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Evaluating the effectiveness of an internet-based behavioral program for increasing physical activity with and without a behavioral coach

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Evaluating the Effectiveness of an Internet-Based Behavioral Program for Increasing Physical Activity With and Without a Behavioral Coach

by

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Dedication

I dedicate this thesis to my parents, Fernando and Olga, who set up a major part of the environment that has promoted success throughout my academic career. Their support and advice were crucial throughout this entire process.

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Abstract

Obesity is a problem of vast social concern in the United States. One factor that has been linked to reduction in body fat and the health problems associated with obesity is increasing physical activity. Although in-person behavioral interventions have been shown effective at increasing physical activity, attention is now being placed on disseminating these interventions through the use of technology. Several internet-based interventions have been developed and are readily available. The purpose of this study was to evaluate "Fitbit," a web-based behavioral intervention for increasing physical activity and losing weight. Additionally, this study examined if the addition of contact from a behavioral coach through videoconference and email enhanced the effectiveness of this program. Through a multiple-baseline design across seven participants this research project evaluated the effectiveness of the "Fitbit" program with and without a behavioral coach. Step counts were recorded by a Fitbit sensor as a measure of physical activity. The Fitbit program alone increased physical activity for some of the participants, and the addition of the behavioral coach resulted in further increases in mean step counts.

Chapter One: Introduction

Obesity is a problem of vast social concern in the United States. Currently, over one third of adults and 17% of children in the United States are considered obese, and these data are on an increasing trend (Centers for Disease Control and Prevention, 2011). Such a high prevalence of obesity is problematic because obesity has been correlated with several health-related problems such as type II diabetes, cardiovascular diseases, and various types of cancers, as well as increased monetary costs for medical treatment (Guh et al., 2009; Trasande & Chatterjee, 2009).

Of more concern are the current trends in obesity and projections for the future. Wang, Beydoun, Liang, Caballero, and Kumanyika (2008) used database data from 1971-2004 to project the future prevalence and distribution of BMI as well as future health costs related to obesity. BMI refers to body mass index, a calculation that takes height and weight into account to provide a numerical value that can be used to judge a person's weight status. The value is calculated using the formula, weight(kg)/height(m)^2. This number is calculated using the same equation for both adults and children, but they are interpreted differently. For adults, BMI scores above 25 are considered overweight, and scores above 30 are considered obese. For children and adolescents, the BMI score is compared to the scores of other children of the same sex and age using a growth-chart, and a percentile rank is calculated. Children who lie in the 85-95% range are considered overweight, and those in the top 95% are considered obese (Centers for Disease Control and Prevention, 2012). Wang et al. found that over the past decades, the increase in overweight and obese adults was faster than in children, and faster in women than in men. They also concluded that, if the current trends continue, by 2048, all US adults would be overweight or obese; with certain populations reaching 100% levels before that (100% of African American

women would be overweight by 2034). Current trends also suggest that total health-care costs related to obesity and overweight will double every decade, reaching up to $956 billion by 2030. This study suggests that the current obesity problem is on a trend for the worse, costing society both health and money.

Although several factors affect obesity and weight loss, engaging in physical activity has been linked with a reduction of body fat, increases in health and fitness, and a decrease in health-related issues that are comorbid with obesity (U.S. Department of Health and Human Services, 2008). Therefore, increasing physical activity is a socially valid issue which could result in a decrease in health problems and the related costs. As a result, behavioral interventions have been evaluated and many found successful at increasing physical activity and reducing weight **(**Levy, Finch, Crowell, Talley, & Jeffrey**,** 2007**).**

Recently, attention has been given to the use of behavior principles to increase the levels of physical activity of individuals in a free-living approach, where individuals are encouraged to incorporate more physical activity and reduce sedentary activity in their daily lives. For example, VanWormer (2004) used a reversal design (ABABCBC) to evaluate an intervention consisting of pedometer feedback and brief counseling through e-mail to increase the number of daily steps of three overweight adults. During baseline, the participants wore the pedometer for 5 days, but it was covered so they could not self-monitor. During the self-monitoring phase, the participants wore the pedometer uncovered and recorded their daily step totals in a spreadsheet. During the self-monitoring plus e-counseling phase, in addition to the self-monitoring component, the participants had a 10-min weekly email conversation with the researchers in which they sent the current graphs, reviewed the current step totals, discussed weekly goals, and received praise. The intervention was effective at increasing the number of daily steps of the participants, with two of

the three participants nearly doubling their baseline rates by the end of the study. However, the increase in physical activity was seen in the self-monitoring phase, and the addition of the e-counseling component only resulted in a significant increase in step totals for one of the participants. This finding suggests that self-monitoring alone can increase physical activity, and that feedback in this way did not produce substantial improvements. Additionally, the two participants who increased their physical activity the most also experienced the most weight loss, while the participant with the smaller increase in daily steps experienced little weight loss during the intervention.

