Many consumer-based physical activity monitors (PAMs) are available but it is not clear how to use them to most effectively promote weight loss. The purpose of this pilot study was to compare the effectiveness of a personal PAM, a guided weight loss program (GWL), and the combination of these approaches on weight loss and metabolic risk. Participants completed the study in two cohorts: Fall 2010 and Spring 2011. A sample of 72 obese individuals in the Ames, IA area were randomized to one of 3 conditions: 1) (GWL, N=31), 2) PAM, N=29, or 3) a combination group (PAM+GWL, N=29). Weight and metabolic syndrome score (MetS), computed from waist circumference (WC), BMI, blood pressure (BP), and lipids were assessed at baseline and following an 8-week intervention. Weight was also assessed four months later. Two-way (Group×Time) ANOVAs examined intervention effects and maintenance. Effect sizes were used to compare magnitude of improvements among groups. During the intervention, all groups demonstrated significant improvements in weight and MetS (mean weight loss=4.16kg,  $p<0.001$ ). Mean weight continued to decline modestly during follow-up, with average weight loss of 4.82kg from baseline ( $p<0.01$ ). There were no group differences for weight loss but the PAM+GWL group had significantly larger changes in MetS score ( $d=0.06$ – $0.77$ ). The use of PAM resulted in significant improvements in weight and MetS that were maintained across a four-month follow-up. Evidence suggests that the addition of GWL contributed to enhanced metabolic outcomes.

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### 1. Introduction

The high prevalence of obesity has led to increased clinical and public health interest in effective weight loss programming (Ford et al., 2014). The classification of obesity as a disease (Breymaier, 2013) and modifications to medical care reimbursements through the Affordable Care Act (Patient Protection and Affordable Care Act, 2010) are both expected to increase clinical referrals for effective supervised weight loss programming. Revised clinical weight loss guidelines will also dramatically increase the number of overweight adults that qualify for weight loss treatments (Jensen et al., 2014). To meet this demand, it is important to evaluate the relative utility of weight loss interventions that have potential for translation to clinical settings.

The underlying goal of clinical weight loss programming is to reduce risk for chronic disease and co-morbidities. Metabolic syndrome is an

established precursor to diabetes and is diagnosed when an individual exhibits a cluster of metabolic-related risk factors including high waist circumference (WC), high triglycerides, reduced high-density lipoprotein cholesterol, high blood pressure (BP), and high fasting blood glucose (Eckel et al., 2010). Studies have demonstrated that 24–78% of obese adults have metabolic syndrome putting them at heightened risk for diabetes and other chronic diseases such as heart disease (van Vliet-Ostapchouk et al., 2014; Mozaffarian et al., 2015). Therefore, it is important for weight loss trials to examine the extent to which weight loss can contribute to addressing co-morbidities such as metabolic syndrome.

Behavior-based lifestyle programs that utilize the support of technology to evoke changes in diet and physical activity are recommended for weight reduction (Curioni and Lourenco, 2005; Looney and Raynor, 2013; Johns et al., 2014; Guide to Community Preventive Services, 2009). Guided weight loss programs (GWL) which aim to increase patient knowledge, motivation and behavior change through individualized counseling have shown consistent efficacy in improving weight and other chronic disease conditions (Mettler et al., 2014; Kivelä et al., 2014; Shahnazari et al., 2013; Chen and Devore, 2015). The effectiveness of web-based approaches have also been documented in comprehensive reviews (Wieland et al., 2012) and several previous studies

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have supported the utility of personal physical activity monitoring devices (PAM) as an adjunct to supervised weight loss programming (Polzien et al., 2007; Pellegrini et al., 2012; Shuger et al., 2011). For example, Shuger et al. and Polzien et al. reported better outcomes when a PAM was included as part of a guided weight loss program, compared to behavior change education or PAM alone (Polzien et al., 2007; Shuger et al., 2011).

An array of new consumer-based PAMs has recently flooded the market. Theoretically, self-monitoring helps participants build self-efficacy through visualized feedback and identifying barriers to long-term maintenance of behavior change (Carels et al., 2005; Racette et al., 2009; Burke et al., 2011). Daily tracking of diet and/or activity promotes healthy dietary and lifestyle changes (Carels et al., 2005; Racette et al., 2009; LeCheminant et al., 2011; Clarke et al., 2007) and consistent on-line self-monitoring has been shown to be effective for achieving clinically relevant weight loss (Krukowski et al., 2013). However, this tracking may be less burdensome using consumer PAM devices which provide objective, easy-to-use data.

The purpose of this study was to determine the independent and interactive benefits of a PAM and a GWL program on weight loss and risk factors associated with metabolic syndrome in obese adults. Outcomes were evaluated following the 8-week intervention as well as four-months later to assess maintenance of positive changes. It was hypothesized that all groups would have an improvement in weight loss and related health outcomes but the combination of PAM and a GWL would yield significantly larger effects than either of the single treatment options.

