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

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A B S T R A C T

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-Ostaptchouk 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.
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; LeCheinianiant et al., 2011; Clarke et al., 2007) and consistent online self-monitoring has been shown to be effective for achieving clinically relevant weight loss (Krukowsi 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: ≥18years of age, BMI≥30kg/m², and weight stable (±4.5kg) for 3months. Exclusionary criteria were: diagnosis of diabetes; heart attack or angina; stroke; cancer; thrombophilic; kidney or peptic ulcer disease; smoking tobacco products; Stage 2 hypertension (>160mmHg systolic and/or >100mmHg diastolic pressure); high triglycerides (>500mg/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, 8weeks, 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 0.2cm, 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, 8weeks 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 8weeks only. At each time point, 15mL venous blood samples were drawn from the antecubital vein after a 10-h overnight
fast. Samples were sent to a clinical laboratory (Quest Diagnostics, Wood Dale, IL, USA) for assessment of total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG), and blood glucose. Low density lipoprotein cholesterol (LDL-C) was estimated using the Friedewald equation (Friedewald et al., 1972).

A continuous metabolic syndrome score (MetS) was calculated based on established methods (Eisenmann, 2008; Yoo et al., 2009; Yoo and Franke, 2013) in order to provide a quantifiable measure of risk. The score reflects the sum of z-score for the five risk factors: waist circumference, mean arterial pressure, triglycerides, glucose, and HDL-cholesterol.

### 2.4.3. Process measures

A subjective rating of program compliance for each week during the 8-week intervention was assessed using a Compliance Score (CS) ranging from 0 to 2. A rating of 0 indicated little or no participation in the coaching session, insufficient progress toward self-selected goals, or failure to respond to coach communications. A rating of 2 indicated full participation in the coaching session, sufficient progress toward goals, and active communication with health coach. Participants with moderate engagement received a rating of 1 for that week. Average CS across the 8-week intervention was used to assess the impact of overall compliance on outcomes.

### 2.5. Analysis

Because data were collected in two cohorts, a preliminary 3-way ANOVA (Cohort×Group×Gender) was conducted to assess for potential cohort effects. Group differences for changes in the primary outcome variables (weight and MetS at 8-weeks and weight at follow-up) were assessed using two-way (Group×Time) ANOVAs with significance set at α=0.05. This statistical approach controls for baseline values and reduces the influence of any pre-existing differences between groups. Additional analyses also added the participant’s average CS to the ANOVA models as a covariate to examine the impact of program compliance on the effect of each treatment. Effect sizes (Cohen’s d) were calculated to compare the magnitude of changes in outcome measures among the three treatment groups.

Changes in MetS were also examined relative to the amount of weight change over the course of the intervention using data from all participants, regardless of treatment group. This analysis used a one-way ANOVA to evaluate differences in change in MetS based on tertiles of weight loss.

### 3. Results

Of the 89 participants enrolled in the study, 78 (32 males and 46 females; 26 from each treatment group) completed the 8-week intervention. Participant flow is depicted in Fig. 1 and descriptive statistics for the 78 participants who completed the intervention are provided in Table 1a. The majority of participants were well educated (69% with ≥4-year degree) and Caucasian (94%). This is consistent with the community from which the sample was recruited (82% Caucasian and 62% of adults 25 years or older possessing a bachelor’s degree or higher). All participants were obese at baseline and 24% of the participants (13 male, 6 female) met criteria for metabolic syndrome (Antonopoulos, 2010–2011, Ames, IA).
Participants who dropped out during the intervention were significantly younger and had lower body fat than the completers (data not shown).

A sample of 53 participants (19 males, 34 females) agreed to return for follow-up measurements after the trial was completed. For follow-up analyses, there was a relatively even distribution of participants by group (21 GWL, 17 PAM, 17 GWL+PAM) and there were no differences in anthropomorphic variables at the end of the 8-week intervention between those who returned for follow-up and those who did not (p>0.05). Descriptive statistics for the 53 participants who completed follow-up measures are provided in Table 1b.

There was a significant difference in weight loss between the Spring and Fall cohorts (p=0.044) with larger amounts of weight loss observed in the spring (5.00kg±3.1) compared with the fall (3.41kg±2.9). However, there were no significant interactions of cohort with any other variables suggesting the differences were likely an effect of season and not of the intervention working differently between the two cohorts. Therefore, these cohort effects were not considered in the remaining analyses. There was also no influence of Gender in this analysis and so, due to small sample size, subsequent results are not separated by gender.

There were no significant differences between the three groups for weight loss at the end of the intervention [F(1,2)=1.01, p=0.37] with all groups achieving meaningful weight loss (p=0.0001, Table 2). There were also no significant between-groups differences for changes in other anthropomorphic measures with all groups showing significant improvements over time (BMI: −1.37kg/m², p<0.001, weight: −4.16kg, p<0.001, WC:−4.25cm, p<0.001, body fat: −0.96%, p<0.001) (changes for all participants collapsed across group). However, a significant Group×Time interaction was evident for the continuous MetS score [F(1,2)=3.80, p=0.027]. Effect sizes for the change in MetS revealed larger effects in the GWL+PAM group compared to the other groups (Fig. 2).

