



# University of Tennessee, Knoxville TRACE: Tennessee Research and Creative Exchange

**Doctoral Dissertations** 

**Graduate School** 

8-2019

# A Two-Part Study of Step Counter Accuracy and Ecological Momentary Assessment of Correlates to Total Physical Activity in Phase II Cardiac Rehabilitation Patients

Lindsay Toth *University of Tennessee*, ltoth2@vols.utk.edu

Follow this and additional works at: https://trace.tennessee.edu/utk\_graddiss

#### **Recommended Citation**

Toth, Lindsay, "A Two-Part Study of Step Counter Accuracy and Ecological Momentary Assessment of Correlates to Total Physical Activity in Phase II Cardiac Rehabilitation Patients." PhD diss., University of Tennessee, 2019.

https://trace.tennessee.edu/utk\_graddiss/5598

This Dissertation is brought to you for free and open access by the Graduate School at TRACE: Tennessee Research and Creative Exchange. It has been accepted for inclusion in Doctoral Dissertations by an authorized administrator of TRACE: Tennessee Research and Creative Exchange. For more information, please contact trace@utk.edu.

To the Graduate Council:

I am submitting herewith a dissertation written by Lindsay Toth entitled "A Two-Part Study of Step Counter Accuracy and Ecological Momentary Assessment of Correlates to Total Physical Activity in Phase II Cardiac Rehabilitation Patients." I have examined the final electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Kinesiology.

David Bassett, Kelley Strohacker, Major Professor

We have read this dissertation and recommend its acceptance:

Scott Crouter, Eugene Fitzhugh, Samantha Ehrlich

Accepted for the Council:

Dixie L. Thompson

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

# A Two-Part Study of Step Counter Accuracy and Ecological Momentary Assessment of Correlates to Total Physical Activity in Phase II Cardiac Rehabilitation Patients

A Dissertation Presented for the

Doctor of Philosophy

Degree

The University of Tennessee, Knoxville

Lindsay Powell Toth

August 2019

Copyright © 2019 by Lindsay Toth

All rights reserved.

#### Acknowledgements

I would like to thank Dr. David Bassett, Jr. for accepting me as your graduate student. I believe that dedicating time to another individual is extremely important and meaningful and I cannot express how appreciative I am of the time that you have dedicated to me over the last four years. I have developed leaps and bounds as a researcher and you will forever continue to inspire me with your kindness, humility, dedication, and continual curiosity.

Thank you, Dr. Kelley Strohacker, for your mentorship and pushing me way beyond my research-related comfort zone. I appreciate your support and patience in guiding me through an area that was completely new to me. I still have much to learn but thank you for the push to try new things. Importantly, thank you also for keeping me grounded with plenty of cat pictures.

The remaining committee members also each deserve an individual thank you. Thank you, Dr. Scott Crouter, for keeping the big picture in mind and guiding me towards developing a sustainable line of research. Thank you, Dr. Eugene Fitzhugh, for the regular check-ins and brain-storming sessions. Thank you, Dr. Samantha Ehrlich, for your guidance with statistics and help with navigating the job market.

Cary Springer, stats consultant extraordinaire, thank you for your patience and assistance.

To the staff at the Heart Lung Vascular Institute of the University of Tennessee Medical Center, thank you. I could not have completed these projects without your buy-in and interest!

To my friends and family – thank you. Thank you to John Maile for pushing me to develop as a researcher, keep my chin up, and for all the time and effort you invested in my programming skills. I will do my best to keep notes next time! To my tennis family here in Knoxville, I love you all. Importantly – thanks to my mom for the love and support! I will do my best to continually supply you with travel destinations. :)

#### Abstract

Cardiac rehabilitation (CR) is an exercise and education program aimed to help individuals improve fitness levels to return to their careers and social lives. The dropout rate is high, between 25% to 50%, and is related to several factors with an early predictor being higher anxiety levels. It is important to understand the patterns and consistency of this variable as it changes throughout the day and its association physical activity (PA) in order to influence interventions. Ecological momentary assessment (EMA) and actigraphy can capture momentary anxiety and PA, respectively, for temporal analysis. This dissertation includes two studies. Study I examined the error in daily steps of four wearable PA monitors (Fitbit Charge 2, Apple Watch Series 2, Fitbit Zip, ActiGraph GT9X) in phase II CR patients. Nineteen patients were activity monitors on the ankle, non-dominant wrist, and waist on two days that they attended CR and two days when they did not. Steps from each monitor were compared to criterion steps from the StepWatch (SW). The Fitbit Charge and Apple Watch captured within 10% of SW steps and most other monitors underestimated steps. Study II examined the consistency and intra- and inter-individual patterns in state anxiety (SA) and PA and described the feasibility of mobile EMA for those in phase II CR. Nine adults received four mobile phone surveys each day, assessing momentary SA, for 14 consecutive days while concurrently wearing an ActiGraph GT3X+ across the day. In this study, participants demonstrated consistent, low levels of SA (ICC = 0.68, average = 9.1 on a scale of 6 to 24). The relationship between PA and SA varied between individuals, showing positive and negative slopes for individual participants. Survey compliance rate and ActiGraph wear time met *a priori* benchmarks for feasibility, but recruitment did not. Lack of smartphone ownership and limited smartphone access at work were the primary challenges to recruitment. This study was the first to describe the patterns of momentary SA for

this population. Individual pattern analysis is necessary for classifying individuals, but further study is needed to direct development of interventions based on ecologically valid data.

## **Table of Contents**

Chapter I: Introduction	1
References	8
Chapter II: Literature Review	16
References	51
Chapter III: Step Count Error of Activity Monitors for Patients in Phas	se II Cardiac
Rehabilitation	72
Abstract	73
Introduction	74
Methods	75
Results	82
Discussion	86
References	93
Chapter IV: Using Ecological Momentary Assessment to Explore Anxie	ety and
Physical Activity for Patients in Phase II Cardiac Rehabilitation	98
Abstract	99
Introduction	101
Methods	103
Results	110
Discussion	118
References	127
Chapter V: Conclusion	133
Appendices	136

Appendix A. Study I Informed Consent	137
Appendix B. Study II Informed Consent	142
Appendix C. Ecological Momentary Assessment Mobile Survey	148
Vita	154

## **List of Tables**

1.	Table 1. Summary of participant characteristics	.83
2.	Table 2. Summary of step data for each monitor and each condition	.84
3.	Table 3. Summary of participant characteristics	.111

## **List of Figures**

1.	Figure 1. Percent of StepWatch steps for each monitor during each condition85
2.	Figure 2. Percent of StepWatch steps for each monitor during cardiac rehabilitation
	sessions87
3.	Figure 3. Mean and standard deviation of state anxiety scores across two weeks112
4.	Figure 4. Three emerging patterns of state anxiety across all survey time points113
5.	Figure 5. Physical activity as a function of state anxiety score for all participants across
	all survey time points
6.	Figure 6. Physical activity as a function of state anxiety scores inclusive of all non-
	missing data points for each participant across all survey time points116
7.	Figure 7. Recruitment and enrollment flow chart detailing all new patients, eligible
	patients, number who enrolled, and reasons eligible individuals did not enroll117

#### **List of Abbreviations**

AACVPR American Association of Cardiovascular and Pulmonary Rehabilitation

ACCF American College of Cardiology Foundation

AG ActiGraph

AHA American Heart Association

Apple Apple Watch Series 2

Charge Fitbit Charge

CR Cardiac rehabilitation CVD Cardiovascular disease

EMA Ecological momentary assessment

GT3X+ ActiGraph GT3X+ GT9X ActiGraph GT9X

LFE Low-frequency extension

PA Physical activity

PAM Physical activity monitor STAI State Trait Anxiety Inventory

SA State anxiety Zip Fitbit Zip

## Chapter I

## Introduction

Cardiovascular disease (CVD) is the leading cause of mortality and is the most prevalent disease in the United States (US) and worldwide (1-3). CVD can refer to several conditions such as heart failure, valvular issues within the heart, myocardial infarction, arrhythmias, atherosclerosis, and stroke (4). Individuals living with these conditions or who have experienced a cardiac event are at increased risk for premature mortality, a secondary cardiac event, other comorbidities, and may experience a reduced quality of life (5). In effort to improve quality of life and to slow or stop the worsening of their condition, cardiac rehabilitation (CR) is recommended for patients who have experienced a myocardial infarction, coronary artery bypass graft surgery, percutaneous coronary intervention, angina, heart transplant, valvular surgery, heart failure, or peripheral artery disease (4, 6, 7). Although there are many benefits associated with completing CR (e.g., reduced cardiovascular-related mortality, improved exercise capacity, improved health-related quality of life (8, 9)), this program is underutilized with poor referral and adherence rates (10).

Cardiac rehabilitation is a multi-component, three-phase intervention to help the patient return to his or her social life and career, reduce the risk of secondary cardiac events, and live a healthier lifestyle through reducing CVD risk factors (7, 11, 12). Phase I begins in the hospital setting following cardiac surgical intervention or event. During this phase, the patient progresses from lying, to sitting, standing, and completing self-care tasks, to allow the safe transition from the hospital to the patients' home (4, 6). Following release from the hospital, patients should be referred to Phase II, which is a 36 session, 6-week outpatient program that includes medically supervised exercise training, educational classes, and psychological counselling (6). Exercise prescriptions are designed and implemented by exercise physiologists or cardiac nurses at outpatient cardiac and pulmonary rehabilitation centers, where the primary goal is to return

patients to a cardiorespiratory fitness level that will allow them to return to work and their typical social obligations (4, 6). Educational sessions are offered during phase II to educate patients on living a healthier lifestyle and psychological counselling is used as needed to reduce anxiety and depression (13) and aid in the adjustment and acceptance of a CVD diagnosis or change in health status following a cardiac event (6). Phase II offers support and education during the transitional time following hospital release, during recovery, through the patients' re-integration to daily life and is highly important for improving self-efficacy in continuing behavior changes. Phase III is the maintenance phase where patients continue exercise either in the outpatient CR setting or in local fitness centers or community facilities (6).

Benefits of comprehensive CR programs (exercise, education, and psychological counselling) include improved quality of life, reduced overall disability, decreased risk of secondary cardiac event, and reduced subsequent hospital visits and healthcare costs (5, 7, 8, 14-16). Despite these benefits, the use of CR remains low (17). Independent researchers and research collaboratives such as the Million Hearts Initiative have been working to address this and have identified referral, enrollment, attendance, and adherence as for areas for immediate improvement (10). Systematic level changes like combined automatic referral via electronic medical records and use of a CR liaison have increased referral rates from 32 to 86% and increased enrollment rates from 29 to 74% (18). Other factors shown to increase enrollment between 10 to 20% are home-based CR programs (19), offering flexible hours for CR sessions (17), and scheduling the first phase II CR session before the patient is discharged from the hospital (20).

Attendance and adherence are two important considerations for improvement because it has been demonstrated that patients who attend a greater number of total CR exercise sessions

have reduced re-hospitalization rates (21) and 5-year mortality rates, with about a 1% reduction in risk of death per session attended (22). Several strategies for improving attendance and adherence rates at the system-level are increasing the diversity of educational classes offered (23), increased group counselling opportunities (as opposed to individual sessions) (23), use of a video to explain the purpose and importance of CR (24), token (e.g., parking passes, water bottles, t-shirts) (24) and financial incentives (25) for regular attendance, and women-only CR exercise sessions (26). However, the very low participation rates (20% to 35% of those diagnosed with myocardial infarction) and high drop-out rates (40% to 70% within the first 6 months) (5, 27, 28) are not only related to systemic issues, but also have been related to behavioral factors like anxiety and depression (29, 30).

Anxiety is suggested as the earliest predictor of non-adherence to a CR program (30) and the exercise portion of CR has been suggested as anxiety-provoking (26). Anxiety is a form of psychological distress that has two divisions: 1.) state-anxiety, which describes the momentary feeling of anxiety, characterized as tension, apprehension, nervousness, and worry and 2.) trait-anxiety, which is the level one is prone to experience state-anxiety in daily life (31). In two meta-analyses, anxiety (both state and trait) measured by various methods has been shown as a risk factor for coronary heart disease (32) and slows the recovery following cardiovascular events (33). Additionally, state-anxiety is commonly experienced amongst those diagnosed with CVD (34) and individuals with higher state-anxiety scores have been shown to have increased rates of drop-out from CR (30, 35-37), with some dropping out during the initial assessment period (30).

Anxiety measurements typically occur cross-sectionally in CR, once at the beginning and then again at the end of the CR program. The early measurement can inform CR nurses of patients for whom psychological counselling would be necessary (6). Recently, however, it has

been shown that measures of depression, anxiety, and affect (38-40) fluctuate throughout the day. These cognitive and emotional factors which were once thought to be stable throughout the day are a potential source for further explaining in-the-moment decisions for engagement with health behaviors (41), such as attending CR sessions. Limited research has been completed investigating the temporal variability of cognitions and emotions, and their effect on health behaviors. With the understanding that anxiety is a predictor of CR drop-out, the within-day fluctuation and trajectory of state-anxiety as it relates to physical activity (a health behavior) should be assessed.

A technique for assessing fluctuations in behavioral cognitions, affect, and feelings is ecological momentary assessment (EMA). EMA is a method that uses repeated surveys to assess feelings and experience in real time, in the participants natural environment (42). The benefits of this method include reduced recall bias (due to momentary recall), measurements at multiple time points to track temporal fluctuations, and improved ecological validity because the participant completes the survey in their natural environment (42). Additionally, the repeated sampling technique allows for within-person analysis. Whereas cross-sectional analyses only describe relationships across the population, intensive longitudinal data can be analyzed to describe variability within- and between-participants. A greater understanding of within-person variability may help to develop novel interventions based on just-in-time adaptive interventions or precision medicine (43, 44). To date, only one study has used EMA with CR patients. This study investigated the temporal association of depression and physical activity in a small sample (n=4) of men after myocardial infarction. The between-participant analysis upheld previous findings of a negative relationship between depression and physical activity. However, the within-participant analysis revealed that the longevity of depression effect on physical activity

differed among participants, fluctuations in depression accounted for different variability in physical activity among participants, and one participant exhibited a reverse effect where physical activity preceded depression (45). Because anxiety is a predictor of CR drop-out (30), physical activity can induce anxiety in the CR population (26), and regular physical activity is a critical component of recovering from cardiovascular events (8), EMA should be used to investigate time-varying fluctuations in anxiety in early phase II CR to investigate the association between anxiety and physical activity.

Concurrent objective physical activity monitoring is suggested for use with EMA. Physical activity monitors (PAMs) provide an objective measure of intensive longitudinal physical activity data that is ecologically valid and, like EMA, can reduce the risk of recall bias and provide a measure of subconscious physical activity (46). Several metrics representative of physical activity are provided by PAMs but steps per day, specifically, is an intuitive metric (47) that has been shown to motivate increased physical activity (48), steps have been associated with health benefits (48-50), and they are a direct assessment of the most common form of physical activity (51-53). In the CR setting, PAM-estimated step counts have been suggested to motivate increased physical activity (54, 55), monitor exercise maintenance (56, 57), and measure post-cardiac event rehabilitation (58). A current limitation to using PAM-estimated step counts is the unknown step-counting error of research- and consumer-grade monitors for those in phase II CR.

Because steps are an intuitive and representative measure of most physical activity completed throughout a typical day, they have the potential to provide an ecologically valid measure of physical activity for those in CR they should be used along with in-the-moment measurements of anxiety to map the trajectory and investigate within-person variability. These assessments could provide in-depth information that better describes physical activity behavior.

Investigating intra-individual trajectories and differences of these measurements may highlight the complexity of repeated health behaviors and reveal insight for areas of improvement in existing cardiac rehabilitation programs. Given the low participation and adherence rates of phase II cardiac rehabilitation, understanding the complexity of physical activity and cognitive and affective factors may aid in developing more efficacious and evidence-based cardiac rehabilitation programs which yield better compliance and adherence.

#### References

- 1. Achievements in Public Health, 1900-1999: Decline in Deaths from Heart Disease and Stroke -- United States, 1900-1999. Atlanta, GA: Centers for Disease Control and Prevention, 1999 8/6/1999. Report No.
- 2. Kochanek KD, Murphy SL, Xu J, Arias E. Mortality in the United States, 2016. Hyattsville, MD: National Center for Health Statistics, 2017 12/2017.
- 3. Ma J, Ward EM, Siegel RL, Jemal A. Temporal trends in mortality in the united states, 1969-2013. JAMA. 2015;314(16):1731-9.
- 4. Thomas RJ, King M, Lui K, Oldridge N, Piña IL, Spertus J, et al. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services: endorsed by the American college of chest physicians, American college of sports medicine, American physical therapy association, Canadian association of cardiac rehabilitation, European association for cardiovascular prevention and rehabilitation, inter-American heart foundation, national association of clinical nurse specialists, preventive cardiovascular nurses association, and the society of thoracic surgeons. J Am Coll Cardiol. 2007;50(14):1400-33.
- 5. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. Prog Cardiovasc Nurs. 2002;17(1):8-17. Epub 2002/03/02.
- 6. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for cardiac rehabilitation and secondary prevention programs. 5th ed. Champaign, IL: Human Kinetics; 2013.

- 7. Leon AS, Franklin BA, Costa F, Balady GJ, Berra KA, Stewart KJ, et al. Cardiac rehabilitation and secondary prevention of coronary heart disease: an American Heart Association scientific statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity), in collaboration with the American association of Cardiovascular and Pulmonary Rehabilitation. Circulation. 2005;111(3):369-76.
- 8. Anderson L, Oldridge N, Thompson DR, Zwisler A-D, Rees K, Martin N, et al. Exercise-Based Cardiac Rehabilitation for Coronary Heart Disease: Cochrane Systematic Review and Meta-Analysis. J Am Coll Cardiol. 2016;67(1):1-12.
- 9. Lavie CJ, Milani RV, Prevention. Disparate effects of improving aerobic exercise capacity and quality of life after cardiac rehabilitation in young and elderly coronary patients. J Cardiopulm Rehabil Prev. 2000;20(4):235-40.
- 10. Ades PA, Keteyian SJ, Wright JS, Hamm LF, Lui K, Newlin K, et al., editors. Increasing cardiac rehabilitation participation from 20% to 70%: a road map from the Million Hearts Cardiac Rehabilitation Collaborative. Mayo Clin Proc; 2017: Elsevier.
- 11. Fletcher GF, Balady GJ, Amsterdam EA, Chaitman B, Eckel R, Fleg J, et al. Exercise standards for testing and training: a statement for healthcare professionals from the American Heart Association. Circulation. 2001;104(14):1694-740.
- 12. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med. 2004;116(10):682-92.

- 13. Linden W, Stossel C, Maurice J. Psychosocial interventions for patients with coronary artery disease: a meta-analysis. Arch Intern Med. 1996;156(7):745-52.
- 14. Smith SC, Allen J, Blair SN, Bonow RO, Brass LM, Fonarow GC, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update: endorsed by the National Heart, Lung, and Blood Institute. J Am Coll Cardiol. 2006;47(10):2130-9.
- 15. Simchen E, Naveh I, Zitser-Gurevich Y, Brown D, Galai N. Is participation in cardiac rehabilitation programs associated with better quality of life and return to work after coronary artery bypass operations? The Israeli CABG Study. Isr Med Assoc J. 2001;3(6):399-403.
- 16. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med. 116(10):682-92.
- 17. Balady GJ, Ades PA, Bittner VA, Franklin BA, Gordon NF, Thomas RJ, et al. Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation. 2011;124(25):2951-60.
- 18. Grace SL, Russell KL, Reid RD, Oh P, Anand S, Rush J, et al. Effect of cardiac rehabilitation referral strategies on utilization rates: a prospective, controlled study. Arch Intern Med. 2011;171(3):235-41.
- 19. Taylor RS, Dalal H, Jolly K, Moxham T, Zawada A. Home-based versus centre-based cardiac rehabilitation. Cochrane Database syst rev. 2010(1):CD007130.

- 20. Pack QR, Mansour M, Barboza JS, Hibner BA, Mahan MG, Ehrman JK, et al. An early appointment to outpatient cardiac rehabilitation at hospital discharge improves attendance at orientation: a randomized, single-blind, controlled trial. Circulation. 2013;127(3):349-55.
- 21. Martin B-J, Hauer T, Arena R, Austford LD, Galbraith PD, Lewin AM, et al. Cardiac rehabilitation attendance and outcomes in coronary artery disease patients. Circulation. 2012;126(6):677-87.
- 22. Suaya JA, Stason WB, Ades PA, Normand S-LT, Shepard DSJJotAcoC. Cardiac rehabilitation and survival in older coronary patients. J Am Coll Cardiol. 2009;54(1):25-33.
- 23. Turk-Adawi KI, Oldridge NB, Tarima SS, Stason WB, Shepard DSJJotAHA. Cardiac rehabilitation patient and organizational factors: what keeps patients in programs? J Am Heart Assoc. 2013;2(5):e000418.
- 24. Pack QR, Johnson LL, Barr LM, Daniels SR, Wolter AD, Squires RW, et al. Improving cardiac rehabilitation attendance and completion through quality improvement activities and a motivational program. Circulation. 2013;33(3):153.
- 25. Gaalema DE, Savage PD, Rengo JL, Cutler AY, Higgins ST, Ades PA. Financial incentives to promote cardiac rehabilitation participation and adherence among Medicaid patients. Prev Med. 2016;92:47-50.
- 26. Beckie TM, Beckstead JW. Predicting cardiac rehabilitation attendance in a gender-tailored randomized clinical trial. J Cardiopulm Rehabil Prev. 2010;30(3):147.
- 27. Centers for Disease Control Prevention. Receipt of outpatient cardiac rehabilitation among heart attack survivors--United States, 2005. MMWR Morb Mortal Wkly Rep. 2008;57(4):89-94.

- 28. Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116(15):1653-62.
- 29. Blumenthal JA, Williams SR, Wallace AG, Williams Jr RB, Needles TL. Physiological and psychological variables predict compliance to prescribed exercise therapy in patients recovering from myocardial infarction. Psychosom Med. 1982;44(6):519-27.
- 30. McGrady A, McGinnis R, Badenhop D, Bentle M, Rajput M. Effects of depression and anxiety on adherence to cardiac rehabilitation. J Cardiopulm Rehabil Prev. 2009;29(6):358-64.
- 31. Spielberger CD. State-trait anxiety inventory for adults: manual instrument, and scoring guide: Mind Garden, Inc; 1983.
- 32. Roest AM, Martens EJ, de Jonge P, Denollet J. Anxiety and risk of incident coronary heart disease: a meta-analysis. J Am Coll Cardiol. 2010;56(1):38-46.
- 33. Rozanski A, Blumenthal JA, Kaplan J. Impact of psychological factors on the pathogenesis of cardiovascular disease and implications for therapy. Circulation. 1999;99(16):2192-217.
- 34. Lavie CJ, Milani RV. Prevalence of anxiety in coronary patients with improvement following cardiac rehabilitation and exercise training. J Am Coll Cardiol. 2004;93(3):336-9.
- 35. Cooper AF, Jackson G, Weinman J, Horne R. Factors associated with cardiac rehabilitation attendance: a systematic review of the literature. Clin Rehabil. 2002;16(5):541-52.
- 36. Whitmarsh A, Koutantji M, Sidell K. Illness perceptions, mood and coping in predicting attendance at cardiac rehabilitation. Br J Health Psychol. 2003;8(2):209-21.
- 37. Yohannes AM, Yalfani A, Doherty P, Bundy C. Predictors of drop-out from an outpatient cardiac rehabilitation programme. Clin Rehabil. 2007;21(3):222-9.

- 38. Moberly NJ, Watkins ERJBR, Therapy. Ruminative self-focus, negative life events, and negative affect. Behav Res Ther. 2008;46(9):1034-9.
- 39. Gallagher MW, Schoemann AM, Pressman SD. Mastery beliefs and intraindividual variability of anxiety. Cognit Ther Res. 2011;35(3):227-31.
- 40. Mor N, Doane LD, Adam EK, Mineka S, Zinbarg RE, Griffith JW, et al. Within-person variations in self-focused attention and negative affect in depression and anxiety: A diary study. Cogn Emot. 2010;24(1):48-62.
- 41. Dunton GF, Atienza AA. The need for time-intensive information in healthful eating and physical activity research: a timely topic. J Am Diet Assoc. 2009;109(1):30-5.
- 42. Shiffman S, Stone AA, Hufford MR. Ecological momentary assessment. Annu Rev Clin Psychol. 2008;4:1-32.
- 43. Nahum-Shani I, Smith SN, Tewari A, Witkiewitz K, Collins LM, Spring B, et al. Just in time adaptive interventions (jitais): An organizing framework for ongoing health behavior support. Methodology Center technical report. 2014;2014:14-126.
- 44. Swendsen J. Applications of Ecological Momentary Assessment in Clinical Practice. Eur Psychiatry. 2015;30:122.
- 45. Rosmalen JG, Wenting AM, Roest AM, de Jonge P, Bos EH. Revealing causal heterogeneity using time series analysis of ambulatory assessments: application to the association between depression and physical activity after myocardial infarction. Psychosom Med. 2012;74(4):377-86.
- 46. Kanning MK, Ebner-Priemer UW, Schlicht WM. How to investigate within-subject associations between physical activity and momentary affective states in everyday life: a position statement based on a literature overview. Front Psychol. 2013;4:187.

- 47. Bassett DR, Toth LP, LaMunion SR, Crouter SE. Step counting: A Review of measurement considerations and health-related applications. Sports Med. 2016;47(7):1303–15.
- 48. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA. 2007;298(19):2296-304.
- 49. Sisson SB, Camhi SM, Church TS, Tudor-Locke C, Johnson WD, Katzmarzyk PT. Accelerometer-determined steps/day and metabolic syndrome. Am J Prev Med. 2010;38(6):575-82.
- 50. Hornbuckle LM, Kingsley JD, Kushnick MR, Moffatt RJ, Haymes EM, Miles R, et al. Effects of a 12-month pedometer-based walking intervention in women of low socioeconomic status. Clin Med Insights Womans Health. 2016;9(Suppl 1):75-84. doi: 10.4137/CMWH.S39636. PubMed PMID: PMC5054940.
- 51. Crespo CJ, Keteyian SJ, Heath GW, Sempos CT. Leisure-time physical activity among US adults: results from the third national health and nutrition examination survey. Arch Intern Med. 1996;156(1):93-8.
- 52. Siegel PZ, Brackbill RM, Heath GW. The epidemiology of walking for exercise: implications for promoting activity among sedentary groups. Am J Public Health. 1995;85(5):706-10.
- 53. Watson KB, Frederick GM, Harris CD, Carlson SA, Fulton JE. US adults' participation in specific activities: Behavioral Risk Factor Surveillance System—2011. J Phys Act Health. 2015;12(s1):S3-S10.

- 54. Cupples M, Dean A, Tully M, Taggart M, McCorkell G, O'Neill S, et al. Using pedometer step-count goals to promote physical activity in cardiac rehabilitation: a feasibility study of a controlled trial. Am J Phys Med Rehabil. 2013;1(07):157-62.
- 55. Frederix I, Driessche NV, Hansen D, Berger J, Bonne K, Alders T, et al. Increasing the medium-term clinical benefits of hospital-based cardiac rehabilitation by physical activity telemonitoring in coronary artery disease patients. Eur J Prev Cardiol. 2015;22(2):150-8.
- 56. Izawa KP, Watanabe S, Omiya K, Hirano Y, Oka K, Osada N, et al. Effect of the self-monitoring approach on exercise maintenance during cardiac rehabilitation: a randomized, controlled trial. Am J Phys Med Rehabil. 2005;84(5):313-21.
- 57. Kitsiou S, Thomas M, Marai GE, Maglaveras N, Kondos G, Arena R, et al., editors.

