

Do Wristbands Used as an Adjunct to a Weight-Loss Program Affect the Outcomes in the Treatment of Obesity?

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ABSTRACT

Objective: The purpose of the present study was to evaluate the efficacy of a wristband as a method for reminding patients of lifestyle modification in weight-loss program.

Methods: Researchers randomly assigned 64 obese patients in our outpatient department to receive either a wristband plus brief lifestyle modification program (wristband group) or a brief lifestyle modification program alone (control group). The primary outcome was the change in body weight at 6 months. The secondary outcomes included the change in body weight at 12 months; the change in waist circumference at 6 and 12 months; the percentage of participants who maintained a weight loss at 6 and 12 months; and the categorical weight loss of the participants at the 6- and 12-month follow-ups.

Results: At 6 months, participants in both groups had lost weight. The mean (\pm SE) weight change among the participants in the wristband group and the control group was -4.5 ± 1.38 and -2.13 ± 1.09 kg, respectively (p -value = 0.193). All of the secondary outcomes displayed a trend in favor of the wristband group.

Conclusion: The results of this trial of a weight-loss intervention provide potential support to use a wristband for habitual change as an adjunct to lifestyle modification in a weight-loss program.

Keywords: Wristband; obesity; lifestyle modification program; weight-loss program; body weight; waist circumference; habit (Siriraj Med J 2018;70: 397-405)

INTRODUCTION

Obesity is a growing problem. Compared to people with normal, or healthy, weight, people who are obese are at increased risk for many serious diseases.¹⁻³ Lifestyle modification is considered the first option to achieve healthy weight.⁴⁻⁷ Several trials, in which primary care providers offered counseling about diet and physical activity, have seen weight losses of 4.6 kg or less over study periods ranging from 6 months to 2 years.⁸⁻¹¹

Behavioral therapy is one of the key components of lifestyle modification. Behavioral therapy refers to a set of principles and techniques for helping obese individuals

modify their eating, activity and thinking habits which are contributing to their excess weight.⁶

Ten Top Tip program (10TT) is a brief and effective weight control intervention that can be delivered without specialist skills. It is suitable for our healthcare environment which has limited resources to select comprehensive lifestyle modification program. It is based on habit-formation theory that had quantitative and qualitative evidences to help lose weight. According to a randomized control trial by RJ Beeken et al., 10TT delivered through primary care is effective in the short-term and a low-cost option over the longer term. Participants receiving

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10TT lost significantly more weight over 3 months than those receiving usual care.¹² 10TT has shown qualitative evidences about the experiences of participants in the program. Participants reported positive experiences, both during and after the interventions. Participants particularly enjoyed the novelty of the interventions as they shifted focus from diet and exercise, to practical everyday habit changes. They also reported indirect health benefits such as increased energy levels, increased confidence and improved self-awareness. 10TT enhanced self-regulatory skills and changes in self-regulatory skills and automaticity mediated the effect of the intervention on weight loss.^{13,14}

Researchers searched for tools that help as an adjunct to a weight-loss program and considered wristbands. These are made from a loop of material that is placed around the wrist, and they are used for many different reasons, but most typically, for identification purposes. Wristbands are an effective intervention for cuing process in habit loop which resulted in reducing drinking among designated drivers.¹⁵ Despite their widespread use, their efficacy in weight loss program has not been evaluated before this study. This tool is based on neurobehavioral model and habit-formation theory that offers a unique perspective from which to derive an approach to weight management.¹⁶⁻²⁰ Habits are automatically triggered actions, learned through repetition of the action in a consistent context. Researchers postulated that wristbands might be the intervention that targets automatic actions in a consistent context. Wristbands might help participants to lose weight, given that they had the potential to enhance particular components of cognitive behavioral therapy by regularly alerting and reminding participants of their goal to lose weight, the need to strive for healthy habits, and the value of regular self-monitoring. Researchers conducted a 12-month, randomized controlled trial to evaluate the effectiveness of wristbands as an adjunct to a simple, weight-loss program.