The participants who returned for follow-up measurement were successful in maintaining weight loss with a mean weight change between 8weeks and 4months post-intervention of −0.15kg (SD=3.67). Values for each of the anthropometric variables measured at 4months

| Characteristic | Treatment group | All | GWL | PAM | GWL+PAM |
|----------------|-----------------|-----|-----|-----|---------|
| N | 78 | 26 | 26 | 26 |
| % Female | 60.2 | 88.5 | 50.0 | 42.3 |
| Age (years)* | 38.6±14.6 | 41.0±14.6 | 38.6±14.7 | 37.9±13.1 |
| Range | 18–72 | 19–72 | 18–72 | 19–67 |
| Weight (kg)* | 109.9±20.6 | 103.8±15.5 | 119.9±20.0 | 114.1±24.6 |
| BMI (kg/m²)* | 36.7±5.5 | 36.8±5.3 | 36.4±3.3 | 37.0±6.0 |
| Body fat (%)* | 38.2±6.4 | 38.2±4.1 | 37.0±7.0 | 36.6±6.2 |
| Waist circumference (cm)* | 120.1±13.8 | 119.9±13.9 | 120.6±13.0 | 119.8±14.8 |
| Systolic blood pressure (mmHg) | 116.6±12.1 | 114.5±12.3 | 116.5±11.8 | 118.9±12.2 |
| Diastolic blood pressure (mmHg) | 76.3±7.6 | 76.0±7.6 | 76.3±6.8 | 76.9±8.6 |
| Glucose (mg/dL) | 93.7±8.2 | 92.5±9.5 | 92.0±7.2 | 96.9±7.0 |
| HDL-C (mg/dL) | 48.7±13.6 | 50.0±10.1 | 48.0±14.8 | 48.1±15.7 |
| Triglycerides (mg/dL) | 161.2±75.3 | 158.8±69.9 | 160.0±74.6 | 160.2±83.1 |
| MetS | 0.007±2.9 | 0.4±2.6 | 0.2±2.7 | 0.7±3.4 |

Education (N[%])
- High school | 1[1.3] | 0[0.0] | 1[3.9] | 0[0.0] |
- Some college | 17[21.8] | 7[26.9] | 5[19.2] | 5[19.2] |
- College or graduate degree | 60[76.9] | 19[73.1] | 20[76.9] | 21[80.8] |
- Married | 44[56.4] | 16[61.5] | 14[53.9] | 14[53.9] |
- Race (N[%])
  - Asian | 1[1.2] | 1[1.9] | 0[0.0] | 1[3.9] |
  - Caucasian | 74[94.9] | 25[96.2] | 25[96.2] | 24[92.3] |
  - Black | 3[3.8] | 1[3.9] | 1[3.9] | 1[3.9] |

Note: BMI=Body mass index. * Mean±standard deviations.
post-intervention were also more favorable than the corresponding 8-week values: weight = −4.82kg (SD = 4.83), BMI = −1.58kg/m² (SD = 1.59), body fat = −1.15% (SD = 2.09), and WC = −4.64cm (SD = 4.69). At follow-up, there were no significant between-group differences (p > 0.05) in weight loss. However, participants in the PAM + GWL treatment group demonstrated the greatest overall improvement in anthropometric outcomes including losing the most weight at follow-up (M = 5.57kg, SD = 5.18). Participants in the GWL group showed the least improvement in all anthropometric outcomes at both time points.

Differences in outcomes by group were directly evaluated by calculating effect sizes. At 8weeks, there was a moderate difference for weight loss between PAM + GWL and GWL (d = 0.38) and a small difference between PAM + GWL and PAM (d = 0.28) (Table 2). A noteworthy difference in MetS was evident between the GWL + PAM group and the other groups (PAM + GWL vs GWL: d = 0.76; PAM + GWL vs PAM: d = 0.54) (Fig. 2). Effect sizes for weight loss among the groups at 4months post-intervention were moderate to small (PAM + GWL vs GWL: 0.2 to 0.78) (Fig. 2). Cohen’s d values for improvements in weight and clinical health indicators. Significant covariate in the relationship between treatment group and health indicators. Further, all three intervention strategies resulted in improvements in a number of clinical measures associated with the metabolic syndrome and associated chronic health conditions. Of the three, the GWL + PAM intervention resulted in the greatest improvement in health indicators.

A related study by Case et al. found that a 6.5% decrease in body weight resulted in substantial reductions of systolic and diastolic blood pressure, blood glucose, triglycerides and total cholesterol following four weeks of a very low calorie diet (Case et al., 2002). Our results demonstrated that improvements in MetS can occur with even modest amounts of weight loss, with participants in the middle tertile of weight loss experiencing over a 1 unit decrease in MetS score with weight losses of only 1.7–3.0kg. This improvement may be clinically significant in terms of quality of life due to the demonstrated relationship between obesity, metabolic health and healthy-life-expectancy (Gregg, 2015; Grover et al., 2015).

