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TAME Health: Testing Activity Monitors' Effect on Health

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Dedication

This dissertation is dedicated first to the late Joe Mack Lewis, whose unconditional love encouraged me to pursue my dreams. Second, this is dedicated to my friends, family, and mentors who have helped make my dreams a reality.

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TAME Health: Testing Activity Monitors' Effect on Health

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To promote physical activity in healthcare, the American Heart Association suggests 5 A's counseling and technology-based resources for individuals at moderate risk for cardiovascular disease. Pedometers are low-tech devices that are often used to supplement counseling. However, the addition of an electronic activity monitor (EAM) to in-clinic counseling may provide more effective behavior change and increase overall motivation for exercise. We conducted a 12-week intervention to compare the effectiveness of 5 A's counseling and self-control with an EAM or a pedometer. Primary care patients (n=40) were eligible for the study if they were 55-74 years of age, inactive, overweight or obese, in good health, and had access to a smart device. Participants were randomized to receive a pedometer (Digi-Walker CW-700/701, YAMAX, San Antonio, TX) or an EAM (UP24, Jawbone, San Francisco, CA) and the partnering UP application (app). They were also invited to participate in a focus group after completing the intervention. Stakeholders (n=36) were also recruited to provide feedback. Our study had three aims: 1) evaluate the feasibility and acceptability of implementing a technology-enhanced brief intervention, 2a) compare counseling plus Jawbone to counseling plus pedometer intervention on physiological outcomes, 2b) compare group effectiveness on motivational outcomes, 3) conduct focus groups with primary care stakeholders. To assess each aim we examined social support within the UP app, study feasibility based on RE-AIM indicators, change in cardiovascular related outcomes, and change in motivation. We found that older adults frequently provide emotional support comments and used self-talk within a mobile app. RE-AIM indicators coincide with previous interventions and some indicators suggest that the EAM monitor is more feasible and acceptable than a low-tech pedometer. Comparatively, the two tested monitors improved CVD related outcomes. The EAM produced small-to-moderate effect sizes on PA, waist-to-hip ratio, and physical function. In addition, the EAM group had a significantly greater impact on SDT constructs compared to the pedometer. Future research should investigate methods to enhance social support and competence, test other behavior change techniques, incorporate counseling on multiple health behaviors, and evaluate long-term maintenance of behavior change.

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List of Abbreviations

Apps	Applications
BMI	Body Mass Index
BREQ—2	Behavioral Regulation in Exercise Questionnaire
CVD	Cardiovascular Disease
CVH	Cardiovascular Health
EAM	Electronic Activity Monitor
GSBS	Graduate School of Biomedical Science
IQR	Inter-Quartile Range
PA	Physical Activity
PRECIS	Pragmatic Explanatory Continuum Indicator Summary
PNSE	Psychological Needs Satisfaction in Exercise Scale
SDT	Self-Determination Theory
SF-36	Medical Outcomes Study Questionnaire Short Form 36
TAME	Testing Activity Monitors' Effect
TDC	Thesis and Dissertation Coordinator
USPSTF	United States Preventive Services Task Force
UTMB	University of Texas Medical Branch

Chapter 1: Introduction

Cardiovascular disease (CVD) was the leading cause of death world-wide in 2002 and it is projected to remain the leading cause of death through 2030.¹ In the United States, CVD accounts for approximately 1 in 3 deaths,^{2,3} with 34% of individuals dying of CVD before the age of 75.³ CVD encompasses several conditions including congenital heart disease, coronary heart disease, heart failure, peripheral arterial disease, rhythm disorders, stroke, and valvar disease.³ Ideal CVH is the absence of CVD and optimal levels of 7 health metrics that are comprised of health behaviors and health factors.³ Health behaviors include healthy diet, energy intake, physical activity (PA) and smoking status. Health factors include blood lipids, blood pressure, and glucose control. Only 18% of US adults meet the criteria for ideal CVH and this prevalence decreases with age. CVD prevention strategies should aim to improve overall CVH. Furthermore, prevention should target older adults who have increased prevalence of CVD and increased mortality rates.³

Physicians are encouraged to assess their patients' risk for CVD regularly.⁴ For individuals with equal to or greater than a 7.5% risk for a cardiovascular event in 10 years, physicians are required to discuss risk factors with them and refer them to prevention guidelines.⁴ Approximately 1 in 3 adults between the ages of 40-79 meet this risk level.⁴ There are several risk factors related to CVD, which include: tobacco use, physical inactivity, nutrition, obesity, genetics, hyperlipidemia, hypertension, diabetes mellitus, and metabolic syndrome.³ Current prevention guidelines focus on intervening on pertinent health behaviors and factors such as blood cholesterol (hyperlipidemia), obesity, and lifestyle management (e.g. PA, diet).^{3,4} Of these behaviors and factors, physical activity is an area for greatest improvements .³

PHYSICAL ACTIVITY AND CARDIOVASCULAR DISEASE

Approximately 12% of CVD deaths are attributed to physical inactivity alone.⁵ Therefore, PA plays an important role in the primary and secondary prevention of CVD.^{6,7} PA is defined as any bodily movement initiated by skeletal muscles that results in energy expenditure⁸ while physical inactivity is defined as minimal body movement and energy expenditure that approximates the basal metabolic level.⁹ Perez-Terzic et. al.⁶ outlined many of the benefits of PA which include: ischemia tolerance, insulin sensitivity control, blood pressure control, weight loss, hyperlipidemia control, increased endothelial function, decreased blood viscosity, depression control, improved cognitive functioning, muscular strength and endurance, increased bone density, improved balance, and decreased cancer incidence.⁶ Some examples of biological improvements related to CVH include triglyceride reduction, decrease in size and number of low-density lipoprotein, increase in high-density lipoprotein, and a decrease in coronary artery calcium.¹⁰ These biological improvements can lead to a decline in CVD and all-cause mortality.^{3,10-13}

Individuals without existing chronic conditions who take part in regular exercise have 27% lower all-cause mortality.³ Among individuals with chronic conditions, there is up to a 46% all-cause mortality reduction with regular exercise.³ In the general population high levels of PA equates to a 35% reduction in CVD mortality and a 33% reduction in all-cause mortality, independent of weight loss.¹⁴ Even moderate-low impact exercise reduces cardiovascular risk. A meta-analysis concluded that high levels of walking reduced the risk of a cardiovascular event by 31% and by 32% for all-cause mortality.¹⁵ This is particularly important for older adults who prefer walking to other PAs.^{16,17} There is a dose-response relationship between PA and CVD, with most cardiovascular benefit reached at high frequency of a moderate level of PA.¹⁸

Everyone can benefit from PA but most individuals seldom exercise.³ The public health guideline for PA is 150 minutes of moderate intensity aerobic activity per week

and muscle-strengthening exercises twice a week.^{3,19} The type of recommended strengthening exercises is modified for older adults but they are also encouraged to get at least 150 minutes of activity a week.²⁰ In 2009, only an estimated 33% of adults were aware of the PA guidelines.²¹ Based on self-reported estimates, approximately 30-50% of U.S. adults do not take part in leisure-time PA.^{3,22} This is likely an overestimate considering most individuals misjudge their level of PA on self-report questionnaires.^{23,24} Based on objective measures, up to 5% of adults actually meet the recommended level of PA.²⁵⁻²⁷

Objective devices, such as accelerometers and pedometers, are often used to measure PA and estimate health risk,²⁸⁻³⁰ therefore the PA guideline has been translated to the number of steps per day. Healthy adults are advised to take 10,000 steps per day²⁸ and older adults are recommended to take 7,000-10,000 steps per day.²⁹ To that end, adults that take fewer than 5,000 steps per day are classified as sedentary.³¹ Data from the 2005-2006 NHANES cycle shows that most adults (60-75 years of age) are sedentary with an collective average number of steps per day of 3,124-6,127.²²

Most adults are below the recommended levels of PA but just meeting the guidelines is not enough for ideal CVH.³ The ideal level of PA for CVD prevention and preservation is more than the 150 minutes of moderate-vigorous activity a week.³ Only 37% of adults over the age of 50 meet ideal levels of PA while 54.3% don't take part in any PAs.³

A recent systematic review synthesized the evidence from several qualitative studies to identify six major themes that explain why older adults do and do not take part in PA.³² Major themes included: social influences, physical limitations, competing priorities, access difficulties, personal benefits of physical activity, and motivation and beliefs.³² Some older adults clearly acknowledge the benefits of PA but they lack the motivation to do the activity.^{32,33} One individual was quoted saying "I know all the theory

about keeping fit and healthy, and healthy heart...It's not through lack of awareness it's just lack of inclination.³²”

MOTIVATION AND PHYSICAL ACTIVITY

The European Society of Cardiology established similar PA guidelines as in the US but with a stress on enjoyable exercise.^{18,34} Enjoyment is an important factor that motivates an individual to take part in a specified behavior.³⁵⁻³⁷ The constructs of motivation are outlined within Self-Determination Theory (SDT).³⁵⁻³⁷ According to SDT, motivation is the product of the fulfillment of the basic psychological needs for autonomy, competence, and relatedness.³⁵⁻³⁸

Autonomy

Autonomy is the sense of willingness and choice in one's action.³⁹ Autonomy can be enhanced through behavioral change techniques such as goal setting, providing information on consequences of behavior, problem solving and barrier identification, and action planning.⁴⁰

Competence

The need for competence reflects an individual's desire to be effective in dealing with their environment.⁴¹ Competence can be enriched by providing feedback, providing instruction, teaching to use prompts, and self-control through self-regulation.⁴⁰ Self-control through self-regulation is particularly impactful for PA behavior. In a review of short-term PA studies, there was a mediation effect in 85% of PA analyses. In the long-term, self-regulation results in a mediation effect in 67% of studies.⁴² This suggests that self-control through self-regulation may be a key facilitator for PA change.

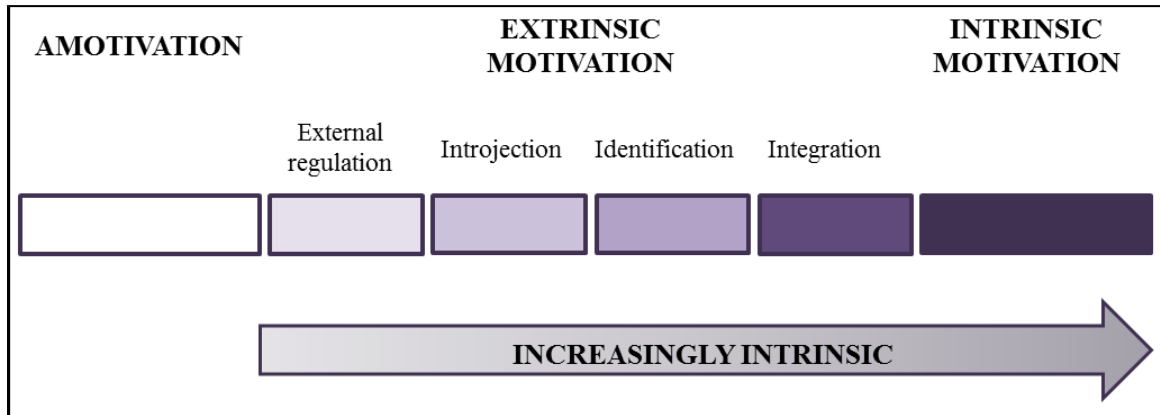
Relatedness

Relatedness is the inherent desire to interact with and be connected to other people.⁴³ Relatedness can be enhanced through social comparison and provide social support.⁴⁰ Providing social support is an influential behavioral change technique that can encourage PA.^{17,40,44-46} Social support can be defined as an interpersonal exchange that offers esteem, acceptance, value, and motivation to individuals.⁴⁷ People within a social support system can help to shape another individual's interpretations of exercise^{48,49} and can foster an accessible exercise environment through physical activity promotion.⁵⁰ Social networks act on social interactions, the social environment, and the physical environment to influence PA.⁵¹

Autonomous and controlled regulation

Motivation (the product of fulfillment in autonomy, competence, and relatedness) is both intrinsic and extrinsic. Intrinsic motivation involves the engagement in activities that are enjoyable and valued.^{35,37,52} Extrinsic motivation involves the engagement in activities based on external factors.^{35,37,52} There are varying degrees of integration of extrinsic motivation: external regulation, introjection, identification, and integration.^{35,52} External regulation is the classic form of extrinsic motivation in that the behavior is controlled by an external contingency. Introjection differs from external regulation in that the external contingencies are administered by the individual themselves and not another person. Identification occurs when an individual acknowledges and accepts the underlying value of a behavior. Integration occurs when an individual accepts the value of a behavior and integrates that behavior into their life to coincide with their other values. Integration ultimately leads to self-regulation of a behavior.^{35,52} On the other hand, an individual that is not regulated to complete a behavior, externally or intrinsically, is amotivated.^{35,52} The spectrum of motivation from amotivation, extrinsic, to intrinsic is displayed in Figure 1-1.