  Development of an innovative mHealth platform for remote physical activity monitoring and health coaching of cardiac rehabilitation patients. The International Conference on Biomedical & Health Informatics; 2017.
- Thijs I, Fresiello L, Oosterlinck W, Sinnaeve P, Rega FJJm, uHealth. Assessment of Physical Activity by Wearable Technology During Rehabilitation After Cardiac Surgery: Explorative Prospective Monocentric Observational Cohort Study. J Med Internet Res. 2019;7(1):e9865.

## **Chapter II**

## **Literature Review**

#### **Cardiac Rehabilitation**

Cardiac rehabilitation (CR) is a three-phased program, including educational, exercise, and psychological counseling, aimed to help cardiac patients recover from a cardiac event, reduce the risk of a secondary cardiac event, stop or slow the worsening of their current cardiac condition, and help them return to their job and social life (1, 2). CR is often ordered for patients who have experienced a myocardial infarction, coronary artery bypass graft surgery, percutaneous coronary intervention, angina, heart transplant, valvular surgery, heart failure, or peripheral artery disease, and may can include some pulmonary patients (3) and is delivered beginning with the patients hospital stay and should be continued throughout the patient's life through a maintenance program (3).

Three main components of CR include exercise training, education, and risk factor and behavioral modification (3, 4). Exercise training offers many benefits for individuals with cardiovascular disease, including improved peak oxygen consumption 15-20% (5), completing activities of daily living with more ease (self-reported) (6), the angina threshold is delayed or completely ameliorated (7, 8), oxygen delivery to skeletal muscle is increased by greater extraction at muscle (9, 10), greater capillary density within the skeletal muscle (11), and heart size, stroke volume, cardiac output, and afterload are increased (10, 12). Education, risk factor and behavioral modification are components of psychosocial management. Educational opportunities offered in CR programs mainly focus on lifestyle modification, how to live with cardiovascular disease, stress management, nutritional counseling, smoking cessation, and exercise education programming. Nutritional counseling aims to reduce improve the lipid profile, reduce weight, and improve blood glucose levels of participants while the exercise classes aim to build maintenance after the patient completes the CR program (4). Risk factor assessments and

Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the predominant organization which outlines and certifies CR programs in the United States, suggests using an individualized approach to assess the risk factors and behavior change that would most benefit the patient while recognizing which behaviors they are willing and ready to alter. Additionally, AACVPR suggests supplying patient's education along with actionable plans and building self-reliance and self-monitoring skills to promote success and independence (3).

To be considered a CR program, the intervention must include those components outlined by the AACVPR (exercise, education, and risk factor/behavioral modification) (4).

Comprehensive CR programs have shown many benefits including reduced all-cause and cardiac mortality (2, 13), improved smoking cessation outcome (14), lowered blood pressure and total cholesterol (14), improved health-related quality of life (15, 16), improved functional capacity (16), and reduced the number of subsequent hospital visits and healthcare costs (13, 17, 18).

Some researchers have investigated exercise-only or psychosocial-only CR programs. Exercise-only programs provided results similar to that of comprehensive programs with regard to all-cause and cardiac mortality (19) but were not as effective in other areas such as smoking cessation, blood pressure, and total cholesterol (14). Additionally, CR programs that do not include exercise have reduced health-related quality of life outcomes (20). Long-term (12 month) maintenance of reduced depression and improved health-related quality of life provided with a comprehensive program (21).

**Phases of cardiac rehabilitation.** Phase I of CR is an inpatient program delivered following a cardiovascular-related surgery or event and typically includes mobilization and early education to prepare the patient for their return home from the hospital (3, 22). Mobility and

readiness for education are first assessed on a case-by-case basis which directs the course of phase I intervention. Mobilization in this phase typically includes a progression of movement from the lying position, to sitting, standing, and ambulating, as well as simple movements of the upper body and trunk (without resistance) (3). As progression continues, activities of daily living (e.g., bathing, dressing, grooming) are included to aid in the safe transition from hospital stay and independent living at home. The educational portion of phase I CR is also individualized for the patient, with the main goal of educating them about safety and proper treatment for their condition (e.g., proper medication use, contact information for physicians and other medical assistance, lifestyle modification, follow-up outpatient programs) (3).

Phase II of CR is a medically supervised outpatient program that can begin within one week of being discharged from the hospital (for uncomplicated percutaneous transluminal coronary angioplasty with or without a stent (3)) or between 3 weeks to 6 months following more complicated the surgical interventions (22). Phase II includes further assessment and management of risk factors for CVD progression through exercise training (three times per week) and educational sessions for lifestyle modification (3, 22). Exercise training is tailored to the individual capabilities and needs of the patient. The primary type of exercise included in this phase is aerobic, where the use of treadmills, stationary bikes, and other aerobic equipment is common, however, resistance training can be included if tolerated (3, 13, 23). During the exercise sessions, patients are continuously monitored (e.g., blood pressure, electrocardiogram, heart rate) and are visually observed by nurses and exercise physiologists to foster a safe exercise environment (3). Phase II programs require the presence of a supervising physician who responds to any medical emergencies that arise during CR sessions and who also reviews the

individualized treatment programs for those in the program. In total, this phase lasts 6 weeks or 36 sessions and the cost is typically covered by medical insurance and Medicare (3, 22).

Phase III is considered the maintenance phase of CR. Those who have successfully completed phase II can enter a phase III program to continue their exercise and lifestyle interventions. This, like phase II, is an outpatient program but monitoring of heart rate, blood pressure, and ECG occur periodically, not continuously. Educational sessions are less common during phase III and lifestyle coaching is also reduced; however, the level of these services can vary amongst phase III programs. Individuals in the maintenance phase may have the opportunity for more diverse exercise modalities like group fitness classes, resistance training, water-based exercise, and restorative practices like yoga or tai-chi (3).

Cardiac rehabilitation attendance and adherence. Participation in CR is very low, ranging from 20% to 35% (24-26). Initial referral, patient enrollment, and program adherence each contain individual issues that contribute to the overall low participation rates. The issues within each of these areas are not only related to participants, but also relate to the healthcare system and overall hospital administration.

Two reasons for low initial participation rates, low referral (22) and enrollment rates (18), stem from unclear communication among physicians and within the healthcare facilities. Referral guidelines include that for cardiovascular disease management, CR is a Class I-Level recommendation (the procedure/treatment should be performed/administered), based on clinical practice guidelines established by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) (27). Those that should be referred include patients with recent myocardial infarction, acute coronary syndrome, chronic stable angina, heart failure, heart or lung transplant, or who have undergone coronary artery bypass graft surgery, percutaneous

coronary intervention, or valve surgery and referral can only be completed by a physician (1, 27, 28). Although the guidelines are seemingly straightforward, a gap in care exists when determining the referring physician, which could be the patient's cardiologist or the cardiologist on call during hospital admission (3). Other reasons for reduced referral rates are lack of CR locations nearby and lack of insurance (16). Characteristics of patients who experience reduced referral rates are female gender, ethnic and racial minorities, older individuals (16, 28-30). A simple intervention with the potential for a large impact for increasing referral rates is automatic enrollment, based on cardiac diagnoses entered into electronic medical records. This method detailed by Grace et al. (31) would automatically refer all patients with eligible diagnoses upon their hospital discharge. Ades et al. (26) suggests this simple solution would triple referral rates.

Low enrollment rates are largely a consequence of gaps in care due to lack of follow up with those who are referred, but do not enroll. Suggested methods of improving enrollment are providing the patient with more individualized attention from a CR liaison to educate and assist with referral and enrollment (e.g., referral and planned start date as a component of hospital discharge), providing transportation or parking plan for CR attendance, and by providing choices for type of CR program (e.g., home, community, or hospital-based program) (3, 28, 32).

Additionally, an important factor of enrollment is reducing the time delay between hospital discharge and enrollment. Pack et al. (33) demonstrated that reducing the time between referral and enrollment, from the average 35 days to 10 days, increased the percent of CR attendance with no increased risk to patient safety. Interventions for the improvement of referral and enrollment are largely suggested for the healthcare facilities. While other issues like attendance and adherence should have interventions catered toward the participants.

Attendance and adherence to CR programs is low with drop-out rates ranging from 40% to 70% within the first 6 months (18, 26). Some common challenges to attendance and adherence include the patients' and physician's perception of the efficacy of CR (34-36), female gender (18, 24, 28, 37), older age (18, 35), low socioeconomic status (38), lower self-efficacy and motivation (39, 40), and increased depression and anxiety (41-44). Of these challenges, higher anxiety scores have been shown as an important and early predictor of adherence (42).

Anxiety. Anxiety is described as severe feelings of concern, worry, or anticipated threats and tension along with physical characteristics including increased blood pressure, sweating, or heart palpitations (45, 46). Two aspects of anxiety can be investigated: state and trait anxiety (47, 48). Trait anxiety has been described as a personality characteristic (or trait); stability in anxiety, day to day, across all situations (47, 49). State anxiety, on the other hand, is the momentary or temporary feeling (emotional state) of anxiousness one may experience in response to stimuli or experiences (47).

Experiencing higher levels of anxiety has been associated with the development, progression, and mortality related to cardiovascular disease (50-53). Hypertension, a common physiological outcome of anxiety and major contributor to the development of cardiovascular disease, predominates the theoretical association between anxiety and cardiovascular disease development (50, 51). For those who have been hospitalized with a cardiac-related diagnosis, CR has been shown to have an anxiety reducing effect (21, 54, 55), however, higher levels of anxiety are also associated with CR drop out (42).

A critical review additionally noted anxiety as an under-researched yet contributing factor to CR drop out (18). A study of 380 patients from a single CR program tracked patients from their initial psychological assessments through the time they either dropped out or

completed the program. Those who had the highest anxiety scores were individuals who dropped out after completing the psychological assessments but before the initial walk test and exercise session (early dropouts). The anxiety scores for the non-completers (those who left the program early) had the second highest anxiety scores. Finally, the completers had the lowest baseline anxiety scores. The scores between the completers and non-completers (both early and all dropouts) were significantly different, thus revealing an early indicator of poor adherence and potential opportunity for intervention (42). Similarly, Lavie and Milani (56) demonstrated that baseline anxiety scores are significantly higher in non-completers of the CR program as compared to completers. Interestingly, higher anxiety is also negatively associated with adherence to physical activity following a CR program (57).

Further investigations surrounding anxiety, cardiac rehabilitation, and physical activity are important as it is possible that decreasing anxiety levels of those in CR may improve attendance and adherence. Bauer et al. (58) demonstrated that reducing depression and anxiety, for those who were hospitalized for acute coronary syndrome, arrythmia, and heart failure, improved several health behaviors, specifically adherence to CR through the first six weeks of the program. This finding suggests that anxiety may be a point of intervention for improved adherence to CR.

A current gap in the literature is understanding the role of anxiety in the decisional process of deciding to engage in CR. Since CR is a repeated health promoting behavior, like regular physical activity, the choice to engage in CR is likely dynamic, depending on the current mood and emotional state of the participant. Currently, fluctuations in state-anxiety have been demonstrated when sampled three times across an 11-day period (59) but to gain insight on the impact of anxiety on the daily decision to engage in CR, one must first determine if this variable

fluctuates across the day. The assumption of one singular, static measure of anxiety representing the experience of an individual across an entire day is unlikely to represent their reality. To understand the decisional process and the influence of anxiety, fluctuation must first be explored across the day to map the trajectory of anxiety while also investigating within-person variability, as this factor is likely to fluctuate differently among individuals. To accomplish this, repeated-measures sampling methods, like experience sampling or ecological momentary assessment, should be implemented.

#### **Ecological Momentary Assessment**

Intensive longitudinal data. Traditional experimental research designs that employ infrequent self-report assessments in laboratory settings can test theories of biological and psychological processes and are necessary for experimental science (60). However, to understand psychological and behavioral processes that lead to the outcome of interest as it occurs in daily life, repeated assessments across the time period during which one exhibits said behavior in the free-living environment are necessary (60, 61). Additionally, over the past three decades, investigating individual-level or within-person responses in the natural, daily environment have been highlighted with significance. Individually assessing outcomes can elucidate how processes change per person and potentially direct key components of altering behaviors, while capturing responses in the natural environment reveals responses as they occur in reality, not controlled or influenced by a more clinical setting such as a doctor's office or laboratory (62-64).

Methods that include repeated samples in the free-living environment with analysis of results on within-person basis, can be described as intensive longitudinal methods. Their aim is to the improve ecological validity of measurements that provide descriptive statistics of

individual participants, allow for the investigation of within-person processes, and provide temporal associations between behaviors and their concurrent psychological and physiological states and environmental context (61). Additionally, this form of data collection reduces reporting bias (e.g., recall and social desirability biases) and the summary of previous feelings or moods, which is often a concern with self-reported information (60, 61).

There are several assessment techniques that fall under the umbrella of intensive longitudinal design (e.g., ecological momentary assessment, experience sampling methods, and ambulatory assessment). Within these techniques, diaries, surveys, event calendars, and objective measures of variables can be utilized to capture intensive longitudinal data (ILD) (61). In the health sciences, the primary technique used for collecting ILD is ecological momentary assessment (EMA) (61).

Ecological momentary assessment. EMA is a technique used to collect self-reported feelings, moods, behavioral cognitions, and contextual information in the moment, repeatedly across time. It allows for the study of unstable variables (e.g., moods, feeling states) and episodic behaviors as they change and are experienced across time or in response to events (65).

Additionally, with this form of ILD, within-subject analyses can be completed thereby providing important information pertaining to how individual subjects react and respond to certain situations and how their cognitive and behavioral factors fluctuation across time (65). Three main tenants of EMA are (1) assessments must be momentary (i.e., responses are based on how the participant feels "right this moment"), (2) measurements are repeated several times throughout the period of inquiry, and (3) responses are captured in the natural, real-world environment (65).

Momentary assessments are necessary for capturing behaviors and feelings as they occur. Momentary assessments reduce recall bias and error in reporting related to summarizing previous feelings or experiences (65, 66). In non-momentary self-report survey questions, participants may be asked to quantify an average amount of an autobiographical event over a specific period of time (e.g., how many alcoholic drinks they have had over the past week). Bradburn et al. (67) found that these responses tend to be unreliable, more so when occurrences of the event are habitual throughout the timeframe under question. Additionally, retrospective autobiographical questions have been found to be influenced by the respondent's current state (e.g., retrospective questions surrounding average pain are shown to be influenced by level of pain while completing the survey or questions surrounding affect have been demonstrated to be biased by the current affective state) (66, 68, 69) and self-reported mood also has been shown to be biased by the most recent or a strongly emotion-changing event the participant experienced that day (70, 71). To avoid the bias and reporting error associated with retrospective survey questions, momentary assessments of the current state of the participant are suggested (72).

Repeated assessments improve the resolution of assessments by establishing withinperson dynamics of the factors of interest. Not only does increasing the number of assessments
reduce recall bias, but it also allows for the capture of changes in mood or affect that change
quickly or in response to a certain event (73). As stated earlier, when non-momentary
assessments are used, an effect of summarizing moods and behaviors distorts the overall
measurement as well as the strong influence of the participants current state (66, 69). Improving
the resolution of behaviors, experiences, and their outcomes is hypothesized to predict lapses in
negative health behaviors. For example, several studies have noted weak correlations between
average mood and lapses in smoking behavior, however, Shiffman et al. (74) found that

regardless of the average level of negative affect, some smokers are more prone to lapse in cessation during momentary instances of negative affect, therefore require a more tailored and real-time intervention than others who are not affected by momentary negative affect. In this study it was important to tease out average negative affect from momentary negative affect to tease out those who are affected by momentary negative affect and those who are not. Dunton et al. (75) suggests that repeated assessments are also necessary to better understand factors related to engagement in health promoting behaviors, such as physical activity.

Capturing moods and behaviors in the real-world environment is necessary for understanding the contextual factors of these outcomes. In order for data to be ecologically valid, it must be collected in the natural environment (including physical location and social cues) of the subject to reveal applicable information for intervention development (76, 77). Several studies have noted that the context of physical environment (outdoors vs indoors) and being alone versus with other individuals influences engagement in physical activity (78-80). Children and adolescents both engage in more physical activity outside of the home and with other individuals (not alone). Children, specifically, engaged in most physical activity in parks while adolescents engaged in most walking at school and outdoors. The ability to identify the places and situations where activities occur can be employed in interventions by suggesting physical activity when individuals are near locations or in situations where activity regularly occurs (81).

Intensive longitudinal data, along with reducing recall bias, allowing for within-person analyses, and providing contextual information to measurements, also allows for investigation of behaviors and feelings as they change across time. Studying temporal associations describe behavior change (the behavior and covariates) as it occurs within an individual. Accurately describing behavior change is critical and necessary because this information can then be used to

predict behavior by identifying causes and outcomes of behaviors. This study is not limited to typical development as one ages, but also is used to describe other behaviors within individuals like engagement in addictions, precursors to lapses when attempting behavior change, and engagement in health-related, repeated behaviors (82).

The time-varying effect model is an approach for mapping behavior and other variables over time, in order to describe the shape of behaviors change. This model is novel in that it does not require the data to take a certain shape (e.g., linear, quadratic, exponential) and it allows for fluctuations in factors of interest. Along with describing the shape of measurements, this model also offers statistical methods to describe the relationship of behavior and covariates over time. Briefly, the statistical model is similar to multilevel modeling, where relationships can be described among several variables, with those variables being organized into several groupings (82). To obtain data that support this type of analysis, EMA is an extraordinary strong method due to the repeated, time stamped assessments (81). Describing data, such as fluctuations across time, is a necessary method to ensure that relationships occur within-individuals, as has been reported between-individuals (75).

Ecological momentary assessment in physical activity. Physical activity is a repeated health promoting behavior that regular engagement at the suggested levels has been shown to reduce the risk of cardiovascular disease, metabolic disorders, and breast and colon cancers, help to maintain a healthy body weight, and promote bone health (83, 84). The current physical activity guidelines for Americans suggest that adults engage in 150 to 300 minutes of aerobic activity at a moderate intensity, 75 to 150 minutes of aerobic activity at a vigorous intensity, or a combination that results in equivalent activity. Additionally, two days of week, or more, of muscle strengthening activity per week is also suggested (84). To date, compliance rates of

American adults meeting this guideline are unavailable, however, compliance with the previous guidelines, which were identical recommendations for time and intensity but required aerobic bouts to last a minimum of 10 minutes, were low. Compliance ranged from 10% to 62% based on assessments via accelerometer or self-report, respectively, despite the health benefits (85).

Given the beneficial outcomes of regular participation in physical activity, improvements to physical activity interventions are needed to improve compliance and extend activity opportunities to the larger population. Some physical activity interventions are based on health behavior theories. It has been suggested that current health behavior theories (e.g., Social Cognitive Theory, Health Belief Model, and Theory of Planned Behavior) are largely based on "limited occurrence" health behaviors (e.g., decisions made once per year like a yearly physical or once every few years like maintaining vaccinations), which do not translate well to repeated health behaviors (81, 86). In fact, meta-analyses comparing the effectiveness of theory-based and non-theory based physical activity interventions demonstrated that theory-based interventions are not more effective than those that are non-theory based (87-89). It is suggested that a limitation to these theories is that they do not account for intra-individual and within-day fluctuating mood states, feelings of affect, and other psychosocial variables or the influence of contextual factors or temporal association (81, 82, 86, 90).

In addition to the high resolution of within-person and within-day psychosocial variables and ecological validity, capturing physiological variables (91) as well as concurrent objective measurement of physical activity (92) is unique to and suggested for use along with EMA of physical activity. Several studies have investigated the feasibility of physical activity EMA while others aimed to determine antecedents, correlates, and outcomes leading to and resulting from physical activity.

Some studies have used EMA to investigate associations between physical activity and other factors in effort to describe ways in which variables are related to the decisional processes that lead to engagement in physical activity and could provide the basis of EMI to promote and increase physical activity. The following section will outline associations found with physical activity that may shape future EMI.

Engagement in physical activity, especially intentional physical activity such as exercise, requires forethought and planning. Fanning et al. (101) notes that time spent mind wandering is a significant percent of our total daily thoughts and that this mind wandering is, in fact, useful for planning and problem solving. In this study, participants were asked to respond to an hourly EMA of mind wandering and affect across one week, while wearing an ActiGraph GT3X+ during all waking hours of each day. The main findings of this study were that episodes of mind wandering, and positive affect were positively associated with higher levels of moderate to vigorous physical activity (101).

A study by Dunton et al. (80) investigated the association between physical activity and affect in adults. In this study, eight mobile surveys were delivered per day (across four days) which assessed physical and social context, affect, and current level of physical activity. The data were analyzed with multilevel modeling in order to determine if current physical activity moderated affect across contexts. The results of this study showed that positive affect was increased when being active with other people and being outdoors reduced negative affect. These findings could be used to modulate affect in physical activity interventions.

Similar studies have been completed looking distinctly at physical location of physical activity and at the predictive capacity of behavioral cognitions. In the study of physical location, Liao et al. (102) found that physical activity and sedentary behavior typically occurred at home

and most of these occurrences were while the participants were alone. Men completed more moderate to vigorous physical activity outside, in public green spaces while women completed more in their yard and driveway. Maher (103) found that of adults' behavioral cognitions (e.g., intention, self-efficacy, outcome expectations) intention to be physically active positively predicted physical activity in the morning and evening while self-efficacy positively predicted physical activity on weekday evenings. This line of research, investigating cognitions, behaviors, and temporal trends surrounding physical activity can identify time or situations of vulnerability that could be intervened upon as to promote physical activity. In the same vein, using other momentary factors, such as physical location along, could help to identify windows of opportunity for physical activity, where a flexible intervention could be implemented (75, 81).

Ecological momentary assessment in cardiac rehabilitation. Only one study using EMA as an assessment method has been conducted in a cardiac rehabilitation setting. This study investigated the direction and temporal association between depression and physical activity in five men who had previous myocardial infarction (104). This study revealed an overall negative relationship between physical activity and depression levels, however, the authors noted important intra-individual differences between the direction of the effect between depression and physical activity. In some participants, physical activity was preceded by depression, and in others, the reverse was true. Fluctuations in depression was shown to be explain more of the variance in physical activity for one participant, but much less for others. Additionally, the duration of the effect of depression on physical activity levels differed between participants. The application of these findings are limited due to the all-male, small sample and the depression-only focus, however, the results of this study represent the importance in accounting for intra-individual differences when exploring correlates and antecedents to physical activity behavior.

*Feasibility.* Mobile EMA has been found to be feasible for children, college-aged and vocational students, adults, and in some clinical populations (93-99).

Dunton et al. (93) completed a study assessing the feasibility of mobile EMA to assess children's physical activity and sedentary behavior. A small sample of children (N = 8, age range = 9 to 13 yrs) were provided with a smartphone (HTC Shadow) with software for collection of EMA data (MyExperience software) and all other features disabled. Children were prompted to answer 20 mobile surveys (2-3 min in duration), sent at random times across a four-day period (surveys were distributed outside of school hours). The surveys included questions of what they were doing at that moment (e.g., sports, exercise, reading, watching TV), location, if they were with other individuals, mood, and if they were enjoying the activity. Each child also wore an ActiGraph GT2M accelerometer during their four days of participation so reports of physical activity could be validated. In this study, the children answered 80% of surveys distributed and reports of exercise and physical activity were validated with higher objectively measured physical activity, indicating that self-reported activities were accurate.

An EMA was administered to a large sample (n=526) of adolescents, over the course of four days, every six months. Participants were provided with a Palm III handheld computer, heart rate monitor, and ActiGraph Mini-Motionlogger during the four days of monitoring. In this study, surveys were delivered via a custom program on the Palm III. This program emitted an audible beep every 30 minutes during waking hours which stimulated the participant to report the activity they were currently engaging in. Participants resulted in a 75% compliance rate with surveys. Activity and heart rate monitor compliance were not reported but the conclusion of this study suggests that these all are feasible means to collect momentary activity data on adolescents (94).

In a large sample of adults (114), EMA of physical activity was also found to be a feasible technique for assessing momentary activity. As outlined in the two previous studies, a four-day EMA of current physical activity was administered using HTC Shadow smartphones with MyExperience software. In this study, participants received eight surveys per day, assessing the current activity they were engaged in. During this study participants also wore an ActiGraph GT2M accelerometer for the objective measurement of activity and sedentary behavior. Overall survey compliance was 82% but, importantly, survey compliance when wearing the accelerometer was 85%. This should be a consideration when using EMA to assess physical activity especially when the validity of activity reports are being assessed as the accelerometer serves as the criterion measure (95).

Dunton and colleagues (94, 95, 100) demonstrated that from childhood to adulthood, EMA of physical activity is feasible. High compliance rates (75% to 85% compliance) was found for these groups. These studies also investigated the reliability of self-reported activity when compared back to accelerometer output. Overall, when physical activity was reported, it was supported by either higher step or activity counts, which indicated activity. This mapping is important to understand the reliability of self-reported activity. However, the current recommendation of objective monitoring along with EMA surveys remains as to capture the more commonly forgotten activity such as light activities of daily living and active transport (92).

The feasibility of EMA to assess physical activity has also been assessed in clinical and middle-aged and clinical populations. Ehlers, Huberty (97) completed a mobile EMA aimed to gather data about current physical activity, self-efficacy, and self-worth in middle-aged women. Surveys were delivered to the participants own mobile phones via short message (which included

a line to a Qualtrics survey) service two to three times throughout the day and during the survey period, participants were asked to wear a GENEActiv activity monitor. Survey compliance in this group was very high, with 91.1% of surveys being completed within the timeframe requested. In this study the survey completion rate while wearing the activity monitor was 80.0%, slightly lower than that reported in younger adults. The results of a usability survey administered at the conclusion of the study showed that 100% of the women agreed that the mobile surveys were easy to complete, they did not take too long to complete, and it was easy to read on the screen of the smartphone. The most common negative thought associated with this study was that the activity monitor was challenging to wear, uncomfortable, or became uncomfortable. Even with the negative feelings toward the accelerometer, the participants had excellent accelerometer wear compliance with 99% during waking hours.

It is necessary to also consider the feasibility of mobile EMA in clinical populations, especially due to the interest in this as a tool for behavior change. The feasibility of EMA surveys and ecological momentary intervention (EMI) responses delivered via a mobile application that participants downloaded to their smartphone. In this study, participants were encouraged to complete nine educational modules and five surveys per day pertaining to weight loss, in preparation for bariatric surgery. Each completed EMA survey triggered an EMI response either praising the participant for engaging in healthy, weight loss behaviors, or suggested exercise or engagement in a healthy behavior. The EMA responses were quite low (only 30% completion rate) but an average of seven out of the nine education modules were completed. Of benefit, those who participated in the study lost 7.3±4.4 kg of body weight as compared to 4.2±7.8 kg of body weight for those who were eligible for the study but did not participate (98). The findings of this study suggest that EMA/EMI is a feasible option for

intervention delivery. The low response rate for the EMA was concerning in this study but authors suggested that this could be the result of only allowing 60 minutes for a response to be valid. They also included that extending beyond that time frame could detract from the momentary analysis and therefore would not capture the variables properly (98).

