



Original Article

Mobile health applications enhance weight loss efficacy following bariatric surgery

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ABSTRACT

Introduction: With the epidemic of obesity numerous mobile health (mHealth) applications have been designed with the goal of facilitating weight loss. This technology has the potential to focus behavioral modification in a manner that's effective for weight loss. We examined the use of this mHealth technology in our bariatric surgery population to evaluate effects on weight loss following surgery.

Methods: Single institution prospective randomized control trial performed at an academic center. 56 patients who recently underwent a laparoscopic sleeve gastrectomy (LSG) were enrolled into a control group with standard post-operative monitoring and a mHealth application group provided with iPad© minis with the MyFitnessPal© mHealth application. Participants were followed for 24 months. The primary outcomes were effect on weight loss as determined by excess body weight loss (%EWL) and excess BMI loss (%EBL).

Results: Statistically significant differences in weight loss outcomes between the groups were present throughout the duration of the study. At 12 months, %EWL was 74.41% (control) vs 81.41% (mHealth) p value 0.047 and at 24 months, it was 59.10% (control) vs 71.47% (mHealth) p value 0.0078. %EBL findings at 12 months was 28.02% (control) vs 32.15% (mHealth) p value 0.0007 and at 24 months, it was 25.39% (control) vs 27.87% (mHealth) p value 0.048.

Conclusion: Our results demonstrate mHealth applications are a useful adjunct to improve and maintain weight loss following bariatric surgery. We suggest mHealth applications should be utilized following bariatric surgery for improved outcomes.

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Introduction

Obesity has reached epidemic proportions within the United States and worldwide leading to major health problems [1]. As a result, weight loss programs have increased exponentially. Despite this growth, a majority of those programs are ineffective at immediate and long term weight loss and are focused on commercial success [2]. Surgical procedures have achieved recognition as the most successful form of weight loss in patients with morbid obesity [3,4]. In addition to sustained weight loss, bariatric surgery has significant health benefits. These include resolution of major

co-morbidities such as diabetes and hypertension [5]. Despite significant health success, weight regain does frequently occur in bariatric surgical patients after surgery [6,7]. It is believed that behavior modification can be implemented into the surgical bariatric population to maintain and improve weight loss.

Non-surgical weight loss programs are centered upon behavior modification with less than 10% of patients achieving clinically significant success [8]. In comparison, bariatric surgery achieves between 50–70% loss of excess body weight after 1 year [3]. Yet as an adjunct to surgery, behavior modification can help achieve and sustain long-term weight loss after bariatric surgery [9]. Self-monitoring with dietary and exercise journals has proven to be the centerpiece of effective behavior modification [10]. Compliance with dietary and exercise journals is low due to the cumbersome nature of that process. With the progressive capabilities of hand-held mobile devices such as smart phones and tablets, there now exists new tools to help aid in behavioral modification. mHealth technology offers the advantages of ease of use and reinforcement

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Table 1
%EWL and %EBL formulas.

| Formulas for calculation of percentage excess weight loss (%EWL) and percentage excess BMI loss (%EBL) | |
|---|---|
| $\%EWL = \frac{\text{preoperative weight} - \text{current weight}}{\text{preoperative weight} - \text{ideal weight}} \times 100.$ | $\%EBL = \frac{\text{preoperative BMI} - \text{current BMI}}{\text{preoperative BMI} - 25} \times 100.$ |

by assisting with calorie counting and exercise tracking. Several studies have demonstrated that mHealth technology can be an effective tool for weight loss [10,11].

The objective of this study was to evaluate the effect of mHealth technology on the bariatric surgery population at our institution. To our knowledge this is the first study to evaluate this technology following bariatric surgery. We utilized one of the most popular mHealth applications currently available *MyFitnessPal*®. We hypothesize that the use of mHealth technology will enhance weight loss and maintenance in patients with morbid obesity following bariatric surgery.

Methods

Design

This single institution prospective randomized control trial compared the use of a mHealth application versus standard weight loss monitoring after bariatric surgery. The study was approved by the performing institution's Institutional Review Board (IRB) and was compliant with all ethical and patient confidentiality protocols. Funding from the U.S. Army Medical Department (AMEDD) Advanced Medical Technology Initiative (AMTI) was used to purchase *iPad*® minis with the *MyFitnessPal*® application installed on the devices. This study was not funded, endorsed, or otherwise supported by the respective commercial entities of *iPad*® or *MyFitnessPal*®. Inclusion criteria were patients between the ages of 18–89 who had undergone a laparoscopic sleeve gastrectomy (LSG) within 1 year of enrollment. Exclusion criteria were pregnant females, subjects with immediate post-operative complications, and patients who were not fluent in English.