Figure 1-1: Motivational spectrum



A lack of motivation, particularly autonomous motivation, is strongly associated with physical inactivity.^{16,33,42,53} Individuals are rarely intrinsically motivated to engage in regular PA.¹⁷ When asked why they don't exercise, individuals are cited as saying "I'm too lazy/not motivated/can't get started" and "I don't enjoy physical activity."¹⁶ Conversely some individuals have identified and introjected motivation toward exercise. These individuals exercise because of the improvements in other personal factors such as health, appearance, social interaction, stress relief, and skill development.¹⁷ To become a regular exerciser, an individual needs to identify the value of PA.¹⁷

It may be possible to intervene on personal values and motivation related to PA within a health care setting. About 50% of older adults seek PA advice and motivational assistance from their health care provider.¹⁶ Furthermore, older patients respect their physician and regularly visit their family doctor.^{54,55} Physicians and other health care professionals play an important role in the initiation and maintenance of PA among older adults.^{54,56}

PRIMARY CARE INTERVENTIONS

PA interventions within primary care are common.^{7,57-62} The advantages of intervening in primary care include the strong clinician-patient relationship and longitudinal nature of primary care.^{56,63} Interventions typically consist of advice, self-

efficacy and barrier assistance, educational materials on PA guidelines, referral to community resources, and written exercise prescriptions.^{58,64,65} The interventions can be administered by physicians, nurses, and other health educators (e.g. exercise consultants, physical therapists, nutritionists).^{59,60,62,65,66} Primary care interventions show modest effect in improving CVD related factors.^{7,58-60,64-66} These include a decrease in total cholesterol levels and low-density lipoprotein levels, blood pressure, fasting glucose levels, diabetes incidence, weight, and overall CVD risk.^{7,66} Furthermore, there is an estimated 15% increase in the proportion of individuals meeting PA guidelines as a result of primary care interventions.⁷ These interventions are diverse but a central component in nearly all interventions is behavioral counseling.^{7,57-59}

Behavioral counseling is an important step for the initiation of PA.^{7,55,65,67} The United States Preventive Services Task Force (USPSTF) defines behavioral counseling as “preventive services that are designed to help persons engage in healthy behaviors and limit unhealthy ones.”^{7,68} In 2002, there was insufficient evidence to support counseling in primary care^{63,69} but as of 2013, it is strongly recommended to decrease the risk of CVD.^{7,55} Effective counseling stems from a patient-centered approach in that a physician or health care provider collaborate with a patient to establish a plan and select individualized goals.^{55,63} In regards to PA, effective counseling should also include two or more of the following strategies: goal setting, providing feedback, incorporate self-monitoring, planning a follow-up, use motivational interviewing, building self-efficacy, reinforcements through rewards, and problem solving.^{63,70}

Counseling is an important primary and secondary prevention technique that can benefit all patients.⁶⁷ Most physicians believe that they have adequate PA knowledge to give advice, but fewer than 30% believe they have the ability to help their patients change their behavior.⁶⁷ Moreover, physicians seldom ask or counsel their patients on PA.⁶⁷ Only two-thirds of physicians ask at least half of their patients about their PA behavior with as low as 8% of physicians providing advice.⁶⁷ Some cited barriers to counseling include

lack of formal education on PA promotion, lack of time, and negative attitudes toward PA from the patients.³³

Despite the low frequency of counseling, approximately 70% of physicians believe that behavioral counseling is their responsibility and it is important to change exercise behavior.⁶⁷ Physicians tend to provide more advice on PA to CVD patients (41%), older patients (61%), and overweight patients (77%).^{33,67} When counseling is conducted in primary care, it is typically condensed to less than 15 minutes^{7,58,59,64} and is typically accompanied with a written exercise prescription and/or a follow-up visit.⁵⁸

Bock and colleagues proposed a conceptual model of behavioral counseling in primary care.⁶⁷ Pertinent factors within the model include physician's characteristics, physician's knowledge, physician's attitudes, patients' factors, organizational barriers, and provisions of preventive services.⁶⁷ Personal and environmental factors cannot be readily changed but healthcare professionals can mandate preventive services. In an effort to mandate behavioral counseling in primary care the USPSTF adopted the Five A's counseling construct.^{63,67,71}

Five A's Counseling

The 5 A's counseling construct was developed by the Canadian Task Force on Preventive Health Care in order to assist physicians in behavioral counseling.⁷¹ The construct was originally developed to encourage smoking cessation but it has been applied to a variety of other behaviors, such as PA.^{55,71} Five A's is a comprehensive and validated counseling technique to elicit behavioral change within a typical medical visit.^{55,71} The components of 5 A's stand for assess, advise, agree, assist, and arrange.

Assess

“Assess refers to assessment of patient behaviors, and may also include assessment of patients' knowledge, beliefs, attitudes, and preferences.⁶³” Assess is important because it identifies individuals who are in need of an intervention to change

behavior, and it gathers relevant information to individualize the intervention.⁷¹ This can be done during a primary care visit or during a brief telephone assessment prior to the clinical visit.⁷¹ Assess often relies on self-reported behavior which tends to underestimate the number of individuals truly at risk. If possible, objective measurements of behaviors should be assessed.^{63,71}

Advise

“Advice establishes behavioral issues as an important part of health care and enhances the patient’s motivation to change.⁷¹” Advice is most effective if it is personalized to the patient by linking behavior to their health concerns, past experiences, social situation, and health literacy.^{63,71} Furthermore, advice should be warm, empathetic, non-judgmental.⁷¹

Agree

Agree occurs when “the patient and clinician ‘come to common ground’ on areas where behavior change is to be considered or undertaken.⁷¹” This collaborative approach allows for patient autonomy⁷¹ which is a foundational component of motivation.³⁵⁻³⁷ Simple questions such as “How important is it for you to exercise” or “How confident are you that you can exercise 30 minutes a day” can help identify avenues for assistance.⁷¹ This aids in actively facilitating in the agreement process which will help prevent resistance with continued counseling.⁷¹

Assist

“Assist includes providing behavioral counseling to help patients to develop a specific tailored action plan.⁶³” There are several assistance strategies that typically incorporate multiple intervention methods. Some of these methods include problem-solving skills training, building social support, providing self-help materials, modeling behavior, stimulus control, self-rewards, contingency contracting, and self-management control.⁷¹ Additional assistance may be necessary outside of the initial visit to produce greater outcomes.⁷¹

Arrange

“Arrange includes making specific plans for subsequent contacts with the primary care team.⁶³” Routine follow-up is essential with any counseling because they allow for the evaluation and adjustment of the behavior plan.⁷¹ This can be done whether the follow-up is during a face-to-face visit, telephone calls, or some other interactive technology.^{63,71} Follow-up are typically arranged within a short period and briefly repeat the first four A’s.⁷¹ Finally, a follow-up prompts maintenance of behavior change and relapse prevention.⁷¹

Five A’s in practice

It is recommended that health care providers counsel all patients with low or moderate risk for CVD using the 5 A’s construct.⁵⁵ In practice, approximately 90% of primary care physicians routinely use at least 1 of the counseling constructs while <10% routinely use all five.⁷² Patients want their clinician to counsel them, particularly Assist and Arrange, but physicians rarely go through those constructs.^{73,74} The most frequent constructs are Advise and Assess.^{73,74} Despite the counseling irregularity, patients find it beneficial. An evaluation of the 5 A’s counseling training found that patients reported a 6.38 out of 7 for provider autonomy support and a 6.33 out of 7 for satisfaction.

Five A’s counseling has the potential to reduce CVD risk however a systematic evaluation of interventions administered by health-care professions found that providing knowledge, materials, and professional support alone was not sufficient to change the behavior of their patients.⁷⁵ The authors suggest that professional support should be combined or replaced with a more effective strategy, such as self-monitoring of behavior.⁷⁵ The use of interactive technologies for self-monitoring can support and extend the primary care intervention.⁶³

Potential of Technology

A healthcare team should incorporate technology-based resources to provide intensive behavioral interventions.^{55,61} Personalized technologies are an affordable, approachable, and accessible method for primary and secondary CVD prevention.⁷⁶ Since primary care providers are typically the first point of contact for individuals, they play a crucial role in the success of personalized technologies. Preliminary evidence shows that technology based interventions result in positive behavior change in well-designed interventions.⁷⁶ In fact, certain technologies are designed to consider individual needs, resource availability, and individual preference. Types of personalized technologies include: websites, weblogs, and wikis; mobile devices and mobile applications (apps); social media and networking channels; video chat, video sharing, and podcast media; and wearable monitors and tracking devices.⁷⁶ In particular, wearable monitors are used to assess exercise patterns and track energy expenditure. Some advanced models are also capable of tracking dietary patterns, setting short- and long-term goals, monitor weight loss, and facilitate social support and social interaction.^{76,77} Wearable activity monitors range from basic pedometers to advanced electronic activity monitors.⁷⁷⁻⁷⁹

PEDOMETER INTERVENTIONS

Since 2000, pedometers have been commonly used as an intervention modality to increase PA.^{78,80,81} Pedometers allow for self-monitoring while providing feedback (in the form of steps per day).^{78,80,81} In pedometer-based interventions participants are given, or choose, a step goal and use the pedometer to monitor their progress.^{78,80,81} Pedometer-based interventions vary from 4 weeks to over a year.^{78,80,81} The step goal used in interventions is based on public health guidelines (e.g. 10,000 steps), a steady progression of activity (e.g. increase by 1,000 every week), or individual preference.^{78,80,81} Pedometers can be given as an intervention itself or in addition to behavioral or motivational counseling.^{80,81}

Pedometers' effectiveness to increase PA, decrease weight, and improve cardiovascular outcomes has been established.^{78,80,81} Increases in steps per day may range from 1,827 to 4,556⁸¹ with a mean increase across 26 studies of 2183 steps per day.⁸⁰ In 2009, the overall effect size of pedometers to increase PA was estimated at 0.68. This effect size is smaller among older adults (mean effect size=0.53).⁷⁸ One meta-analysis found the mean weight loss in pedometer-based interventions to be -1.27 kg, with observed weight change ranging from -3.7 kg to +0.3 kg.⁸¹ Cardiovascular outcomes influenced by pedometers include body mass index (BMI) and blood pressure.⁸⁰ The observed mean decrease in BMI was -0.38 kg/m², systolic blood pressure was -3.8 mmHg, and diastolic blood pressure was -0.3 mmHg.⁸⁰

