

UC San Diego

UC San Diego Electronic Theses and Dissertations

Title

A wearable sensor (Fitbit One) and text-messaging to promote physical activity and participants' level of engagement (a randomized controlled feasibility trial)

Permalink

<https://escholarship.org/uc/item/2qc0r3sb>

Author

Wang, Julie

Publication Date

2014

Peer reviewed|Thesis/dissertation

UNIVERSITY OF CALIFORNIA, SAN DIEGO
SAN DIEGO STATE UNIVERSITY

A Wearable Sensor (Fitbit One) and Text-Messaging to Promote Physical Activity and
Participants' Level of Engagement (A Randomized Controlled Feasibility Trial)

A dissertation submitted in partial satisfaction of the
requirements for the degree Doctor of Philosophy

in

Public Health (Health Behavior)

by

Julie Wang

Committee in charge:

University of California, San Diego

Professor John Pierce, Chair
Professor Lisa Cadmus-Bertram, Co-Chair
Professor Loki Natarajan

San Diego State University

Professor Guadalupe Ayala
Professor Hala Madanat
Professor Jeanne Nichols

2014

Copyright

© Julie Wang, 2014

All rights reserved

This Dissertation of Julie Wang is approved, and it is acceptable in quality and form
for publication on microfilm and electronically:

Co-Chair

Chair

University of California, San Diego

San Diego State University

2014

DEDICATION

To Mom & Dad

EPIGRAPH

Om

TABLE OF CONTENTS

SIGNATURE PAGE.....	iii
DEDICATION.....	iv
EPIGRAPH	v
TABLE OF CONTENTS.....	vi
LIST OF ABBREVIATIONS.....	viii
LIST OF FIGURES	ix
LIST OF TABLES	x
ACKNOWLEDGEMENTS.....	xii
VITA.....	xiv
ABSTRACT OF THE DISSERTATION	xvi
INTRODUCTION.....	1
CHAPTER 1.....	10
CHAPTER 2.....	40
CHAPTER 3.....	71
DISCUSSION.....	95
APPENDICES.....	104
Appendix 1. Text2bfit pilot study recruitment flyer	104
Appendix 2. Text2bfit pilot study consent form.....	105
Appendix 3. Text2bfit pilot study telephone screening eligibility questionnaire	108
Appendix 4. Physical activity readiness questionnaire	112
Appendix 5. Text2bfit pilot study baseline questionnaire	113
Appendix 6. Text2bfit pilot study brief intervention counseling form	118
Appendix 7. Text2bfit pilot study daily data collection form on REDCap (sample)	120
Appendix 8. Text2bfit study 6-week follow-up questionnaire	122

Appendix 9. Text message bank.....	123
------------------------------------	-----

LIST OF ABBREVIATIONS

BMI, body mass index

CES-D, Center for Epidemiologic Studies Depression Scale

MVPA, moderate-to-vigorous intensity physical activity

MET, metabolic equivalent

PA, physical activity

SCT, Social Cognitive Theory

SDSU, San Diego State University

WHEL, Women's Healthy Eating & Living

UCSD, University of California, San Diego

LIST OF FIGURES

Figure 1.1. Participant flow (CONSORT figure)	31
Figure 1.2.A-C. Fitbit measure of physical activity from baseline (week 0) to week 6 adjusted for baseline wear-time (minutes/week).....	34

LIST OF TABLES

Table 1.1. Participants' baseline characteristics, mean (SD) or %.....	32
Table 1.2. Actigraph GT3X+ change in physical activity levels from baseline to 6-week follow-up stratified by baseline confidence in reaching MVPA recommendations, adjusted for wear-time (min/wk), mean (SE).....	33
Table 2.1. Baseline demographic characteristics, technology-use, and social cognitive construct scores (N=67), mean (SD) or N (%)	62
Table 2.2. Participants' responses to follow-up questionnaire items on attitudes and level of engagement with the Fitbit One (N=61), mean (SD) or N (%)	63
Table 2.3. Participants' responses to follow-up questionnaire items on attitudes and level of engagement with simple text message prompts for PA (N=31), mean (SD) .	64
Table 2.4. Mean (SE) steps by level of engagement with the Fitbit One and text-messaging as simple reminders, adjusted for device wear-time minutes (Actigraph GT3X+)	65
Table 2.5. Odds of high level of engagement in self-monitoring with the Fitbit One and text-messaging as simple reminders by baseline level of self-efficacy and outcome expectations.....	66
Table 3.1. Participant characteristics by 6-Item CES-D cutoff scores of ≥ 5 indicating baseline depressive symptoms (N=2,817).....	88

Table 3.2. Odds of not completing dietary assessments and clinic visits at year 1 and year 4 follow-up by baseline 6-item CES-D depression cutoff scores of > 5 indicating baseline depressive symptoms, adjusted for age, BMI, and PA	89
--	----

Table 3.3. Mean (SE) total plasma carotenoid concentrations, dietary fiber, and percent energy from fat	90
---	----

Table 3.4. Mean (SE) percent change in dietary targets from baseline to year 1 and year 1 to year 4 by 6-Item CES-D depression cutoff scores of ≥ 5 in intervention group participants.....	91
--	----

ACKNOWLEDGEMENTS

I would like to extend my gratitude to my chair, Dr. John P. Pierce, for providing me with the opportunity to conduct this randomized controlled trial as part of my dissertation work. Thank you for the many hours you have dedicated in making improvements to this body of research. This would not have been possible without your expertise and enthusiasm. I would like to thank my co-chair, Dr. Lisa Cadmus-Bertram, for her expertise and guidance. You are remarkable in being able to do all that you do. To Dr. Loki Natarajan, thank you for being brilliant and warm. I wish there were more people like you in this world. I would also like to thank Dr. Guadalupe Ayala for her expertise and guidance. I am especially grateful for your time in helping to make significant improvements to this work. I would like to thank Drs. Hala Madanat and Jeanne Nichols for their expertise and serving on my committee.

To Shirley Flatt, Martha White, and Susan Wancewicz at UCSD Cancer Prevention and Control, many thanks for being amazingly generous with your expertise and time. Thank you for answering a gazillion questions. Hollie Ward and Nicole Campbell, thank you for your support and encouragement. I would like to thank UCSD undergraduate interns, Quynh Diem and Amy Nham, for the countless hours you have given me to successfully implement the Text2bfit Pilot Study. I wish you both the best in your future endeavors.

I would like to acknowledge the many mentors I have had along the way: Drs. Shu-Hong Zhu, Gary Tedeschi, Virginia Kreisworth, and Cheryl Anderson. You have all taught me a great deal in research and in life. I am so grateful for the many opportunities that you have provided me. Thank you all for your genuine support and kindness. I would also like to acknowledge my uncle, Dr. Ko-Pen Wang. You have

been a tremendous inspiration. To my brother, Charlie Wang, your support and enthusiasm to change the world provides me with strength and courage in times of fear. I would also like to acknowledge Brent Zettel. You are possibly one of the most amazing human beings on earth. Thank you for coming along this wild ride.

I would like to thank the Carol Vassiliadis family for their financial support. The WHEL study was supported by NCI grant CA69375; University of California, San Diego General Clinical Research Center NIH grant M01-RR00827; University of California, San Francisco General Clinical Research Center NIH grant M01-RR00079; Stanford University General Clinical Research Center NIH grant M01-RR0070; and the Walton Family Foundation.

Chapter 1 is currently being prepared for submission for the publication of the material. Julie Wang, Lisa Cadmus-Bertram, Loki Natarajan, Martha White, Guadalupe Ayala, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

Chapter 2 is currently being prepared for submission for the publication of the material. Julie Wang, Guadalupe Ayala, Lisa Cadmus-Bertram, Loki Natarajan, Martha White, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

Chapter 3 is currently being prepared for submission for the publication of the material. Julie Wang, Shirley Flatt, Lisa Cadmus-Bertram, Loki Natarajan, Vicky Newman, Guadalupe Ayala, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

VITA

Education

- | | |
|------|--|
| 2014 | PhD in Public Health (Health Behavior), San Diego State University / University of California, San Diego |
| 2005 | MPH in Global Health Promotion, The George Washington University |
| 2001 | BA in Liberal Arts, The George Washington University |

Research & Professional Experience

- | | |
|-----------|--|
| 2009-2014 | Graduate Student Researcher, University of California, San Diego |
| 2013-2014 | Teaching Assistant, University of California, San Diego |
| 2013 | Course Instructor, San Diego State University |
| 2012 | Teaching Assistant, San Diego State University |
| 2009 | Clinical Research Assistant, Scripps Mercy Hospital |
| 2006-2009 | Project Manager, UCSD Moores Cancer Center |
| 2005 | Counselor, California Smokers' Helpline (UCSD) |
| 2004 | Project Assistant, Global Alliance against Trafficking in Women |
| 2002-2004 | Intern, United Nations Foundation |

PUBLICATIONS

Wang, J.B., Patterson, R.E., Ang, A., Emond, J.A., Shetty, N., & Arab, L. (2013). Timing of energy intake during the day is associated with the risk of obesity in adults. *Journal of Human Nutrition & Dietetics*. doi:10.1111/jhn.12141.

Cadmus-Bertram, L.A., **Wang, J.B.**, Patterson, R.E., Newman, V.A., Parker, B.A. & Pierce, J.P. (2012). Web-based self-monitoring for weight loss among overweight/obese women at increased risk for breast cancer: the HELP pilot study. *Psycho-Oncology*, 1099-1611. doi:10.1002/pon.3219.

Gorman, J., Brewer, N.J., **Wang, J.B.**, & Chambers, C.D. (2012). Theory-based

predictors of influenza vaccination among pregnant women. *Vaccine*, 31(1), 213-218.
doi:10.1016/j.bbr.2011.03.031

Zhu, S-H, **Wang, J.B.**, Hartman, A., Zhuang, Y. Gamst, A. Gibson, J.T., Gilljam, H. & Galanti, M.R. (2009). Quitting cigarettes completely or switching to smokeless tobacco: Do U.S. data replicate Swedish results? *Tobacco Control*, 18, 82-87.
doi:10.1136/tc.2008.028209.

ABSTRACT OF THE DISSERTATION

A Wearable Sensor (Fitbit One) and Text-Messaging to Promote Physical Activity and
Participants' Level of Engagement (A Randomized Controlled Feasibility Trial)

by

Julie Wang

Doctor of Philosophy in Public Health (Health Behavior)

University of California, San Diego, San Diego, 2014

San Diego State University, 2014

Professor John P. Pierce, Chair

Professor Lisa Cadmus-Bertram, Co-Chair

Background: Low-cost health interventions are needed to prevent disease at the population level. Advances in technology offer researchers opportunities to test new strategies and modalities. This dissertation examined the utility of a wearable device/sensor with website (Fitbit One) and SMS text messaging prompts to increase physical activity (PA) in overweight/obese adults. It also examined participants' level of engagement with intervention components and factors associated with engagement.

Methods: In a 6-week randomized controlled pilot trial, 67 participants were provided a Fitbit One for self-monitoring and half were randomized to receive daily text messaging PA prompts. Primary outcomes were objectively measured steps and minutes of PA by intensity level using Actigraph GT3X+ and Fitbit One. Self-reported baseline and follow-up surveys were analyzed to assess participants' attitudes and level of engagement with intervention components (Fitbit One and text messages), and whether self-efficacy and outcome expectations could predict level of engagement.

Secondary data were analyzed from the Women's Healthy Eating and Living (WHEL) Study to examine adherence to study protocols and dietary change by baseline depressive symptoms in women who were enrolled in a large dietary trial that focused on behavioral activation components.

Results: (1) Daily text messaging prompts were associated with short-term PA increases but only for 1 week, and Fitbit One (without text messages) was associated with an increase in MVPA at week 6. (2) Participants who used the Fitbit mobile app increased their steps at week 6. (3) Baseline depressive symptoms predicted lower adherence to study protocols, but only in control participants, and (among those furthest from recommended targets at baseline) less improvements in change in plasma carotenoid concentrations, fiber, and fat.

Conclusions: Participants' level of engagement with the study intervention was associated with health behavior change. Text messages as PA prompts were insufficient to keep participants engaged to maintain PA changes beyond 1 week. Fitbit One, particularly the Fitbit mobile app, which is both accessible and provides

instant detailed feedback for self-monitoring, was helpful in increasing PA. Lastly, a dietary intervention with behavioral activation components increased level of engagement in both non-depressed and depressed women who made dietary improvements.

INTRODUCTION

In the U.S., the majority of chronic conditions are associated with three modifiable risk factors: tobacco use, physical inactivity, and an unhealthy diet.¹ An important task among public health researchers is to develop, test, and implement effective programs to promote healthy behaviors at the population level. “At the population level” is what sets the field of public health apart from other health disciplines, along with its emphasis on prevention. Effective public health programs should therefore also have the capability to reach large audiences. More importantly, programs should be cost-effective for wide-scale dissemination. Advances in technology continuously provide researchers with opportunities to develop and test novel intervention modalities that have the potential to deliver effective low cost interventions at the population level.

Researchers have tested web-based and *mHealth* (mobile health) interventions including SMS text-messaging that have used an array of strategies across health behaviors; and many of these studies have proven to be efficacious.²⁻⁴ More recently, commercially available products such as wearable device/sensor technologies and mobile applications software (mobile apps) on smartphones and tablet computers have become increasingly popular among the general public. There are significant advantages for researchers to test commercially available products. A major advantage is that the main intervention component (or product) has already been developed, tested, and even marketed by a team of experts. Second, many of these products are self-monitoring tools that allow users to collect and manage their own health data, and this is congruent with self-regulatory approaches, which are considered effective strategies among physical activity and dietary interventions.⁵

The task of researchers is therefore to test the utility and effectiveness of these products across populations. If a product or category of products is found to be cost-effective in producing and maintaining behavior change, a third advantage is that dissemination might simply entail a public health recommendation or endorsement of a specific product which is already widely distributed and available for purchase in retail stores. Furthermore, it is likely that the company will spend their own advertising dollars to promote this endorsement to generate sales. These products will evolve rapidly, and as access/usage rates continue to rise,⁶ it is imperative health behavior researchers understand how people use and respond to these products; whether they are effective in changing health behavior; and the underlying mechanisms attributable to change. In this dissertation, we examined the utility of a wearable device/sensor (Fitbit One) for self-monitoring of PA and SMS text-messaging as simple prompts to promote PA. Additionally, we examined participants' level of engagement with these intervention components in addition to other factors associated with participant engagement and behavior change.

We conducted a randomized controlled trial (N=67) to test the effects of SMS text messaging as simple PA prompts in a sample of overweight/obese adults (Text2bfit Pilot Study). Health behavior researchers and practitioners alike are interested in text messaging because it has the capacity to reach large populations, including traditionally underserved populations, and the potential to reach them at a lower cost compared to more conventional modalities (e.g., in-person one-on-one). Previous studies have shown text messaging alone or in combination with other strategies can increase PA levels.⁷⁻²⁷ However, it is largely unknown whether these study effects were due to the intervention content vs. the delivery mode. Further, most of these studies collected self-reported PA measures, which are less accurate

compared to objective measurement tools like the Actigraph GT3X+.²⁸ The **primary aim** of this dissertation was to test the effects of text messaging as simple PA prompts on PA change using objective measures in a sample of overweight/obese adults (Chapter 1).

In the Text2bFit Pilot Study, all participants were provided the Fitbit One, which allowed the opportunity to examine the utility of a commercially popular wearable sensor/device for self-monitoring of PA. Researchers have identified self-regulatory techniques, particularly self-monitoring, as an effective intervention strategy for improving PA and dietary behavior.⁵ The Fitbit One is among a handful of commercially available wearable devices/sensors that allow users themselves to collect large amounts of objective data to monitor their own performance. However, simply recommending or providing such a device does not necessarily mean that participants will use the product. There is currently little research on how and how much people interact with these devices. In the case of the Fitbit One, it would be useful to know people's attitudes and level of engagement with the tracker, website, and/or mobile app to understand which components are at work. A secondary aim of this dissertation was to assess participants' attitudes and level of engagement with specific intervention components (Chapter 2).

The issue of participant engagement in health behavior interventions is important because there is evidence to suggest a link between level of engagement (or intervention dose) with behavioral outcomes.²⁹ There are also other factors known to predict behavioral effects. For example, Social Cognitive Theory (SCT) posits an interrelationship between the person, environment, and behavior, in which each of these factors influence one another.³⁰ Studies have shown that specific social cognitive constructs can predict health behaviors, with *self-efficacy* consistently

producing robust results.^{31–36} Researchers have used this knowledge to develop intervention strategies specifically designed to target these factors that mediate behavior change. It is lesser known however how these factors influence self-monitoring behavior (which could inform strategies to increase self-monitoring). In this dissertation, we tested the constructs of *self-efficacy* and *outcome expectations* to determine whether these factors could predict participants' level of engagement with the Fitbit One and text messages (Chapter 2).

Depression is also an important predictor of participants' level of engagement and it is linked to unhealthy behaviors including physical inactivity and poorer dietary behavior.³⁷ Previous studies have shown that participants with depression were less engaged and had higher dropout rates.^{38,39} However, there are few recommendations on how interventions should treat this subgroup of participants that seemingly needs more (or alternative) help in keeping them engaged enough to achieve behavioral change. We conducted secondary analysis using data from a large randomized controlled dietary trial among postmenopausal breast cancer survivors. The Women's Healthy Eating and Living (WHEL) Study provided the unique opportunity to examine effects of an intensive telephone-based dietary counseling intervention that focused on *behavioral activation* strategies. The WHEL study dataset had the added rigor of a biologic indicator of dietary change (i.e., total plasma carotenoid concentrations as a biomarker of fruits and vegetables intake). In this dissertation, we examined adherence to study protocols and dietary outcomes by baseline depression levels (Chapter 3).

In summary, the primary aim of this dissertation was (1) to test the effects of text messages as simple PA prompts in a sample of overweight/obese adults; secondary aims were (2) to examine attitudes and level of engagement with the Fitbit

One (i.e., tracker, website, and mobile app) and text messages; (3) to determine whether measures of self-efficacy and outcome expectations for PA change can predict level of engagement with the Fitbit One and text messages; and (4) to examine study effects of an intensive dietary intervention in a stratified analysis by baseline depressive symptoms level. Findings from these analyses will provide insight on the utility of the Fitbit One for self-monitoring and text messages as simple PA prompts, and factors associated with participants' level of engagement in health behavior interventions, to inform future studies.

REFERENCES

1. WHO | Overview - Preventing chronic diseases: a vital investment.
2. Norman GJ, Zabinski MF, Adams MA, Rosenberg DE, Yaroch AL, Atienza AA. A review of eHealth interventions for physical activity and dietary behavior change. *Am J Prev Med.* 2007;33(4):336-345. doi:10.1016/j.amepre.2007.05.007.
3. Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The effectiveness of Web-based vs. non-Web-based interventions: a meta-analysis of behavioral change outcomes. *J Med Internet Res.* 2004;6(4):e40. doi:10.2196/jmir.6.4.e40.
4. Head KJ, Noar SM, Iannarino NT, Grant Harrington N. Efficacy of text messaging-based interventions for health promotion: a meta-analysis. *Soc Sci Med.* 2013;97:41-8. doi:10.1016/j.socscimed.2013.08.003.
5. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychol.* 2009;28(6):690-701. doi:10.1037/a0016136.
6. *The Mobile Consumer: A Global Snapshot (February 2013).* New York; 2013.
7. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev.* 2010;32(1):56-69. doi:10.1093/epirev/mxq004.
8. Hanauer DA, Wentzell K, Laffel N, Laffel LM. Computerized Automated Reminder Diabetes System (CARDS): e-mail and SMS cell phone text messaging reminders to support diabetes management. *Diabetes Technol Ther.* 2009;11(2):99-106. doi:10.1089/dia.2008.0022.
9. Franklin V, Waller A, Pagliari C, Greene S. "Sweet Talk": text messaging support for intensive insulin therapy for young people with diabetes. *Diabetes Technol Ther.* 2003;5(6):991-6. doi:10.1089/152091503322641042.
10. Rodgers A, Corbett T, Bramley D, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control.* 2005;14(4):255-61. doi:10.1136/tc.2005.011577.
11. Free C, Knight R, Robertson S, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial. *Lancet.* 2011;378(9785):49-55. doi:10.1016/S0140-6736(11)60701-0.

12. Obermayer JL, Riley WT, Asif O, Jean-Mary J. College smoking-cessation using cell phone text messaging. *J Am Coll Health*. 53(2):71-8. doi:10.3200/JACH.53.2.71-78.
13. Riley W, Obermayer J, Jean-Mary J. Internet and mobile phone text messaging intervention for college smokers. *J Am Coll Health*. 57(2):245-8. doi:10.3200/JACH.57.2.245-248.
14. Bramley D, Riddell T, Whittaker R, et al. Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori. *N Z Med J*. 2005;118(1216):U1494.
15. Haug S, Meyer C, Schorr G, Bauer S, John U. Continuous individual support of smoking cessation using text messaging: a pilot experimental study. *Nicotine Tob Res*. 2009;11(8):915-23. doi:10.1093/ntr/ntp084.
16. Patrick K, Raab F, Adams MA, et al. A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res*. 2009;11(1):e1. doi:10.2196/jmir.1100.
17. Gerber BS, Stolley MR, Thompson AL, Sharp LK, Fitzgibbon ML. Mobile phone text messaging to promote healthy behaviors and weight loss maintenance: a feasibility study. *Health Informatics J*. 2009;15(1):17-25. doi:10.1177/1460458208099865.
18. Napolitano MA, Hayes S, Bennett GG, Ives AK, Foster GD. Using Facebook and text messaging to deliver a weight loss program to college students. *Obesity (Silver Spring)*. 2013;21(1):25-31. doi:10.1002/oby.20232.
19. Shapiro JR, Bauer S, Hamer RM, Kordy H, Ward D, Bulik CM. Use of text messaging for monitoring sugar-sweetened beverages, physical activity, and screen time in children: a pilot study. *J Nutr Educ Behav*. 40(6):385-91. doi:10.1016/j.jneb.2007.09.014.
20. Cheung PP, Chow BC, Parfitt G. Using Environmental Stimuli in Physical Activity Intervention for School Teachers: A Pilot Study. *Glob J Heal Educ Promot*. 2008;11(1).
21. Hurling R, Catt M, Boni M De, et al. Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. *J Med Internet Res*. 2007;9(2):e7. doi:10.2196/jmir.9.2.e7.
22. Prestwich A, Perugini M, Hurling R. Can the effects of implementation intentions on exercise be enhanced using text messages? *Psychol Health*. 2009;24(6):677-87. doi:10.1080/08870440802040715.

23. Prestwich A, Perugini M, Hurling R. Can implementation intentions and text messages promote brisk walking? A randomized trial. *Health Psychol.* 2010;29(1):40-9. doi:10.1037/a0016993.
24. Conroy MB, Yang K, Elci OU, et al. Physical activity self-monitoring and weight loss: 6-month results of the SMART trial. *Med Sci Sports Exerc.* 2011;43(8):1568-74. doi:10.1249/MSS.0b013e31820b9395.
25. Antypas K, Wangberg SC. An Internet- and mobile-based tailored intervention to enhance maintenance of physical activity after cardiac rehabilitation: short-term results of a randomized controlled trial. *J Med Internet Res.* 2014;16(3):e77. doi:10.2196/jmir.3132.
26. Fjeldsoe BS, Miller YD, Marshall AL. MobileMums: a randomized controlled trial of an SMS-based physical activity intervention. *Ann Behav Med.* 2010;39(2):101-11. doi:10.1007/s12160-010-9170-z.
27. King AC, Ahn DK, Oliveira BM, Atienza AA, Castro CM, Gardner CD. Promoting physical activity through hand-held computer technology. *Am J Prev Med.* 2008;34(2):138-42. doi:10.1016/j.amepre.2007.09.025.
28. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc.* 2008;40(1):181-8. doi:10.1249/mss.0b013e31815a51b3.
29. Linnan L, Steckler A. Process Evaluation for Public Health Interventions and Research. *media.johnwiley.com.au.*
30. Bandura A. *Social Learning Theory.* Oxford, England: Prentice-Hall; 1977.
31. Anderson ES, Winett RA, Wojcik JR, Williams DM. Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: social support, self-efficacy, outcome expectations and self-regulation in the guide-to-health trial. *J Health Psychol.* 2010;15(1):21-32. doi:10.1177/1359105309342297.
32. McAuley E, Jacobson L. Self-Efficacy and Exercise Participation in Sedentary Adult Females. *Am J Heal Promot.* 1991;5(3):185-207. doi:10.4278/0890-1171-5.3.185.
33. McAuley E, Courneya KS. Adherence to exercise and physical activity as health-promoting behaviors: Attitudinal and self-efficacy influences. *Appl Prev Psychol.* 1993;2(2):65-77. doi:10.1016/S0962-1849(05)80113-1.
34. Dzewaltowski DA, Noble JM, Shaw JM. Physical activity participation: Social cognitive theory versus the theories of reasoned action and planned behavior.

35. Hofstetter CR, Hovell MF, Macera C, et al. Illness, injury, and correlates of aerobic exercise and walking: a community study. *Res Q Exerc Sport*. 1991;62(1):1-9.
36. Sallis JF, Hovell MF, Hofstetter CR, et al. A multivariate study of determinants of vigorous exercise in a community sample. *Prev Med (Baltim)*. 1989;18(1):20-34.
37. Whooley MA, de Jonge P, Vittinghoff E, et al. Depressive symptoms, health behaviors, and risk of cardiovascular events in patients with coronary heart disease. *JAMA*. 2008;300(20):2379-88. doi:10.1001/jama.2008.711.
38. Somerset SM, Graham L, Markwell K. Depression scores predict adherence in a dietary weight loss intervention trial. *Clin Nutr*. 2011;30(5):593-8. doi:10.1016/j.clnu.2011.04.004.
39. Williamson DA, Anton SD, Han H, et al. Adherence is a multi-dimensional construct in the POUNDS LOST trial. *J Behav Med*. 2010;33(1):35-46. doi:10.1007/s10865-009-9230-7.

