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An Evaluation of Methods to Assess Whether Health Information Technology-Based Tools Improve Weight Loss Measures in Bariatric Surgery Patients

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AN EVALUATION OF METHODS TO ASSESS WHETHER HEALTH INFORMATION TECHNOLOGY-BASED TOOLS IMPROVE WEIGHT LOSS MEASURES IN BARIATRIC SURGERY PATIENTS

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by

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ABSTRACT

AN EVALUATION OF METHODS TO ASSESS WHETHER HEALTH INFORMATION TECHNOLOGY-BASED TOOLS IMPROVE WEIGHT LOSS MEASURES IN BARIATRIC SURGERY PATIENTS

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Obesity is a chronic and growing disease defined by weighing 20% or more than the ideal, or having a body mass index (BMI) of 30 kg/m^2 or more. While natural weight loss is available, many patients are choosing weight loss surgery (i.e., bariatric surgery) as an alternative to lose weight and reduce their risks for comorbidities such as diabetes, heart disease, and sleep apnea. Tools and resources for post-surgical support in the bariatric surgery community have been limited and, in the past, most tools and resources for weight loss have focused on non-surgical weight loss communities; as such, analysis methods for measuring success in this population have not been clearly developed and tested. This research proposes and evaluates analysis methods that may be used in such studies. These analysis methods are evaluated using data from the Weight and Exercise Lifestyle Support study at Baystate Medical Center in Springfield, MA. In this study, a group of participants (n = 6) approved for bariatric surgery were followed by the research team starting roughly one month before surgery through three months after surgery. Participants received pedometers and weight scales, and access to an online patient portal where they could review their physical activity levels, and receive support from others in the study and an exercise consultant. Data collected included pre- and post-study dietary and exercise self-efficacy levels, self-reported and objective physical activity measures, self-reported dietary adherence, device usage, and usability and satisfaction with the program. This research evaluates whether the proposed measures can help determine the presence and nature of the relationships between the aforementioned variables. If these measures prove to be useful, they can be used in future interventions that use technology to support post-surgical weight loss communities.

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CHAPTER 1

INTRODUCTION

Obesity is a chronic disease caused by a combination of biological, environmental, and socio-demographic factors. Medical costs in 2008 for treating obesity-related conditions, such as type 2 diabetes and heart disease, were estimated at $147 billion according to the Center for Disease Control and Prevention (CDC); furthermore, obese patients paid on average $1,429 more in healthcare costs per year than their non-obese counterparts [1]. Though not a "magic bullet," bariatric surgery has been shown to be the most effective treatment for obesity [2] and can reduce the risks associated with it and other obesity-related diseases. Reports have shown patients struggle with weight plateau, weight regain, and obesity-related illness (such as HbA1c) between 12 and 18 months after surgery [3], emphasizing the need for post-surgical weight loss support. Past research has shown that weight loss is highly dependent upon perceived self-efficacy levels [4-9], a measure of a person's belief that they will succeed in a task, which according to Bandura affects the effort patients put into that task [10].

While post-surgical follow-up is provided in most bariatric surgery programs, this follow-up is generally limited to consultations with the bariatric surgeon to address any medical concerns, and may include some dietetic counseling. The patient is made aware of the importance of lifestyle change (e.g., improved diet and exercise behaviors), but these changes are typically not supported through any structured program. At present, patient weight tracking following surgery is limited to clinic visits only and loss of patients to follow-up over time is a serious problem. Support groups for post-surgical patients have proven to be beneficial in terms of helping patients sustain weight loss, but such programs are often not available or are offered at times or places that are inconvenient to patients. Researchers have shown that a structured, long-term follow-up program aimed at this population can be feasible, acceptable to patients, and successful in improving the patient exercise and lifestyle behaviors so important to the maintenance of post-surgical weight loss [11]. Health information technology-based tools, such as websites and social media, may be scalable and cost-effective forms of these structured, long-term follow-up programs.

Unfortunately, weight loss surgery researchers and practitioners lack a robust set of measures to help them determine whether and why these long-term post-surgical interventions are beneficial. In particular, there is a need to develop evaluation measures specific to health information technology-based tools for post-surgical bariatric patients. This study seeks to propose and evaluate a comprehensive set of measures that will capture data relevant to the success of these health information technology-based tools, present these data in traditional formats (e.g., aggregated averages), and perhaps most importantly present these data in non-traditional formats that preserve individual differences and changes in these data over time. We will evaluate these measures using data from participants enrolled in the Weight and Exercise Lifestyle Support (WELS) study administered through Baystate Medical Center (BMC) in Springfield, MA.

WELS is a web-based weight loss support program that targets post-operative bariatric surgery patients. The web-based program is scalable, and incorporates feedback, virtual and in-person counseling, and virtual patient social support. The feedback to participants includes their daily activity and weekly weight measurements, recorded by a wireless activity monitor and weight scale. The data is sent to an online patient portal for on-demand viewing, and is also made accessible to the participant's health care providers for counseling purposes. The participants can also engage with each other, if desired, in an anonymous online community. The WELS program will ideally help participants without access to in-person support groups or structured follow-up programs to enjoy the benefits of such programs in terms of sustained weight loss and improved health outcomes. This program will ideally provide a novel, scalable and cost effective model of patient support.

During this study, I evaluate whether a proposed set of measures can help answer the following high-level research questions relevant to health information technology-based tools for post-surgical bariatric patients, each with sub-questions described in the Methods section. The rationale for these questions and measures will also be described in more detail in the Methods section:

Q1: Do higher scores related to the usability of the health information technology-based tools correlate with patient engagement in, and perception of, the intervention?

Q2: Do the health information technology-based tools for post-surgical bariatric patients increase participants' levels of self-efficacy?

Q3: Do increases in self-efficacy levels correlate with more desirable weight loss behaviors and outcomes?

Q4: How are weight loss behaviors and weight loss outcomes related?

CHAPTER 2

LITERATURE REVIEW

This literature review focuses on three main topics: (1) typical weight loss intervention outcome measures; (2) how diet-, exercise-, and weight loss-related self-efficacy may affect weight loss outcomes, and (3) prior weight loss and weight maintenance programs that utilize technology and the Internet. The WELS study and others that use technology to support post-bariatric surgery patients are relatively new and not well-studied; therefore, we evaluate what outcomes have been used to evaluate the success of other weight loss interventions. In existing research, self-efficacy is seen as a key variable in predicting weight loss. We therefore review the literature in an attempt to understand how technology-based interventions might affect self-efficacy, thereby affecting weigh loss outcomes. Finally, we review existing interventions that use technology or the Internet to support weight loss or weight maintenance. While not focused on bariatric surgery patients, these studies can provide insight into the design and evaluation of similar interventions.

2.1 Typical Weight Loss Intervention Outcome Measures

Weight loss interventions and maintenance programs (WLPs) have targeted many different populations with timeframes varying from 3 weeks [12] to over 3 years [13], using interventions as traditional as diet and exercise counseling to alternative medicine and pharmaceuticals. Systematic reviews and meta-analyses show that the primary outcome measure in non-surgical weight loss interventions or maintenance programs are total or sustained weight change [12-25]. Other common outcome measures used are

BMI [14-16, 18, 24, 26], blood pressure [13, 15, 18, 20, 24, 26], and cholesterol and lipid levels [13, 16, 18, 20, 24, 26]; followed by changes in physical activity levels [13, 15, 17, 23-24] and diet (by decreasing calorie intake or improving food choices) [13, 15-17, 24]. Less commonly used outcome measures are changes in waist circumference [14, 15, 26], body fat percentage [13-15], working heart rate [14, 16], quality of life and incidence of cardiovascular events [13, 20], insulin, glucose, or incidence of diabetes [13, 16, 18, 24, 26], and percentage of weight loss maintained after a follow-up period [15, 22].

Neve *et al*. [19] evaluated the efficacy of a web-based intervention for non-surgical adults using traditional outcome measures (weight change, mean percentage weight change), but also by observing the correlation between weight change and usage of the study website, attendance to meetings, usage and satisfaction of peer support, and whether they self-monitored their diet and exercise. Five studies reported that more logins correlated with significantly more weight loss. Higher rates of self-monitoring of diet or exercise in six of nine studies correlated with weight change. Only four studies reported the correlation between usage of social support (attendance of online meetings/chat sessions, bulletin boards) and weight loss, and three of them showed they were positively related [19].

Unfortunately, few studies have evaluated the efficacy of a WLP targeted toward the bariatric surgery community. One study by Nijamkin *et al.* did this by introducing nutrition education and behavior modification to a Hispanic American post-operative population in a randomized controlled trial. Their main measured outcomes were changes in weight, BMI, excess weight and excess percent of weight lost, and change in physical activity levels. Those in the intervention group significantly increased their intensity and involvement in physical activity from 6 to 12 months after surgery, while there was no significant change in physical activity in the control group. There were significant differences in changes in weight, BMI, excess weight lost, and percent of excess weight lost between the intervention and control groups [27].

This thesis will propose a set of measures for assessing the impact of WLPs, which can be used by researchers and practitioners to develop or evaluate future programs.

2.2 Self Efficacy and Weight Loss Outcomes

Weight loss and weight maintenance programs succeed when they create successes at the individual level, starting with subjects' levels of confidence to succeed in this task. Prior studies have shown that increases in confidence, or self-efficacy as defined by Bandura [10], are positively correlated with weight loss, weight maintenance, and increased physical activity in several demographic groups [4-8]. However, higher initial values of self-efficacy have resulted in lower weight loss measures in low-income subjects [7], and while the reasons for this are not clear, study researchers believe this may be due to participants' overconfidence or lack of experience. A separate weight-loss intervention study using a different self-efficacy measurement [9] found higher initial self-efficacy scores relating to how participants set and revised goals resulted in higher weight loss post-intervention. While subjects who increased their self-efficacy in these studies showed success at their post-treatment follow-up, there is some evidence that high self-efficacy alone may not contribute to long-term weight maintenance [5].

Many clinical studies have used the Weight Efficacy Life-Style (WEL) questionnaire to measure weight loss self-efficacy in their participants. This 20-item tool developed by Clark *et al.* [28] uses a series of statements beginning with the language "I can resist eating when..." to assess components of subjects' self-efficacy, such as Negative Emotions, Social Pressure, and Availability. While this tool has successfully predicted weight loss in some populations [7, 8], Linde *et al.* found the WEL self-efficacy measures did not predict weight loss in men [29]. Furthermore, Fontaine and Cheskin found that none of the WEL measures were correlated with either attendance or weight loss [30] during their weight loss intervention.

Previous studies of post-operative bariatric patients have found that only exercise (not dietary) factors predicted weight loss in their populations [31, 32]; while this sounds contradictory to the results of previous studies using the WEL tool, which suggest high dietary self-efficacy measures correlate positively with weight loss measures, none of these studies included bariatric or specialty patients in their interventions or programs. In fact, there is a gap in the literature assessing weight loss and weight maintenance programs for these populations in general [33]. The work completed for this thesis will provide much needed insight into how we can systematically measure whether dietary- and exercise-related self-efficacy relate to the success of these patients in a post-surgical weight-loss program.

2.3 The Efficacy of Web-Based Weight Loss and Maintenance Programs

As science advances, people live longer, and the price of healthcare continues to rise, providers and researchers are constantly looking for new ways to decrease costs of treatment. One way healthcare providers have done this is by using the Internet as a means of providing information, services (such as online appointment scheduling), and support outside of office visits. While it is known that people are looking for information and tools to help them with weight loss and weight maintenance, the impact of the information and tools remains unclear [34]. Here, we investigate the results of several studies observing effects of web-based compared to in-person weight loss and weight maintenance programs, and "basic" (information only) web programs compared to "enhanced" (tailored or social) web programs. The WELS program belongs to the latter web-based weight loss support group as it provides tailored feedback and information, if desired, for its participants.

Web-based weight loss and maintenance programs differ just as in-person programs do. Some give participants access to an online interface with forum-style chat rooms available to build peer support contacts [35-37], while others provide calorie- and exercise-tracking tools, comparable to a food diary [38-41]. Program coordinators can further add to these programs by incorporating e-mail counseling, tailored feedback, or challenges. Sapperstein, Atkinson and Gold, after reviewing the efficacy of several web-based weight loss programs, suggest "the positive effects found in the studies are not the result of just having web access, but rather to the nature of the interventions themselves" [34].