Pedometers particularly show promise in primary care interventions for older adults. primary care pedometer-based interventions typically take place remotely but rely on recruitment of patients through the clinic.⁸²⁻⁸⁸ Interventions rely on providing the pedometer and instructions alone⁸³⁻⁸⁶ or in combination with counseling.^{82,87,88}

Pedometer alone

Pedometer interventions among primary care patients consisted of providing a pedometer in combination with a low-calorie diet and exercise prescription,⁸⁴ reports of PA level,⁸³ and an exercise prescription with other self-monitoring devices.⁸⁵ The pedometer group was compared to other exercise prescription strategies⁸⁵ and to individuals that received a diet and exercise prescription but no pedometer.⁸⁴ Results of these studies did not find a difference in activity level across different exercise prescription strategies⁸⁵ but did find a significant increase in PA among those receiving a pedometer compared to those who did not.⁸⁴ All studies found that a pedometer was associated with an increase in PA levels after 12- weeks^{84,85} and 21-weeks.⁸³ This change in PA was maintained after 59 weeks.⁸³ Pedometers were also associated with improvement in BMI and blood pressure in the short term⁸³⁻⁸⁵ and in the long term.⁸³

Pedometers with usual care, without counseling, resulted in equivalent results as 5 A's counseling.⁸⁶ Aittasalo and colleagues⁸⁶ conducted a study that recruited primary care patient 65-years and older to receive 5 A's counseling or usual care. A proportion of patients receiving usual care were given a pedometer to self-monitor their activity. At the end of the intervention, participants that received 5 A's counseling completed significantly more PA sessions than those just receiving usual care. Whereas participants that received a pedometer had significantly more minutes of PA than those just receiving usual care. The authors did not report on the difference of PA sessions or minutes of PA between participants that received 5 A's counseling and those that received a pedometer but the results appear equivalent. The number of PA sessions completed at the end of the intervention were 7.4 and 7.3 and the minutes of PA were 546 and 647 for the 5 A's group and pedometer group, respectively. These rates were maintained through follow-up.⁸⁶ This study did not evaluate the additive benefits of a pedometer to 5 A's counseling⁸⁶ but other studies have investigated the use of a pedometer in combination with other behavioral counseling techniques.^{82,87,88}

Pedometer and counseling

Pedometers have been used in combination with nurse-led consultations^{82,87} and a standardized primary-care counseling program (Green Prescription).⁸⁸ The counseling was delivered in-person at the start of the intervention and monthly over the phone with a PA counselor,⁸⁸ monthly in-person with a nurse,⁸⁷ or twice over a 12-week period.⁸² Pedometer and counseling were compared to wait-list controls⁸² and usual care.^{87,88} After 3-months, providing a pedometer with counseling resulted in a significant increase in PA.^{82,87,88} PA was maintained after 6 months⁸² and 12 months.^{87,88}

Qualitative results

Quantitative results consistently showed that pedometers can increase PA level and improve other cardiovascular outcomes alone or in combination with counseling.⁸²⁻⁸⁸ However, qualitative reports from participant interviews and focus groups have been

inconsistent.^{57,82,87} Two of the studies described above^{82,87} conducted subsequent interviews and focus groups with their participants. Normansell et al.⁵⁷ conducted phone interviews on participants enrolled in the PACE-UP study⁸⁹, a predecessor pedometer primary-care based study to the PACE trial.⁸⁷ The quantitative results from this study have not been reported.⁵⁷ Some participants responded very well to the intervention and liked the pedometer. Below are direct quotes from participants in the interventions.

*I love the pedometer. I still use it. I'll put it on one day, because it's easy to forget, you know, sometimes you can only do like 6,000 or something, and if that is happening, I'll maybe put it on for a couple days then I'll think, right, I've got to do a bit more. So it's probably just to give me that motivation again.*⁵⁷

*Well I think we were motivated because we had... little pace... step counters, you know on your side, and so of course we kept checking to make sure that you tried to achieve the... steps a day, and we sort of kept motivated.*⁸⁷

*When you're out you're so aware "I've got to get this steps going,"... walk round a longer route or do something... I found writing it down, it made me, do more. I did say 7000 today; tomorrow I'll do 8.*⁸²

Alternatively, other participants had negative remarks regarding the pedometer.

*I gave up wearing the pedometer because I didn't find that it registered the steps I was doing and, actually, I was quite disappointed when I first started wearing that because I thought, well, I've been walking for over an hour today and it had registered something like about 30 steps, and you think, well that's obviously wrong, so I didn't find the pedometer itself very useful and I soon gave up using that.*⁵⁷

*I probably could have accomplished the steps much more easily if I'd just worn it all the time as suggested. I didn't, I tended to wait until I was actually going to do something.*⁸²

Limitations of pedometers

Pedometers are effective but they have their limitations. Secondary analysis of the study conducted by Kolt et. al.⁸⁸ found that the addition of pedometers to a standardized

primary-care counseling program (Green Prescription) did not increase perceived motives or decrease perceived barriers.⁹⁰ Perceived motives were both intrinsic (e.g. ‘I liked being active’) and extrinsic (e.g. ‘I wanted to be physically active to keep healthy’, ‘My family/friends/colleagues wanted me to be physical active’).⁹⁰ Perceived barriers were based on the SDT principle of competence (e.g. ‘I felt too old to be physically active’).⁹⁰ Based on these results, one can presume that, although pedometers are a motivational tool,⁹¹ they do not enhance the principles of SDT.

In addition, pedometers provided poor step-count accuracy at slow speeds, which can be a source of frustration among obese persons, who typically have slow walking speeds.⁹¹ This was directly observed above by Normansell and colleagues.⁵⁷ For prevention of CVD, self-monitoring technologies should also provide education, personalized feedback, and they should be customizable.⁷⁶ Since pedometers cannot provide all of these features, in combination with their poor accuracy and lack of enhancing SDT principles, they may not be optimal for CVD prevention.

ELECTRONIC ACTIVITY MONITOR INTERVENTIONS

The American Heart Association recently conducted a systematic review to identify the impact of mobile health technologies on CVD prevention.⁹² The authors found that texting or SMS messaging on mobile phones, pedometers, email, and use of the Internet were the most common strategies used to promote PA in CVD prevention interventions. There is evidence of their effectiveness but the authors recommended the use of more sophisticated monitoring systems that are emerging in the literature.⁹² Furthermore, they recommend using these systems with behavioral treatments, such as behavioral counseling.⁹² The system they recommend are commercially available electronic activity monitors (EAMs).⁹²

An electronic activity monitor is defined as “a wearable device that objectively measures lifestyle PA and can provide feedback, beyond the display of basic activity

count information, via the monitor display or through a partnering app to elicit continual self-monitoring of activity behavior.^{77,78} EAMs are growing in popularity with an estimated 3.3 million units sold in 2014⁹³ and a sales projection of \$5 billion by 2019.⁹⁴ Like pedometers, EAMs count total steps, but they can also measure duration and intensity of PA. EAMs can sync wirelessly to an app on a smart device (phone or tablet). The data it collects are displayed clearly and concisely through the app and EAMs are programmable in that the individual can set his or her personal activity goals.⁷⁷ Lyons and colleagues found that EAMs include numerous behavioral techniques commonly associated with PA change including:^{57,95} self-monitoring, feedback, goal-setting, planning, social support, social comparisons, commitment, instructions on how to perform a behavior, and information on consequences.⁹⁶ In particular, information on consequences and social support strongly influence PA change among older adults.⁶⁰ Despite their popularity and potential to deliver behavior change techniques, the efficacy of EAMs are still unclear.^{77,97}

A review of EAMs interventions conducted prior to 2015 found that the devices can increase PA but their efficacy compared to other interventions could not be determined.⁷⁷ The effect size of EAM interventions to increase PA compared to baseline levels is as high as 1.9. EAMs also appear to be feasible with most studies reporting adequate retention and wear time.⁷⁷ In light of this systematic review, more EAM interventions have been conducted.^{98,99} These studies found that an EAM is associated with an increase in PA after 16-weeks⁹⁸ and it can improve CVD related outcomes more effectively than a pedometer.⁹⁹ However, there is also evidence that EAMs result in less significant weight outcomes compared to standard behavioral counseling.¹⁰⁰

It is evident that EAMs have the potential to change behavior alone, but they will likely be more successful if combine with structured engagement,⁹⁷ such as a research intervention or 5 A's counseling. The intervention conducted by Verwey and colleagues is the first of its kind to test an EAM system with 5 A's counseling.¹⁰¹ The EAM system

(*It's LiFe!* tool) comprised an accelerometer connected wirelessly to a mobile phone. The *It's LiFe!* tool provided feedback compared to a personal goal and periodic feedback messages and dialog sessions based on historic performance. In addition, participants received 5 A's counseling from a nurse over three consultation periods. The intervention was successful in increasing PA by approximately 10 minutes a day after 3 months. Participants found the intervention encouraging; one participant was quoted saying "It motivates me to become more active. I am now aware of what I do and that is, as a matter of fact, far less than expected, especially in the evenings."¹⁰¹ Although participants included in this study were chronically ill patients, this intervention design shows promise in preventing CVD.

Virtual social support

Researchers are actively investigating the efficacy of EAMs to change PA behavior. However, there is little evaluation of the behavior change techniques that may drive the change in behavior, in particular, social support. Social support through the Internet and social media is understood¹⁰²⁻¹⁰⁶ but there is limited appraisal on the social support features within an EAM.¹⁰⁷

With advances in technology, social support has moved from in-person support to social networking sites and other forms of social media. Social networking and social media are more than a method of communication. Social media can be a catalyst to promote desirable health behaviors by providing guidance and emotional support, facilitating behavior change interventions, and connecting individuals with resources.^{45,108-111} De La Pena and Quintanilla believed that a supportive, virtual community can simultaneously provide knowledge and encouragement to its members in an effort to change behavior.¹⁰⁸

Social support, through social media or conventional means, can be emotional, informational, instrumental, or appraisal as described by Heaney and Israel.¹⁰⁹ Emotional

support is an expression of empathy, love, trust or care. Informational support provides tangible aid. Instrumental support provides advice or information. Appraisal support provides information that is useful for self-evaluation.¹⁰⁹ Support can also come from within the individual through self-talk.^{112,113} Self-talk can be a discussion with oneself or a multi-party dialogue¹¹³ and it can be positive or negative among older adults.¹¹² In addition to types of social support there are varying types of individuals that provide social support. The 90-9-1 principle suggests that 90% of individuals that participate in social support through social media are lurkers, 9% are contributors, and 1% are superusers.¹¹² Contributors and superusers are active participants that interact with others¹¹⁴ while lurkers are passive participants in the support system.^{110,115-117}

Incorporating the Internet and social media into PA interventions for supplementing social support is feasible and moderately effective. Virtual support can take many forms including: e-mail d,¹⁰⁵ online forums,^{104,106} and websites¹⁰³. Support through the Internet produces equivocal changes in PA and perceived social support as in-person support.^{105,106} Within special populations the perceived support from the Internet surpasses the support received by traditional methods.^{103,104} Further evaluation of the virtual support shows that posts given by older adults follow the themes of informational, appraisal (esteem), and emotional support.¹⁰⁶ In addition to providing theory-based support for behavior change, virtual social support can help older adults find new friends and learn tips for increasing exercise from their peers.¹¹⁸

SPECIFIC AIMS

In sum, CVD is a prevalent condition that can be prevented through regular PA.^{3,5-7} More research is needed to determine what type of PA interventions are effective with older adults,⁵⁹ the efficacy of EAMs,^{77,92,97} and the influence of social support through EAMs. Researchers suggest that interventions should incorporate 5 A's

counseling and technology to prevent CVD among individuals at moderate risk for disease.⁵⁵

We conducted a 12-week intervention, called TAME health (Testing Activity Monitors' Effect on health), that aimed to fill the current literature gaps.¹¹⁹ TAME health incorporated 5 A's counseling and self-monitoring with an activity monitor among older primary care patients. The efficacy of the EAM system was tested against the addition of a basic pedometer in the context of 5 A's counseling. As a follow up to the intervention, separate focus groups with research participants and primary care stakeholders were conducted to gauge the intervention's feasibility and acceptability.¹¹⁹

The intervention had three Specific Aims:

AIM 1: Evaluate the feasibility and acceptability of implementing a technology-enhanced brief intervention to increase PA in a primary care setting. Measures of feasibility included days the EAM was worn, usage of the app, technological problems, attrition, self-regulation and adverse events. Acceptability was measured by self-report and focus groups.