CHAPTER 1

Text Message Reminders and a Wearable Sensor (Fitbit One) to Promote Physical
Activity in Overweight/Obese Adults (A Randomized Controlled Pilot Trial)

ABSTRACT

Background: Previous studies suggest SMS text messaging can modify health behaviors including physical activity (PA).

Purpose: To test SMS text messaging as simple PA prompts and a wearable sensor for self-monitoring of PA (Fitbit One).

Design: A 2-group design in which all participants were provided the Fitbit One and half were randomized to receive SMS-based PA prompts.

Setting/ Participants: Overweight/obese adults that were mostly women (N=67).

Intervention: All participants were provided a Fitbit One to collect PA data using the tracker and self-monitor PA using the tracker for instant feedback and website for daily PA summary data. Intervention participants were provided 3 daily text messages that prompted PA.

Main Outcomes: Outcome measures were steps and minutes of PA by intensity level using two accelerometers: Actigraph GT3X+ (primary) at baseline and 6-week follow-up and Fitbit One (secondary) at baseline and weeks 1 through 6.

Results: Mixed-model repeated measures analysis of primary PA measures indicated no group differences in PA from baseline to week 6, and a significant within-group increase of +4.3 (SE=2.0) min/wk of MVPA among control participants (Fitbit

only) ($p=0.04$). Secondary measures indicated effects of text-messaging lasted only one week: the intervention group increased by +1266.4 steps ($SE=490.5$; $p=0.01$), +17.8 min/wk MPVA ($SE=8.5$; $p=0.04$), and +38.3 min/wk total PA ($SE=15.9$; $p=0.02$). Comparatively, there were no significant PA changes in control group participants during the same period. There were significant between-group differences for steps ($p=0.01$) and total active minutes ($p=0.02$), but not fairly and very active minutes ($p=0.10$).

Conclusion: In this sample of overweight/obese adults, text messaging to prompt PA was insufficient to produce PA change beyond one week and suggests further research is needed to test more individualized and adaptive strategies. Additionally, there is evidence to suggest a wearable sensor/device with an integrated website could facilitate self-monitoring to increase PA, although more research is needed to examine the utility and effects of these technologies.

INTRODUCTION

The combination of excess weight and lack of physical activity are associated with a number of chronic conditions including diabetes, cardiovascular disease, and many cancers.¹⁻³ With over a third of US adults obese^{4,5} and half not meeting recommended levels of 150 minutes per week of moderate-to-vigorous intensity physical activity (MVPA),^{6,7} developing low cost interventions to increase physical activity levels is a public health priority.

Interventions to increase physical activity have involved a number of different modalities, including in-person (individual or group), telephone, and web-based counseling/coaching approaches.⁸⁻¹¹ More recently, there is growing interest among health behavior researchers in *mHealth* interventions that use mobile technologies such as mobile phones.¹² In the U.S., mobile phone usage is ubiquitous where approximately 86% of subscribers in 2012 indicated that they used the SMS text-messaging feature.¹³ Researchers agree that text messaging has the *potential* to reach large audiences, including traditionally underserved populations,¹⁴ and serve as an inexpensive intervention modality.¹⁵ Previous studies have reported successful use of text messaging as the primary mode of communication including interventions on diabetes management,¹⁵⁻¹⁷ smoking cessation,¹⁸⁻²³ and diet and/or physical activity for weight loss.²⁴⁻²⁷ In these studies, text messaging components were used in a variety of ways ranging from simple reminders for medication adherence to rapid feedback responses to promote physical activity. The majority of studies with text messaging as a main intervention component to increase physical activity reported higher levels at follow-up compared to their respective comparison groups,²⁸⁻³⁵ with a few showing no improvement.³⁶⁻³⁸ It is unclear however whether these study effects

were due to the content (and/or intensity) of the text-messaging or simply because participants were receiving text messages that reminded them to increase their activity levels. No studies have tested the effects of text messaging in its basic form, as simple reminders, to promote physical activity.

An analysis of different behavioral strategies across 122 diet and physical activity intervention studies concluded that the greatest effects were achieved when the intervention used self-regulatory techniques, particularly self-monitoring plus at least one other self-regulatory technique (i.e., intention formation, specific goal-setting, review of behavioral goals, and feedback on performance).³⁹ New technologies such as wearable sensors with integrated websites are now commercially available that offer the public a user-friendly tool to monitor their own physical activity performance. They allow users to objectively collect personal physical activity data with a wearable accelerometer, upload these data onto a personal web account, and view summary data to monitor their performance. No published studies are currently available to describe the usability of wearable sensor technology with an integrated web component and its effects on increasing physical activity levels.

In the present study, the primary objective was to fill a gap in the literature to test the effects of text messaging as simple reminders to increase physical activity.⁴⁰ All study participants were provided with a wearable accelerometer (Fitbit One) that linked to a website for self-monitoring of physical activity (<http://fitbit.com>). Specifically, the study tested and compared the effects of a 6-week daily text messaging intervention plus self-monitoring with the Fitbit One (intervention) vs. self-monitoring with the Fitbit One (active control). Objective measures of physical activity were collected including steps and minutes of physical activity by intensity level using

both the Actigraph GT3X+ and Fitbit One. The primary hypothesis was that the intervention (text messaging plus Fitbit One) would show a greater increase in steps and minutes of physical activity compared to the active control (Fitbit One only) throughout the 6-week study period.

METHODS

Study Design & Participants

The present study used a 2-group design to test the effects of daily text messaging as simple reminders to increase physical activity in a sample of overweight and obese adults (**Figure 1**). Initial screening eligibility criteria were assessed over the telephone and included being a non-smoker, age 18-69 years, overweight or obese ($\text{BMI} \geq 25 \text{ kg/m}^2$), self-reported not meeting recommended levels of moderate-to-vigorous intensity physical activity (<150 minutes/week of MVPA), passing a self-reported physical activity assessment using the “Physical Activity Readiness Questionnaire” (PAR-Q), ability to use SMS text messaging using a personal mobile phone, and meeting specific computer operation systems’ requirements that were compatible with the Fitbit One. Additionally, participants were eligible if they indicated willingness to make changes toward increasing their physical activity levels within 1 month of screening (to assess motivation). The majority of those who were ineligible at telephone screening either did not meet the BMI ($\leq 25 \text{ kg/m}^2$) and/or physical activity requirement (>150 minutes/week of MVPA).

The study recruitment pool consisted of 177 subjects of which approximately 69% were contacted by telephone among women who had consented during their

mammography appointment at UCSD willingness to be reached for research opportunities and/or were ineligible for larger weight loss studies at UCSD Moores Cancer Center. Additionally, 19% were recruited via word-of-mouth and 12% from flyers throughout the community including the UCSD and SDSU campuses. Those who were interested in study participation were asked to contact the study for assessment. The UCSD institutional review board approved the study protocol and consent, and all participants were asked to provide written informed consent.

Intervention

Baseline Clinic Visit & Run-In Period (Prior to Randomization)

Participants who met the initial telephone eligibility screening criteria were invited to a 1-hour baseline clinic visit at UCSD Moores Cancer Center and asked to complete further study assessments which included measured height and weight (to verify self-reported BMI taken during telephone screening). Study personnel provided brief intervention counseling that consisted of a 5-minute review of motivation, goal setting (i.e., toward 10,000 steps per day), and planning to provide participants with basic information and review on recommended levels of MVPA. They were also provided print materials from the U.S. Department of Health and Human Services (2008 *Physical Activity Guidelines for Americans*).⁴¹ Study personnel provided participants with a 5-minute brief intervention to review motivation, goal-setting, and planning for physical activity. A brief intervention was delivered (1) to minimize the risk of no physical activity in a sample of inactive overweight and obese adults who may or may not have any knowledge or previous experience with PA, and this was conducted prior to randomization, (2) to isolate the main intervention component to ensure that study effects at follow-up were due to the text messaging PA prompts

(and not the brief intervention). Additionally, study personnel demonstrated how to wear the Actigraph GT3X+ (on an elastic belt clipped at the hip) and Fitbit One (clipped at the pocket, hip, or bra), and how to use the Fitbit One tracker and website including charging the tracker, wirelessly uploading data, and navigating the website which displays summary data. Study personnel demonstrated how to view Fitbit “dashboards” for daily summaries of physical activity levels (i.e., steps, minutes of physical activity by “lightly,” “fairly,” and “very” active minutes), and highlighted the importance of charging and uploading data almost daily to minimize missing data. Participants were asked to concurrently wear the Actigraph GT3X+ and Fitbit One during a baseline run-in period. ActiLife 6.10 software was used to process Actigraph GT3X+ data to begin non-wear bouts after 90 minutes, set the spike tolerance at 2 minutes, ignore wear periods less than 10 minutes, and flag days as invalid if the wear time was less than 600 minutes. A “valid” wear day was defined as wearing a device for a minimum of 10 hours, or 600 minutes, per day. Only those who provided at least 5 valid days with at least 1 weekend day from both devices met the complete study eligibility criteria for randomization.

Text Messaging & Self-Monitoring Intervention

Those who were randomly assigned to the intervention group were asked to indicate 3 preferred times of the day to receive text messages as reminders to do physical activity. Messages were programmed for automatic delivery according to participants' preferred times using a commercial text messaging website (EzTexting.com). Messages were limited to 150 characters, typically stated the time of delivery, and prompted participants to do physical activity (Example: “Good morning [name]! This is your 9AM reminder to do at least a 10-minute bout of

moderate-to-vigorous intensity physical activity.”). A complete list of text messages that were constructed and used in the study is listed in **Appendix A**. In the present study, a total of 42 text messages were delivered sequentially so that 3 text messages were delivered every day within a 14-day cycle. This pattern was repeated every 2 weeks throughout the 6-week study period. Additionally, participants were asked to continue wearing the Fitbit One and upload data every day for the duration of the study.

Self-Monitoring Only (Active Controls)

Participants who were randomly assigned to the control group were also asked to continue wearing the Fitbit One and upload data every day for the duration of the study.

Outcomes

Physical Activity Assessments

The study objectively measured physical activity levels that included number of steps per day and minutes of physical activity by intensity levels (i.e., medium-to-high intensity and total activity). Primary assessment of physical activity levels was conducted at baseline (week 0) and follow-up (week 6) using Actigraph GT3X+, which is a validated and reliable measure of physical activity in adults.^{42,43} “Steps” and minutes of “moderate-to-vigorous” intensity and “total” physical activity were compared for baseline (week 0) and week 6. In the present study, the Fitbit One was used as part of the intervention for self-monitoring of physical activity but its unique technology also facilitated collection of *daily* physical activity data by the participants *themselves* throughout the entire study period (or 49 days). Therefore, secondary

assessment of physical activity levels was conducted at baseline (week 0) and weeks 1 through 6 using the Fitbit One for *daily* measures of “steps” and “fairly and vey” active minutes and “total” active minutes.

Both devices are tri-axial activity monitors that use Micro-Electro-Mechanical System (MEMS) technology to measure acceleration across 3 planes. Additionally, Fitbit One has a MEMS altimeter that measures vertical climbing up stairs and hills. The study used a wear-time criterion of ≥ 600 minutes as a valid wear day for analysis. Actigraph GT3X+ data were processed and scored using Troiano default settings in ActiLife Version 6.10. Study personnel (with permission) accessed each participant’s Fitbit.com accounts, visually scanned wear times, and collected daily summary data. Days were marked as “non-typical” if the activity appeared starkly different compared to other days and Fitbit PA graphs indicated absolutely no movement for 4 or more hours. More specifically, if it appeared that the tracker was not worn consistently or data were not recorded due to possibly a depleted battery. Non-typical days were excluded in the analysis but they were rare during baseline and follow-up weeks, and ranged from 5%-9% of observations for all participants days across weeks 1-5. Therefore, although the study took measures to identify non-wear, the number of these days was minimal. Overall, differences in wear times did not allow direct comparison of data collected between Actigraph GT3X+ and Fitbit One data, but previous validation has been reported elsewhere for recorded steps.⁴⁴

Baseline Questionnaire

Participants were asked to complete a brief self-administered baseline questionnaire during the clinic visit that included items on demographics (i.e., age, sex, race, education), technology use including previous web or app use to monitor

physical activity, personal and environmental factors that might affect physical activity including motivation, attitudes on self-monitoring and text messaging to increase physical activity, and medical history that might limit physical activity. Three items were used to calculate a composite index score to assess participants' baseline levels of text-messaging use: (1) number of days text messaging was used in a typical week (Likert-type response options range: 1-5), (2) average number of text messages *received* per day (range: 1-4), and (3) average number of text messages *sent* per day (range: 1-4). Participants' responses were summed and categorized around the median split to indicate whether their text messaging use was either "frequent" or "infrequent."

Follow-Up Questionnaire

Additionally, participants were asked to complete a brief 5-10 minute telephone follow-up questionnaire that assessed use and attitudes about the Fitbit device, including perceived helpfulness of both the tracker and website, and in the intervention group only, perceived helpfulness of daily text messaging in increasing physical activity levels. Detailed results of the follow-up assessment are reported elsewhere (J Wang, UCSD, unpublished observations, 2014).

Randomization

A study staff member who was not involved in conducting baseline clinic visits was assigned to allocate participants into study groups using a permuted-block randomization procedure. Once randomized, participants were contacted by email to notify them of their group assignments.

Statistical Analysis

Baseline group differences were compared using 2-sided t-tests or chi-square tests to assess differences in demographic variables (including age, sex, education, and race/ethnicity), BMI, physical activity levels (i.e., steps and minutes by intensity level measured by Actigraph GT3X+), text-messaging use, and previous web or app use for monitoring physical activity levels. A mixed-model repeated-measures analysis⁴⁵ was conducted to test intervention efficacy; the outcome in the models was daily estimates of PA assessed via Actigraph GT3X+ at pre- (i.e., baseline) , and post-intervention (i.e., 6 weeks) with up to 7 measures per time-point. A random subject-specific intercept was included to model between subject variability; fixed effects included in the models were time (i.e., pre-, and post-intervention), group, and the group by time interactions; a statistically significant group*time interaction indicates that pre- to post-intervention changes in PA differed between study arms. All analyses were adjusted for daily wear-time minutes of the accelerometer. Models were fitted in an overall analysis and stratified analysis by baseline confidence in being able to meet MVPA recommendations ('very confident' vs. 'confident' or 'somewhat confident') for (a) steps (b) minutes of moderate-to-vigorous intensity physical, and (c) total minutes of physical activity, leading to a total of 9 mixed model analyses. Adherence to modeling assumptions was tested using residual plots (e.g., qqplots to examine if residuals followed a Gaussian distribution).

Similarly, a total of 3 mixed-model repeated-measures analysis were conducted that were also adjusted for wear-time minutes for Fitbit One measures of physical activity levels at weeks 0, 1, 2, 3, 4, 5, and 6 for (a) steps, (b) minutes of "fairly and very" active minutes, and (c) minutes of "total" active minutes. All reported

p-values were considered statistically significant at *alpha*-level < 0.05. Analyses were conducted using SAS software, version 9.3 (SAS Institute Inc., Cary, North Carolina).

RESULTS

Study Sample

A total of 117 participants completed the initial telephone eligibility screening among which 67 were randomized during a 12-month recruitment period from January 2013 – January 2014 (**see Figure 1.1 for Consort figure**). Thirty-three participants were allocated to the intervention group and 34 in the active control group. Two participants were lost to follow-up in each study group. Additionally, 2 participants in the control group indicated they were too busy and withdrew from the study within 1 week of randomization. All results were based on an intent-to-treat analysis.

The study sample was 91% female, 61% college graduates, 67% non-Hispanic White, with a mean (SD) age of 48.2 (11.7) years (range: 19-66 years), and a BMI of 31.0 (3.7) kg/m²; 49% were overweight (BMI 25-29 kg/m²) and 51% obese (BMI ≥ 30 kg/m²). (**Table 1.1**) At baseline, approximately 50% reported that they frequently used SMS text messaging. A total of 39% reported previously using a web or mobile app to monitor physical activity levels. Randomization achieved comparable study groups on each of these baseline measures with the exception of participants' confidence levels in meeting recommended MVPA levels by the end of the 6-week study period. Specifically, participants were asked to rate on a 4-point scale (from "Very confident" to "Not at All Confident"): "How confident are you in your ability to

increase your current physical activity levels to 150 minutes per week of moderate-to-vigorous intensity physical activity in the next 6 weeks?" In this sample, approximately 38% in the intervention group and 53% in the control group indicated "Very Confident," and 62% in the intervention group and 47% in the control group indicated either "Confident" or "Somewhat Confident," that they would be able to reach recommended MVPA levels by the end of the study ($p < 0.0001$). Baseline physical activity levels indicated a nearly significant group difference in steps ($p=0.05$) and significant difference in MVPA ($p=0.04$) between those who were "Very Confident" vs. "Confident" or "Somewhat Confident" (data not shown).

Primary Assessment of Physical Activity Change: Baseline and Week 6

Primary assessment of physical activity was measured using Actigraph GT3X+ at baseline (week 0) and follow-up (week 6). Device wear-times were comparable between assessment periods, in which the baseline median was 7 days (range: 5-7 days) and 843.8 min/day (range: 601.0-1178.3 min/day) and week 6 follow-up was 7 days (range: 5-7 days) and 872.5 min/day (range: 607.3-1110.3 min/day). Three-way interactions of group by time by baseline confidence level were not significant for steps ($p=0.63$), MVPA ($p=0.60$), or total PA ($p=0.67$). However, both overall and stratified analyses of physical activity outcomes from baseline to week 6 were presented in **Table 1.2**. In general, participants who were "Very Confident" had higher physical activity levels than those who were "Confident" or "Somewhat Confident," and this association had borderline significance for steps ($p=0.09$). There were no study group differences in physical activity levels although there was a significant within-group increase of +4.3 (SE=2.0) minutes per week of MVPA from baseline to week 6 ($p=0.04$) among control group participants (Fitbit only).

Secondary Assessment of Physical Activity Change: Baseline and Weeks 1-6

Secondary assessment of physical activity was measured using Fitbit One at baseline (week 0) and weeks 1 through 6. At week 1, intervention group participants significantly increased their steps by +1266.4 ($SE=490.5$; $p=0.01$), fairly and very active minutes per week by +17.8 ($SE=8.5$; $p=0.04$), and total active minutes per week by +38.3 ($SE=15.9$; $p=0.02$) (**Figure 1.2.A-C**). During the same period, there were no significant differences in physical activity among control group participants (steps: -48.1, $SE=240.2$, $p=0.84$; fairly and very active minutes per week: +2.3, $SE=4.1$, $p=0.57$; and total active minutes per week: -6.7, $SE=11.7$, $p=0.55$). Study groups were significantly different between baseline to week 1 for change in steps (group*time interaction $p=0.01$) and total active minutes ($p=0.02$), but not fairly and very active minutes ($p=0.10$). These changes however were short-term and not maintained through weeks 2-6, although overall, there were statistically significant group by time interactions for (a) steps ($p=0.02$), (b) fairly and very active minutes ($p=0.0006$), and (c) total active minutes ($p=0.04$).

DISCUSSION

In the present study, there were no significant study group differences in physical activity levels from baseline to week 6 to indicate that an intervention consisting of daily text messaging as simple reminders plus the Fitbit One for self-monitoring could not achieve long-term increases in physical activity levels in a small sample of overweight and obese adults. Analysis of data using the primary physical activity assessment (Actigraph GT3X+) indicated there was a small and significant

increase in MVPA (min/wk) from baseline to week 6 among active control participants who were only provided the Fitbit One (and no text messaging). Secondary physical activity assessment using daily Fibit data indicated that, overall, daily text messaging as simple reminders was only able to achieve a significant short-term effect at week 1 that were not sustained for the remainder of the study.

Self-Monitoring (Fitbit One) Only

There is some evidence to support that participants in the active control group had a small and statistically significant increase in Actigraph GT3X+ measured MVPA (mins/wk) from baseline to week 6. It is possible control group participants were more engaged in the Fitbit because they did not rely on text messaging as the primary intervention component. The study conducted a 6-week follow-up questionnaire that asked participants about their experience using the Fitbit tracker and website. Details of these results are reported elsewhere (J Wang, UCSD, unpublished observations, 2014), but more generally, a greater proportion of control (vs. intervention) participants reported on a 4-point scale that on a typical day they viewed their trackers “Very Often” or “Often” for steps (90% vs. 71%) and distance travelled (70% vs. 55%).

Cognitive processes are difficult to measure including whether a higher frequency of viewing the Fitbit tracker actually motivated physical activity performance. In the present study, there is some evidence to support that those who frequently viewed the tracker were probably more engaged in self-monitoring (even compared to viewing the website since the tracker was worn on the body and therefore much more accessible) and that this frequency and/or accessibility might have helped participants to develop self-regulatory skills over time. Indeed a number

of studies have also shown a positive association between self-monitoring and change in physical activity levels.^{46–50} However, more research is needed to examine specifically the use of wearable sensor technology and its ability to facilitate change in behaviors including physical activity.

Short-Term Effects of Text Messaging as Simple Reminders

Daily Fitbit measures of physical activity levels provided the unique opportunity to examine participant collected data throughout the entire study period. This secondary assessment of physical activity provided data for all study weeks and provided the data to show a significant short-term effect of the text messaging intervention at week 1. In the present study, the primary objective was to test a text messaging intervention in its most basic form, as reminders, to prompt physical activity. These results indicate that 3 daily text messages as simple reminders could not sustain changes beyond the first week to suggest that participants no longer responded to the messages after the first week.

There are several possibilities to explain why participants no longer responded to the text messaging reminders. First, previous text-messaging interventions to promote physical activity have ranged in frequency of messages. Comparatively, in this study, frequency of messages at 3 per day for 42 days might have been too high. Participants were asked to indicate pre-set times of the day as to when they might be able to perform at least a 10-minute bout of physical activity. However, it is possible that these messages did not always reach the participants when they were available in order to engage in a bout of activity. At the completion of the study, approximately half of the intervention participants indicated in a follow-up assessment that the 3 daily text messages that prompted daily physical activity were “Too Many” (J Wang,

UCSD, unpublished observations, 2014). Therefore, the text messaging intervention might have created some participant burden that could have prompted them to disengage in participating in the study.

Another possible explanation is that the basic content and repetition of text messages was insufficient to keep participants engaged in the study. The study objective was to test text messaging in its basic form and therefore required minimal content of the messages. Study personnel created 42 basic text message reminders and these messages were repeated every 2 weeks for 6 weeks. Therefore, it is possible that some participants were no longer engaged after the first week because the messages became repetitive. In fact, at follow-up, most participants provided responses to an open-ended question about the text messaging intervention with the most popular comment being that they had stopped reading them after realizing that the messages were “automated.” Other key phrases were “did not feel accountable,” messages were “inconvenient” (n=5), “annoying” (n=3), and “impersonal” (n=2). This suggests that text-messaging interventions likely require more content than basic reminders to achieve longer-term effects.

Previous studies have used more intensive messaging strategies to promote physical activity^{28,30–35} including a study that used automated messages focused on helping participants to identify/reduce barriers and identify motivating benefits.²⁹ This 9-week intervention however reported similar results to the present study - an increase in MVPA during the first week that was not maintained (assessed using a wrist-worn accelerometer).²⁹ The similarity in results of these two studies suggests that it might be the automated nature of SMS texting messaging rather than the content of the messages that was associated with the studies’ inability to maintain an intervention effect for longer than one week. In the present study, once participants’

realized that the text messages were automated, this diminished their accountability, which might explain the loss of effects (J Wang, UCSD, unpublished observations, 2014). Other studies have reported longer-term results but were limited by self-reported measures of physical activity.^{32,34,35}

In summary, there are several possible explanations why text messaging as simple reminders had short-term effects on physical activity including the frequency, redundancy, and the automation of text messages. Furthermore, it is possible that text messaging and/or self-monitoring using wearable sensor technology might not be an appropriate strategy among a sample of overweight and obese adults particularly for long-term changes in physical activity levels. Results from this pilot study suggest that text-messaging interventions to promote physical activity require significantly more than simple reminders to prompt activity. More research is needed to develop and test more individualized and adaptive strategies to achieve longer-term effects.

Study Limitations

Generalizability of these study results is limited to a small sample size that consisted mostly of overweight and obese women. In this pilot study, study personnel provided a brief 5-minute intervention counseling at baseline to all study participants prior to baseline measure of physical activity that might have diminished the overall effects of the study. However, it was imperative to provide at least minimal PA intervention on a sample of inactive overweight and obese adults prior to randomization to avoid potentially no PA participation and properly test the effects of the intervention components. Additionally, in order to minimize missing data, study personnel monitored whether participants uploaded their Fitbit tracker to their individual web-based accounts and provided email, SMS text message, or telephone

reminders to those who were missing such data and close to reaching the memory limit on the Fitbit tracker. Finally, the content of the SMS text messaging as simple reminders was not developed with focus groups and so it was unlikely the message frequency and/or content were optimized for this population.

Conclusions

Results from this pilot study support that self-monitoring using a wearable sensor technology such as the Fitbit One (without text messaging) was able to increase MVPA in a sample of overweight and obese consisting mostly of women. Overall, text messaging as simple reminders appeared to have only a short-term (1 week) effect in increasing physical activity levels. Findings from this study provide new evidence to support that wearable sensor technology might facilitate self-monitoring to promote physical activity. Furthermore, text-messaging interventions to promote physical activity might require more individualized and adaptive strategies particularly among overweight and obese adults. More studies are needed to investigate the utility of text messaging and wearable sensors in promoting physical activity including identifying subpopulations that might be much more responsive to these technologies for self-monitoring and changing health behaviors.

ACKNOWLEDGEMENTS

This research was supported by a gift from the Carol Vassiliadis family. The study would also like to acknowledge UCSD undergraduate interns Quynh Nguyen and Amy Nham for their role in data collection.