Anxiety assessment. State-anxiety will be assessed using the six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI short form). State-anxiety is related to temporary condition, emotion, or reaction to a situation and is largely momentary, fluctuating throughout one day and varies from day to day (48). In general, anxiety has been reported to negatively influences participation in cardiac rehabilitation (44, 105), associated with early drop out from cardiac rehabilitation (44, 106), and for those who have suffered myocardial infarction, anxiety is a predictor of impaired quality of life, as reported from 12-month follow-up (44). Specifically, state-anxiety has been found to be higher for individuals who do not complete cardiac rehabilitation (44) and for those who do not engage in cardiac rehabilitation at all (107).

The STAI short form will be used to assess this factor because it is highly correlated with the original long form (r = .95) (108) and its brevity suits the requirements of repeated measurements (four measurements per day) as this reduces participant burden (the original form includes 20 items while the short form includes 6 items). The STAI short form was developed and validated with pregnant women (108) and since has been used to assess state-anxiety with several other populations, (e.g., those with gestational diabetes (109), older individuals (110), those at risk for exposure to an outbreak of swine flu (111), management of hypertension (112), and those undergoing computed tomography angiography (113).

## **Physical Activity Monitors**

Physical activity monitors (PAMs) are small, wearable devices that are used to objectively assess physical activity. Physical activity metrics provided these monitors typically includes step count per day, caloric expenditure, physical activity intensity or active minutes, and distance ambulated. Of these metrics, the most intuitive and commonly used is steps per day, therefore this review will focus on step count accuracy of the PAMs used in the current study.

Commonly, PAMs are small, wearable devices that contain at least contain an accelerometer, battery, processing chip, and internal memory in a plastic housing, however, other sensors may also measure heart rate, blood oxygen saturation, electrocardiogram waveforms, altitude, and body temperature (114-116). To assess physical activity, PAMs measure the changes in bodily accelerations and then process the raw acceleration data in ways that vary per manufacturer. Thresholds that have been calibrated to criterion measurements representing activity intensity or algorithms that are designed to count steps are then applied in order to translate the acceleration data into metrics representative of physical activity (e.g., activity counts, step counts) (116, 117).

Monitors are typically considered to fall within one of two categories: research-or consumer-grade (114). Research-grade activity monitors are typified by physically storing all raw data on the monitors physical memory, including a real-time clock within the device, and requiring monitor-specific software for data processing, while consumer-grade monitors typically transfer data at regular intervals to a separate computer or smartphone, are available for retail purchase, and are considerably less expensive(114, 118). Where research-grade activity monitors were once very commonly used, consumer-grade monitors are now considered an option for clinical and population-level research. For example, two Fitbit monitors, Fitbit Charge

2 and Alta, are used to track physical activity in the All of Us Study, a large cohort study initiated by the National Institutes of Health. Additionally, according to a recent search of clinicaltrials.gov, there are over 300 reported trials utilizing Fitbits in a variety of patient populations including cancer, gastric bypass, spinal stenosis, joint replacement, cardiovascular disease, and renal disease. Although there is a surge of consumer-grade monitor use, a similar search of the most commonly used research-grade monitor, ActiGraph, on clinicaltrials.gov returned over 600 studies utilizing this brand of monitor. Due to the wide use of both consumerand research-grade monitors, the accuracy of their measurements must be assessed.

Step count. Daily step counts are one of the most common and easily understood metrics provided by activity monitors. Along with their intuitive nature, benefits of using daily step counts as a metric include associations with positive health outcomes (e.g., accruing higher steps per day has been associated with reduced risk of metabolic syndrome (119), reduced body mass (120, 121), lowered systolic blood pressure (121)), they are a direct measure of walking and jogging, two of the most common physical activities in the US (122-124), and they are a motivator for increasing daily physical activity when a daily step count goal, along with concurrent monitoring is used (121). As researchers increase their use of consumer-grade activity monitors (114) and maintain use of research-grade monitors, it is necessary to investigate their accuracy across a variety of populations (e.g., varied health status, ages, and body sizes) (125, 126).

Many studies have assessed step count accuracy across many devices during treadmill ambulation, activities of daily living, and across all walking hours of a day. In general, findings suggest that many devices under-count steps when walking speed falls below <80 m/min (127-130), stepping is not continuous (e.g., bouts of stepping < 4 seconds in duration) or steps occur in

an irregular pattern (e.g., stepping during vacuuming) (131-133). When monitors are worn on the wrist, steps are over-estimated during non-ambulatory activities such as folding laundry (134) and under-estimated when patients use assistive walking devices like canes and walkers (135-137) or when healthy adults push strollers (131). Some other limitations of activity monitors include the inability to capture non-ambulatory activity (e.g., swimming, cycling, rowing) (138), data collection is dependent upon participants wearing the monitor, and monitors do not provide the mode of activity or contextual information (e.g., geographical location, indoor or outdoor setting, exercise versus physical activity) (81, 92).

StepWatch. The StepWatch activity monitor is a small and lightweight research grade, step counting device (70 X 50 X 20 mm; 38g), that is worn on the side of the ankle, directly above the lateral malleoli, affixed by a Velcro strap. This device is initialized using a docking station attached to a computer with the Modus software installed. When initializing the StepWatch, the participants height must be entered, age and weight are optional. Height impacts the cadence and sensitivity step count settings for this monitor. The cadence setting determines the duration of time that must be waited following one step, before another step can be counted. To solve for the applied delay time, the cadence setting (reported by the Modus software following initialization) can be multiplied by 0.01-sec. The sensitivity setting describes the acceleration threshold that a participant must surpass to count a step (139).

There are several preprogrammed StepWatch settings that can help to tailor the cadence and sensitivity settings for individuals with different gait patterns. The cadence and sensitivity settings are based on four main criteria: 1.) if the participant engages in quick stepping, 2.) walking speed, 3.) range of walking speeds, 4.) and leg motions. Based on the participants typical gait pattern and walking speed, the researcher can select the appropriate options per

participant and thus their cadence and sensitivity will be adjusted (140). To complete initialization, an epoch for step reporting is selected (3-sec to 120-sec). The StepWatch has limited memory so the selected epoch will determine the total number of days data can be collected. At the shorted epoch selected, the StepWatch will be limited to 48 hours of data collection, meanwhile when 120-sec is selected, 15 days of continuous data can be collected (141).

At the end of the data collection period, data are downloaded by connecting to a docking station attached to a computer with the Modus software. The Modus software provides total stride count for the selected epoch (139, 142). To obtain total step count, researchers are required to multiply the stride count by two in order to obtain total step count.

The step counting accuracy of the StepWatch has been assessed during treadmill walking in several studies with healthy adults (132, 140, 143, 144). For speeds of 1.5 to 4.5 mph, Hickey et al. (132) found the StepWatch to capture 99% of hand counted steps. Feito et al. (143) found similar results for 1.5 to 3 mph and Toth et al. (140) additionally found that the StepWatch captured 99% of hand counted steps between 2 and 4 mph while walking on a treadmill. At speeds of 5 mph and greater, the step count error increases, however, Toth et al. (140) determined that by adjusting the cadence setting to 70% of the default and by increasing the sensitivity setting to 16, the range of treadmill walking and running speeds where the StepWatch can capture within 5% of all hand counted steps is expanded from 2 to 10 mph. The StepWatch step count accuracy has also been assessed and the monitor has been validated for several clinical populations (e.g., Parkinson's disease, post-stroke, multiple sclerosis) (145-148) and those who walk slowly (e.g., elderly, COPD) (136, 149, 150).

Bergman et al. (149) examined the step count validity of the StepWatch over a one-tenth mile walk with older adults (N=21, mean age 78.6 yr) where average walking speed was 1.5 mph. Participants were asked to walk at a self-selected pace, continuously, for one-tenth mile while wearing the StepWatch. All steps were hand counted during the trial which served as the step count criterion for comparison. Overall, the StepWatch overestimated total steps by 2.5% (a difference of 11 steps for an average trial of 433 hand counted steps). The DigiWalker SW-200, another pedometer was included in this study and worn during the same trial. The DigiWalker had greater step counting error, on average underestimating steps by 52%.

Similar to that of Bergman, Treacy et al. (150) investigated the validity of 8 step counting monitors in a slow-walking population. In this study inpatient participants (N=166) ambulated at speeds ranging from 0.9 to 2.7 mph and steps count accuracy was assessed during a 6 Minute Walk Test. The StepWatch was the most accurate step counting monitor across all speeds, maintaining a 98% agreement with GAITRite counted steps, the criterion step count used in this study. Other monitors ranged from 84% agreement (Fitbit One) to 26% agreement (ActiGraph GT3X+).

Laboratory based studies of activities of daily living have been completed to assess PAMs during specific activities. Overall, the step count error is greater during activities of daily living than during continuous walking. Hickey et al. (132) demonstrated that the percent error for several multidirectional (13.5%) and side-to-side (10.6%) activities of daily living resulted in increased error over that of forward-motion locomotor activities (6.2%). Similar results were found by Toth et al. (140) where continuous treadmill ambulation ranged from 1 to 5% error but expanded up to 12% error for vacuuming, tennis, cleaning counter tops, and dusting.

In a study completed in the most ecologically valid setting, free-living across one day, participants wore a chest mounted GoPro video camera and recorded all steps taken across one day. At the same time, they wore several activity monitors, including four StepWatch activity monitors, each initialized with a different quick start setting: (1) default, (2) quick stepping, (3) both extremes (of walking speed), and (4) quick stepping with dynamic/fidgety leg motion. All steps captured on the video were hand counted (criterion measure) and the total step counts from each StepWatch were compared back to the criterion. The StepWatch results are as follows, each percent representing the percent of hand counted steps: default setting captured 102%, both extremes captured 97%, quick stepping captured 100%, and quick stepping with dynamic/fidgety leg motion captured 94%. The StepWatch resulted in the least error of all monitors included in this study, and due to the superior step counting accuracy of this device, it was concluded that it could be confidently used as a criterion method for future studies investigating the error of step counting monitors (118).

ActiGraph, LLC. ActiGraph, LLC (Pensacola, FL) is a research-grade activity monitor manufacturer. Current ActiGraph activity monitors include ActiGraph GT3X+, ActiGraph GT3X-BT, and ActiGraph GT9X. Only the GT9X will be detailed in the following section because it was the only ActiGraph utilized in the current study.

ActiGraph GT9X Link. The ActiGraph GT9X Link (GT9X) is a small, lightweight (35 X 35 X 10mm, 14g) research-grade activity monitor that can be worn on the wrist, waist, ankle, or thigh. This monitor includes a primary tri-axial accelerometer, an inertial measurement unit with a secondary accelerometer, gyroscope, and magnetometer, and Bluetooth LE and USB connectivity. This monitor is initialized by and data are downloaded with ActiLife software (ActiGraph LLC, Pensacola, FL). Depending on initialization configuration, the battery life of

GT9X monitors is up to 14 days (151). Three methods of processing GT9X step count data are available. First, the ActiLife step counting algorithm is the basic algorithm included within the ActiLife software. For slower walking or older individuals, the low-frequency extension can be enabled, which broadens the bandpass filter, to allow more low end accelerations included for step count analysis (152). Lastly, the Moving Average Vector Magnitude algorithm can be applied to GT9X raw data (153).

Relatively few studies have investigated the step count accuracy of the GT9X worn on the hip. The most comprehensive study is one described above, where total daily steps were compared back to hand counted steps video recorded across one day. In this study, the GT9X data were processed with the ActiLife algorithm, with the low-frequency extension, and with the moving average vector magnitude algorithm. Across one day, the ActiLife algorithm was found to undercount steps, capturing only 68% of hand counted steps. Enabling the low frequency extension caused steps to be over-counted, capturing 126% of hand counted steps. Finally, the moving average vector magnitude algorithm had similar outcomes as the ActiLife algorithm, capturing 70% of hand counted steps (118).

Fitbit Charge 2. The Fitbit Charge 2 is a consumer-grade fitness tracker that is worn on the wrist, placed one finger's width away from the ulnar styloid process, toward the elbow(154). It includes a tri-axial accelerometer, altimeter, and an optical heart rate tracker. Some of the variables displayed are steps, sleep duration, heart rate, and gross caloric expenditure. Battery life of this device is up to five days. Minute-by-minute physical activity data are saved for seven days, and daily totals are saved for 30 days. This device includes an organic light-emitting diode (OLED) display, allowing users to read data directly from the device, and can be synchronized

with mobile devices (e.g., smartphones and tablets) and computers via Bluetooth LE wireless connectivity (154, 155).

The majority of studies that have investigated the Fitbit Charge 2 focused on heart rate accuracy. To date, no studies have assessed the step count error with this specific model. Many studies, however, have investigated steps with the Fitbit Charge and Fitbit Charge HR (118, 133, 150, 156). In a laboratory based-study, participants were asked to wear a Charge and other equipment while participating in 20 minutes of sedentary desk work, 25 minutes of aerobic exercise, and 25 minutes of activities of daily living. Steps were collected before and after each activity type and were compared to the criterion method for counting steps in this study, which were step counts reported from a Yamax DigiWalker. The Charge captured 107.5% of DigiWalker captured steps for all activities combined. Interestingly, the Charge captured an average of 1002 steps during the activities of daily living, while the DigiWalker only captured an average of 571 steps (156). This signifies a difference in sensitivity between these two monitors. Because steps were not hand counted or a StepWatch was not included in this study, one cannot determine if the Charge over or under-estimates true steps.

It was also noted that when systematically investigating intermittent walking, the step counting algorithm includes a six second continuous step counting requirement. In this study, participants were asked to walk a specific number of steps (4, 6, 8, 10, and 12), then pause for 10 seconds and repeat this for two minutes. The Charge did not begin to add steps to the overall count until at least six seconds of stepping was completed. In the second part of the study, participants were asked to take four steps and then rest for a certain length of time (1, 2, 4, 6, 8, and 10 seconds) and repeat this for two minutes. This part of the study was completed in effort to find the minimum rest time that would clear the step cache, thereby restarting the continuous

stepping requirement. For the Charge, it was found that any rest longer than one second would restart the stepping requirement. These findings of a six second stepping requirement and a pause longer than one second would refresh this requirement are notable because these limitations prevent short walking bouts (less than six seconds in duration) from being added to the aggregate step count, thereby explaining some of the under-counted steps across one day (133).

When assessed with inpatient stroke rehabilitation patients where were older and slower walking, it was noted that during a six-minute walk test, the percent agreement with directly observed steps was poor, with only 52% agreement. Additionally, the intra-class correlation with observed steps was low (ICC = 0.399). It was concluded that the poor agreement for the Charge was largely driven by slow walking in this population. Upon grouping walking speeds, the percentage accuracy of Charge monitors showed a steep decline at 0.59 m/s and slower speeds. It was concluded that for very slow walking individuals, Charge monitors largely under-estimate steps. Other monitors such as StepWatch and Fitbit One (worn on the ankle) would be more appropriate for step count assessment for these individuals (150).

Fitbit Zip. The Fitbit Zip is a waist-worn consumer-grade wireless activity tracker. It is a small and lightweight device (35.6 X 28.9 X 9.6mm, 8g) and can be worn in three locations (waistband, pants pocket, or bra) attached via the silicone clip (157). This device includes a triaxial accelerometer and a replaceable watch battery that lasts up to 6 months. Step count, caloric expenditure, distance ambulated, and active minutes are displayed on the LCD screen and the device can sync with and display data on mobile devices (e.g., smartphones and tablets) and computers via Bluetooth 4.0 wireless connectivity (158).

Several laboratory-based studies have investigated the step count accuracy of the Fitbit Zip (159, 160). Huang et al. (159) investigated the Zip in three scenarios: flat, overground

walking (400 m) at a self-selected speed, walking up and down 16 flights of stairs, and treadmill walking at 2, 3, and 4 mph. The Zip results showed low error scores, missing  $0.1 \pm 0.6\%$  (M  $\pm$  SD) of hand counted steps taken during the flat, overground walking,  $1.1 \pm 2.7\%$  walking up flights of stairs, and  $5.3 \pm 10.0\%$  walking down flights of stairs. These results were not significantly lower than any of the other devices assessed. No significant difference in error scores between 2, 3, and 4 mph resulted from the treadmill walking conditions for the Zip. Each speed resulted in slight step count underestimations (-2.7  $\pm$  6.6, -5.8  $\pm$  11.6 -3.4  $\pm$  5.7, respectively) (159).

Imboden et al. (160) specifically investigated the Zip in slow walking conditions (0.6 mph, 1.2 mph, and 1.9 mph). In this study, participants were asked to walk 100 steps while wearing the monitor and error scores were calculated. Results showed the trend for step count error to decrease as walking speed increased. In the 0.6 mph condition, percent error was quite high at 96.0%, it decreased drastically to 17.3% in the 1.2 mph condition and was negligible at -0.7% for the 1.9 mph condition. For individuals who walk slower than 1.9 mph, the Zip should be used with caution as this monitor will under-estimate steps (160).

Nelson et al. (134) investigated the step count error of the Zip during several activities but added including household activities. Earlier studies showed low step count error for continuous walking above 1.9 mph, however, the error associated with household activities was much larger. The mean absolute percentage error for this activity was 70%. The mean absolute error in terms of steps is challenging to interpret for this study, as the number of hand-counted steps for the household activities are not published. In comparison to other monitors included in this study, the Zip had showed a greater mean absolute percentage error than the Fitbit Flex

(58%) and the Jawbone Up (54%), however, the Omron HJ-722 (79%) and Fitbit One (71%) both had slightly greater error than the Zip (134).

Apple Watch Series 2. The Apple Watch Series 2 is a wrist-worn consumer-grade smartwatch with fitness tracking capabilities. The Apple Watch Series 2 is sold in two sizes (38 and 42mm) and the unit chosen for this study is the smaller and lighter unit (38.6 X 33.3 X 11.4, 28.2g). Sensors included in this monitor are an optical heart rate sensor, tri-axial accelerometer, gyroscope, and global positioning system (GPS) and data are displayed via an OLED display (161). Physical activity estimates provided directly on the Apple Watch display include step count, caloric expenditure, distance ambulated, and hourly stand count. A record of physical activity and heart rate data is maintained by syncing the Apple Watch to an iPhone, via Bluetooth 4.0 connectivity. The battery life of the Apple Watch Series 2 is approximately 18 hours (161, 162).

The Apple Watch is of particular interest to the medical community for its platform for health-related research, integration of patient-driven health data with electronic medical records, and opportunities for personalized health management for patients. The Apple ResearchKit offers a platform, support, and framework for app development for health-related research. The platform is designed for clinical trials, allowing for patient-driven, intensive longitudinal data to be collected passively via the Apple Watch, supplementing the data collected from the app created for the trial (163, 164). The Apple HealthKit allows for the collection and storage of health-related data (both stable characteristics like allergies and chronic conditions and intensive longitudinal data (i.e., step count per day and heart rate variability) all in one place. The HealthKit is currently integrated with EPIC electronic health records (EMRs) and the Mayo Clinic to supplement medical records with notes of symptoms, medication tracking,

immunization records, and changes in health status (164, 165). Additionally, Apple CareKit is a platform for creating apps that can help individuals track trends and changes in personal health, symptoms, and medications and even communicate with health care teams to manage medical conditions more effectively and on a more personalized basis (163).

Several studies have assessed the step count accuracy of the Apple Watch. The majority of these studies assessed step count error with treadmill walking and running (166, 167). Wallen et al. (167) examined the step count error of the Apple Watch during the first three stages of a Bruce Treadmill test, with speeds ranging from 1.7 to 3.4 mph, beginning with a 10% grade in the first stage and increasing to 14% grade in the third stage. The results of this study revealed that steps were underestimated, when compared to hand counted steps, however Pearson's correlation coefficient between the Apple Watch and hand counted steps was strong (r = 0.70)and the average step counting error of all devices included were low (4 to 6% error). Modave et al. (166) completed a similar study of step count error and treadmill walking with the Apple Watch Series 2, however this protocol included 1000 steps of treadmill walking at a self-selected speed between 2 and 3 mph and stratified for three age groups (18-39, 40-64, 65-84 yrs). For the 18-39 and 40-64 yr age groups, the Apple Watch slightly undercounted steps, by 2 and 3%, respectively, and slightly overestimated steps for the oldest group (2% overestimation). These small errors were not significant for any of these age groups. One study by Veerabhadrappa et al. (168) investigated step count error at three walking and one running speed (1.9, 3.0, 4.0, and 5.2 mph) on a treadmill. Compared to hand counted steps, the Apple Watch slightly overestimated steps for all walking speeds (-2.6, -0.9, and -1.6%, at 1.9, 3.0, and 4.0 mph, respectively) and slightly overestimated (3.4%) for jogging at 5.2 mph.

To date, only one study has investigated the step count accuracy of an Apple Watch during free living activities in a laboratory setting. Participants completed 25 minutes of freeliving activities (e.g., sweeping, stretching, and folding laundry), 20 minutes of sedentary activities (e.g., using a laptop and reading a book), and 25 minutes of treadmill walking or running at a self-selected speed. Step counts were assessed before and after each 20- or 25minute activity segment, thus activity specific error was not analyzed. During the free-living activities, Apple Watch monitors overestimated steps resulting in a mean percent error of 148%, steps taking during sedentary activities were underestimated by -272%, and treadmill walking or running resulted in the least error, 0.7%. The authors suggested that the overestimation from the free-living activities was due to the wrist-worn monitor capturing arm movements and misclassifying those movements as steps. It was noted that many of the activities included in this protocol were non-ambulatory, but did require repetitive movements of the arms (156). An overestimation of steps during non-ambulatory activities has been found with other wrist-worn monitors like Fitbit Flex, Garmin Vivofit, and Jawbone Up (127) for folding laundry and the Jawbone Up for outdoor cycling, washing and drying dishes, and rowing (169).

Steps per day and cardiac rehabilitation. Steps per day are an intuitive metric which are scaled to the physical capabilities of participants (170). Specifically, in cardiac rehabilitation, researchers have shown interest with using steps as a predictor of hospitalization (171) and as a physical activity goal to meet in cardiac rehabilitation interventions or programs (172, 173) or a more general goal for secondary prevention (174).

Takahashi et al. (171) gathered a sample steps per day, from inpatient cardiac surgery patients, post-surgery. One year later, following the step collection, patients were asked to complete a survey regarding their health condition. The purpose of this study was to determine if

a certain inpatient step count value predicted cardiac re-hospitalization within one year of discharge. From a sample of 133 patients, 16 were re-hospitalized within the year follow up. These patients had significantly lower steps counts than those who were not re-hospitalized. The cut point determined by the receiver operating curve was 1,308 steps per day. Out of several other factors measured (e.g., anxiety and depression score, operation type, ejection fraction, hospital stay length) the strongest predictor of cardiac re-hospitalization was a low step count prior to discharge (Takahashi et al., 2015).

Steps goals have been integrated into cardiac rehabilitation interventions in order to improve the participation in these programs. A study developed by Cupples et al. (173) invited patients from a traditional cardiac rehabilitation program to join a community-based program that aimed to promote continued physical activity following cardiac rehabilitation. The intervention simply provided participants with an individualized step count goal per week, and this was delivered by a clinical facilitator, who was a cardiac rehabilitation specialist. It was found that this program, that was tailored for each participant was feasible for promotion of continued physical activity. This simplistic intervention maintained and even was shown to increase step count per week by about 2,000 steps (173).

Earlier work has determined a target step goal for the secondary prevention of CVD. Researchers developed the goal by correlating step count with a range of caloric expenditure above 1,000 kcal per week, which is a level that should be exceeded for secondary prevention. The daily step count found to match this level of activity and provide adequate physical activity as to protect against secondary cardiovascular events is an accumulation of 6,500 to 8,500 steps per day (174).

Determining cut points and interventions that aim to maintain physical activity and protect against secondary events are necessary, but they also must be translatable, and the monitors selected for measurement must be assessed. For example, in the study that determined a target step goal for secondary prevention, the Kenz Lifecorder was used to assess step count (174). It has been established that Lifecorder monitors undercount steps at walking speeds below 67 m/min (130), therefore it is likely that the goal recommended would be slightly higher if a more sensitive monitor, like the StepWatch, was chosen for the original investigation. This and the increasing popularity of reliance on wearable activity monitors and step count for tracking of clinical populations (114) demonstrate the importance of investigating the error of these monitors for various populations and to work towards harmonization among monitor manufacturers.

## References

- Thomas RJ, Balady G, Banka G, Beckie TM, Chiu J, Gokak S, et al. 2018 ACC/AHA
   Clinical Performance and Quality Measures for Cardiac Rehabilitation: A Report of the

   American College of Cardiology/American Heart Association Task Force on Performance
   Measures. J Am Coll Cardiol. 2018:24587.
- 2. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med. 2004;116(10):682-92.
- 3. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for cardiac rehabilitation and secondary prevention programs. 5th ed. Champaign, IL: Human Kinetics; 2013.
- 4. Balady GJ, Fletcher BJ, Froelicher ES, Hartley LH, Krauss RM, Oberman A, et al. Cardiac rehabilitation programs. A statement for healthcare professionals from the American Heart Association. AHA Medical/Scientific Statement. Positioning Statement. Circ J. 1994;90(3):1602-10.
- 5. Wenger N, Froelicher E, Smith L, Ades P, Berra K, Blumenthal J, et al. Cardiac Rehabilitation. Clinical Practice Guideline No. 17. Rockville, MD: US Department of Health and Human Services. 1995.
- 6. Ades PA, Maloney A, Savage P, Carhart RL. Determinants of physical functioning in coronary patients: response to cardiac rehabilitation. Arch Intern Med. 1999;159(19):2357-60.
- 7. Redwood DR, Rosing DR, Epstein SE. Circulatory and symptomatic effects of physical training in patients with coronary-artery disease and angina pectoris. N Engl J Med. 1972;286(18):959-65.

- 8. Ades PA, Grunvald MH, Weiss RM, Hanson JS. Usefulness of myocardial ischemia as predictor of training effect in cardiac rehabilitation after acute myocardial infarction or coronary artery bypass grafting. Am J Cardiol. 1989;63(15):1032-6.
- 9. Ehsani AA, Biello DR, Schultz J, Sobel BE, Holloszy J. Improvement of left ventricular contractile function by exercise training in patients with coronary artery disease. Circulation. 1986;74(2):350-8.
- 10. Ades PA, Waldmann ML, Meyer WL, Brown KA, Poehlman ET, Pendlebury WW, et al. Skeletal muscle and cardiovascular adaptations to exercise conditioning in older coronary patients. Circulation. 1996;94(3):323-30.
- 11. Hambrecht R, Wolf A, Gielen S, Linke A, Hofer J, Erbs S, et al. Effect of exercise on coronary endothelial function in patients with coronary artery disease. N Engl J Med. 2000;342(7):454-60.
- 12. Hagberg JM. Physiologic adaptations to prolonged high-intensity exercise training in patients with coronary artery disease. Med Sci Sports Exerc. 1991;23(6):661-7.
- 13. Anderson L, Oldridge N, Thompson DR, Zwisler A-D, Rees K, Martin N, et al. Exercise-based cardiac rehabilitation for coronart heart disease: Cochrane systematic review and meta-analysis. J Am Coll Cardiol. 2016;67(1):1-12.
- 14. Jolliffe J, Rees K, Taylor R, Thompson D, Oldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease. Cochrane Database syst rev. 2001(1):CD001800.
- 15. Simchen E, Naveh I, Zitser-Gurevich Y, Brown D, Galai N. Is participation in cardiac rehabilitation programs associated with better quality of life and return to work after coronary artery bypass operations? The Israeli CABG Study. Isr Med Assoc J. 2001;3(6):399-403. Epub 2001/07/04. PubMed PMID: 11433629.