We randomized the enrolled patients into two cohorts; a control cohort and a mHealth cohort. For the mHealth cohort patients an individual one hour training session on how to use the *iPad*® and *MyFitnessPal*® application was performed by the research coordinator to ensure proficiency. Furthermore, the research coordinator ensured the patients in the mHealth group were regularly using the application and assisted with any technical issues using the application. The research coordinator had access to each *MyFitnessPal*® application profile and would contact patients who did not record any data in the application for greater than 48 h. When the research coordinator contacted patients in the mHealth group it was simply to either remind them to use the application or provide technical support for the application and they did not instruct, educate, or in any other way alter the patients' behavioral patterns. The coordinator was not allowed in any way encourage or ensure mHealth patients were being compliant with the post-operative nutritional and caloric guidelines. For patients in the control group they were specifically instructed to not use any mobile health applications as to prevent confounding results. The control patients were informed and encouraged to use self-monitoring journals if they would like however it was not required. For all the study patients they received the exact same standard post-operative care which involved structured outpatient follow-up with the Bariatric Surgery team at 2 weeks, 1 month, 3 months, 6 months, and annually following their index surgery. The research protocol was written to exclude any patients that developed technical failures during the study observation that would lead to suboptimal outcomes following (e.g. dilated sleeve requiring re-sleeve or conversion to Roux-en-Y gas-

tric bypass); however no study participants developed technical failures.

During the randomization process we balanced the cohorts in regard to how far out the collective patients in each cohort were from their index surgical date to ensure no significant discrepancy between the two cohorts. Additionally, we balanced the cohorts in regard to the collective weight loss at the time of study enrollment to ensure no significant differences were present. We then followed the enrolled patients for 24 months from their enrollment date to track particular outcomes.

Power analysis

A power analysis was performed to determine the necessary amount of study participants to allow determination of significant findings. Group sample sizes of 25 achieved an 81% power to detect a difference a 10% difference between the null hypothesis that both groups have similar weight loss. The power analysis also incorporated a significance level (alpha) of 0.05 using a one-sided two-sample t-test. The final mixed-model analysis of covariance predicted high confidence that at total of 50 study participants would allow detection of clinically important group differences. Accounting for a 10% attrition rate, approximately 55 subjects were calculated as the target study enrollment number. At total of 56 patients were enrolled.

Outcome/dependent variables

The primary outcome variables were percent of excess body weight loss (%EWL) and percent of excess BMI loss (%EBL). The formulas for those calculations are depicted in Table 1. Secondary outcome variables were related to quality of life (QoL) via RAND 36 survey testing. RAND 36 surveys consist of physical functioning, role limitations due to a physical health, role limitations due to emotional problems, energy/fatigue, emotional wellbeing, social functioning, pain, and general health. Data collection was performed at the onset of enrolling in the study, at twelve months post-enrollment, and twenty four months post-enrollment.

Explanatory/independent variables

When evaluating differences between QoL variables for the different groups evaluation of additional explanatory variables such as gender, body weight excess, comorbidities, medications, and medication changes were taken into consideration during analysis. The same explanatory variables and QoL parameters were also used to evaluate mean differences of %EBL. Briefly, QoL parameters acted as both a dependent and independent variable in this study.

Statistical analysis

The error residuals of continuous variables were analyzed with a Kruskal-Wallis test for normality. For descriptive statistics, normally distributed variables were analyzed by ANOVA and are presented as means and standard deviation while non-normally distributed variables were analyzed with a Wilcoxon and presented as median and range. Categorical variables are presented as frequency percent and were analyzed with a Chi-Square test for proportion. Differences between the control and mHealth group

Table 2
Baseline characteristics.

| Variable | Control group (N = 28) | mHealth group (N = 28) | p Value |
|------------------------------|------------------------|------------------------|---------|
| Age | 53 (+/- 10.6) | 52.5 (+/- 9.0) | 0.89 |
| Percentage female | 92% | 84% | 0.54 |
| Days post-operative from LSG | 192 (+/- 19.5) | 185.5 (+/- 24.5) | 0.29 |
| BMI | 36.97 (+/- 6.91) | 35.34 (+/- 8.27) | 0.43 |
| %EWL | 37.67% (+/- 6.9%) | 40.07% (+/- 6.9%) | 0.37 |
| %EBL | 13.50% (+/- 2.27%) | 13.58% (+/- 2.22%) | 0.93 |