Chapter 1 is currently being prepared for submission for the publication of the material. Julie Wang, Lisa Cadmus-Bertram, Loki Natarajan, Martha White, Guadalupe Ayala, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

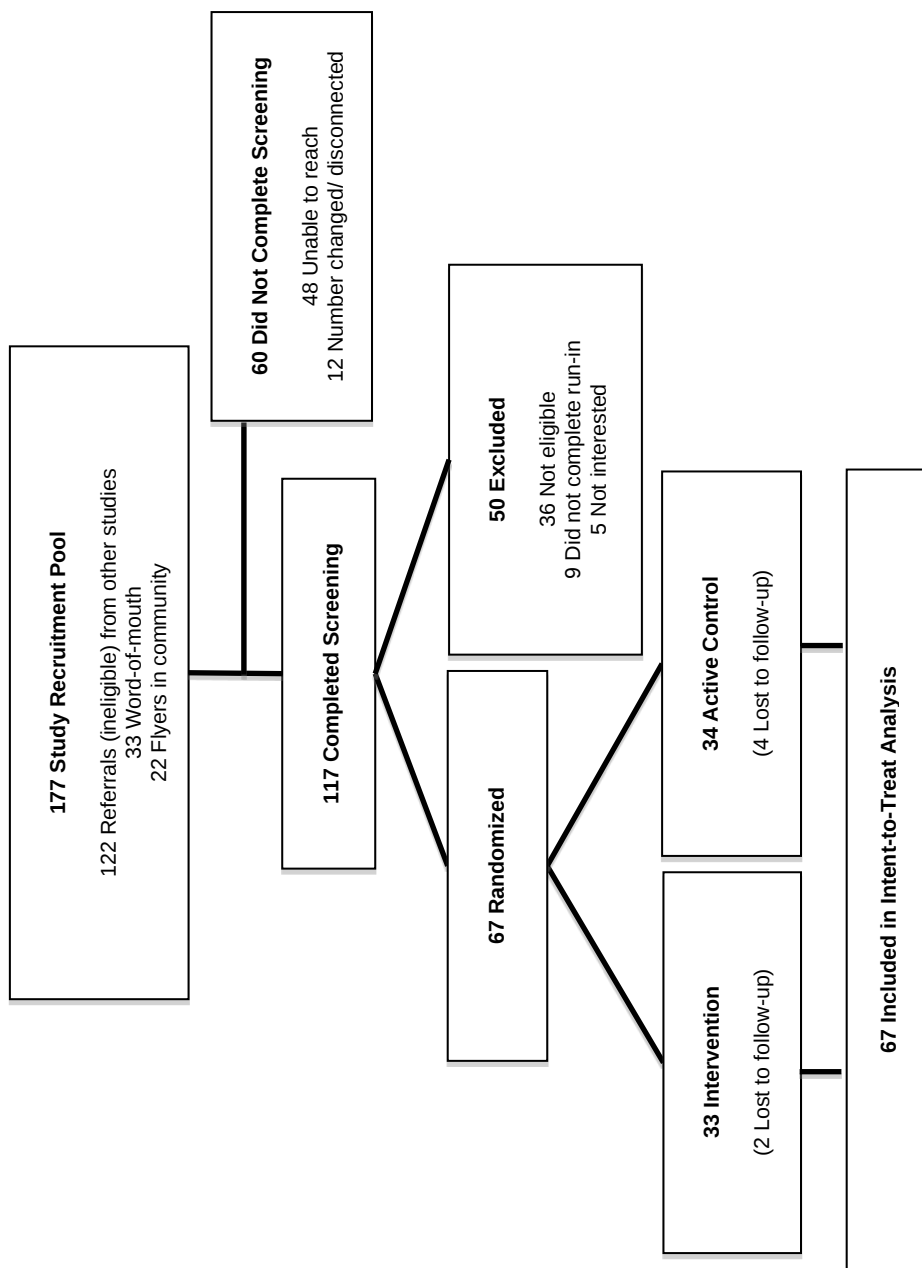


Figure 1.1. Participant flow (CONSORT figure)

Table 1.1. Participants' baseline characteristics, mean (SD) or %

	N	Intervention (n=33)	Comparison (n=34)	p-value
Age (years)	67	49.3 (11.5)	47.1 (11.9)	0.45
Sex				
Female	61	88	94	0.38
Male	6	12	6	
Education				
< College	26	33	67	0.37
≥ College graduate	41	44	56	
Race/ Ethnicity				
White	45	67	68	0.83
Hispanic	11	18	15	
African-American	3	12	9	
Asian	2	3	3	
Other	2	0	6	
BMI (kg/m²)				
25-29	33	52	47	0.72
≥ 30	34	48	53	
Physical Activity				
Steps per day	67	6909 (415)	6732 (401)	0.58
MVPA (min/wk)	67	34.6 (3.0)	32.7 (2.9)	0.46
Total PA (min/wk)	67	154.6(5.3)	149.9 (6.8)	0.30
Wear-time (min/day)	67	847.7 (122.2)	835.0 (119.1)	0.26
Text Messaging Use				
Frequent	34	52	47	0.12
Infrequent [†]	33	48	53	
Web or App Use[‡]				
Yes	27	41	37	0.26
No	40	59	63	
Confidence Change PA				
Very confident	31	38	53	<.0001*
Confident/ Somewhat	36	62	47	

* Chi-square or t-tests, α-level p < .05

† 3-item composite index score assessed "frequent" and "infrequent" text-messaging use: 1) # days text messaging used in a typical week, (2) average # text messages received per day, (3) average # of text messages sent per day

‡ Previous web or app use to monitor physical activity

Table 1.2. Actigraph GT3X+ change in physical activity levels from baseline to 6-week follow-up stratified by baseline confidence in reaching MVPA recommendations, adjusted for wear-time (min/wk), mean (SE)

	Intervention Group			Control Group			p-value [†]
	Baseline	Week 6	Change	Baseline	Week 6	Change	
All	(n=33)	(n=30)		(n=34)	(n=29)		
Steps (# per day)	6884.8 (637.8)	6908.8 (414.7)	24.0 (276.3)	7165.1 (416.6)	6732.4 (400.7)	-432.74 (221.5)	0.20
Physical activity (min per week)							
Moderate-to-vigorous intensity	34.6 (3.0)	35.7 (2.5)	-1.1 (2.4)	32.7 (2.9)	36.9 (3.4)	4.3 (2.0)	0.33
All intensity	154.6 (5.3)	153.0 (6.5)	-1.6 (4.5)	149.9 (6.8)	157.7 (6.9)	7.8 (4.2)	0.13
'Very Confident'	(n=12)	(n=12)		(n=18)	(n=15)		
Steps (# per day)	8036.6 (800.5)	7575.4 (727.2)	-461.2 (495.7)	7359.9 (493.3)	7657.0 (629.1)	297.1 (364.4)	0.24
Physical activity (min per week)							
Moderate-to-vigorous intensity	41.8 (5.0)	39.9 (4.7)	-1.9 (4.9)	36.9 (4.2)	41.2 (5.6)	4.3 (3.5)	0.32
All intensity	173.2 (8.7)	167.5 (12.8)	-5.8 (8.2)	150.8 (6.3)	158.69 (7.3)	7.9 (6.3)	0.20
'Confident' or 'Somewhat Confident'	(n=21)	(n=18)		(n=16)	(n=14)		
Steps (# per day)	6263.6 (397.7)	6486.3 (376.0)	222.8 (309.5)	6040.6 (6621.4)	6621.4 (508.6)	580.8 (230.1)	0.36
Physical activity (min per week)							
Moderate-to-vigorous intensity	30.5 (3.6)	33.0 (3.0)	2.5 (2.4)	28.2 (3.8)	32.2 (3.3)	4.0 (1.9)	0.61
All intensity	144.1 (5.6)	144.5 (6.6)	0.43 (5.4)	149.1 (12.6)	156.7 (12.0)	7.6 (5.5)	0.34

[†] Mixed-model repeated-measures (group*time), α -level $p < .05$

[‡] Mixed-model repeated-measures 3-way interaction (group*time*baseline confidence), steps: $p = 0.63$; MVPA: $p = 0.60$; all intensity: $p = 0.67$

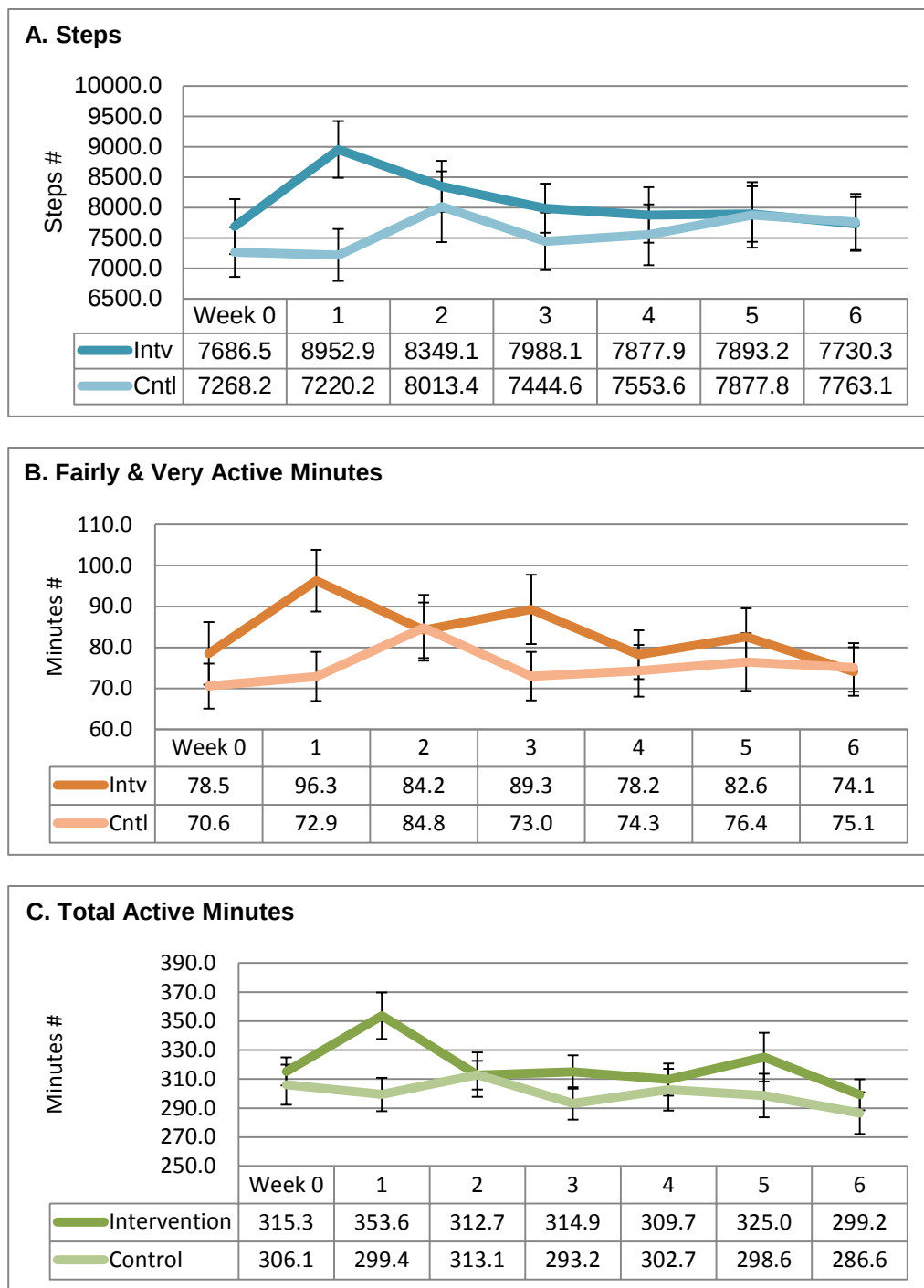


Figure 1.2.A-C. Fitbit measure of physical activity from baseline (week 0) to week 6 adjusted for baseline wear-time (minutes/week)

REFERENCES

1. Bassuk SS, Manson JE. Epidemiological evidence for the role of physical activity in reducing risk of type 2 diabetes and cardiovascular disease. *J Appl Physiol*. 2005;99(3):1193-204. doi:10.1152/japplphysiol.00160.2005.
2. Ehemann C, Henley SJ, Ballard-Barbash R, et al. Annual Report to the Nation on the status of cancer, 1975-2008, featuring cancers associated with excess weight and lack of sufficient physical activity. *Cancer*. 2012;118(9):2338-66. doi:10.1002/cncr.27514.
3. Malnick SDH, Knobler H. The medical complications of obesity. *QJM*. 2006;99(9):565-79. doi:10.1093/qjmed/hcl085.
4. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. *JAMA*. 2010;303(3):235-41. doi:10.1001/jama.2009.2014.
5. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity in the United States, 2009-2010. *NCHS Data Brief*. 2012;(82):1-8.
6. Prevalence of self-reported physically active adults--United States, 2007. *MMWR Morb Mortal Wkly Rep*. 2008;57(48):1297-300.
7. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc*. 2008;40(1):181-8. doi:10.1249/mss.0b013e31815a51b3.
8. Jakicic JM, Marcus BH, Lang W, Janney C. Effect of exercise on 24-month weight loss maintenance in overweight women. *Arch Intern Med*. 2008;168(14):1550-9; discussion 1559-60. doi:10.1001/archinte.168.14.1550.
9. Irwin ML, Alvarez-Reeves M, Cadmus L, et al. Exercise Improves Body Fat, Lean Mass, and Bone Mass in Breast Cancer Survivors. *Obesity*. 17(8):1534-1541.
10. Rock CL, Flatt SW, Sherwood NE, Karanja N, Pakiz B, Thomson CA. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. *JAMA*. 2010;304(16):1803-10. doi:10.1001/jama.2010.1503.
11. Pierce JP, Natarajan L, Caan BJ, et al. Influence of a diet very high in vegetables, fruit, and fiber and low in fat on prognosis following treatment for breast cancer: the Women's Healthy Eating and Living (WHEL) randomized trial. *JAMA*. 2007;298(3):289-98. doi:10.1001/jama.298.3.289.

12. Norman GJ, Zabinski MF, Adams MA, Rosenberg DE, Yaroch AL, Atienza AA. A review of eHealth interventions for physical activity and dietary behavior change. *Am J Prev Med.* 2007;33(4):336-345. doi:10.1016/j.amepre.2007.05.007.
13. *The Mobile Consumer: A Global Snapshot (February 2013).* New York; 2013.
14. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *Am J Prev Med.* 2009;36(2):165-73. doi:10.1016/j.amepre.2008.09.040.
15. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev.* 2010;32(1):56-69. doi:10.1093/epirev/mxq004.
16. Hanauer DA, Wentzell K, Laffel N, Laffel LM. Computerized Automated Reminder Diabetes System (CARDS): e-mail and SMS cell phone text messaging reminders to support diabetes management. *Diabetes Technol Ther.* 2009;11(2):99-106. doi:10.1089/dia.2008.0022.
17. Franklin V, Waller A, Pagliari C, Greene S. "Sweet Talk": text messaging support for intensive insulin therapy for young people with diabetes. *Diabetes Technol Ther.* 2003;5(6):991-6. doi:10.1089/152091503322641042.
18. Rodgers A, Corbett T, Bramley D, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control.* 2005;14(4):255-61. doi:10.1136/tc.2005.011577.
19. Free C, Knight R, Robertson S, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial. *Lancet.* 2011;378(9785):49-55. doi:10.1016/S0140-6736(11)60701-0.
20. Obermayer JL, Riley WT, Asif O, Jean-Mary J. College smoking-cessation using cell phone text messaging. *J Am Coll Health.* 53(2):71-8. doi:10.3200/JACH.53.2.71-78.
21. Riley W, Obermayer J, Jean-Mary J. Internet and mobile phone text messaging intervention for college smokers. *J Am Coll Health.* 57(2):245-8. doi:10.3200/JACH.57.2.245-248.
22. Bramley D, Riddell T, Whittaker R, et al. Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori. *N Z Med J.* 2005;118(1216):U1494.
23. Haug S, Meyer C, Schorr G, Bauer S, John U. Continuous individual support of smoking cessation using text messaging: a pilot experimental study. *Nicotine Tob Res.* 2009;11(8):915-23. doi:10.1093/ntr/ntp084.

24. Patrick K, Raab F, Adams MA, et al. A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res*. 2009;11(1):e1. doi:10.2196/jmir.1100.
25. Gerber BS, Stolley MR, Thompson AL, Sharp LK, Fitzgibbon ML. Mobile phone text messaging to promote healthy behaviors and weight loss maintenance: a feasibility study. *Health Informatics J*. 2009;15(1):17-25. doi:10.1177/1460458208099865.
26. Napolitano MA, Hayes S, Bennett GG, Ives AK, Foster GD. Using Facebook and text messaging to deliver a weight loss program to college students. *Obesity (Silver Spring)*. 2013;21(1):25-31. doi:10.1002/oby.20232.
27. Shapiro JR, Bauer S, Hamer RM, Kordy H, Ward D, Bulik CM. Use of text messaging for monitoring sugar-sweetened beverages, physical activity, and screen time in children: a pilot study. *J Nutr Educ Behav*. 40(6):385-91. doi:10.1016/j.jneb.2007.09.014.
28. Cheung PP, Chow BC, Parfitt G. Using Environmental Stimuli in Physical Activity Intervention for School Teachers: A Pilot Study. *Glob J Heal Educ Promot*. 2008;11(1).
29. Hurling R, Catt M, Boni M De, et al. Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. *J Med Internet Res*. 2007;9(2):e7. doi:10.2196/jmir.9.2.e7.
30. Prestwich A, Perugini M, Hurling R. Can the effects of implementation intentions on exercise be enhanced using text messages? *Psychol Health*. 2009;24(6):677-87. doi:10.1080/08870440802040715.
31. Prestwich A, Perugini M, Hurling R. Can implementation intentions and text messages promote brisk walking? A randomized trial. *Health Psychol*. 2010;29(1):40-9. doi:10.1037/a0016993.
32. Conroy MB, Yang K, Elci OU, et al. Physical activity self-monitoring and weight loss: 6-month results of the SMART trial. *Med Sci Sports Exerc*. 2011;43(8):1568-74. doi:10.1249/MSS.0b013e31820b9395.
33. Antypas K, Wangberg SC. An Internet- and mobile-based tailored intervention to enhance maintenance of physical activity after cardiac rehabilitation: short-term results of a randomized controlled trial. *J Med Internet Res*. 2014;16(3):e77. doi:10.2196/jmir.3132.
34. Fjeldsoe BS, Miller YD, Marshall AL. MobileMums: a randomized controlled trial of an SMS-based physical activity intervention. *Ann Behav Med*. 2010;39(2):101-11. doi:10.1007/s12160-010-9170-z.

35. King AC, Ahn DK, Oliveira BM, Atienza AA, Castro CM, Gardner CD. Promoting physical activity through hand-held computer technology. *Am J Prev Med*. 2008;34(2):138-42. doi:10.1016/j.amepre.2007.09.025.
36. Haapala I, Barengo NC, Biggs S, Surakka L, Manninen P. Weight loss by mobile phone: a 1-year effectiveness study. *Public Health Nutr*. 2009;12(12):2382-91. doi:10.1017/S1368980009005230.
37. Nguyen HQ, Gill DP, Wolpin S, Steele BG, Benditt JO. Pilot study of a cell phone-based exercise persistence intervention post-rehabilitation for COPD. *Int J Chron Obstruct Pulmon Dis*. 2009;4:301-13.
38. Gasser R, Brodbeck D, Degen M, Luthiger J, Wyss R, Reichlin S. *Persuasive Technology*. (IJsselsteijn WA, Kort YAW, Midden C, Eggen B, Hoven E, eds.). Berlin, Heidelberg: Springer Berlin Heidelberg; 2006:27-38. doi:10.1007/11755494.
39. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychol*. 2009;28(6):690-701. doi:10.1037/a0016136.
40. Williams AD. Use of a Text Messaging Program to Promote Adherence to Daily Physical Activity Guidelines: A Review of the Literature. *Bariatr Nurs Surg Patient Care*. 2012;7(1):13-16. doi:10.1089/bar.2012.9999.
41. US Department of Health and Human Services and UD of H and HS. *Physical Activity Guidelines for Americans.*; 2008:21-25.
42. Le Masurier GC, Lee SM, Tudor-Locke C. Motion sensor accuracy under controlled and free-living conditions. *Med Sci Sports Exerc*. 2004;36(5):905-10.
43. Bassett DR, Dinesh J. "Use of pedometers and accelerometers in clinical populations: validity and reliability issues." . *Phys Ther Rev*. 2010;15.3(135).
44. Takacs J, Pollock CL, Guenther JR, Bahar M, Napier C, Hunt MA. Validation of the Fitbit One activity monitor device during treadmill walking. *J Sci Med Sport*. 2013. doi:10.1016/j.jsams.2013.10.241.
45. Cnaan A, Laird NM, Slasor P. Using the general linear mixed model to analyse unbalanced repeated measures and longitudinal data. *Stat Med*. 1997;16(20):2349-80.
46. Carels RA, Darby LA, Rydin S, Douglass OM, Cacciapaglia HM, O'Brien WH. The relationship between self-monitoring, outcome expectancies, difficulties with eating and exercise, and physical activity and weight loss treatment outcomes. *Ann Behav Med*. 2005;30(3):182-90. doi:10.1207/s15324796abm3003_2.

47. Gleeson-Kreig JM. Self-monitoring of physical activity: effects on self-efficacy and behavior in people with type 2 diabetes. *Diabetes Educ.* 32(1):69-77. doi:10.1177/0145721705284285.
48. Napolitano MA, Fotheringham M, Tate D, et al. Evaluation of an internet-based physical activity intervention: a preliminary investigation. *Ann Behav Med.* 2003;25(2):92-9.
49. Tudor-Locke C, Bassett DR, Swartz AM, et al. A preliminary study of one year of pedometer self-monitoring. *Ann Behav Med.* 2004;28(3):158-62. doi:10.1207/s15324796abm2803_3.
50. Tate DF. Using Internet Technology to Deliver a Behavioral Weight Loss Program. *JAMA.* 2001;285(9):1172. doi:10.1001/jama.285.9.1172.

CHAPTER 2

Using the Fitbit One Mobile Application Software (App) is Associated with Increased Steps in a 6-Week Physical Activity Intervention among Overweight/Obese Adults

ABSTRACT

Background: New technologies offer lower-cost opportunities to assist people increase their physical activity (PA) levels. The Fitbit One is a commercially popular accelerometer/altimeter which allows users to objectively record and upload PA data onto a website for self-regulation.

Objective: 1) To test whether providing the Fitbit One and daily text-messaging PA prompts among overweight middle aged participants' led to increases in objectively measured steps. 2) To identify whether participants' baseline self-efficacy and outcome expectations were associated with the level of engagement in using the Fitbit One and text messages.

Methods: Participants (N=67) were enrolled in a 6-week randomized feasibility PA trial that provided both groups with a Fitbit One and assigned half to also receive text message prompts for PA (Text2bfit Pilot Study). Self-reported baseline assessment included items on demographic variables, text-messaging experience, previous PA web/app use, and social cognitive variables. Follow-up assessment asked about attitudes and behaviors on the Fitbit One and text messages. Participants were categorized on level of engagement in using technology during the study (i.e., Fitbit tracker, website, mobile app, and/or text messages). Factor analysis established construct validity for self-efficacy and outcome expectations. Response items were scored/ used to categorize participants into high/low categories. Steps were measured at baseline and follow-up using a standard accelerometer (Actigraph GT3X+).

Results: Participants reported the Fitbit One was easy to use, and both the tracker and website helped them to be more physically active. Approximately 22 participants (36%) reported using the Fitbit mobile app and they had a statistically significant increase of +545 steps/day ($SE=265$) at 6 weeks ($p=0.04$). Comparatively, 39 participants (64%) did not use the mobile app and had a decrease of -28 steps/day ($SE=242$). Frequently viewing the Fitbit tracker for distance or steps readings and logging onto the Fitbit website were also associated increased steps (+349, $SE=214$; +280, $SE=224$; +266, $SE=227$). Frequently performing a bout of PA after receiving text messages was not associated with increased steps, although there was a positive association among those who typically engaged in PA within < 2 hours of receiving a text. There were no statistically significant group differences. Neither the self-efficacy nor outcome expectations measures were a significant predictor of level of engagement in using the Fitbit One and text messages.

Conclusions: These preliminary findings suggest higher engagement with the Fitbit One, particularly the mobile app, was associated with increased steps at follow-up in a sample of overweight/obese adults. In this study, text-messaging reminders were not effective. Further experimentation with new technologies offers considerable promise in developing cost-effective interventions to promote PA.

INTRODUCTION

The growing and linked epidemics of obesity and physical inactivity are expected to have severe health consequences in the United States.¹⁻⁴ and there is a need to develop low cost interventions to assist those who are at-risk to increase their physical activity levels. Successful interventions often focus on self-regulatory skills whereby people are encouraged to manage their own behavior change by setting sequential proximal goals, self-monitoring their behavior, and building self-efficacy to implement change.^{5,6} For example, pedometer-⁷⁻¹⁰ and/or web-based¹¹⁻¹³ interventions have shown that providing participants with feedback on performance and asking them to record their steps can motivate them to increase their physical activity levels. Advancements in technology provide increasingly more opportunities to help people build self-regulatory skills including self-monitoring of physical activity. Fitbit One is a commercially popular device that measures physical activity with a small tracker (wearable accelerometer) that has a small display for instant physical activity (PA) readings. These data can be uploaded to a personal website (Fitbit.com) or the Fitbit mobile application software (app) on a mobile device (e.g. smartphone or tablet) for more comprehensive summaries of daily PA data across time – through which individuals can organize their self-regulatory change processes.