AIM 2a: Compare the counseling plus EAM intervention to a counseling plus pedometer intervention. Primary outcomes were changes in PA and cardiovascular risk. We also investigated secondary outcomes (differences in adherence, weight and body composition, health status, physical function). The conceptual framework for the intervention is shown in Figure 1-2 and Table 1.

AIM 2b: Compare the counseling plus EAM intervention to a counseling plus pedometer intervention on changes in Self-Determination Theory construct variables. These variables include autonomous regulation and basic psychological need fulfillment.

Figure 1-2: Conceptual framework

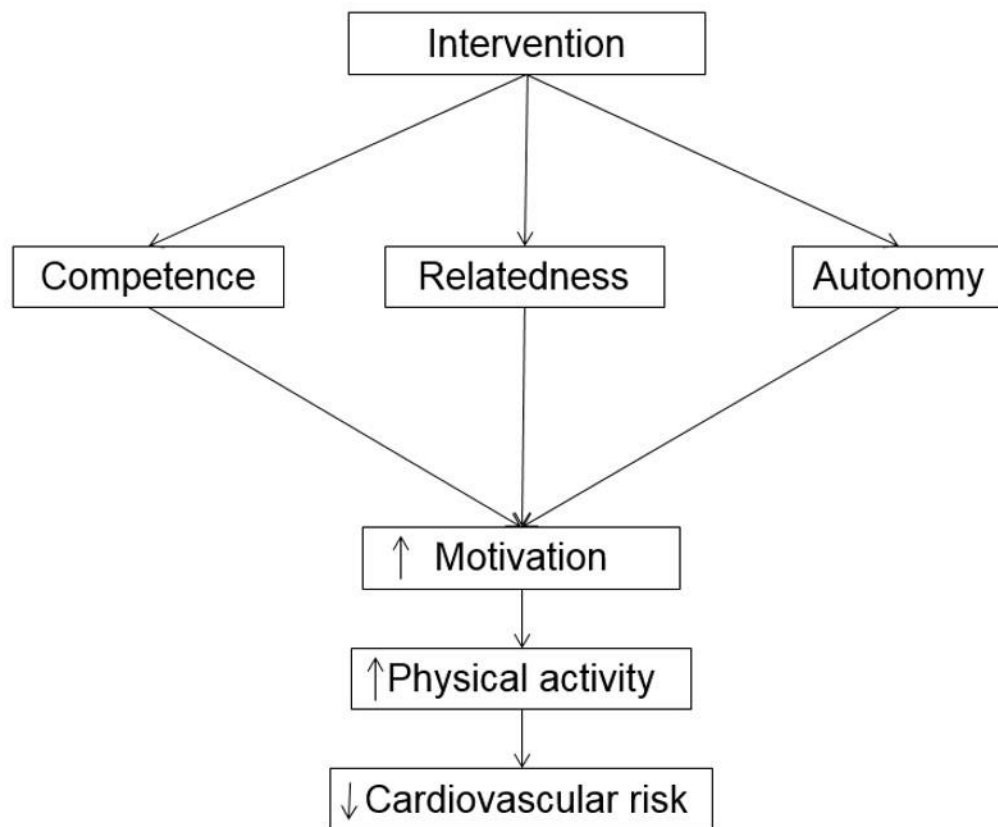


Table 1-1: Conceptual constructs underpinning the research design

Theoretical Construct	Behavioral change techniques ^a	Intervention Components		
Self-Determination Theory		5A's Counseling (both groups)	Pedometer	EAM
Autonomy	Goal-setting/ intention formation	X		X
	Provide information on consequences of behavior in general			X
	Barrier identification/ problem solving	X		X
	Action planning	X		X
Competence	Provide feedback on performance	X	X	X
	Provide instruction	X		X
	Teach to use prompts/cues			X
	Self-Control: Prompt self-monitoring of behavior		X	X
Relatedness	Facilitate social comparison			X
	Social support	X		X

^a Behavioral change techniques described are associated with Self-Determination Theory constructs based on previous research ¹²⁰⁻¹²³

AIM 3: Conduct focus groups with primary health care stakeholders to determine the feasibility of implementing the intervention within the clinic.

Hypotheses

The specific hypotheses for aims 1 and 2 are as follows:

AIM 1

1. The intervention will be feasible among several improvement metrics including days the monitor is worn, attrition compared to other primary case-based studies, app usage, technical difficulties, self-regulation and adverse events.
2. The intervention will be acceptable based on self-report questionnaires and focus group responses.
3. The EAM group will show higher feasibility and acceptability compared to the pedometer group.

AIM 2a

1. The EAM group will demonstrate greater improvement in PA and cardiovascular risk compared to the pedometer group.
2. The EAM group will demonstrate greater improvement in secondary variables of interest (adherence differences, anthropometrics, body composition, health status, and physical function) compared to the pedometer group.

AIM 2b

1. The EAM group will demonstrate greater improvement in the Behavioral Regulation in Exercise Questionnaire—2 and the Psychological Need Satisfaction in Exercise Scale sub-scales compared to the pedometer group.

The acceptability and feasibility findings from the intervention and stakeholder input will guide intervention refinement and design of a larger trial to test intervention efficacy. This project will lay the ground work and establish the infrastructure for a successful program of related research. There is a need for scalable, relatively inexpensive, and low-intensity interventions that could be delivered across a large population.⁵⁹ Ultimately, we hope to use the results of our research program to translate effective PA intervention components into primary care clinics for CVD prevention on a population level.

Chapter 2: Methodology

The detailed methodology for this project has already been published by the authors.¹¹⁹ For the purposes of this report, the methodology is described in full below. This study was approved by the UTMB's Institutional Review Board.

PRELIMINARY STUDIES

Several preliminary studies have shaped the TAME health intervention. In a pre-experimental pilot study, we recruited 10 sedentary older adults (55-79 years of age) into a six-week intervention in which they received an EAM (UP by Jawbone), a mini tablet, and weekly counseling. Adding an EAM to the PA intervention was both feasible and acceptable within this older adult population that already used smart devices. Nine out of the 10 participants agreed or strongly agreed with the following statements: "I would continue to wear the monitor"; "I felt very confident using the tablet"; "The UP application encouraged me to view my steps"; and "It was convenient for me to use the UP app." As a follow-up, we completed a pilot intervention to determine changes in PA outcomes within this same population using an UP24 by Jawbone (IMPACT study). Compared to wait-list controls, the Jawbone recipients significantly increased their stepping time per day (under publication review). Among 35 participants to complete the intervention and utilize the social features, we found that nearly all used social support features of some kind. Several participants (34%) even commented over 100 times across the 12-week period (described further in Chapter 3).

In addition to conducting PA interventions, we analyzed the content of EAMs. We evaluated 13 different EAMs and coded them for present behavioral change techniques⁷⁹ and validated their measurements of steps over the span of week compared

to research-grade activity monitor. We found that EAMs commonly incorporated important behavioral change techniques⁷⁹ and they reasonably estimated the number of steps per day (unpublished data).

The research team, led by ZHL, also conducted a systematic review of PA interventions that utilized EAMs.⁷⁷ This review evaluated different intervention methodologies and EAMs used by researchers. Findings suggested that EAM interventions produced equivocal results when compared to behavioral counseling alone. However, the devices investigated did not provide social support and used apps with fewer behavior change techniques than provided in Jawbone's app. Compliance outcomes indicated that devices were regularly worn and utilized by participants.⁷⁷ Overall, our work to date suggests that EAMs are motivational devices that are acceptable for use by older adults and can change PA behavior in conjunction with behavioral counseling.

PARTICIPANTS

We recruited forty (N=40) older primary care patients to participate in the 12-week TAME health study. Primary eligibility criteria included: age (55-74), physically inactive (less than 60 min/week of PA), BMI between 25-35, in good health as measured by the PA Readiness Questionnaire Plus (Par-Q+)¹²⁴ and access to a smart device. Reports suggest that 45% of adults over the age of 65 own a smart device.¹²⁵ A smart device was defined as a mobile phone or tablet using the iOS operating system or Android 4.3 or later. Individuals were excluded from the study if participation in PA is inadvisable by their doctor, involved in another PA intervention currently or within the past 6 months, utilized an electronic activity monitor in the past 6 months, unwilling to travel for scheduled visits, currently taking medications that affect body composition, a

current smoker, report of alcohol or drug problem, institutionalizations for psychiatric illness within the last year, or did not consent. As advised in the Par-Q+,¹²⁴ participants with co-morbid conditions were eligible if they provided a letter from their physician stating that it was safe for them to participate in PA.

RECRUITMENT AND SCREENING PROCEDURES

Participants were recruited from two UTMB affiliated clinics in October 2015-June 2016: The Primary Care Pavilion and the Multispecialty Center and Stark Diabetes Clinic. Prospective participants were recruited from flyer postings in the waiting room and in patient rooms, direct solicitation from a recruitment table in the lobby (Illustration 1).

Illustration 1: Recruitment table



Patient eligibility was determined by using a screening script. Screening was completed in person at the recruitment table or over the phone. Once patients were

deemed eligible, informed consent was obtained and a participant information sheet was filled out. The information sheet was for contact purposes only and stored separately from study data. For patients that were screened at the recruitment table, consent was obtained promptly after screening for eligibility. For patients that were screened over the phone, a researcher arranged a meeting with the patient at their primary care clinic to obtain informed consent.

After obtaining informed consent, an assessment visit was scheduled. Patients were recruited over a 3-month period before that start of the intervention on January 1st, 2016, therefore assessment visits were scheduled after this date. Participants were sent reminders about the orientation meeting via email monthly and one week prior to the scheduled meeting. In addition, participants received a phone call reminder the day before the meeting. Enrollment into the intervention was postponed until after January 1st 2016 to minimize seasonal variations in PA.¹²⁶

INTERVENTION PROCEDURES

5 A's Counseling

All participants received brief PA counseling following the USPSTF 5 A's model.^{71,127} The counseling provided in this intervention was referred to the "5A-S model" for it emphasizes the importance of self-control. The counseling components included: assess, advise, agree, assist, arrange, and self-monitor. The brief PA counseling occurred during the private assessment visit at the participant's primary care clinic, before randomization. The counseling was conducted by an experienced PA counselor with a background in exercise physiology and training in motivational interviewing. To facilitate transition into clinical practice, participants went through counseling at baseline and were instructed to self-monitor with their assigned device for the subsequent 12-weeks (Appendix A). After counseling, the researcher provided the participant with an

exercise prescription to follow (Appendix B). A phone call was arranged with the participant a week after the counseling to assess progress and resolve technical issues.