## 2. Methods

### 2.1. Design

The study was conducted as a randomized pilot study to evaluate the relative efficacy of three different weight loss treatment approaches: 1) GWL, 2) a self-monitoring program using a commercial PAM or 3) a combined program that included both GWL and a PAM. (PAM+GWL). Regardless of intervention group, participants were randomized to a health coach who monitored their participation in the study and, on a weekly basis, collected process data and ensured there were no technical issues with the PAM (PAM and PAM+GWL groups).

### 2.2. Intervention

The intervention was delivered by graduate student health coaches who were trained and supervised by the Principal Investigator and a Registered Dietician. Training was provided on general health coaching principles, delivery of the GWL program, and effective use of the PAM for behavior change applications. The intervention was 8weeks in duration with data collected at entry, 8weeks (i.e., end of intervention) and 4months after the intervention ended.

#### 2.2.1. Group 1: Guided weight loss

The GWL program provided participants with structured one-on-one weekly meetings with a health coach lasting approximately 1h. Topics included food cues, support and social cues, fiber, mindful eating, sleep, stress, and special event eating. Participants were provided with a booklet on diet and weight loss strategies and were encouraged to make self-directed changes in lifestyle behaviors each week.

#### 2.2.2. Group 2: Physical activity monitor

The PAM condition provided participants with access to a multisensory PAM worn on the back of the left triceps (SenseWear® armband, Jawbone, San Francisco, CA, USA) and instructions on the use of the associated online weight management system (WMS) designed for self-monitoring applications. Participants were encouraged to use the monitor daily and were provided with a wristwatch display that provided

real-time estimates of caloric expenditure, minutes of moderate and vigorous physical activity, and number of steps taken during the day. Participants were also encouraged to enter dietary intake into the WMS and view reports of energy balance, nutrition, and physical activity. Weekly contact with coaches was solely focused on addressing any technical issues with the monitor or online system.

#### 2.2.3. Group 3: Physical activity monitor and guided weight loss

Participants in the PAM+GWL condition received a combined program including the Guided Weight Loss as described above, including hour-long weekly meetings with coaches, in combination with PAM and access to the WMS.

### 2.3. Sample

A total of 89 individuals from central Iowa (USA) were recruited to participate in the study. Promotional strategies included advertisements in newspapers and radio as well as posted flyers and word of mouth. Potential participants attended an informational session and completed a diet and medical history questionnaire to determine eligibility. Inclusion criteria were:  $\geq 18$  years of age, BMI  $\geq 30$  kg/m<sup>2</sup>, and weight stable ( $\pm 4.5$  kg) for 3 months. Exclusionary criteria were: diagnosis of diabetes; heart attack or angina; stroke; cancer; thrombophlebitis; kidney or peptic ulcer disease; smoking tobacco products; Stage 2 hypertension ( $>160$  mmHg systolic and/or  $>100$  mmHg diastolic pressure); high triglycerides ( $>500$  mg/dL); history of anorexia or bulimia; past bariatric surgery; chronic use of corticosteroids; use of medications in which physical activity, dietary change or weight loss would affect dosage; current or planned pregnancy within the study duration; or current participation in another weight loss program or study.

Participants were enrolled in the intervention in two cohorts to maximize sample size [Fall 2010 ( $n=39$ ) and Spring 2011 ( $n=39$ )]. All eligible participants obtained approval from their primary care physician to enter a weight loss program and provided informed consent prior to beginning the study. Participants were randomized to a trained coach and one of the three treatment groups (Fig. 1) using standard randomization procedures for clinical trials. Due to the participants' active involvement in the study, blinding was not feasible. The study protocol was approved by the Iowa State University Institutional Review Board.

### 2.4. Measures

#### 2.4.1. Anthropometric measures

Anthropometric measures were assessed at baseline, 8 weeks, and follow-up (4-months post-intervention). Height and weight were measured without shoes using an electronic scale (Detecto model 6856, Webb City, MO, USA) and wall-mounted stadiometer (Ayrton model S100, Prior Lake, MN, USA). Waist circumference was measured at the umbilical region by a trained laboratory staff member. All measurements were taken twice with the average of the two measurements recorded. If the duplicate measurements for height or waist circumference were not within 0.2 cm, a third measurement was taken and the two closest measurements were averaged. Replicate measurements were taken by an additional researcher on every tenth participant as a quality control procedure. Percent body fat was estimated using a handheld bioelectrical impedance analysis device (Omron Fat Loss Monitor HBF-306, Bannockburn, IL, USA).

#### 2.4.2. Clinical measures

A variety of clinical risk factors were collected to facilitate calculation of a continuous metabolic syndrome score. Resting blood pressure (BP) was measured at baseline, 8 weeks and follow-up using an automated oscillometric device (Omron Digital Blood Pressure Monitor HEM-907XL, Schaumburg, IL, USA). Fasting blood draws were performed at baseline and at 8 weeks only. At each time point, 15 mL venous blood samples were drawn from the antecubital vein after a 10-h overnight

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