The Fitbit One has the capacity to build self-regulatory skills for PA, but the level of engagement in using the device is ultimately up to the individual. More importantly, this level of engagement will probably influence self-regulatory skills and activate change. Process evaluations of health interventions often assess intervention dose-delivered vs. dose-received in an effort to identify participants' actual level of engagement.¹⁴ Likewise, simply providing a Fitbit One does not necessarily indicate

that people will actively use the device for self-monitoring of physical activity. Therefore, it is necessary to examine participants' level of engagement (or dose-received) with the device to assess the utility of this technology in prompting physical activity.

A 6-week feasibility randomized trial (Text2bfit Pilot Study) provided participants with the Fitbit One with/without automated text message prompts for PA. Overall, the study intervention was not successful in increasing PA levels for more than one week (JBW, University of California, San Diego, unpublished observations, 2014). In the Text2bfit Pilot Study, it is possible that although participants were provided with the Fitbit and text messages, there might have been minimal engagement with these intervention components, which could help explain the loss of the study effects. Further, it is also possible that participants' actual level of engagement with the intervention components was associated with change in their physical activity levels. In this analysis, we hypothesized participants' level of engagement in using the intervention components (i.e., Fitbit tracker, FB website, FB mobile app, and text messages) would be positively associated with objectively measured steps at 6-week follow-up (Actigraph GT3X+).

This paper also examined baseline measures of common social cognitive predictors of physical activity behavior: self-efficacy and outcome expectations.^{15,16} "Self-efficacy" is defined as the belief in one's ability to change a given behavior.¹⁷ "Outcome expectations" is defined as the expected positive and/or negative consequences of performing the behavior.¹⁶ Previous studies have shown that these constructs can predict change in physical activity behavior.¹⁸⁻²⁴ In the Text2bfit Pilot Study, social cognitive constructs were used to develop baseline items to assess factors that might be associated with change in physical activity levels. In this

analysis, we hypothesized that participants' baseline self-efficacy and/or outcome expectations scores would be positively associated with their level of engagement with the Fitbit One and text messages.

METHODS

Study Design & Population

In the Text2bfit Pilot Study, 67 adults were provided a Fitbit One in which half were randomly assigned to receive text messages as simple reminders to prompt PA. The study recruited participants in San Diego from January 2013 – January 2014, which consisted mostly of women who had consented during a mammography appointment at the Moores UC San Diego Cancer Center their willingness to be reached for research opportunities and/or they did not meet eligibility criteria for larger weight loss trials being conducted at UCSD Moores Cancer Center. Additionally, participants were recruited via word-of-mouth and flyers that were posted throughout the community including the UC San Diego and SDSU campuses. Initial study eligibility was assessed over the telephone and the criteria included being a non-smoker, 19-69 years of age, overweight or obese ($BMI > 25 \text{ kg/m}^2$), and physically inactive ($<150 \text{ min/wk MVPA}$). Additionally, the eligibility criteria included self-reported motivation to change PA levels within a month from screening (using a 1-item question), meeting criteria using the self-reported “Physical Activity Readiness Questionnaire” (PAR-Q), ability to use SMS text messaging, and access to a computer capable of running the Fitbit One software. The UC San Diego institutional review board approved the study protocol and consent, and all participants were

asked to provide written informed consent. Details of the Text2bfit Pilot Study methods are reported elsewhere (JBW, University of California, San Diego, unpublished observations, 2014).

Study Procedures

Those who met the initial telephone eligibility criteria were invited to the UC San Diego Moores Cancer Center for a 1-hour clinic visit for further assessment including measured height and weight and to complete a self-administered baseline questionnaire. Prior to randomization, study personnel provided participants with a 5-minute brief intervention to review motivation, goal setting, and planning for physical activity. This intervention was needed to maintain motivation to undertake the measurements required in the study. Study personnel also demonstrated how to wear and use the Actigraph GT3X+ and Fitbit One tracker and website (Fitbit.com). Participants were asked to concurrently wear both devices for baseline measure of PA levels and provide 5 valid days of wear (≥ 600 minutes per day). Those who provided at least 5 valid days were eligible for randomization into a study group.

Interventions

Simple Text Message Reminders for PA

Participants who were randomly assigned to the intervention group were contacted by either telephone and/or email to indicate 3 preferred times of the day (for each day of the week) to receive text message reminders to undertake a PA event. They were informed that they could contact the study at any time if they wanted to change their pre-set schedule. Study personnel constructed 2-weeks-worth or 42 short text reminder messages (< 150 characters) and used a commercially

available website (Eztexting.com) to program and schedule the delivery of all text messages. The full set of text messages was delivered over a 2-week period and was then repeated through the 6-week study period. The content of the messages were basic reminders to engage in PA (e.g., “Good morning [name]! This is your 9AM reminder to do at least a 10-minute bout of moderate-to-vigorous intensity physical activity.”).

Self-Monitoring with the Fitbit One

All participants in both intervention and control groups were asked to wear a Fitbit One tracker every day and to upload PA data from the tracker to the website (Fitbit.com). They were provided instructions on how to navigate through the Fitbit website including viewing their “dashboards” for daily summaries of their PA data. Participants also had the option to use the Fitbit mobile app on their smartphones or tablet computers to upload their data and view their PA summaries. Study personnel emphasized the importance of uploading and charging the Fitbit One in an effort to minimize missing data.

Measures

Baseline Questionnaire

At baseline clinic visit, participants were asked to complete a self-administered questionnaire. Sections included demographics, technology use, and items guided by social cognitive constructs to assess factors associated with change in PA, and history of performing moderate-to-vigorous intensity physical activity (MVPA). Most items consisted of Likert-type response options that were assigned numeric values for scoring purposes. Items were as follows:

Demographics. Variables included age, sex, level of education, and race/ethnicity.

Technology Use. Items aimed to assess whether participants were frequent users of SMS text messaging prior to the start of the study. Three items were used to calculate a summary scores and the median. A “frequent” user of SMS text messaging was defined as those with a summary score above the median split. Participants were also asked about the previous web or app use for PA. **Text messaging use** items were: “In a typical week, approximately how many days do you text message?” [Response options: everyday (7 days/wk)=5, most days (5 days/wk)=4, some days (3-5 days/wk)=3, rarely (1-2 days/wk)=2, or never (0 days/wk)=1], “On those days, approximately how many text messages do you receive?” [Response options: 0 messages=1, 1-5 messages=2, 6-10 messages=3, or > 10 messages=4], and “On those days, approximately how many text messages do you send?” [Response options: 0 messages=1, 1-5 messages=2, 6-10 messages=3, or > 10 messages=4]. **Web or app use for PA** items were: “Have you ever used a website or app on your mobile phone or tablet to track and/or monitor your physical activity levels?” [Response options: yes=1, no=0].

Social Cognitive Constructs. The baseline questionnaire included items that were guided by social cognitive constructs to assess factors that might predict participants’ level of engagement and change in PA. Factor analysis was conducted to identify 2 main constructs: “self-efficacy” and “outcome expectations.” Items with factor loadings of < .49 were excluded and Cronbach’s alphas were calculated for 5 items for self-efficacy ($\alpha=0.79$) and 6 items for outcome expectations ($\alpha=0.74$). Response scores were summed and medians were calculated. Having high self-efficacy or high

outcome expectations was defined as having a summary score above each respective median score. There were a total of 5 **self-efficacy** items ($\alpha=0.79$): “How confident are you in your ability to handle the following situations that may prevent you from doing any physical activity? When you are... not feeling well? [factor loading: 0.64], ...not feeling motivated?” [factor loading: 0.61], ...short on time [factor loading: 0.60], ...feeling stressed? [factor loading: 0.56]” and “How confident are you in your ability to increase your current physical activity levels to 150 min/wk of MVPA in the next 6 weeks? (factor loading: 0.49).” [Response options: very confident=4, confident=3, somewhat confident=2, or not at all confident=1]. Six **outcome expectations** items ($\alpha=0.74$) were: “Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 min/wk of MVPA. You will... lose weight [factor loading: 0.76], ...look better [factor loading: 0.67], ...increase your energy level [factor loading: 0.55], ...reduce stress [factor loading: 0.50], ...burn calories [factor loading: 0.50], ...reduce the risk of disease [factor loading: 0.49]. [Response options: very likely=4, likely=3, somewhat likely=2, or not at all likely=1].

Recent History of MVPA. At baseline, participants were also asked whether they ever met recommended levels of MVPA, and if so, how far back in time. A “recent history of MVPA” was defined as having performed recommended levels of MVPA less than 5 year ago. Items were: “In the past, have you ever performed at least 150 min/wk of MVPA?” [Response options: yes or no]. If yes, “How long ago did you last perform at least 150 min/wk of MVPA?” [Response options: < 1 year ago, 1-2 years ago, 3-4 years ago, 5-10 years ago, or > 10 years ago].

Follow-Up Questionnaire

A brief follow-up questionnaire was conducted over the telephone at the end of the 6-week study period. Items asked participants' about their attitudes and use of the Fitbit One (i.e., tracker, website, and mobile app), and in the intervention group only, their attitudes and response to the text message reminders.

Attitudes on Intervention Components. These items assessed participants' attitudes about the Fitbit One and text message reminders and whether they thought these intervention components were useful in helping them to increase their activity levels. Higher response scores indicated more favorable attitudes. Items on the **Fitbit One tracker & website** were: "The Fitbit tracker was easy to use," "Overall, the Fitbit tracker helped me to be more physically active," "The Fitbit website was easy to use," and "Overall, the Fitbit website helped me to be more physically active" [Response options: strongly agree=5, agree=4, neutral=3, disagree=2, or strongly disagree=1]. Items on **text messaging as simple reminders for PA** were: "Daily text messages that prompted me to be physically active helped me to be more physically active" [Response options: strongly agree=5, agree=4, neutral=3, disagree=2, or strongly disagree=1] and "The 3 daily text messages that prompted me to be physically active were..." [Response options: too many=3, just right=2, or too few=1].

Use of the Fitbit One. Participants were asked about their level of engagement with the Fitbit One and text messages. These items were intervention "dose-received" or process variables since they reflect participants' actual use/response to each intervention component. Higher response scores indicated a higher dose (or level of engagement). Items on using the **Fitbit tracker** were: "On a typical day, I checked the

Fitbit tracker to see... how many steps I've taken," " ...how much distance I've travelled," and "...if the flower grew taller." [Response options were: very often=5 (high dose), often=4 (high dose), sometimes=3 (low dose), rarely=2 (low dose), or never=1 (low dose)]. Item on the **Fitbit website (fitbit.com)** was: "In a typical week, I logged onto my Fitbit.com account..." [Response options: everyday (7 days/week)=5 (high dose), most days (5 days/week)=4 (high dose), some days (3-5 days/week)=3 (high dose), rarely (1-2 days/week)=2 (low dose), and never (0 days/week)=1 (low dose)]. Items on **Fitbit mobile app** were: "Did you use the Fitbit mobile app?" [Response options: yes=2 or no=1]. If yes, "How often did you use the Fitbit mobile app? [Response options: more than once a day=6 (high dose), about once a day=5 (high dose), few times per week=4 (low dose), couple times per week=3 (low dose), about once per week=2 (low dose), or less than once per week=1 (low dose)].

Response to Text Messages. Items were: "Overall, did you engage in at least a 10-minute bout of physical activity after receiving a text message from the study? Would you say..." [Response options: always=5 (high dose), usually=4 (high dose), about half the time=3 (high dose), rarely=2 (low dose), or never=1 (low dose)] and "How soon after receiving a text message did you engage in at least a 10-minute bout of physical activity? On average, would you say..." [Response options: 1-30 minutes=7 (high dose), 31-59 minutes=6 (high dose), 1-2 hours=5 (high dose), 3-6 hours=4 (low dose), 7-9 hours=3 (low dose), 10-12 hours=2 (low dose), or more than 12 hours=1 (low dose)].

Physical Activity Outcome: Steps

The primary dependent variable was objective measures of *steps* that were assessed at baseline and 6-week follow-up using a standard accelerometer. Actigraph GT3X+ is a tri-axial activity monitor that uses Micro-Electro-Mechanical System (MEMS) technology to measure acceleration across 3 planes. It is widely used in physical activity research, and a valid and reliable measure of physical activity in adults.^{25,26} ActiLife 6.10 software was used to process Actigraph GT3X+ data to begin non-wear bouts after 90 minutes, set the spike tolerance at 2 minutes, ignore wear periods less than 10 minutes, and flag days as invalid if the wear time was less than 600 minutes. A “valid” wear day was defined as wearing the device for a minimum of 10 hours, or 600 minutes, per day. Troiano default settings were used for scoring step counts.

Statistical Analysis

Descriptive statistics were conducted for all variables. A mixed-model repeated measures analysis²⁷ was conducted to test whether high vs. low “dose” or level of engagement with the Fitbit One (i.e. tracker, website, and mobile app) and text messages were associated with steps assessed at pre- (i.e., baseline) and post-intervention (i.e., 6 weeks) with up to 7 measures per time-point. A random subject-specific intercept was included to model between subject variability. Fixed effects included in the models were time (i.e., pre-, and post-intervention), group (i.e., high vs. low engagement), and the group by time interactions. A statistically significant group by time interaction indicated that pre- and post-intervention change in steps differed between high vs. low engagement categories. All models were adjusted for daily wear-time minutes of the accelerometer. Adherence to modeling assumptions

was tested using residual plots (e.g., qqplots to examine if residuals followed a Gaussian distribution). Logistic regression models were fitted to calculate odds of having a high level of engagement with the Fitbit One and/or text messages by baseline assessment of self-efficacy and outcome expectation scores. Chi-square tests of associations were conducted to compare differences in their attitudes and use/response to intervention components. All analyses were conducted using SAS software, version 9.3 (SAS Institute Inc., Cary, North Carolina).

RESULTS

Study Sample

The study sample (N=67) was 91% female, 61% college graduates, 67% non-Hispanic White, with a mean (SD) age of 48.2 (11.7) years (range: 19-66 years), and a BMI of 31.0 (3.7) kg/m², 49% were overweight (BMI 25-29 kg/m²). **(Table 2.1)** At baseline, approximately 50% reported that they frequently used SMS text messaging, 40% had previously used a web or mobile app to monitor physical activity levels, and 85% reported that they had previously met MVPA recommendations less than 5 years ago (from the date of assessment). Mean (SD) self-efficacy score was 13.4 (2.6) and outcome expectations score was 20.7 (2.5). Approximately 46 participants (69%) had high self-efficacy and 42 participants (63%) had high outcome expectations.

Follow-Up Assessments

Attitudes & Level of Engagement: Fitbit One

A total of 61 participants completed the follow-up questionnaire. **(Table 2.2)** Mean (SD) response scores indicated that overall participants agreed that the Fitbit tracker (4.7; SD=0.6) and Fitbit website (4.3; SD=0.8) were easy to use. Participants also indicated that the Fitbit tracker (4.0; SD=0.8) was helpful in being more physically active, and the Fitbit website (3.8; SD=0.8) was slightly less helpful. They reported checking their Fitbit trackers often to view their steps (4.2; SD=0.8), and distance (3.7; SD=1.1) and intensity (3.4; SD=1.1) less often. Overall, participants logged onto their personal Fitbit.com web accounts most days of the week (4.0; SD=1.0). A total of 22 participants (36%) reported that they used the Fitbit mobile app, of which they also indicated that they used the app a few times per week (4.2; SD=2.).

Attitudes & Response to Text Messages as Simple Reminders

In the Text2bfit Pilot Study, only half of the participants were randomly assigned to receive text messages. Therefore, only half were asked items about the text messaging intervention. A total of 31 participants completed these items. **(Table 2.3)** Mean (SD) response scores indicated that overall participants were neutral about whether the text messages were helpful in helping them to be more physically active (3.0; SD=1.0). Participants' responses indicated that the frequency of messages were closer to "too many" (2.5; SD=0.6). Overall, participants engaged in a 10-minute bout of physical activity between "half the time" and "rarely" after receiving a text message (2.5; SD=1.0). If they did engage in a 10-minute bout of physical activity, the activity was performed approximately 3-6 hours after receiving a text message (4.7; SD=1.2).

Change in Steps by Level of Engagement with Intervention Components

(Table 2.4) Mean (SE) change in steps per day were higher at 6-week follow-up among participants who had a higher level of engagement with the Fitbit One and/or the text messages. There was a statistically significant increase of 545 (265) steps/day from baseline to follow-up in those who reported that they had used the Fitbit mobile app ($p=0.04$) (unadjusted and adjusted for previous web and/or app use for physical activity). Those who reported that they checked their trackers “very often” or “often” (vs. “sometimes,” “rarely,” or “never”) throughout the day for their distance had an increase of +349 (214) steps/day (vs. -38, SE: 327), and those who frequently checked their steps had an increase of +280 (224) steps/day (vs. -135, SE: 243). A higher frequency of checking the flower for PA intensity was not associated with a greater increase in steps at follow-up.

As for the Fitbit website, participants with a higher level of engagement had greater increases in steps at follow-up. Those who logged onto Fitbit.com 5-7 days per week (vs. < 5 days per week) had an increase of +266 (231) steps/day (vs. -43, SE=264). Only half the participants who received text messages engaged in at least a 10-minute bout of PA “always,” “usually,” or “half the time” (vs. “rarely” or “never”) and this was associated with a small increase of +8 (454) steps/day (vs. -66, SE=336). Although, among those who engaged in a 10-minute bout of PA < 2 hours (vs. $\geq$ 2 hours), there was an increase of +172 (442) steps/day (vs. -211, SE=1). Group by time interactions were not statistically significant.

Self-Efficacy, Outcome Expectations, and Level of Engagement

(Table 2.5) In this limited sample, associations of self-efficacy and outcome expectations were not statistically significant. However, overall, a trend in the data

indicated baseline measures of self-efficacy and/or outcome expectations scores were positively associated with level of engagement. Participants with high self-efficacy had a higher odds of logging onto the Fitbit website almost every day (or 5-7 days/week) (OR=1.69; 95% CI: 0.50-5.71), checking the Fitbit tracker “very often” or “often” throughout the day for PA intensity (flower) (OR=1.38; CI: 0.46-4.10) and steps (OR=1.13; CI: 0.30-4.35). Additionally, self-efficacy was also associated with engaging in a bout of PA < 2 hours from receiving a text message (OR=1.65; CI: 0.36-7.60) and engaging in a bout of PA “always,” “usually,” or “half the time” after receiving a text message (OR=1.36; CI: 0.30-6.28). Overall, participants’ outcome expectations scores were associated with using the Fitbit mobile app (OR=1.66; CI: 0.55-4.96), and checking the Fitbit tracker “very often” or “often” throughout the day to view steps (OR=1.72; CI: 0.48-6.15), distance (OR=1.32; CI: 0.46-3.79), and PA intensity (flower) (OR=1.12; CI: 0.40-3.14). Additionally, outcome expectations were associated with engaging in a bout of PA “always,” “usually,” or “half the time” after receiving a text message (OR=1.19; CI: 0.32-3.41).

Additional Analysis

A higher percentage of those who received the text message prompts for PA (vs. no text messages) responded either “strongly agree” or “agree” that the Fitbit One tracker (84% vs. 70%) and website (94% vs. 78%) helped to increase their physical activity levels. Conversely, a higher percentage of those who did not receive the text messages (vs. text messages) responded “very often” or “often” to checking the Fitbit tracker for their step (90% vs. 71%), distance (70% vs. 55%), and PA intensity from the flower (45% vs. 50%). There were no statistically significant group differences. (Data not shown)

DISCUSSION

These results provide preliminary data on how a sample of overweight and obese adults used the Fitbit One to increase their physical activity levels and how they responded to text messages that prompted PA. Higher engagement with these components was positively associated with change in steps from baseline to 6-week follow-up, although this was only statistically significant among participants who used (vs. did not use) the Fitbit mobile app ($p=0.04$). There were also positive associations between level of engagement and change in steps among participants who frequently checked their Fitbit trackers for steps and/or distance and/or frequently logged onto the Fitbit website. In the group that received daily text messages, only half indicated that they engaged in a bout PA after receiving a text message, although those who did engage in a bout of activity within 2 hours of receiving a text message increased their steps at follow-up. There were no statistically significant group differences. These results also provide insight on participants' self-efficacy, outcome expectations, and their level of engagement with the Fitbit One and text messages. In this sample, self-efficacy and outcome expectations were not predictive of level of engagement of using the Fitbit One or responding to the text messages.

FitBit One Tracker, Website, and Mobile App

In this study, participants who used the Fitbit mobile app had a significant increase in physical activity at follow-up (significant). The Fitbit mobile app is a fusion of the tracker and website in that it is easily accessible, provides instant feedback on performance, and is capable of providing more in-depth PA data such as minutes of activity by intensity level (i.e., light, fairly, and very active minutes). Previous

pedometer- and/or web-based interventions have shown to be efficacious in increasing PA levels.^{7-12,28-33} In these studies, self-monitoring components involved keeping PA records and logs on a calendar or on a webpage. Similarly, in this study, participants who used the tracker and website also increased their steps at follow-up (although these associations were not statistically significant).

Research on mobile apps is scarce despite their increasing popularity as devices like the iPhone include built-in sensors including accelerometers that allow even more opportunities for users to self-monitor their own health behavior. Results from this study provide data to indicate a significant positive association between using a PA mobile app and an increase in steps at follow-up. In this sample of overweight/obese adults, these results were stable even after adjusting for factors such as baseline motivation. Still, there are probably segments of the general population that might be more receptive to such technologies in monitoring their own PA levels.

In this study, there was some indication that those with higher positive outcome expectations at baseline had greater odds of using the Fitbit mobile app (not significant). This suggests that those who sought benefits from performing physical activity also used the self-monitoring option that was both highly accessible *and* provided in-depth PA data. Additionally, using the mobile app was associated with increased steps at follow-up. Further research is needed to identify and test mobile apps, assess users' level of engagement, and identify factors associated with users' level of engagement.

SMS Text Messaging to Prompt Self-Monitoring with Fitbit One

The primary outcome study showed that text messages as simple reminders to prompt PA were only able to achieve short-term effects that did not last past week 1 (JBW, University of California, San Diego, unpublished observations, 2014). In this analysis, more than half of the participants who received text messages indicated that they “rarely” or “never” did a bout of PA after receiving a text message. Overall, text messages as simple reminders were not successful in promoting physical activity. Other text messaging PA interventions, with comparatively more content and intensity, have also reported short-term effects.^{34,35} Based on these findings, it is recommended that future studies test the utility of text messages to prompt self-monitoring. Studies have shown that it is possible to effectively train or coach participants, including those who were overweight, to self-monitor their PA by keeping records/logs in a diary, webpage, or PDA.^{12,28,36,37} Future studies could test text messaging to prompt self-monitoring of PA (e.g., increase level of engagement with the Fitbit One) to increase PA.

Limitations

This study consisted of a small sample of overweight and obese adults (mostly women) who were inactive prior to the start of a 6-week PA trial. Results are not representative of other populations. Also, it might be possible that such a small sample size did not provide adequate power to detect statistically significant group differences. The study relied on self-reported measures of participants’ level of engagement with the Fitbit One and text messages. Self-report is often prone to measurement biases including social desirability that can result in errors.³⁸ However, the nature of the problem created challenges in obtaining objective measures of

participants' level of engagement primarily because researchers do not have access to data such as number of times participants logged onto the Fitbit website and duration of active time spent on the website. It is recommended that researchers collaborate with private companies like Fitbit Inc. to obtain objective measures of these activities for future research purposes (with permission from study participants). This study did not assess these questions and recommend future studies to include these assessments (among others) to gather more insight on participants' use of the device. Lastly, baseline social cognitive construct items were not validated prior to assessment. However, factor analysis was conducted to reduce items and establish construct validity. Cronbach's alphas indicated good inter-item correlations for both self-efficacy ($\alpha=0.79$) and outcome expectations ($\alpha=0.74$).

Conclusions

As wearable sensors/devices and other technologies including mobile applications become increasingly popular, there is a need to examine how and how much people use these devices for self-monitoring and changing PA behavior. In this study, greater use of self-monitoring components, particularly the use of the Fitbit mobile app, was associated with more physical activity. Mobile apps are accessible, instantaneous, and comprehensive having the potential to optimize people's self-regulatory skills in setting and reaching their PA goals. More research is needed to examine people's level of engagement in new technologies including mobile apps to determine whether these modalities might be cost-effective strategies in future intervention research and practice.

ACKNOWLEDGEMENTS

This research was supported by a gift from the Carol Vassiliadis family.