Normand (2008) evaluated the effectiveness of a multi-component intervention for increasing the physical activity of four healthy non-obese adults. Using a multiple-baseline design across participants in addition to a reversal (for three out of four participants), the participants received intervention consisting of goal setting, self-monitoring, and feedback. During baseline, participants wore pedometers that were covered (to prevent feedback), and the investigator recorded the daily totals. During the intervention phase, daily goals were set at the average for the step totals of the preceding week, as long as the participant had met the goal on at least four of the seven previous days. The participants wore the pedometers uncovered (open feedback), and reported the daily totals to the experimenters in a daily email. The feedback consisted of praise for meeting goals, encouragement via email in response to not meeting goals daily, as well as weekly face-to-face meetings in which the experimenters reviewed graphs of the data to that date, and discussed trends and reasons for meeting or not meeting goals. The intervention resulted in an increase in the daily step totals for three out of the four participants. Additionally, all of the participants maintained their weight throughout the study. The

researchers concluded that a simple, low cost intervention like this can result in an increase in physical activity of healthy non-obese adults.

Donaldson and Normand (2009) evaluated the effect of a similar multi-component intervention (goal setting, self-monitoring, and feedback) on five adults (four obese and one overweight) participating in a weight-management program. In this study, daily calorie expenditure (as calculated by Polar F6^{TM} heart rate monitors) was used as the dependent measure. The experimenters implemented the intervention within a multiple baseline design across participants, and included a reversal for three out of the five participants. During baseline the participants wore sealed heart-rate monitors, and the experimenters recorded the daily calorie expenditure without providing any feedback. During the intervention, participants set their goals at 10% increase from baseline, wore the heart-rate monitors uncovered so they could monitor them throughout the day, and sent daily updated graphs through email to the researchers who responded with brief daily written feedback. Additionally, they met once a week with the experimenter for more thorough feedback. However, there were some limitations; the interventions were modified for some of the participants, the daily calorie expenditure data varied significantly from day to day within participants, and baseline levels did not always return during reversals. Although the intervention resulted in higher energy expenditure for all participants, the authors suggested a component analysis to determine which part of the intervention resulted in the behavior change.

The results of these studies are consistent with conclusions made by Levy et al. (2007), that comprehensive behavioral interventions (consisting of behavioral components such as goal-setting, self-monitoring, stimulus control, social support, and reinforcement) are the most studied and effective strategies to treat obesity aside from surgery and pharmaceuticals. Given that

interventions that incorporate several behavioral components have been found effective at increasing physical activity, attention has now turned to the dissemination of these interventions. One promising outlet for these programs is the internet, and several interventions that use websites and phone applications are being developed and evaluated (LaPlante & Peg, 2011).

For example, Harvey-Berino et al. (2010) evaluated the effectiveness of a comprehensive behavioral intervention for weight loss delivered in person, over the internet, or in a hybrid combination of the two. The investigators assigned 481 participants into one of three conditions, all of which received an identical behavioral intervention, and the only thing that differed was the method of dissemination. The intervention consisted of goal-setting, self-monitoring, stimulus control, and assertiveness training, and participants were instructed to keep daily records of their weight, calorie consumption, and min engaged in physical activity. For the in-person condition, participants met in person once a week with a group of 15-20 other participants and an investigator who led the group meeting. For the internet condition, the meeting was identical, except that it took place over web-conference every week. The third and final condition was the hybrid condition, in which the participants met in person three times a month, and had an online meeting one time per month. The researchers found that in terms of mean weight loss, the in-person condition was significantly superior to the other two conditions (which didn't significantly differ from each other). The in-person condition also had the highest number of participants reaching a 7% weight loss. However, there was no significant difference between the three conditions in the number of participants who achieved a 5% weight loss. In terms of the behavioral measures (self-reported calorie intake and energy expenditure), there was an increase in energy expenditure and a decrease in caloric intake among all groups, with no significant differences between the conditions. The results of this study suggest that in-person dissemination

is superior to online dissemination of behavioral interventions for weight loss. However, there was some weight loss achieved with the online condition, and more research is needed to find ways to improve the outcome of behavioral interventions delivered through the internet.

Although several studies have evaluated internet-based interventions for increasing physical activity, findings have been mixed. Two recent reviews of the literature have concluded that there is not sufficient evidence to determine their effectiveness or make claims about their superiority compared to previously used methods of dissemination (LaPLante & Peng, 2011; Vandelanotte, Spathonis, Eakin, & Owen, 2007). However, LaPlante and Peng (2011) point out that although some internet-based interventions were not more effective than the alternative methods, there were no cases where the internet-based program was significantly less effective than the alternative. The authors suggest that even though these interventions may only be equally effective as previously used methods, they may still be beneficial in that they can increase the accessibility of the interventions and reach a greater population, and therefore merit investigation. The authors suggest that future research on physical activity promotion should be carried out for at least 6 months to demonstrate maintenance. Also, future studies should use objective measures of physical activity (such as pedometers and accelerometers), rather than rely on self-report and questionnaires, as has been the case in the majority of studies to this date.

Consequently, several readily available programs that incorporate behavioral principles have been created to increase physical activity and promote weight loss. Stevens, Allen, Dennison, and Himmelfarb (2011) summarize and briefly describe some of the existing programs such as “Lose it!” (http://www.loseit.com), “Weight Watchers” (http://www.weightwatchers.com/index.aspx), and Calorie Tracker by Livestrong (http://Livestrong.com). These programs use web-sites and phone applications for users to track

their physical activity and calorie consumption. They incorporate components such as feedback, self-monitoring, goal-setting, and social support, and disseminate these tools through the internet. The authors suggest that cardiovascular nurses should educate and encourage patients to use these readily available programs.