The efficacy of web-based weight loss and weight maintenance programs is not entirely clear. Harvey-Berino *et al.* found that, in a 6-month weight loss program followed up by a 12-month maintenance program, their online intervention group gained back twice as much weight at 18 months as those enrolled in minimal or frequent in-person support [35]. This is in direct contrast with results they found in a replicated study two years later [36], where they concluded "an Internet weight maintenance program could sustain comparable long-term weight loss compared with a similar program conducted in person and over the phone." Results from Haugen *et al*. support this statement, as both web-based and in-person interventions produced a 7% weight loss at 6 months from baseline; however, those who elected to not participate in an intervention group regained roughly 17% of their weight loss [38]. In a review of 49 eHealth intervention studies ranging from 1 to 12 months, Norman *et al.* found that 21 (51%) of the 41 comparison studies included reported the eHealth intervention produced better results than the alternative; 24 of the studies had indeterminate results [42]. Weinstein found 4 out of 5 web-based intervention groups had better results than their counterparts [43] in studies ranging from 6 to 12 months. These results suggest that web-based weight loss and maintenance programs can produce comparable weight loss measures and results to in-person programs in the short- and long-term.

If it can be shown that web-based programs are effective, what elements of these programs make them so? Several comparison studies have observed the effects of "basic" information-only program websites vs. "enhanced" websites that included extra elements such as behavioral therapy [41], peer contact interaction [37], or e-mail correspondence from diet and fitness professionals [39, 40]. According to Manzoni *et al.*, in general, basic web-based programs have smaller effect sizes than tailored intervention programs; in fact, they found that a tailored program as short as 6 weeks can have better results than an information-based program does at both 3 and 6 months [33]. Behavior therapy and counseling programs have produced significantly larger amounts of weight loss [40], less caloric consumption [41], and have been shown to be just as effective as human feedback at 3 months [39].

While peer support groups have proven to be effective [36], there is a natural over-abundance of women included in these program studies [33]. In the SHED-IT study, a weight-loss technology program tailored toward men, the authors found significant differences in weight loss measurements (weight, waist circumference, BMI) not in web users or information-only users, but in compliers vs. non-compliers [37]. "Less than 50% of men complied with recommended online self-monitoring instructions… both our quantitative and qualitative process evaluation indicated that men did not engage in the online board and men suggested that weight loss was a personal endeavor." This result, showing a lack of desire in men to use peer contact socialization to enhance their weight loss, is considered in the WELS study by introducing other means of interaction, such as group and peer challenges, as opposed to chat rooms only.

The WELS weight loss program for post-operative bariatric surgery patients was delivered via an online platform and utilized some of the aforementioned successful features such as e-mail and social support (chat). My research aimed to evaluate whether self-efficacy measures in weight loss programs targeting the bariatric surgery community are a useful mechanism for examining the feasibility of the web-based WELS program.

CHAPTER 3

METHODS

Here, I propose several quantitative and qualitative measures that may be helpful in assessing the efficacy of health information technology-based tools for post-surgical bariatric patients. I will test the value of these measures in the context of the Weight Loss Surgery (WLS) program at BMC. I will also discuss how this research will affect and influence future work in assisting and assessing intervention success in the bariatric surgery population.

3.1 Research Questions

This research will provide an analysis of possible methods that can be used to measure the effectiveness of health information technology-based tools for the bariatric surgery population, using data from the Weight and Exercise Lifestyle Support study participants. Figure 1 shows the framework for how the concepts I hope to capture are related to one another, and associated research questions that may be addressed via this framework. I will elaborate on this figure in section 3.3.

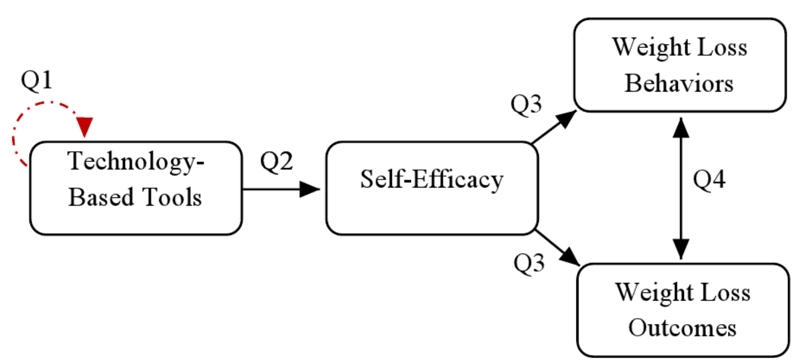


Figure 1. Basic framework for measures to be collected

Q1: Do higher scores related to the usability of the health information technology-based tools for post-surgical bariatric patients correlate with patient engagement in, and perception of, the intervention?

Q1.1 Do higher usability scores correlate with higher physical activity device usage?

Q1.2 Do higher usability scores correlate with higher satisfaction scores with the overall weight loss program?

Q2: Do the proposed health information technology-based tools for post-surgical bariatric patients correlate with participants' levels of self-efficacy?

Q2.1 Do the health information technology-based tools correlate with changes in participants' exercise self-efficacy levels?

Q2.2 Do health information technology-based tools correlate with changes in participants' dietary self-efficacy levels?

Q3: Do increases in self-efficacy levels correlate with more desirable weight loss behaviors and outcomes?

Q3.1 Do positive changes in dietary self-efficacy correlate with higher self-reported dietary adherence?

Q3.2 Do positive changes in exercise self-efficacy correlate with higher self-reported exercise adherence?

Q3.3 Do positive changes in exercise self-efficacy correlate with higher objective physical activity measures?

Q3.4 Do positive changes in overall self-efficacy correlate with better weight loss measures?

Q4: How are weight loss behaviors and weight loss outcomes related?

Q4.1 Which self-reported dietary and physical activity behaviors are most strongly correlated with successful weight loss outcomes?

Q4.2 Which objective physical activity behaviors are most strongly correlated with successful weight loss outcomes?

In the following sections, I will describe the expanded theoretical framework and how I will quantify and analyze the data needed to answer these questions.

3.2 Theoretical Framework and Data Analysis

The expanded framework in Figure 2 shows how access to health information technology-based feedback may influence changes in self-efficacy, weight loss behaviors and weight loss outcomes.

To develop this framework, I defined the concepts of interest for studies of this type, which include weight loss measures, dietary and exercise self-efficacy, objective and self-reported physical activity measures, etc. Starting with the dependent variable of Weight Loss Outcomes, I created a correlation model, using lettered arrows to signify potential associations between concepts. Currently, there are not reliable ways to objectively collect dietary habits over time, so we do not use this measure in any analysis.

Table 2 lists, for each lettered association, the research question(s) from Section 3.1 related to the association, the hypothesis for the association, and available references supporting the hypotheses, where available. Of note, some relationships between concepts and variables collected are unclear at this time. While one would expect diet adherence to lead to better weight loss outcomes it has been shown that, in the bariatric community, diet is not necessarily a predictor of weight loss [15, 16]. Other relationships between activity measures (step counts, distance, and activity minutes) are hypothesized to be present and positive so will be analyzed in such a way as to show how strongly they are correlated with outcomes.

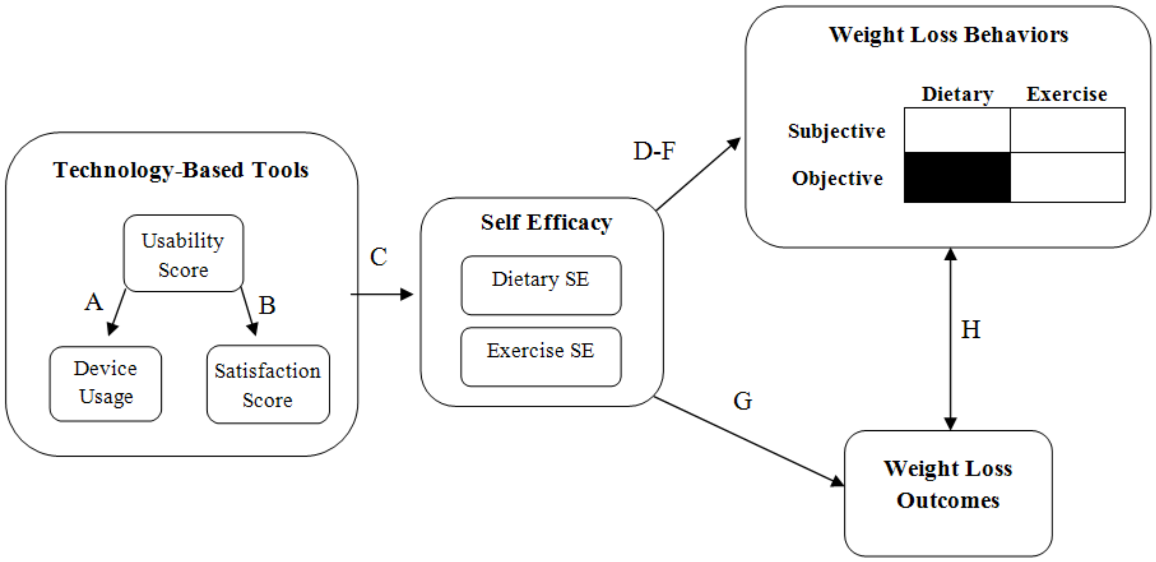


Figure 2. Expanded framework showing correlation hypotheses

Table 1. Hypothesized relationships between study variables

Figure reference	Research question(s)	Hypothesis	References
A	Q1.1	Higher usability scores will correlate with higher device usage.	36, 37
B	Q1.2	Higher usability scores will correlate with higher overall program satisfaction scores.	36, 37
C	Q2.1, 2.2	Higher adherence with the proposed health information technology-based tools will create a positive change in participants' dietary- and exercise-related self-efficacy levels.	
D	Q3.1	Positive changes in dietary self-efficacy will correlate with higher self-reported dietary adherence.	10, 33
E	Q3.2	Positive changes in exercise self-efficacy will correlate with higher self-reported exercise adherence.	10, 33
F	Q3.3	Positive changes in exercise self-efficacy will correlate with higher objective physical activity measures.	10
G	Q3.4	Positive changes in overall self-efficacy scores will result in higher success with weight loss measures over time.	34
H	Q4	Some weight loss behaviors are more strongly correlated with successful weight loss outcomes than others.	

3.3 Definitions and Descriptions of Measures

Table 2details how the aforementioned measures were defined and/or quantified as variables in the context of the WELS study. Success in bariatric surgery is often measured as pounds lost between date of surgery and a given end point in the future.

This measure is the one most commonly used by patients as it requires little equipment and the data is collected quickly and is easy to track. In addition to this measure, I collected the percentage of excess body weight lost and change in BMI. These alternative objective measures provide a deeper understanding of how patients' body compositions have changed and are less likely to be confounded by things like lean mass, heavy clothing, or body water.

As previously noted, self-efficacy is thought to be a major factor affecting weight loss outcomes. To capture participants' self-efficacy data, both diet- and exercise-related self-efficacy were collected at study entry and exit.

Two factors that may influence the success of any weight-loss effort are the patient's diet and exercise routine. Participants in WELS received an activity monitor that provided objective activity data throughout the study such as step count and total activity minutes. A device usage report was also created to assess the relationship between participants' use of the devices (objective physical activity data) and their weight loss outcomes. This report measured what percentage of days the device transmitted data over the study time frame and after a recovery period (defined and discussed in Results). We also measured subjective diet and exercise activity at exit to better understand participants' self-reported behaviors.

Usability and satisfaction levels were collected at study exit.

Table 2. Descriptions of study concepts and variables.

Concept from Theoretical Framework		Data Collection	Variable	Definition	Scoring Method
Technology-Based Tools	Device usage	Pre/During	1) # of device readings over study timeframe	Overall % of days receiving consistent data from a working device (pedometer/weight scale) during the study timeframe	Objective values throughout study timeframe
			2) # of device readings after recovery period	Overall % of days receiving consistent data from a working device after a defined "recovery period" post-surgery	
	Usability	Post	Device usability score	6-point Likert scale rating of the usability of the pedometer, website, and weight scale, including they it helped them attain post-surgical goals.	Aggregate scoring method (0-100)
	Satisfaction	Post	Program satisfaction score	6-point Likert scale rating of participants' satisfaction with the program as a whole ("I was happy with," "this was helpful," etc.).	
Self-Efficacy	Self-efficacy	Pre/Post	1) Dietary self-efficacy	Score based on responses to diet- based self-efficacy questionnaire	Objective change in pre/post values
		Pre/Post	2) Exercise self-efficacy	Score based on responses to exercise-based self-efficacy questionnaire	
Weight Loss Behaviors	Subjective Diet and Exercise	Post	1) Adherence to diet	Score based on responses to a self-reported questionnaire of items asking about adherence to dietary and nutritional practices	Aggregate scoring method (0-100)
		Post	2) Adherence to exercise	Score based on responses to a self-reported questionnaire of items asking about adherence to exercise practices	
	Objective Exercise	Pre/During	1) Number of steps	Average daily number of steps (including walking, running, and "fidgeting" movements) accumulated over the study timeframe	Objective values throughout study timeframe
		Pre/During	2) Total distance travelled	Average daily distance calculated by speed of strides taken and foot-strike pattern	
		Pre/During	3) Number of activity minutes	Average daily number of minutes patient spends in movement	
		Pre/During	4) Calories burned	Average daily calories burned calculated based on all of the above factors	
Weight Loss Outcomes	Weight Loss Outcomes	Pre/Post(/During)	1) Body weight loss	The change in the participant's weight in the pre- to post-study timeframe	Objective change in pre/post values
		Pre/Post	2) % Excess body weight loss	Difference of body weights pre- and post-study / Excess body weight pre-study	
		Pre/Post	3) BF % change	Difference between pre- and post-study body composition	

* Ideal body weights calculated using *Metropolitan Life* standard height-weight tables, 1943.