Chapter 2 is currently being prepared for submission for the publication of the material. Julie Wang, Guadalupe Ayala, Lisa Cadmus-Bertram, Loki Natarajan, Martha White, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

Table 2.1. Baseline demographic characteristics, technology-use, and social cognitive construct scores (N=67), mean (SD), mean (SD) or N (%)

	Mean (SD) or N (%)
Demographics	
Age	48.2 (11.7)
Female	61 (91.0%)
≥ College	41 (61.2%)
Non-Hispanic White	45 (67.2%)
Technology Use	
Frequent Text-Messaging Use ^a	8.2 (2.9)
1. In a typical week, approximately how many days do you text message? (Range 1-5) ^b	4.4 (1.1)
2. On those days, approximately how many text messages do you receive? (Range 1-4) ^c	2.7 (0.9)
3. On those days, approximately how many text messages do you send? (Range 1-4) ^d	2.7 (1.0)
Previous Web or App Use for PA	
Have you ever used a website or app on your mobile phone or tablet to track and/or monitor PA levels? (Yes)	27 (40.3%)
Social Cognitive Constructs	
Self-efficacy score ^{e, f}	13.4 (2.6)
Outcome expectations score ^g	20.7 (2.5)
Previously met MVPA recommendations < 5 years ago ^h	57 (85.1%)

- ^a "Frequent" text-messaging was being above the median split from a summary score of 3 items: # days, # texts received, and # texts sent
- ^b Response options: Everyday (7 days/week) (5); Most days (5 days/week) (4); Some days (3-5 days/week) (3); Rarely (1-2 days/week) (2); Never (1)
- ^c Response options: > 10 (4), 6-10 (3), 1-5 (2), 0 (1)
- ^d Response options: Very confident (4), Confident (3), Somewhat confident (2), Not at all confident (1)
- ^e Self-efficacy score was the sum of response options from 5 items ($\alpha=.79$):
- ^f Outcome expectations score was the sum of response options from 8 items ($\alpha=.74$)
- ^g Responses to 2 items and responses were used to assess whether participants met the previously met MVPA recommendations less (vs. more) than 5 years ago: "In the past, have you ever performed at least 150 min/wk of MVPA" (response: yes). If "yes," then "How long ago did you last perform at least 150 min/wk of MVPA?" (response: < 1 year, 1-2 years ago, or 3-4 years ago)

Table 2.2. Participants' responses to follow-up questionnaire items on attitudes and level of engagement with the Fitbit One (N=61), mean (SD), mean (SD) or N (%)

	Mean (SD) or N (%)
Attitudes ^a	
The Fitbit tracker was easy to use (Range: 1-5)	4.7 (0.6)
The Fitbit website was easy to use (Range: 1-5)	4.3 (0.8)
Overall, the Fitbit tracker helped me to be more physically active (Range: 1-5)	4.0 (0.8)
Overall, the Fitbit website helped me to be more physically active (Range: 1-5)	3.8 (0.8)
Level of Engagement (Dose-Received)	
Fitbit Tracker ^b	
On a typical day, I checked the Fitbit tracker to see how many steps I've taken (Range: 1-5)	4.2 (0.8)
On a typical day, I checked the Fitbit tracker to see how much distance I've travelled (Range: 1-5)	3.7 (1.1)
On a typical day, I checked the Fitbit tracker to see if the flower ^c grew taller (Range: 1-5)	3.4 (1.1)
Fitbit Website: In a typical week, I logged onto my Fitbit account... "every day" to "never" (Range: 1-5) ^d	4.0 (1.0)
Fitbit Mobile App	
Did you use the Fitbit mobile app? (Yes/No)	22 (36%)
(If yes) How often did you use the Fitbit mobile app? (Range 1-6) ^e	4.2 (2.0)

^a Response options: strongly agree (5), agree (4), neutral (3), disagree (2), and strongly disagree (1)

^b Response options: very often (5), often (4), sometimes (3), rarely (2), and never (1)

^c A picture of a flower appears on the Fitbit tracker display and grows taller/shorter to indicate the level of activity

^d Response options: everyday (7 days/week) (5); most days (5 days/week) (4); some days (3-5 days/week) (3); rarely (1-2 days/week) (2); and never (1)

^e Response options: more than once/day (6), about once/day (5), few times/week (4), couple of times/week (3), about once/week (2), less than once/week (1)

Table 2.3. Participants' responses to follow-up questionnaire items on attitudes and level of engagement with simple text message prompts for PA (N=31), mean (SD)

	Mean (SD)
Attitudes	
Daily text messages that prompted me to be physically active helped me to be more physically active. (Range: 1-5) ^a	3.0 (1.0)
The three daily text messages that prompted me to be physically active were... "Too many" to "Too few" (Range: 1-3) ^b	2.5 (0.6)
Level of Engagement (Dose Received)	
Overall, did you engage in at least a 10-minute bout of physical activity after receiving a text messages from the study? Would you say... "Always" to "Never" (Range: 1-5) ^c	2.5 (1.0)
How soon after receiving a text message did you engage in at least a 10-minute bout of physical activity? On average, would you say... "1-30 minutes" to "More than 12 hours" (Range: 1-7) ^d	4.7 (1.2)

^a Response options: Strongly agree (5), Agree (4), Neutral (3), Disagree (2), and Strongly disagree (1)

^b Response options: Too many (3), Just right (2), and Too few (1)

^c Response options: Always (5), Usually (4), About half the time (3), Rarely (2), and Never (1)

^d Response options: 1-30 minutes (7), 31 to 59 minutes (6), 1-2 hours (5), 3-6 hours (4), 7-9 hours (3), 10-12 hours (2), and more than 12 hours (1)

Table 2.4. Mean (SE) steps by level of engagement with the Fitbit One and text-messaging as simple reminders, adjusted for device wear-time minutes (Actigraph GT3X+)

	N	Baseline	Week 6	Δ Steps	P-value*
Engagement with Self-Monitoring w/ Fitbit One					
FB Tracker Use (per day)	61				
Frequency of viewing steps					
Sometimes, Rarely, or Never	12	6624 (486)	6488 (466)	-135 (243)	0.22
Very Often or Often	49	6840 (365)	7120 (345)	280 (224)	
Frequency of viewing distance					
Sometimes, Rarely, or Never	23	6564 (426)	6602 (357)	-38 (327)	0.33
Very Often or Often	38	6917 (444)	7266 (382)	349 (214)	
Frequency of viewing flower for PA intensity					
Sometimes, Rarely, or Never	32	6242 (336)	6507 (339)	265 (200)	0.72
Very Often or Often	29	7417 (508)	7537 (474)	120 (340)	
FB Website Use (day/week)					
< 5 days	15	6497 (510)	6454 (374)	-43 (264)	0.38
5-7 days	46	6895 (374)	7162 (366)	266 (227)	
FB Mobile App Use					
No	39	7123 (364)	7065 (366)	-28 (242)	0.12
Yes†	22	6228 (468)	6773 (481)	545 (265)	
Engagement with Text-Messaging					
Performed PA after receiving text message	31				
Rarely or Never	17	6461 (425)	6426 (351)	-66 (336)	0.90
Always, Usually, or Half the time	14	7599 (788)	7606 (690)	8 (454)	
Performed PA soon after receiving text message					
≥ 2 hours	16	7579 (678)	7369 (581)	-211 (11)	0.50
< 2 hours	15	6363 (492)	6535 (468)	172 (442)	

* Mixed-model repeated measures adjusted for wear-time minutes (group by time interactions), significance at $p < .05$

† Within-group difference was statistically significant ($p=0.04$)

Table 2.5. Odds of high level of engagement in self-monitoring with the Fitbit One and text-messaging as simple reminders by baseline level of self-efficacy and outcome expectations

	N	OR (95% CI)	
		Self-Efficacy (high)	Outcome Expectations (high)
Self-Monitoring w/ Fitbit One (Dose-Received)	61		
FB Tracker Use (per day)			
Frequency of viewing steps "Very often" or "Often"	49	1.13 (0.30-4.35)	1.72 (0.48-6.15)
Frequency of viewing distance "Very often" or "Often"	38	0.95 (0.31-2.91)	1.32 (0.46-3.79)
Frequency of viewing flower for PA intensity "Very often" or "Often"	29	1.38 (0.46-4.10)	1.12 (0.40-3.14)
FB Website Use: logged onto Fitbit.com 5-7 days/week	46	1.69 (0.50-5.71)	1.04 (0.32-3.41)
FB Mobile App Use (yes)	22	0.69 (0.23-2.09)	1.66 (0.55-4.96)
Text-Messaging (Dose-Received)	31		
Engaged in PA after receiving text messages "Always," "Usually," or "Half the time"	14	1.36 (0.30-6.28)	1.19 (0.29-4.92)
Engaged in PA < 2 hours after receiving text messages	15	1.65 (0.36-7.60)	0.89 (0.22-3.66)

* Logistic regression, significance at $p < .05$

REFERENCES

1. Bassuk SS, Manson JE. Epidemiological evidence for the role of physical activity in reducing risk of type 2 diabetes and cardiovascular disease. *J Appl Physiol*. 2005;99(3):1193-204. doi:10.1152/jappphysiol.00160.2005.
2. Ehemann C, Henley SJ, Ballard-Barbash R, et al. Annual Report to the Nation on the status of cancer, 1975-2008, featuring cancers associated with excess weight and lack of sufficient physical activity. *Cancer*. 2012;118(9):2338-66. doi:10.1002/cncr.27514.
3. Malnick SDH, Knobler H. The medical complications of obesity. *QJM*. 2006;99(9):565-79. doi:10.1093/qjmed/hcl085.
4. Beasley JM, Kwan ML, Chen WY, et al. Meeting the physical activity guidelines and survival after breast cancer: findings from the after breast cancer pooling project. *Breast Cancer Res Treat*. 2012;131(2):637-43. doi:10.1007/s10549-011-1770-1.
5. Bandura A. Social cognitive theory of self-regulation. *Organ Behav Hum Decis Process*. 1991;50(2):248-287. doi:10.1016/0749-5978(91)90022-L.
6. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychol*. 2009;28(6):690-701. doi:10.1037/a0016136.
7. DuVall C, Dinger MK, Taylor EL, Bembien D. Minimal-contact physical activity interventions in women: a pilot study. *Am J Health Behav*. 28(3):280-6.
8. Tudor-Locke C. A preliminary study to determine instrument responsiveness to change with a walking program: physical activity logs versus pedometers. *Res Q Exerc Sport*. 2001;72(3):288-92.
9. Chan CB, Ryan DAJ, Tudor-Locke C. Health benefits of a pedometer-based physical activity intervention in sedentary workers. *Prev Med (Baltim)*. 2004;39(6):1215-22. doi:10.1016/j.ypmed.2004.04.053.
10. Kang M, Marshall SJ, Barreira T V., Lee J-O. Effect of Pedometer-Based Physical Activity Interventions. *Res Q Exerc Sport*. 2009;80(3):648-655. doi:10.1080/02701367.2009.10599604.
11. Faghri PD, Omokaro C, Parker C, Nichols E, Gustavesen S, Blozie E. E-technology and pedometer walking program to increase physical activity at work. *J Prim Prev*. 2008;29(1):73-91. doi:10.1007/s10935-007-0121-9.
12. Cadmus-Bertram L, Wang JB, Patterson RE, Newman VA, Parker BA, Pierce JP. Web-based self-monitoring for weight loss among overweight/obese

- women at increased risk for breast cancer: the HELP pilot study. *Psychooncology*. 2013;22(8):1821-8. doi:10.1002/pon.3219.
13. Vandelandotte C, Spathonis KM, Eakin EG, Owen N. Website-delivered physical activity interventions a review of the literature. *Am J Prev Med*. 2007;33(1):54-64. doi:10.1016/j.amepre.2007.02.041.
 14. Linnan L, Steckler A. Process Evaluation for Public Health Interventions and Research. *media.johnwiley.com.au*.
 15. Bandura A. *Self-Efficacy: The Exercise of Control*. Worth Publishers; 1997:604.
 16. Bandura A. Health promotion by social cognitive means. *Health Educ Behav*. 2004;31(2):143-64. doi:10.1177/1090198104263660.
 17. Bandura A. *Social Learning Theory*. Oxford, England: Prentice-Hall; 1977.
 18. Anderson ES, Winett RA, Wojcik JR, Williams DM. Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: social support, self-efficacy, outcome expectations and self-regulation in the guide-to-health trial. *J Health Psychol*. 2010;15(1):21-32. doi:10.1177/1359105309342297.
 19. McAuley E, Jacobson L. Self-Efficacy and Exercise Participation in Sedentary Adult Females. *Am J Heal Promot*. 1991;5(3):185-207. doi:10.4278/0890-1171-5.3.185.
 20. Mcauley E, Courneya KS. Adherence to exercise and physical activity as health-promoting behaviors: Attitudinal and self-efficacy influences. *Appl Prev Psychol*. 1993;2(2):65-77. doi:10.1016/S0962-1849(05)80113-1.
 21. Dzewaltowski DA, Noble JM, Shaw JM. Physical activity participation: Social cognitive theory versus the theories of reasoned action and planned behavior.
 22. Hofstetter CR, Hovell MF, Macera C, et al. Illness, injury, and correlates of aerobic exercise and walking: a community study. *Res Q Exerc Sport*. 1991;62(1):1-9.
 23. Sallis JF, Hovell MF, Hofstetter CR, et al. A multivariate study of determinants of vigorous exercise in a community sample. *Prev Med (Baltim)*. 1989;18(1):20-34.
 24. Carels RA, Darby LA, Rydin S, Douglass OM, Cacciapaglia HM, O'Brien WH. The relationship between self-monitoring, outcome expectancies, difficulties with eating and exercise, and physical activity and weight loss treatment outcomes. *Ann Behav Med*. 2005;30(3):182-90. doi:10.1207/s15324796abm3003_2.

25. Le Masurier GC, Lee SM, Tudor-Locke C. Motion sensor accuracy under controlled and free-living conditions. *Med Sci Sports Exerc.* 2004;36(5):905-10.
26. Bassett DR, Dinesh J. "Use of pedometers and accelerometers in clinical populations: validity and reliability issues." *Phys Ther Rev.* 2010;15.3(135).
27. Cnaan A, Laird NM, Slasor P. Using the general linear mixed model to analyse unbalanced repeated measures and longitudinal data. *Stat Med.* 1997;16(20):2349-80.
28. Watson A, Bickmore T, Cange A, Kulshreshtha A, Kvedar J. An internet-based virtual coach to promote physical activity adherence in overweight adults: randomized controlled trial. *J Med Internet Res.* 2012;14(1):e1. doi:10.2196/jmir.1629.
29. Harvey-Berino J, Pintauro SJ, Gold EC. The feasibility of using Internet support for the maintenance of weight loss. *Behav Modif.* 2002;26(1):103-16.
30. Harvey-Berino J, Pintauro S, Buzzell P, et al. Does using the Internet facilitate the maintenance of weight loss? *Int J Obes Relat Metab Disord.* 2002;26(9):1254-60. doi:10.1038/sj.ijo.0802051.
31. Harvey-Berino J, Pintauro S, Buzzell P, Gold EC. Effect of internet support on the long-term maintenance of weight loss. *Obes Res.* 2004;12(2):320-9. doi:10.1038/oby.2004.40.
32. Tate DF. Using Internet Technology to Deliver a Behavioral Weight Loss Program. *JAMA.* 2001;285(9):1172. doi:10.1001/jama.285.9.1172.
33. Tate DF, Jackvony EH, Wing RR. Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: A randomized trial.
34. Hurling R, Catt M, Boni M De, et al. Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. *J Med Internet Res.* 2007;9(2):e7. doi:10.2196/jmir.9.2.e7.
35. Conroy MB, Yang K, Elci OU, et al. Physical activity self-monitoring and weight loss: 6-month results of the SMART trial. *Med Sci Sports Exerc.* 2011;43(8):1568-74. doi:10.1249/MSS.0b013e31820b9395.
36. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. *J Am Diet Assoc.* 2011;111(1):92-102. doi:10.1016/j.jada.2010.10.008.
37. Gleeson-Kreig JM. Self-monitoring of physical activity: effects on self-efficacy and behavior in people with type 2 diabetes. *Diabetes Educ.* 32(1):69-77. doi:10.1177/0145721705284285.

38. Dilorio CK. *Measurement in Health Behavior: Methods for Research and Evaluation (Google eBook)*. John Wiley & Sons; 2006:336.

CHAPTER 3

Associations of Baseline Depressive Symptoms with Adherence to Study Protocols and Changes in Dietary Behavior

ABSTRACT

Background: Behavioral activation strategies may limit effects of depressive symptoms on higher attrition and lower behavioral change.

Purpose: To identify whether the Women's Healthy Eating and Living (WHEL) study intervention improved protocol adherence and plant-based dietary change in those with elevated depressive symptoms.

Methods: A 6-item CES-D questionnaire identified elevated depressive symptoms at baseline in 2,817 WHEL study participants. Dietary assessments (set of four 24 hour telephone recalls) and clinic visits (blood sample) occurred at baseline, year 1 and 4. Plasma carotenoids provided objective measures of change in vegetable-fruit consumption.

Results: Less protocol adherence in depressed participants occurred in control but not intervention groups. Even in depressive participants with poor baseline diet, the intervention increased intake of vegetables-fruits (+37.2%) and fiber (+49.0%), and reducing fat (-22.4%) over a longer term.

Conclusions: Adding behavioral activation to dietary interventions improves study engagement and achieves long-term change.

INTRODUCTION

Approximately one fifth of female breast cancer survivors who join behavior research studies have elevated depressive symptoms.^{1,2} Such women are more likely to have lower quality dietary patterns at baseline,³ resign from trials (dropout), and less likely to achieve study intervention targets.^{4,5} Thus, it would appear there is a need for behavioral interventions to incorporate strategies to reduce the effects of elevated depressive symptoms that might confound study results.

A popular therapeutic approach for treating depression is “behavioral activation.” In this framework, elevated depressive symptoms develop following periods of negative mood and behavioral avoidance, which are associated with a low rate of response-contingent positive reinforcement.⁶ This low rate of positive reinforcements could occur due to a combination of the following four conditions: (1) decreased number of reinforcing events, (2) decreased availability of reinforcers, (3) deficits in behavior needed to experience reward, and (4) increased experience of aversive/punishing stimuli. Interventions containing behavioral activation strategies focus on overcoming these four conditions.⁷

The Women’s Healthy Eating and Living (WHEL) study consisted of a telephone counseling intervention that used client-centered counseling techniques including those consistent with behavioral activation and social cognitive theory.⁸ The study focused on building motivation for dietary change prior to the start of counseling. In Phase 1, the counseling intervention focused on helping participants to set challenging but attainable proximal goals, self-monitor, and evaluate performance such as acknowledging their successes to maintain their motivation and encourage further attempts to modify their diet. Phase 2 of the intervention focused on assisting

participants to identify and make a plan to reduce potential barriers in an effort to consolidate these new dietary changes into their daily lifestyles. The WHEL study intervention consisted largely of behavioral activation strategies, and thus, likely increased the number of reinforcing events among participants with elevated depressive symptoms. Specifically, study components increased the availability of reinforcers by providing many opportunities to receive rewards. Previous studies have already reported this intervention was successful in achieving and maintaining major long-term change in dietary patterns across the entire intervention group,⁸ however, the effect of the intervention on those with elevated depressive symptoms remains unclear.

In this analysis, we hypothesized that participants with elevated depressive symptoms were more likely to be unhealthy compared to the rest of the study sample. Additionally, we hypothesized those with elevated depressive symptoms would have higher dropout rates from key study assessments, and that these dropout rates would be higher in control group participants. In terms of dietary change (intervention group only), we hypothesized that elevated depressive symptoms were associated with lower levels of dietary change, particularly among those who had to make the most change to meet study behavioral targets.

METHODS

Study Population

The WHEL study population recruited women within 4 years of an early stage breast cancer diagnosis from 7 clinical sites in the south and west regions of the

United States. Study recruitment included sending invitation letters to women listed on cancer center registries or identified through medical record searches as well as advertisements with cancer support groups, cancer event fund-raisers, and the general media. Inclusion criteria included women aged 18-70 years at time of breast cancer diagnosis, with no co-morbidity for which the study dietary pattern might be contraindicated, and a life expectancy of at least 10 years. In this analysis, we excluded all women who had an additional breast event or died prior to the 4-year study point, resulting in a sample size of 2817 women.

Intervention Targets

Participants were informed that they would be randomized to implement one of two healthy dietary patterns: (1) United States Department of Agriculture (USDA) Dietary Guidelines for Americans, National Cancer Institute (NCI): 5 vegetables or fruits, 20 grams of fiber and 30% energy from fat^{9,10} or (2) the WHEL dietary intervention: 5 vegetable servings, 16 ounces of vegetable juice, 3 fruits, 30 grams of fiber, and 20% energy from fat.⁹

Intervention Components

The WHEL study intervention arm included telephone counseling, 12 cooking classes in the first year of the intervention, and the provision of regular newsletters and print materials as an adjunct to the telephone coaching. The four-phase telephone intervention began with pre-counseling motivation for self-change. Phase 1 counseling was an intensive 3-8 calls (call durations targeted 45 min) over 4-6 weeks focused on self-regulatory skills to explore maximal dietary change; phase 2 involved 16 calls over 4 months (similar call durations) focused on consolidating change into

lifestyle; and phase 3 started with 9 monthly calls followed by quarterly calls (call duration targeted 20 minutes) throughout the 6 year intervention period. Participants in the WHEL study arm received an average of 31 intervention calls. Those in the NCI comparison group arm were provided print materials on dietary guidelines from the USDA and the NCI in addition to 4 cooking classes and newsletters (not associated with components of the targeted dietary pattern).

Extrinsic Incentives for Completion of Study Assessments

The study used a “frequent flyer” type program to motivate participants to complete study-based assessments including questionnaires, dietary recalls, clinic visits including blood draws, and semi-annual check-in calls. Points were assigned to each activity according to its importance to the study and awarded to participants’ “accounts” after the activity was completed. Both study groups could receive the same points for completing assessments. Participants could retrieve their points through gift certificates donated from either Walmart or Macy’s or they could put their points into a once-per-year raffle for two within-the-United States round-trip tickets from Southwest Airlines.

Measures

Depressive Symptoms

The validated 6-item short form of the Center for Epidemiologic Studies Depression Scale (CES-D) was used to assess depressive symptoms.^{11,12} Participants were asked to rate how often they experienced the following in the past week: (1) You felt depressed, (2) Your sleep was restless, (3) You enjoyed life, (4) You had crying spells, (5) You felt sad, and (6) You felt that people disliked you.

Items were scored as 0 = rarely or none of the time (< 1 day), 1 = some or a little of the time (1-2 days), 2 = occasionally or a moderate amount of the time (3-4 days), or 3 = most or all of the time (5-7 days). Item 3 was reverse-scored. The standard threshold value of greater or equal to 5 was used to define a higher level of depressive symptoms.¹¹⁻¹⁴

Dietary Assessments

Self-reported dietary intake was collected using sets of four 24-hour recalls at baseline, 6 months (half sample), year 1, year 2 (half sample), year 3 (half sample), year 4, and year 6. Prior to the start of the study, baseline, years 1 and 4 were identified as the critical assessment periods for measure of adherence. Trained assessors scheduled dietary assessment calls from 4 randomly selected days stratified by week and weekend days within a 3-week window around the year 1 time-point. All dietary assessments used the multiple-pass and multiple-probe approach within the Minnesota Nutritional Data System software (NDS-R, 1994-2006). Dietary assessments were scheduled around clinic visits for anthropometric measurement and venipuncture blood collection.

Measurement of Carotenoids Intake

The WHEL study group intervention was aimed at achieving a major increase in circulating carotenoids from vegetables (mainly) and fruit intake. Details of laboratory procedures for analysis of plasma content (in $\mu\text{mol/L}$) of α -carotene, β -carotene, lycopene, β -cryptoxanthin, and lutein plus zeaxanthin have been previously published.¹⁵ Measurement error analyses showed the superiority of the measurement

of change using plasma carotenoids compared to self-reported consumption of vegetables-fruits.¹⁶

Physical Activity Measure

The study used (and validated) a 9-item scale assessing recreational walking and light, moderate, and vigorous physical activity using a standard frequency by duration item format.¹⁷

Statistical analysis

Chi-square tests were conducted to compare proportions of baseline CES-D cutoff scores within age, education, race, BMI (kg/m²), physical activity (MET-hrs/wk), years since breast cancer diagnosis to study entry, and dietary intake categories. Adherence rates of dietary assessments and clinic visits were calculated by study group and CES-D cutoff scores for years 1 and 4. Logistic regression models were also used to calculate the odds of completing assessments and attending clinic visits by study group and CES-D cutoff scores. Previous analyses have indicated that participants with poorer dietary intake at baseline were associated with greater improvements in dietary changes at follow-up.¹⁸ Accordingly, in the present study, dietary variables were dichotomized. The median of baseline plasma total carotenoid concentration was used to categorize participants as meeting (above median) or not meeting (below median) national recommendations for daily intake of fruits & vegetables (5 servings), fiber (25 grams for women), and percent energy from fat (27.5%, mean of recommended range 25%-30%). Tests of associations were conducted to examine percent change of dietary targets from baseline to year 1 and

year 1 to year 4. All models were adjusted for age, BMI, and physical activity, and as needed, also adjusted for baseline dietary intake. Statistical analysis was performed using SAS 9.3 (SAS Institute Cary, NC).

RESULTS

Of the 2,817 women included in this study, most were non-Hispanic White (86%), college graduates or higher (54%), over the age of 50 (64%), and with a body mass index (42% normal, 31% overweight and 27% obese. Approximately 21% met the threshold criteria for having elevated depressive symptoms.

Table 3.1 compares characteristics of study participants with and without elevated depressive symptoms. Those with elevated depressive symptoms were equally allocated to each study group. Elevated symptoms were more likely in younger survivors (< 50 years of age; $p=0.001$), obese ($\text{BMI} \geq 30 \text{ kg/m}^2$; $p < .0001$), minority ethnicity ($p=0.04$), less physically active (< 10 MET-hrs/wk; $p < .0001$), and recently diagnosed with breast cancer (< 2 years since diagnosis compared to 3 or 4 years since diagnosis; $p < 0.001$). Additionally, $\text{CES-D} \geq 5$ was associated with lower self-reported intake of fruits and vegetables ($p < .0001$), lower measured plasma carotenoid concentrations ($p < 0.01$), and a higher percent of energy from fat ($p=0.03$). Elevated depressive symptoms were not associated with levels of education ($p=0.19$), intake of fiber ($p=0.29$).

The association between elevated symptoms and non-completion of study assessments at study time-points, years 1 and 4, for both study arms is presented in **Table 3.2**. At the year 1 time-point, control group participants with elevated

depressive symptoms (compared to those without) had significantly higher odds of not completing dietary assessments (12% vs. 6%, OR=1.94; 95% CI: 1.26, 3.00). There were no significant differences in completion rates by depressive symptoms in the intervention group. Although, intervention participants without depressive symptoms had a non-completion rate of 12%, which was similar to that of control participants with elevated depression symptoms (12%) and well above control participants without elevated depression symptoms (6%).