Table 3
Weight loss results.

| Variable | Control group (N = 28) | mHealth group (N = 28) | p Value |
|---------------|------------------------|------------------------|---------|
| %EWL 12 month | 74.4% (+/- 8.0%) | 81.41% (+/- 6.9%) | 0.0468 |
| %EWL 24 month | 59.10% (+/- 9.9%) | 71.4% (+/- 6.8%) | 0.0078 |
| %EBL 12 month | 28.02% (+/- 2.26%) | 32.15% (+/- 2.26%) | 0.0007 |
| %EBL 24 month | 25.39% (+/- 2.20%) | 27.87% (+/- 2.20%) | 0.0479 |

means were analyzed by way of repeated measures mixed model analysis of variance and mixed model analysis of covariance where subject identification was nominated as a random effects and a compound symmetry covariance structure. The least squares means from the time of observation and patient group were compared to the post-operative baseline with a Tukey's adjustment and presented as least squares means and standard error. All multivariate evaluated models included treatment group and time of observation. Using an enter method, additional covariates relating to comorbidities, medication, change of medications, and QoL were evaluated one at a time for significance as confounding effects. All analyses were considered significant at p value <0.05 and were carried out with SAS 9.3 statistical software (Cary, NC).

Results

Demographics

The baseline characteristics of the two groups at the time of enrollment are depicted in Table 2. When comparing the control group to the mHealth group, no statistical differences were observed for any of the baseline characteristics. Specifically, in regard to post-operative weight loss characteristics, both groups had statistically similar %EWL and %EBL at the time of enrollment.

Weight loss results

The weight loss results, as evaluated by %EWL and %EBL, are shown in Table 3. Throughout the duration of the study the mHealth group had statistically better %EWL or %EBL compared to the control group. The weight loss differences between the mHealth and control groups are depicted in Figs. 1 and 2. The mHealth group also had more stable weight loss throughout the study period as determined by a lesser decrease in %EWL rates at the 12 and 24 month marks, 10.01% vs 15.3%, which reached statistically significance (p value 0.0003).

Quality of life (QoL) parameters

The QoL parameters as evaluated by RAND 36 surveys found no significant differences for any of the QoL parameters between the mHealth and control groups as show in Table 4.

Discussion

As the epidemic of obesity increased during the end of the 20th century, research endeavors have been initiated to counteract the

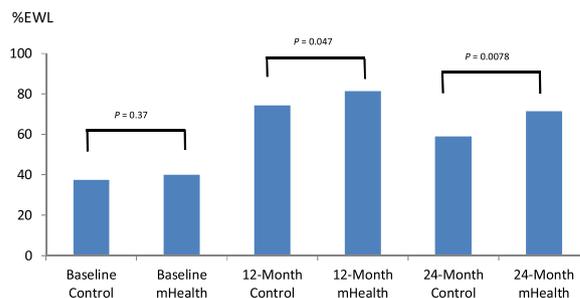


Fig. 1. Legend: Excess body weight loss percentage (%EWL) between the control and mHealth groups at 12 and 24 months following study enrollment. The mHealth group had statistically significant improved %EWL at both time points; enhanced %EWL of 7% and 12% at 12 and 24 months respectively.

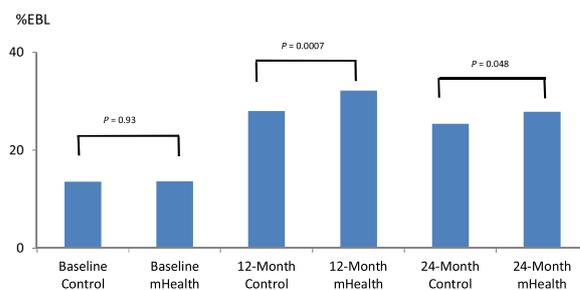


Fig. 2. Legend: Excess BMI loss percentage (%EBL) between the control and mHealth groups at 12 and 24 months following study enrollment. The mHealth group had statistically significant improved %EBL at both time points; enhanced %EBL of 4% and 2% at 12 and 24 months respectively.