Table 3 summarizes these variables in the context of the correlation model. Of note, correlation H will be used to determine which of the objective and subjective weight loss behaviors have the strongest correlation with collected weight loss outcomes (see Table 1).

Table 3. Correlation matrix for variables defined in Figure 2.

	Usability	Device Usage	Satisfaction	Δ Diet SE	Δ Exercise SE	Subj Diet	Subj Ex	Obj Ex - Steps	Obj Ex - Time	Obj Ex - Dis	Obj Ex - Cals	WLO1 - ΔWeight	WLO2 - %ExWL	WLO3 - ΔBMI
Usability														
Device Usage	A													
Satisfaction	B													
Δ Diet SE		C												
Δ Exercise SE		C												
Subj Diet				D										
Subj Ex					E									
Obj Ex - Steps					F									
Obj Ex - Time					F									
Obj Ex - Dis					F									
Obj Ex - Cals					F									
WLO1 - ΔWeight				G	G	H	H	H	H	H	H			
WLO2 - %ExWL				G	G	H	H	H	H	H	H			
WLO3 - ΔBMI				G	G	H	H	H	H	H	H			

3.4 Data Collection

The four-month WELS study is a virtual patient support program that included six pre-surgical patients recruited from the bariatric surgery (WLS) program at BMC who were scheduled to have bariatric surgery within four to six weeks of enrollment. The participants had one of the following surgical types: roux-en-Y gastric bypass [RNY], laparoscopic gastric banding [LGB], or laparoscopic sleeve gastrectomy [LSG]. All eligible patients were required to have a computer with Internet access in their home (to transmit device data and view a patient portal website), and weighed less than 380 pounds at baseline (due to the limit of the weight scale).

Participants had one baseline (one month pre-surgery) and one follow-up research visit (three months post-surgery), both conducted in person with the study PI and/or the research coordinator (myself). Both visits took place in a private room at the WLS program office suite at BMC and lasted approximately 60 minutes.

At the baseline visit, the PI and/or research coordinator met with participants individually to:

1. Review and complete the informed consent document
2. Perform clinical measurements (i.e., weight, height, body composition)
3. Complete a demographic questionnaire
4. Complete a questionnaire measuring diet- and exercise-related self-efficacy
5. Demonstrate how to use the FitLinxx activity monitor and ActiLink USB antenna that all participants used for the four months of the program. The activity monitor is a small pedometer that tracks step count, activity level, distance, and estimates calories burned; the USB antenna uploads the data wirelessly to the patient portal website

(described below). Participants were encouraged to begin using this monitor immediately (i.e., prior to their surgery), and told to call the research staff if they encountered any problems with these devices.

6. Demonstrate how to use the FitLinxx ActiScale weight scale. Participants were encouraged to begin using this scale immediately (i.e., prior to surgery) and told to call the research staff if they encountered any problems with this device.
7. Demonstrate how to access and use the patient portal website (ActiHealth.com). This included having the participant select from a list of de-identified usernames and setting up the participant's ActiHealth.com account, as well as giving the participant a tour of the website and its available features. Participants were encouraged to begin using the patient portal website immediately (i.e., prior to their surgery).
8. Review handouts describing the e-mail support available through the program, including a description of the study exercise physiologist. Participants were encouraged to e-mail this staff member with any questions and to expect a response within a week. Participants who preferred not to use their personal e-mail address for this communication were encouraged to set up a new e-mail account through a free e-mail provider (e.g., Gmail, Hotmail, etc.) and were assisted in this process as needed.

All participants were asked to wear their study activity monitor daily during waking hours. Participants were asked to weigh themselves on their study weight scale once a week under consistent settings (e.g., right after waking up wearing light clothing). Data collected from these devices were automatically uploaded to secure servers maintained by our FitLinxx IT partners via a wireless USB antenna plugged into a computer in the participants' homes.

Throughout the four-month study period, participants had 24-hour access to their personal patient portal website, through which they were able to view their device data, compete in weight- and activity-based challenges with other group participants (optional), and send brief messages to the group participants (optional). Weight and activity data were uploaded in an easy-to-interpret graphical format to the participant's password-protected, secure file on the patient portal website set up by our FitLinxx IT partners. This information was also printed by the study research coordinator and included in the participant's medical chart for use by the BMC WLS program clinicians.

Participants were provided with the option to contact an exercise physiologist facilitated through the PI and/or myself via e-mail. The role of the exercise physiologist was to respond regularly (i.e., at least once a week) to questions e-mailed by the PI or myself and provide general education and support as needed. However, no clinical care was administered via e-mail. Participants were advised to direct all clinical care-related questions to the WLS clinicians at BMC.

FitLinxx technicians provided IT support for any technical problems encountered by the participant via a 24-hour support hotline, and research staff was available to assist program participants during regular business hours.

Once uploaded to the patient portal, the participant's weight and activity data was available for immediate review by the participant and the research staff. The study PI and research coordinator tracked participation data (i.e., chat room usage) on a weekly basis. Participants who failed to transmit device data for one week were contacted by e-mail and/or by phone to determine the cause of the missing data.

At the follow-up research visit (approximately three months after the patient's bariatric surgery), the PI and/or research coordinator met with participants individually to:

1. Perform clinical measurements (i.e., weight, height, body composition)
2. Complete questionnaires measuring diet- and exercise-related self-efficacy
3. Complete a questionnaire measuring adherence to recommended post-surgical behaviors
4. Complete a questionnaire measuring participant satisfaction with the program components (i.e., weight scale, activity monitor, patient portal website, e-mail support system)
5. Complete a questionnaire measuring the patient's perception of the usability of the program components (i.e., weight scale, activity monitor, patient portal website, e-mail support system)
6. Return the study devices

Aside from these two research visits, all other contact with participants was made via e-mail or by phone as needed.

Data collected from all participants included, as shown in Table 2:

1) Overall number of device readings, calculated as a percent of the days the study team received consistent data from a working device; and Satisfaction and Usability data for the home monitoring devices (assessed by questionnaires which were developed for this study);
2) Self-Efficacy Data: dietary- and exercise- self-efficacy data (assessed by validated questionnaires modified for this study);

3) Behavioral Data: data on adherence to recommended post-surgical behaviors (diet and exercise, assessed using an existing, validated questionnaire); activity data (number of steps, total distance traveled, number of activity minutes, calories burned; uploaded automatically from the activity monitor via wireless transmission);
4) Clinical Data: weight, height and body composition measured at baseline and follow-up using a Tanita® body composition scale, as well as weekly as measured using wireless weight scale from home;
5) Socio-demographic data: name, gender, age, home address, race/ethnicity, marital status, employment status, education level.

CHAPTER 4

RESULTS

Six participants enrolled in the WELS study. Most participants were white females, and all three surgical types were represented. All collected demographic data can be found in Table 4.

Table 4. Summary of demographic data for WELS participants

	No. (percent)
Age (Average)	54.8
Sex	
Male	1 (16.67%)
Female	5 (83.33%)
Race	
White	5 (83.33%)
Black	1 (16.67%)
Ethnicity	
Hispanic	2 (33.33%)
Non-Hispanic	3 (50%)
Unknown	1 (16.67%)
Career (or most recent)	
Military	1 (16.67%)
Homemaker	2 (33.33%)
Unemployed	2 (33.33%)
Other	1 (16.67%)
Education	
9th-12th grade, no diploma	1 (16.67%)
High school graduate	1 (16.67%)
Some college, no degree	3 (50%)
Graduate or professional degree	1 (16.67%)
Marital Status	
Married	4 (66.67%)
Divorced	2 (33.33%)
Surgery Type	
Bypass	3 (50%)
Sleeve	1 (16.67%)
Band	2 (33.33%)

4.1 Outcome Measures

Clinical data were collected at baseline and follow-up visits. Weight and BMI were measured using a TANITA® body composition scale after the participants had removed shoes, jewelry, and heavy clothing. Table 5 summarizes the averages for all clinical data collected for WELS participants.

Table 5. Summary of clinical data for WELS participants

	Baseline	**Follow Up**	**Change**
Weight	252.2	205.3	-46.9
% excess body weight	42.4%	29.3%	-13.0%
BMI	41.3	35.0	-6.2

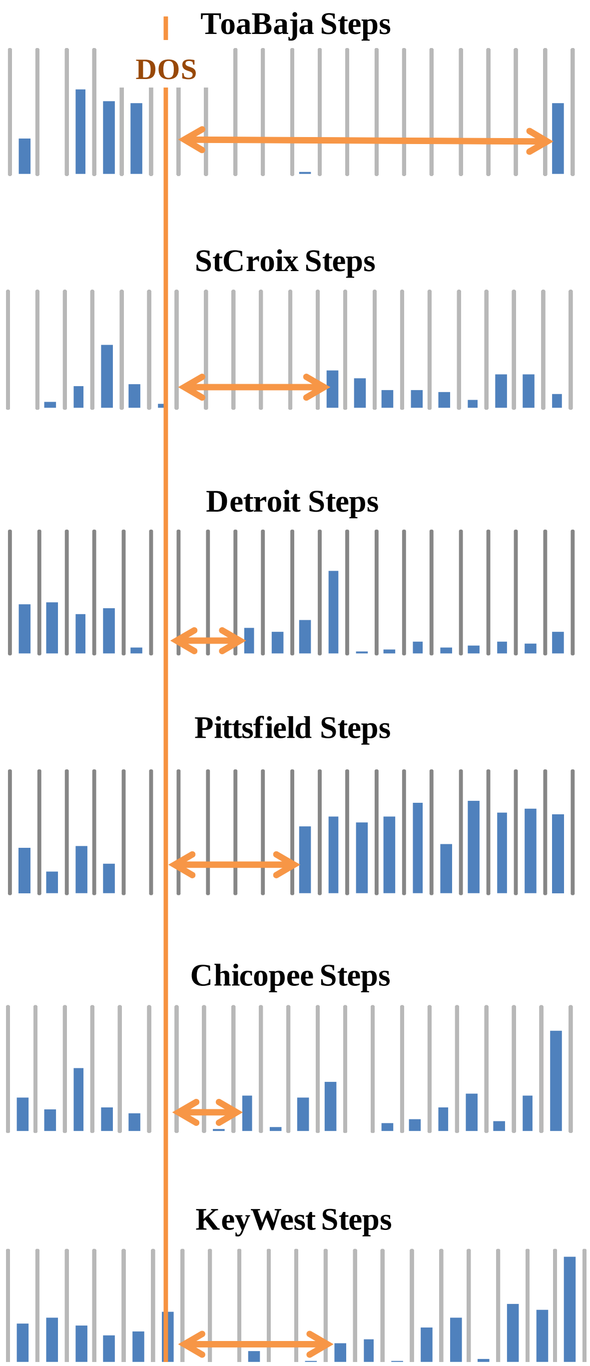
4.2 Usage, Usability, and Satisfaction

Device usage was calculated as:

$$\frac{\text{number of days data was collected}}{\text{number of days participant was enrolled in WELS}}$$

Usage of the activity monitor ranged from 44%-99% of days enrolled in the study with two-thirds of participants using their monitor at least 60% of the days; this usage only takes into account dates when the monitor collected data.

The aforementioned measure only provides an aggregate value across all days. However, immediately after surgery, participants typically stopped using the devices for some period of time, what we term “recovery periods.” We assume the recovery period ended on the post-surgical day that participants increased their step count to at least half of their pre-surgical average, though this assumption could be changed. Recovery periods ranged from three days to two weeks, but on average participants took six days to return to using their devices. Charts showing these recovery periods for step counts and activity minutes are shown in Figures 3 and 4. We have aligned the charts based on the participants' dates of surgery (DOS), shown in bold vertical lines.