MATERIALS AND METHODS

Study design

Researchers randomized patients in a controlled trial that compared the clinical consequences of a wristband plus brief lifestyle modification program (wristband group), versus a brief lifestyle modification program alone (control group).

The study, conducted between November 2013 and March 2016, was approved by the Research Ethics Board of the Panyanantapikkhu Chonprathan Medical Center (PCMC), Srinakharinwirot University.

Study participants

Participants were recruited and treated at the outpatient department at PCMC.

For inclusion in the study, participants had to be 18 years of age or older and have a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of 30 or higher.

Exclusion criteria were chronic kidney disease with an estimated GFR below 30; pregnancy; lactation; a weight loss of 5 kg or more in the previous 3 months; an eating disorder; a thyroid disease; major surgery in the previous 3 months; severe comorbidity; and receiving a medication that affected the body weight in the previous 3 months (e.g., diuretics, glucocorticoids, insulin or thiazolidinedione).

Interventions

All participants were prescribed a brief lifestyle-modification program encompassing three principal components: diet, physical activity, and behavioral therapy. By permission of J Wardle, the behavioral treatment was based on the Ten Top Tips program.²¹

Wristband group

Researchers prescribed a brief lifestyle-modification program encompassing three, principal components: diet, physical activity, and behavioral therapy. The behavioral treatment was based on the Ten Top Tip program. The model consists of a list of ten behaviors. Seven are simple behaviors associated with a negative energy balance that is estimated to create a daily deficit of 800-900 kcal for a person changing from doing none of the behaviors to doing all of them. Two additional behaviors are designed to improve awareness of food intake, while the tenth behavior promotes routines.²¹ Health professionals were provided with a script to assist them to deliver the intervention in a standardized way. Immediately after randomization, patients received the Ten Top Tips leaflet, a simple logbook for self-monitoring of target behaviors and weight issued by Weight Concern and Cancer Research UK²² together with a wristband made from silicone, which was labelled "Healthy habits". Researchers encouraged participants to wear the wristband all the time, if possible, to help in reminding them about both their commitment to lose weight and the need for regular, healthy habits formation. A 15-minute session was provided to take participants through the leaflet and logbook using a flip chart and defined script. These leaflets outline weight-loss tips and suggest how to develop healthy lifestyle-habits.

At 2 months, researchers reviewed the participants' logbooks and emphasized the importance of having a healthy diet. In addition, researchers gave instructions on how to use a food diary provided to them during the session, so that they could begin to record their food and calorie intakes. At 4 months, researchers reviewed their logbooks and the food-and-calorie-intake records in their food diaries. As well, researchers discussed the benefits of doing exercise and physical activities. At 6 months, researchers emphasized the need for habit formation for weight maintenance. The researchers made no further contact with the participants until the 12 months follow-up, although the participants still attended the hospital as needed to receive ongoing follow-up for their various and individual medical conditions.

Control group

Participants randomized to control group, except for the wristband, were provided the same simple, self-guided, lifestyle-modification program, including leaflet, logbook and sessions, as the wristband group.

Outcomes and assessments

The primary outcome was the change in body weight at 6 months for members of each group.

The secondary outcomes included the change in body weight at 12 months; the change in waist circumference at the 6- and 12-month follow-ups; the percentage of participants who maintained a weight loss at the 6- and 12-month follow-ups; and the categorical weight loss at the 6- and 12-month follow-ups (categorized into participants whose initial weight had decreased by less than 3%, 3% or more, 5% or more, 7% or more, and 10% or more).²³

Screening, randomization and blinding

The participants were recruited by physician-referral for obesity management. After screening for the inclusion and exclusion criteria, participants gave their informed consent and were then assessed by means of standardized measures for weight, height, waist circumference, blood pressure and laboratory tests (namely, FPG, HbA1c, total cholesterol, triglyceride, HDL and LDL).