However, there is limited research examining the effectiveness of these available programs. In terms of future research in exercise promotion, Cushing and Steele (2011), in a book chapter on establishing and maintaining physical exercise, suggests that rather than finding new theories to account for the effectiveness of interventions, attention should be turned to carrying out studies to identify whether existing interventions are effective in natural settings and what contextual factors influence these interventions. As can be seen in the literature review by Neve, Morgan, Jones, and Collins (2010), many of these interventions include multiple components from various theoretical backgrounds. Although the researchers identify the need for component analyses to better understand what components are responsible for behavior change, it is clear that multi-component interventions are effective. Future studies should focus on evaluating existing programs.

One such program which incorporates behavioral principles and is commercially available online is Fitbit (http://www.fitbit.com). The Fitbit program consists of a website and phone application where users track their physical activity, calorie consumption, and weight. This author could not find any studies evaluating the effectiveness of this widely used program. Furthermore, this particular program was selected for the practicality of allowing participants to sync their data (sending it to the investigators) without logging in and accessing the accounts- a critical component of the baseline phase. Therefore, an evaluation of this online and phone based behavioral program is merited. Additionally, Vandelanotte et al. (2007) found that

interventions in which participants have more contact from researchers result in more positive outcomes. More specifically, interventions in which the participants had one to five contacts through internet (either through email, chat sessions, video conferencing, or guidance from an online coach) had significantly fewer (17%) positive outcomes compared to interventions with five or more contacts (78%).

Consequently, the purpose of this study was to (1) evaluate the effectiveness of an existing internet-based program for increasing physical activity and (2) compare the effectiveness of the program alone versus the program with the addition of contact from a behavioral coach.

Chapter Two: Method

Participants

Seven participants were recruited through flyers sent out through university electronic mailing lists, asking whether they are overweight and would like to participate in a weight loss study. Participants met the following inclusion criteria: have a BMI of 25 or more (considered at least overweight), be at least 18 years old, have not participated in a weight loss treatment program in the past 3 months, own a computer and a smartphone that supports the Fitbit mobile application, and answer no to all seven questions in the Physical Activity Readiness Questionnaire (see appendix A). The first seven participants who contacted the investigators and met the inclusion criteria were selected for the study. Les was a 53-year-old female with a BMI of 31.6. Cindy was a 48-year-old female with a BMI of 40.7. Holly was a 52-year-old female with a 38.1 BMI. Fire was a 57-year-old female with a BMI of 28.2. Blaze was a 44-year-old female with a 28.0 BMI. Meiling was a 46-year-old female with a BMI of 32.1. Byron was a 48-year-old male who was married to Meiling. His BMI was 36.5.

Setting

During all phases of the study the participants were instructed to wear a Fitbit sensor from the time they woke up to the time they went to sleep across all settings. Meetings with the investigator, weigh-ins, and interactions with the online program with the computer occurred in the participants' homes, and across all settings with their mobile phones.

Materials

Fitbit One tracker (http://www.fitbit.com) was used to track step-counts and calorie expenditure. This sensor uploaded the user's activity to the website. The Fitbit Aria Wi-Fi Scale (http://www.fitbit.com/aria) was used to measure the participant's weight. This scale uploaded the user's weight to the website when they weighted-in.

Validity and Reliability

Before the beginning of the study, the investigators tested the validity and reliability of the pedometer function of the Fitbit One Tracker using a method similar to that used by Ek and Miltenberger (2012). The validity evaluation was done by having a participant wear the Fitbit tracker for 15 min while two observers counted the number of steps with a clicker. The agreement between the observers' recording and the device was calculated. Additionally, the reliability was assessed by having participants wear two devices at the same time (one on each side of the hip), and walk for 15 min. The agreement between the two sensors was calculated. Participants were instructed to incorporate a variety of movements, such as walking, jumping, jogging, and skipping to account for potentially different topographies of steps. Three sessions were conducted under each condition.

The overall reliability (agreement between the two Fitbit sensors) was 99.50%. The overall validity (agreement between the observers and the Fitbit sensors) was 99.02%. Specifically, the mean agreement between observer 1 and sensor one was 99.07%, the mean agreement between observer 1 and sensor 2 was 99.04%, the mean agreement between observer 2 and sensor 1 was 98.90% and the mean agreement between observer 2 and sensor 2 was 99.07%,

Target Behaviors and Data Collection

The primary dependent measure collected in this study was daily step count and daily weight. Step count data were uploaded daily to the website by the Fitbit One Tracker before participants went to sleep. Participant weight data were collected through the Fitbit Aria Wifi Scale, which uploaded the participants' weight as they stepped on the scale every morning before eating breakfast. These data were collected across all phases of the study. The Fitbit One can monitor min-by-min activity of the sensor, which helped identify potentially fraudulent data. Because all data collection was automated and objective, there was no need to collect inter-observer agreement data.