Data for 1st Day Post-Recover Period			
AvgPre	1,258	1st Day Step	2,300
DOS	2/5	1st Day Date	2/19
Step count % for 1st day post recovery			183%
Recovery Period		14 days	

Data for 1st Day Post-Recover Period			
AvgPre	1,679	1st Day Step	6,244
DOS	2/26	1st Day Date	3/4
Step count % for 1st day post recovery			372%
Recovery Period		6 days	

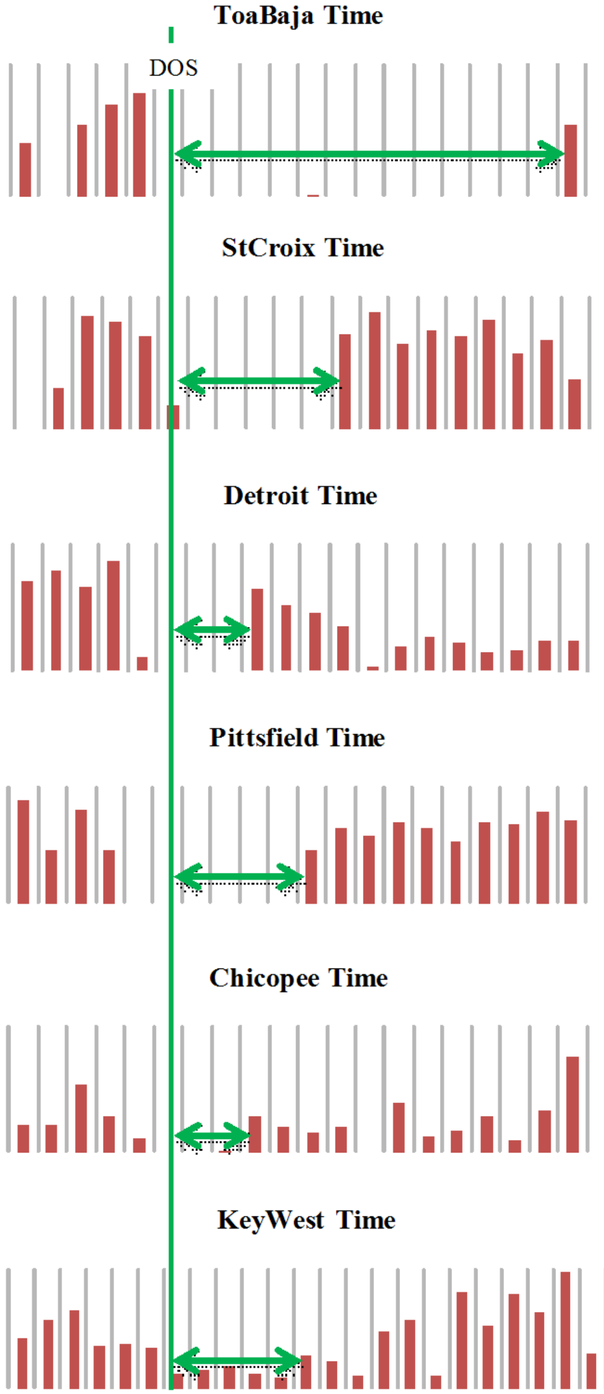
Data for 1st Day Post-Recover Period			
AvgPre	789	1st Day Step	640
DOS	2/13	1st Day Date	2/16
Step count % for 1st day post recovery			81%
Recovery Period		3 days	

Data for 1st Day Post-Recover Period			
AvgPre	2,367	1st Day Step	2,300
DOS	3/12	1st Day Date	3/17
Step count % for 1st day post recovery			97%
Recovery Period		5 days	

Data for 1st Day Post-Recover Period			
AvgPre	3,191	1st Day Step	4,212
DOS	3/12	1st Day Date	3/15
Step count % for 1st day post recovery			132%
Recovery Period		3 days	

Data for 1st Day Post-Recover Period			
AvgPre	1,275	1st Day Step	668
DOS	3/25	1st Day Date	3/31
Step count % for 1st day post recovery			52%
Recovery Period		6 days	

Figure 3. Graph and corresponding tables for each participant displaying step count data for recovery periods.



Data for 1st Day Post-Recover Period			
AvgPre	1:09:47	1st Day Step	1:00:54
DOS	2/5	1st Day Date	2/19
Activity time %, 1st day post recovery			87%
Recovery Period		14 days	

Data for 1st Day Post-Recover Period			
AvgPre	2:38:46	1st Day Step	3:25:22
DOS	2/26	1st Day Date	3/4
Activity time %, 1st day post recovery			129%
Recovery Period		6 days	

Data for 1st Day Post-Recover Period			
AvgPre	1:24:09	1st Day Step	1:33:18
DOS	2/13	1st Day Date	2/16
Activity time %, 1st day post recovery			111%
Recovery Period		3 days	

Data for 1st Day Post-Recover Period			
AvgPre	1:48:41	1st Day Step	1:19:10
DOS	3/12	1st Day Date	3/17
Activity time %, 1st day post recovery			73%
Recovery Period		5 days	

Data for 1st Day Post-Recover Period			
AvgPre	1:13:33	1st Day Step	1:19:48
DOS	3/12	1st Day Date	3/15
Activity time %, 1st day post recovery			108%
Recovery Period		3 days	

Data for 1st Day Post-Recover Period			
AvgPre	1:25:16	1st Day Step	0:53:08
DOS	3/25	1st Day Date	3/31
Activity time %, 1st day post recovery			62%
Recovery Period		6 days	

Figure 4. Graphs and corresponding tables for activity minute data for recovery periods.

These graphs and tables allow us to determine average recovery periods and identify outliers in recovery periods; we can then make further insights into whether these outliers vary based on their surgery type, demographic variables, etc. We can also observe usage in a slightly different way, by observing it only after the recovery period ends. This post-recovery device usage is calculated as:

$$\frac{\text{number of days data was collected after the defined recovery period}}{\text{number of days participant was enrolled in WELS after defined recovery period}}$$

After the recovery period, usage of the activity monitor ranged from 39-100%, with participants using the device about 75% of days on average. Compared to usage over the entire study timeframe, only one participant's usage decreased when observing only post-recovery use days. This suggests that usage rates from entry to right before the recovery period ended were actually lower than those after recovery, consequently pulling the study-long usage average down, ultimately indicating that early usage may not predict usage patterns over time.

Weight scale and website usage were monitored via weight scale readings taken over the study timeframe and via chat room postings. Figures 5 and 6 show how each participant utilized the scale and chat room over time; while Figure 5 is normalized based on entry, Figure 6 shows the data in real time to illustrate the potential effects of staggering participants' entrance to the study. Each diamond marker denotes a day with at least one reading or posting.

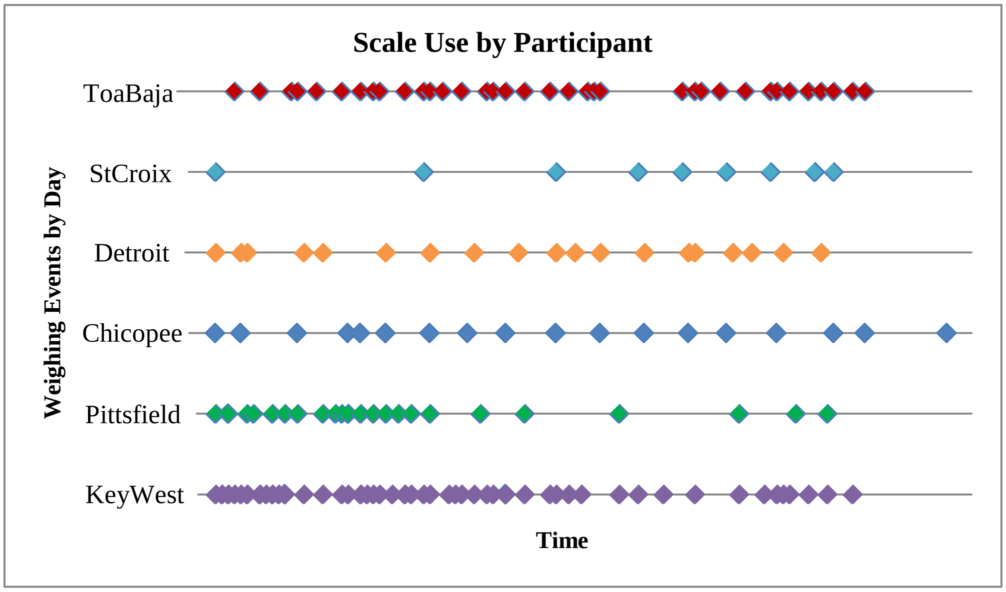


Figure 5. Weight scale readings by participants over time.

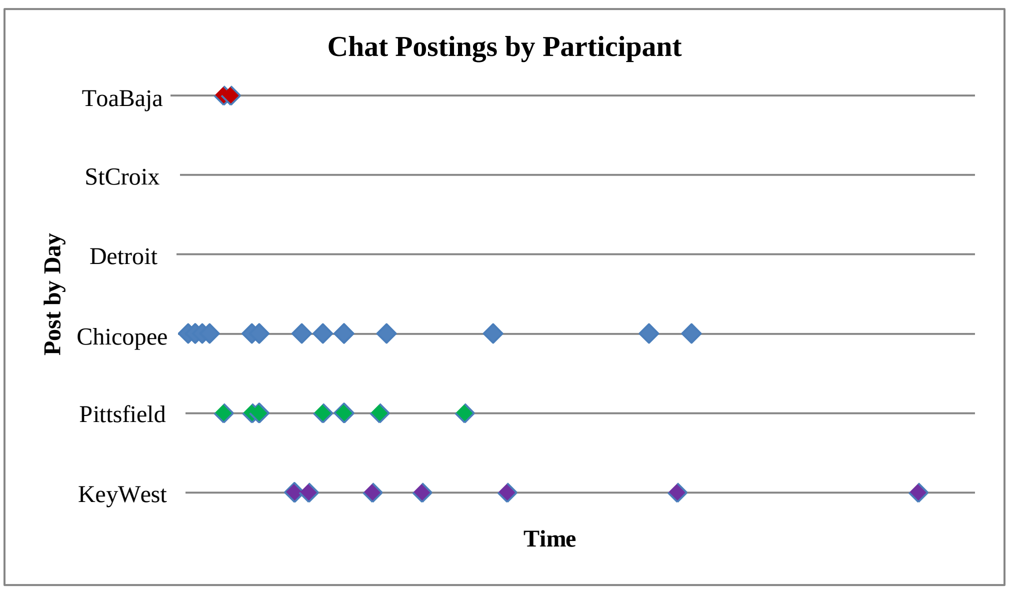


Figure 6. Chat postings by participants over time.

These graphs provide value into observing social media use patterns and attrition over time. Participants were told to weigh themselves on a weekly basis, however the data presented in Figure 5 indicates that none of the participants' behavior reflected this, as there were several weights recorded each week, sometimes more than once per day.

Conversely, clusters of diamonds in Figure 6 over time reveal high initial chat-room activity that dissipates as the study goes on. This may occur because of disinterest in continuing use of the chat room option or from participants exiting the study in stages, resulting in less activity for later participants.

Usability was calculated by weighing all 22 of the 5-point Likert items on the Usability survey (Appendix D) equally. Each item had a maximum score of 4 (with higher scores indicating higher usability) for a maximum score of 88, which was then normalized to a score out of 100. A similar approach was used for the 5-point Likert scale Satisfaction questionnaire (Appendix E). The average Usability score was 94 out of 100, with scores ranging from 89 to 98; the average Satisfaction score was 95, with scores ranging from 81 to 100.

4.3 Self-Efficacy

Dietary self-efficacy was calculated using participants' responses about their confidence in their ability to carry out, and their perceived importance ratings for 8 dietary behaviors (items 1-8 and 12-19 in a section from BMC's Bariatric Surgery Self Management Questionnaire (BSSQ), Appendix A). Exercise self-efficacy was calculated based on participants' responses about their confidence in their ability to carry out, and their perceived importance ratings for 3 exercise behaviors (items 9-11 and 20-22, Appendix A). The responses were all captured using a 4-point Likert scale and scored similarly to the Usability and Satisfaction surveys, for a final score out of 100. These dietary and exercise scores were averaged to capture an overall self-efficacy score.

Participants were then asked their confidence that they could complete physical activity tasks in twelve situations based on a 5-point Likert scale and scored according to

Sallis et. al (1996) Survey for Exercise Behaviors (Appendix B); this provided scores for "sticking with it" and "making time for exercise," which were normalized out of 100. The scores, which may be more or less useful than the aforementioned exercise self-efficacy score, are reported separately in the following tables and figures.

The following is summarized in Table 6 below. The average overall baseline self-efficacy score (calculated as the average of the dietary and exercise SE scores from the BSSQ tool) was 85, and ranged from 74 to 99. The average baseline dietary self-efficacy score was 79 and ranged from 63 to 98; exercise self -efficacy (calculated using the BSSQ tool) at entry averaged at 90 and ranged from 71 to 100. Overall self-efficacy at exit increased on average by three points to 88, ranging from 73 to 97. Dietary self-efficacy at exit increased on average 8 points to 87 and ranged from 70 to 95; while the lowest exercise self-efficacy score at exit increased and resulted in a range of 75 to 100, the average stayed the same at 90.