Participants were randomly assigned to either the control or the wristband group with the aid of computer-generated assignment with block randomization, using a block size of 4. The researchers and the participants were blinded to the group assignment status until the envelope was opened, from when neither the physicians conducting the investigations nor the participants were blinded, as specified by the protocol.

In addition, both the data collector and the statistician (responsible for administering the outcome assessments, managing the databases and analyzing the data) were blinded to the group assignments.

Statistical analysis

Changes in body weight in the intention-to-treat participants were compared with the use of repeated measure ANOVA. An independent t-test was used to analyze the differences in the changes in the waist circumferences. Either a chi-squared test or a Fisher's exact test was used to determine the differences in the percentage of participants who maintained a weight loss and in the categorical weight loss for each group.

This is the first study to assess efficacy of wristband for weight loss. The study had a power of 80% to detect a 2-kg difference in the body-weight change at the 6-month follow-up for each group. A p-value of 0.05 or less was considered to show statistical significance. Researchers set 2 kg difference in weight change because an analysis of Diabetes Prevention Program lifestyle intervention data showed that weight loss was the dominant determinant of the reduced risk of diabetes. For every kilogram lost, there was a 16% reduction in risk. This effect began with losses as low as 2% of body weight which was estimated to be 2 kg in this study. The intervention should have clinically meaningful benefit if it can achieve that target.²⁴

RESULTS

Study population

From November 4, 2013 through September 31, 2015, a total of 72 participants were assessed for eligibility. A total of 64 participants met the eligibility criteria and were randomly assigned to receive either a wristband plus brief lifestyle modification program (wristband group with 32 participants), or a brief, lifestyle-modification program alone (control group, with 32 participants).

The main reasons that participants did not undergo randomization were not meeting the inclusion criteria (BMI less than or equal to 30 kg/m², n = 2, and taking drugs that affect body weight, n = 3).

Of the 64 initial participants, 47 completed the trial. In the wristband group, 1 participant died (from pneumonia) after randomization, and 6 participants were lost to follow-up. In the control group, 8 patients were lost to follow-up, and 2 patients became pregnant during the follow-up period (Fig 1).

The baseline demographic and clinical characteristics were similar for both groups (Table 1). The mean age of the participants was 51.4 years, the mean body weight at baseline was 100.2 kg, the mean BMI was 39.5 kg/m²,

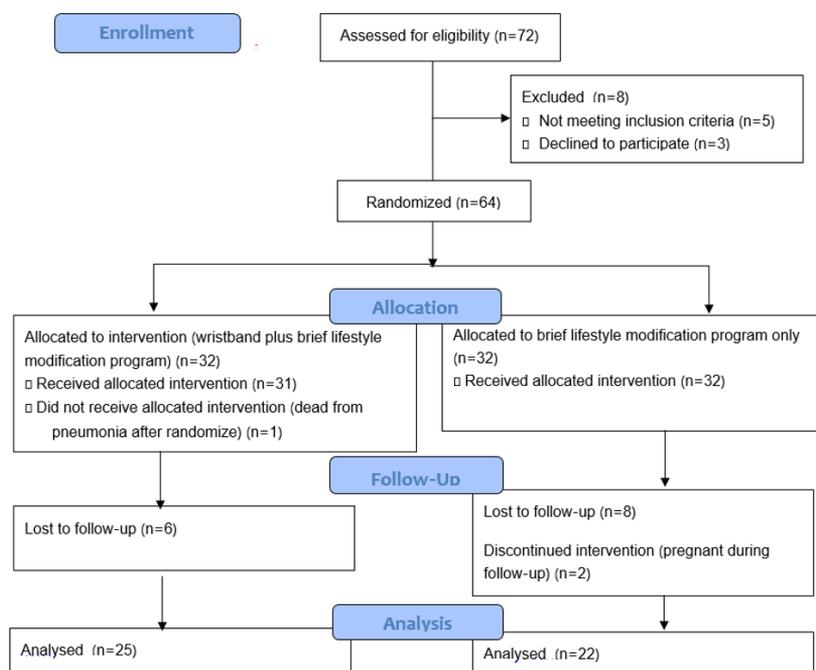


Fig 1. Flow diagram.