For the first year clinic visit, the control group had a higher non-completion rate among those with vs. without elevated depressive symptoms (19% vs. 12%, OR=1.66; 95% CI: 1.17, 2.34) (Table 2). No such difference was observed by depressive symptoms in the intervention groups, although non-completion was higher in the intervention group without depressive symptoms (15%) compared to the control group without depressive symptoms (12%).

Similarly, in year 4, control participants with elevated depressive symptoms (compared to those without) had significantly higher odds of both non-completion of dietary assessments (18% vs. 9%; OR=2.03; 95% CI: 1.40, 2.97) and clinic visits (22% vs. 15%; OR=1.48; CI: 1.06, 2.07). Again, in the intervention group, there was no significant difference by depressive symptoms for completion of either dietary assessments (19% vs. 16%) or clinic visits (25% vs. 12%). As in year 1, intervention participants without elevated depressive symptoms had a non-completion rate of 12%, which was closer to those in the control group with elevated depressive symptoms (22%) and below control participant without elevated depressive symptoms (15%).

The between-group level of change in the study between baseline and year 4 is presented in **Table 3.3**. There was no between-group difference in plasma

carotenoids at baseline, however, the intervention group increased by 47.4% by four years compared to an increase of only 6.2% in the control group ($p<0.0001$).

Similarly, there was no between-group difference in fiber intake at baseline but a major increase in the intervention group by year 4 (25.9%), whereas there was a reduction of 4.9% in the control group ($p<0.0001$). Finally, there was no between-group difference in percent energy consumed from fat sources at baseline. By year 4, there was a very slight decline in this measure of fat consumption in the intervention group with a 14.4% increase in the control group ($p<0.0001$).

The mean (SD) percent changes in key dietary targets among depression subgroups within the intervention group are presented for study time-points years 1 and 4 in **Table 3.4**. Vegetable and fruit consumption was categorized according to self-reported intake at baseline, and percent changes in plasma carotenoids (a biomarker of vegetable and fruit consumption) were reported. Starting with changes over the first year, among those who reported intake of < 5 vegetables-fruits at baseline, the percent change in plasma carotenoids (although high) was much lower among those with elevated depressive symptoms compared to those without (37.2% vs. 69.7%, $p=0.02$). Similar subgroup differences in percent change were observed in those with lower intake of fiber at baseline (61.2% vs. 49.0%; $p=0.008$), and higher intake of energy from fat (-27.7% vs. -22.4%; $p=0.02$). There were no significant differences in percent change among those who were in the higher categories of intake for vegetables and fruits (75.5% vs. 73.2%) or fiber (12.8% vs. 9.2%) or the lower category of energy from fat (-6.6% vs. -8.0%).

Additionally, **Table 3.4** presents analysis of whether depressive symptoms impacted the degree of relapse prevention achieved by the intervention. There were no differences by depressive symptoms in the decline of vegetables and fruits

(decline of 6-15% in all groups) or fiber (decline of 8-12% in all groups). However, there was a significant difference among those who consumed more energy from fat at baseline; those with depressive symptoms increased more of their fat intake than those without (38% vs. 27%, $p=0.04$).

DISCUSSION

Although the WHEL study enrolled and randomized a high percentage of breast cancer survivors who were screened, the proportion of these participants with elevated depressive symptoms was similar to that reported in other studies.^{4,19,20} Previously, we have reported that the majority of these depressive symptoms were not related to their breast cancer diagnosis.²¹ Compared to study participants who did not have elevated depressive symptoms, these women were less likely to have healthy behaviors, particularly eating at least 5 vegetable-fruit servings per day, the major dietary target of this study. In addition, those with elevated depressive symptoms were much more likely to be obese and have lower levels of physical activity. As this study aimed to test the role of changing to a plant-based dietary pattern, it was important to maintain participants' engagement in the study and to assist them to make a major long term change in eating pattern.

The minimum-contact control group demonstrated the known effect that those with elevated depressive symptoms were less likely to adhere to study assessments. Those with elevated depressive symptoms were almost twice as likely to miss the 1 year dietary assessments and they had significantly lower attendance at the study clinic visit. These non-completion rates increased over time, and at least for the dietary assessment, the gap between those with and without depressive symptoms

increased. However, while this effect was similar to the inverse relationship between depression levels and engagement among other studies,^{11,22} the level of engagement in the WHEL study was significantly higher than those studies. This is probably attributable to the innovative use of extrinsic motivators to maximize these completion rates. Some have explained the inverse effect of depressive symptoms on study engagement by noting that those with elevated depressive symptoms are more likely to have “ruminative responses” that involve repetitively and passively thinking about negative emotions and focusing on symptoms that cause distress.²³

A standard treatment for elevated depressive symptoms is behavioral activation^{24,25} which sets out to increase positive reinforcements.^{26,27} The WHEL study intervention can also be characterized as a behavioral activation intervention. The first component of the intervention focused on building motivation to make the dietary change and the evidence that the behavior change could significantly reduce one of participants’ greatest fears - a return of their cancer. By working closely with participants and using client-centered counseling, the counseling component should have significantly increased the number of reinforcing events as telephone coaches assisted participants in setting challenging but achievable goals and providing frequent positive feedback on the participant's performance.

There was no such difference between those with and without depressive symptoms in the intervention group, either in completion of dietary assessments or attendance at clinic visits at either year 1 or year 4 study time-points. This is the most desirable result for comparing the effect of the study intervention on those with and without depressive symptoms. However, it was unexpected that the completion rate in the intervention group was comparable to the lower completion rate in the control group with elevated depressive symptoms. This occurred for both dietary

assessments and clinic visits at both year 1 and year 4 time-points. One possible reason for this was the level of participant burden that was involved with the intensive intervention. In the first year, there were approximately 20 telephone coaching calls of approximately 45 minutes in duration.^{19,28} This lack of difference in the intervention group could not be attributed to the extrinsic motivation program as this only applied to the study assessments and the rewards were equivalent across study groups.

As noted, the equivalent completion rates for assessment between those in the intervention group with and without elevated depressive symptoms created the ideal setting to compare the relative effectiveness of the intervention in each of these groups. First of all, we noted that the intervention achieved large levels of change compared to the control group in each of the three major dietary targets in this population that were maintained over four years. Plasma carotenoids (objective marker of vegetables-fruit) increased by almost 50%, fiber increased by 25%, and energy consumed from fat sources were stable in the intervention group but increased in the control group.

To better understand the possible differential effect with depressive symptoms, we dichotomized the intervention group on the quality of their dietary pattern at baseline. Over the first year of the study, for the sub-population that needed to make the least change to achieve the study dietary targets, there were no differences in the change achieved by those with and without elevated depressive symptoms for any of the 3 major dietary targets. The major emphasis of the intervention on using vegetable juice was undoubtedly the reason why plasma carotenoids increased so markedly in this group, regardless of depressive symptoms. Changes in fiber and fat were much smaller and reflected the proximity of the baseline diet to the study targets.

For the sub-population furthest from the dietary target at baseline, the changes achieved by those with elevated depressive symptoms were significantly less than those achieved by those without depressive symptoms for each dietary variable. However the changes achieved in each of the dietary targets were much higher than those reported for a number of other studies.²⁹ Between year 1 and year 4, there was a consistent decline for both those with and without depressive symptoms in plasma carotenoids (6-8%) and in dietary fiber intake (8-12%). However, the increase in consumption of energy from fat was significantly higher among those with elevated depressive symptoms compared to those without. This suggests that the dietary fat goal was the more difficult one to adhere to in the study. Shortly after the study started, the Atkins diet started to be heavily promoted and each 6 month intake of participants had a baseline intake of energy from fat that was 0.5 percentage points higher than the previous intake.³⁰ Those with elevated depressive symptoms were also more likely to be overweight or obese and the media messages promoting a high fat dietary pattern were probably more salient for them.

A limitation of this study is that it did not measure the components of the theory for how behavioral activation should work. However, a noted strength is that the study was a large randomized trial with a significant sub-population with elevated depressive symptoms. The study population consisted of females who were mostly over the age of 50 who are in one of the highest population groups with elevated depressive symptoms. However, generalizability of results is limited as this is a sample of breast cancer survivors who were highly motivated to make a behavior change that might reduce their risk of recurrence. Importantly, previous studies have indicated that breast cancer diagnosis was not associated with their elevated depressive symptoms.²¹ Another limitation was that this study relied on a 6-item self-

reported depression instrument (Burnam screen) that could have also measured participants' anxiety and psychological distress,¹² although this depression screening instrument has high sensitivity and specificity for diagnosing clinical depression. Another major strength of the study was the availability of a biological measure of carotenoids intake, the source of which is consumption of vegetables and fruits - the major behavior change targeted in the study.

Conclusions

Elevated depressive symptoms at baseline reduced adherence to important study assessments for both the behavior being targeted (dietary pattern) and clinic visits that included the collection of biological samples. The WHEL intervention included a number of components in common with behavioral activation interventions for people with depression. This intervention maintained a level of engagement in participants with elevated depressive symptoms at an equal level as those without such symptoms. Additionally, it was highly successful in encouraging participants to make major changes to their dietary pattern. For those closest to the dietary targets at baseline, there was no difference in the level of change achieved by those with and without elevated depressive symptoms. For those with baseline dietary patterns that required the most change to achieve the study targets, those with elevated depressive symptoms made large changes to their dietary pattern, but these changes were less than those made by participants without elevated depressive symptoms. These findings suggest that future behavior change studies should include components of behavioral activation into the intervention. However, further research is needed to elucidate the mechanisms by which this combination intervention has its effect.

ACKNOWLEDGEMENTS

This study was supported by a gift from the Vissiliadis family. The WHEL study was support by NCI grant CA69375; University of California, San Diego General Clinical Research Center NIH grant M01-RR00827; University of California, San Francisco General Clinical Research Center NIH gran M01-RR00079; Stanford University General Clinical Research Center NIH grant M01-RR0070; and the Walton Family Foundation. The study would like to thank Susan Wancewicz for her assistance in gathering WHEL data.

Chapter 3 is currently being prepared for submission for the publication of the material. Julie Wang, Shirley Flatt, Lisa Cadmus-Bertram, Loki Natarajan, Vicky Newman, Guadalupe Ayala, Hala Madanat, Jeanne Nichols, and John Pierce. The dissertation author was the primary investigator and author of this material.

Table 3.1. Participant characteristics by 6-Item CES-D cutoff scores of ≥ 5 indicating baseline depressive symptoms (N=2,817)

	N	< 5	≥ 5	p-value
Study Group				0.77
Intervention	1398	79	21	
Control	1419	80	20	
Age (years)				0.001*
< 50	1010	76	24	
≥ 50	1807	81	19	
Education				0.19
Never attended college	424	78	22	
Some college	866	78	22	
College graduate or higher	1527	81	19	
Race				0.04*
Non-Hispanic White	2409	80	20	
Other	408	75	25	
BMI (kg/m²)				<.0001*
< 30	2081	82	19	
≥ 30	736	73	27	
Physical activity**				<.0001*
< 10 MET-hrs/wk	1348	75	25	
≥ 10 MET-hrs/wk	1469	83	17	
Breast cancer diagnosis to study entry				0.003*
< 1 year ago	624	76	24	
1-2 years ago	911	77	23	
2-3 years ago	701	83	17	
3 or more years ago	578	82	18	
Total blood carotenoids ($\mu\text{mol/L}$)				.006*
<1.99 (below median)	1416	77	23	
≥ 1.99 (above median)	1401	81	19	
STUDY TARGETS				
Fruit & vegetable (svgs/day)				<.0001*
<5	715	74	26	
≥ 5	2102	81	19	
Fiber (g/day)				0.29
>25	726	81	19	
<25	2091	79	21	
%Energy from fat				0.03*
< 27.5	1246	81	19	
≥ 27.5	1571	78	22	

* Chi-square significance level $p < 0.05$

** A cutoff of 10 MET-hours physical activity was used to approximate recommended guidelines of 150 minutes/week

Table 3.2. Odds of not completing dietary assessments and clinic visits at year 1 and year 4 follow-up by baseline 6-item CES-D depression cutoff scores of ≥ 5 indicating baseline depressive symptoms, adjusted for age, BMI, and PA

	N	Dietary Assessments		Clinic Visits	
		% Not Completed	OR (95% CI)	% Not Completed	OR (95% CI)
YEAR 1					
Intervention					
CES-D < 5	1106	12		15	
CES-D ≥ 5	292	13	1.06 (0.72 – 1.57)	17	1.00 (0.70 – 1.43)
Control					
CES-D < 5	1129	6		12	
CES-D ≥ 5	290	12	1.94 (1.26 – 3.00)*	19	1.66 (1.17 – 2.34)*
YEAR 4					
Intervention					
CES-D < 5	1012	16		22	
CES-D ≥ 5	275	19	1.02 (0.72 – 1.46)	25	1.01 (0.73 – 1.40)
Control					
CES-D < 5	1028	9		15	
CES-D ≥ 5	274	18	2.03 (1.40 – 2.97)*	22	1.48 (1.06 – 2.07)*

* Logistic regression significance level $p < 0.05$

Table 3.3. Mean (SE) total plasma carotenoid concentrations, dietary fiber, and percent energy from fat

	Mean (SE)		<i>p</i> -value
	Intervention	Control	
Carotenoids (μmol/L) at baseline	2.3 (0.04)	2.3 (0.04)	0.33
Carotenoids (μmol/L) at year 4	3.2 (0.07)	2.2 (0.04)	<.0001*
% difference from baseline-year 4	47.7 (3.0)	6.2 (1.5)	<.0001*
Fiber grams/day at baseline	21.2 (0.2)	21.2 (0.2)	0.98
Fiber grams/day at year 4	25.2 (0.3)	19.3 (0.2)	<.0001*
% difference baseline-year 4	25.9 (1.6)	-4.9 (1.0)	<.0001*
% Energy from fat at baseline	28.4 (0.2)	28.7 (0.2)	0.34
% Energy from fat at year 4	27.2 (0.2)	31.4 (0.2)	<.0001*
% difference baseline-year 4	-0.0 (1.0)	14.4 (1.0)	<.0001*

* 2-sample t-tests significance level $p < 0.05$

Table 3.4. Mean (SE) percent change in dietary targets from baseline to year 1 and year 1 to year 4 by 6-Item CES-D depression cutoff scores of ≥ 5 in intervention group participants

	N	< 5	N	≥ 5	p-value
BASELINE TO YEAR 1					
Carotenoids by baseline vegetables-fruits intake					
<5 servings/day	210	69.7 (6.9)	72	37.2 (7.2)	0.02*
≥ 5 servings/day	717	75.5 (3.3)	166	73.2 (8.2)	0.54
Fiber (grams/day)					
< 25	723	61.2 (2.2)	186	49.0 (4.2)	< 0.01*
≥ 25	253	12.8 (1.9)	67	9.2 (4.6)	0.57
% Energy from fat (per day)					
< 27.5	449	-6.6 (1.4)	105	-8.0 (3.3)	0.73
≥ 27.5	527	-26.7 (0.9)	148	-22.4 (1.8)	0.02*
YEAR 1 – YEAR 4					
Carotenoids by baseline vegetables-fruits intake					
< 5 serv/d	153	-6.1 (3.8)	56	-7.3 (5.1)	0.34
≥ 5 serv/d	557	-7.9 (1.7)	130	-6.6 (4.6)	0.76
Fiber (grams per day)					
< 25	601	-11.4 (1.2)	161	-11.6 (2.6)	0.86
≥ 25	218	-7.8 (1.7)	58	-9.5 (3.5)	0.87
% Energy from fat (per day)					
< 27.5	376	27.3 (2.0)	88	37.9 (5.9)	0.04*
≥ 27.5	443	24.7 (1.9)	131	23.7 (3.7)	0.68

* ANCOVA significance level $p < 0.05$, adjusted for baseline dietary intake, age, BMI, and physical activity

REFERENCES

1. Massie MJ. Prevalence of depression in patients with cancer. *J Natl Cancer Inst Monogr.* 2004;2004(32):57-71. doi:10.1093/jncimonographs/lgh014.
2. Bower JE, Ganz PA, Irwin MR, Kwan L, Breen EC, Cole SW. Inflammation and behavioral symptoms after breast cancer treatment: do fatigue, depression, and sleep disturbance share a common underlying mechanism? *J Clin Oncol.* 2011;29(26):3517-22. doi:10.1200/JCO.2011.36.1154.
3. Appelhans BM, Whited MC, Schneider KL, et al. Depression severity, diet quality, and physical activity in women with obesity and depression. *J Acad Nutr Diet.* 2012;112(5):693-8. doi:10.1016/j.jand.2012.02.006.
4. Somerset SM, Graham L, Markwell K. Depression scores predict adherence in a dietary weight loss intervention trial. *Clin Nutr.* 2011;30(5):593-8. doi:10.1016/j.clnu.2011.04.004.
5. Williamson DA, Anton SD, Han H, et al. Adherence is a multi-dimensional construct in the POUNDS LOST trial. *J Behav Med.* 2010;33(1):35-46. doi:10.1007/s10865-009-9230-7.
6. Dimidjian S, Barrera M, Martell C, Muñoz RF, Lewinsohn PM. The origins and current status of behavioral activation treatments for depression. *Annu Rev Clin Psychol.* 2011;7:1-38. doi:10.1146/annurev-clinpsy-032210-104535.
7. Hershenberg R, Paulson D, Gros DF, Acierno R. Does Amount and Type of Activity Matter in Behavioral Activation? A Preliminary Investigation of the Relationship between Pleasant, Functional, and Social Activities and Outcome. *Behav Cogn Psychother.* 2014:1-16. doi:10.1017/S1352465813001185.
8. Pierce JP, Natarajan L, Caan BJ, et al. Influence of a diet very high in vegetables, fruit, and fiber and low in fat on prognosis following treatment for breast cancer: the Women's Healthy Eating and Living (WHEL) randomized trial. *JAMA.* 2007;298(3):289-98. doi:10.1001/jama.298.3.289.
9. Pierce JP, Faerber S, Wright FA, et al. Feasibility of a randomized trial of a high-vegetable diet to prevent breast cancer recurrence. *Nutr Cancer.* 1997;28(3):282-8. doi:10.1080/01635589709514589.
10. Rock CL, Newman V, Flatt SW, Faerber S, Wright FA, Pierce JP. Nutrient intakes from foods and dietary supplements in women at risk for breast cancer recurrence. The Women's Healthy Eating and Living Study Group. *Nutr Cancer.* 1997;29(2):133-9. doi:10.1080/01635589709514614.
11. Wassertheil-Smoller S, Shumaker S, Ockene J, et al. Depression and cardiovascular sequelae in postmenopausal women. The Women's Health

- Initiative (WHI). *Arch Intern Med*. 2004;164(3):289-98. doi:10.1001/archinte.164.3.289.
12. Aggarwal A, Freund K, Sato A, et al. Are depressive symptoms associated with cancer screening and cancer stage at diagnosis among postmenopausal women? The Women's Health Initiative observational cohort. *J Womens Health (Larchmt)*. 2008;17(8):1353-61. doi:10.1089/jwh.2007.0544.
 13. Robins LN, Helzer JE, Croughan J, Ratcliff KS. National Institute of Mental Health Diagnostic Interview Schedule. Its history, characteristics, and validity. *Arch Gen Psychiatry*. 1981;38(4):381-9.
 14. Tuunainen A, Langer RD, Klauber MR, Kripke DF. Short version of the CES-D (Burnam screen) for depression in reference to the structured psychiatric interview. *Psychiatry Res*. 2001;103(2-3):261-70.
 15. Pierce JP, Natarajan L, Sun S, et al. Increases in plasma carotenoid concentrations in response to a major dietary change in the women's healthy eating and living study. *Cancer Epidemiol Biomarkers Prev*. 2006;15(10):1886-92. doi:10.1158/1055-9965.EPI-05-0928.
 16. Natarajan L, Pu M, Fan J, et al. Measurement error of dietary self-report in intervention trials. *Am J Epidemiol*. 2010;172(7):819-27. doi:10.1093/aje/kwq216.
 17. Johnson-Kozlow M, Rock CL, Gilpin EA, Hollenbach KA, Pierce JP. Validation of the WHI brief physical activity questionnaire among women diagnosed with breast cancer. *Am J Health Behav*. 31(2):193-202. doi:10.5555/ajhb.2007.31.2.193.
 18. Pierce JP, Newman VA, Natarajan L, et al. Telephone counseling helps maintain long-term adherence to a high-vegetable dietary pattern. *J Nutr*. 2007;137(10):2291-6.
 19. Pierce JP, Faerber S, Wright FA, et al. A randomized trial of the effect of a plant-based dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living (WHEL) Study. *Control Clin Trials*. 2002;23(6):728-56.
 20. Golden-Kreutz DM, Andersen BL. Depressive symptoms after breast cancer surgery: relationships with global, cancer-related, and life event stress. *Psychooncology*. 2004;13(3):211-20. doi:10.1002/pon.736.
 21. Bardwell WA, Natarajan L, Dimsdale JE, et al. Objective cancer-related variables are not associated with depressive symptoms in women treated for early-stage breast cancer. *J Clin Oncol*. 2006;24(16):2420-7. doi:10.1200/JCO.2005.02.0081.

22. Lanza E, Yu B, Murphy G, et al. The polyp prevention trial continued follow-up study: no effect of a low-fat, high-fiber, high-fruit, and -vegetable diet on adenoma recurrence eight years after randomization. *Cancer Epidemiol Biomarkers Prev.* 2007;16(9):1745-52. doi:10.1158/1055-9965.EPI-07-0127.
23. Nolen-Hoeksema S. The role of rumination in depressive disorders and mixed anxiety/depressive symptoms. *J Abnorm Psychol.* 2000;109(3):504-511. doi:10.1037/0021-843X.109.3.504.
24. Hopko DR, Lejuez CW, Ruggiero KJ, Eifert GH. Contemporary behavioral activation treatments for depression: Procedures, principles, and progress. *Clin Psychol Rev.* 2003;23(5):699-717. doi:10.1016/S0272-7358(03)00070-9.
25. Jacobson NS, Dobson KS, Truax PA, et al. A component analysis of cognitive-behavioral treatment for depression. *J Consult Clin Psychol.* 1996;64(2):295-304. doi:10.1037/0022-006X.64.2.295.
26. Addis ME, Jacobson NS. Reasons for depression and the process and outcome of cognitive-behavioral psychotherapies. *J Consult Clin Psychol.* 1996;64(6):1417-1424. doi:10.1037/0022-006X.64.6.1417.
27. Dichter GS, Felder JN, Smoski MJ. The effects of Brief Behavioral Activation Therapy for Depression on cognitive control in affective contexts: An fMRI investigation. *J Affect Disord.* 2010;126(1-2):236-44. doi:10.1016/j.jad.2010.03.022.
28. Newman VA, Thomson CA, Rock CL, et al. Achieving substantial changes in eating behavior among women previously treated for breast cancer--an overview of the intervention. *J Am Diet Assoc.* 2005;105(3):382-91; quiz 488. doi:10.1016/j.jada.2004.12.008.
29. Lara J, Hobbs N, Moynihan PJ, et al. Effectiveness of dietary interventions among adults of retirement age: a systematic review and meta-analysis of randomized controlled trials. *BMC Med.* 2014;12(1):60. doi:10.1186/1741-7015-12-60.
30. Pierce JP, Natarajan L, Caan BJ, et al. Influence of a diet very high in vegetables, fruit, and fiber and low in fat on prognosis following treatment for breast cancer: the Women's Healthy Eating and Living (WHEL) randomized trial. *JAMA.* 2007;298(3):289-98. doi:10.1001/jama.298.3.289.

DISCUSSION

In this dissertation, we examined the utility of two technologies with promising futures in advancing the field of health behavior research and practice. The first is SMS text messaging as an intervention modality to reach large audiences at potentially low cost and the other a commercially popular wearable sensor/device technology (Fitbit One) as a user-centered intervention approach for self-monitoring of PA. We tested these two technology-based interventions in a randomized controlled trial (Text2bfit Pilot Study) in a sample of overweight/obese adults, and examined participants' attitudes and level of engagement with each intervention component. We examined cognitive factors including self-efficacy and outcome expectations that might predict participants' level of engagement in using these devices. And finally, we examined the effects of an intensive telephone-based dietary counseling intervention, which consisted of behavioral activation strategies to increase level of engagement, among a large sample of post-menopausal breast cancer survivors with and without depressive symptoms. We provide the following summary of findings and recommendations for future research.

Summary of Findings & Recommendations

Study #1: Fitbit One for Self-Monitoring of PA and Text Messages as PA Prompts

In a randomized controlled feasibility trial (N=67), we tested the effects of SMS text messaging as simple PA prompts to increase PA. There were 2 main study results. First, there was a brief 1-week effect of the daily text messaging PA prompts, in which there were statistically significant increases of +1266 steps (SE=+491; $p=0.01$), +18 fairly and very active min/wk (SE=9; $p=0.04$), and +38 total active

min/wk ($SE=16$; $p=0.02$) with statistically significant study group differences (i.e., intervention vs. control). However, these effects occurred at week 1 and were not maintained thereafter. Therefore, text messaging in its basic form as simple PA prompts was not an effective intervention.

This result provides researchers with information on the use of text messaging in PA interventions. Specifically, text-messaging interventions to promote PA require significantly more than simple prompts. Previous text-messaging interventions have delivered significantly more content and have proven to be efficacious.¹ Therefore, we can conclude that it is not merely the experience of receiving a text message that triggers PA behavior; it appears that content of these text messages matter, or possibly other factors. In Chapter 1, a discussion on this result proposed the notion that it might not be the content to explain the positive study effects. A comparable PA intervention study with significantly more text messaging content also reported short-term effects, in which results were also based on objective measures of PA.² Taken together, the short-term study effects observed in both studies suggests that it might be possible the impersonal and automated nature of these 2 interventions were insufficient in keeping participants engaged for more than a week. Therefore, we recommend future text messaging interventions employ strategies that maintain participants' level of engagement such as those that are more individualized, adaptive, provide feedback, and/or are interactive.