All participants were given an activity monitor to encourage self-control of PA. After counseling, participants were randomized to one of the two groups: pedometer or EAM group. A random number generator available online was used to randomly allocate group assignment, randomizer.org.¹²⁸ Assignment into the EAM group was selected randomly by the generator using the following settings: 1 set, 5 unique numbers, numbers range from 1 to 10, sorted lowest to highest. This process was repeated for 3 more sets of numbers ranging from 11-20, 21-30, and 31-40. Each number represented a participant identification number selected to be in the EAM group. Group assignment was written on a piece of paper wrapped in foil and carbon paper and concealed inside an envelope prior to group allocation. A blinded researcher prepared all of the envelopes. After group allocation, participants were given all intervention materials by their assigned group and detailed instructions on all intervention components (Appendices H and I). For participants in the EAM group, the researcher also tested the monitor and the participant's smart device to ensure they were working properly. Due to the nature of the intervention, the participants and the assessor were not blinded to group assignment after randomization.

Pedometer Group

All participants were given a digital pedometer (Digi-walker CW-700/701, YAMAX, San Antonio, TX) (Illustration 2). The pedometer records total number of steps (steps), activity time (hour/minute), distance walked (mile), and calorie burned (kcal). The device stores this information every day and up to the previous 7 days. Weekly totals for steps, activity time, distance walked, and calories burned are stored for the current and previous week. The pedometer also displays a clock and an informative graph the estimates the number of calories burned based on the number of steps.¹²⁹

Participants were asked to log their daily steps, activity time, and distance walked measured by the pedometer in an activity diary.

Illustration 2: Digi-walker pedometer



EAM Group

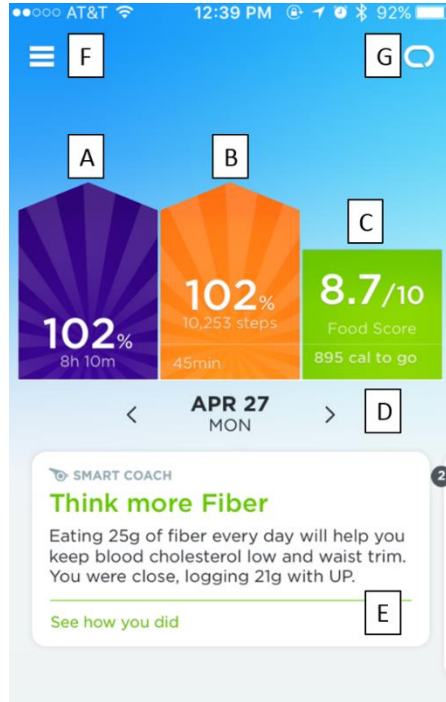
All participants were given an EAM (UP24 by Jawbone, San Francisco, CA) and the corresponding UP application (app) on their smart device (Illustration 3). UP24 by Jawbone is widely used and is one of the top selling EAMs.¹³⁰ Furthermore, UP24 implements the most behavior change techniques compared to other available EAMs and provides vital techniques that are missing in the counseling.⁷⁹ In total, Jawbone UP 24 provides 27 behavior change techniques. Some examples include goal setting on behavior and on an outcome, self-monitoring of behavior, emotional social support, providing instructions, providing information on consequences, social comparison, prompts, and focus on past success.⁷⁹ For these reasons, UP24 was selected for the intervention.

Illustration 3: UP24 monitor



The UP app provides information related to physical activity, diet, weight, sleep, and socialization (Illustration 4). Participants were not counseled on improving sleep or diet, but they are additive features of the monitor. The home screen of the app provides immediate feedback to the user on their activity for the day. If the user scrolls down on the home screen they can also view their activity feed which displays all activities from the user and their teammates. All activities in the app are stored forever so the user can review all of their activity. In addition, the app allows the user to set goals, record activity, and review activity trends (Illustration 5). The user can also set reminders for activity and learn more information about their health from the Smart Coach tailoring messaging feature. The specific features throughout the app are described below.¹³¹ All screen shot photographs were taken on September 30th, 2015. The UP app is updated regularly and some aspects may be different in future version of the app.

Illustration 4: UP app home screen



A: Sleep activity from the previous night. From the home screen the user can view their total sleep time and the percent of their sleep goal they met. B: Physical activity progress for the day. From the home screen the user can view how many steps they've taken, how many minutes they were active, and what percent of their step goal is met. C: Dietary activity for the day. From the home screen users can see the score of their food source and how many more calories they can consume. D: Displays the date for the activity shown. The user has the option to go forward or backward to view other days. E: The UP Smart Coach provides information and tips to improve the user's health. The user can swipe to the right to view more advice from the Smart Coach. F: This takes the user to the main menu where they can review all their activity, reset goals, view activity trends, view their team, create duels between other teammates, review messages from teammates, view partnering apps with UP, and view the UP Marketplace where users can purchase other health devices that partner with UP. G: This takes the user to their device information where they can view their battery life, start sleep or activity.

Illustration 5: UP goal setting, recording, and tracking



A: Users can set their own daily goals for steps and sleep as well as long-term weight goal. The app provides recommendations based on public health agencies and comparisons based on the average activity from UP users. The app also suggests a healthy range for weight based on the user's BMI. B: Users can manually report their activity. From left to right the user can report their physical activity, feelings, food intake, weight, and sleep. C: The user can view their sleep, physical activity, diet and weight trends by day, week, or month.

Physical Activity

The UP24 monitor measures PA objectively and sends the information to the UP app via Bluetooth. The monitor is sufficiently accurate at estimating steps per day.¹³² In addition to the number of steps per day, the monitor also estimates distance walked, calories burned, active time, percent of goal achieved, and sedentary time. The app displays a graph which depicts the level of activity throughout the day. Any activity that was manually entered or recorded in stop watch mode will appear on the graph as icons (Illustration 6A). When the user reviews their PA for the day in the app they also receive feedback on their progress toward their step goal for the past 7 days (Illustration 6B).

Illustration 6: PA feedback



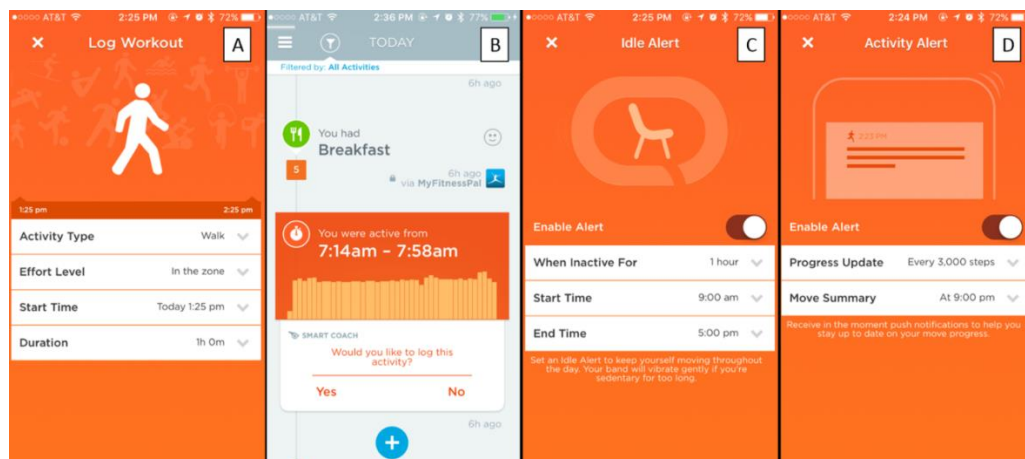
Stopwatch mode is a feature that allows the user to specify an exercise activity. The user can start and stop stopwatch mode by pressing the button on the monitor or within the app. Once the user completes an exercise in stopwatch mode they can specify within the app the exercise they completed. The user must select the specific type of activity from a list of activities (e.g. walking, biking, Zumba, etc.) or select “other” if the exercise was not on the list. Then the user must select their effort level. The specific effort levels include: easy, moderate, in the zone, difficult, and GUT BUSTER! The effort level is also depicted graphically to help select the appropriate level. If the user forgot to start the stopwatch mode before they started the exercise they can record in the app later (Illustration 7A). They will need to provide the same information described above, the start time, and the duration of the exercise. In addition, the app can detect PA patterns that appear to be exercise. It will appear in their activity feed and will ask the user if they want to log the activity (Illustration 7B).

Idle alerts are a unique feature of the UP24 system (Illustration 7C). The user can program the monitor to vibrate after a pre-specified amount of idle time. The specified times range from 15 minutes to 2 hours with 15 minute increments. The monitor will only vibrate if the wearer was idle for the specified time, if they are not idle for an extended

period of time the alert will not go off. When setting up the idle alerts, the user must also specify when the alerts will be active to ensure that alerts will not go off while the user is sleeping. Idle alerts can be enabled and disabled at the user's discretion.

In addition to the idle alerts, the user can program activity alerts (Illustration 7D). The app will send notifications about the wearer's step progress after a specified number of steps. The progress updates can be scheduled to appear after every 1,000 and up to 15,000 steps. The user can also program when to receive a move summary, which reports the total number of steps per day. Activity alerts can be enabled and disabled at the user's discretion.

Illustration 7: PA features

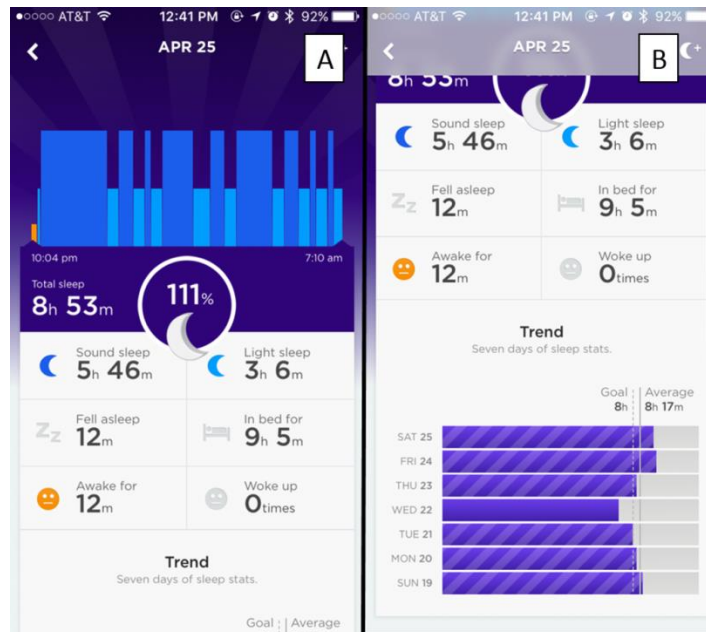


Sleep

Similar to PA, sleep is measured objectively by the monitor. The user puts the monitor into sleep mode by pressing a button on the monitor or directly in the app. This process is similar to setting activity mode. The next morning, the app displays the total sleep time, percent goal achieved, sound sleep time, light sleep time, the number of times the user woke up, as well as the amount of time it took to fall asleep, how many minutes the user was awake in bed, and how long the user was in bed. The app also displays a graph that illustrates the amount of time awake, in sound sleep, and in light sleep during the night (Illustration 8A). Also, like PA, the app provides a chart of the 7-day trend

(Illustration 8B). If the user forgets to log their sleep, the app may detect a possible sleep pattern. It will appear in their feed and will ask the user if they want to log their sleep.