Adherence was measured as whether the participants uploaded their daily weight and calorie expenditure/step information. If participants uploaded both weight and activity information in a given day, it was scored as 100% adherence for that day (50% if only one of the two measures was uploaded, and 0% if neither was uploaded). Additionally, the Fitbit recorded other measures which were not the focus of this study such as self-reported daily calorie consumption and calorie expenditure (calculated by the Fitbit and any self-reported exercise).

Experimental Design

A multiple baseline design across participants was used to assess the effectiveness of the Fitbit intervention alone for seven participants and the Fitbit intervention with the addition of contact from a behavioral coach for four participants.

Procedure

Throughout all phases of the study participants wore the Fitbit One sensor from the time they woke up until the time they went to bed. They also synchronized the sensors every night on

their computer uploading their activity data to their accounts. Participants did this across all phases, regardless of whether the Fitbit One was covered or not.

Baseline. After obtaining consent and confirming that the participants' BMIs were above 25, the participants were started in the study. In this phase, the participants were given a covered Fitbit One tracker, and told to wear the sensor every day from the time they wake up until the time they go to sleep. The sensors were covered with tamper-evident tape to ensure that the participants did not have access to the data from the sensor. They were told to do this until they receive further instructions from the researchers about the start of the program. Participant weight was measured and recorded pre- and post- baseline. Participants were instructed not to use any other weight loss or physical activity programs while taking part in the study. As an incentive to wear the sensor, the participants were told they would be compensated for participating in the study not contingent on any outcome measures. Since there were extended times without direct contact from the investigators, the following contingency was in place for adhering to the program. If participants submitted 90% of their data every two weeks, they received a $5 towards a Visa gift card for as long as they are in the study.

Intervention 1. After the completion of baseline, the investigator scheduled a meeting at the participants' homes to introduce them to the first intervention. This intervention consisted of using a currently existing web-based program for promoting physical activity and weight loss called Fitbit. This program included an internet webpage and a phone application that delivered a behavioral weight loss intervention that was available for free. The program incorporates behavioral components of self-monitoring (tracking calorie consumption/expenditure, steps, BMI, and weight on automated graphs), goal-setting (setting goals for a certain number of steps per week), feedback (earning badges, discussion forums), and social support (discussion forums

and friend groups). The researchers created an account for each participant on the Fitbit.com website and gave the participants the login information at the meeting. The researchers helped install the mobile phone application to each participant's smart phone. The researchers only helped the participants set up the equipment and link it to the accounts while answering any technical questions, not related to the actual intervention. The Fitbit One sensors were uncovered so that the participants could monitor their step-counts and calorie expenditure throughout the day. The participants were instructed to begin using the website and phone application to track their calorie expenditure/intake and weight, while continuing to wear the sensor. Additionally participants were given the Fitbit Aria Wifi Scale and instructed to weight themselves each morning before eating breakfast using the scale we provided. The investigator told the participants to begin using the program, and continue to do so until they receive further instructions. Throughout this phase of the study, there was no direct contact between the participants and the investigators. A weekly email (see Appendix B) was sent to all participants thanking them for participating in the study and reminding them of the gift card contingency, but this email was a general contact not tailored in any way to each participant based on his or her progress with the intervention. During this phase the contingency was expanded to include weight data (participants could submit data 28 times (2 times daily, one for weight data, one for calorie information) every two weeks, so they were required to submit data at least 26 times every two weeks to earn the $5 for that portion of the study.

Intervention 2. After stability was reached in the in the first intervention, the investigators contacted the participants to inform them of the beginning of the next phase of the study. This phase was identical to the first intervention, with the addition of contact from a behavioral coach. The participants continued to wear the uncovered sensor, weigh in daily, and

have complete access to the website and mobile app. However, the behavioral coach now had contact with the participants. The researchers scheduled a weekly meeting through video conferencing in which the behavioral coach helped the participants set reasonable goals, provided them with tailored feedback and social support (praise) on their progress, and gave them recommendations to increase exercise. The reasonable goals provided by the coach were based on percentile schedules (Galbika, 1994), meaning that the participant had actually reached the new goal level of performance in the previous days (specifically the eighth highest step-count from the last 10 days). In order to maintain consistency between the coaching calls, all coaching calls were conducted by the same behavioral coach, and a checklist of the different components to be included in the coaching calls was created (see Appendix C). The audio of the conference calls were recorded, and at least 33% of coaching calls for each participant were scored for including all components on the checklist- this integrity measure was 100% for all calls scored. Additionally, if the participants failed to upload their weight or calorie expenditure on a given day, the investigators sent them an email the following day inquiring about why the data were not collected, and reminding them of the gift card contingency (see Appendix D). The participants were also told that they could contact the investigators at any time through email with any questions or comments about the intervention.

Chapter Three: Results

Phase change decisions were made based on the daily step-count data displayed in figures 1 and 2. The first intervention consisting of the Fitbit program alone resulted in a mean increase in daily steps for three out of the seven participants (Les, Holly, and Fire). Intervention two which consisted of the addition of the behavioral coach resulted in a mean increase in daily steps for four out of four participants who received the intervention.