The study's second finding was a significant increase of +4.3 min/wk of MVPA ($SE=2.0$; $p=0.04$) from baseline to 6-week follow-up in participants who received *only* the Fitbit One *without* the text messages (within-group). Both intervention and control group participants were provided a Fitbit One but only control participants increased their MVPA. In our exit survey, we found that our text messaging intervention might

have created some participant burden that caused them to disengage from study participation and this might have included the use of the Fitbit One. It turns out that a higher percentage of control group participants compared to the intervention group reported they frequently used the Fitbit One tracker for self-monitoring of PA levels. These results suggest that a wearable device/sensor, the Fitbit One, was effective in increasing MVPA. However, study group differences were not statistically significant and therefore warrant further research.

Study #2: Attitudes & Level of Engagement with the Fitbit One & Text Messages

In this analysis, we examined responses to study surveys to evaluate participants' attitudes and level of engagement with the Fitbit One and text messages. We found that most study participants reported that the Fitbit One was easy to use and helpful in increasing their level of PA, and there seemed to be a slight preference for the tracker compared to the website (for both ease of use and perceived helpfulness). The Fitbit One provides users with 3 options to self-monitor their PA levels: 1) tracker 2) website and 3) mobile app. In this trial, participants were asked to wear the tracker and upload their PA data every day. They had the option to download the Fitbit mobile app on their smartphones or tablets, and at follow-up, 36% of participants reported that they had used the Fitbit mobile app during the study. In this small sample of overweight/obese adults, which consisted mostly of middle-aged women, there was a statistically significant within-group increase of +545 steps/day (SE=265) from baseline to 6-week follow-up among those who reported that they had used the Fitbit mobile app ($p=0.04$). Comparatively, there were also increases in steps among participants who reported that they frequently used the tracker or website, but these results were not statistically significant. The Fitbit mobile app was

associated with higher steps at follow-up and this was stable even after adjusting for factors such as baseline motivation and previous web or app use for monitoring PA. Therefore, there is some indication that the mobile app might be a better option for self-monitoring of PA than the tracker or website.

Previous studies support that self-regulatory skills such as self-monitoring are effective in PA and dietary interventions.^{3,4} Fitbit One components, specifically the tracker, website, and mobile app, offer users with varying degrees of self-monitoring. The tracker, which is similar to a standard pedometer, is easily accessible as it is worn on the body and it provides instant feedback on PA performance. On the other hand, the website requires a little more effort since it typically involves access to a computer, but it provides significantly more detailed summaries of daily PA data. The mobile app offers a combination of the tracker and the website, in that, like the tracker, people have easier access to their mobile devices than their computers; and like the website, the mobile app is capable of providing more in-depth PA information than the tracker. Therefore, it might be possible that the mobile app provided more opportunities for self-monitoring with respect to both frequency (i.e., # times viewed) and intensity (i.e., amount of PA information processed). However, this result is limited in its interpretation as it is merely an association and lacks representation due to a small sample. Further, the between-group difference in steps among those who used mobile app vs. did not use mobile app was not statistically significant. Therefore, we recommend that future studies examine the utility of mobile apps as they become increasingly more accessible and popular among the general population. Further we recommend studies will examine more closely participants' level of engagement in using these technologies which are already widely available and used by the general public.

In the Text2bfit Pilot Study, more than half the intervention participants (55%) indicated that they ‘rarely’ or ‘never’ participated in a bout of PA after receiving a text message, which indicates a low level of engagement (or response) to text messages. In Chapter 1, we concluded that the text-messaging intervention was not effective in increasing PA levels (beyond 1 week). These results suggest that overall text messages as simple PA prompts were also not effective in keeping participants engaged. We observed in other studies that it is possible to train participants to self-monitor their PA performance using diaries and websites.⁵⁻⁸ Therefore, we recommend future studies will test the utility of text messaging to prompt self-monitoring of PA. Additionally, in this analysis, we did not find any evidence that self-efficacy or outcome expectations predicted self-monitoring. Therefore, studies are needed to examine whether such social cognitive measures might be useful in predicting self-monitoring behavior.

Study #3: Behavioral Activation for Depression to Enhance Level of Engagement

In a secondary analysis using data from the WHEL Study (N=2,817), our results supported the existing literature, depression was associated with higher rates of non-completion of study assessments and less dietary change (among those furthest from recommended levels at baseline). In this sample of post-menopausal breast cancer survivors, approximately 21% met the threshold criteria for having elevated depressive symptoms (CES-D score ≥ 5). There were 2 main study results. First, we found that women who had higher depressive symptoms were approximately 2-times more likely to *not* complete their dietary assessments or attend clinic visits at year 1 (OR=1.94, 95% CI: 1.26-3.00 or OR=2.03, CI: 1.40-2.97), and approximately 1.5-times more likely to *not* complete dietary assessments or attend

clinic visits at year 4 (OR=1.66, CI: 1.17-2.34 or OR=1.48, CI: 1.06-2.07). However, this was only observed in control group participants. The second main result was, we found that among intervention group participants, at year 1, women who had higher depressive symptoms (and who were furthest from recommended dietary targets at baseline) had significantly less improvements in dietary change compared to those with lower depressive symptoms, specifically, in their plasma carotenoid concentration levels (69.7% vs. 37.3%; $p=0.02$), fiber (61.2% vs. 49.0%; $p < .01$), and percent energy from fat (-27.7% vs. -22.4%; $p=0.02$).

If we consider these 2 main study results, it is clear that baseline depressive symptoms was associated with both non-completion of study assessments and clinic visits, and lower rates of making dietary improvements at year 1 follow-up. *But* higher non-completion by depression levels was only observed in the control group, which indicates that being in the WHEL intervention helped even women who were depressed to engage in completing study assessments and attending clinic visits. Additionally, while dietary changes were lower in women with higher depression levels, it is important to note that the WHEL Study intervention was still able to achieve considerable dietary change even among those who were depressed.

A closer examination of the WHEL Study intervention indicated that intervention components were congruent with behavioral activation strategies that are commonly used to treat patients with depression including increasing activity (engagement) with rewarding behaviors and reducing behavioral avoidance.^{9,10} It is important to note that additional analysis did not indicate change in depressive symptom scores across time. However, the WHEL intervention was still able keep participants engaged to complete assessments, attend clinic visits, and achieve dietary change. These study results strengthen the evidence to support a clear link

between depression and unhealthy behaviors including poorer diet. It adds that a possible recommendation in handling a subgroup of participants with high depressive symptoms might be the use of behavioral activation components to increase participants' level of engagement in the study. Therefore, we recommend future interventions not only identify this subpopulation to prevent drop-outs/missing data, but also consider the addition of supplemental intervention strategies to include behavioral activation components in keeping participants with higher depressive symptoms more engaged.

Conclusions

In a sample of overweight/obese adults, there was evidence to support that the Fitbit One was useful in helping participants to increase their PA levels. Overall, this dissertation suggests that a possible underlying mechanism for successful behavior change is participants' level of engagement irrespective of intervention modality or intervention approach. There are several findings from this study to support this claim. We found that an SMS text-messaging intervention that used simple PA prompts was not enough to keep participants engaged in the study and thus was not able to sustain changes beyond 1 week. We also found that those who used the Fitbit One, particularly the Fitbit mobile app, might have had more opportunities for self-monitoring of PA. Finally, we found that a large dietary intervention focused on behavioral activation was able to increase participation even among participants with higher depressive symptoms.

Collectively, this body of research suggests that interventions that focus on keeping participants engaged in the study are more likely to succeed in promoting change. Currently, there are a growing number of new technologies to facilitate self-

monitoring, which fits within the constructs of behavioral activation since it creates opportunities for rewarding behavior and reducing behavioral avoidance. However, level of engagement is completely up to the individual. Therefore, we need to have a better understanding of what factors are associated with self-monitoring. As new technologies come and go it is imperative that health behavior researchers examine the underlying principles to help us explain what motivates change. Nonetheless, there are significant advantages to testing commercially available products. Public-private partnerships in health behavior research might be the next big leap in health promotion at the population level.

REFERENCES

1. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev.* 2010;32(1):56-69. doi:10.1093/epirev/mxq004.
2. Hurling R, Catt M, Boni M De, et al. Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. *J Med Internet Res.* 2007;9(2):e7. doi:10.2196/jmir.9.2.e7.
3. Bandura A. Social cognitive theory of self-regulation. *Organ Behav Hum Decis Process.* 1991;50(2):248-287. doi:10.1016/0749-5978(91)90022-L.
4. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychol.* 2009;28(6):690-701. doi:10.1037/a0016136.
5. Cadmus-Bertram L, Wang JB, Patterson RE, Newman VA, Parker BA, Pierce JP. Web-based self-monitoring for weight loss among overweight/obese women at increased risk for breast cancer: the HELP pilot study. *Psychooncology.* 2013;22(8):1821-8. doi:10.1002/pon.3219.
6. Watson A, Bickmore T, Cange A, Kulshreshtha A, Kvedar J. An internet-based virtual coach to promote physical activity adherence in overweight adults: randomized controlled trial. *J Med Internet Res.* 2012;14(1):e1. doi:10.2196/jmir.1629.
7. Burke LE, Wang J, Sevvick MA. Self-monitoring in weight loss: a systematic review of the literature. *J Am Diet Assoc.* 2011;111(1):92-102. doi:10.1016/j.jada.2010.10.008.
8. Gleeson-Kreig JM. Self-monitoring of physical activity: effects on self-efficacy and behavior in people with type 2 diabetes. *Diabetes Educ.* 32(1):69-77. doi:10.1177/0145721705284285.
9. Hopko DR, Lejuez CW, Ruggiero KJ, Eifert GH. Contemporary behavioral activation treatments for depression: Procedures, principles, and progress. *Clin Psychol Rev.* 2003;23(5):699-717. doi:10.1016/S0272-7358(03)00070-9.
10. Jacobson NS, Dobson KS, Truax PA, et al. A component analysis of cognitive-behavioral treatment for depression. *J Consult Clin Psychol.* 1996;64(2):295-304. doi:10.1037/0022-006X.64.2.295.

APPENDICES

Appendix 1. Text2bfit pilot study recruitment flyer

Do You Want to Get FIT?

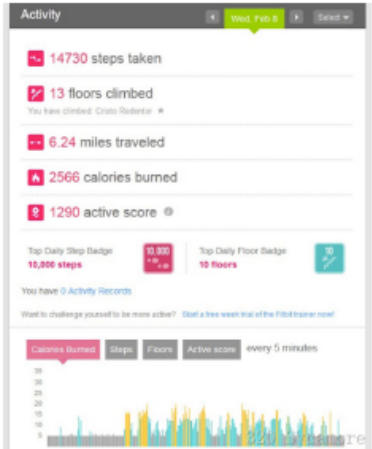
You May be Eligible for the UCSD **TXT2BFIT** Study...

Are you...?

- ☐ Between the ages of 18 – 69 years
- ☐ Overweight or obese
- ☐ A mobile phone owner
- ☐ Able to receive text messages
- ☐ A personal computer owner
- ☐ Able to access high speed internet
- ☐ Motivated to be more physically active AND
- ☐ Fluent in English



SOURCE: FITBIT.COM



SOURCE: FITBIT.COM

Are you willing to...?

- ☐ Participate in a 6-week study
- ☐ Receive text messages prompting exercise
- ☐ Wear a small device(s) to track & monitor physical activity
- ☐ Attend 1 study visit at UCSD
- ☐ Complete 1 questionnaire at study visit
- ☐ Complete 1 follow-up questionnaire (via telephone)

FOR MORE INFORMATION:
CALL (858) 822-2988

 UC San Diego
MOORES CANCER CENTER

Appendix 2. Text2bfit pilot study consent form

1 of 3
#130024**TXT2BFIT Pilot Study**
University of California, San Diego
Consent to Act as a Research Subject

John Pierce, PhD and his associates are conducting a research study to determine whether it may be possible to promote an increase in physical activity using the FitBit and daily text messages. You will be 1 of 48 participants in a 6-week intervention.

Participants who enroll in this study will be asked to wear the FitBit tracker and sync the data from their FitBit tracker to fitbit.com every day during the 6-week study period. Those who are randomly assigned (like a coin toss) into the treatment group will also receive 3 text messages every day throughout the 6-week study period. The messages will be delivered according to a preset schedule customized by the participant at the time of group randomization.

In addition, participants will be asked to concurrently wear the FitBit tracker and Actigraph GT3X, which are devices that monitor physical activity levels, for 7 consecutive days at 2 time-points: 1) the week prior to the start of the study, and again, 2) during Week 6 of the study. All participants will be asked to complete a baseline and follow-up questionnaire.

During the study period:

Attend One Study Appointment

You will be asked to attend a total of one study visit at the UCSD Moores Cancer Center. During this 1-hour visit, we will provide information about the study and ask for you to provide written signed consent. We will ask you to complete a brief survey and plan your physical activity goals for a typical week. We will also take your weight and height measurement for your BMI and show you how to use the FitBit activity meter, including instructions on how to return the device. The cost of parking will be paid by the study.

Study Surveys

As part of the study, you will complete a baseline questionnaire during the single study visit at the UCSD Moores Cancer Center and complete a follow-up questionnaire at the end of the 6-week study period *over the telephone*. The questionnaires are brief: the baseline questionnaire administered at the study visit will take about 10-15 minutes. The follow-up questionnaire at the end of the 6-week study period will be administered over the phone and take about 15-20 minutes. The information collected from the questionnaires will be private and confidential. Any identifiable information will be removed when the information is analyzed.

Wearing the FitBit & Actigraph GT3X

You will be provided a FitBit tracker and instructions on how to use the FitBit website (fitbit.com). You will be asked to wear the FitBit tracker and wirelessly sync the data every day for at least 10 hours per day for the entire 6-week study period. You will also be asked to concurrently wear the FitBit with the Actigraph for at least 10 hours per day for 7 consecutive days: 1 week at the beginning of the study (prior to being assigned into a study group) and 1 week toward the end of the study (Week 6 of the study period).

The FitBit also works alongside a website that shows your activity levels and allows you to track your activity, eating habits, and weight. You are encouraged to use the added online web features to conduct self-monitoring of your progress. The information collected by your FitBit can be viewed

Text2bfit Pilot Study Consent Form

PARTICIPANT ID:

online by you and can be accessed by our study staff through a shared account.

Study staff members will provide you with thorough instructions on returning and receiving devices via USPS mail. All postage will be provided by the study.

Receiving Text Messages

You will be notified of your study group over the telephone. If you are assigned to the treatment group, you will be asked to provide times of the day (in a typical week) in which you would like to receive text messages as simple reminders to prompt some physical activity such as going out for a brisk walk. You will receive only text messages based on your customized schedule. Further, you will receive text messages as simple reminders to put on your devices. All participants, regardless of their group assignment, may receive periodic text messages as reminders to wear their devices as needed. As mentioned in the telephone screening questionnaire, participants will be responsible for any costs incurred for text messages to/from this study.

Possible risks

Participation in the study may involve some minor risks and/or discomforts:

- Participation in physical activity carries an inherent risk for physical discomfort such as shortness of breath, potential risk for muscle/joint soreness, and other potential injuries.
- There is a possible, but unlikely, risk for loss of confidentiality. To minimize this risk, all paper records will be kept in locked filing cabinets in a locked file room at the Moores UCSD Cancer Center. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. All computerized study data is password protected and only accessible to key study personnel.
- In addition, because this is an investigational study, there may be some unknown risks that are currently unforeseeable.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject or to report research-related problems. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program at (858) 657-5100 for more information about this consent form or to report research-related problems.

Alternatives to Participation

If you decide not to participate, you can contact your regular medical provider about options to help you become more physically active.

Study Benefits

All participants will be provided the FitBit for use during the study and provided instructions on self-monitoring their activity levels online. Both the Fitbit tracker and website is commercially available to help people increase their physical activity levels and improve other health behaviors. This product will be offered to you for use during the study period and may help you to learn more about your own physical activity patterns and other health habits. (Note: you may not keep the device after the study period but will have the option to purchase for discounted rate.)

3 of 3
#130024

The study will cover parking costs for the one study visit to UCSD Moores Cancer Center. We will also provide you with a self-addressed prepaid package to return the devices as needed. In addition, we will also provide you with a \$25 gift card after successful completion of the study. However, you will be responsible for any expenses that have to do with other aspects of your participation (e.g., the study will not pay for your cell phone bill including text messaging charges; Internet access; equipment and/or memberships participate in physical activity).

Study Withdrawal

Participation in research is entirely voluntary. You may refuse to participate or withdraw any time by notifying any of our study staff members via telephone or email, at which point you will be asked to return any device to our study site using the return packages provided to you. You may be asked for your reasons for early termination. Any data collected prior to your withdrawal from the study may be used in our analysis of the study data. Per our standard protocol, no identifiable information will be linked to the information that we collect from you. Please be advised that you may be asked to withdraw from the study as a result of circumstantial events such as development of a medical condition that may prohibit you from adhering to the study procedures. Study researchers will let you know if significant new findings develop during the study that may influence your willingness to participate.

Research records and any information provided to study staff will be kept confidential to the extent provided by law.

_____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach the principal investigator, John Pierce, PhD, at (858) 822-2380.

You have received a copy of this consent document and a copy of "The Experimental Subject's Bill of Rights" for your records. You agree to participate.

Signature of Participant

Signature of Witness

Date

Appendix 3. Text2bfit pilot study telephone screening eligibility questionnaire

Confidential Page 1 of 4

Eligibility_Screening

Please complete the survey below.

Thank you!

Participant Number _____

Token _____

First Name _____

Last Name _____

Mobile Phone Number _____

Email Address _____

Street Address _____

City _____

Zip Code _____

1. How would you describe your current level of physical activity?

☐ Very active (exclusion)
☐ Active (exclusion)
☐ Somewhat active
☐ Not at all active
☐ Don't know/ refused (exclusion)

2. In general, how intense is the activity that you're doing when you are being physically active?

☐ Very intense
☐ Intense
☐ Somewhat intense
☐ Not intense
☐ Don't know/ refused (exclusion)

3. In a typical week, approximately how many DAYS are you physically active? This includes any activity that you do for at least 10 minutes that causes an increase in your breathing or heart rate (i.e., activities for work, transportation, and recreational/ leisure activities).

4. On those days, approximately how much time do you spend doing physical activity (MINUTES per day)?

5. How satisfied are you with your current level of physical activity?

☐ Very satisfied
☐ Somewhat satisfied
☐ Not at all satisfied
☐ Don't know/ refused (exclusion)

6. How committed are you to increasing your current level of physical activity?

☐ Very committed
☐ Somewhat committed
☐ Not at all committed (exclusion)
☐ Don't know/ refused (exclusion)

7. How much time would you be willing to commit each week to changing your current level of physical activity?

☐ 3 or more hours per week
☐ 2 hours per week
☐ 1 hour per week (exclusion)
☐ < 1 hour per week (exclusion)
☐ Don't know/ refused (exclusion)

www.project-redcap.org 

Confidential

Page 2 of 4

8. How soon would you be willing to make changes toward increasing your current physical activity levels?
- ☐ In the next 1-2 weeks
☐ In the next 3-4 weeks
☐ More than 1 month from today (exclusion)
☐ Don't know/ refused (exclusion)
9. Do you have any medical problems that limit your daily activity or your ability to perform regular exercise?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
10. Has your doctor ever said that you have a heart condition AND that you should only do physical activity recommended by a doctor?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
11. Do you feel pain in your chest when you do physical activity?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
12. In the past month, have you had chest pain when you were not doing physical activity?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
13. Do you lose your balance because of dizziness or do you ever lose consciousness?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
14. 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?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
15. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
16. Do you know of any other reasons why you should not do physical activity?
- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)
17. Do you have a personal cell phone?
- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)
18. Are you able to receive and send text messages from this cell phone?
- ☐ Yes,
☐ No (exclusion)
☐ Don't know/ refused (exclusion)
19. Do you have a monthly unlimited text messaging plan?
- ☐ Yes
☐ No
☐ Don't know/ refused (exclusion)
- 19a. Are you willing to be charged and pay for possible text messaging fees from your wireless carrier during the study period?
- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)
20. Would you be willing to keep your cell phone with you and turned on during waking hours throughout the 6-week study period?
- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)
21. If you're assigned to the treatment group, would you be willing and able to receive approximately 3 text messages every day during the 6-week study?
- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)
22. Do you have access to a personal computer?
- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

Confidential

Page 3 of 4

23. Which of the following describes the operating system installed on your computer?

- ☐ Windows XP/ Vista 7
☐ Mac OS X 10.5, 10.6, 10.7
☐ Other (exclusion)
☐ Don't know/ refused (exclusion)

24. Do you have Internet access in your home?

- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

25. How comfortable are you with using a computer?

- ☐ Very comfortable
☐ Comfortable
☐ Somewhat comfortable
☐ Not at all comfortable (exclusion)
☐ Don't know/ refused (exclusion)

26. How comfortable are you with downloading a free online computer software?

- ☐ Very comfortable
☐ Comfortable
☐ Somewhat comfortable
☐ Not at all comfortable (exclusion)
☐ Don't know/ refused (exclusion)

27. How comfortable are you with logging onto a website using an account name and password?

- ☐ Very comfortable
☐ Comfortable
☐ Somewhat comfortable
☐ Not at all comfortable (exclusion)
☐ Don't know/ refused (exclusion)

28. Would you be willing and able to attend 1 visit to our study site at UCSD in La Jolla? The visit will take approximately 1 hour.

- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

29. Participants will be asked to wear 2 small physical activity monitors (i.e., FitBit & Actigraph) for a total duration of 2 weeks: 1 week at the beginning of the study and 1 week toward the end of the study. Would you be willing to wear the 2 devices as instructed?

- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

30. Would you be willing and able to install the free FitBit software onto your personal computer?

- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

31. Would you be willing and able to wear the FitBit tracker for at least 10 hours per day (every day) throughout the 6-week study period?

- ☐ Yes
☐ No (exclusion)
☐ Don't know/ refused (exclusion)

32. May I confirm that you are male/ female?

- ☐ Male
☐ Female
☐ Don't know/ refused (exclusion)

33. What is your current age?

34a. What is your current height (feet' inches")?

 (NOTE: Screener must convert value to centimeters.)

34b. What is your current weight (lbs)?

 (NOTE: Screener must convert value to kilograms.)

34c. Your current height & weight indicates that your BMI is:

 (Calculate BMI using
<http://www.nhlbisupport.com/bmi/>)

34d. (DO NOT READ) Select BMI category

- ☐ BMI < 25 (exclusion)
☐ BMI: 25 - 39
☐ BMI: >= 40 (exclusion)
☐ Don't know/ refused (exclusion)

Confidential

Page 4 of 4

35. (If female) Are you pregnant?

- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)

36. Do you smoke cigarettes?

- ☐ Yes (exclusion)
☐ No
☐ Don't know/ refused (exclusion)

37. Are you currently participating in any other research studies?

- ☐ Yes (possible exclusion)
☐ No
☐ Don't know/ refused (possible exclusion)
(Exclude if other study is related to physical activity)

Baseline Visit Appointment (M-D-Y H:M)

(DO NOT READ) Admin Only: Transferred PAR-Q questions to hard copy for participant's signature.

- ☐ Yes
☐ No
(ADMIN)

(DO NOT READ) Admin Only: Emailed directions

- ☐ Yes
☐ No
(ADMIN)

(DO NOT READ) Admin Only: Programmed text message reminder for baseline clinic visit.

- ☐ Yes
☐ No
(ADMIN)

Appendix 4. Physical activity readiness questionnaire

Physical Activity Readiness
Questionnaire - PAR-Q
(revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

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: check YES or NO.

YES	NO	
☐	☐	1. Has your doctor ever said that you have a heart condition <u>and</u> 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 <u>any other reason</u> why you should not do physical activity?

If you answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active — begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal — this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever — wait until you feel better; or
- if you are or may be pregnant — talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME: _____

SIGNATURE: _____ DATE: _____

SIGNATURE OF PARENT _____ WITNESS: _____
or GUARDIAN (for participants under the age of majority)

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

 © Canadian Society for Exercise Physiology www.csep.ca/forms

Appendix 5. Text2bfit pilot study baseline questionnaire

Confidential		TXT2Bfit Study Page 1 of 6	
Baseline_Questionnaire			
Participant ID _____			
[SECTION A: DEMOGRAPHICS] These questions ask for some basic background information. A1. What is the highest level of education that you've completed?		☐ Grade school or some high school ☐ High school diploma or GED ☐ Some college or an Associate Degree ☐ College graduate ☐ Graduate degree (Master's, PhD, MD, JD, etc.)	
A2. What is your current marital status? (Mark one that best describes you)		☐ Never married ☐ Married ☐ Divorced or separated ☐ Widowed ☐ Living with a partner	
A3. List the people currently living in your household. (Mark all that apply)		☐ Spouse or partner ☐ Sister or brother ☐ Children ☐ Grandchildren ☐ Friend(s) ☐ Live alone ☐ Other	
A4. What is your current job status? (Mark all that apply)		☐ Working part-time (< 35 hours per week) ☐ Working full-time (>35 hours per week) ☐ Student ☐ Retired ☐ Not working for pay or wages	
A5. Which of the following best describes your race/ethnicity? (Mark all that apply)		☐ American Indian/ Alaska Native ☐ Asian ☐ Black or African-American ☐ Hispanic or Latino ☐ Native Hawaiian or Pacific Islander ☐ White ☐ Mixed race ☐ Other	
[SECTION B. BASELINE TECHNOLOGY USE] You mentioned during our first call that you have a cell phone. The following questions ask about your cell phone and text messaging usage. B1. In a typical week, approximately how many days do you text message?		☐ Everyday (7 days per week) ☐ Most days (5 days per week) ☐ Some days (3-5 days per week) ☐ Rarely (1-2 days per week) ☐ Never (0 days per week) â†’ Go to question B2	
B1a. On those days, approximately how many text messages do you RECEIVE?		☐ 0 ☐ 1-5 ☐ 6-10 ☐ > 10	
B1b. On those days, approximately how many text messages do you SEND?		☐ 0 ☐ 1-5 ☐ 6-10 ☐ > 10	
B2. In a typical day, during your waking hours, where do you typically keep your mobile phone?		☐ Purse ☐ Pocket ☐ On the charger ☐ Out on a desk/ table (in close proximity) ☐ In another room	
B3. Do you use a smart phone with a data plan (e.g., Blackberry, Palm, iPhone)?		☐ Yes ☐ No	
		www.project-redcap.org 	

Confidential

Page 2 of 6

B4. Have you ever used a website or app on your mobile phone or tablet to track and/or monitor your physical activity levels?