Illustration 8: Sleep feedback



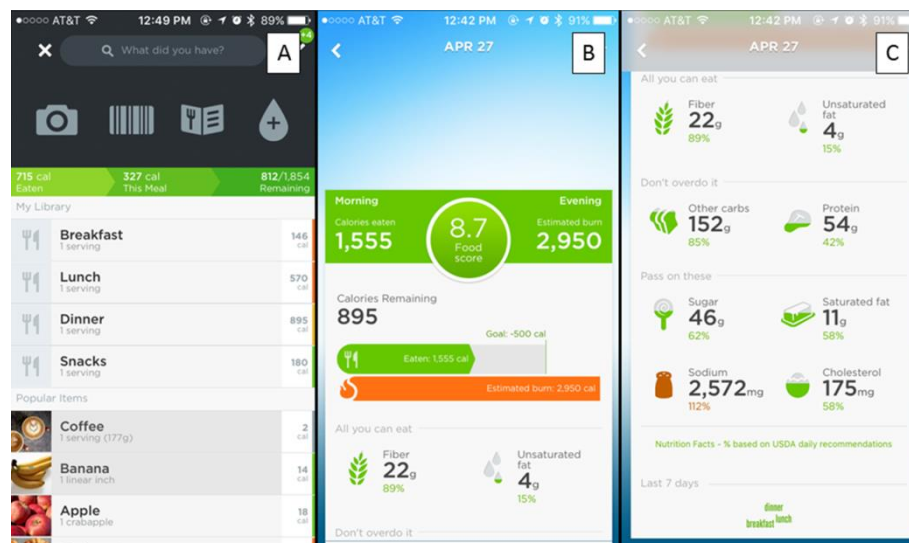
The user can also program the monitor into “power nap” mode if they take a nap during the day. This process is similar to setting it into sleep mode at night. An additional sleep feature is the smart alarm. The user can program the monitor to vibrate when it is time to wake up. Within the app, the user must set the alarm time and a “smart alarm window” up to 30 minutes before the alarm time. The monitor vibrates during the window time and at the alarm time. The user can set the alarm to repeat on any desired day and the user can program multiple smart alarms.

Dietary Intake

The app allows users to log their dietary intake directly into the app or in one of their partnering apps. The user can log food by searching for a specific food item, scanning the barcode of a food item, or searching through nearby restaurant menus (Illustration 9A). The user can modify the quantity of food to match how much food they consumed. As the user enters food the app displays how many calories they consumed

earlier that day, how many calories are in the meal they are logging, and how many calories they have left to consumed based on the expected burned calories. The user also has the option to take a picture of the food as part of the diary. Once the food is entered the app will display a score for their diet, the amount of calories consumed compared to the estimated calories burned, and the amount of nutrients consumed (Illustration 9B). The Food Score ranges from 0 to 10 with higher numbers representing healthier foods based on the nutrient value. The nutrients are broken down into “all you can eat” (fiber, unsaturated fat), “don’t overdo it” (other carbohydrates, protein), and “pass on these” (sugar, saturated fat, sodium, and cholesterol) (Illustration 9C). The app will also display a word map of the most common foods consumed in the past 7 days.

Illustration 9: Diet feedback



Weight

Users can enter their weight into the app to track their weight change. If the user uses a compatible wireless electronic scale their weight will automatically update in the app. The app displays the weight graphically to illustrate the weight change (Illustration 10).

Illustration 10: Weight feedback



Smart Coach

The Smart Coach provides the user with information and tips daily on all aspects of health. The information is both general (Illusion 11A) and individualized (Illusion 11C). The user can choose to “learn more” and the Smart Coach will send them to a link with more reading material (Illusion 11B, 11D).

The Smart Coach is also a motivational tool that tracks the user’s progress and encourages them to meet their goal. Smart Coach will offer a “Today I Will” based on the user’s activity. The “Today I Will” is a commitment the user makes with Smart Coach to accomplish a goal for that day related to PA, sleep, or diet. The “Today I Will” appears at random but will repeat daily, once accepted, until the user doesn’t accept the challenge (Illusion 12).

The Smart Coach also appears throughout the user’s activity feed to provide encouragement and advice. Some specific examples of Smart Coach feedback is displayed in Illustration 13.

Illustration 11: Smart Coach 1

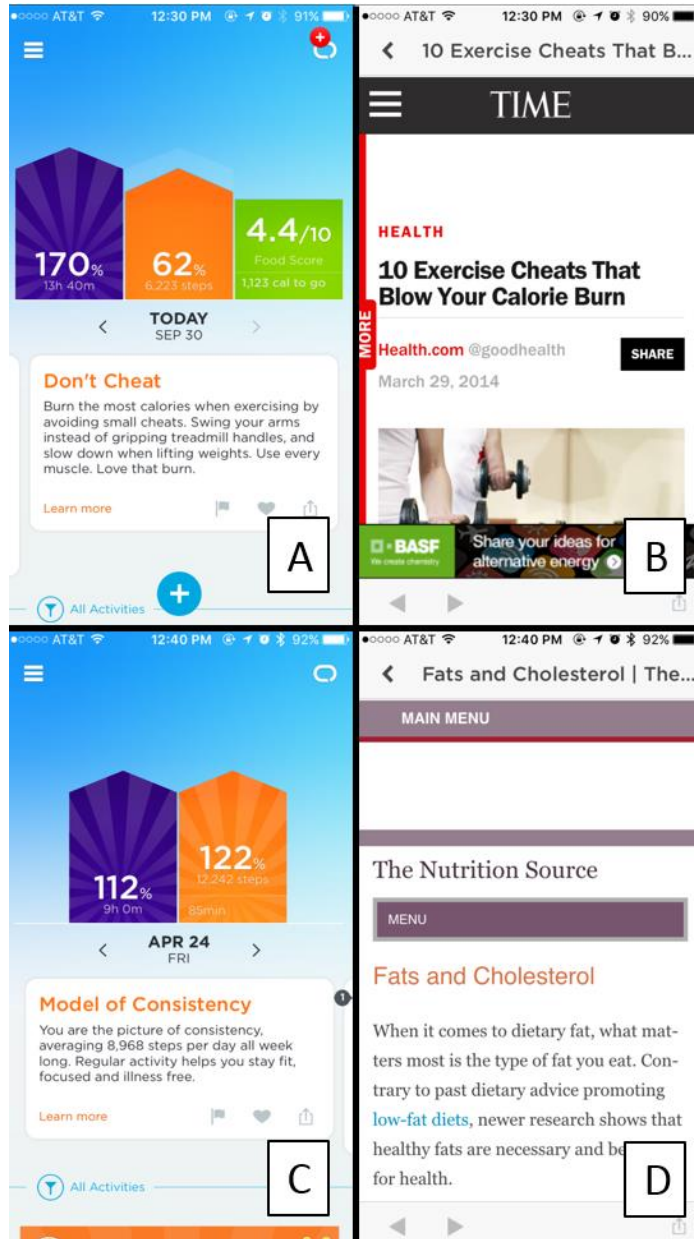


Illustration 12: Smart Coach 2

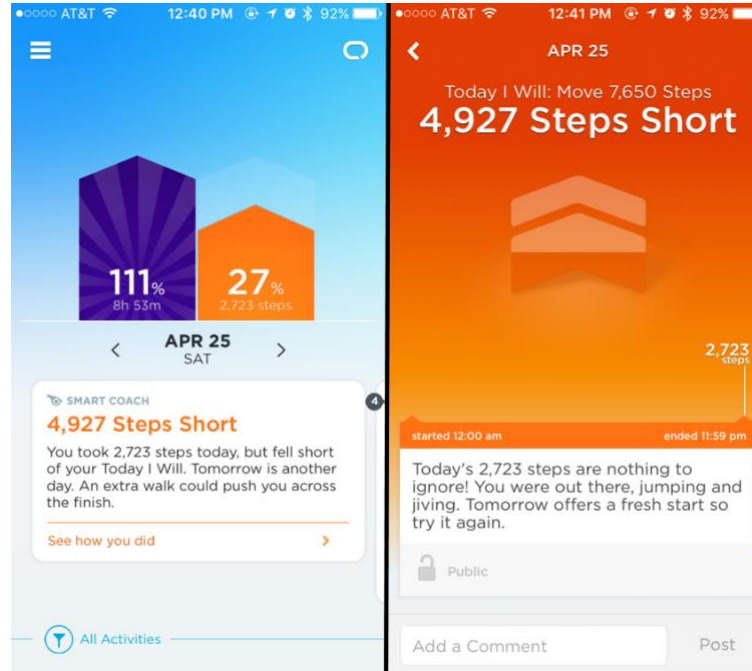
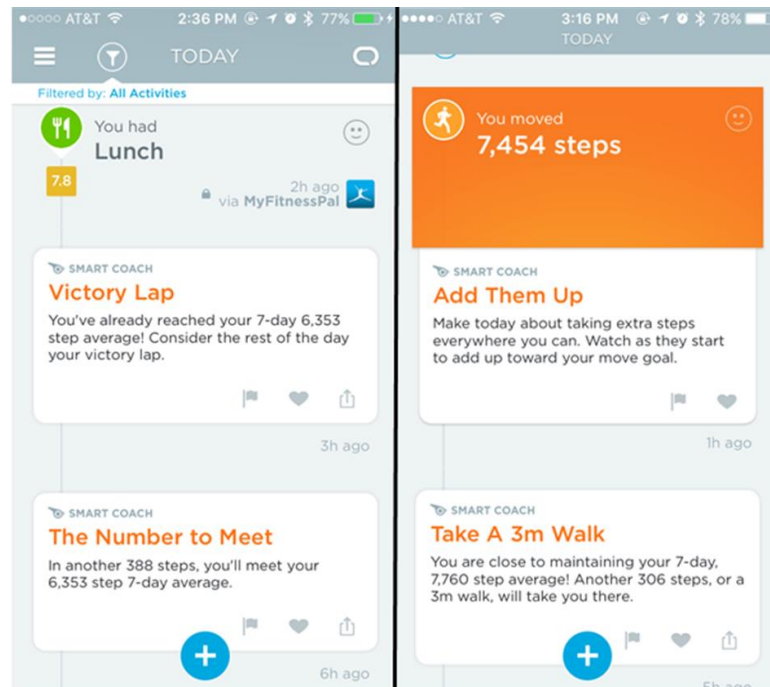


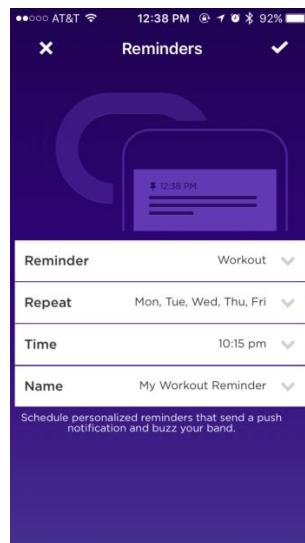
Illustration 13: Smart Coach 3



Reminders

The user can program personalized reminders with the app (Illustration 14). The band will vibrate and the wearer will receive a notification alert from the app when the reminder is scheduled to go off. The reminders can be scheduled for a bedtime, workout, meal, or pill. There is also a “custom” option for the user to customize their reminder. The user can program the reminder to repeat on desired day and time. The user can also personalize the reminder by giving it a name.