TABLE 1. Baseline characteristics of the participants.

Characteristic	Wristband (n = 25)	Control (n = 22)	p-value
Gender n (%)			
Male	5 (20%)	8 (36.4%)	0.211
Female	20 (80%)	14 (63.6%)	
Age, mean (SD), years	51.64 ± 14.8	51.18 ± 12.61	0.91
Education, n (%)			
Less than high school	2 (8%)	1 (4.5%)	0.757
High school	14 (56%)	11 (50%)	
College or above	9 (36%)	10 (45.5%)	
Medical conditions n (%)			
Diabetes mellitus	15 (60%)	10 (45.5%)	0.319
Hypertension	23 (92%)	21 (95.5%)	1
Hypercholesterolemia	21 (84%)	20 (90.9%)	0.67
Coronary artery disease	4 (16%)	3 (13.6%)	1
Sleep disorder	4 (16%)	4 (18.2%)	1
Weight (kg)	101.29 ± 26.8	99.11 ± 19.03	0.753
Height (cm)	156.88 ± 9.78	160.64 ± 9.07	0.181
Body-mass index (kg m ⁻²)	40.72 ± 7.44	38.31 ± 6.39	0.243
Waist circumference (cm)	114.76 ± 19.06	115.55 ± 14.37	0.875
Blood pressure (mmHg)			
Systolic	136.32 ± 18.58	134.66 ± 18.87	0.763
Diastolic	80.48 ± 12.38	81.18 ± 11.92	0.844
Fasting glucose (mg/dL)	158.79 ± 68.79	139.27 ± 50.08	0.438
HbA1c	7.4 ± 1.87	7.23 ± 1.97	0.855
Cholesterol (mg/dL)	182.23 ± 49.12	168.5 ± 26.53	0.478
Triglyceride (mg/dL)	187 ± 166.46	100 ± 19.89	0.19
High-density lipoprotein	48.38 ± 9.98	59.86 ± 15.23	0.056
Low-density lipoprotein	96.25 ± 36.61	99.08 ± 25.97	0.83

and the mean waist circumference was 115.1 centimeters. A total of 72.3% of the patients were women, 53.2% had diabetes mellitus, 93.6% had hypertension, 87.2% had hyperlipidemia, 14.9% had coronary artery disease, and 12.7% reported a history of osteoarthritis of the lower extremities.

Outcomes

Weight loss

During the initial 6-month period, participants in the wristband group tended to lose more body weight than those participants who were in the control group. However, this did not reach statistical significance (Fig 2).

By the 6-month follow-up, participants in both groups had lost weight. The mean (\pm SE) weight change for the participants in the wristband group was -4.5 ± 1.38 kg, whereas those who were in the control group was -2.13 ± 1.09 kg. Nevertheless, the difference between the two groups was not statistically significant (p -value = 0.193).

Twelve months after the commencement of the study, 56% (14/25) of the participants in the wristband group and 54.5% (12/22) of the patients in the control group were followed up. The mean (\pm SE) weight changes for the wristband group and the control group were -4.25 ± 1.26 and -1.83 ± 1.13 kg (p -value = 0.169), respectively (Table 2). The percentage reduction from the initial body weight and the changes in the participants' BMI are also in Table 2.

Waist circumference

By the 6-month follow-up, participants in both groups had decreased their waist circumference, with the mean (\pm SE) waist-circumference change among participants in the wristband group and the control group being -2.84 ± 0.99 and -1.3 ± 0.92 cm (p -value = 0.269), respectively.

At the 12-month follow-up, the mean waist-circumference loss for the wristband group was still numerically larger than for the control group, with losses of -2.27 ± 1.18 and -0.57 ± 1.15 cm (p -value = 0.314), respectively.