Exercise SE scores from the Exercise Behaviors questionnaire returned two scores: one that measured participants' willingness or likelihood of "sticking with" their exercise behaviors, and another that measured a willingness or likelihood that they would make time for their exercise behaviors. At entry, participants' scores for "sticking with it" averaged 84 and ranged from 60 to 95; scores for "making time" averaged 90 and ranged from 80 to 100. At exit, these scores increased to averages of 94 and 100 (respectively), and ranged from 89 to 100 for sticking with it, while all participants scored 100 for the "making time" portion.

Table 6. Summary of average self-efficacy scores at entry and exit.

	BSSQ Tool			SE for Ex Behaviors	
	Dietary SE	Exercise SE	Overall SE	"Sticking with it"	"Making time for exercise"
Entry Average *(Range)*	79 *(63-98)*	90 *(71-100)*	85 *(74-99)*	84 *(60-95)*	90 *(80-100)*
Exit Average *(Range)*	87 *(70-95)*	90 *(75-100)*	88 *(73-97)*	94 (*89-100)*	100 *(100-100)*

4.4 Weight Loss Behaviors

Weight loss behavior data included (1) subjective diet and subjective exercise activity levels and (2) objective exercise activity levels. Subjective diet and exercise activity levels were collected via a questionnaire at follow-up and scored by weighing each 5-point Likert scaled item equally and normalizing the final scores to have a maximum score of 100. Scores on the diet portion ranged from 67 to 92 and averaged 78; subjective exercise scores ranged from 22 to 100 and averaged 76.

Objective physical activity data were measured by collecting daily step counts, activity times, distances travelled, and calories burned. These were averaged by the days participants were enrolled and summarized in Table 7.

Table 7. Summary of average daily objective exercise data over study timeframe.

User	Data	TOTAL	Pre	Post	Change
ToaBaja	Steps	3,988	1,991	4,535	2,544
	Time	1:27:14	1:09:47	1:33:02	0:23:15
	Calories	264	112	305	193
	Distance	2.07	1.04	2.35	1.31
StCroix	Steps	4,843	4,199	4,975	776
	Time	2:32:45	2:38:46	2:31:31	-0:07:15
	Calories	302	270	309	40
	Distance	2.51	2.22	2.57	0.35
Detroit	Steps	2,174	920	2,259	1,339
	Time	1:22:45	1:24:09	1:22:39	-0:01:30
	Calories	158	88	163	75
	Distance	1.00	0.53	1.03	0.50
Chicopee	Steps	4,823	3,359	5,184	1,825
	Time	2:06:29	1:13:33	2:19:02	1:05:29
	Calories	500	383	530	147
	Distance	6.90	1.69	8.08	6.38
Pittsfield	Steps	4,982	2,998	5,858	2,860
	Time	2:00:16	1:48:41	2:05:22	0:16:42
	Calories	460	235	559	324
	Distance	2.49	1.43	2.96	1.54
KeyWest	Steps	1,473	1,275	1,589	313
	Time	1:43:49	1:25:16	1:52:10	0:26:54
	Calories	126	113	134	22
	Distance	0.83	0.74	0.89	0.15

Figures 7-10 show trends over time for these measures, aligned by day of surgery. These are extensions of the graphs shown in Figures 3 and 4. In addition, Figures 7 and 8 show cumulative step count behavior and activity time over the course of the study; orange lines show each patient's date of surgery.

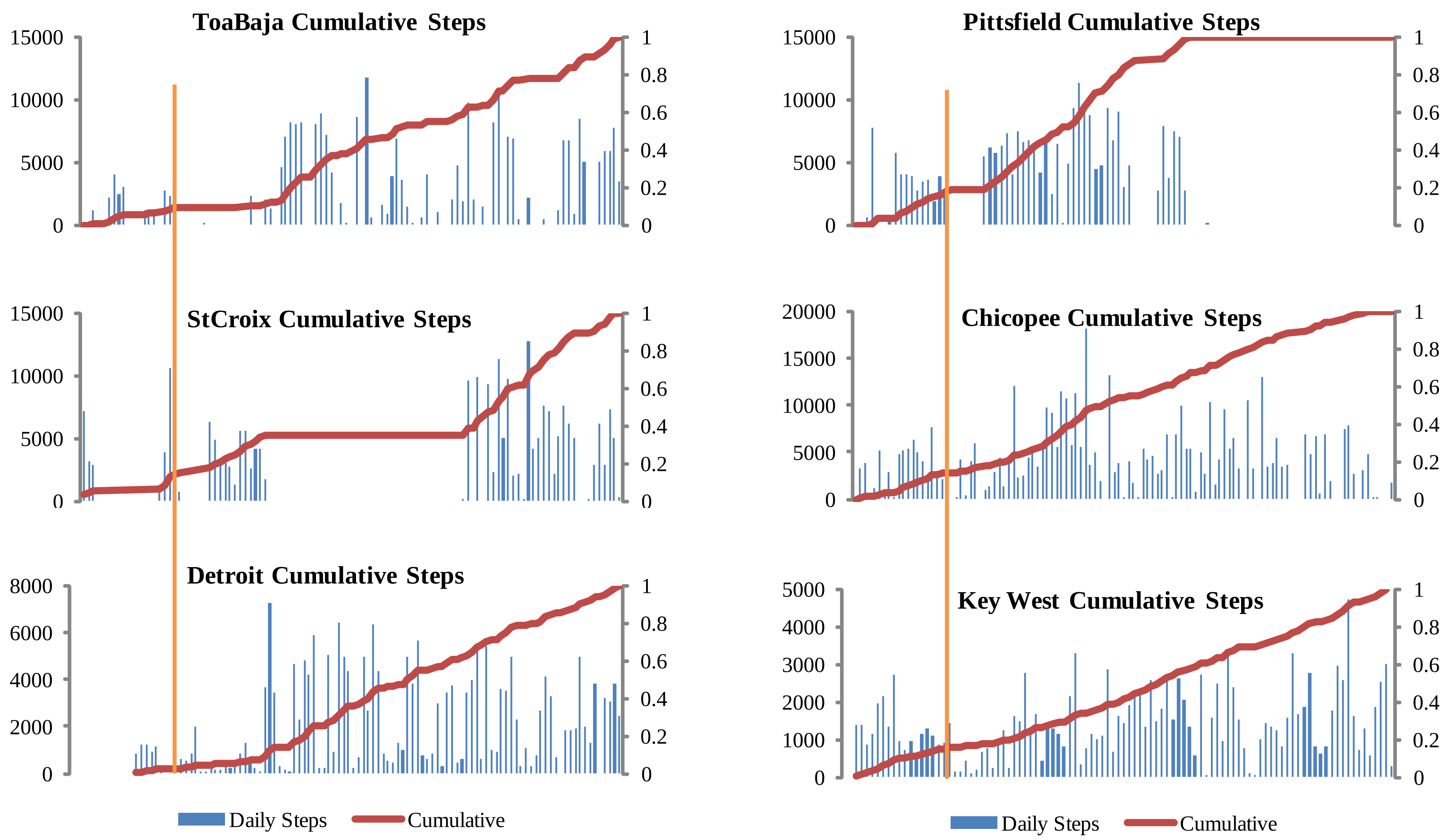


Figure 7. Daily and cumulative step count data for participants over study timeframe.

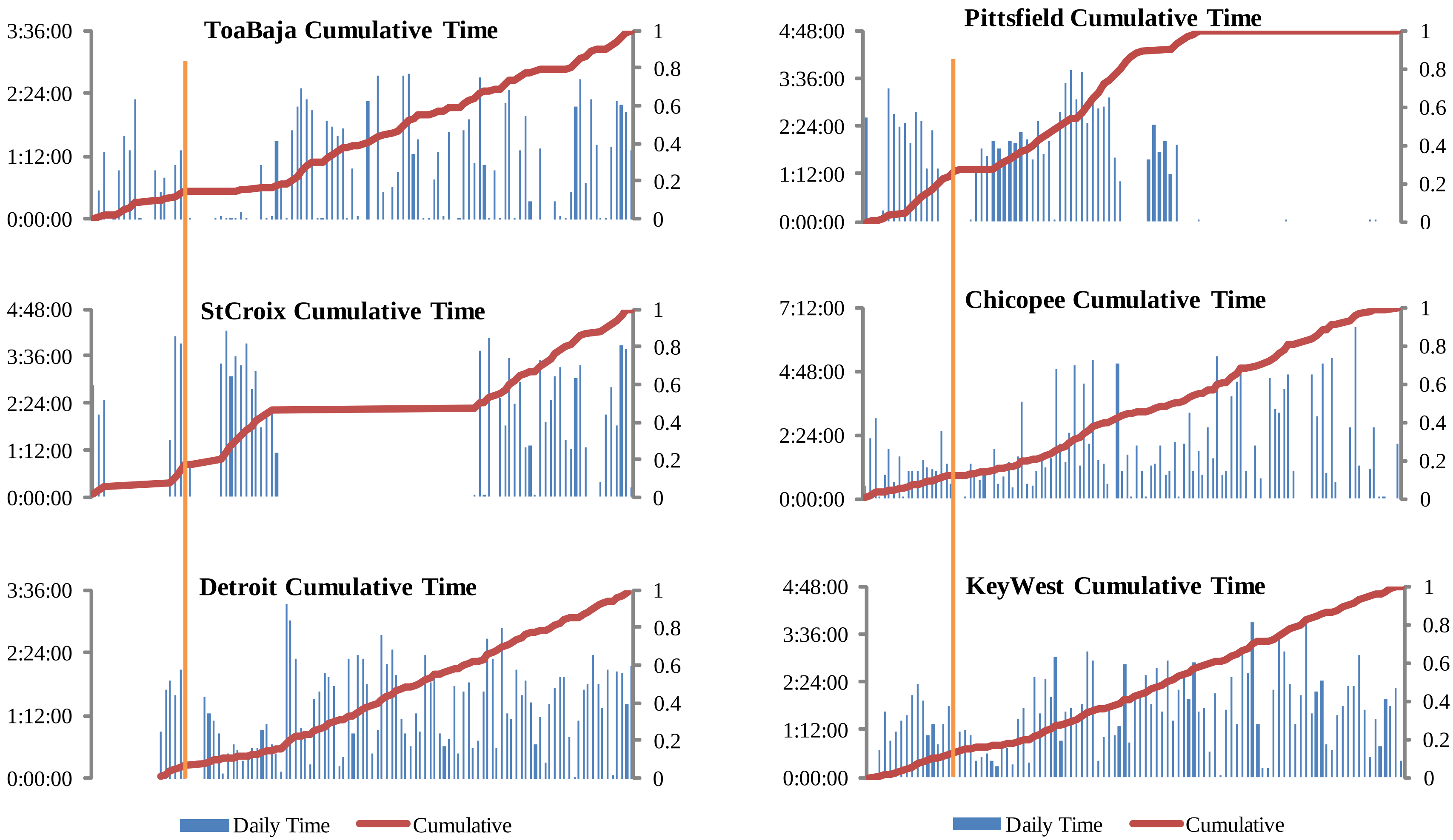


Figure 8. Daily and cumulative activity time data for participants over study timeframe