Furthermore, we calculated the means of the last 15 days of each phase for all participants in order to represent the participants' behavior at the end of the phase when reactivity would be minimized and the environmental conditions in each phase had affected behavior. For Les, the means for the last 15 days in each phase show a less noticeable increase in steps from baseline to intervention 1, while a more noticeable increase to intervention 2. For Cindy, the means of the last 15 days made the increase in step counts from intervention 1 to intervention 2 slightly higher. For Fire and Byron, considering the mean of only the end of the phases did not noticeably change the mean step counts.

In addition to the step count mean data, changes in weight during each phase, as well as compliance data were also recorded. A summary of each individual participant's step-count means, end of phase step-count means, weight change, and compliance can be seen in table 1.

Table 1. Individual participant step-count means, end of phase step-count means, weight change, and compliance.

Participant	BL Mean Step-count	Int. 1 Mean Step-count	Int. 2 Mean Step-count	BL (last 15 days) Mean Step-count	Int. 1 (last 15 days) Mean Step-count	Int. 2 (last 15 days) Mean Step-count	Weight Change (lb.) BL	Weight Change (lb.) Int. 1	Weight Change (lb.) Int. 2	Overall Compliance
Les	4,049	6,301 (+55.6%)	7,406 (+82.9%)	4,049	5,175 (+27.8%)	8,211 (+102.8%)	-.1 (-.05%)	-3.8 (-2.06%)	-.07 (-1.4%)	90%
Cindy	3,443	3,167 (-8.0%)	4,684 (+36.0%)	3,361	3,020 (-10.1%)	4,963 (+44.1%)	-0.7 (-0.30%)	-1.0 (-0.44%	+3.2 (+1.4%)	95%
Holly	2,979	4,289 (+44.0%)	N/A	3,004	5,384 (+79.2%)	N/A	+.09 (+0.46%)	-1.4 (-0.72%)	N/A	88%
Fire	5,545	11,045 (+99.2%)	N/A	5,338	9,742 (+82.5%)	N/A	-1.7 (-0.95%)	-12.4 (-7.0%)	N/A	92%
Blaze	7,329	7,830 (+6.4%)	N/A	7,156	7,813 (+9.2%)	N/A	-2.5 (-1.39%)	-3.9 (-2.20%)	N/A	92%
Meiling	4,704	4,645 (-1.3%)	7,371 (+56.7%)	1,987	5,941 (+199.0%)	7,623 (+283.6%)	+4.7 (+2.26%)	-9.4 (-4.43%)	-1.2 (-0.6%)	98%
Byron	9,865	10,514 (+6.6%)	11,376 (+15.3%)	10,128	10,595 (+4.6%)	10,687 (+5.5%)	-0.2 (-0.07%)	-12.2 (-4.54%)	-2.5 (-0.97%)	97%