Categorical weight loss

Fig 3 shows that the percentage of participants who maintained their weight losses at both the 6-month and 12-month follow-ups were greater for the wristband group than for the control group, although the effect was not statistically significant.

Fig 4 shows that participants in the wristband group tended to lose more weight than participants in the control group.

Adverse effect

There were few adverse events. One participant in the wristband group died from pneumonia after randomization, but before commencing the intervention, while 2 participants in the control group became pregnant during the six-month follow-up period.

The study physician deemed that none of the adverse events were related to the intervention.

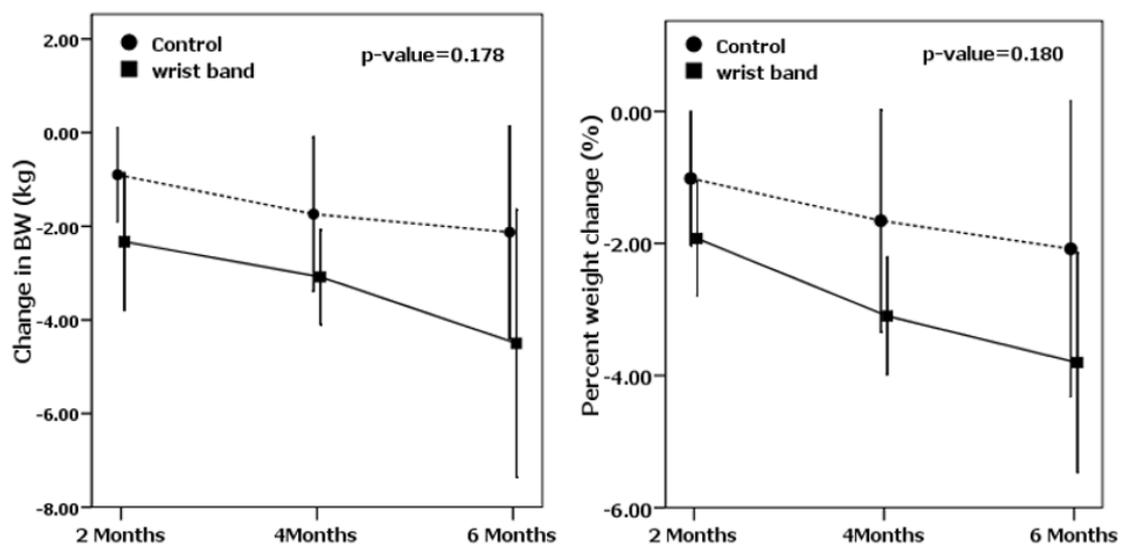


Fig 2. Changes in body weight (kg) and percentage of weight change (%) over 6-month period. p -value corresponds to repeated measure ANOVA.

TABLE 2. Estimated mean weight loss, percentage reduction in body weight, change in Body-Mass Index, and change in waist circumference over a 12-month period. Values presented as mean \pm SE. p-value corresponds to the independent t-test.

	Wristband		Control		p-value
	n	Mean \pm SE.	n	Mean \pm SE.	
Change in BW (kg)					
At month 2	23	-2.33 \pm 0.71	22	-0.9 \pm 0.48	0.106
At month 4	22	-3.08 \pm 0.49	22	-1.74 \pm 0.79	0.156
At month 6	25	-4.5 \pm 1.38	22	-2.13 \pm 1.09	0.193
At month 12	14	-4.25 \pm 1.26	12	-1.83 \pm 1.13	0.169
Change in BW (%)					
At month 2	23	-1.93 \pm 0.42	22	-1.01 \pm 0.49	0.160
At month 4	22	-3.1 \pm 0.43	22	-1.65 \pm 0.81	0.125
At month 6	25	-3.8 \pm 0.81	22	-2.08 \pm 1.08	0.201
At month 12	14	-3.84 \pm 1.04	12	-1.73 \pm 1.07	0.171
Change in BMI (kg m ²)					
At month 2	23	-0.85 \pm 0.22	22	-0.35 \pm 0.18	0.089
At month 4	22	-1.23 \pm 0.18	22	-0.64 \pm 0.29	0.091
At month 6	25	-1.67 \pm 0.43	22	-0.74 \pm 0.41	0.127
At month 12	14	-1.7 \pm 0.51	12	-0.69 \pm 0.42	0.147
Change in Waist circumference (cm)					
At month 6	25	-2.84 \pm 0.99	20	-1.3 \pm 0.92	0.269
At month 12	15	-2.27 \pm 1.18	14	-0.57 \pm 1.15	0.314