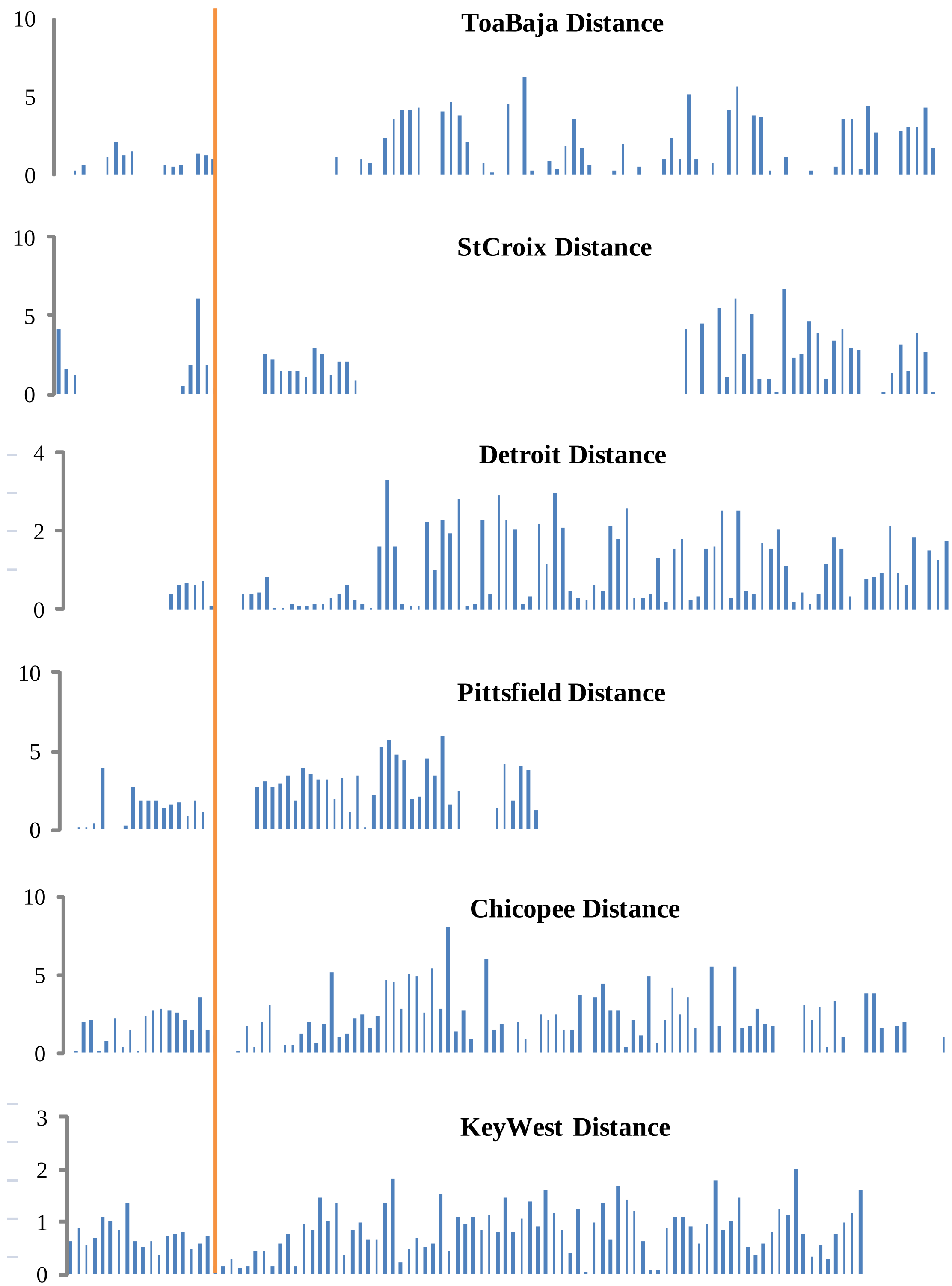


Figure 9. Daily distance traveled normalized to participants' dates of surgery.

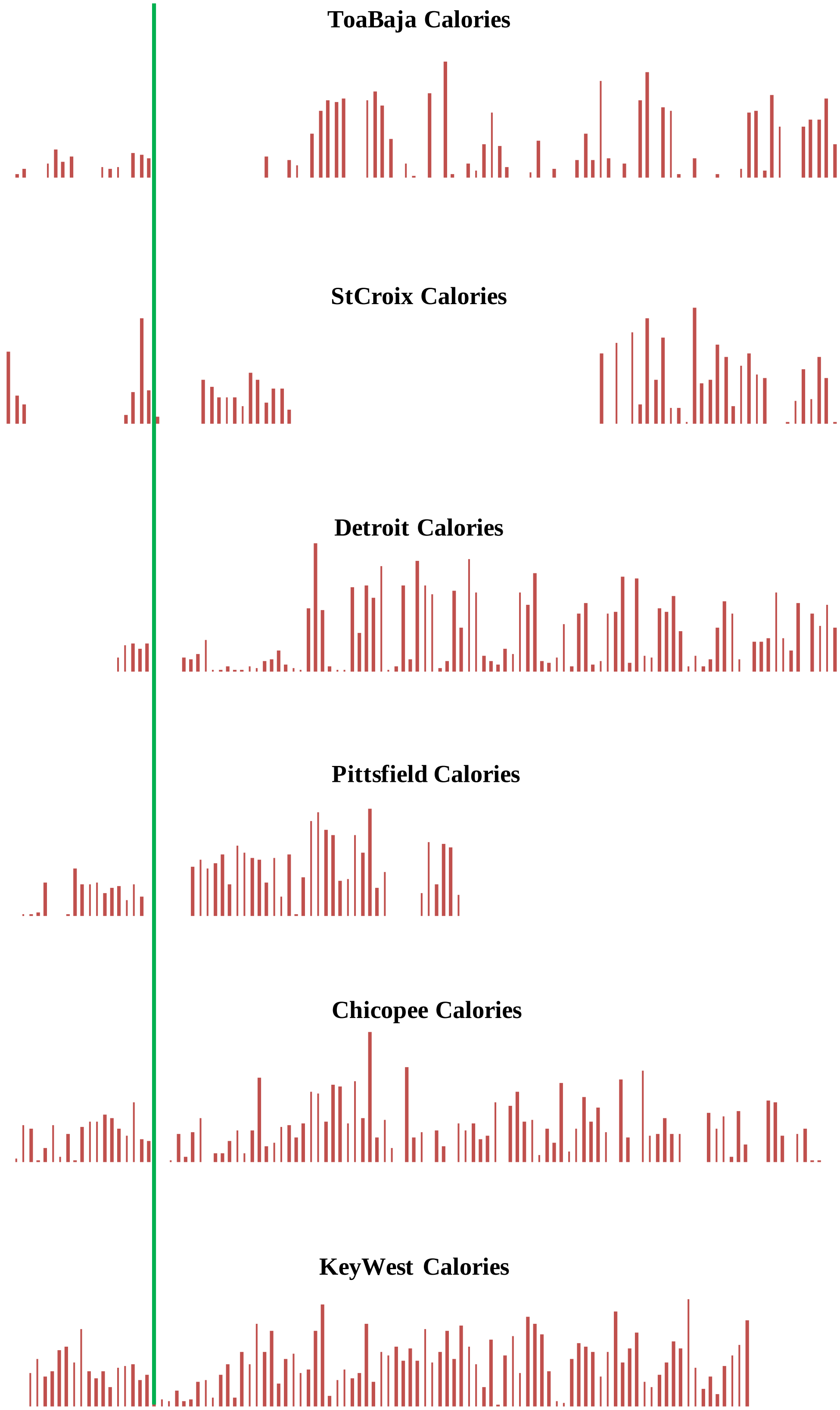


Figure 10. Daily calories burned normalized to participants' dates of surgery.

Each vertical bar on the daily graphs (left graphs in Figures 7 and 8) is the amount of activity captured on a single day during the study (i.e., the higher the bar, the more steps that day, etc.). The cumulative graphs in Figures 7 and 8 increase over time as patients increase their activity--the steeper the line, the higher the participant's activity over time. These daily graphs along with their cumulative counterparts reveal patterns over time that may not be immediately apparent, such as whether participants' activity levels are staying constant, increasing, or decreasing after their DOS.

4.5 Relationships Between Variables

Shown in Table 8, usability scores resulted in correlation coefficients 0.47, 0.41, and -0.50 for usage (all days), post-recovery usage, and satisfaction, respectively. Higher device usage post-recovery showed higher (albeit moderate) correlations with diet- (0.14) and exercise-related self-efficacy (0.22 for the BSSQ tool score [BSSQ], 0.16 for "sticking with it" [SW], and 0.06 for making time [MT]), respectively), while study-long usage (all days) showed little to no correlation with diet (0.10) or exercise SE (0.07 [BSSQ], 0.01 [SW], -0.02 [MT]). Diet-related self-efficacy was positively correlated with subjective diet adherence (0.19). Exercise-related self efficacy followed this trend for the BSSQ (target behaviors) and "sticking with it" scores, but was negatively associated with the "making time for it" score (0.43, 0.18, and -0.33, respectively). The relationships between all exercise self-efficacy scores and objective exercise averages were near 0 or negative. Exercise SE scores had modestly negative correlations for step count (-0.19 [BSSQ], -0.13 [SW], -0.10[MT]), distance (0.04 [BSSQ], -0.19 [SW], -0.22 [MT]), and calories burned (-0.17 [BSSQ], -0.17 [SW], -0.20 [MT]), while exercise SE and time showed more moderately negative values (-0.55 [BSSQ], -0.65 [SW], -0.26 [MT]).

Changes in exercise self-efficacy scores were negatively associated with all three weight loss outcomes (WLOs): (1) weight loss (-0.26 [BSSQ], -0.47 [SW], -0.36 [MT]), (2) percent excess weight lost (-0.41 [BSSQ], -0.59 [SW], -0.47 [MT]), and (3) change in BMI (-0.78 [BSSQ], -0.91 [SW], -0.46 [MT]); this could imply that increases in exercise self-efficacy scores from entry to exit resulted in (1) lower changes in weight loss, (2) lower percent excess weight lost at exit, and (3) lower changes in BMI. Changes in dietary self-efficacy scores were positively correlated with weight changes (0.54) but not so for excess weight lost (-0.39) or BMI (-0.18).

Self-reported (subjective) dietary weight-loss behaviors were positively correlated with weight lost (0.48), percent excess weight lost (0.79), and BMI (0.58). Subjective exercise behaviors showed little to no relationship with weight lost (0.02) and BMI (-0.15), but did show a moderately positive correlation with percent excess weight lost (0.46).

All objective weight loss behaviors were positively correlated with weight loss outcomes. Time showed a statistically significant relationship with both excess weight lost (0.89) and BMI (0.83), while weight was significantly related to both distance (0.88) and calories (0.81).

All of the objective activity measures were calculated as averages over the study timeframe; there may be different results based on the changes in these activities over time. Because the sample size of WELS was small, no conclusions about statistical significance can be made with respect to the intervention. However, given a larger study and comparison group, Table 8 would provide deeper insight into the relationships between the variables observed here. Tables 1 and 2 and Figure 2 are also extended below in Table 8 and 9 and Figure 11 with the correlation results reported above.

Table 8. Correlation table for variables as defined in Figure 2.

	Usability	Device Usage - All Days	Device Usage - Post Rcvry	Satisfaction	Δ Diet SE	Δ Exercise SE*			Subj Diet	Subj Ex	Obj Ex - Steps	Obj Ex - Time	Obj Ex - Dis	Obj Ex - Cals	WLO1 - ΔWeight	WLO2 - %ExWL	WLO3 - ΔBMI
Usability																	
Device Usage - All Days	0.47																
Device Usage - Post Rcvry	0.41																
Satisfaction	-0.50																
Δ Diet SE		0.10	0.14														
Δ Exercise SE		0.07 0.01 -0.02	0.22 0.16 0.06														
Subj Diet					0.19												
Subj Ex						0.43	0.18	-0.33									
Obj Ex - Steps						0.01	-0.10	-0.21									
Obj Ex - Time						-0.55	-0.65	-0.26									
Obj Ex - Dis						0.04	-0.19	-0.22									
Obj Ex - Cals						-0.15	-0.27	-0.21									
WLO1 - ΔWeight					0.54	-0.26	-0.47	-0.36	0.48	0.02	0.49	0.37	**0.88**	**0.81**			
WLO2 - %ExWL					-0.39	-0.41	-0.59	-0.47	**0.79**	0.46	0.39	**0.89**	0.29	0.22			
WLO3 - ΔBMI					-0.18	**-0.78**	***-0.91***	-0.46	0.58	-0.15	0.50	**0.83**	0.45	0.61			

Bolded = $p < 0.10$; ***Bolded italics*** = $p < 0.05$.
*Δ Exercise SE includes difference between pre-/post-survey scores from (1) 3-item self-efficacy [BSSQ] tool, (2) "sticking to it" [SW] and (3) "making time" [MT] scores from SE for Ex Behaviors tool as described in 4.3.