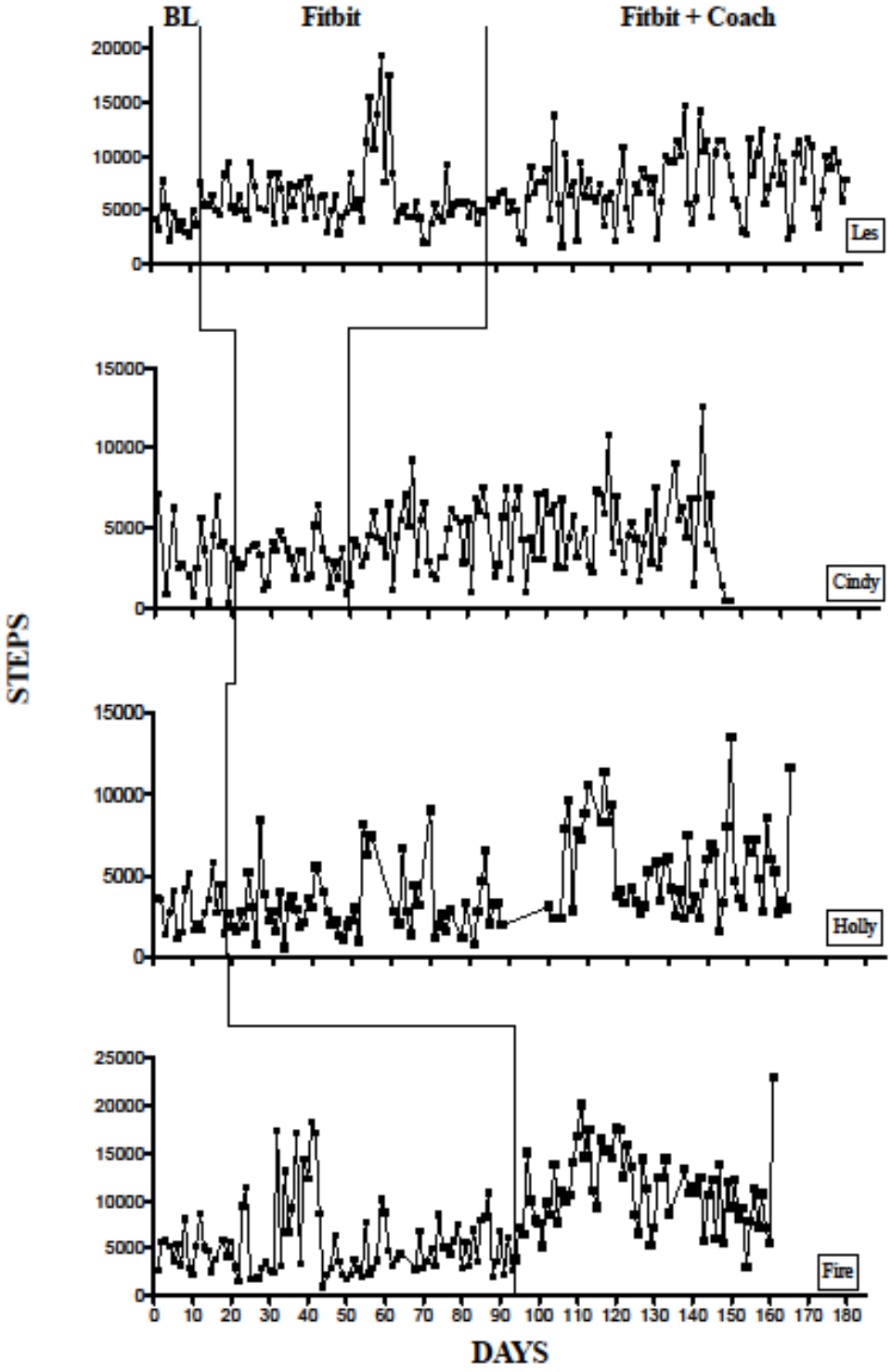

Figure 1. Daily step counts across participants Les, Cindy, Holly, and Fire.

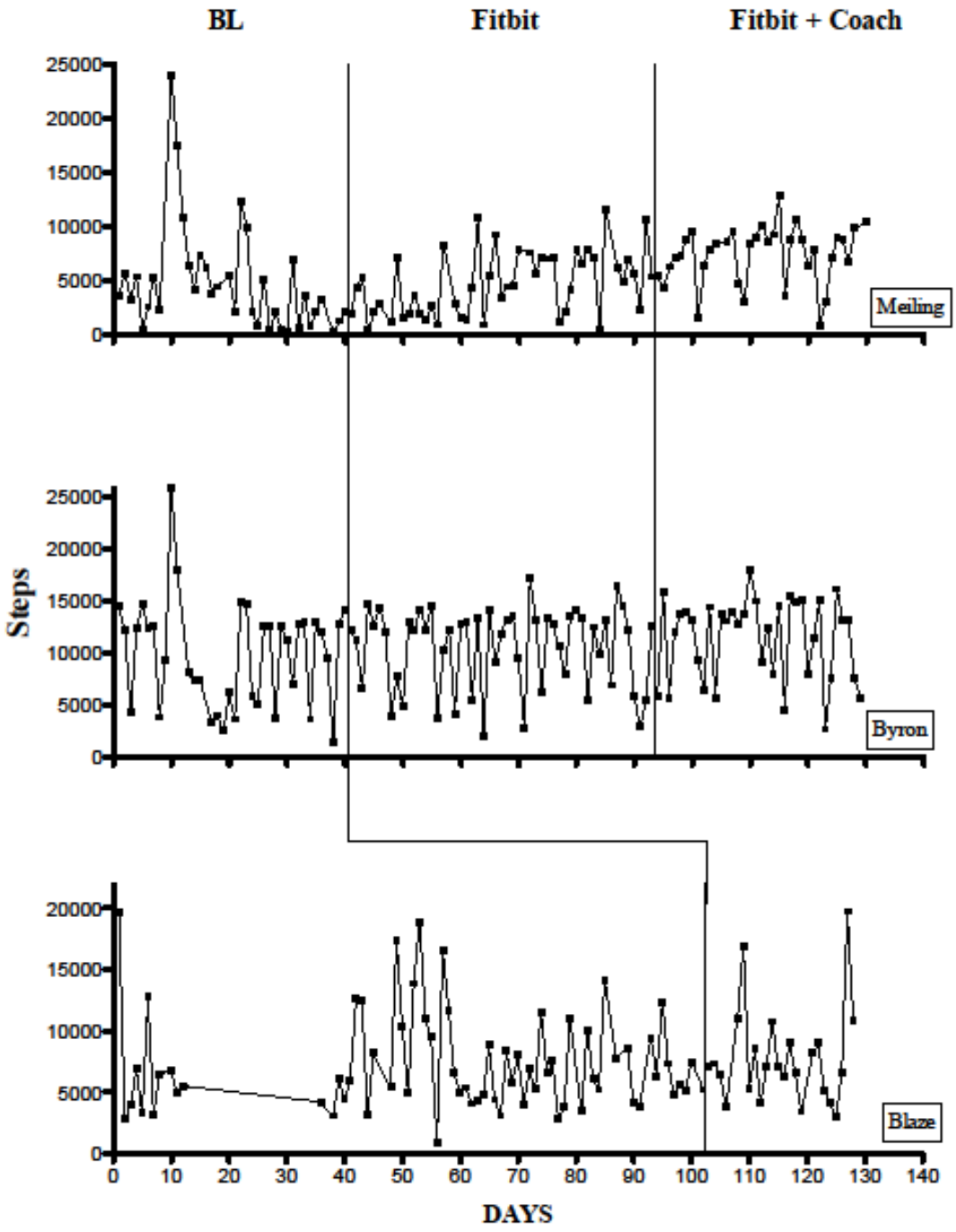

Figure 2. Daily step-counts across participants Meiling, Byron, and Blaze.