- 16. Leon AS, Franklin BA, Costa F, Balady GJ, Berra KA, Stewart KJ, et al. Cardiac rehabilitation and secondary prevention of coronary heart disease: an American Heart Association scientific statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity), in collaboration with the American association of Cardiovascular and Pulmonary Rehabilitation. Circulation. 2005;111(3):369-76.
- 17. Ades PA. Cardiac rehabilitation and secondary prevention of coronary heart disease. N Engl J Med. 2001;345(12):892-902.
- 18. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. Prog Cardiovasc Nurs. 2002;17(1):8-17. Epub 2002/03/02. PubMed PMID: 11872976.
- 19. Lawler PR, Filion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation post–myocardial infarction: A systematic review and meta-analysis of randomized controlled trials. Am Heart J. 2011;162(4):571-84. e2.
- 20. Shepherd CW, While AE. Cardiac rehabilitation and quality of life: a systematic review. Int J Nurs Stud. 2012;49(6):755-71.
- 21. Yohannes AM, Doherty P, Bundy C, Yalfani A. The long-term benefits of cardiac rehabilitation on depression, anxiety, physical activity and quality of life. J Clin Nurs. 2010;19(19-20):2806-13.
- 22. Thomas RJ, King M, Lui K, Oldridge N, Piña IL, Spertus J, et al. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services: endorsed by the American college of chest

physicians, American college of sports medicine, American physical therapy association, Canadian association of cardiac rehabilitation, European association for cardiovascular prevention and rehabilitation, inter-American heart foundation, national association of clinical nurse specialists, preventive cardiovascular nurses association, and the society of thoracic surgeons. J Am Coll Cardiol. 2007;50(14):1400-33.

- 23. Fletcher GF, Balady GJ, Amsterdam EA, Chaitman B, Eckel R, Fleg J, et al. Exercise standards for testing and training: a statement for healthcare professionals from the American Heart Association. Circulation. 2001;104(14):1694-740.
- 24. Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116(15):1653-62. Epub 2007/09/26. doi: 10.1161/circulationaha.107.701466. PubMed PMID: 17893274.
- 25. Centers for Disease Control Prevention. Receipt of outpatient cardiac rehabilitation among heart attack survivors--United States, 2005. MMWR Morb Mortal Wkly Rep. 2008;57(4):89-94. Epub 2008/02/01. PubMed PMID: 18235423.
- 26. Ades PA, Keteyian SJ, Wright JS, Hamm LF, Lui K, Newlin K, et al., editors. Increasing cardiac rehabilitation participation from 20% to 70%: a road map from the million hearts cardiac rehabilitation collaborative. Mayo Clin Proc; 2017: Elsevier.
- 27. Thomas RJ, King M, Lui K, Oldridge N, Piña IL, Spertus J. AACVPR/ACCF/AHA 2010
  Update: Performance Measures on Cardiac Rehabilitation for Referral to Cardiac
  Rehabilitation/Secondary Prevention Services: Endorsed by the American College of Chest
  Physicians, the American College of Sports Medicine, the American Physical Therapy
  Association, the Canadian Association of Cardiac Rehabilitation, the Clinical Exercise

Physiology Association, the European Association for Cardiovascular Prevention and Rehabilitation, the Inter-American Heart Foundation, the National Association of Clinical Nurse Specialists, the Preventive Cardiovascular Nurses Association, and the Society of Thoracic Surgeons. Journal of the American College of Cardiology 2010;56(14):1159-67.

- 28. Balady GJ, Ades PA, Bittner VA, Franklin BA, Gordon NF, Thomas RJ, et al. Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation. 2011;124(25):2951-60.
- 29. Plach SK. Women and cardiac rehabilitation after heart surgery: patterns of referral and adherence. Rehabil Nurs. 2002;27(3):104-9.
- 30. Missik E. Women and cardiac rehabilitation: accessibility issues and policy recommendations. Rehabil Nurs. 2001;26(4):141-7.
- 31. Grace SL, Russell KL, Reid RD, Oh P, Anand S, Rush J, et al. Effect of cardiac rehabilitation referral strategies on utilization rates: a prospective, controlled study. Arch Intern Med. 2011;171(3):235-41.
- 32. Higgins RO, Murphy BM, Goble AJ, Le Grande MR, Elliott PC, Worcester M. Cardiac rehabilitation program attendance after coronary artery bypass surgery: overcoming the barriers. Med J Aust. 2008;188(12):712.
- 33. Pack QR, Mansour M, Barboza JS, Hibner BA, Mahan MG, Ehrman JK, et al. An early appointment to outpatient cardiac rehabilitation at hospital discharge improves attendance at orientation: a randomized, single-blind, controlled trial. Circulation. 2013;127(3):349-55.

- 34. Ades PA, Waldmann ML, McCann WJ, Weaver SO. Predictors of cardiac rehabilitation participation in older coronary patients. Arch Intern Med. 1992;152(5):1033-5.
- 35. Jackson L, Leclerc J, Erskine Y, Linden W. Getting the most out of cardiac rehabilitation: a review of referral and adherence predictors. Heart. 2005;91(1):10-4.
- 36. Hellman EA. Use of the stages of change in exercise adherence model among older adults with a cardiac diagnosis. J Cardiopulm Rehabil Prev. 1997;17(3):145-55.
- 37. Doll JA, Hellkamp A, Ho PM, Kontos MC, Whooley MA, Peterson ED, et al. Participation in cardiac rehabilitation programs among older patients after acute myocardial infarction. JAMA Internal Medicine. 2015;175(10):1700-2.
- 38. Harlan III WR, Sandier SA, Lee KL, Lam LC, Mark DB. Importance of baseline functional and socioeconomic factors for participation in cardiac rehabilitation. The American journal of cardiology. 1995;76(1-2):36-9.
- 39. Rhodes R, Morrissey MJ, Ward A. Self-motivation: a driving force for elders in cardiac rehabilitation. Geriatric Nursing. 1992;13(2):94-8.
- 40. Woodgate J, Brawley LR, Weston ZJ. Maintenance cardiac rehabilitation exercise adherence: Effects of task and self-regulatory self-efficacy. J Appl Soc Psychol. 2005;35(1):183-222.
- 41. Lavie CJ, Milani RV. Prevalence of anxiety in coronary patients with improvement following cardiac rehabilitation and exercise training. J Am Coll Cardiol. 2004;93(3):336-9.
- 42. McGrady A, McGinnis R, Badenhop D, Bentle M, Rajput M. Effects of depression and anxiety on adherence to cardiac rehabilitation. J Cardiopulm Rehabil Prev. 2009;29(6):358-64.

- 43. Caulin-Glaser T, Maciejewski PK, Snow R, LaLonde M, Mazure C. Depressive symptoms and sex affect completion rates and clinical outcomes in cardiac rehabilitation. Prev Cardiol. 2007;10(1):15-21.
- 44. Yohannes AM, Yalfani A, Doherty P, Bundy C. Predictors of drop-out from an outpatient cardiac rehabilitation programme. Clin Rehabil. 2007;21(3):222-9.
- 45. American Psychological Association. Anxiety Washington, DC: American Psychological Association; [cited 2019 5/15]. Available from: https://www.apa.org/topics/anxiety/.
- 46. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (DSM-5®): American Psychiatric Pub; 2013.
- 47. Spielberger C, Gorsuch R, Lushene R, Vagg P, Jacobs G. Manual for the state-trait anxiety inventory. Palo Alto. CA: Consulting psychologists press; 1970.
- 48. Spielberger CD. State-trait anxiety inventory for adults: manual instrument, and scoring guide: Mind Garden, Inc; 1983.
- 49. Gidron Y. Trait Anxiety. In: Gellman MD, Turner JR, editors. Encyclopedia of Behavioral Medicine. New York, NY: Springer New York; 2013. p. 1989-.
- 50. Player MS, Peterson LE. Anxiety disorders, hypertension, and cardiovascular risk: a review. Int J Psychiatry Med. 2011;41(4):365-77.
- 51. Batelaan NM, Seldenrijk A, Bot M, Van Balkom AJ, Penninx BW. Anxiety and new onset of cardiovascular disease: critical review and meta-analysis. Br J Psychiatry. 2016;208(3):223-31.
- 52. Denollet J, Maas K, Knottnerus A, Keyzer JJ, Pop VJ. Anxiety predicted premature all-cause and cardiovascular death in a 10-year follow-up of middle-aged women. J Clin Epidemiol. 2009;62(4):452-6.

- 53. Rosengren A, Tibblin G, Wilhelmsen L. Self-perceived psychological stress and incidence of coronary artery disease in middle-aged men. J Am Coll Cardiol. 1991;68(11):1171-5.
- 54. Egger E, Schmid J-P, Schmid RW, Saner H, Känel Rv. Depression and anxiety symptoms affect change in exercise capacity during cardiac rehabilitation. European journal of preventive cardiology. 2008;15(6):704-8.
- 55. Thomas JJ. Reducing anxiety during phase I cardiac rehabilitation. J Psychosom Res. 1995;39(3):295-304.
- 56. Lavie CJ, Milani RV. Adverse Psychological and Coronary Risk Profiles in Young Patients With Coronary Artery Disease and Benefits of Formal Cardiac Rehabilitation. JAMA Internal Medicine. 2006;166(17):1878-83. doi: 10.1001/archinte.166.17.1878 %J JAMA Internal Medicine.
- 57. Leong J, Molassiotis A, Marsh H. Adherence to health recommendations after a cardiac rehabilitation programme in post-myocardial infarction patients: the role of health beliefs, locus of control and psychological status. Clin Eff Nurs. 2004;8(1):26-38.
- 58. Bauer LK, Caro MA, Beach SR, Mastromauro CA, Lenihan E, Januzzi JL, et al. Effects of depression and anxiety improvement on adherence to medication and health behaviors in recently hospitalized cardiac patients. The American journal of cardiology. 2012;109(9):1266-71.
- 59. Gerstorf D, Siedlecki KL, Tucker-Drob EM, Salthouse TA. Within-person variability in state anxiety across adulthood: Magnitude and associations with between-person characteristics. Int J Behav Dev. 2009;33(1):55-64.

- 60. Bolger N, Laurenceau J. Intensive longitudinal methods: An introduction to diary and experience. New York, NY: Guilford; 2013.
- 61. Walls TA, Schafer JL. Models for intensive longitudinal data: Oxford University Press; 2006.
- 62. Sliwinski MJ, Almeida DM, Smyth J, Stawski RS. Intraindividual change and variability in daily stress processes: Findings from two measurement-burst diary studies. Psychol Aging. 2009;24(4):828.
- 63. Stone AA, Neale JM. New measure of daily coping: development and preliminary results. J Pers Soc Psychol. 1984;46(4):892.
- 64. Bolger N, DeLongis A, Kessler RC, Schilling EA. Effects of daily stress on negative mood. J Pers Soc Psychol. 1989;57(5):808.
- 65. Shiffman S, Stone AA, Hufford MR. Ecological momentary assessment. Annu Rev Clin Psychol. 2008;4:1-32.
- 66. Stone AA, Shiffman S. Capturing momentary, self-report data: A proposal for reporting guidelines. Ann Behav Med. 2002;24(3):236-43.
- 67. Bradburn NM, Rips LJ, Shevell SK. Answering autobiographical questions: The impact of memory and inference on surveys. Science. 1987;236(4798):157-61.
- 68. Eich E, Reeves JL, Jaeger B, Graff-Radford SB. Memory for pain: relation between past and present pain intensity. Pain. 1985;23(4):375-80.
- 69. Clark DM, Teasdale JD. Diurnal variation in clinical depression and accessibility of memories of positive and negative experiences. J Abnorm Psychol. 1982;91(2):87.
- 70. Strongman K, Russell P. Salience of emotion in recall. Bulletin of the Psychonomic Society. 1986;24(1):25-7.

- 71. Thomas DL, Diener E. Memory accuracy in the recall of emotions. J Pers Soc Psychol. 1990;59(2):291.
- 72. Schwarz N. Retrospective and concurrent self-reports: The rationale for real-time data capture. The science of real-time data capture: Self-reports in health research. 2007;11:26.
- 73. Wray TB, Merrill JE, Monti PM. Using ecological momentary assessment (EMA) to assess situation-level predictors of alcohol use and alcohol-related consequences. Alcohol reserach: current reviews. 2014;36(1):19.
- 74. Shiffman S, Balabanis MH, Gwaltney CJ, Paty JA, Gnys M, Kassel JD, et al. Prediction of lapse from associations between smoking and situational antecedents assessed by ecological momentary assessment. Drug Alcohol Depend. 2007;91(2):159-68.
- 75. Dunton GF, Atienza AA. The need for time-intensive information in healthful eating and physical activity research: a timely topic. J Am Diet Assoc. 2009;109(1):30-5.
- 76. Brannon EE, Cushing CC, Crick CJ, Mitchell TB. The promise of wearable sensors and ecological momentary assessment measures for dynamical systems modeling in adolescents: a feasibility and acceptability study. Transl Behav Med. 2016;6(4):558-65.
- 77. Shiffman S. Ecological Momentary Assessment (EMA) in Studies of Substance Use. Psychol Assess. 2009;21(4):486-97. doi: 10.1037/a0017074. PubMed PMID: PMC2846437.
- 78. Dunton GF, Kawabata K, Intille S, Wolch J, Pentz MA. Assessing the social and physical contexts of children's leisure-time physical activity: an ecological momentary assessment study.

  Am J Health Promot. 2012;26(3):135-42.
- 79. Dunton GF, Whalen CK, Jamner LD, Floro JN. Mapping the social and physical contexts of physical activity across adolescence using ecological momentary assessment. Ann Behav Med. 2007;34(2):144-53.

- 80. Dunton GF, Liao Y, Intille S, Huh J, Leventhal A. Momentary assessment of contextual influences on affective response during physical activity. Health Psychol. 2015;34(12):1145.
- 81. Dunton GF. Ecological Momentary Assessment in Physical Activity Research. Exerc Sport Sci Rev. 2017;45(1):48-54.
- 82. Tan X, Shiyko MP, Li R, Li Y, Dierker L. A time-varying effect model for intensive longitudinal data. Psychol Methods. 2012;17(1):61.
- 83. Kesaniemi A, Danforth E, Jensen MD, Kopelman PG, Lefebvre P, Reeder BA. Doseresponse issues concerning physical activity and health: an evidence-based symposium. Med Sci Sports Exerc. 2001;33(6):S351-S8.
- 84. Piercy KL, Troiano RP, Ballard RM, Carlson SA, Fulton JE, Galuska DA, et al. The physical activity guidelines for Americans. JAMA. 2018;320(19):2020-8.
- 85. Tucker JM, Welk GJ, Beyler NK. Physical activity in US adults: compliance with the physical activity guidelines for Americans. Am J Prev Med. 2011;40(4):454-61.
- 86. Kanning MK, Schoebi D. Momentary affective states are associated with momentary volume, prospective trends, and fluctuation of daily physical activity. Front Psychol. 2016;7:744.
- 87. Prestwich A, Sniehotta FF, Whittington C, Dombrowski SU, Rogers L, Michie S. Does theory influence the effectiveness of health behavior interventions? Meta-analysis. Health Psychol. 2014;33(5):465.
- 88. Gardner B, Wardle J, Poston L, Croker H. Changing diet and physical activity to reduce gestational weight gain: a meta-analysis. Obes Rev. 2011;12(7):e602-e20.
- 89. Mehtälä MAK, Sääkslahti AK, Inkinen ME, Poskiparta MEH. A socio-ecological approach to physical activity interventions in childcare: a systematic review. International Journal of Behavioral Nutrition and Physical Activity. 2014;11(1):22.

- 90. Bauman AE, Sallis JF, Dzewaltowski DA, Owen N. Toward a better understanding of the influences on physical activity: the role of determinants, correlates, causal variables, mediators, moderators, and confounders. Am J Prev Med. 2002;23(2):5-14.
- 91. Kamarck TW, Janicki DL, Shiffman S, Polk DE, Muldoon MF, Liebenauer LL, et al. Psychosocial demands and ambulatory blood pressure: a field assessment approach. 2002;77(4-5):699-704.
- 92. Kanning MK, Ebner-Priemer UW, Schlicht WM. How to investigate within-subject associations between physical activity and momentary affective states in everyday life: a position statement based on a literature overview. Front Psychol. 2013;4:187.
- 93. Dunton GF, Liao Y, Intille SS, Spruijt-Metz D, Pentz M. Investigating children's physical activity and sedentary behavior using ecological momentary assessment with mobile phones.

  Obesity. 2011;19(6):1205-12.
- 94. Dunton GF, Whalen CK, Jamner LD, Henker B, Floro JN. Using ecologic momentary assessment to measure physical activity during adolescence. Am J Prev Med. 2005;29(4):281-7.
- 95. Dunton GF, Liao Y, Kawabata K, Intille S. Momentary assessment of adults' physical activity and sedentary behavior: feasibility and validity. Front Psychol. 2012;3:260.
- 96. Marszalek J, Morgulec-Adamowicz N, Rutkowska I, Kosmol A. Using ecological momentary assessment to evaluate current physical activity. BioMed research international. 2014;2014.
- 97. Ehlers DK, Huberty J, Buman M, Hooker S, Todd M, de Vreede G-J. A novel inexpensive use of smartphone technology for ecological momentary assessment in middle-aged women. J Phys Act Health. 2016;13(3):262-8.

- 98. Mundi MS, Lorentz PA, Grothe K, Kellogg TA, Collazo-Clavell ML. Feasibility of smartphone-based education modules and ecological momentary assessment/intervention in prebariatric surgery patients. Obes Surg. 2015;25(10):1875-81.
- 99. Hacker ED, Ferrans CE. Ecological momentary assessment of fatigue in patients receiving intensive cancer therapy. Journal of pain symptom management. 2007;33(3):267-75.
- 100. Dunton GF, Huh J, Leventhal AM, Riggs N, Hedeker D, Spruijt-Metz D, et al. Momentary assessment of affect, physical feeling states, and physical activity in children. Health Psychol. 2014;33(3):255.
- 101. Fanning J, Mackenzie M, Roberts S, Crato I, Ehlers D, McAuley E. Physical activity, mind wandering, affect, and sleep: an ecological momentary assessment. JMIR mHealth and uHealth. 2016;4(3):e104.
- 102. Liao Y, Intille SS, Dunton GF. Using ecological momentary assessment to understand where and with whom adults' physical and sedentary activity occur. Int J Behav Med. 2015;22(1):51-61.
- 103. Maher JP, Rhodes RE, Dzubur E, Huh J, Intille S, Dunton GF. Momentary assessment of physical activity intention-behavior coupling in adults. Transl Behav Med. 2017;7(4):709-18.
- 104. Rosmalen JG, Wenting AM, Roest AM, de Jonge P, Bos EH. Revealing causal heterogeneity using time series analysis of ambulatory assessments: application to the association between depression and physical activity after myocardial infarction. Psychosom Med. 2012;74(4):377-86.
- 105. Clark AM, King-Shier KM, Spaling MA, Duncan AS, Stone JA, Jaglal SB, et al. Factors influencing participation in cardiac rehabilitation programmes after referral and initial attendance: qualitative systematic review and meta-synthesis. Clin Rehabil. 2013;27(10):948-59.

- 106. Cooper AF, Jackson G, Weinman J, Horne R. Factors associated with cardiac rehabilitation attendance: a systematic review of the literature. Clin Rehabil. 2002;16(5):541-52. doi: 10.1191/0269215502cr524oa.
- 107. Lane D, Carroll D, Ring C, Beevers DG, Lip GY. Predictors of attendance at cardiac rehabilitation after myocardial infarction. J Psychosom Res. 2001;51(3):497-501.
- 108. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State—Trait Anxiety Inventory (STAI). Br J Clin Psychol. 1992;31(3):301-6.
- 109. Crowther CA, Hiller JE, Moss JR, McPhee AJ, Jeffries WS, Robinson JS. Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. N Engl J Med. 2005;352(24):2477-86.
- 110. Levy BR, Hausdorff JM, Hencke R, Wei JY. Reducing Cardiovascular Stress With Positive Self-Stereotypes of Aging. The Journals of Gerontology: Series B. 2000;55(4):P205-P13. doi: 10.1093/geronb/55.4.P205.
- 111. Rubin GJ, Amlôt R, Page L, Wessely S. Public perceptions, anxiety, and behaviour change in relation to the swine flu outbreak: cross sectional telephone survey. BMJ. 2009;339:b2651.
- 112. McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. The Lancet. 2010;376(9736):163-72.
- 113. Devcich DA, Ellis CJ, Broadbent E, Gamble G, Petrie KJ. The psychological impact of test results following diagnostic coronary CT angiography. Health Psychol. 2012;31(6):738.

- 114. Wright SP, Brown TSH, Collier SR, Sandberg K. How consumer physical activity monitors could transform human physiology research. Am J Physiol Regul Integr Comp Physiol. 2017:ajpregu. 00349.2016.
- 115. Appelboom G, Yang AH, Christophe BR, Bruce EM, Slomian J, Bruyère O, et al. The promise of wearable activity sensors to define patient recovery. J Clin Neurosci. 2014;21(7):1089-93.
- 116. Ainsworth B, Cahalin L, Buman M, Ross R. The current state of physical activity assessment tools. Prog Cardiovasc Dis. 2015;57(4):387-95.
- 117. Butte NF, Ekelund U, Westerterp KR. Assessing physical activity using wearable monitors: measures of physical activity. Exerc Sport Sci Rev. 2012;44(1S):S5-S12.
- 118. Toth LP, Park S, Springer CM, Feyerabend M, Steeves JA, Bassett DR. Video-recorded validation of wearable step counters under free-living conditions. Med Sci Sports Exerc. 2018;50(6):1315-22.
- 119. Sisson SB, Camhi SM, Church TS, Tudor-Locke C, Johnson WD, Katzmarzyk PT. Accelerometer-determined steps/day and metabolic syndrome. Am J Prev Med. 2010;38(6):575-82.
- 120. Hornbuckle LM, Kingsley JD, Kushnick MR, Moffatt RJ, Haymes EM, Miles R, et al. Effects of a 12-month pedometer-based walking intervention in women of low socioeconomic status. Clin Med Insights Womans Health. 2016;9(Suppl 1):75-84. doi: 10.4137/CMWH.S39636. PubMed PMID: PMC5054940.
- 121. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA. 2007;298(19):2296-304.

- 122. Crespo CJ, Keteyian SJ, Heath GW, Sempos CT. Leisure-time physical activity among US adults: results from the third national health and nutrition examination survey. Arch Intern Med. 1996;156(1):93-8.
- 123. Siegel PZ, Brackbill RM, Heath GW. The epidemiology of walking for exercise: implications for promoting activity among sedentary groups. Am J Public Health. 1995;85(5):706-10.
- 124. Watson KB, Frederick GM, Harris CD, Carlson SA, Fulton JE. US adults' participation in specific activities: Behavioral Risk Factor Surveillance System—2011. J Phys Act Health. 2015;12(s1):S3-S10.
- 125. Martin SS, Feldman DI, Blumenthal RS, Jones SR, Post WS, McKibben RA, et al. mActive: a randomized clinical trial of an automated mHealth intervention for physical activity promotion. Journal of the American Heart Association. 2015;4(11):e002239.
- 126. Chiauzzi E, Rodarte C, DasMahapatra P. Patient-centered activity monitoring in the self-management of chronic health conditions. BMC Med. 2015;13(1):77.
- 127. Chen MD, Kuo CC, Pellegrini CA, Hsu MJ. Accuracy of wristband activity monitors during ambulation and activities. Med Sci Sports Exerc. 2016;48(10):1942-9.
- 128. Dondzila CJ, Swartz AM, Miller NE, Lenz EK, Strath SJ. Accuracy of uploadable pedometers in laboratory, overground, and free-living conditions in young and older adults. Int J Behav Nutr Phys Act. 2012;9(1):143.
- 129. Fokkema T, Kooiman TJ, Krijnen WP, Van Der Schans CP, De Groot M. Reliability and validity of ten consumer activity trackers depend on walking speed. Med Sci Sports Exerc. 2017;49(4):793-800.

- 130. Crouter SE, Schneider PL, Karabulut M, Bassett DR. Validity of 10 electronic pedometers for measuring steps, distance, and energy cost. Med Sci Sports Exerc. 2003;35(8):1455-60.
- 131. Toth LP, Park S, Pittman WL, Sarisaltik D, Hibbing PR, Morton AL, et al. Validity of activity tracker step counts during walking, running, and activities of daily living. Translational Journal of the American College of Sports Medicine. 2018;3(7):52-9.
- 132. Hickey A, John D, Sasaki J, Mavilia M, Freedson P. Validity of activity monitor step detection is related to movement patterns. J Phys Act Health. 2016;13(2):145-53.
- 133. Toth LP, Park S, Pittman WL, Sarisaltik D, Hibbing PR, Morton AL, et al. Effects of brief intermittent walking bouts on step count accuracy of wearable devices. Journal for the Measurement of Physical Behaviour. 2019;2(1):13-21.
- 134. Nelson MB, Kaminsky LA, Dickin DC, Montoye A. Validity of consumer-based physical activity monitors for specific activity types. Med Sci Sports Exerc. 2016;48(8):1619–28.
- 135. Floegel TA, Florez-Pregonero A, Hekler EB, Buman MP. Validation of Consumer-Based Hip and Wrist Activity Monitors in Older Adults With Varied Ambulatory Abilities. J Gerontol A Biol Sci Med Sci. 2017;72(2):229-36. doi: 10.1093/gerona/glw098.
- 136. Whye CNL, Jenkins S, Hill K. Accuracy and responsiveness of the stepwatch activity monitor and ActivPAL in patients with COPD when walking with and without a rollator. Disabil Rehabil. 2012;34(15):1317-22.
- 137. Korpan SM, Schafer JL, Wilson KC, Webber SC. Effect of ActiGraph GT3X+ position and algorithm choice on step count accuracy in older adults. Journal of aging and physical activity. 2015;23(3):377-82.

- 138. Prince SA, Adamo KB, Hamel ME, Hardt J, Gorber SC, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. International Journal of Behavioral Nutrition and Physical Activity. 2008;5(1):56.
- 139. Coleman KL, Smith DG, Boone DA, Joseph AW, del Aguila MA. Step activity monitor: long-term, continuous recording of ambulatory function. J Rehabil Res Dev. 1999;36(1):8-18.
- 140. Toth LP, Bassett DR, Crouter SE, Overstreet BS, LaMunion SR, Park S, et al. StepWatch accuracy during walking, running, and intermittent activities. Gait Posture. 2017;52:165-70.
- 141. Modus Health LLC. StepWatch 3 user's manual. Washington, D.C.2014.
- 142. Boone DA, Coleman KL. Use of a step activity monitor in determining outcomes. J Prosthet Orthot. 2006;18(6):86-92.
- 143. Feito Y, Bassett DR, Thompson DL. Evaluation of activity monitors in controlled and free-living environments. Med Sci Sports Exerc. 2012;44(4):733-41. Epub 2011/09/10.
- 144. Karabulut M, Crouter SE, Bassett DR. Comparison of two waist-mounted and two anklemounted electronic pedometers. Eur J Appl Physiol. 2005;95(4):335-43.
- 145. Mudge S, Stott NS, Walt SE. Criterion validity of the StepWatch Activity Monitor as a measure of walking activity in patients after stroke. Arch Phys Med Rehabil. 2007;88(12):1710-5.
- 146. Sandroff BM, Motl RW, Pilutti LA, Learmonth YC, Ensari I, Dlugonski D, et al. Accuracy of StepWatch™ and ActiGraph accelerometers for measuring steps taken among persons with multiple sclerosis. PLoS One. 2014;9(4):e93511.
- 147. Schmidt AL, Pennypacker ML, Thrush AH, Leiper CI, Craik RL. Validity of the StepWatch step activity monitor: preliminary findings for use in persons with Parkinson disease and multiple sclerosis. J Geriatr Phys Ther. 2011;34(1):41-5.