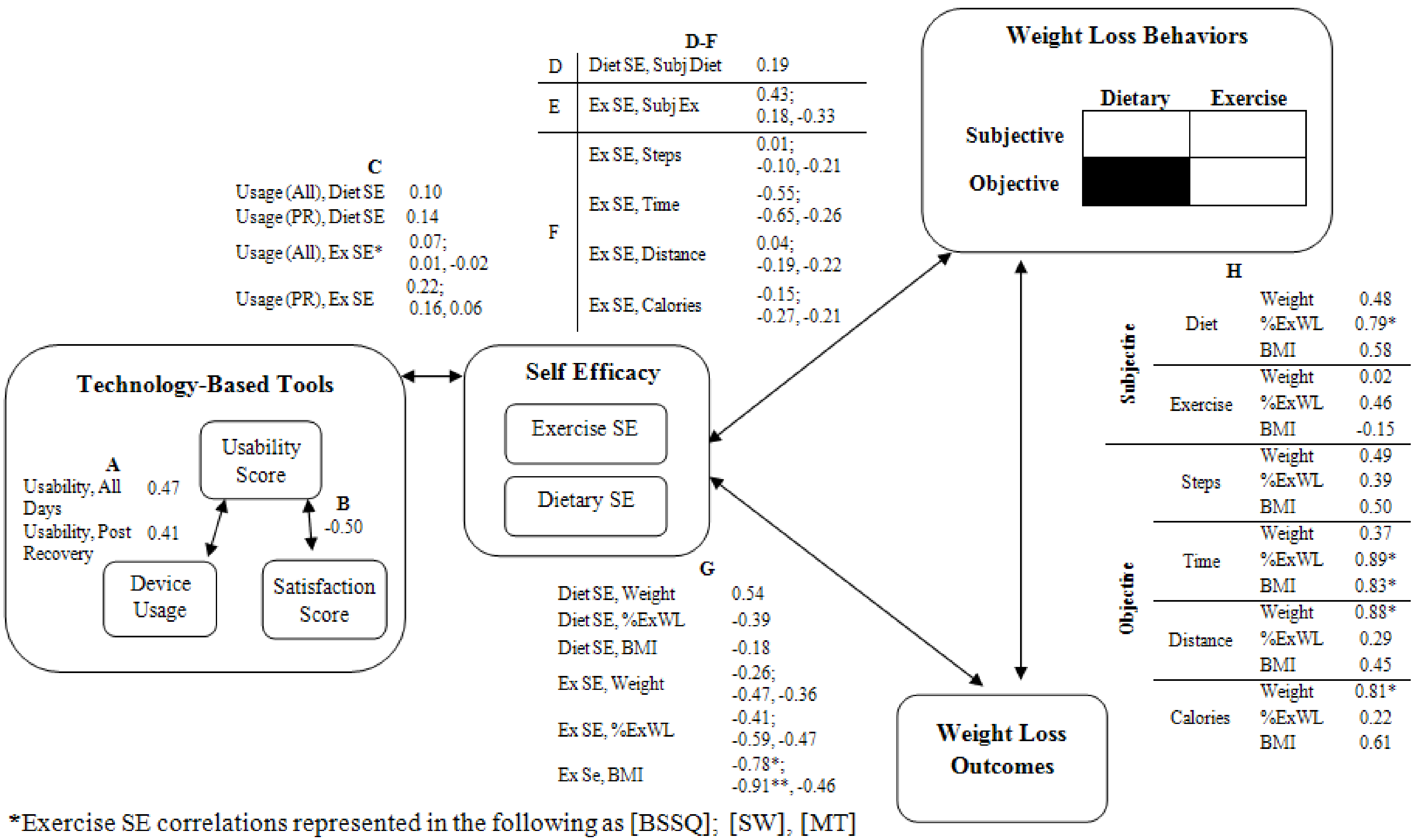


Figure 11. Expanded framework with correlation values from WELS results

Table 9. Table of reference hypotheses and correlation values for Figure 11.

Figure reference	Research question(s)	Hypothesis	Correlation
A	Q1.1	Higher usability scores will correlate with higher device usage.	
		• All Days	0.47
		• Post-recovery days only	0.41
B	Q1.2	Higher usability scores will correlate with higher overall program satisfaction scores.	-0.50
C	Q2.1, 2.2	Higher adherence with the proposed health information technology-based tools will create a positive change in participants' dietary- and exercise-related self-efficacy levels.	
		• Diet SE, All days	0.10
		• Exercise SE, All days	0.07; 0.01, -0.02
		• Diet SE, Post-recovery days only	0.14
		• Exercise SE, Post-recovery days only	0.22; 0.16, 0.06
D	Q3.1	Positive changes in dietary self-efficacy will correlate with higher self-reported dietary adherence.	0.19
E	Q3.2	Positive changes in exercise self-efficacy will correlate with higher self-reported exercise adherence.	0.43; 0.18, -0.33
F	Q3.3	Positive changes in exercise self-efficacy will correlate with higher objective physical activity measures.	
		• SE, Steps	0.01; -0.10, -0.21
		• SE, Time	-0.55; -0.65, -0.26
		• SE, Distance	0.04; -0.19, -0.22
		• SE, Calories	-0.15; -0.27, -0.21
G	Q3.4	Positive changes in overall self-efficacy scores will result in higher success with weight loss measures over time.	
		• Diet SE, Weight	0.54
		• Diet SE, %ExWL	-0.39
		• Diet SE, BMI	-0.18
		• Ex SE, Weight	-0.26; -0.47, -0.36
		• Ex SE, %ExWL	-0.41; -0.59, -0.47
		• Ex SE, BMI	-0.78*; -0.91**, -0.46
H	Q4	Some weight loss behaviors are more strongly correlated with successful weight loss outcomes than others.	
		• Subj Diet, Weight	0.48
		• Subj Diet, %ExWL	0.79*
		• Subj Diet, BMI	0.58
		• Subj Ex, Weight	0.02
		• Subj Ex, %ExWL	0.46
		• Subj Ex, BMI	-0.15
		• Steps, Weight	0.49
		• Steps, %ExWL	0.39
		• Steps, BMI	0.50
		• Time, Weight	0.37
		• Time, %ExWL	0.89*
		• Time, BMI	0.83*
		• Distance, Weight	0.88*
		• Distance, %ExWL	0.29
		• Distance, BMI	0.45
		• Calories, Weight	0.81*
		• Calories, %ExWL	0.22
		• Calories, BMI	0.61

*$p < 0.05$; **$p < 0.01$. Exercise SE scores represented as [BSSQ]; [SW], [MT]

CHAPTER 5

DISCUSSION AND LIMITATIONS

This study proposed and evaluated a set of measures to capture data relevant to the success of these health information technology-based tools. First, positive contributions and potential drawbacks of each analysis method will be discussed, followed by limitations of the WELS study.

5.1 Benefits and drawbacks of analysis methods

While many analysis methods were proposed, they exist in six subcategories: (1) outcome measures, (2) usage, (3) usability and satisfaction, (4) self-efficacy, (5) subjective diet and exercise, and (6) objective exercise.

5.1.1 Outcome Measures Analysis Methods

Outcome measures included changes in weight, percent excess body weight, and BMI. These outcomes were summarized using averages and changes at entry and exit from the study, methods commonly used in other research. One important benefit of capturing these three outcome measures is a reduced chance of overshadowing participants' success by the success of others. A change in body weight must be considered in relation to where the change originated from; in other words, the percent body weight lost "levels the playing field" in that it compares each patient to their baseline body weight at entry and looks at the relative percent change at exit.

5.1.2 Usage Analysis Methods

Usage data collected included percent of days participants had activity monitor readings, counts of chat room postings and scale readings over time, and provided a visual way to observe recovery periods. The variety of data collected from the activity monitor (steps, calories, distance, minutes) provided a valuable insight into not only if the participants used the device, but how they chose to use it over time. However, the lack of transparency into participants' activity levels when they did not wear the monitor is one important drawback to consider.

Other drawbacks to these methods include no true knowledge of how often participants used the patient portal. Without accessible login records, the only way to know when the website was being accessed was when participants left a visible timestamp themselves. This provides only a lower bound of use as participants may have used the website to access their activity data stats or alter settings, etc., without utilizing chat room feature.

One participant, St Croix, was included in the study as she met all eligibility criteria, including regular access to internet. However, her PC had recently been replaced with a tablet computer, on which the FitLinxx software and website are not compatible. Because of this, she was unable to upload her data regularly, leading to a loss of interest and/or data over time. We considered removing her from the analysis, as her usage scores pulled down the average and recalculation or truncation for a more accurate result was not possible. However, removing her as an outlier would also cause us to lose valuable self-efficacy, outcome and behavior data from an already limited sample size. The consequential usage scores were not the cause of data error and can still be considered valid results. Her removal also would have changed the distribution of the data, which would have made analysis far more difficult.

Recovery periods, while easy to see on charts and graphs provided, are not necessarily consistent with participants' true recovery periods. This again is because of the lack of transparency into participants' activity levels when the activity monitor was not worn.

5.1.3 Usability and Satisfaction Analysis Methods

Usability and satisfaction with WELS were measured using twenty-four- and nine-item Likert scales, respectively, along with follow-up open-ended questions. The usability questionnaire asked questions and requested feedback specific to the activity monitor, weight scale, and patient portal, while the satisfaction questionnaire asked for feedback on the program as a whole. These questionnaires gave us the ability to measure usability and satisfaction both quantitatively and qualitatively, as participants were able to give specific written feedback about the program as they desired. These surveys, however, were developed for this study and are not validated.

Oddly, our results indicated that as device usability increases, satisfaction with the program actually decreases regardless of which usage score is utilized (all days or post-recovery). This was unexpected and could be the result of participants encountering more issues the more they used the program. Comments from participants from the satisfaction survey indicated that, while they found the program and devices very easy to follow and use, they desired more features, higher chat room participation, and the ability to use the device and portal with their tablets or smart phones.

5.1.4 Self-Efficacy Analysis Methods

Self-efficacy was measured in two questionnaires: one utilized a twenty-two-item, four-point Likert scale split into eight dietary behaviors and three exercise behaviors that assessed participants' feelings about each "target behavior's" level of importance and their ability to follow through with them on a daily basis; this is one of seven sections from a larger survey developed, tested, and verified by BMC called the Bariatric Surgery Self Management Questionnaire (BSSQ). The Exercise Self-Efficacy Scale utilized a twelve-item, six-point Likert scale assessing participants' confidence they could carry out the statements made about physical activity and their lifestyle, which is also published and verified, and returns scores for participants "sticking to" exercise and "making time for it." Though both scales have been validated, the former has not been tested or validated as a stand-alone tool for use in measuring self-efficacy. Regardless, both provide valuable insight particularly into participants' exercise-related self-efficacy, as most of the data captured for WELS measured physical activity. However, this resulted in a shallow insight of participants' dietary self-efficacy, which, when paired with no proper way of capturing dietary activity, resulted in a large gap in data collection and potential conclusions.

There was also a prominent "ceiling effect" for some participants. If self-efficacy was very high at the beginning and stayed high throughout, there was a threshold that could not be broken (i.e., a score of 100/100) to indicate any further change. This creates a potentially deceptive picture when variance cannot be measured or estimated beyond this pre-specified level.

5.1.5 Subjective Diet and Exercise Analysis Methods

The same questionnaire that was taken from BMC's BSSQ and used to assess self-efficacy was used to assess participants' diet and exercise levels, which was slightly modified and scored according to methods described in Results and compared at entry and exit. Again, this is one section of a larger study that is validated as a whole, and may not be proper to use for measuring these behaviors alone. This tool was also only used at exit to capture the participants' behaviors the week before they exited the study, not taking into account (worse or better) behavior patterns throughout the rest of the study timeframe.

5.1.6 Objective Exercise Analysis Methods

Objective exercise data collected included daily step counts, activity minutes calories burned, and distance, which were averaged both before and after each participant's DOS and compared. The daily measures were aligned by DOS either alone or compared alongside cumulative counts over the study timeframe. This analysis method is what provided the visualization of the recovery period and daily variability in activity. The cumulative graphs show that, while daily activity varies, it appears to stay relatively consistent over time. However, most participants experience a lull in activity immediately after their DOS (recovery) and then their cumulative graph increases until it becomes somewhat linear; this would suggest that once the recovery period has passed, a steady routine is established.

Normalizing the activity graphs by DOS gives us common reference point to view participants' progress over time. Normal ebbs and flows of activity can be observed and outliers quickly spotted. While normalization is typical in this type of analysis, it does not take into account the effects of peer support that programs like WELS are grounded on. Participants who enter in the beginning of the study may not experience the benefits peer support brings, while later participants may have support at the beginning but show a steady decrease towards the end as participants exit. This would be remedied by enrolling all participants in a similar timeframe, which seems unlikely based on the enrollment results of WELS.

Because most participants did not have 100% usage of their devices, averages over time are dependent on how often each participant used their device. In other words, we are only accounting for activity that got recorded. This could cause participants with higher usage to appear more active because, though unlikely the case, we assume participants had zero activity (steps, distance, calories, and time) on days when no data was logged.

5.2 Limitations of WELS

WELS was designed to be a small pilot study to examine the efficacy of an emerging web-based weight-loss support program for the bariatric surgery community. The limitations that came along with this design will be discussed in the section to follow, along with potential areas for future work.

Because of WELS's design as a pilot study, the sample size was very small and limited to one intervention group without a control or comparison group; it is our hope that these results will prove useful in showing differences between groups of participants in future intervention studies for this population. Correlations and relationships could therefore be observed but not determined to be statistically significant with respect to the intervention. The timeframe of the study was also narrow compared to other weight loss intervention programs, as seen in the Literature Review. Though it seems to be consistent with the demographics of the bariatric community, the distribution of male-to-female participants was skewed, as was the distribution of surgical type. A larger, future study of this type should include a more diverse participant pool with a much longer timeframe to assess attrition rates.

Real-time usage of the website was also not available. This lost us the ability to observe those participants who wished to use the website for self-guidance or educational purposes and not participate in social functionalities, such as the competitions or chat room. Data was also lost on the days data was not transmitted from the user not wearing the device, mentioned previously in 5.1.6.