Chapter Four: Discussion

Cushing and Steele (2011) highlight the importance of evaluating the many different existing multi-component behavioral interventions that are readily available to the public. The present study adds to the literature by demonstrating an efficient method for evaluating existing internet-based programs, in this case Fitbit, using single-subject methodology. The results of this study found that for three out of seven participants (Les, Holly, Fire), the Fitbit program alone increased mean daily step-counts, but the increases appeared to be on a decreasing trend throughout the phase for Les and Fire. This observation is supported by the fact that the mean data at end of phases (last 15 days) for intervention 1 show a less noticeable effect than when considering the mean of the entire phase for these participants. Meiling is an exception, as her mean steps increase drastically when considering only the last 15 days of intervention 1. This effect, however, can be attributed to limitations caused by this participant's schedule which will be discussed later in the discussion. Intervention 2, the addition of the behavioral coach, resulted in an increase in the mean daily steps for four out of four participants. Furthermore, daily steps appear to be increasing throughout the phase, as the mean of the last 15 days of intervention 2 shows more noticeable increases for all four participants.

Donaldson and Normand (2008) effectively increased PA for obese/overweight adults with an in-person multi-component behavioral intervention. The current study extends these findings to an internet-delivered program, showing that internet delivered multi-component behavioral interventions can produce a modest increase PA for this population. The results of this study are consistent with conclusions made by Vandelanotte et al. (2007), interventions in

which participants have more contact with the investigators result in more positive outcomes. The addition of the behavioral coach appeared to increase physical activity more markedly, as physical activity decreased closer to baseline levels towards the end of intervention 1 when participants were using the program on their own as if they had purchased the equipment themselves. There are several possible reasons for the increase in PA during intervention 2. The added social support in the form of praise from the coach may have served as motivation to meet the goals. Also, the coaching call served as an opportunity for participants to come in contact with their graphs and data, ensuring that self-monitoring was occurring, as the coach went over these figures with each participant during the call. It may be that, although participants were accessing the Fitbit website, they were not actually accessing the areas where they could see the graphs and the results of their self-monitoring. Another aspect of the behavioral coaching that may have helped increase PA was the reasonable daily step goals provided by the investigator. Prior to the coaching phase, the Fitbit program came pre-loaded with a daily step goal of 10,000 steps. None of the participants had modified this goal on their own. This 10,000 step goal was substantially higher than the average step counts during baseline (for all participants except 7), and this meant that participants hardly ever met their goal during intervention 1. The daily step goals set by the investigator were based on a percentile schedule (Galbika, 1994). The daily step goal for each week was a step-count that the participant had actually achieved in one of the previous 10 days, meaning it was a feasible goal. Having a more reasonable goal may have allowed participants to come into contact with the reinforcement from meeting these goals, something that was not occurring during the first intervention.

A strength of the study was the high compliance in data submission by the participants (93% across all participants). The gift card contingency may have resulted in the high

compliance. Another possibility is that the general weekly reminder email about the contingency served as a prompt or added motivation. Given the need for extended periods of time with limited contact from investigators when evaluating a program in a naturalistic way, the strategy employed by the authors may be helpful in future research with internet-based programs.

There were several limitations encountered throughout the course of the study. One challenge faced was the schedule of the participants affecting the data. For example, as mentioned earlier, Meiling was the only one to show such a marked increase in the mean of the last 15 days of the intervention 1 phase. The investigators were later informed that, in the middle of the intervention 1 phase, the participant went back to work (she was a teacher and it was the beginning of the school year). The increase in activity towards the end of the phase can potentially be attributed to the change in her routine, rather than as a result of being exposed to the experimental conditions for a longer time.

Another related issue was when participants had work-related trips or vacations. For example, the week with a huge increase in daily step counts during intervention 1 for Les, and in baseline for Fire were a result of a work-related trip to New York City. The participants had to walk very long distances while being in the city, resulting in very high step counts, which would not be similar to the steps they would be taking in their normal routines back home. Blaze also went on a vacation around the middle of her baseline phase. This was a trip to a national park, and there were several days of hiking which resulted in very high step-counts. These events in participants' lives which are not typical and representative of their normal activity, particularly when resulting in such high increases in activity, can noticeably alter the means within the phases where they occur. This effect is partially ameliorated when looking at the mean of only the last 15 days of each phase, rather than the entire phase mean.

Another issue encountered was equipment loss and damages. Because there was limited contact between the investigators and the participants, whenever there were issues with equipment, it took about a week for it to be communicated to the investigators. Holly lost her Fitbit sensor towards the middle of the intervention 1 phase. Blaze continued to wear a Fitbit sensor thinking that it was working, when in fact it was not recording her activity. It took a couple of weeks for Fitbit customer support to replace the broken Fitbit. These events resulted in missing data for these participants. Les also encountered technological difficulties with the webcam on her laptop. She took it to get repaired a number of times throughout the intervention 2 phase, which resulted in having to reschedule and postpone some of her coaching calls.