The observation that the combination of PAM with GWL yielded larger reductions in MetS deserves further study. Previous studies by Polzien et al. and Shuger et al. reported larger reductions in weight when a PAM was combined with a GWL (Polzien et al., 2007; Shuger et al., 2011); however a more recent study (Jakicic et al., 2016) reported no benefit of wearable technology for enhancing weight loss (compared

### Table 2

|                  | GWL   | PAM   | PAM + GWL | PAM + GWL vs GWL | PAM + GWL vs PAM |
|------------------|-------|-------|-----------|------------------|------------------|
| **N**            | 26    | 26    | 26        |                  |                  |
| **Mean**         | 3.69  | 4.05  | 4.88      | 0.38             | 0.28             |
| **95% CI**       | 2.4–5.0 | 2.9–5.2 | 3.6–6.2 |                  |                  |
| **Weight loss (kg)** |       |       |           |                  |                  |
| **Follow-up**    | 21    | 15    | 17        |                  |                  |
| **Mean**         | 3.94  | 5.2   | 5.57      | 0.36             | 0.07             |
| **95% CI**       | 2.0–5.9 | 2.3–8.1 | 2.9–8.2 |                  |                  |
| **MetS change**  | ⍺<sup>⁎</sup> (sum of z-scores) | ⍺<sup>⁎</sup> | ⍺<sup>⁎</sup> |                  |                  |
| **8weeks**       | 26    | 26    | 26        |                  |                  |
| **Mean**         | −0.78 | −1.06 | −2.08     | ⍺<sup>⁎</sup>   | ⍺<sup>⁎</sup>    |
| **95% CI**       | −0.2 to −1.4 | −0.3 to −1.8 | −1.3 to −2.8 | ⍺<sup>⁎</sup> | ⍺<sup>⁎</sup>       |

* Significant improvement from baseline (p < 0.0001).
** Significant improvement from baseline (p < 0.05).
*** Significant difference between treatment groups (p < 0.05).

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4. **Discussion**

The results demonstrate that the PAM offered an effective approach for improvements in weight and clinical health indicators. Significant improvements occurred over the intervention period for all three groups, with participants losing an average of 4.2kg over 8weeks with these improvements being maintained through four months of no contact with study staff. This change in weight was within the recommended guidelines of healthy, gradual weight loss of 1–2lb/week (or 0.45–0.91kg/week) and is similar to results from previous weight-loss interventions (Polzien et al., 2007; Carels et al., 2005; Morgan et al., 2009; McDoniel et al., 2010). Further, all three intervention strategies resulted in improvements in a number of clinical measures associated with the metabolic syndrome and associated chronic health conditions. Of the three, the GWL + PAM intervention resulted in the greatest improvement in health indicators.

Fig. 2. Change in metabolic syndrome score by group (2010–2011, Ames, IA). Change in continuous metabolic syndrome score from baseline to 8weeks between the guided weight loss program (GWL), the physical activity monitor only (PAM), and the combined (PAM + GWL) interventions.
the findings since it is more typical of real-world applications. Lastly, this study examined the additive influence of a specific guided weight loss curriculum. Other behavioral strategies that incorporate motivational interviewing and patient-directed goal setting may be more successful. The lack of a true control group prevents us from evaluating the independent benefits of each treatment but the focus was on evaluating the value of combining PAM and GWL approaches, compared to using either approach in isolation. While a true control group would have enhanced the interpretability of the results of this study, the primary aim was to compare these treatment options to inform a larger and more comprehensive clinical trial.

5. Conclusions

In summary, our results demonstrate that the systematic use of a personal activity monitor yields improvements in weight and MetS that are similar to those achieved through a standard GWL program. However, the combination of an activity monitor with GWL results in significantly larger reductions in metabolic syndrome score than either approach alone. Interventions that address lifestyle changes in both diet and physical activity behaviors have been effective for improving weight and metabolic health, but in-person behavior change counseling can be time- and cost-intensive (Archer et al., 2012). Given recent revisions in clinical weight loss guidelines [4], there will likely be an increased demand for effective weight loss treatments. This pilot study provides initial evidence that cost-effective self-monitoring devices may provide potential for supervised weight loss. However, future expansions on this study that include larger and more diverse samples are warranted to understand the most appropriate dose and duration of behavior change strategies to effectively supplement the use of these PAMs for maintenance of behavior change. Given the increasing number of PAMs on the market, comparisons of different monitor features as well as varying doses and frequency of coaching warrant closer examination. Studies with longer durations, both for use of PAM and follow-up after cessation of PAM use, are needed to more clearly evaluate the potential of these devices for facilitated behavior change.

Transparency document

The Transparency document associated with this article can be found, in online version.

Conflict of interest

The authors declare that they have no competing interests or conflicts of interest.

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