Table 4
QoL Results.

| Quality of life (QoL) variables | Control group (N = 28) | mHealth group (N = 28) | p Value |
|--|------------------------|------------------------|---------|
| General health perception | 69.1 | 77.3 | 0.59 |
| Energy level | 67.4 | 71.5 | 0.98 |
| Emotional well-being | 84 | 84 | 0.41 |
| Pain level | 78.5 | 77.5 | 0.29 |
| Social functioning | 100 | 90 | 0.48 |
| Physical functioning | 82.5 | 100 | 0.15 |
| Limitations caused by physical health | 100 | 100 | 0.29 |
| Limitations caused by emotional health | 100 | 100 | 0.29 |

epidemic. Historically, the core concept in achieving successful weight loss in the obese population was modifying behaviors that lead to obesity. One of the most common methods of behavior modification was caloric counting via dietary journals. Yet, that method was cumbersome and patient compliance was very low. Numerous medical studies based around that core concept of behavioral modification showed promise for successful weight loss [13–16]. However, medical management nearly universally fails to achieve sustained weight loss thus prompting the 1992 NIH consensus statement on promoting bariatric surgery as the standard for sustained weight loss in the morbidly obese population [8]. Behavioral

modifications have been shown to be a successful adjunct following bariatric surgery to improve and sustain weight loss [9]. It is possible that mHealth technology, by making behavioral modifications easier to obtain, can be utilized to improve weight loss following bariatric surgery.

Current mobile technology offers patients a user-friendly format for recording food intake and exercise, potentially enhancing weight loss after bariatric surgery and enhancing macronutrient nutrition. Internet based calorie counting and text messaging have been used with some success to help sustain weight loss in non-surgical patients [10]. Non-randomized trials have also found successful weight loss in the non-surgical population with mHealth applications [12]. With more widespread use of mobile devices, patients are now able to access and download health-related topics and receive instant advice and feedback from nearly any location at any time. One mobile device application, *MyFitnessPal*[®], features an exercise and calorie intake diary, a weight tracker, and social networking capability to encourage support and accountability. Each account maintains a history of activity for both social networking interactions and dietary tracking. This data can be tracked from mobile devices via a web-page platform, which lends itself to convenient and reliable monitoring by both patients and researchers. That is why the *MyFitnessPal*[®] application was chosen as the mHealth application to be utilized in this study. In this study the simple use of the *MyFitnessPal*[®] application was researched and the specific sub-functions of the application, e.g. social networking and specific calculators, were not tracked.

In our study, we were able to show significant improvement in weight loss results as well as weight loss maintenance following LSG with the use of a mHealth application. We propose the ease of using the mHealth application translated into more efficient behavioral modification as opposed to standard dietary and exercise journals. There are several limitations to our study. First, the number of study participants was relatively small. Only having 28 patients per group could have led to a type I error. Secondly, the true effect of a mHealth application on weight loss could have been elucidated by enrolling study participants prior to surgery and following them out for a longer period of time. Due to time constraints of the study funding, we were unable to enroll patients prior to surgery. Finally, if the study had followed the patients for a longer period of time the results would have stronger clinical implications. Successful weight loss following bariatric surgery is determined by achieving greater than 50% %EWL at 5 years post-operatively. Thus, if we had followed patients for 5 years and found that patients utilizing mHealth applications were more successful at hitting that benchmark the use of mHealth applications following bariatric surgery could be more enthusiastically recommended. Another potential study limitation was the study coordinator ensuring the experimental cohort patients were using the mHealth application could have contributed to improved weight loss in that cohort. As stated in the Methods section the study coordinator simply controlled for mHealth application use and did not provide any additional education, encouragement, or other influence that would significantly alter weight loss. Yet, the simple reinforcement of mHealth application use in the experimental group could have contributed to increased weight loss. While considering the study limitations our results should encourage continued research into mHealth applications with morbid obesity and bariatric surgery.

Conclusion

While a developing technology with vast potential, mHealth applications have the ability to significantly improve weight loss results and weight loss maintenance following bariatric surgery. The mHealth applications however do not appear to improve QoL outcomes. The results from our study suggest mHealth applications could be an efficacious tool for improved weight loss results following bariatric surgery. There were several study limitations present that could have confounded our findings thus further study on this topic is required to fully elucidate the effects of mHealth technology.

Ethical statement

This study was approved by the institutional review board (IRB) and was compliant with all ethical and clinical guidelines.

Conflicts of interest

All authors have no conflicts of interest or financial disclosures.

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