Another limitation of this study was the high variability of data across all phases of the study. Similar variability has been observed in other studies using step-counts as dependent measures (e. g., Ek & Miltenberger, 2012; Normand, 2008). This variability, which is typical in data of this nature, makes it challenging to complete traditional visual analysis, as there are many overlapping data points between phases. Researchers should investigate whether there are more useful ways of re-expressing these kinds of data, such as in weekly averages or moving averages, that can help minimize the variability in the data without altering the data.

Future research should also examine the other measures recorded by the Fitbit such as calorie expenditure, stairs, distance travelled, and calorie consumption. Although the focus of this intervention was on increasing physical activity (measured by step counts), it may be helpful to consider some of the other measures. For example, Meiling and Byron did not show a vast increase in physical activity during intervention 1. However, the weight loss during this phase was the highest for these two participants (Meiling lost 4.43% of her body weight during this phase, and Byron lost 4.54% of his body weight). When examining some of the other data

recorded on the Fitbit website, it was found that Meiling and Byron consistently input their calorie consumption data. Inputting these data did not have any role on the compliance contingency in place, and these two participants are the only two who consistently reported their food intake. It could be that their weight loss was a result of reducing their calorie consumption, rather than increasing their physical activity. Future studies could consider evaluating the usefulness of these other measures, and may consider a similar contingency for reporting calorie intake data if this measure is a focus of the research.

Future studies may also investigate the effectiveness of similar internet-based behavioral weight loss programs with other populations. One limitation of this study that is consistent with much of the literature is the sample bias of having mostly female participants (LaPlante & Peng, 2011; Vandelanotte et al., 2007). Future research should evaluate these programs with more diverse populations, including sampling mostly males, varied ages, varied cultural or ethnic backgrounds, or evaluating them with individuals with developmental disabilities. Another area for future research is to complete a component analysis on these programs to identify which components are responsible for behavior change. This type of component analysis could potentially be achieved by developing software which allows components (such as goal-setting, feedback, and self-monitoring) to be added or removed systematically.

This study provides an effective method for evaluating existing internet based programs. The Fitbit program alone increased PA for some participants, and these increases were enhanced by the addition of a behavioral coach. Similar methodology can be applied to evaluating other commonly used existing weight loss programs.

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Appendices

Appendix A: PAR-Q

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: answer YES or NO.

1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

2. Do you feel pain in your chest when you do physical activity?

3. In the past month, have you had chest pain when you were not doing physical activity?

4. Do you lose your balance because of dizziness or do you ever lose consciousness?

5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

7. Do you know of any other reason why you should not do physical activity?

Appendix B: Weekly Email

Dear Participant,

Thank you for participating in the study. Remember that if you submit your data on 90% of the days every two weeks, you will receive $5 towards a Visa gift card.

Thank you,

Researcher

Appendix C: Video-Conference Call

Include the following in the behavioral coaching conference call:

Behavioral Coaching Conference Call Task Analysis	Completed
*Thank participants for participation to this point	
*Explain the following phase of study (behavioral coaching)	
*Discuss data and progress of participants while they used program alone	
*Set initial weekly goal	
Build rapport with participant	
Prompt participants to log-in to fitbit.com and access their dashboard	
Provide feedback on step-count goal performance (Praise or constructive feedback)	
Modify goal for following week (focus on step-count)	
Have participants access monthly graphs (for steps, calories, and weight) and discuss progress	
Identify day (or days) with Highest step-count in week and discuss contextual variables	
Identify day (or days) with lowest step-count in week and discuss contextual variables	
Discuss potential strategies that address contextual variables provide some (from list) for increasing physical activity	
Praise participants for using other components (calorie consumption) and encourage maintaining a negative caloric intake/expenditure ratio.	
Ask participants if they have any questions	
Tell participants they can now email usfabainvestigator@gmail.com with questions	
Schedule time for coaching call for following week	

* Only for the initial coaching session

Appendix D: Email for Missing Data

Dear Participant,

I am aware that you did not submit your weight and calorie data yesterday (date). Was there any particular reason for which you were unable to send your data? Remember that if you submit your data on 90% of the days, you will receive a $50 gift card at the end of the study.

Thank you,

Researcher

Appendix E: IRB Approval Letter

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

December 12, 2012

Diego Valbuena
ABA-Applied Behavior Analysis
Tampa, FL 33612

RE: **Expedited Approval** for Initial Review
IRB#: Pro00010589
Title: Evaluating the Effectiveness of an Internet-Based Behavioral Weight Loss Program With and Without a Behavioral Coach

Dear Mr. Valbuena:

On 12/11/2012, the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol. Please note that your approval for this study will expire on 12/11/2013.

Approved Items:
Protocol Document(s):
valbuena protocol

Consent/Assent Documents:
Informed Consent Form.pdf
Please note, the informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on the form - which can be found under your Attachment Tab. Valid consent must be documented on a copy of the most recently IRB-approved consent form.
(Waiver of Informed Consent Documentation granted for the Pre-Screening ICF (does not need an IRB stamp))

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review categories:

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at **45 CFR 46.117 (c):** An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John A Schinka, Ph.D.

John Schinka, PhD, Chairperson
USF Institutional Review Board