Illustration 14: UP Reminders

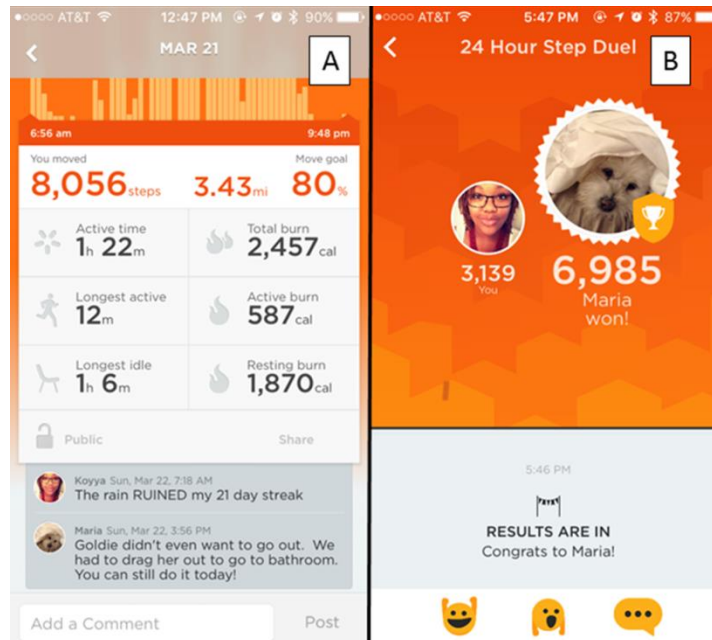


Socialization

The app includes several features that allow for socializing between UP users. The user can invite their friends to the app to join their team. The user can view their teammate's activity in their feed or the user can go to their UP page. Users can comment or “like” their teammate's activity (Illustration 15A) to provide social support. Users can view how they compare to their teammates through the leaderboard. The leaderboard displays the total steps from the past 7 days and ranks teammates from highest to lowest number of steps. Users can directly compete with one another through duels (Illustration 15B). Duels may last for 24 hours, 3 days, or 1 week. The user creating the duel can

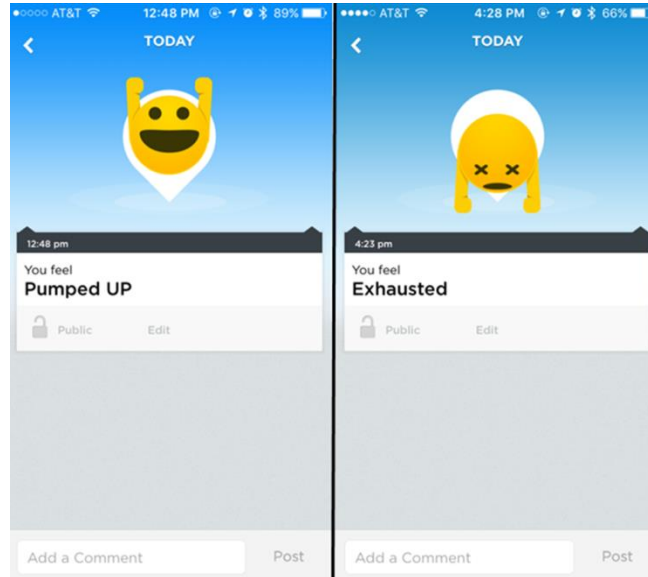
decide to make it public to all teammates of both duelers or private between the two duelers. One user creates the duel and invites another teammate to join. The teammate can accept or decline the invitation. The user with the most steps after the designated time is the winner.

Illustration 15: UP Socialization



The app also allows for interactions with the app through “feelings”. Users can express how they are feeling for the day through an emoticon (Illustration 16). The designated “feelings” include: totally done, exhausted, dragging, meh, good, energized, pumped UP, or amazing! The user can also customize their feeling.

Illustration 16: Feelings



All participants were given a de-identified account with an anonymous name and icon to use in the app. We chose to use board game pieces' names and icon pictures (e.g. Battleship, Cat, Hotel). Participants were required add other participants as their “teammate” in order to utilize the socializing features within the app. Only PA information was required to be visible by their teammates. Participants were able to customize their account if they wished to share any other behaviors with their teammates. Participants that did not consent to have their de-identified information shared with other participants were ineligible and dropped from the intervention. In order to view the participant’s activity, the participants also added the research account as a teammate. The researchers did not socialize or interact with the participants through the app, using it for surveillance purposes only. Participants were given a trouble-shooting guide to help with any issues with the app. The researchers also reviewed and resolved any technical issues reported during the “Arrange” phone call. The app stored all activity throughout the entire intervention period. The researchers also download a csv file with all of the data from each participant during the intervention period from the Jawbone website.

ASSESSMENT PROCEDURES

The primary purpose of this study was to investigate the feasibility and acceptability of a low-intensity intervention that combined 5 A's counseling and an EAM system. We also compared the effects of these high-tech activity monitors to low-tech ones (pedometers) on PA and other cardiovascular risk indicators (Framingham risk calculator, fitness). The study included two assessments conducted at baseline and 12 weeks. Upon initial recruitment at the clinic, participants provided informed consent. Approximately 7 days before their initial assessment, participants were given a baseline questionnaire (Appendix C) and a research-grade activity monitor (discussed below) to wear for a 7-day baseline period. Participants returned to their primary care facility to complete the assessments. At 11-weeks, participants were given a follow-up questionnaire (Appendix D) and another monitor to wear for 7 days. At 12-weeks, participants returned to their clinic to complete assessments identical to baseline. A researcher followed a checklist at all visits to ensure all assessments were completed. As reimbursement for taking part in this study all participants received a \$25 gift card at the end of the 12-week assessment, at that time participants also forfeited their device.

The primary outcomes of interest were feasibility and acceptability. Feasibility was operationalized in several ways. Number of days logged for activity, interactions with other users in the mobile app, and additional use of the app were abstracted using procedures we have previously pilot tested successfully. Acceptability was measured using self-report (modeled on items previously developed¹³³) and focus groups conducted after completion of the intervention. The primary physiological variables of interest included cardiovascular risk indicators and PA. Secondary outcome variables were anthropometrics, body composition, blood pressure, exercise motivation, health status and quality of life, physical function, psychological feelings, resting pulse, and self-regulation. All physiological study variables are listed in Table 2-1.

Table 2-1: Study physiological variables

Variable	Measure	Sub-scales	Alpha
Primary Variables			
CVD risk	Framingham non-laboratory risk score calculator	Age: yrs.; Body Mass Index: kg/m^2 ; Systolic blood pressure: mmHg;	
	Six minute walk test	Distance walked in 6 minutes: ft.	
PA	SenseWear armband (BodyMedia, Pittsburgh, PA)	Minutes of METs ≥ 3 (7 days of measurement); Steps per day	
Secondary Variables			
Anthropometrics	Stadiometer (Seca Corp., Hamburg, Germany); scale (Tanita, Arlington Heights, IL)	Height (baseline only): cm; weight: kg; Body Mass Index: kg/m^2	
Body Composition	Tape measure (Singer, China)	Waist circumference: cm; Hip circumference: cm; Waist to Hip ratio	
Blood pressure	Sphygmomanometer (Omron BP742N, Lake Forest, IL)	Systolic blood pressure: mmHg; diastolic blood pressure: mmHg	
Demographics	Self-report	Age: yrs.; sex; race/ethnicity; education	
Exercise motivation	Behavioral Regulation in Exercise Questionnaire—2	Intrinsic, identified, introjected, extrinsic, amotivation	0.73-0.86
Health Status and quality of life	Medical Outcomes Study Short Form (SF)-36	Physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, energy/vitality, pain	0.76-0.90
Physical function	Short Physical Performance Battery	Repeated chair stands, balance, semi-tandem stand, side-by-side stand, tandem stand, 8 feet walk	
	PROMIS SF v1.2-Physical function 8b	Upper extremities, lower extremities, central regions	
Psychological feelings	Psychological Need Satisfaction in Exercise Scale	Perceived competence, perceived autonomy, perceived relatedness	>0.90
Resting pulse	Sphygmomanometer (Omron BP791T, Lake Forest, IL)	Heart rate: bpm	
Self-regulation	Rovinak et. al. scale	Exercise goals, exercise plans	0.87-0.89

CVD: cardiovascular disease, PA: physical activity

Cardiovascular Risk

CVD risk was determined by measuring 10-year risk of cardiac event from the Framingham non-laboratory equation¹³⁴ and from fitness measured by a six minute walk test.¹³⁵ The six minute walk test was an additive assessment of CVD risk because cardiorespiratory fitness is more strongly related to clinical outcomes than PA.¹³⁶ The Framingham equation has been used to estimate CVD risk in previous studies.^{137,138} It required a combination of self-report and objective measures.^{134,139} Self-report measures included sex, age, treatment of hypertension, and diagnosis of diabetes. Objective measures included blood pressure and BMI.^{134,139}

The six-minute walk test required participants to walk a 100 feet course continuously for 6 minutes. It has been validated in older adults to measure physical endurance ($0.71 < r < 0.82$).¹³⁵ Percentile norms on the test have been established for active older adults.¹⁴⁰

Physical Activity

PA was measured with a SenseWear Armband for both study groups. Although the participants received feedback on their PA from their designated activity monitor, their device was meant as a motivational tool and PA measured by the two devices could not be compared. Therefore, PA outcome was measured using the validated SenseWear armband.

The SenseWear armband is a multi-sensor, research grade accelerometer that provides a valid and reliable estimation of minutes of activity and energy expenditure in older adults.¹⁴¹⁻¹⁴³ The armband was worn on the upper arm for 7 days. SenseWear quantified PA by measuring expended kcal/week, minutes of activity a day, and steps per day. There is a mean error <5% in measuring total minutes of PA with the SenseWear armband.¹⁴³ To properly program the armband age, gender, and BMI were collected at

enrollment. These variables were also formally measured at study allocation, described below.

Anthropometrics and Body Composition

Anthropometrics included height (cm), weight (kg), and BMI (kg/m^2). To ensure accurate measurement of anthropometrics, height and weight was measured to the nearest 0.1 unit. Participants were instructed to remove their shoes and any bulky clothing before measurement. Height was measured using a portable stadiometer¹⁴⁴ and weight was measured using a calibrated electronic scale.¹⁴⁵ The same equipment was used at both clinics. The electronic scale was transported in a cushioned carrying case to ensure it remained calibrated. BMI was calculated by converting height into meters and squaring that value, then dividing weight by this value.¹⁴⁶

Body composition was estimated based on the waist circumference (cm), hip circumference (cm), and waist-to-hip ratio. The waist was measured at the smallest circumference of the torso while the hip was measured at the largest circumference at or below the anterior superior iliac spine.¹⁴⁷ The waist-to-hip ratio was calculated by dividing the waist circumference by the hip circumference.¹⁴⁷ All anthropometrics and body composition measurements were taken three times and the averages were used.

Blood Pressure and resting pulse

Blood pressure and resting pulse was measured by a sphygmomanometer (Omron BP742N, Lake Forest, IL).¹⁴⁸ Blood pressure was measured after the participant was sitting for at least five minutes and before any other measurements were taken. The sphygmomanometer is validated for clinical and personal use according to the European Society of Hypertension International Protocol.¹⁴⁸

Demographics

Although it was not an outcome variable, demographic information was collected at both assessments. This information included age, race/ethnicity, educational level, and medication use.

Health Status and Quality of Life

The 36-Item Short Form Health Survey (SF-36) was used to estimate health status and quality of life. It is a self-report measure that was included into the questionnaire. Sub-scale of this instrument include physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, energy/vitality, and pain.¹⁴⁹

Physical function

Physical function was measured objectively and subjectively. Physical function was objectively assessed using the short physical performance battery. Total functional capacity was based on a composite score from the following sub-tests: repeated chair stands, balance (semi-tandem stand, side-by-side stand, tandem stand), 8 feet up walk.¹⁵⁰ Physical function was subjectively assessed using the PROMIS Short Form v1.2-Physical function 8b.¹⁵¹

Motivation, self-regulation, and psychological feelings

Several self-report measures were used to estimate exercise motivation, self-regulation of exercise, and psychological feelings toward exercise.¹⁵²⁻¹⁵⁴ Each measure included sub-scales. Exercise motivation consisted of intrinsic, identified, introjected, extrinsic, and amotivation.¹⁵² Self-regulation consisted of exercise goals and exercise plans.¹⁵⁴ Psychological feelings toward exercise consisted of perceived competence, perceived autonomy, and perceived relatedness.¹⁵³

FOCUS GROUPS

We conducted several focus groups with research participants at the end of the intervention to further evaluate feasibility and acceptability. These sessions consisted of 5-8 individuals and lasted 1.5-2 hours. A trained professional facilitated all of the focus groups. Groups were separated based on the intervention modality and two groups were completed for each study arm. The focus groups explored the perceived effectiveness of the 5 A-S counseling and the monitoring device. Participants were also asked questions pertaining to their overall feelings toward the intervention and their thought of the intervention implemented through their primary care physician (Appendix E).