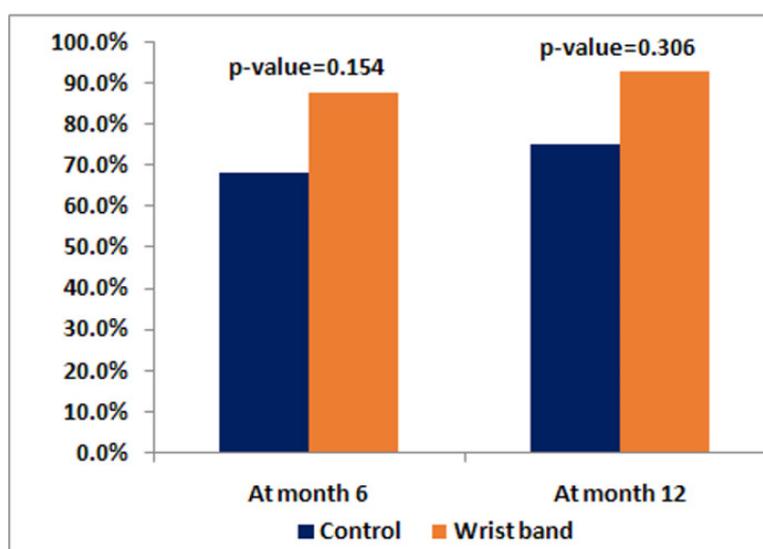


Fig 3. Percentage of participants in each group who maintained their weight losses at the 6- and 12-month follow-ups.

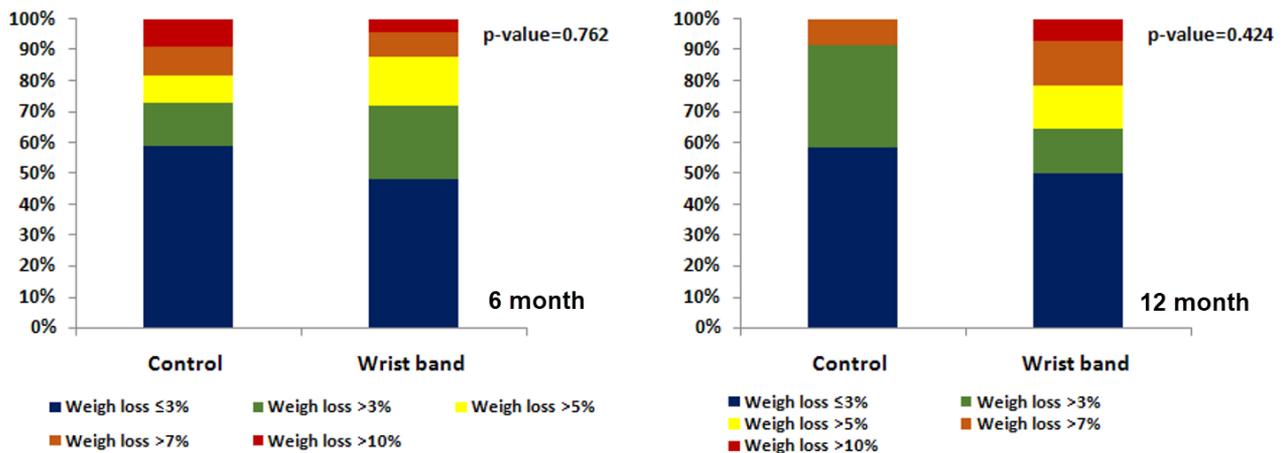


Fig 4. Categorical weight losses at the 6 and 12-month follow-ups.