There was a problem for one user who, though was eligible for having internet access, had a tablet computer and did not have consistent access to a PC. The website and software used is not currently compatible with tablet PCs and therefore was not regularly accessible to her. If using these devices and software in the future, participants will need access to laptops or tower-based PCs or Apple computers until tablet compatibility is available.

Lastly, important to mention is the lack of our current ability to gather objective dietary data.

CHAPTER 6

CONCLUSION

As technology continues to evolve, it becomes more affordable and accessible. This is especially important in health care where costs are ever increasing and the sick ever present. Research into weight loss support interventions in the bariatric surgery population is lacking, even amidst the growing obesity problem and popularity of bariatric surgery. The goal of this study was to determine what analysis methods would provide the most worth in assessing the value of technology-based tools to bariatric surgery patients.

Using WELS, a small pilot study utilizing an activity monitor and web-based patient portal, we tested and evaluated our methods. A total of fourteen variables were considered and measured using surveys, questionnaires, participant-controlled activity and weight devices, and clinical measurements. The results of these measurements were organized and displayed via charts, graphs, figures, and tables by individual and cumulative data points, quantitative relationships (correlations), and averages. Despite some limitations in the study design used, these methods could easily be repeated and extended to a larger and more complex study.

We found that our analysis methods paired with typical methods used by weight loss intervention studies provide a fuller picture of participants' progress post-surgery. Graphs and charts like those used to display daily physical activity, weight readings, and chat postings reveal patterns established over time that averages and cumulative values often miss, and give insight into other factors like recovery periods.

APPENDIX A

WEIGHT LOSS SURGERY GOALS (DIET AND EXERCISE SELF-EFFICACY) QUESTIONNAIRE

Baystate Medical Center
Weight Loss Surgery Goals Questionnaire

Adapting new eating habits and getting exercise are important parts of a weight-loss surgery follow-up plan. However, weight-loss surgery patients often have different opinions at any given time about the importance of carrying these activities out. They also differ in their confidence that they could do these things if they decided to try. This questionnaire is designed to find out more about your opinions on these issues.

Instructions: Please read the questions below, then circle the number from 1-5 that best describes your feelings for each statement.

Part 1: How **important** to you right now are the following activities?

Eating behaviors	Not Important	A Little Important	Moderately Important	Highly Important	Extremely Important
1. Eating a minimum of five mini meals or snacks during the day	1	2	3	4	5
2. Eating slowly, and putting your utensils or food down between bites	1	2	3	4	5
3. Taking about 20-30 minutes to eat your meals	1	2	3	4	5
4. Chewing your food until it is a pureed consistency like baby food	1	2	3	4	5
5. Using a bread-and-butter plate or a salad plate instead of a regular-sized plate for your meals	1	2	3	4	5
6. Checking for a feeling of fullness after every bite	1	2	3	4	5
7. Stopping eating immediately if you	1	2	3	4	5

have any feelings of fullness or discomfort					
8. Using a baby spoon, fork and knife instead of regular-sized ones	1	2	3	4	5
Exercise behaviors					
9. Getting at least 30-60 minutes of exercise at least five days a week (e.g., walking, using exercise equipment at home or at a gym, fitness class, etc.)	1	2	3	4	5
10. Building some exercise into your daily routines (e.g., taking the stairs, walking around the supermarket or mall before shopping, etc.)	1	2	3	4	5
11. Building some weight training into your exercise program (e.g., hand weights, weight machines, etc.)	1	2	3	4	5

Instructions: Please read the questions below, then circle the number from 1-5 that best describes your feelings for each statement.

Part 2: How **confident** are you right now that you can do the following activities?

Eating behaviors	**Not Confident**	**A Little Confident**	**Moderately Confident**	**Highly Confident**	**Extremely Confident**
12. Eat a minimum of five mini meals or snacks during the day	1	2	3	4	5
13. Eat slowly, and put your utensils or food down between bites	1	2	3	4	5
14. Take about 20-30 minutes to eat your meals	1	2	3	4	5

15. Chew your food until it is a pureed consistency like baby food	1	2	3	4	5
16. Use a bread-and-butter plate or a salad plate instead of a regular-sized plate for your meals	1	2	3	4	5
17. Check for a feeling of fullness after every bite	1	2	3	4	5
18. Stop eating immediately if you have any feelings of fullness or discomfort	1	2	3	4	5
19. Use a baby spoon, fork and knife instead of regular-sized ones	1	2	3	4	5
Exercise behaviors					
20. Get at least 30-60 minutes of exercise at least five days a week (e.g., walk, use exercise equipment at home or at a gym, attend a fitness class, etc.)	1	2	3	4	5
21. Build some exercise into your daily routines (e.g., take the stairs, walk around the supermarket or mall before shopping, etc.)	1	2	3	4	5
22. Build some weight training into your exercise program (e.g., hand weights, weight machines, etc.)	1	2	3	4	5

APPENDIX B

EXERCISE SELF-EFFICACY QUESTIONNAIRE

Baystate Medical Center
Exercise Confidence Survey

Instructions: Below is a list of things people might do while trying to increase or continue regular exercise. We are interested in exercises like brisk walking, swimming, hiking, or bicycle riding. Whether you get regular exercise or not, please rate how confident you are that you could really motivate yourself to do things like these consistently, for at least six months. Please fill in one bubble for each question.

How confident are you that you can do these things?

	I know I cannot		**Maybe I can**		**I know I can**	**Does not Apply**
1. Get up early, even on weekends, to get exercise	○	○	○	○	○	○
2. Stick to your exercise program even when you have excessive demands at work	○	○	○	○	○	○
3. Engage in exercise even though you feel depressed	○	○	○	○	○	○
4. Set aside time for an exercise program, that is, walking, swimming, biking, or other activities for 30 minutes most days of the week	○	○	○	○	○	○
5. Continue to engage in exercise with others even though they seem too fast or too slow for you	○	○	○	○	○	○
6. Stick to your exercise program when undergoing a stressful life change (e.g., divorce, death in the family, moving)	○	○	○	○	○	○
7. Get up earlier to get your exercise done	○	○	○	○	○	○
8. Stick to your exercise program when your family is demanding more time from you	○	○	○	○	○	○
9. Stick to your exercise program when you have	○	○	○	○	○	○

household chores to attend to						
10. Stick to your exercise program after a long tiring day at work	○	○	○	○	○	○
11. Stick to your exercise program when social obligations are very time consuming	○	○	○	○	○	○
12. Read or study less in order to engage in exercise more	○	○	○	○	○	○

APPENDIX C

TARGET BEHAVIORS (SUBJECTIVE DIET AND EXERCISE)

QUESTIONNAIRE

Baystate Medical Center
Bariatric Surgery Target Behaviors Questionnaire

Date of surgery ______/______/______ Today's date ______/______/______

Below are some questions about your daily lifestyle habits since your bariatric surgery.

Instructions: Answer the following questions based on what you did this *past week*. Check the circle that best applies to you.

Meals, snacks, and eating:	Always	Mostly	Sometimes	Never
1. I ate a minimum of 5 mini meals or snacks during the day	❍	❍	❍	❍
2. I ate slowly, putting my utensils or food down between bites	❍	❍	❍	❍
3. It took about 20-30 minutes for me to eat my meals	❍	❍	❍	❍
4. I chewed my food until it was a pureed consistency like baby food	❍	❍	❍	❍
5. I used a bread and butter plate or dessert plate instead of a regular-sized plate for my meals	❍	❍	❍	❍
6. I checked for feeling of a feeling of fullness after every bite	❍	❍	❍	❍
7. I stopped eating immediately if I had any feelings of fullness or	❍	❍	❍	❍
8. I used a baby spoon, fork, and knife instead of regular sized ones	❍	❍	❍	❍

Exercise:	Always	Mostly	Sometimes	Never
9. I got 30-60 minutes of exercise 5 days or more in the past week (e.g., walking, exercise equipment at home, health club, class, etc)	❍	❍	❍	❍
10. I built some exercise into my daily routines (I took the stairs, walked around the supermarket or mall before shopping, etc.)	❍	❍	❍	❍

11. I built some weight training into my exercise program (hand weights, climbing stairs, weight machines, etc)	❍	❍	❍	❍

APPENDIX D

USABILITY QUESTIONNAIRE

Baystate Medical Center
WELS Usability Questionnaire

Date of surgery ______/______/________ Today's date ______/______/________

What was your experience with the devices you used in our weight loss support program?

Instructions: For each statement below, please fill in the circle that gives the best answer for you.

A. *The following items are related to the WEIGHT SCALE.*
Please rate your experience using the WEIGHT SCALE in your home.

	Strongly Agree	Slightly Agree	Not Sure	Slightly Disagree	Strongly Disagree	N/A
1. The weight scale was easy to use.	❍	❍	❍	❍	❍	❍
Comments?						
2. The weight scale worked well, or if there were problems they were quickly fixed.	❍	❍	❍	❍	❍	❍
Comments?						
3. The weight scale display was clear and easy to read.	❍	❍	❍	❍	❍	❍
Comments?						
4. It was easy to remember to weigh myself at the same time every week.	❍	❍	❍	❍	❍	❍
Comments?						
5. I was able to set the weight scale up in a convenient place in my home.	❍	❍	❍	❍	❍	❍
Comments?						

6. The weight scale was useful in helping me reach my post-surgical goals.	❍	❍	❍	❍	❍	❍
7. Where did you keep the weight scale in your home? - ________________________________						

8. If you could change anything about what the weight scale can do or how it works in your home, what would you change?

B. The following items are related to the PEDOMETER.
Please rate your experience using the PEDOMETER to monitor your daily step count totals.

	Strongly Agree	**Slightly Agree**	**Not Sure**	**Slightly Disagree**	**Strongly Disagree**	**N/A**
9. The pedometer was easy to use.	❍	❍	❍	❍	❍	❍
Comments?						
10. Using the pedometer fit easily into my daily routines.	❍	❍	❍	❍	❍	❍
Comments?						
11. The pedometer was useful in helping me reach my post-surgical goals.	❍	❍	❍	❍	❍	❍
Comments?						

12. If you could change anything about the pedometer and how it works for you, what would you change?

C. The following items are related to the PATIENT PORTAL WEBSITE (i.e., the website with your weight scale and pedometer data graphs).
Please rate your experience using the PATIENT PORTAL WEBSITE.

	Strongly Agree	**Slightly Agree**	**Not Sure**	**Slightly Disagree**	**Strongly Disagree**	**N/A**
13. The patient portal website was easy to use	❍	❍	❍	❍	❍	❍

and access.						
Comments?						
14. The patient portal website data was clear and easy to read.	❍	❍	❍	❍	❍	❍
Comments?						
15. It was easy to post questions to other patients and program staff.	❍	❍	❍	❍	❍	❍
Comments?						
16. It was easy for me to share the data from the patient portal website, as desired.	❍	❍	❍	❍	❍	❍
Comments?						
17. Using the patient portal website fit easily into my weekly routine.	❍	❍	❍	❍	❍	❍
Comments?						
18. The patient portal website was useful in helping me reach my post-surgical goals.	❍	❍	❍	❍	❍	❍
Comments?						

19. If you could change anything about the patient portal website and how it works for you, what would you change?

APPENDIX E

SATISFACTION QUESTIONNAIRE

Baystate Medical Center
WELS Satisfaction Questionnaire

Date of surgery ______/______/______ Today's date ______/______/_____

What was your experience with our weight loss support program?

Instructions: For each statement below, please fill in the circle that gives the best answer for you.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. I am happy with the training that I received before using the monitoring devices (weight scale and pedometer) at home.	❍	❍	❍	❍	❍
Comments?					
2. The graph showing my weekly weights was helpful to me.	❍	❍	❍	❍	❍
Comments?					
3. The graph showing my pedometer step count data was helpful to me.	❍	❍	❍	❍	❍
Comments?					
4. I am happy with the training that I received before using the program website at home.	❍	❍	❍	❍	❍
Comments?					
5. I liked being able to get help from my home (through the program website) rather than traveling to the clinic or a live support group meeting.	❍	❍	❍	❍	❍
Comments?					
6. The virtual support you got from	❍	❍	❍	❍	❍

other patients on the study website was helpful.					
Comments?					
7. The virtual support you got from the program staff (e.g., peer mentor, exercise consultant) was helpful.	❍	❍	❍	❍	❍
Comments?					

10. Though I know that continuing on this program is not currently an option, if it were an option, for how long do you think you would want to follow this program? Please check one:

☐ Would not want to continue ☐ Three months ☐ Six months
☐ One year ☐ Indefinitely

11. How could we improve this program?

12. What did you enjoy *most* about this program?

13. What did you enjoy *least* about this program?

14. Other comments?

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