- 148. Fulk GD, Combs SA, Danks KA, Nirider CD, Raja B, Reisman DS. Accuracy of 2 activity monitors in detecting steps in people with stroke and traumatic brain injury. Phys Ther. 2014;94(2):222-9.
- 149. Bergman RJ, Bassett DR, Klein DA. Validity of 2 devices for measuring steps taken by older adults in assisted-living facilities. J Phys Act Health. 2008;5(s1):S166-S75.
- 150. Treacy D, Hassett L, Schurr K, Chagpar S, Paul SS, Sherrington C. Validity of different activity monitors to count steps in an inpatient rehabilitation setting. Phys Ther. 2017;97(5):581-8.
- 151. ActiGraph LLC. User Guide: ActiGraph GT9X Link + ActiLife. 3 ed. Pensacola, FL2019.
- 152. Feito Y, Hornbuckle LM, Reid LA, Crouter SE. Effect of ActiGraph's low frequency extension for estimating steps and physical activity intensity. PLoS One. 2017;12(11):e0188242.
- 153. ActiGraph LLC. Moving average vector magnitude (v.1) step algorithm. Pensacola, FL.: ActiGraph, LLC; 2017. p. 1-7.
- 154. Fitbit I. Fitbit Charge 2 User Manual v1.2. 2018.
- 155. Fitbit I. Fitbit Charge 2, Specifications 2018 [cited 2018 7/3]. Available from: https://www.fitbit.com/shop/charge2?activeFeature=specs.
- 156. Bai Y, Hibbing P, Mantis C, Welk GJ. Comparative evaluation of heart rate-based monitors: Apple Watch vs Fitbit Charge HR. J Sports Sci. 2018;36(15):1734-41.
- 157. Fitbit I. Fitbit Zip Wireless Activity Tracker User Manual v.1.2. 2014.
- 158. Fitbit I. Fitbit Zip Activity Tracker Specs 2018 [cited 2018 7/3]. Available from: https://www.fitbit.com/shop/zip.

- 159. Huang Y, Xu J, Yu B, Shull PB. Validity of FitBit, Jawbone UP, Nike+ and other wearable devices for level and stair walking. Gait Posture. 2016;48:36-41.
- 160. Imboden MT, Nelson MB, Kaminsky LA, Montoye AH. Comparison of four Fitbit and Jawbone activity monitors with a research-grade ActiGraph accelerometer for estimating physical activity and energy expenditure. Br J Sports Med. 2018;52(13):844-50.
- 161. Apple I. Apple Watch Series 2 Technical Specifications 2018 [cited 2018 7/3]. Available from: https://support.apple.com/kb/SP746?locale=en\_US.
- 162. Apple I. Apple Watch User Guide 2018 [cited 2018 7/5]. Available from: https://help.apple.com/watch/.
- 163. Apple I. ResearchKit and CareKit 2019 [cited 2019 4/13]. Available from: https://www.apple.com/researchkit/.
- 164. Wood WA, Bennett AV, Basch E. Emerging uses of patient generated health data in clinical research. Mol Oncol. 2015;9(5):1018-24.
- 165. Talmor G, Nguyen B, Keibel A, Temelkovska T, Saxon L. Use of Software Applications to Improve Medication Adherence and Achieve More Integrated Disease Management in Heart Failure A Review. Trends Cardiovasc Med. 2018.
- 166. Modave F, Guo Y, Bian J, Gurka MJ, Parish A, Smith MD, et al. Mobile device accuracy for step counting across age groups. JMIR mHealth and uHealth. 2017;5(6):e88.
- 167. Wallen MP, Gomersall SR, Keating SE, Wisløff U, Coombes JS. Accuracy of heart rate watches: implications for weight management. PLoS One. 2016;11(5):e0154420.
- 168. Veerabhadrappa P, Moran MD, Renninger MD, Rhudy MB, Dreisbach SB, Gift KM. Tracking Steps on Apple Watch at Different Walking Speeds. J Gen Intern Med. 2018;33(6):795-6.

- 169. O'Connell S, ÓLaighin G, Quinlan LR. When a step is not a step! Specificity analysis of five physical activity monitors. PLoS One. 2017;12(1):e0169616.
- 170. Bassett DR, Toth LP, LaMunion SR, Crouter SE. Step counting: A Review of measurement considerations and health-related applications. Sports Med. 2016;47(7):1303–15.
- 171. Takahashi T, Kumamaru M, Jenkins S, Saitoh M, Morisawa T, Matsuda H. In-patient step count predicts re-hospitalization after cardiac surgery. J Cardiol. 2015;66(4):286-91.
- 172. Butler L, Furber S, Phongsavan P, Mark A, Bauman A. Effects of a pedometer-based intervention on physical activity levels after cardiac rehabilitation: a randomized controlled trial. J Cardiopulm Rehabil Prev. 2009;29(2):105-14.
- 173. Cupples M, Dean A, Tully M, Taggart M, McCorkell G, O'Neill S, et al. Using pedometer step-count goals to promote physical activity in cardiac rehabilitation: a feasibility study of a controlled trial. International Journal of Physical Medicine and Rehabilitation. 2013;1(07):157-62.
- 174. Ayabe M, Brubaker PH, Dobrosielski D, Miller HS, Kiyonaga A, Shindo M, et al. Target step count for the secondary prevention of cardiovascular disease. Circ J. 2008;72(2):299-303.

# **Chapter III**

Step Count Error of Activity Monitors for Patients in Phase II Cardiac Rehabilitation

#### Abstract

**Purpose**: To investigate the step counting error of four wearable physical activity monitors compared to StepWatch (SW) steps across the day for patients in Phase II cardiac rehabilitation (CR) during free-living. **Methods**: Nineteen phase II CR patients (mean  $\pm$  SD,  $68 \pm 7$  yr, BMI  $31.7 \pm 14.7$  kg/m<sup>2</sup>) wore a StepWatch (SW; criterion step method) on the ankle for five consecutive days. For the first 2.5 days participants also wore one wrist and one waist worn monitor, then replaced those with different wrist and waist worn monitors for the last 2.5 days. Monitors included in this study were Fitbit Charge 2 (Charge) and Apple Watch Series 2 (Apple) on the non-dominant wrist and Fitbit Zip and ActiGraph GT9X (GT9X) on the waist. GT9X steps were processed with and without the low-frequency extension (LFE) and with the moving average vector magnitude algorithm. Daily steps for each monitor were summed across selfreported wear time, converted to percent of SW steps, and compared across three conditions; days attended CR (ACR), days attended CR with CR removed (AACR), and whole days without CR (NCR). **Results**: Step counts from all monitors were significantly different from 100% of SW steps, except for the Apple in ACR and Charge in ACR and AACR conditions. Steps were underestimated when compared to SW steps for most monitors (range 5% to 55%) except for overestimates in AGLFE (34% to 59%) and Charge in the AACR condition (2%). **Conclusion**: For those in phase II CR, the Charge and Apple yielded the least stepping error when compared to SW steps and time spent in CR did not greatly contribute to error for this population.

#### Introduction

Worldwide, wearable physical activity monitors (PAMs) are a multibillion-dollar industry (1). PAMs are popular among consumers for goal setting, personal tracking, and motivation (2) and for researchers, these monitors allow for continuous and passive physical activity surveillance (3). Use of PAMs in health care is growing as physicians and clinicians gain interest in using them to track disease progression, recovery following surgery, and in homebased rehabilitation programs (4).

Several measures of physical activity are typically provided by PAMs (e.g., minutes of aerobic exercise, caloric expenditure, daily steps), but an easily understood outcome available on almost all monitors are steps. Steps are a direct assessment of walking, which is the most commonly reported physical activity by American adults (5), and also is common to occupational, transportation, and household activities (6, 7). Physical activity interventions aimed at increasing daily steps have been shown to reduce waist girth (8), resting heart rate (8), body mass (9), systolic blood pressure (2), high-sensitivity C reactive protein (10) and improve blood lipid profiles (11). Stepping goals also provide motivation for increased total physical activity (2).

For those diagnosed with cardiovascular disease or who have experienced a cardiac event, cardiac rehabilitation (CR), an exercise and education program, is suggested to help patients regain cardiac function to return to their careers and social life, reduce the risk of a secondary cardiac event, and to delay or slow the progression of CVD (12-14). Although improvements in cardiac function and overall health are well established results of CR attendance (13, 14), adherence to classic CR programs is relatively poor, with a 40% to 70% dropout rate within six months of beginning a CR program (15). To improve CR compliance and

overall engagement in regular physical activity for those with CVD, the Million Hearts Initiative of the U.S. Department of Health and Human Services established a need for innovative homebased or hybrid CR interventions that include mobile monitoring technologies such as PAMs (16). Additionally, the use of pedometers to measure baseline physical activity for those in CR have been suggested to guide physical activity counseling as a core component to align with the American Heart Association/American College of Cardiology Secondary Prevention Guidelines (17).

Due to the increasing interest of using PAMs and step counting in health care settings (4), investigating the daily step counting error in various clinical populations is needed. In order to provide a criterion measure of steps across the day, StepWatch 3 Activity Monitor (SW) was selected because when compared to video-recorded, hand-counted steps across one single day, the SW was shown to capture 102% of hand-counted steps (18). The purpose of this study was to investigate the daily error in steps, as compared to SW steps, in Fitbit Charge 2, Fitbit Zip, Apple Watch Series 2, and ActiGraph GT9X monitors for phase II CR patients.

#### Methods

# **Participants and Recruitment**

Adult participants between 18 and 80 years of age were recruited from the phase II cardiac rehabilitation program at the Heart Lung Vascular Institute of the University of Tennessee Medical Center in Knoxville, TN. Individuals with < 35% ejection fraction, a diagnosis of a disease with memory or cognitive decline, who could not engage in the exercise portion of CR, who could not walk without an assistive device, or have had heart valve surgery or valve replacement were excluded from participating in the study. The research protocol was approved by the Institutional Review Boards of The University of Tennessee Health Sciences

Center and The University of Tennessee, Knoxville campus. All participants provided written informed consent before participating.

Eligibility was determined with a two-step screening process. First, CR nurses and exercise physiologists reviewed the health-related exclusionary criteria (i.e., ejection fraction <35%, diagnosed with conditions related to cognitive decline, memory impairment, or pulmonary disease, and referred to CR following valvular surgery or heart transplant) for each patient in the CR program and each new patient who entered during the four month data collection period (February to June 2019) to determine eligibility. Those who were determined to be eligible were referred to the researcher who met with each patient individually at a CR session and confirmed eligibility based on the need of assistive walking device. The researcher then explained the study requirements and written informed consent was collected from each patient who agreed to participate.

## **Protocol**

Participants were asked to wear an activity monitor on their non-dominant wrist, over the right hip, and on their right ankle for five weekdays (Monday through Friday). The five days of participation were divided into two periods (2.5 days each), with a different wrist (Fitbit Charge 2 and Apple Watch Series 2) and waist (ActiGraph GT9X and Fitbit Zip) monitor worn during the first and second period. The ankle worn SW was worn for all five days and used as the criterion estimate of steps. Wrist and waist worn monitors were randomized so each participant would receive one of the two wrist and waist worn monitors for the first study period and the other wrist and waist monitors for the second period.

On the first day, the researcher met each participant before their first CR session of the week, showed them how to wear the SW and each monitor that was randomized to them for the

first study period, and how to record monitor wear time on a paper log provided to them. The participant then affixed the fully charged monitors, logged the time of day on the data sheet, and went about their day. Participants were asked to wear the monitors throughout the entire day except during times of bathing or swimming. At the end of the day, before participants went to bed, they were asked to remove the monitors and record the time at which they were removed.

On the following day, day two, participants were asked to wear all three monitors from the time they woke up in the morning until the time they went to bed in the evening and to record these times on the wear time log. On day three, participants were asked to affix the monitors in the morning upon waking and record the time of day. The researcher then met each participant before their CR session, asked them to remove the wrist and waist worn monitors, recorded the time of day they were removed, and provided each participant with the second pair of monitors. Participants were instructed on how to wear the new monitors and were asked to wear them until they went to bed. On day four the participants were asked to follow the same protocol as day two. On the fifth day, participants affixed the monitors in the morning after waking up, recorded the time of day, and wore them until they met the researcher before their CR session and were asked to remove the monitors. All three monitors and data recording sheet were collected.

## **Physical Activity Monitors**

Apple Watch Series 2. The Apple Watch Series 2 (software version 5.1.3, [Apple]) is a wrist worn consumer-grade smartwatch with physical activity tracking capabilities. The Apple Watch is available in two screen sizes (38 and 42 mm); the unit chosen for this study was the smaller and lighter unit  $(38.6 \times 33.3 \times 11.4 \text{ mm}, 28.2 \text{ g}, 38 \text{ mm screen})$ . Sensors included in this unit are a tri-axial accelerometer, gyroscope, optical heart rate sensor, and global positioning system (GPS). Physical activity data includes steps, active caloric expenditure, minutes of

exercise, distance ambulated, and a count of hours where standing and moving for at least one minute was detected at least once. It only synchronizes with iPhones which uses Bluetooth 4.0 connectivity. The battery life on this model is approximately 18 hours (19, 20).

Prior to each participant starting, the Apple was synchronized to an iPhone with the My Watch mobile app using the participant's height, weight, and birthdate, left or right wrist placement and heart rate monitoring was disabled. Due to the short battery life, the Apple required nightly charging, so each participant was provided with an Apple charger to charge the monitor at night while sleeping. Minute-by-minute step count data from the Apple could not be extracted, so participants were asked to record step counts in the morning and in the evening on the wear time log.

Fithit Charge 2. The Fithit Charge 2 (firmware version 22.55.2, [Charge]) is a consumer-grade, wrist worn fitness tracker (218.4 × 22.8 × 12.7 mm, 34.9 g). The manufacturer's suggested wear location is one finger's width away from the ulnar styloid process, in the direction of the elbow (21). The Charge includes a tri-axial accelerometer, altimeter, and optical heart rate tracker and has a battery life of up to five days. Steps, heart rate, and gross caloric expenditure for the current day are displayed on the screen of the monitor, but minute-by-minute physical activity data are stored on the internal memory for seven days and daily totals are saved for 30 days. Users can access hourly totals after synchronizing to the Fitbit mobile app (for Android or iOS) via Bluetooth connectivity but minute-by-minute data are only available through third party programs (21). Battery life on this device is estimated at 5 days, however, disabling heart rate detection can improve battery life (22).

*Fitbit Zip.* The Fitbit Zip (firmware version 90, [Zip]) is a waist worn consumer-grade activity tracker. It is a small  $(35.6 \times 28.9 \times 9.6 \text{ mm})$  and lightweight monitor (8 g) that can be

worn on the waistband, bra, or in a pocket (23). The Zip includes a tri-axial accelerometer and a replaceable watch battery (CR2025) that lasts up to 6 months. Total steps, caloric expenditure, distance ambulated, and active minutes for the current day are displayed on the LCD screen of the monitor but minute-by-minute physical activity data are stored on the internal memory for seven days and can be retrieved with synchronization with a smartphone and the Fitbit mobile app via Bluetooth 4.0 wireless connectivity. Hourly physical activity data are available on the app, but minute-by-minute data are only available through third-party programs. Physical activity data be displayed and stored on the Fitbit mobile app (for Android and iOS) (24).

Fitabase. Fitbit and Fitabase (Small Steps Labs, LLC, San Diego, CA) accounts were created for each Fitbit monitor. Before participation, each participant's height, weight, and birthdate were entered into the Fitbit account through the Fitbit mobile app via iPhone and heart rate detection was disabled. For the Charge, wrist preference (left or right) for wearing the monitor was selected. The app and monitor were then synchronized. Following participation, Fitbits were synchronized with the Fitbit mobile app which transferred minute-by-minute step data to the Fitbit servers then were then extracted using Fitabase; a paid third-party program that can access date and time-stamped, minute-by-minute Fitbit data.

ActiGraph GT9X. The ActiGraph GT9X (firmware version 1.7.2, [GT9X]) is a small (35 X 35 X 10 mm), lightweight (14 g) research-grade activity monitor that can be worn on the wrist, waist, ankle, or thigh. This monitor includes a primary tri-axial accelerometer, an inertial measurement unit with a secondary accelerometer, gyroscope, and magnetometer, Bluetooth LE, and USB connectivity via a GT9X docking station. Depending on initialization configuration, the battery life of GT9X monitors is up to 14 days (25).

Before participation, AG monitors were initialized to be worn on the waist and to sample data at 30 Hz using the ActiLife software (ActiGraph LLC, Pensacola, FL, version 6.13.3). Following GT9X wear, data were downloaded using ActiLife software which was used to generate steps per 60 seconds with the low-frequency extension enabled (AGLFE) and without it (AG). Additionally, ActiGraph's moving average vector magnitude (MAVM) algorithm was applied to each raw acceleration file using specialized Scilab (Scilab Enterprises, Rungis, France) and R (R core team) code in order to retrieve minute-by-minute MAVM steps. MAVM steps can also be read from the screen of the GT9X.

StepWatch 3 Activity Monitor. The StepWatch 3 Activity Monitor (SW) is a small ( $70 \times 50 \times 20$  mm) and lightweight (38 g) research-grade, activity monitor that is worn on the lateral aspect of the ankle, directly above the lateral malleoli, affixed by a Velcro strap. SW monitors are initialized with the participants height and weight via a dock that connects to a computer with Modus Health software. This monitor includes a non-rechargeable battery which lasts up to 7 years and an internal memory that can hold up to 50 days of stepping data (26).

SW activity monitors were initialized with the Modus Health software (Edmonds, WA, software version 3.4) by entering the participant's height and weight, selecting the default cadence and sensitivity settings, and selecting the options for normal walking speed, uses a moderate range of speeds, and normal leg motions. Steps were stored in 60-sec epochs because this provided enough memory which allowed participants to wear the same SW for all five days of the study. After participation, SW data were downloaded using the Modus software which provided date and time-stamped steps in 60-sec epochs.

## **Data Analysis**

First, steps per minute were summed across the self-reported wear time for each day for the SW, Charge, Zip, and AG monitors. Missing data were days when less than 500 steps were counted and for those days only the monitor with missing data was excluded from analysis. This produced two conditions, daily steps for days they attended CR (ACR) and for when they did not attend CR (NCR). Next, steps during each CR session (60-min duration) were summed and subtracted from the daily total for each monitor, including the criterion, on CR days. This produced the third condition, adjusted ACR (AACR). Adjustments were made to determine if CR impacted the magnitude of the error in steps. For Apple monitors, daily steps were found by subtracting the morning steps from the evening steps. Because minute-by-minute data was not available, the AACR condition could not be investigated for the Apple monitor.

The first, third, and fifth days of the study yielded steps across partial days. In the first study period, during the first day, monitors were affixed before the CR session and were removed at night before bed. On the morning of the third day, they were affixed in the morning upon waking, but were removed before the CR session. Steps from these partial days, within the same study period were added to create a single day for each monitor. In the second study period, steps from the second half of the third day, which included the CR session through removal before bed, were added to the step values on the fifth day (wake through the beginning of the CR session). Concatenating these days within the same study period was performed in order to report results in units of steps per day. The second and fourth days represented all waking hours of one day, therefore no treatment was necessary.

## **Statistical analysis**

For each monitor and method, mean ± standard deviation, mean bias (criterion – step estimate), and mean absolute percent error (MAPE) were calculated. Steps were converted to percent of SW steps ((monitor estimate / SW steps) × 100) for statistical analysis to scale all data points so days with higher steps did not weight the sample (18, 27). Repeated measures analysis of variance (ANOVA) was used to compare the conditions (ACR, AACR, and NCR) separately for each estimated step method. One sample t-tests were used to determine if the percent of SW steps from each monitor, for each condition, was significantly different from 100% of SW steps. Statistical analysis was completed with SPSS Version 25 for Windows, (SPSS Inc., Chicago, IL).

#### Results

Nineteen adult participants were recruited. A summary of participant characteristics is presented in Table 1. The participants were predominately right-handed (89%) and male (84%). Across the entire sample, a total of 9 days of missing data (days when no steps were counted by a monitor) were found for SW steps, accounting for 8% of the entire sample. For the other monitors, the percentage of missing days varied as follows: AG (14%), AGLFE (14%), AGMAVM (28%), Charge (5%), Zip (2%), and Apple (9%).

Mean steps per day, mean bias, and MAPE are shown in Table 2 and percent of SW steps are presented in Figure 1. The results of the repeated measures ANOVA showed that percent of SW steps differed significantly among the ACR, AACR, and NCR conditions for AGMAVM [F(1.9, 11.2)=4.5, p=0.04] but post hoc tests using Bonferroni correction showed no significant differences among the conditions (p>0.05). For the other monitors, no differences among the three conditions were found (p>0.05). Of note, the Apple was not included in this analysis since

Table 1. Summary of participant characteristics.

	$\mathbf{All}\;(\mathbf{N}=19)$	Men (n = 16)	Women $(n = 3)$
Age (yr)	$68 \pm 7$	$67 \pm 7.2$	$70 \pm 5.1$
Height (cm)	$178.1 \pm 8.6$	$180.3 \pm 7.4$	$165.9 \pm 6.4$
Weight (kg)	$100.4\pm14.7$	$103.5 \pm 12.7$	$84.1 \pm 18.9$
BMI (kg/m²)	$31.7 \pm 4.7$	$31.9 \pm 4.0$	$31.0 \pm 9.2$
Reason for CR	MI and Stent: 3 Stent: 9 CABG: 7	MI and Stent: 1 Stent: 8 CABG: 7	MI and Stent: 2 Stent: 1 CABG: 0

Table 2. Summary of step data for each monitor and each condition.

Monitor	Condition	N	Mean ± SD	Mean bias	MAPE (%)	95% CI	
			steps per day			LL	UL
SW	ACR	37	$5204 \pm 2496$	-	-	-	-
	<b>AACR</b>	33	$3375 \pm 2242$	-	-	-	-
	NCR	35	$8418 \pm 4225$	-	-	-	-
AG	ACR*	17	3514 ± 1155	1690	38.2	-47.4	-27.5
	AACR*	13	$2267 \pm 1152$	1108	40.1	-51.8	-0.6
	NCR*	16	$4348 \pm 2658$	4070	49.8	-56.8	-42.7
AGLFE	ACR*	17	7473 ± 2596	-2269	34.0	12.3	55.7
	AACR*	13	$5396 \pm 2900$	-2021	80.3	14.2	145.4
	NCR*	16	$10614 \pm 4286$	-2196	34.9	19.0	50.7
AGMAVM	ACR*	16	2666 ± 1116	2538	55.2	-64.6	-45.8
	AACR*	9	$1360 \pm 664$	2015	48.4	-70.7	-26.0
	NCR*	15	$3128 \pm 2214$	5290	63.4	-71.7	-55.5
Apple	ACR	18	4293 ± 1212	911	31.7	-27.5	0.9
	<b>AACR</b>	-	-	-	-	-	-
	NCR*	16	$5594 \pm 2602$	2824	27.9	-37.8	-7.6
Charge	ACR*	18	4562 ± 2655	642	33.1	-31.6	-4.7
	<b>AACR</b>	13	$3276 \pm 2212$	99	47.1	-41.2	17.4
	NCR*	17	$6180 \pm 3501$	2238	27.7	-35.5	-11.6
Zip	ACR*	18	$3202 \pm 1955$	2002	34.4	-38.3	-22.4
	AACR*	17	$2326 \pm 1815$	1049	33.9	-44.5	-17.0
	NCR*	16	$5329 \pm 3387$	3089	42.2	-50.0	-21.0

MAPE, Mean Absolute Percent Error; 95% CI, 95% Confidence Interval; LL, lower level; UL, upper level; SW, StepWatch3 Activity Monitor; AG, ActiGraph without low frequency extension; AGLFE, ActiGraph with low frequency extension; AGMAVM, ActiGraph with moving average vector magnitude algorithm; Apple, Apple Watch Series 2; Charge, Fitbit Charge 2; Zip, Fitbit Zip; ACR, Attended cardiac rehabilitation; AACR, Adjusted attended cardiac rehabilitation; NCR, no cardiac rehabilitation.

\*Significantly different from StepWatch steps to 100% (p < 0.05).

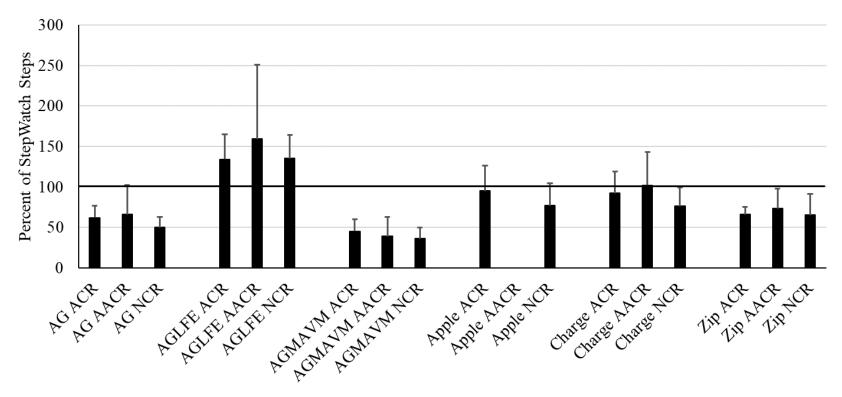


Figure 1. Percent of StepWatch Steps for each monitor (AG, ActiGraph without low frequency extension; AGLFE, ActiGraph with low frequency extension; AGMAVM, ActiGraph with moving average vector magnitude algorithm; Apple, Apple Watch Series 2; Charge, Fitbit Charge 2; Zip, Fitbit Zip) during each condition (ACR, Attended cardiac rehabilitation; AACR, Adjusted attended cardiac rehabilitation; NCR, no cardiac rehabilitation). Horizontal bar represents 100% of StepWatch steps and error bars represent standard deviation.

the AACR condition could not be determined because this analysis required the removal of all steps taken during CR and without minute-by-minute steps, this was not possible.

Compared to the SW, steps were significantly underestimated during each condition (ACR, AACR, and NCR) for the AG (range: 34% to 50%, p < 0.05), AGMAVM (range: 55% to 64%, p < 0.01), and Zip (range: 27% to 35%, p < 0.001) monitors. The Charge significantly underestimated SW steps for the NCR (24%, p = 0.001). Results showed the Charge slightly underestimated for ACR (8%, p > 0.05) and slightly overestimated AACR conditions (102%, p > 0.05), both of which were not significantly different from 100% of SW steps. The Apple significantly underestimated SW steps for the NCR condition (23%, p > 0.01) but not for the ACR condition (5%, p > 0.05). The AGLFE overestimated steps per day (range: 34% to 59%, p < 0.05) for all three conditions. During time spent in CR, steps were underestimated by each monitor (range: 5% to 54% of SW steps) (Figure 2). The Charge and Apple had the lowest MAPE values, both for the NCR condition, 27.7% and 27.9%, respectively. All other MAPE values were above 30% with the highest value being 80.3% for the AACR condition of AGLFE.