DISCUSSION

Participants in both groups in this study had lost weight by the 6- and 12-month follow-ups, compared to their baseline measurements. The extent of the body weight loss tended to be greater among participants in the wristband group, although the differences in the weight loss between the two groups did not reach statistical significance. Similar trends were observed for the changes in waist circumference, BMI, and percentage weight-loss.

The reasons for the results not reaching statistical significance were mostly due to a high attrition rate and substantial variations in the degree of weight loss. Researchers aimed to randomize 64 participants in this trial and collect data from at least 50 participants, but due to underestimating the extent of participant loss at follow-up, researchers were only able to collect data from 47 participants.

The difference in point estimate between the 2 groups was 2.37 kg, which researchers had estimated would be > 2 kg, but the confidence interval was large, which shows that there were substantial variations in the degrees of individual weight losses. A larger study may provide more reliable outcomes.

In this study, by the 6-month follow-up, participants in the control group had lost a mean weight of 2.13 kg compared to a mean weight loss of 4.5 kg in the wristband group. The magnitude of those reductions in body weight was comparable with losses reported in several other trials in which the primary care providers also offered brief counseling sessions.⁸⁻¹¹

By the 12-month follow-up, during weight maintenance phase, participants in both groups maintained their

reduced body weight, although they regained 0.25 to 0.3 kg from 6-month. This degree of regained weight has been consistently observed in several comprehensive lifestyle modification program trials.^{25,26}

Researchers advised the participants in intervention group to use the wristband as a cue, a trigger that told participants to go into automatic mode and which habit to use to control weight and create habitual health behaviors. The body-weight and waist-circumference reductions in the wristband group were likely to result from the wristbands helping participants by regularly reminding them of their goal to lose weight, the need to strive for healthy habits, and the value of regular self-monitoring.

All participants in this study had chronic medical conditions requiring them to regularly attend the OPD to follow up those conditions. However, the results of this study may be applied to a healthy, but overweight population, in which case they may have greater potential due to the higher exercise capacity and physical activity of a healthy population.²⁷⁻²⁹

There is important limitation to this study. According to the study protocol, both participants and physicians were not blinded to the group assignment, so this may have affected the subsequent, differential cointerventions, or biased the assessments of the outcomes. Researchers tried to reduce this bias by standardizing the protocol and blinding the data collector and the statistician to the group assignments.

To date, there have been no other studies evaluating wristbands or other similar, wearable tools (such as a smartwatch or a wearable fitness tracker) which could be used to compare with this study. However, there is an ongoing trial to evaluate the effectiveness of an

experimental intervention that is based on standard diet recommendations plus a free smartphone application and a wearable device for weight loss.³⁰

The use of a smartphone with weight loss applications (but without a wearable device) has been shown to be effective for weight loss.³¹⁻³⁶ Unfortunately, many smartphone applications are sophisticated, which can make their use challenging for some people, and there is an associated cost for the smartphone, which can be a financial barrier to uptake. In contrast, this study has shown that the use of only a simple wristband may help with weight loss.

Although this study lacked the power to detect statistically-significant differences between the control and intervention groups in terms of the differences in weight changes, the trends supported our hypothesis. Therefore, researchers encourage the use of a wristband to help with weight loss, particularly given this tool's zero adverse events and very low cost.

CONCLUSION

The utilization of a wristband as an adjunct to a weight-loss program showed a trend toward a decreased body weight and waist circumference at the 6- and 12-month follow-ups. Because this tool is risk-free, low-cost and potentially beneficial, it is worth using with obese patients.

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The authors declare that there is no conflict of interest regarding the publication of this paper.

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