- ☐ Yes
☐ No → Go to Section C

B4a. Please specify which website(s) and/or app(s) you've used to track and/or monitor your physical activity levels.

[SECTION C: PHYSICAL ACTIVITY] The next set of questions will ask about your physical activity levels. C1. How confident are you in your ability to increase your current physical activity levels to 150 minutes of moderate-to-vigorous intensity physical activity per week in the next 6 weeks?

- ☐ Very confident
☐ Confident
☐ Somewhat confident
☐ Not at all confident
☐ Don't know/ refused
 (Note: Moderate-to-vigorous intensity means a large increase in your breathing and/or heart rate.)

C2. In the past, have you ever performed at least 150 minutes of moderate-to-vigorous intensity physical activity per week?

- ☐ Yes
☐ No → Go to question C3

C2a. How long ago did you last perform at least 150 minutes of moderate-to-vigorous intensity physical activity per week?

- ☐ < 1 year ago
☐ 1-2 years ago → Go to question C3
☐ 3-5 years ago → Go to question C3
☐ 5-10 years ago → Go to question C3
☐ > 10 years ago → Go to question C3

C2b. In the past year, how frequently did you meet the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week?

- ☐ Always
☐ Most of the time
☐ Some times
☐ Not at all → Go to question C3

C2c. Please specify the types of physical activities that you performed in the past where you reached at least 150 minutes of moderate-to-vigorous intensity physical activity per week?

C3. In a typical week, do you currently perform any moderate-to-vigorous intensity physical activities for at least 10 minutes at a time? This includes any activities that may cause moderate to large increases in your breathing and/or heart rate.

- ☐ Yes
☐ No → Go to question C4

C3a. Please specify types of physical activities that you do in a typical week that cause moderate-to-large increases in your breathing and/or heart rate for at least 10 minutes.

C4. In general, would you say that people in your immediate social circles such as family, friends, and co-workers are:

- ☐ Very physically active
☐ Somewhat physically active
☐ Not very physically active
☐ Not at all physically active

C5. How often would you say that people in your immediate social circles try to persuade you to be more physically active?

- ☐ Always
☐ Most of the time
☐ Some times
☐ Not at all

C6a. How confident are you in your ability to handle the following situations that may prevent you from doing any physical activity? When you are: NOT FEELING WELL

- ☐ Very confident
☐ Confident
☐ Somewhat confident
☐ Not at all confident

C6b. How confident are you in your ability to handle the following situations that may prevent you from doing any physical activity? When you are: NOT FEELING MOTIVATED

- ☐ Very confident
☐ Confident
☐ Somewhat confident
☐ Not at all confident

Confidential

Page 4 of 6

C7j. Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week. You will: HAVE AN INJURY

- ☐ Very likely
☐ Likely
☐ Somewhat likely
☐ Not at all likely

C7k. Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week. You will: IMPROVE MOOD

- ☐ Very likely
☐ Likely
☐ Somewhat likely
☐ Not at all likely

C7l. Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week. You will: NEGLECT OTHER RESPONSIBILITIES (e.g., chores)

- ☐ Very likely
☐ Likely
☐ Somewhat likely
☐ Not at all likely

C7m. Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week. You will: REDUCE STRESS

- ☐ Very likely
☐ Likely
☐ Somewhat likely
☐ Not at all likely

C7n. Please rate how likely or not likely the following situations will occur if you are actually doing the recommended levels of 150 minutes of moderate-to-vigorous intensity physical activity per week. You will: HAVE SORE MUSCLES

- ☐ Very likely
☐ Likely
☐ Somewhat likely
☐ Not at all likely

C8a. Please rate how strongly you agree or disagree with the following statements. Being physically active is important to most of my: FRIENDS

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable

C8b. Please rate how strongly you agree or disagree with the following statements. Being physically active is important to most of my: FAMILY MEMBERS

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable

C8c. Please rate how strongly you agree or disagree with the following statements. Being physically active is important to most of my: COLLEAGUES (i.e., coworkers, classmates, etc.)

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable

C8d. Please rate how strongly you agree or disagree with the following statements. Being physically active is important to most of my: NEIGHBORHOOD/ COMMUNITY

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable

C9a. How much support do you expect to receive from the following people to help you to be more physically active: FRIENDS

- ☐ A lot of support
☐ Some support
☐ Not much support
☐ No support
☐ Not applicable

Confidential

Page 5 of 6

C9b. How much support do you expect to receive from the following people to help you to be more physically active: FAMILY

- ☐ A lot of support
☐ Some support
☐ Not much support
☐ No support
☐ Not applicable

C9c. How much support do you expect to receive from the following people to help you to be more physically active: COLLEAGUES (i.e., coworkers, classmates, etc.)

- ☐ A lot of support
☐ Some support
☐ Not much support
☐ No support
☐ Not applicable

C9d. How much support do you expect to receive from the following people to help you to be more physically active: NEIGHBORHOOD/ COMMUNITY

- ☐ A lot of support
☐ Some support
☐ Not much support
☐ No support
☐ Not applicable

C10. In a typical week, how often are you exposed to media advertisements including television commercials, print and/or web ads, billboards, other signs, and/or any other prompts reminding you to increase your physical activity levels?

- ☐ Everyday (7 days per week)
☐ Most days (5 days per week)
☐ Some days (3-5 days per week)
☐ Rarely (1-2 days per week)
☐ Never (0 days per week)

C11. If you were unable to reach your physical activity goals by the end of the 6-week study, how disappointed will you be:

- ☐ Very disappointed
☐ Disappointed
☐ A little disappointed
☐ Not at all disappointed

[Environmental Supports for Physical Activity] Now I will be asking you some questions about the neighborhood in which you live, followed by some questions about the community in which you live. For the purposes of this interview, neighborhood is defined as the area within one-half mile or a ten-minute walk from your house and community is defined as a 5-mile or 10-minute drive from your house. C12a. In general, would you say that the people in your NEIGHBORHOOD are...

- ☐ Very physically active
☐ Somewhat physically active
☐ Not very physically active
☐ Not at all physically active

C12b. Overall, how would you rate your neighborhood as a place to walk? Would you say...

- ☐ Very pleasant
☐ Somewhat pleasant
☐ Not very pleasant

C12c. For walking at night, would you describe the street lighting in your neighborhood as...

- ☐ Very good
☐ Good
☐ Fair
☐ Poor
☐ Very poor

C12d. How safe from crime do you consider your neighborhood to be? Would you say...

- ☐ Extremely safe
☐ Quite safe
☐ Slightly safe
☐ Not at all safe

C12e. Generally speaking, would you say most people in your neighborhood can be trusted...

- ☐ Yes
☐ No

C12f. Does your neighborhood have any sidewalks?

- ☐ Yes
☐ No

C12g. Do you use any private or membership-only recreation facilities in your community for physical activity?

- ☐ Yes
☐ No
☐ My community does not have these facilities

C12h. Do you use walking trails, parks, playgrounds, sports fields in your community for physical activity?

- ☐ Yes
☐ No
☐ My community does not have these facilities

h

Confidential

Page 6 of 6

C12i. Do you use shopping malls in your community for physical activity and/or walking programs?

- ☐ Yes
☐ No
☐ My community does not have shopping malls

C12j. Do you use any public recreation centers in your community for physical activity?

- ☐ Yes
☐ No
☐ My community does not have public recreation facilities

C12k. Do you use schools that are open in your community for public recreation activities?

- ☐ Yes
☐ No
☐ Schools in my community are not open for the public to use

[SECTION D: ATTITUDES ON FITBIT & TEXT MESSAGING]

This section will ask your opinion about what you think about the FitBit and text messages as simple reminders to promote an increase your physical activity levels. D1. How strongly do you agree or disagree that the following items will help you to be more physically active: FITBIT TRACKER

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree

D2. How strongly do you agree or disagree that the following items will help you to be more physically active: FITBIT WEBSITE

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree

D3. How strongly do you agree or disagree that the following items will help you to be more physically active: DAILY TEXT MESSAGES (as simple reminders to prompt physical activity)

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree

[SECTION E: SMOKING STATUS] The next set of questions asks about your smoking history. E1. During your entire life, have you smoked at least 100 cigarettes?

- ☐ No â†’ Skip to Section F
☐ Yes

[If 'yes' to E1]... E1a. Do you smoke cigarettes now?

- ☐ No
☐ Yes

[If 'yes' to E1a]... E1b. On average, how many cigarettes do you (did you) usually smoke each day?

- ☐ Less than 1
☐ 1-4
☐ 5-14
☐ 15-24
☐ 25-34
☐ 35-44
☐ 45 or more

SECTION F: MEDICAL HISTORY F1. During the last year, have you been diagnosed with any type of disease? If yes, please describe or list disease(s) and/ or conditions(s):

Appendix 6. Text2bfit pilot study brief intervention counseling form

1												
Text2bfit Study Brief Intervention Counseling												
<i>The recommended level of physical activity for adults is at least 150-minutes of moderate-to-vigorous intensity physical activity each week. One way to reach this goal is to gradually increase and keep track of your total number of steps per day. As part of this study, your goal is to reach at least 10,000 steps per day. If 10,000 steps per day becomes easy for you, your goal is to gradually increase the number of steps and/or pace of your steps per day. In other words, walk more and/or walk faster.</i> <i>Before you begin, it's important to address what's motivating you to increase your activity levels. Also, we'll identify any challenges you might encounter along the way and come up with a plan on how you might be able to overcome some of these challenges.</i> <i>First...</i> 1. What are the top three reasons motivating you now to be more physically active? Reason #1: _____ _____ Reason #2: _____ _____ Reason #3: _____ _____ 2. What types of physical activity or activities do you think you will do more regularly to help you reach your physical activity goals? (Mark all that apply) ☐ Brisk walks ☐ Jogging ☐ Running ☐ Bicycling ☐ Other (Please Specify): _____ ☐ Don't Know/ Refused 3. Where do you plan to do the activity/ these activities? And will you need any special equipment? <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black; width: 33%;">Activity</th> <th style="text-align: left; border-bottom: 1px solid black; width: 33%;">Location</th> <th style="text-align: left; border-bottom: 1px solid black; width: 33%;">Equipment</th> </tr> </thead> <tbody> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> </tbody> </table> PARTICIPANT ID: _____	Activity	Location	Equipment	_____	_____	_____	_____	_____	_____	_____	_____	_____
Activity	Location	Equipment										
_____	_____	_____										
_____	_____	_____										
_____	_____	_____										

4. Do you plan to do this activity (these activities) alone or with someone else?

- ☐ Alone
- ☐ Spouse/ significant other
- ☐ Family member(s) (please specify): _____
- ☐ Friend(s)
- ☐ Co-workers
- ☐ Other (please specify): _____
- ☐ Don't Know/ Refused

5. What are some possible situations that might prevent you from being physically active/ exercise?
(fill out below)

6. What are some ways that you can handle this situation (these situations) so that you can successfully follow through with your plans to be physically active/ exercise? (fill out below)

5. Situation

6. Plan

PARTICIPANT ID:

Appendix 7. Text2bfit pilot study daily data collection form on REDCap (sample)

Confidential		TX2Bfit Study Page 1 of 2	
RunIn_Day_1			
Participant ID			
Validate ACTIGRAPH wear-time of at least 10 hrs/day (600 min/day) for 7 days.	☐ Valid â†' PROCEED ☐ Not valid â†' STOP (see note below) (If no, STOP here. Ask participant to re-wear missing number of days according to weekday/weekend day.)		
Run-In Day 1: FITBIT START Wear-Time			
Run-In Day 1: FITBIT STOP Wear-Time			
Run-In Day 1: Date			
Run-In Day 1: Day of Week	☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday		
Run-In Day 1: FITBIT Number of Steps			
Run-In Day 1: FITBIT Active Score			
Run-In Day 1: FITBIT Minutes of LIGHTLY ACTIVE			
Run-In Day 1: FITBIT Minutes of FAIRLY ACTIVE			
Run-In Day 1: FITBIT Minutes of VERY ACTIVE			
Log: FOOD	☐ Breakfast ☐ Morning snack ☐ Lunch ☐ Afternoon snack ☐ Dinner ☐ Anytime ☐ Water consumed ☐ None		
Log: ACTIVITY	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 or more		
Log: WEIGHT	☐ Yes ☐ No		
Log: JOURNAL	☐ Mood only ☐ Journal entry only ☐ Mood AND journal entry ☐ None		
Any activity in FitBit Community?	☐ Yes ☐ No		
Run-In Day 1: ACTIGRAPH Number of Steps			
Run-In Day 1: ACTIGRAPH METs			
www.project-redcap.org 			

*Confidential**Page 2 of 2*

Run-In Day 1: ACTIGRAPH Total Minutes of Physical
Activity

NOTES:

Appendix 8. Text2bfit study 6-week follow-up questionnaire

Confidential		TXT2BFIT Study Page 1 of 4	
FU_Questionnaire			
Participant ID _____			
[SECTION A: FITBIT] The following questions ask about using the FitBit tracker and website. Please rate the following statements. A1. The FitBit tracker was easy to use.		☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree (Read aloud answer choices to participant.)	
A2. Overall, the FitBit tracker helped me to be more physically active.		☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree (Read aloud answer choices to participant.)	
A2a. On a typical day, I checked the FitBit tracker to see how many STEPS I've taken...		☐ Very often ☐ Often ☐ Sometimes ☐ Rarely ☐ Never (Read aloud answer choices to participant.)	
A2b. On a typical day, I checked the FitBit tracker to see how much DISTANCE I've travelled...		☐ Very often ☐ Often ☐ Sometimes ☐ Rarely ☐ Never (Read aloud answer choices to participant.)	
A2c. On a typical day, I checked the FitBit tracker to see if the FLOWER grew taller...		☐ Very often ☐ Often ☐ Sometimes ☐ Rarely ☐ Never (Read aloud answer choices to participant.)	
A3. The FitBit website was easy to use.		☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree (Read aloud answer choices to participant.)	
A4. Overall, I enjoyed using the FitBit website.		☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree (Read aloud answer choices to participant.)	
A5. In a typical week, I logged onto my FitBit account...		☐ Everyday (7 days per week) ☐ Most days (5 days per week) ☐ Some days (3-5 days per week) ☐ Rarely (1-2 days per week) ☐ Never (0 days per week) (Read aloud answer choices to participant.)	
A6. In a typical week, I synced data from my FitBit tracker onto fitbit.com...		☐ Everyday (7 days per week) ☐ Most days (5 days per week) ☐ Some days (3-5 days per week) ☐ Rarely (1-2 days per week) ☐ Never (0 days per week) (Read aloud answer choices to participant.)	
		www.project-redcap.org 	

Confidential

Page 2 of 4

A7. Overall, the FitBit website (fitbit.com) helped me to be more physically active.

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
 (Read aloud answer choices to participant.)

A7a. Now I will read a list of features that appear on the FitBit website. Please indicate which features you used during the 6-week study. (Mark all that apply).

- ☐ Monitored steps taken on dashboard
☐ Monitored floors climbed
☐ Monitored distance traveled on dashboard
☐ Monitored calories burned on dashboard
☐ Monitored active score on dashboard
☐ Logged food
☐ Logged activity
☐ Tracked weight
☐ Tracked sleep
☐ Wrote journal entries
☐ Logged heart rate
☐ Logged blood pressure
☐ Logged glucose levels
☐ Read posts in the 'community' section
☐ Posted comments in the 'community' section
☐ Joined a public group
☐ Created a group
☐ Found friends who also have fitbit.com accounts
☐ Connected with Facebook from FitBit account
☐ Shared with friends achievements and personal best stats
☐ Competed with friends on the leader board
☐ Encouraged friends to stay active
 (Read aloud answer choices to participant.)

A7b. Among the FitBit website features you've just mentioned, which one(s) did you find MOST HELPFUL in increasing your physical activity level? (Mark all that apply).

- ☐ Monitored steps taken on dashboard
☐ Monitored floors climbed
☐ Monitored distance traveled on dashboard
☐ Monitored calories burned on dashboard
☐ Monitored active score on dashboard
☐ Logged food
☐ Logged activity
☐ Tracked weight
☐ Tracked sleep
☐ Wrote journal entries
☐ Logged heart rate
☐ Logged blood pressure
☐ Logged glucose levels
☐ Read posts in the 'community' section
☐ Posted comments in the 'community' section
☐ Joined a public group
☐ Created a group
☐ Found friends who also have fitbit.com accounts
☐ Connected with Facebook from FitBit account
☐ Shared with friends achievements and personal best stats
☐ Competed with friends on the leader board
☐ Encouraged friends to stay active
 (Read aloud answer choices to participant.)

A8. Did you use the FitBit Mobile App?

- ☐ Yes
☐ No â†’ Skip to A9

A8a. How often did you use the FitBit Mobile App?

- ☐ More than once a day
☐ About once a day
☐ A few times a week
☐ Just a couple of times a week
☐ About once a week
☐ Less than once a week
 (Read aloud answer choices to participant.)

Confidential

Page 3 of 4

A9. Please describe in your own words how the FitBit was useful or not useful in increasing your physical activity levels.

[DO NOT READ] Participant Group Assignment:

- ☐ Intervention group â† Proceed to SECTION B
☐ Control group â† Skip to SECTION C
 (DO NOT READ)

[SECTION B: TEXT MESSAGES] The next questions ask about the daily text messages sent to your mobile phone as simple reminders to be physically active. Please rate the following statements. B1. Daily text messages sent to my mobile phone that prompted me to be physically active helped me to be more physically active.

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B2. Daily text messages that prompted me to be physically active were delivered to me as scheduled.

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B3. The three daily text messages that prompted me to be physical activity were...

- ☐ Too many
☐ Just right
☐ Too few
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B4. Typically, when did you read the text messages after it was sent to your cell phone?

- ☐ Immediately
☐ 1-30 minutes
☐ 31 minutes to 1 hour
☐ 1 hour - 2 hours
☐ 3 hours or more
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B5. Overall, did you engage in at least a 10-minute bout of physical activity after receiving a text message from the study? Would you say...

- ☐ Always
☐ Usually
☐ About half the time
☐ Rarely
☐ Never â† Skip to question B7
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B6. How soon after receiving a text message did you engage in at least a 10-minute bout of physical activity? On average, would you say...

- ☐ 1-30 minutes
☐ 31 minutes to 1 hour
☐ 1 hour - 2 hours
☐ 3 hours - 6 hours
☐ 7 hours - 9 hours
☐ 10 hours - 12 hours
☐ More than 12 hours
☐ Not applicable (control group)
 (If control group, mark 'not applicable' to continue.)

B7. Please describe in your own words how the text messages were useful or not useful in increasing your physical activity levels.

(If control group, mark 'NA')

Confidential

Page 4 of 4

[SECTION C: PHYSICAL ACTIVITY LEVELS] C1. In a typical week, approximately how many days are you doing at least a 10-minute bout of moderate-to-vigorous intensity physical activity?

- ☐ Everyday (7 days per week)
☐ Most days (5 days per week)
☐ Some days (3-5 days per week)
☐ Rarely (1-2 days per week)
☐ Never (0 days per week) â† skip to C3
 (Read aloud answer choices for participant.)

C2. On those days, approximately how many hours/minutes of moderate-to-vigorous intensity physical activity are you doing?

 (Note: Enter data in minutes)

C3. On those days, what types of physical activities are you doing (e.g., brisk walks, running, bicycling, etc.)?

C4. Where are you performing these activities (e.g., home, outside, gym/other facility, etc.)?

C5. Did you use any special equipment to perform these activities (e.g. treadmill, stationary bike, weights, etc.)?

[SECTION D: QUALITY OF SERVICE] The last couple of questions ask about the overall quality of service of the study period. Please rate the following statements. D1. Instructions provided for study participation during the initial study visit were clear and easy to follow.

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
 (Read aloud answer choices to participant.)

D2. Overall, the quality of this study was:

- ☐ Very good
☐ Good
☐ Neutral
☐ Fair
☐ Poor
 (Read aloud answer choices to participant.)

D3. Study staff members were available to assist me when I needed help. Do you...

- ☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree
☐ Not applicable
 (Read aloud answer choices to participant.)

D4. How could we improve any aspect of this program for the future?

D5. Did you participate in a weight loss program such as Weight Watchers or Jenny Craig at any point during the study period?

- ☐ Yes
☐ No

This completes your participation in the study. Did you end up purchasing a FitBit through the study?

- ☐ Yes
☐ No

Thanks again. We will send you a gift card in the amount of \$20 as a 'thank you' for successfully completing our study protocol. Take care. [DO NOT READ: Mark 'yes' after you've emailed Julie to send participant a gift card]

- ☐ Yes
☐ No
 (Notify Julie to send gift card & close file)

Appendix 9. Text message bank

Week 1	
Sunday	Morning Good morning [name]. It's time to start your day off with at least a 10-minute bout of moderate-to-vigorous intensity activity. Afternoon It's [time] PM. Another reminder to do at least a 10-minute bout of activity today. Your aim is to increase your heart rate. Evening Hello [name]. Hope your day is going well. This is your last reminder of the day for another bout of physical activity.
Monday	Morning Good morning [name]. This is your [time] AM reminder to start your day off with a 10-minute bout (or more) of physical activity. Afternoon Hope your afternoon is going well. This is just your [time] PM reminder to engage in at least a 10-minute bout of physical activity. Evening Hi [name]. This is your last reminder of the day to get at least a 10-minute bout to break a sweat & increase your heart rate.
Tuesday	Morning Time for a 10-minute or more bout of activity. Be sure to increase your heart rate. This is your [time] AM reminder. Afternoon Hi [name]. Hope you're having a nice day. This is your [time] PM reminder to do at least a 10-minute bout of activity. Evening Good evening [name]. It's [time] PM. Time for another 10-minute bout or more of physical activity to wrap up your day.
Wednesday	Morning This is your morning reminder to engage in at least a 10-minute bout of moderate-to-vigorous intensity physical activity. Afternoon Hi [name]. Time for another 10-minute bout or more of activity. Again, your aim is to do activity that will increase your heart rate. Evening Hope you're having a nice day. This is your last reminder of the day to do a 10-minute bout or more of activity.
Thursday	Morning Hi [name]. This is your [time] AM reminder to start the day off with a bit of moderate-to-vigorous intensity physical activity. Afternoon This is your [time] PM reminder to engage in at least a 10-minute bout of physical activity. Evening Hi [name]. Last chance to do a 10-minute bout (or more) of activity.
Friday	Morning Hi [name]. Hope you're having a nice morning. This is your [time] AM reminder for a 10-minute or more bout of physical activity. Afternoon Good afternoon. This is a reminder to engage in physical activity that will increase your heart rate for at least 10 minutes. Evening Hi [name]. It's [time] PM. Time for another 10-minute bout or more of physical activity to end your day.
Saturday	Morning Good morning [name]. This is your morning reminder to start your day off with at least a 10-minute bout of physical activity. Afternoon Hi [name]. This is your [time] PM reminder to increase your heart rate with a bout of physical activity. Evening Last chance to get in that 10-minute bout or more of some physical activity.
WEEK 2	
Sunday	Morning Hi [name]. Try to start off your day by increasing your heart rate with at least a 10-minute bout of physical activity. Afternoon Hope you're having a nice day. This is your [time] PM reminder to do at least a 10-minute bout of activity. Evening Good evening [name]. Hope your day is going well. Last reminder for a bout of moderate-to-vigorous intensity activity.
Monday	Morning Good morning [name]. This is your morning reminder to try and engage in some physical activity. Afternoon Hi [name]. This is your [time] PM reminder. Don't forget to get in a 10-minute or more bout of physical activity. Evening Hello. It's [time] PM. Remember to engage in at least 10 minutes or more of physical activity that will increase your heart rate.
Tuesday	Morning Hi [name]. It's [time] AM. This is a reminder for you to get in at least 10 minutes of moderate-to-vigorous intensity physical activity. Afternoon Hope your day is going well [name]. This is your reminder to engage in at least a 10-minute bout of physical activity. Evening This is your last reminder of the day to do some physical activity.
Wednesday	Morning Hello [name]. Your goal is to do at least a 10-minute bout of physical activity. Afternoon Good afternoon [name]. This is your [time] PM reminder to engage in at least a 10-minute bout of physical activity. Evening Good evening. This is another reminder to increase your heart rate with at least a 10-minute bout of physical activity.
Thursday	Morning It's [time] AM. Time to start the day off with a 10-minute bout or more of moderate-to-vigorous intensity activity. Afternoon Good afternoon! This is your [time] PM reminder to do at least a 10-minute bout of physical activity that will increase your heart rate. Evening Hi [name]. Last chance of the day to do some moderate-to-vigorous physical activity.
Friday	Morning Good morning [name]. Time to start the day with at least a 10-minute bout of moderate-to-vigorous intensity physical activity. Afternoon Hi [name]. Time for a 10-minute bout or more of physical activity. Make sure to break a sweat and increase your heart rate. Evening Hello. This is your evening reminder to engage in a 10-minute bout or more of physical activity.
Saturday	Morning Hi [name]. This is your morning reminder to start the day off with a 10-minute bout or more of physical activity. Afternoon Hi [name]. It's your [time] PM reminder for another chance to do at least 10 minutes of moderate-to-vigorous physical activity. Evening Good evening [name]. Remember to do at least a 10-minute bout of physical activity before the end of the day.