#### **Discussion**

The Charge (ACR and AACR) and Apple (ACR) both captured within 10% of SW steps for patients in phase II CR. The AG, AGMAVM, and Zip significantly underestimated SW steps per day, on days when they attended a CR session (non-adjusted values) and days when they did not. The MAVM method underestimated to the greatest extent (55% to 64%) and the AGLFE was the only method to overestimate for the ACR and NCR conditions. For the adjusted steps, the AG, Charge, and Zip monitors captured a slightly greater percentage of SW steps, and the Charge slightly exceeded 100% of SW steps. This adjustment, however, removed 60 minutes of daily activity from each monitor which renders these results less useful for practical application

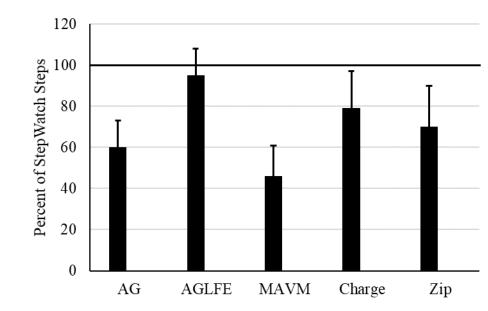


Figure 2. Percent of StepWatch steps for each monitor (AG, ActiGraph without low frequency extension; AGLFE, ActiGraph with low frequency extension; AGMAVM, ActiGraph with moving average vector magnitude algorithm; Apple, Apple Watch Series 2; Charge, Fitbit Charge 2; Zip, Fitbit Zip) during cardiac rehabilitation sessions. Horizontal bar represents 100% of StepWatch steps and error bars represent standard deviation.

when considering that monitors are worn across an entire day. Steps were underestimated by 5% to 54% during CR sessions.

Underestimated total daily steps for each of the monitors, except for AGLFE, were similar to the results of an earlier study comparing multiple monitors to hand-counted, video recorded steps across a single day, in young, healthy adults (18). Results showed the Fitbit Charge, Fitbit Zip, and waist worn GT9X without LFE and with MAVM underestimated steps when compared to hand-counted steps by 23%, 25%, 31%, and 30%, respectively while the ActiGraph with LFE worn on the waist overestimated by 26% of hand counted steps. During NCR days, days similar to healthy adults without a gym-based exercise session, current findings show the Charge (24%), Zip (35%), and AGLFE (35%) similarly underestimate steps, with error within 10% of the earlier study. The AG (50%) and AGMAVM (64%) showed greater differences between populations. Of note, different criterion methods were used in these studies, but the SW was shown to capture within 2% of hand-counted steps, thus the criterion steps are comparable (18).

The commonality of underestimated steps may be related to consecutive stepping requirements used in step counting algorithms. The step counting algorithms in several PAMs include a consecutive stepping requirement that only adds steps to the aggregate count once a stepping bout exceeds 4-6 steps (or 4-6 seconds) that occur in succession, without pause (27). If a bout ends before 4-6 steps are accumulated or before the continuous movement requirement has been met, those steps are discarded and are not included in the aggregate total. The purpose of this is to prevent miscellaneous, non-ambulatory movements from being incorrectly counted as steps (27). However, it is possible that many short bouts of steps are not added to the

aggregate bout because bouts four steps or less are the most common stepping bout taken across the day, accounting for 17% of total stepping bouts (28).

In a study of continuous stepping requirements, regardless of stepping bout duration and varied pause lengths between bouts, the SW was shown to collect within 10% of hand-counted steps. Not only is the SW sensitive to capturing slow, light steps, it does not require continuous walking to accumulate steps, thereby it captures a greater percentage of hand counted steps than the other monitors (27, 29). The Fitbit Charge and the Zip were found to require eight and six continuous steps, respectively, before adding steps to the aggregate count and a pause of at least one second would end a bout for these monitors. Waist worn ActiGraph GT3X monitors with and without LFE captured steps consistently across all stepping conditions, suggesting a continuous stepping requirement is not included in this algorithm. For the MAVM algorithm, a greater percent of hand-counted steps were captured following a continuous bout of six steps. Additionally, with the MAVM, a pause of at least two seconds reduced the number of steps captured, suggesting that the MAVM algorithm requires at least two seconds of continuous walking before accumulating steps when worn on the waist and a pause of two seconds will end a bout (27).

Some activities of daily living and movement patterns have been demonstrated as sources of step counting error. Walking slower than 2 mph and multidirectional movements have been shown to cause undercounted steps. In slow walking the acceleration signal created during heel strike is insufficient to trigger a step (30, 31) and in some cases, this could be true for multidirectional movement. However, steps are also undercounted during tennis and ballroom dancing, which create larger acceleration signals that should be captured (29, 32). Specific to wrist worn monitors, activities where the hands are placed on a stable support while ambulating

(e.g., pushing a stroller) will prevent steps from being counted as the acceleration required to trigger a step is attenuated by the stable object (33). Conversely, activities like folding laundry and washing dishes (33, 34) have been shown to overestimate steps, however, the extent to which steps are undercounted masks this error across the day. For waist and ankle worn monitors, cycling (35) causes steps to be overcounted. Cycling was a common activity for those in CR, but the relatively short time participants cycled (<5 min/day) did not overcome the overall trend in undercounting steps across the day.

The AGLFE was the only monitor to vastly overcount steps. The LFE reduces the attenuation of the low frequency accelerations that occur at the lower end of the physical activity intensity spectrum. This was done for the purpose of aligning the acceleration outputs for the GT3X with the older ActiGraph 7164 (36); it was not done to improve step counting accuracy. Nevertheless, enabling the LFE improves step estimates for older, slower moving individuals (37) but greatly overestimates daily steps for healthy adults (18). Hickey et al. (38) found that when the LFE is enabled, false-positive steps are captured during light, non-ambulatory activities such as filing papers and they suggest that this could be a source of overestimation for daily steps (39). In the current study, steps were underestimated during the 60-min CR session, which is a departure from the typical pattern of overcounted steps. This could be due to the higher intensity activity being captured as it normally would, and less time spent in low intensity activity that may induce false positive step counting.

Few studies have investigated the Apple Watch step estimate error. In a study by Bai et al. (40), the Apple Watch series 1 was found to overcount Yamax Digiwalker steps by 5% during an 80 min protocol including sedentary behaviors, light physical activities, and aerobic exercise. In a separate study, when hand counted steps were compared to the Digiwalker across all

walking hours of one day, the Digiwalker was found to underestimate steps by 21% (18). The overestimate found by Bai and colleagues may be interpreted differently if the criterion measure were hand-counted or SW steps. Veerabhadrappa et al. (41) found the Apple Watch to capture steps within 5% of hand counted steps for treadmill ambulation of 2, 3, 4, and 5 mph. Although treadmill walking is symmetric, rhythmic, and continuous, assessing this activity provides insight about error in step counting across a range of speeds which may help to explain errors in more ecologically valid assessments.

The strengths of this study were the use of the SW as a criterion as this enabled steps to be measured across the entire day without video recording and the ability to assess a specific clinical population (phase II CR). Limitations to this study were the inability to extract minute-by-minute data from the Apple Watch; this precluded the separate analysis for adjusted CR days. Additionally, it is unknown if participants were each PAM as reported on the wear time log.

This study provided ecologically valid insights into the error of PAMs for patients enrolled in phase II CR for days with and without CR and time spent in CR. When errors during 60-min CR sessions were compared to error across the day, the pattern and extent by which steps were undercounted for all monitors, except for the AGLFE, which were similar to steps across ACR and NCR days, thereby suggesting that CR does not greatly contribute to error in daily steps. Given the importance of CR for recovery and secondary prevention of cardiovascular disease, and the call for innovative home-based or mobile health delivery of CR programs, the use of consumer-grade PAMs for tracking and setting physical activity goals are a viable option as the wrist worn consumer monitors showed relatively consistent results when compared to a healthy population. Because the SW is the most accurate monitor for step counting and to easily

compare results of future studies, researchers should consider using the SW as the criterion step count when hand-counted steps through video analysis is not feasible.

### References

- Statista. Wearable device sales revenue worldwide from 2016 to 2022 (in billion U.S. dollars) 2017 [cited 2019 3/27/2019]. Available from:
   https://www.statista.com/statistics/610447/wearable-device-revenue-worldwide/.
- 2. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA. 2007;298(19):2296-304.
- 3. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc. 2008;40(1):181-8.
- 4. Chiauzzi E, Rodarte C, DasMahapatra P. Patient-centered activity monitoring in the self-management of chronic health conditions. BMC Med. 2015;13(1):77.
- 5. Simpson ME, Serdula M, Galuska DA, Gillespie C, Donehoo R, Macera C, et al. Walking trends among US adults: the behavioral risk factor surveillance system, 1987–2000. Am J Prev Med. 2003;25(2):95-100.
- 6. Kruger J, Ham SA, Berrigan D, Ballard-Barbash R. Prevalence of transportation and leisure walking among US adults. Prev Med. 2008;47(3):329-34.
- 7. Whitt MC, DuBose KD, Ainsworth BE, Tudor-Locke C. Walking patterns in a sample of African American, Native American, and Caucasian women: the cross-cultural activity participation study. Health Educ Behav. 2004;31(4\_suppl):45S-56S.
- 8. Chan CB, Ryan DAJ, Tudor-Locke C. Health benefits of a pedometer-based physical activity intervention in sedentary workers. Prev Med. 2004;39(6):1215-22. doi: 10.1016/j.ypmed.2004.04.053.

- 9. Richardson CR, Newton TL, Abraham JJ, Sen A, Jimbo M, Swartz AM. A meta-analysis of pedometer-based walking interventions and weight loss. Ann Fam Med. 2008;6(1):69-77.
- 10. Hornbuckle LM, Kingsley JD, Kushnick MR, Moffatt RJ, Haymes EM, Miles R, et al. Effects of a 12-month pedometer-based walking intervention in women of low socioeconomic status. Clin Med Insights Womans Health. 2016;9(Suppl 1):75-84. doi: 10.4137/CMWH.S39636. PubMed PMID: PMC5054940.
- 11. Sugiura H, Sugiura H, Kajima K, Mirbod SM, Iwata H, Matsuoka T. Effects of long-term moderate exercise and increase in number of daily steps on serum lipids in women: randomised controlled trial [ISRCTN21921919]. BMC Womens Health. 2002;2(1):3.
- 12. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for cardiac rehabilitation and secondary prevention programs. 5th ed. Champaign, IL: Human Kinetics; 2013.
- 13. Lavie CJ, Thomas RJ, Squires RW, Allison TG, Milani RV, editors. Exercise training and cardiac rehabilitation in primary and secondary prevention of coronary heart disease. Mayo Clin Proc; 2009: Elsevier.
- 14. Ades PA. Cardiac rehabilitation and secondary prevention of coronary heart disease. N Engl J Med. 2001;345(12):892-902.
- 15. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. Prog Cardiovasc Nurs. 2002;17(1):8-17. Epub 2002/03/02. PubMed PMID: 11872976.
- 16. Ades PA, Keteyian SJ, Wright JS, Hamm LF, Lui K, Newlin K, et al., editors. Increasing cardiac rehabilitation participation from 20% to 70%: a road map from the million hearts cardiac rehabilitation collaborative. Mayo Clin Proc; 2017: Elsevier.

- 17. Balady GJ, Williams MA, Ades PA, Bittner V, Comoss P, Foody JM, et al. Core components of cardiac rehabilitation/secondary prevention programs: 2007 update: A scientific statement from the american heart association exercise, cardiac rehabilitation, and prevention committee, the council on clinical cardiology; the councils on cardiovascular nursing, epidemiology and prevention, and nutrition, physical activity, and metabolism; and the american association of cardiovascular and pulmonary rehabilitation. Circulation. 2007;115(20):2675-82.
- 18. Toth LP, Park S, Springer CM, Feyerabend M, Steeves JA, Bassett DR. Video-recorded validation of wearable step counters under free-living conditions. Med Sci Sports Exerc. 2018;50(6):1315-22.
- 19. Apple I. Apple Watch Series 2 Technical Specifications 2018 [cited 2018 7/3]. Available from: https://support.apple.com/kb/SP746?locale=en\_US.
- 20. Apple I. Apple Watch User Guide 2018 [cited 2018 7/5]. Available from: https://help.apple.com/watch/.
- 21. Fitbit I. Fitbit Charge 2 User Manual v1.2. 2018.
- 22. Fitbit I. Fitbit Charge 2, Specifications 2018 [cited 2018 7/3]. Available from: https://www.fitbit.com/shop/charge2?activeFeature=specs.
- 23. Fitbit I. Fitbit Zip Wireless Activity Tracker User Manual v.1.2. 2014.
- 24. Fitbit I. Fitbit Zip Activity Tracker Specs 2018 [cited 2018 7/3]. Available from: https://www.fitbit.com/shop/zip.
- 25. ActiGraph LLC. User Guide: ActiGraph GT9X Link + ActiLife. 3 ed. Pensacola, FL2019.
- 26. Modus Health LLC. StepWatch 3 user's manual. Washington, D.C.2014.

- 27. Toth LP, Park S, Pittman WL, Sarisaltik D, Hibbing PR, Morton AL, et al. Effects of brief intermittent walking bouts on step count accuracy of wearable devices. Journal for the Measurement of Physical Behaviour. 2019;2(1):13-21.
- 28. Orendurff MS, Schoen JA, Bernatz GC, Segal AD. How humans walk: bout duration, steps per bout, and rest duration. J Rehabil Res Dev. 2008;45(7):1077.
- 29. Toth LP, Bassett DR, Crouter SE, Overstreet BS, LaMunion SR, Park S, et al. StepWatch accuracy during walking, running, and intermittent activities. Gait Posture. 2017;52:165-70.
- 30. Feito Y, Bassett DR, Thompson DL. Evaluation of activity monitors in controlled and free-living environments. Med Sci Sports Exerc. 2012;44(4):733-41. Epub 2011/09/10.
- 31. Toth LP, Park S, Pittman WL, Sarisaltik D, Hibbing PR, Morton AL, et al. Validity of activity tracker step counts during walking, running, and activities of daily living. Translational Journal of the American College of Sports Medicine. 2018;3(7):52-9.
- 32. Steeves JA, Tyo BM, Connolly CP, Gregory DA, Stark NA, Bassett DR. Validity and reliability of the Omron HJ-303 tri-axial accelerometer-based pedometer. J Phys Act Health. 2011;8(7):1014-20.
- 33. Chen MD, Kuo CC, Pellegrini CA, Hsu MJ. Accuracy of wristband activity monitors during ambulation and activities. Med Sci Sports Exerc. 2016;48(10):1942-9.
- 34. O'Connell S, ÓLaighin G, Quinlan LR. When a step is not a step! Specificity analysis of five physical activity monitors. PLoS One. 2017;12(1):e0169616.
- 35. Karabulut M, Crouter SE, Bassett DR. Comparison of two waist-mounted and two anklemounted electronic pedometers. Eur J Appl Physiol. 2005;95(4):335-43.

- 36. Cain KL, Conway TL, Adams MA, Husak LE, Sallis JF. Comparison of older and newer generations of ActiGraph accelerometers with the normal filter and the low frequency extension. Int J Nutr Phys Act. 2013;10(1):51.
- 37. Webber SC, John PDS. Comparison of ActiGraph GT3X+ and StepWatch step count accuracy in geriatric rehabilitation patients. J Aging Phys Act. 2016;24(3):451-8.
- 38. Hickey A, John D, Sasaki J, Mavilia M, Freedson P. Validity of activity monitor step detection is related to movement patterns. J Phys Act Health. 2016;13(2):145-53.
- 39. Matthews CE, Chen KY, Freedson PS, Buchowski MS, Beech BM, Pate RR, et al. Amount of time spent in sedentary behaviors in the United States, 2003–2004. Am J Epidemiol. 2008;167(7):875-81.
- 40. Bai Y, Hibbing P, Mantis C, Welk GJ. Comparative evaluation of heart rate-based monitors: Apple Watch vs Fitbit Charge HR. J Sports Sci. 2018;36(15):1734-41.
- 41. Veerabhadrappa P, Moran MD, Renninger MD, Rhudy MB, Dreisbach SB, Gift KM.

  Tracking steps on Apple Watch at different walking speeds. J Gen Intern Med. 2018;33(6):795-6.

# Chapter IV

Using Ecological Momentary Assessment to Explore Anxiety and Physical Activity for Patients in Phase II Cardiac Rehabilitation

#### Abstract

**Background:** Higher levels of anxiety are a predictor of dropout in outpatient cardiac rehabilitation (CR) but little is known about the between- and within-person consistency of this construct or its association with physical activity. **Objective:** Three aims were to 1. determine the consistency of state anxiety (SA) across a two week period, 2. investigate the association between SA and physical activity (PA) between and within participants, and 3. describe the feasibility of mobile ecological momentary assessment (EMA) with ActiGraph GT3X+ (GT3X+) wear for those in early phase II CR. **Methods:** Nine adults (33% female, M±SD age:  $59.1 \pm 8.9$  yrs) were recruited. EMA surveys of SA were delivered to participant's smartphones four times per day, for 14 consecutive days (total 56 surveys) while they wore a GT3X+ during all waking hours. An intraclass correlation coefficient was used to describe the SA consistency across all 56 surveys. Visual assessment of line graphs of SA and scatterplots of SA and PA across 56 time points were used to describe intra-individual patterns. Feasibility of recruitment, survey completion, and GT3X+ wear time were assessed. Results: SA scores were low and consistent. Individual plots showed three patterns in SA across 56 time points and slopes per participant for the association between PA and SA showed mixed positive and negative results. Survey compliance rates and GT3X+ wear time met a priori standards, but recruitment rate did not. **Conclusions:** EMA data provides the resolution to identify patterns for further subgroup analysis but recruitment limitations must be addressed.

#### Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States (1) and world-wide (2). Although the age-adjusted CVD mortality rate has reportedly fallen by a range of 1.6% to 3.8% per year since 1970 (3-5), CVD continues to account for 30% of all deaths (5). The monetary cost of CVD in the United States is \$200 billion annually (inclusive of hospitalizations, medications, and productivity loss) (6), and is a leading cause of hospitalization (7).

For those that have been diagnosed with CVD or who have experienced a cardiovascular related event or surgery (e.g., myocardial infarction, percutaneous coronary intervention, coronary artery bypass surgery), participation in cardiac rehabilitation (CR) is recommended by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Heart Association, and American College of Cardiology (7). CR is a four-phased exercise and educational program that begins while the patient is in the hospital, immediately following their cardiac event or surgery and ends with a maintenance phase of independent exercise. The first phase consists of hallway walking and activities of daily living to prepare for the transfer from the hospital to the patient's home (7). Phase II is a 36-session outpatient program, covered by insurance, that includes monitored (e.g., blood pressure, continuous ambulatory electrocardiogram, or heart rate) exercise and educational components aimed to help patients return to their typical social and vocational activities (7). Phase III is an outpatient program that is not covered by insurance where patients transition from continuously monitored and directed exercise sessions to independent exercise. Blood pressure and educational sessions are available, but the participant selects their own mode of exercise and creates their own exercise schedule (7). The fourth phase of CR is considered the maintenance phase, where patients create a longterm plan for continued independent exercise. Phase IV is not covered by insurance and monitoring is not offered because this phase usually occurs at home or in an independent recreational or fitness facility (8).

Completing outpatient CR has many benefits but this program is underutilized. Regular CR attendance reduces total and cardiac mortality (9, 10) and hospital readmission rates (10), improves health-related quality of life and modifiable CVD risk factors (9), and increases perceived physical function scores (11). Regardless of these benefits, 30 to 70% of participants drop out of CR programs (12). Increased risk for drop out is associated with sociodemographic and psychological factors. Sociodemographic factors (e.g., being older, female, and having a lower educational and economic status (12)) require intervention at the policy and health-care system level and may include items such as providing transportation, home-based programs, or more flexible hours of attendance (13). Psychological variables related to drop out, such as anxiety, can be intervened upon and addressed at the person-level within a CR program to improve overall program attendance and physical activity (PA) levels outside of CR, but such interventions are needed (12, 14).

Anxiety is described as feelings of concern, worry, or anticipated threats and tension along with physical characteristics including increased blood pressure, sweating, or heart palpitations (15). Living with higher levels of anxiety has been associated with the development of CVD because hypertension, a common physiological outcome of anxiety, is a major contributor to CVD development (16, 17). Additionally, higher levels of anxiety have been shown to predict CR drop out within the first two weeks of the program (14). Several validated scales have been used to survey symptoms of general anxiety that are unrelated to anxiety disorders. These scales include questions of both state and trait anxiety, which are the two

dimensions of general anxiety (18). Trait anxiety is a personality characteristic (or trait) that is stable form day to day, across many situations (19) and state anxiety is typically a momentary response or temporary feeling (emotional state) of anxiousness that occurs in response to an experience or situation (19).

In practice and research, general anxiety is typically measured cross-sectionally and is accepted as a static construct within each individual. For CR programs, a pre-program anxiety measure is used to refer patients to psychological counselling (7). In research focused on barriers or correlates of CR non-adherence, summary anxiety scores, determined by averaging the multiple measures, are used to predict drop out (14, 20). Inter-individual differences in anxiety as it relates to CR attendance are described; however, single or averaged scores are limited when attempting to understand the intra-individual differences in decisional processes leading to repeated occurrence health behaviors (21).

Repeated health behaviors, such as PA, require regular engagement to maintain or improve overall health. Decisions to complete these behaviors are influenced by experiences, feelings, contextual elements, and temporal factors across the day (21). Assessing factors repeatedly over time is critical for capturing changes in those that influence behavior. Entering a measure of variability of self-efficacy and intention into predictive models were shown to predict PA better than using static, trait-level individual mean values (22). Thus, although anxiety is a predictor of CR drop out, temporal variance of state anxiety and its influence on PA engagement for those in CR are unknown. State anxiety was selected for this study because it has been shown to be highly variable within and between individuals across occasions on three separate days (23) but longer-term consistency (across two weeks) is unknown.

The current study was designed to address this gap by conducting an ecological momentary assessment (EMA) of state anxiety over two weeks in adults attending early phase II CR. EMA is a technique for collecting in-the-moment, repeated measures across the time period where a variable is expected to undulate in the free-living environment, typically using mobile technology (24). Repeated assessments provide improved resolution of factors and allow for descriptions of patterns and variability at the individual level, which could help to identify antecedents of behaviors as they vary from person to person and within one person. When using EMA to study PA behavior, concurrent use of wearable activity monitors is strongly suggested to reduce recall bias associated with self-reported PA and to capture subconscious activity, such as short walking bouts to complete tasks at work or during activities within the home (25). This study has three aims: 1. to determine the consistency of state anxiety across 56 time points over a two week period, 2. to investigate the association between state anxiety and subsequent step counts between and within participants, and 3. to describe the feasibility of mobile EMA while wearing an ActiGraph GT3X+ (GT3X+) for those in early phase II CR.

#### Methods

# **Study Design**

Individuals within the first three weeks, or nine sessions, of phase II CR were recruited for this study. Consenting participants received four mobile EMA survey links per day that were delivered to their smartphones via SMS (short message service), at four predetermined times, for 14 consecutive days. Participants were encouraged to answer the surveys within 60 min of receipt in order to capture a measure of momentary state anxiety. Participants concurrently were asked to wear the GT3X+ on their waist during all waking hours of each day.

## **Participants and Recruitment**

Adult participants between 18 and 80 years of age were recruited from the phase II cardiac rehabilitation program at the Heart Lung Vascular Institute of the University of Tennessee Medical Center in Knoxville, TN. Exclusionary criteria included individuals who did not own a smartphone or have access to a data plan, previously completed a CR program, had been enrolled in CR longer than three weeks, had an ejection fraction <35%, were diagnosed with pulmonary disease and/or diseases that are related to cognitive decline or memory impairment, required an assistive device for ambulation, or were referred to CR following valvular surgery or heart transplant. The research protocol was approved by the University of Tennessee Graduate School of Medicine and the University of Tennessee, Knoxville Institutional Review Boards. All participants provided written informed consent before participating in this study.

Rolling recruitment was completed with a two-step process over a four-month time period (February to June 2019). First, CR nurses and exercise physiologists reviewed the health-related exclusionary criteria (i.e., age, ejection fraction <35%, diagnosed with pulmonary disease and/or diseases that are related to cognitive decline or memory impairment, and referred to CR following valvular surgery or heart transplant) for each new patient entering the CR program to determine eligibility. Eligible patients were then referred to the researcher. In the second step of recruitment, the researcher individually approached each referred participant at their CR session and determined if they were eligible based on the need of assistive walking device and smartphone ownership. For those who remained eligible, the researcher explained the study and participation requirements. Each enrolled participant provided written, informed consent.

#### **Protocol**

Enrolled participants met the researcher at the subsequent CR session to receive and complete a mock survey to determine smartphone capabilities, to provide clarification, and to address questions or concerns. At this time, participants were reminded to answer surveys within 60 min of receipt for the duration of the study. Each participant was then provided a GT3X+ and log to record when the monitor was worn and they were shown how to use both. The GT3X+ monitors were attached to an elastic belt and the monitor was positioned over the right hip. Participants were asked to wear the GT3X+ during all waking hours, except during water activities, during each of the 14 survey days.

Following the mock survey session, the researcher programmed mobile survey distribution for the following 14-day period. Surveys were programmed for delivery four times per day (07:45, 11:45, 15:45, and 19:45), every day, for two consecutive weeks. Survey links were delivered via SMS to the participant's mobile phone. By tapping on the active link, the survey opened in the primary web browser on the participant's mobile phone, enabling them to report in-the-moment state anxiety. Survey results and metadata (e.g., time of day surveys were opened and duration of time between when the survey was opened to completion) were automatically stored upon survey completion.

#### Instrumentation

*Mobile surveys*. Qualtrics Research Core (Qualtrics, Provo, UT) was used to create, deliver, collect, and store survey results and metadata. It is a research platform that allows users to create surveys by means of point and click choices, providing an array of response options (e.g., sliding scale, multiple choice, matrix table) enabling the researcher to choose response types that suit their question and intended statistical analyses. Several benefits of the Qualtrics

platform are the options for delivery of surveys, ease of survey completion for participants, and data storage and security (26).

Spielberger State-Trait Anxiety Inventory (STAI) Short Form. The original STAI is a 40-item inventory consisting of 20 items related to state anxiety and 20 items related to trait anxiety. The state and trait inventories are scored separately, providing a measure for each construct (27). A short form of the state anxiety inventory was developed using six items from the original form to reduce participant burden when brevity was necessary. The short and original form yield state anxiety scores that are highly correlated (r = .95) (28). Additionally, it has been validated in several clinical and non-clinical populations such as those who are critically ill or on ventilatory support (29), previous myocardial infarction (30), respiratory patients (31), new parents to infants with and without abnormal newborn screens (32), and nursing and medical students (28).

Each STAI short form item is scored with a four-point Likert scale. For items that indicate the presence of anxiety (e.g., "I am tense" or "I feel upset"), a rating of four indicated a high level of anxiety. For the other items, (e.g., "I am relaxed" or "I feel content"), a rating of four indicates the absence of anxiety (19). After the scores for the anxiety-absent items were reversed, all scores from each STAI short form item were summed to create a total score which ranged from 6 to 24. Higher total scores represent higher levels of state-anxiety.

ActiGraph GT3X+. The GT3X+ activity monitor  $(4.6 \times 3.3 \times 1.5 \text{ cm}, 19\text{g})$  was used to assess PA. GT3X+ monitors include a triaxial accelerometer that measures raw accelerations in a range of  $\pm 6$  G. Sampling frequency is determined by the user at a rate between 30 and 100 Hz during monitor initialization. Raw acceleration data is stored on the internal memory of the monitor until it is downloaded (33).

GT3X+ monitors were initialized to sample data at 30 Hz using the ActiLife software (v. 6.13.3, ActiGraph LLC, Pensacola, FL), distributed to participants, and worn during the 14-day study. When initialized at 30 Hz, the battery life and memory limit are 31 and 42.5 days (33), respectively, so participants were able to wear the same monitor for the duration of the study. After completing the protocol, GT3X+ monitors were collected then acceleration data were downloaded and converted to activity counts using the ActiLife software without the low frequency extension enabled. Count data for each participant were then processed with the ActiLife Wear Time Validation tool using the Choi Algorithm to establish GT3X+ wear time for each participant. Next, using the Global Time Filters on the Scoring tab within ActiLife, steps were summed during periods of Choi validated wear time across the four hours following surveys (07:45 to 11:45, 11:46 to 15:45, and 15:46 to 19:45). This process provided the step count and the minutes of valid wear time across the given four-hour block. Some participants did not wear the GT3X+ for the total duration of each four-hour block so total steps for the four-hour time period were scaled to steps per hour. Steps per hour were calculated by first dividing the steps per four-hour block by minutes of wear time for the given block and then multiplying that value by 60. This step was important so comparisons could be made using the same unit of PA, therefore, individuals who provided more wear time did not unfairly weight the sample.

# **Data Processing**

Mobile survey data. Mobile survey responses and metadata were downloaded from the Qualtrics platform in separate comma separated values files for each survey delivery time.

Metadata (i.e., survey start date and time, end date and time, recorded date and time, survey duration, and recipient identification name), STAI short form responses, and step count per hour were entered into an Excel database. The STAI short form responses were summed in this

database to produce the state anxiety score. Each state anxiety score was labeled for its time block denoting the time of delivery where T1, T2, T3, and T4 represented 07:45, 11:45, 15:45, and 19:45, respectively, and were labeled sequentially (1 through 56) for time course analysis. When step counts per hour were entered into the database, they were aligned with the survey delivered at the beginning of the four-hour block that was used to calculate steps per hour (e.g., the step count per hour aligned with the 07:45 survey represented step per hour from 07:45 to 11:45). Data were visually inspected to remove all mock survey responses, identify missing data, and flag responses that were completed more than 60 minutes following survey receipt. The following shows the number of missing PA or state anxiety scores data points and the number of state anxiety scores removed for survey completion >60 minutes following receipt:

- 07:45: 10 missing, 20 removed;
- 11:45: 8 missing, 13 removed;
- 15:45: 17 missing, 10 removed; and
- 19:45: 9 missing, 10 removed.

Further data management is discussed for each separate analysis.

**Data Analyses**. Separate analyses for state anxiety consistency, association between state anxiety and PA, and mobile EMA feasibility were completed to address each purpose of this study.

The first aim was to determine the consistency of state anxiety across 56 time points over a two-week period. Consistency of state anxiety was assessed by determining an intraclass correlation coefficient (ICC) across all 56 time points for each participant. For this analysis, missing state anxiety scores (44 missing out of a possible 504 scores) were imputed using the participant's mean state anxiety score for the corresponding day. Cicchetti interpretations for

ICCs were used to describe the level of consistency; < 0.40 = poor, 0.40 to 0.59 = fair, 0.60 to 0.74 = good, and 0.75 to 1.00 = excellent (34). Standard deviations of state anxiety for each participant were also included as a measure of individual variability and figures showing state anxiety scores across each survey (56 time points) were created. Descriptive statistics were completed with SPSS Version 25 for Windows, (SPSS Inc., Chicago, IL).

Aim two was to investigate the association between state anxiety and subsequent step counts between and within participants. Scatterplots with linear trendlines along with linear regressions were used to assess the direction and strength of the association between PA and state anxiety score and to determine if repeated measures analysis (rmcorr) could be used to assess associations while accounting for time-dependent data within individuals. Linear regression was only used to determine if slopes were positive or negative and correlation coefficients should be interpreted with caution because repeated assessments violates the assumption of independence of observations. Strength of association was not assessed. No data were imputed for missing values and entries that were completed more than 60 min after receipt were also removed from this analysis to avoid convoluting the temporal sequence of momentary anxiety score to PA across the following four hours. Entries with missing data for state anxiety score or step count per hour were not included in the scatterplots. State anxiety scores were entered on the x-axis and steps per hour were entered on the y-axis. State anxiety was explored as a predictive variable to PA because a strong association between high state anxiety and low PA would indicate state anxiety to be an important component for intervention.

The third aim was to describe the feasibility of mobile EMA with GT3X+ wear for those in early phase II CR. Specifically, feasibility for recruitment, survey completion rates, and GT3X+ wear time were assessed using *a priori* benchmarks. The *a priori* benchmark for

recruitment was set at one participant per week which was based upon estimated phase II CR program recruitment of zero to six patients per week. A survey completion rate of 75% within 60 minutes of receipt was set because if one survey was missed, temporal associations could be preserved with at least one morning and one afternoon measurement. A 60-minute survey response time was used to maintain temporal sequence between momentary measurement of state anxiety and the PA outcome. Finally, 10 hours of GT3X+ wear time was set as the *a priori* benchmark as it is a commonly accepted wear time benchmark (35) and should allow for capture of activity across a large proportion of the time surveyed, however the limitations of this benchmark are discussed.

#### Results

**Participant Characteristics.** Of the 53 (18 women, 35 men) new CR participants during four months of recruitment, 25 (6 women, 19 men) were eligible and approached for recruitment. Of those individuals, nine participants (33% female, mean  $\pm$  SD age, 59.1  $\pm$  8.9 yr) were enrolled in this study (Table 3).

Consistency of state anxiety. The average state anxiety score across the 14-day period was 9.1 on a scale of 6 to 24 (Figure 3). Across all 56 time points, consistency of reported anxiety was considered good (ICC = 0.68, 95% CI: 0.49 - 0.89, P < 0.01). One participant completed all surveys, four participants had one imputed score, three participants had between three and 10 imputed scores, and one participant had 19 imputed scores.

Figure 4 shows examples depicting anxiety scores at each time point. Three emerging patterns in state anxiety scores were a high intra-individual consistency with an individual mean lower than the grand mean, greater intra-individual variation with individual mean higher than

Table 3. Summary of participant characteristics.

	All $(N = 9)$	Women $(n = 3)$	Men (n = 6)
Age (yr)	59 ± 9	63 ± 4	57 ± 11
Height (cm)	$173.6 \pm 10.5$	$160.9 \pm 3.9$	$179.9 \pm 6.9$
Weight (kg)	$93.4 \pm 9.5$	$96.4 \pm 11.5$	$92.0 \pm 10.1$
BMI (kg/m²)	$31.3 \pm 4.9$	$37.2 \pm 3.6$	$28.4 \pm 2.7$
Reason for CR	MI: 1	MI: 1	MI: 0
	Stent: 3	Stent: 0	Stent: 3
	MI and Stent: 2	MI and Stent: 1	MI and Stent: 1
	CABG: 3	CABG: 1	CABG: 2

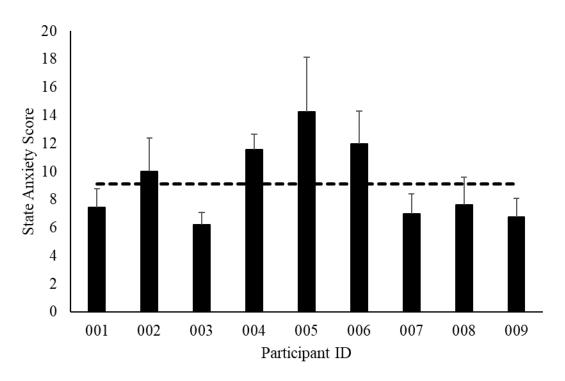


Figure 3. Mean and standard deviation of state anxiety scores across two weeks, for each participant. Dashed horizontal line represents the grand mean anxiety score for all participants.

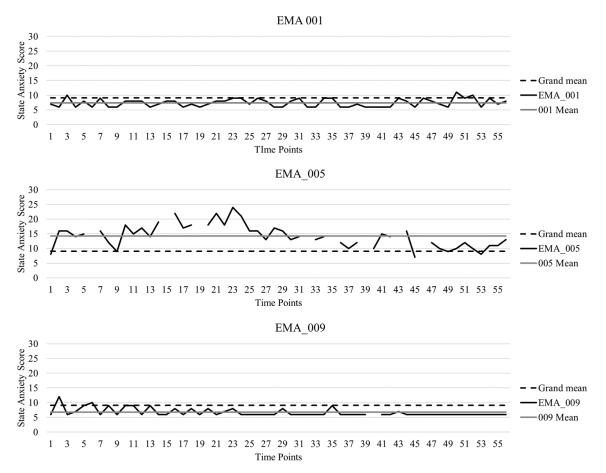


Figure 4. Three emerging patterns of state anxiety across all 56 survey time points. A. high intraindividual consistency with an individual mean lower than the grand mean, B. greater intraindividual variation with individual mean higher than the grand mean, and C. a tapered effect greater state anxiety variability during the first week but became highly consistent during the second week.

the grand mean, and a tapered effect showing greater variability in state anxiety during the first week that became more consistent during the second week.

Association of state anxiety and PA. A scatterplot of all participant state anxiety and PA data showed a negative slope ( $\beta$  = -25.5, r = -.264) between state anxiety and the steps per hour across the hours following the anxiety measure (Figure 5). Figure 6 shows scatterplots for each participant with linear trendlines. Slopes and correlation coefficients show three positive slopes and six negative slopes for individual participants, which were used to determine that due to the mixed directions of the slopes, rmcorr could not be utilized because this method of analysis requires slopes of the same direction (36).

Feasibility of mobile EMA with GT3X+ wear. For recruitment, the a priori benchmark of enrolling one participant each week was not met since only nine participants were recruited across a four-month period. Of eligible participants, only 36% consented and were enrolled in this study (Figure 7).

Of the total 504 surveys distributed, 91.3% were completed, with individual participants completing a range of 66 to 100% of the surveys distributed to them. On average, participants completed each survey in 3.9 min and surveys were returned 29±42 min after receipt. The *a priori* benchmark of completing at least 75% of surveys within 60 min of receipt was met; in total 85% of surveys were completed within 60 min. Survey compliance at each time point was as follows: 07:45, 75%; 11:45, 84%; 15:45, 70%; and 19:45, 83%.

Average Choi Algorithm determined GT3X+ wear time was 10.3±2.7 hr per day (range: 0.1 to 14.5 hr per day), which met the *a priori* benchmark for valid wear time (10 hrs per day). During the 12 hours of interest that corresponded to survey delivery (07:45 to 19:45), only 27% of days resulted in 12 hours of accelerometer data.

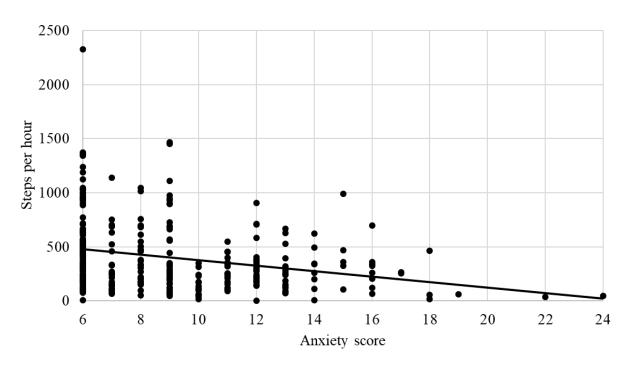


Figure 5. Physical activity as a function of state anxiety score for all participants across all survey time points.

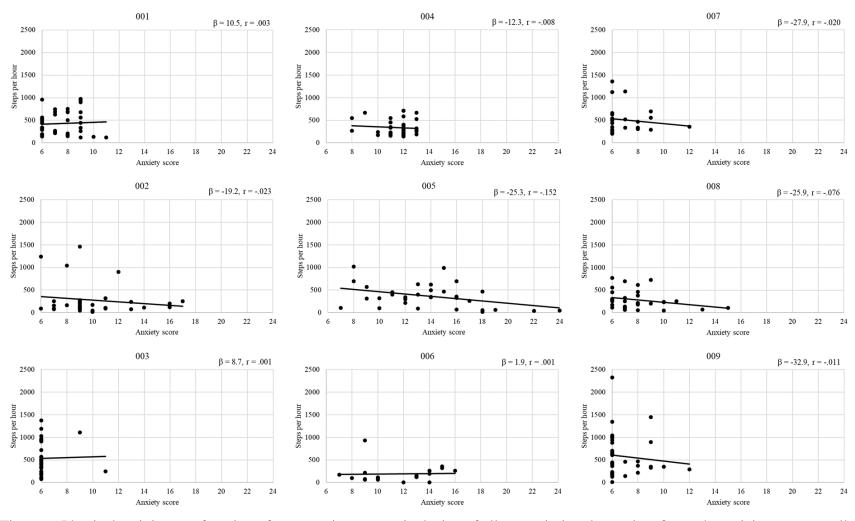


Figure 6. Physical activity as a function of state anxiety scores inclusive of all non-missing data points for each participant across all survey time points.

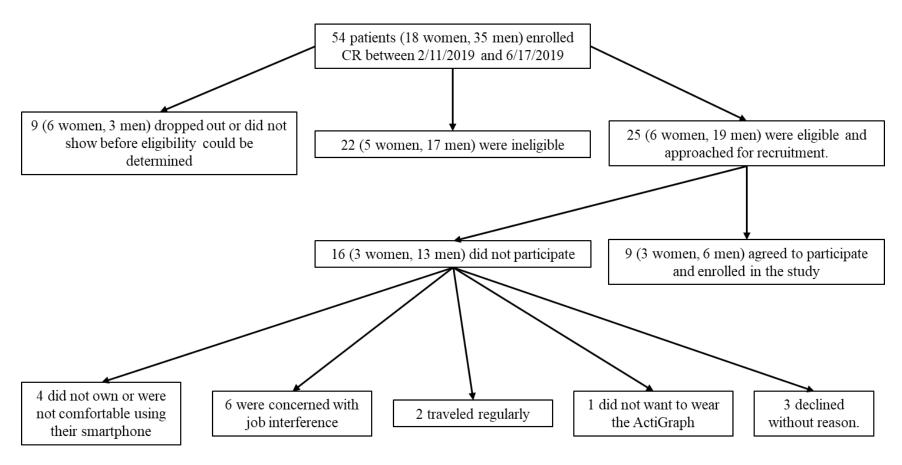


Figure 7. Recruitment and enrollment flow chart detailing all new patients, eligible patients, number who enrolled, and reasons eligible individuals did not enroll.

Before the first day of participation, all 56 surveys per participant were scheduled for delivery. This process took approximately one hour per participant. If two or more participants were beginning on the same day, their surveys could be scheduled at the same time, therefore reducing administrator burden as two or more participants could be scheduled in the same amount of time that one participant could be scheduled. For this study, approximately 7 hours were spent scheduling survey delivery. Preparing, downloading and processing, and analyzing accelerometer data and step count output required minimal time (5 min, 8 min, and 30 min, respectively) and in total, the time spent was about 6.5 hrs. Relatively little time was spent face-to-face with each participant, with the majority of this time being spent navigating through the sample survey and explaining proper accelerometer wear (approximately 15 min). Total time spent face to face was about 2.3 hrs. The total administrator time burden for delivery, download, and training was 15.8 hrs.

### **Discussion**

Participants in this study had relatively low and consistent state anxiety scores across the 14-day study according to ICC and average state anxiety results. When all participant data were included on one scatterplot with a linear trendline showing the steps per hour as a function of state anxiety, the negative slope suggests higher state anxiety is followed by a period of fewer steps per hour. Upon further inspection of scatterplots created for each participant, three positive and six negative slopes were found, thereby showing inconsistent between-person associations between PA and state anxiety. Because the directionality of individually plotted slopes differed, it is likely that a direct individual-level association between PA and state anxiety does not exist or other factors are confounding the relationship. Feasibility of mobile EMA and activity monitor

wear was also assessed in this study. Briefly, the *a priori* benchmark for survey completion and GT3X+ wear time were met, however, recruitment rate was not.

As compared to similar populations, state anxiety scores in the current sample were low. To compare state anxiety scores from this study to the percentile norms shown in the original State Trait Anxiety Inventory, results were multiplied by 3.3. This adjustment was determined by dividing the lowest score from the original form by the lowest score for the short form which provided the adjustment factor. The risk of inflation of scores and variance due to extreme scores should be considered when prorating sub-scales or short forms (37). After prorating the short form mean state anxiety score (9.1  $\times$  3.3 = 30.0), participants fell in the 40<sup>th</sup> to 47<sup>th</sup> percentiles for similarly aged individuals (50-69 yrs) (27). Because 88% of individuals received some type of cardiac-related surgical intervention (i.e., stent placement or bypass surgery), state anxiety scores were also compared to percentile ranks for general medical and surgical patients. On average, general medical and surgical patients had higher mean state anxiety scores than the current sample, 42.4 vs 30.0, respectively, and fell in the 21st percentile rank. When compared to a larger sample of CR attendees, the current sample showed a slightly lower mean state anxiety score (32.1 larger CR sample vs 30.0 current sample) (38). In comparison to other populations which used the short form state anxiety inventory, the current sample, with an average score of 9.1, scored slightly greater than pregnant women (8.7), student nurses (7.0), and medical students (6.7)(32).

The consistency of state anxiety in this population could be related to the frequency of low state anxiety scores. Consistency, measured with ICCs across all 56 time points (ICC = 0.68), was "good" using the Cicchetti interpretations (34). These interpretations, however, were developed to assess inter-rater agreement, not consistency in repeated behavioral construct

measures across one participant. Therefore, application of ICCs in this study are somewhat limited but have been previously used to describe consistency in similar repeated intra-individual assessments (39). Scores with high frequencies may also contribute to consistency. Among all of the results, the most frequently reported state anxiety score was 6, accounting for 137 out of 407 (33.7%) total responses. The clustering of this score indicates a floor effect, thereby suggesting the STAI short form may not have the resolution necessary to measure state anxiety for those who generally experience low state anxiety.

Exploring measures of variability, not only average-level data, is suggested to account for the dynamic nature of emotions, feelings, and constructs one experiences throughout the day (21). Entering a value representing instability, such as standard deviation, of factors that naturally fluctuate have provided meaningful outcomes in describing relationships between variables above that of mean-level data. Gerstorf et al. (23) assessed the variability of state anxiety across three occasions during an 11-day span in adults using standardized standard deviations. This sample, on average, reported low mean state anxiety scores, but 94% of the sample showed variability in scores across the three assessment points. The authors note that individual variance was patterned asymmetrically around the mean and should be considered a source of information when investigating correlates with predictive modeling.

For constructs that do fluctuate throughout the day, accounting for variability has been shown to predict PA outcomes more strongly than mean-level data. Dunton et al. (40) found that a higher level of stability in positive and negative affect in children was significantly related to higher levels of moderate to vigorous PA; previous research showed no relation between mean levels of affect and PA. Additionally, Pickering et al. (22) showed that while individual-level means for self-efficacy and intention were unrelated to moderate to vigorous PA, entering a

measure of instability for both of these constructs demonstrated that the greater instability was related to higher amounts of moderate to vigorous PA. These findings indicate that measures of instability should be considered for within-individual predictive models.

Visually exploring the landscape of data is a unique opportunity to identify emerging patterns within the data. To further explore the within-person patterns of anxiety score, individual line graphs for each participant were created including each survey time point (56 instances) plotted across the x-axis and state anxiety scores plotted along the y-axis were created. Three identifiable patterns emerged from inspecting these graphs and a spike in anxiety was easily identifiable during an anecdotal, state anxiety inducing event. The emerging patterns showed that some participants appeared to have higher levels of score consistency with individual means lower than the grand mean; some showed more instability with individual means higher than the grand mean and one participant showed a tapered effect where state anxiety was more variable during the first than the second week. In larger studies, if these patterns recur, associations between CR attendance or level of PA engagement should be investigated similar to that in weight loss research. Three classifications of weight loss patterns, modest, moderate and steady, and substantial and early, have been identified through studying variance in individual weight loss patterns and weight loss predictor variables (e.g., PA, social support, psychosocial variables) differ among each classification (41). Identifying homogeneous subgroups has provided weight loss researchers with a classification scheme and specific area for intervention that are tailored per each subgroup to improve interventions.

Visually assessing individual slopes can also guide investigators toward appropriate statistical treatments. A recently developed approach for investigated associations between variables for repeated measures data is rmcorr. This was appealing because traditional linear

regression or correlation methods assume independent observations, which was violated by the repeated measures within each individual. Although linear regression was used in this study, it was only to assess the direction of the slope for the association between PA and state anxiety, it was not used to determine significant relationships. Non-independence is accounted for in rmcorr by statistically adjusting for inter-individual variance, allowing for common intra-individual variance to be assessed. In this technique, a common slope is fit to each participant with individual intercepts and the rmcorr coefficient represents the strength of the linear association (36). However, for this data rmcorr was not appropriate because all slopes must be in the same direction and in this sample, they are not.

The varied slope directionality and weak associations may be a result of state anxiety assessment inventory or the selected metric of PA. The floor effect elicited from the state anxiety short form indicates that this scale may be inappropriate for individuals with low anxiety. Visual analogue scales have been validated for the assessment of anxiety and therefore could be considered for future use to gain a measure of anxiety across a spectrum of 0 to 100 (42). The PA metric of steps is a possible limitation to this study. The total volume of PA as measured by steps may be inappropriate because step counts included in this analysis captured both exercise and activities of daily living. Steps taken during work or home-based activities may be completed regardless of one's level of state anxiety because these steps are associated with obligations of life. Therefore, it is possible that anxiety is more related exercise activity and a measure of moderate to vigorous activity would be more appropriate. Also, the time span in which steps were investigated (across four hours) may be too long of a duration to pair with momentary state anxiety. The frequency in which state anxiety fluctuates remains unknown but higher resolution data can inform the appropriate time comparison.

The final purpose of this study was to assess feasibility of mobile EMA in terms of recruitment, survey compliance, and GT3X+ wear time for those in early phase II CR. The largest challenges to recruitment were smartphone ownership, interference with careers, and low numbers of women enrolled in CR. Findings of a recent Pew Research Center report show that as of 2019, 81% of all Americans own a smartphone which is reduced to 79% for those 50-64 years and 53% of those 65 and older (43). The decline in ownership with increasing age is important for researchers to consider when the target population is typically older. Future studies could consider providing easy-to-use smartphones to their participants. The other most commonly occurring reason for non-participation was interference with their career. According to the Bureau of Labor Statistics, full-time employed individuals are at work for 8.5 hours on week days (44), which accounts for 68% of waking hours, assuming 8 hours of sleep. Being unable to capture momentary assessments during this time not only provides an incomplete picture for the participant but also prevents momentary assessment of topics such as workplace related anxiety and stress. A consideration is to utilize passive measurements of biological markers such as cortisol or heart rate variability to capture stress, but user input of context and experiences would be a limitation. Additionally, survey delivery before and after work hours could be employed; however, individualizing survey distribution schedules for each participant will increase administrator burden.

In the current study, only 33% of the participants were women which is not surprising given women are an underrepresented group in outpatient CR. Participation rates of women range from 15 to 20% as compared to 25 to 31% for men (12). Clinicians and physicians more often refer men than women to CR programs and this same bias has also been found for older adults and ethnic minorities (45). Additionally, women often hold caregiving roles and tend to

report more feelings that exercise is not important for them or they express that is it uncomfortable exercising around men (12).

Earlier studies have demonstrated that mobile surveys, as opposed to paper and pencil surveys, have higher compliance rates, 96% vs 70%, for young adults (46) with mobile versus paper and pencil surveys. Although mobile technology such as smartphones are becoming increasingly ubiquitous, compliance in middle-aged to older adults must be assessed. Ehlers, Huberty (39) assessed the mobile survey compliance of female adults aged 46±8 yrs receiving two to three mobile surveys per day and found high compliance, with the women completing 91.1% of the surveys delivered within 2.5 hrs of receipt. These findings are similar to that of the current study where the average age of the participants was 59.1 yrs and 85% of surveys were completed within 60 min of receipt. Of note, during this study there was one instance of late survey delivery (affecting three participants). This error was due to Qualtrics server malfunction, which the researcher confirmed by calling the Qualtrics help desk. These surveys were delivered approximately 60 min late which caused removal of these responses from the association analysis. Requiring survey response within 60 minutes helped to maintain the temporal association between anxiety score and subsequent steps per hour. Because both EMA responses and PA measures are time stamped, the late responses could be paired with the correct measure of PA, however, statistical methods in predictive modeling, like multi-level modeling, are robust to missing data, therefore, reducing administrator burden.

Wearable activity monitors are suggested for use with EMA of PA to gain an objective measure of activity (25). A benefit of utilizing activity monitors is the ability to capture light activity that is often completed subconsciously and is often under-reported or not assessed in validated self-report methods (47). Compliance with GT3X+ wear met the *a priori* benchmark

for feasibility. This benchmark was selected because of its widespread use but researchers should consider their study design and the wear time required to capture the time periods surveyed. For this study, 12 hours of wear time, specifically 07:45 to 19:45, would have adequately captured the times corresponding to survey delivery and steps per hour across the four subsequent hours. Only 27% of days in this sample showed valid GT3X+ wear time during the 12-hour block of interest. To account for missing time and to provide an evenly weighted metric across all participants, a scaled measure of PA, steps per hour, was utilized. Other studies have employed 24-hour monitoring protocols on the waist and the wrist, both showing excellent compliance with waist wear of 22.6 hr/day (48) and wrist wear of 23.9 hr/day (39).

To date there has only been one other EMA in a population of those diagnosed with CVD. Rosmalen et al. (49) analyzed the causal relationship between depression and PA in five men post-myocardial infarction. PA and depression were assessed once per day for three months. Vector autoregressive modeling was used to assess temporal changes in the variables of interest and made causal inferences about the dynamics between depression and PA. Although this sample was small, analysis of individual participants showed evidence that PA preceded depression and in others, depression preceded PA. As noted by the challenges experienced in recruiting for the current study, small samples are expected for EMA of clinical populations.

This study offered novel findings in a clinical population, but several limitations must be noted. First the findings of this study may not be generalizable to females due to the small sample of women. Because participants were required to own a smartphone, those of low socioeconomic status could not participate, and therefore the results may not apply to them.

Additionally, those with higher state anxiety levels were not captured in this sample. Selecting steps per hour was a limitation as this value includes obligatory steps that are taken regardless of

anxiety level, therefore, entering the optional moderate and vigorous activity may yield different results.

This was the first study to explore the consistency and patterns in state anxiety and to investigate its relationship with PA, several times per day, across a 14-day period. Assessing the temporal patterns and associations at the mean and individual levels are aligned with the first phase of intervention development outlined by the Obesity-Related Behavioral Intervention Trial, which requires defining and refining variables for intervention development (50). However, to capture this data, challenges to recruitment and the accessibility of participating in EMA-type studies must be addressed.

#### References

- 1. Kochanek KD, Murphy SL, Xu J, Arias E. Mortality in the United States, 2016. Hyattsville, MD: National Center for Health Statistics, 2017 12/2017. Report No.: 293.
- 2. World Health Organization. The top 10 causes of death 2018 [cited 2019 June 11]. Available from: https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death.
- 3. Ma J, Ward EM, Siegel RL, Jemal A. Temporal trends in mortality in the united states, 1969-2013. JAMA. 2015;314(16):1731-9. doi: 10.1001/jama.2015.12319.
- 4. Sidney S, Quesenberry CP, Jaffe MG, Sorel M, Nguyen-Huynh MN, Kushi LH, et al. Recent trends in cardiovascular mortality in the United States and public health goals. JAMA Cardiology. 2016;1(5):594-9.
- 5. Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. JAMA. 2005;294(10):1255-9.
- 6. Centers for Disease Control Prevention. Heart disease fact sheet: National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention.; 2017 [cited 2019 3/19]. Available from: https://www.cdc.gov/dhdsp/data\_statistics/fact\_sheets/fs\_heart\_disease.htm.
- 7. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for cardiac rehabilitation and secondary prevention programs. 5th ed. Champaign, IL: Human Kinetics; 2013.
- 8. Thow M, Rafferty D, Kelly H. Exercise motives of long-term phase IV cardiac rehabilitation participants. Physiotherapy. 2008;94(4):281-5.

- 9. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med. 2004;116(10):682-92.
- 10. Anderson L, Oldridge N, Thompson DR, Zwisler A-D, Rees K, Martin N, et al. Exercise-based cardiac rehabilitation for coronart heart disease: Cochrane systematic review and meta-analysis. J Am Coll Cardiol. 2016;67(1):1-12.
- 11. Rejeski WJ, Foy CG, Brawley LR, Brubaker PH, Focht BC, Smith M. Older adults in cardiac rehabilitation: a new strategy for enhancing physical function. Med Sci Sports Exerc. 2002;34(11):1705-13.
- 12. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. Prog Cardiovasc Nurs. 2002;17(1):8-17. Epub 2002/03/02. PubMed PMID: 11872976.
- 13. Ades PA, Keteyian SJ, Wright JS, Hamm LF, Lui K, Newlin K, et al., editors. Increasing cardiac rehabilitation participation from 20% to 70%: a road map from the million hearts cardiac rehabilitation collaborative. Mayo Clin Proc; 2017: Elsevier.
- 14. McGrady A, McGinnis R, Badenhop D, Bentle M, Rajput M. Effects of depression and anxiety on adherence to cardiac rehabilitation. J Cardiopulm Rehabil Prev. 2009;29(6):358-64.
- 15. American Psychological Association. Anxiety Washington, DC: American Psychological Association; [cited 2019 5/15]. Available from: https://www.apa.org/topics/anxiety/.
- 16. Player MS, Peterson LE. Anxiety disorders, hypertension, and cardiovascular risk: a review. Int J Psychiatry Med. 2011;41(4):365-77.

- 17. Batelaan NM, Seldenrijk A, Bot M, Van Balkom AJ, Penninx BW. Anxiety and new onset of cardiovascular disease: critical review and meta-analysis. Br J Psychiatry. 2016;208(3):223-31.
- 18. Julian L. Measures of anxiety: state-trait anxiety inventory (STAI), Beck anxiety inventory (BAI), and Hospital anxiety and Depression scale-anxiety (HADS-A). Arthritis Care Res (Hoboken). 2011;63(S11):S467-S72.
- 19. Spielberger C, Gorsuch R, Lushene R, Vagg P, Jacobs G. Manual for the state-trait anxiety inventory. Palo Alto. CA: Consulting psychologists press; 1970.
- 20. Lavie CJ, Milani RV. Prevalence of anxiety in coronary patients with improvement following cardiac rehabilitation and exercise training. J Am Coll Cardiol. 2004;93(3):336-9.
- 21. Dunton GF, Atienza AA. The need for time-intensive information in healthful eating and physical activity research: a timely topic. J Am Diet Assoc. 2009;109(1):30-5.
- 22. Pickering TA, Huh J, Intille S, Liao Y, Pentz MA, Dunton GF. Physical activity and variation in momentary behavioral cognitions: an ecological momentary assessment study. J Phys Act Health. 2016;13(3):344-51.
- 23. Gerstorf D, Siedlecki KL, Tucker-Drob EM, Salthouse TA. Within-person variability in state anxiety across adulthood: Magnitude and associations with between-person characteristics. Int J Behav Dev. 2009;33(1):55-64.
- 24. Shiffman S, Stone AA, Hufford MR. Ecological momentary assessment. Annu Rev Clin Psychol. 2008;4:1-32.
- 25. Kanning MK, Ebner-Priemer UW, Schlicht WM. How to investigate within-subject associations between physical activity and momentary affective states in everyday life: a position statement based on a literature overview. Front Psychol. 2013;4:187.

- 26. Qualtrics. Security Statement 2018 [cited 2019 7/26]. Available from: https://www.qualtrics.com/security-statement/.
- 27. Spielberger CD. State-trait anxiety inventory for adults: manual instrument, and scoring guide: Mind Garden, Inc; 1983.
- 28. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State—Trait Anxiety Inventory (STAI). Br J Clin Psychol. 1992;31(3):301-6.
- 29. Chlan L, Savik K, Weinert C. Development of a shortened state anxiety scale from the Spielberger State-Trait Anxiety Inventory (STAI) for patients receiving mechanical ventilatory support. J Nurs Meas. 2003;11(3):283-93.
- 30. Abed MA, Hall LA, Moser DK. Spielberger's State Anxiety Inventory: Development of a shortened version for critically ill patients. Issues Ment Health Nurs. 2011;32(4):220-7.
- 31. Perpiñá-Galvañ J, Richart-Martínez M, Cabañero-Martínez MJ. Reliability and validity of a short version of the STAI anxiety measurement scale in respiratory patients. J Archivos de Bronconeumología. 2011;47(4):184-9.
- 32. Tluczek A, Henriques JB, Brown RL. Support for the reliability and validity of a six-item state anxiety scale derived from the State-Trait Anxiety Inventory. J Nurs Meas. 2009;17(1):19.
- 33. ActiGraph L. GT3X+ and wGT3X+ Device Manual. Pensacola, FL: 2013.
- 34. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. Psychol Assess. 1994;6(4):284.
- 35. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc. 2008;40(1):181-8.
- 36. Bakdash JZ, Marusich LR. Repeated measures correlation. Front Psychol. 2017;8:456.

- 37. Tellegen A, Briggs PF. Old wine in new skins: Grouping Wechsler subtests into new scales. J Consult Psychol. 1967;31(5):499.
- 38. Lane D, Carroll D, Ring C, Beevers DG, Lip GY. Predictors of attendance at cardiac rehabilitation after myocardial infarction. J Psychosom Res. 2001;51(3):497-501.
- 39. Ehlers DK, Huberty J, Buman M, Hooker S, Todd M, de Vreede G-J. A novel inexpensive use of smartphone technology for ecological momentary assessment in middle-aged women. J Phys Act Health. 2016;13(3):262-8.
- 40. Dunton GF, Huh J, Leventhal AM, Riggs N, Hedeker D, Spruijt-Metz D, et al. Momentary assessment of affect, physical feeling states, and physical activity in children. Health Psychol. 2014;33(3):255.
- 41. Yank V, Xiao L, Wilson SR, Stafford RS, Rosas LG, Ma J. Short-term weight loss patterns, baseline predictors, and longer-term follow-up within a randomized controlled trial. Obesity. 2014;22(1):45-51.
- 42. Hornblow A, Kidson M-A. The visual analogue scale for anxiety: a validation study. Aust N Z J Med. 1976;10(4):339-41.
- 43. Pew Research Center. Mobile fact sheet. Pew Research Center, 2019.
- 44. Bureau of Labor Statistics. American Time Use Survey Summary. Washington, DC2019.
- 45. Balady GJ, Ades PA, Bittner VA, Franklin BA, Gordon NF, Thomas RJ, et al. Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation. 2011;124(25):2951-60.

- 46. Berkman ET, Giuliani NR, Pruitt AK. Comparison of text messaging and paper-and-pencil for ecological momentary assessment of food craving and intake. Appetite. 2014;81:131-7.
- 47. Richardson MT, Ainsworth BE, Jacobs JR DR, Leon AS. Validation of the Stanford 7-day recall to assess habitual physical activity. Ann Epidemiol. 2001;11(2):145-53.
- 48. Tudor-Locke C, Barreira TV, Schuna JM, Mire EF, Chaput J-P, Fogelholm M, et al. Improving wear time compliance with a 24-hour waist-worn accelerometer protocol in the International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE). Int J Behav Nutr Phys Act. 2015;12(1):11.
- 49. Rosmalen JG, Wenting AM, Roest AM, de Jonge P, Bos EH. Revealing causal heterogeneity using time series analysis of ambulatory assessments: application to the association between depression and physical activity after myocardial infarction. Psychosom Med. 2012;74(4):377-86.
- 50. Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, et al. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol. 2015;34(10):971.

## Chapter V

## Conclusion

In part one of this two-part dissertation, the step count error of several physical activity monitors (PAMs) was assessed for those in phase II cardiac rehabilitation (CR). Analyzing step counting error across the day provides researchers insight on monitor function in an ecologically valid setting and it may guide users to a monitor better suited to their intended population. Part two is an exploration of state anxiety and physical activity using ecological momentary assessment (EMA) with ActiGraph wear across 14 days for patients in early phase II CR. Part two had three aims: 1. to investigate the consistency of state anxiety, 2. to explore the association between state anxiety and physical activity, 3. to determine the feasibility of a 14-day EMA of state anxiety and physical activity delivered via smartphone.

In the first study, step count error for the Fitbit Charge 2, Fitbit Zip, Apple Watch Series 2, ActiGraph GT9X with and without the low-frequency extension enabled and processed with the moving average vector magnitude algorithm was assessed on days when participants attended CR, days when they attended CR with steps taken during CR were removed, and days when they did not attend CR. Additionally, step error was assessed during CR sessions. Overall, monitors tended to underestimate steps and the Fitbit Charge and Apple Watch monitors showed the least step counting error for each condition when compared to criterion (StepWatch) steps. Error rates during CR sessions were similar to that during the day, therefore suggesting that CR activities do not intensify step counting error. Assessing the error in wearable activity monitors in clinical populations is warranted as these devices are becoming increasingly popular in healthcare and mobile health interventions.

Study two was the first study to explore intra- and inter-individual patterns in state anxiety and the association between state anxiety and physical activity during early phase II CR using ecological momentary assessment. Although this sample had relatively low and consistent

state anxiety, three patterns of anxiety emerged and, interestingly, the individual associations of state anxiety and physical activity varied across the sample, with some participants showing positive and some showing negative relationships. Assessing temporal and associative patterns enables defining and refining variables for intervention development. However, improving the accessibility to and recruitment for this type of study must be addressed.

When utilizing ecological momentary assessment to investigate physical activity, use of an objective physical activity monitor has been recommended. Taken together, the first study assessed the step counting error of several activity monitors that could be used along with an ecological momentary assessment and in the second study, the activity monitor was implemented and specifics on wear time and activity metrics were discussed. Ecological momentary assessment of self-reported data and objectively assessed data are well suited for use concurrently in order to capture all physical activity objectively while using momentary assessments to define contextual information as well as feelings and other experiences associated with that same period of time.

## Appendices

# Appendix A Study I Informed Consent

IRB NUMBER: 4452

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### Consent to Take Part in a Research Study

## Title: Accuracy of Wearable Step Counters for Patients in Phase II Cardiac Rehabilitation

#### Principal Investigator: Lindsay Toth, M.S.

The purpose of this study is to determine if the step count displayed on wearable physical activity monitors is accurate for people in phase II cardiac rehabilitation. Participants will wear three physical activity monitors (one on their wrist, one on their waist, and one on their ankle) for five days, from the time they wake up, until the time the go to sleep. Participants will be asked to write down the step counts from some of the monitors in the morning and the evening. The total study duration is six days. The greatest risk of this study includes a loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. Your participation is voluntary. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time.

#### What is the purpose of the study?

The purpose of the study is to determine the step count accuracy of four wearable physical activity monitors as compared to the StepWatch Activity monitor (step counting gold standard).

#### How long will I be in the study?

You will be in the study for six days.

Initials of Consentee Page 1 of 4

IRB NUMBER: 4452 IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### What will happen to me during the study?

The following tests or procedures that are required in this study for research purposes are:

- Day 1
  - Height and weight will be measured
  - You will be shown how to wear the physical activity monitors and how to record step counts
- Days 2-6
  - O You will wear the physical activity monitors (one on your wrist, one on your waist, and one on your ankle) from the time you wake up in the morning until the time when go to sleep at night
    - You will record the step counts from some of the monitors in the morning and at night
    - You will be asked to remove the devices any time you come into contact with water (e.g., swimming or bathing)

#### What side effects or risks can I expect from being in the study?

The potential risks to you include:

- a) Physical activity monitors emit electromagnetic radio waves that can temporarily inhibit a single beat from pacemakers, but the pacemaker's regular signals are quickly restored when the activity monitor is moved away from the pacemaker according to the American Heart Association. Physical activity monitors fall under the category of consumer appliances and electronics that pose little to no risk for individuals with cardiac pacemakers. They should be kept at least six inches away from a pacemaker.
- b) A risk of participating in this study is a loss of confidentiality. To reduce the risk of this violation, each participant will be assigned a number. Only the PI will know the number associated with each participant. All signed informed consent documents and data sheets will be stored in separate locked file cabinets. Informed consent documents will be store in a locked file cabinet in the Applied Physiology Laboratory in the Health, Physical Education, and Recreation Building in room 317. All data sheets will be stored in a locked file cabinet in the Applied Physiology Laboratory in the Health, Physical Education, and Recreation Building in room 303. Informed consent documents and data sheets will be kept for three (3) years after the study has been completed.

#### Are there benefits to taking part in the study?

The potential benefit includes:

a) The possible benefits to society may improve scientific knowledge concerning the relationships between state-anxiety, core affect, fatigue, self-efficacy, and intentions as they relate to physical activity during phase II cardiac rehabilitation. This information may be used to guide future cardiac rehabilitation interventions better promote continued attendance and participation.

Initials of Consentee	Page 2 of 4
-----------------------	-------------

Version Date: November 30, 2018

IRB NUMBER: 4452

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### What other choices do I have if I do not take part in this study?

If you do not choose to take part in this study, you will complete phase II cardiac rehabilitation as ordered by your physician.

#### How many people will be in the study?

About 60 people will be in this study at UT Medical Center (UTMC).

What will it cost me to be in the study?

There are no costs to you or your insurance for taking part in this study.

Will I be paid for taking part?

You will not be paid for taking part in this study.

Is the Investigator paid to do this study?

No, the investigator is not being paid to enroll people in this study.

What if I am injured in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

It is important that you tell your study leader, Lindsay Toth, if you feel that you have been injured because of taking part in this study. You can tell her in person or call her at 412600-4342. You may also tell your doctor if you feel you have been injured because of taking part in this study.

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who do I call if I have questions about the study? Questions about the study:

Lindsay Toth, M.S.

Phone: 412-600-4342

Email: Ltoth2@vols.utk.edu

Questions about your rights as a research subject: You may contact the UT Graduate School of Medicine Institutional Review Board (IRB) at 865-305-9781. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

Initials of Consentee Page 3 of 4

IRB NUMBER: 4452

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### Can I stop being in the study?

You may withdraw from the study at any time. Your treatment, payment or enroll ment in any health plans or eligibility for benefits will not be affected if you decide not to take part.

#### Could I be removed from the study?

You may be withdrawn for the study for any of the following reasons:

- You are unable to wear the physical activity monitors
- You are unable to read the screen of the activity monitors

#### Identifiable private information or identifiable biospecimens:

Identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

#### **CONSENT OF SUBJECT:**

I freely volunteer to take part in this study.

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I will receive a copy of this form after it is signed.

Printed Name of Subject	Signature of Subject or Authorized Representative	Date & Time
Printed name of person Obtaining Consent	Signature of person Obtaining Consent	Date
Printed name of Investigator	Signature of Investigator	Date

## Appendix B

## **Study II Informed Consent**

Version Date: 11/22/2018

#### Consent to Take Part in a Research Study

## Title: Ecological Momentary Assessment of Affective and Cognitive Factors Related to Total Physical Activity in Early Phase II Cardiac Rehabilitation Patients

#### Principal Investigator: Lindsay Toth, M.S.

The purpose of this research study is to investigate how your feelings and perceptions are related to your daily physical activity level and how they change across your first few weeks in phase II cardiac rehabilitation, for individuals who are engaging in cardiac rehabilitation for the first time. Participants will undergo a brief screening consisting of one questionnaire, measurement of height at weight, they will be shown how to use and enter responses for the surveys used in this study, and how to wear the physical activity monitor. This visit will take approximately 40 minutes. Participants in this study will be asked to complete four surveys sent to their smartphones each day, for 14 consecutive days. Each survey can be completed in less than 5 minutes. Participants will be asked to wear a non-invasive physical activity monitor on their waist for those same 14 days and complete a log of when they put the monitor on in the morning and took it off at night. During the period of participation, participants are only asked to answer surveys and wear an activity monitor while maintaining their usual behavior. No additional lifestyle changes are requested. When the 14-day participation period is over, the physical activity monitor and log will be collected from the participants. Total study duration is 16 days. The greatest risk of this study is the loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

#### What is the purpose of the study?

The purpose of the study is to investigate if there are certain feelings and perceptions that are associated with engagement in daily physical activity for those who are enrolled in phase II cardiac rehabilitation for the first time.

#### How long will I be in the study?

You will be in the study for 16 days.

#### What will happen to me during the study?

The following tests or procedures that are required in this study for research purposes are:

- Day 1
  - o Height and weight will be measured one time
  - You will be shown how to use the electronic survey and how to enter your responses

Initials of Consentee Page 1 of 5

Version Date: 11/22/2018 IRB NUMBER: 4453

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

 You will be shown how to wear the physical activity monitor on your waist and how to complete the wear-time log

- Days 2-15
  - You will put on the physical activity monitor in the morning when you wake up and wear it throughout the day, until you go to sleep at night
    - You will record the time you put the monitor on in the morning and what time you take the monitor off at night on the wear-time log
  - O You will receive a text message at 7:45am, 11:45am, 3:45pm, and 7:45pm that contains a link to a survey
  - You will tap on the link and complete the survey within one hour of receiving the text message
- Day 16
  - You will return the physical activity monitor and wear-time log

#### What side effects or risks can I expect from being in the study?

The potential risks to you include.

- a) ActiGraph GT3X physical activity monitors emit electromagnetic radio waves that can temporarily inhibit a single beat from pacemakers, but the pacemaker's regular signals are quickly restored when the activity tracker is moved away from the pacemaker according to the American Heart Association. Physical activity monitors fall under the category of consumer appliances and electronics that pose little to no risk for individuals with cardiac pacemakers. They should be kept at least six inches away from a pacemaker. In this study participants will wear the activity monitor on their right hip, therefore it will be worn more than six inches away from a pacemaker.
- b) A risk of participating in this study is a loss of confidentiality. To reduce the risk of this violation, each participant will be assigned a number. Only the PI will know the number associated with each participant. All signed informed consent documents and data sheets will be stored in separate locked file cabinets. Informed consent documents will be store in a locked file cabinet in the Applied Physiology Laboratory in the Health, Physical Education, and Recreation Building in room 317. All data sheets will be stored in a locked file cabinet in the Applied Physiology Laboratory in the Health, Physical Education, and Recreation Building in room 303. Informed consent documents and data sheets will be kept for three (3) years after the study has been completed.

#### Are there benefits to taking part in the study?

The potential benefits to you include.

a) The possible benefits to society may improve scientific knowledge concerning the relationships between state-anxiety, core affect, fatigue, self-efficacy, and intentions as they relate to physical activity during phase II cardiac rehabilitation. This information may be used to guide future cardiac rehabilitation interventions better promote continued attendance and participation.

Initials of Consentee	Page 2 of 5
-----------------------	-------------

Version Date: 11/22/2018

IRB NUMBER: 4453

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### What other choices do I have if I do not take part in this study?

If you do not choose to take part in this study, you will complete phase II cardiac rehabilitation as ordered by your physician.

#### How many people will be in the study?

About 30 people will be in this study at UT Medical Center (UTMC).

What will it cost me to be in the study?

There are no costs to you or your insurance for taking part in this study.

Will I be paid for taking part?

You will not be paid for taking part in this study.

Is the Investigator paid to do this study?

No, the investigator is not being paid to enroll people in this study.

What if I am injured in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

It is important that you tell your study leader, Lindsay Toth, if you feel that you have been injured because of taking part in this study. You can tell her in person or call her at 412600-4342. You may also tell your doctor if you feel you have been injured because of taking part in this study.

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who do I call if I have questions about the study?

Questions about the study:

Lindsay Toth, M.S.

Phone: 412-600-4342

Email: Ltoth2@v ols.utk.edu

Initials of Consentee Page 3 of 5

Version Date: 11/22/2018 IRB NUMBER: 4453

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

Questions about your rights as a research subject: You may contact the UT Graduate School of Medicine Institutional Review Board (IRB) at 865-305-9781. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

#### Can I stop being in the study?

You may withdraw from the study at any time. Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part.

#### Could I be removed from the study?

You may be withdrawn for the study for any of the following reasons:

- Survey compliance rates fall below 50%
- You are unable to respond to the mobile surveys

#### Identifiable private information or identifiable biospecimens:

Identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Initials of Consentee Page 4 of 5

Version Date: 11/22/2018 IRB NUMBER: 4453

IRB APPROVAL DATE: 01/10/2019 IRB EXPIRATION DATE: 01/09/2020

#### CONSENT OF SUBJECT:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I will receive a copy of this form after it is signed.

I freely volunteer to take part in t	his study.	
Printed Name of Subject	Signature of Subject or Authorized Representative	Date & Time
Printed name of person Obtaining Consent	Signature of person Obtaining Consent	Date
Printed name of Investigator	Signature of Investigator	Date

Initials of Consentee Page 5 of 5

## Appendix C

## **Ecological Momentary Assessment Mobile Survey**

#### **Default Question Block**

For each of the following questions, mark how you feel right now, at this moment. Do not spend too much time on any one statement, just mark the answer that describes your feelings at present. There are no right or wrong answers.

How are you feeling right now, in this very moment?

	Not at all			Very much
	1	2	3	4
I feel calm	0	0	0	0
I am tense	0	0	0	0
I feel upset	0	0	0	0

How are you feeling right now, in this very moment?

	Not at all			Very much
	1	2	3	4
I am relaxed	0	0	0	0
I feel content	0	0	0	0
I am worried	0	0	0	0

For the following questions, drag the slider along the scale to mark your answer. You must move the slider to advance to the next question.

How "worked up" do you feel right now, at this moment in time?

Not at all Completely 0 10 20 30 40 50 60 70 80 90 100

https://utix.co1.qualtrics.com/ControlPanel/Ajax.php?action=GetSurveyPrintPreview

11/20/2018

Qualtrics Survey Software

How are you feeling right now, at this moment in time?

Very bad Very good

0 10 20 30 40 50 60 70 80 90 100

To what extent do you feel fatigued?

----

Not at all Completely

0 10 20 30 40 50 60 70 80 90 100

To what degree do you intend to attend your next cardiac rehabilitation session?

No intention to attend Fully intend to attend

0 10 20 30 40 50 60 70 80 90 100

How confident are you that you can complete the exercise prescribed to you at your next cardiac rehabilitation session?

Not at all confident Completely confident
0 10 20 30 40 50 60 70 80 90 100

To what degree are you experiencing pain or discomfort related to the following reasons, right now, at this moment in time?

None Severe 0 10 20 30 40 50 60 70 80 90 100

Muscle soreness

Joint stiffness

https://utk.co1.qualtrics.com/ControlPanel/Ajax.php?action=GetSurveyPrintPreview

11/20/2018					Qualtr	los Survey (	Software					
	Nor	ne								Sev	ere	
	0	10	20	30	40	50	60	70	80	90	100	
Cardiovas related proced medical reas attending c	lure or son for											
	Other											
=	-											
Between the not include ar									follow	ing ac	tivities? (D	00
Slow walkir	na											
☐ Brisk walkir												
Jogging												
Using aerol	bic exercise	equipr	ment									
■ Moderate c	hores (swe	eping, o	cleanin	g with n	nodera	te effort	)					
Heavy chor	res (moving	furnitu	re, vigo	rous flo	or scn	ubbing)						
Swimming												
─ Weight Lifti	ng (Free W	eights o	or Mach	nines)								
Bicycing												
Dancing												
Hiking												
Aerobics												
Other (plea	se specify i	n text b	ox belo	ow)								
☐ I did not en	gage in any	physic	al activ	ity duri	ng the	last four	hours					
Please indica	te how ma	any mir	nutes y	you spe	ent en	gaged	in eac	h exer	cise			
						ı	Minute	S				
» Slow walkin	g											
» Brisk walkin	g											
» Jogging												
» Using aerob exercise equip												
https://utk.co1.qualtrics.co	om/ControlPanel	/Ajax.php?	action=Ge	etSurveyPr	intPrevie	w						3/5

1/20/2018	Qualtrics Survey Software
	Minutes
» Moderate chores (sweeping, cleaning with moderate effort)	
» Heavy chores (moving furniture, vigorous floor scrubbing)	
» Swimming	
» Weight Lift "(Free Weights or Machines)	
» Bicycing	
» Dancing	
» Hiking	
» Aerobics	
» Other (please specify in text box below)	
» I did not engage in any physical activity during the last four hours	
	ou have spent SITTING in the following situations  (X: (Please enter 0 if you did not engage in the listed
	Minutes
While traveling to and from places	
While at school/work	
While watching television	
While using a computer, tablet, cell phone, or other media device for school or work	
While using a computer, tablet, cell phone, or other media device (e.g. gaming system) for social (e.g. facebook) or video game play	
nttps://utik.co1.guaitrics.com/ControlPanel/Ajax.php?action=GetSu	irvevPrintPreview 4/5

11/20/2018	Qualtrics Survey Software
	Minutes
In your leisure time, NOT including television or computer time (e.g., visiting friends, movies, dining out, etc)	
	ve spent napping between the hours of XX:XX nt in actual sleep and enter 0 if you did not nap
	Minutes
Nap duration	
Power	ed by Qualtrics

https://utik.co1.qualtrics.com/ControlPanel/Ajax.php?action=GetSurveyPrintPreview

#### Vita

Lindsay Powell Toth was born in Pittsburgh, PA on January 5, 1990. She was raised in Sewickley, PA where she graduated from Quaker Valley High School in 2008. In 2012 she graduated from Barton College (Wilson, NC) with a Bachelor of Science in Fitness Management and Sports Management. She then attended Western Michigan University (Kalamazoo, MI), where she completed a Master of Science degree in Exercise and Sports Medicine with a concentration in Exercise Physiology in 2014. After working for one year as a Faculty Specialist at Western Michigan University, she was accepted and began her doctoral work at The University of Tennessee (Knoxville, TN). In 2019 she graduated with her Doctor of Philosophy degree in Education, with a concentration in Exercise Physiology, cognate in Public Health, and minor in Epidemiology. She has accepted a position of Assistant Professor at the University of North Florida (Jacksonville, FL).