Focus groups following the same structure but with primary care stakeholders were also conducted at the conclusion of the intervention. Stakeholders (N=36) consisted of medical doctors, nurses, medical residents, physician assistants, and other staff personnel. Stakeholders were recruited through flyers with the coordination with the Department of Internal Medicine and Family Medicine. All participants consented to be a part of the focus group and were given the opportunity to wear the UP24 for one month. During the focus groups, stakeholders were asked questions related to their perception of the intervention. Materials and equipment from the intervention were provided and preliminary results of the intervention were presented. The goal of the focus groups was to elicit reactions regarding the feasibility and acceptability of including this intervention into their primary care clinic (Appendix F). Stakeholders were also asked about their familiarity with 5 A's counseling and the extent of its use in practice. Stakeholder completed a brief questionnaire before (Appendix G) and after (Appendix H) the focus group. In addition, stakeholders that wore the UP24 for one month completed a feasibility questionnaire upon returning the monitor (Appendix I).

STATISTICAL ANALYSES

The Statistical Package for the Social Sciences (IBM-SPSS, version 20) was used to perform all quantitative statistical analyses. Analyses were completed using the intent-to-treat principle, carrying baseline measurements to follow-up. The α -level to determine significance was set at 0.05. The specific statistical procedures, by research aim, are described below.

Aim 1

Feasibility findings were primarily descriptive and used as a metric for improvement when compared to similar studies. For example, days worn was compared to other EAM studies whereas attrition was compared to other primary care-based studies. Rather than determine dichotomous feasibility or not, we used relative feasibility to determine areas of focus for intervention refinement; which was addressed in the follow-up questionnaire and in focus groups. Comparisons of adherence between EAM and pedometer groups was covered under Aim 2 below and the procedures for analyzing focus groups were identical to procedures outlined in Aim 3 below.

We hypothesized that the intervention would be feasible among several improvement metrics including $\geq 70\%$ days the monitor was worn⁷⁷, $< 20\%$ attrition¹⁵⁵, and < 8 moderate or higher adverse events ($< 20\%$ of participants reporting an adverse event^{87,156,157}). Hypotheses based on other feasibility metrics include a low frequency of technical difficulties and a high frequency of app usage. Additionally, we hypothesized that the intervention would be accepted among participants based on self-report questionnaires and focus group responses. We also hypothesized that the EAM group will show higher feasibility and acceptability compared to the pedometer group.

Aim 2a

Descriptive analyses were completed using means and frequencies for baseline characteristics. These characteristics included age, gender, race/ethnicity, educational level, CVD risk, PA, fitness, weight, BMI, blood pressure, pulse, waist and hip circumference, physical function, exercise motivation, health status, and self-regulation. Mean group differences were examined using independent samples t-tests for normally distributed data and non-parametric tests (Mann-Whitney U) for non-normally distributed data. Differences in variable frequencies were examined using Chi-Square tests. Little's Missing Completely at Random test was performed to check if outcome data is missing at random.

Group mean values for adherence variables at 12 weeks (retention rate, days the monitor worn) was analyzed by an Independent T-Test. Analysis of covariance (ANCOVA) was used to test the post-intervention difference at 12-weeks (PA, CVD risk, fitness) between the two groups. The covariates in the analysis included baseline values of the dependent variable, clinic location, and any variables significantly different between groups at baseline. This same procedure was used to assess differences in weight, BMI, body composition, health status, physical function, and self-regulation. Cohen's d effect sizes¹⁵⁸ were generated from the mean change in the tested variable. Effect sizes were used in conjunction with ANCOVA to emphasize effect where significance was not reached due to the lack of power.

The primary purpose of this study is to evaluate its feasibility and acceptability; therefore, the analyses described in this section are exploratory in nature and no pre-specified power calculation is needed. Although this was a pilot study and was not powered to detect significant difference in small-to-moderate effects, we hypothesized that the EAM group would demonstrate greater improvement in all of the aforementioned variables compared to the pedometer group.

Aim 2b

Descriptive statistics were analyzed in a similar manner to Aim 2a. ANCOVA was used to test post-intervention difference at 12-weeks in the Behavioral Regulation in Exercise Questionnaire and Psychological Needs in Exercise Scale sub-scales between the two groups. The covariate in the analysis was the baseline value of the dependent variable.

Aim 3

NVivo 11 Pro (QSR International) was used to perform qualitative analyses. Thematic analysis was conducted to analyze the focus groups.¹⁵⁹ Codes were developed prior to the focus groups. Additional codes were processed while the focus groups were conducted, adding codes based on new data. After including all study participants, the completed code list was used to code transcripts of all groups. The PRECIS tool was also be used to estimate the intervention's potential success in real clinical application.¹⁶⁰

Power Calculation

Although the aim of the intervention was to improve behavioral and health outcomes related to cardiovascular risk, the primary purpose of this study was to investigate the feasibility of intervention components and study procedures and to inform a larger intervention. This is necessary in research related to CVD.¹⁶¹ For these reasons, a sample size of 40 was deemed appropriate to test the intervention. The sample size of 40 would be able to detect an increase of 1000 steps from baseline to follow-up, which is below the minimum expected increase in steps from pedometer-based interventions.⁷⁸ The findings from this pilot study will be used to establish initial effect sizes and inform the power and sample size estimates for future larger trials.

Journal Manuscripts

This project will present findings in four manuscripts. The first manuscript describes an exploratory evaluation of the social support patterns of participants enrolled in a pilot study (described in the Methodology chapter) using the UP app. Participants in this study were different from TAME health participants, but were of similar age, activity level and were recruited from the same area. The results of this preliminary evaluation guided the examination of social support within the TAME study, which is presented in the second manuscript. The second manuscript reports feasibility and acceptability results from Aim 1 and 3. The first two manuscripts evaluate the usability of the UP system and the adoptability of the entire TAME health intervention.

The third manuscript presents the outcome findings from Aim 2a. The final manuscript is an in-depth evaluation of the variables outlined in Aim 2b related to Self-Determination Theory. The subsequent two chapters aim to identify meaningful outcomes and estimate the effect of the intervention. Figure 2-1 is a visual representation of the following chapters.

Figure 2-1: Chapter Outline

Chapter 3	Chapter 4	Chapter 5	Chapter 6	Chapter 7
<ul style="list-style-type: none">• Preliminary study results	<ul style="list-style-type: none">• Aim 1• Aim 3	<ul style="list-style-type: none">• Aim 2a	<ul style="list-style-type: none">• Aim 2b	<ul style="list-style-type: none">• Synthesized discussion

CHAPTER 3: SOCIAL SUPPORT PATTERNS OF OLDER ADULTS WITHIN A PHYSICAL ACTIVITY MOBILE APPLICATION: A BRIEF REPORT

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Background: Social support is an influential behavioral change technique to encourage physical activity. Social media and social networking sites are widely used to provide virtual social support. A better understanding of how they are used could improve intervention efforts. **Purpose:** We aimed to describe the social support patterns of older adults using a mobile application (app) as part of a behavioral physical activity intervention. **Methods:** Forty participants were randomized into the intervention group or the wait-list control group of a 12-week physical activity intervention. The 35 participants from both groups were used for this investigation. The intervention provided participants with a Jawbone Up24 activity monitor and an Apple iPad mini installed with the UP application (app) to facilitate self-monitoring and social interaction. All participants were given an anonymous account and were encouraged to interact with other participants in the app. Social support features included comments and “likes”. **Results:** Over the 12-week intervention, participants provided a total of 3,153 likes and 1,759 comments. Most participants (n=25) were contributors with four categorized as superusers and six categorized as lurkers. Comments were coded as emotional support, informational support, instrumental support, self-talk, and other, with emotional support being the most prevalent comment type. **Conclusions:** Older adults are willing to use social features in a physical activity app to communicate with unknown, anonymous peers. These apps are a promising tool for delivering social support.

Keywords: social support, older adults, physical activity, technology, wearable activity monitor

Introduction

Optimal levels of physical activity (PA) are seldom achieved among older adults.²⁶ Providing social support is an influential behavioral change technique that can encourage PA.^{40,44,45} Social support can be defined as an interpersonal exchange that offers esteem, acceptance, value, and motivation to individuals.⁴⁷ People within a support system can help to shape another individual's interpretations of exercise^{48,49} and can foster an accessible exercise environment through PA promotion.⁵⁰

With advances in technology, social support has moved from in-person support to social networking sites and other forms of social media. Social networking and social media are more than a method of communication. Social media can be a catalyst to promote desirable health behaviors by providing guidance and emotional support, facilitating behavior change interventions, and connecting individuals with resources.^{45,102,108-111} De La Pena and Quintanilla believed that a supportive, virtual community can simultaneously provide knowledge and encouragement to its members in an effort to change behavior.¹⁰⁸

Social support, through social media or conventional means, can be categorized as emotional, informational, instrumental, or appraisal support as described by Heaney and Israel.¹⁰⁹ Emotional support is an expression of empathy, love, trust or care. Informational support provides tangible aid. Instrumental support provides advice or information. Appraisal support provides information that is useful for self-evaluation.¹⁰⁹ Support can also come from within the individual through self-talk.^{112,113} Self-talk can be a discussion with oneself or a multi-party dialogue¹¹³ and it can be positive or negative among older adults.¹¹² In addition to types of social support there are varying types of individuals that provide social support. The 90-9-1 principle suggests that 90% of individuals that participate in social support through social media are lurkers, 9% are contributors, and 1% are superusers.¹⁶² Contributors and superusers are active

participants who interact with others,¹¹⁴ while lurkers are passive participants in the support system.^{110,115-117}

Despite the popularity of social support through social media there is still a need for further evaluation of their usability for health and PA promotion,¹⁶³ particularly among older adults. There is preliminary evidence that older adults who use virtual support provide comments that align with social support theory¹⁰⁶ but they are cited as being apprehensive about communicating with strangers.¹¹⁸ It is unclear whether older adults will use social support features among strangers and the types of support they will provide, if any. The purpose of this secondary data analysis of a randomized controlled trial (IMPACT study) is to describe the use of social support features among older adults using a mobile application (app) as part of a behavioral PA intervention. Furthermore, we aimed to describe the socializing patterns within the context of social support theory.

Methods

PARTICIPANTS

Participants were recruited into a 12-week behavioral PA study through local newspaper advertisements, online mailing lists, and university announcements. Individuals were eligible if they were 55-79 years of age, had a body mass index of 25 to 35, able to read and understand English, and able to read the print off of a tablet. Exclusion criteria included: more than 60 minutes of planned PA per week, health issues where exercise is inadvisable, psychological issues, and alcohol or drug abuse. Eligible participants were also screened using the Physical Activity Readiness Questionnaire which requires participants with chronic medical conditions to obtain written physician's approval before starting an exercise program.¹²⁴

MATERIALS AND PROCEDURES

The overall study protocol was approved by the University's Institutional Review Board and all participants provided informed consent. Eligible participants were randomized to one of two groups—intervention or wait-list control—in 2014 and 2015 on a rolling basis. The intervention group was lent an electronic activity monitor (Jawbone UP24) and a mobile tablet device (Apple iPad mini) and received brief weekly telephone counseling (based on motivational interviewing and self-determination theory). The wait-list control group received all of the intervention components after their 12-week final assessment. The UP app was pre-installed on the tablets so that the participants could view their activity and interact with the other participants. All participants were given an anonymous account and were “friended” with the other participants and the interventionists. The participants were encouraged, but not required, to socialize with others when they received the intervention material. During the weekly counseling calls, the counselor answered technical questions about the social features and only promoted social interactions if the participant expressed interest. Interventionists used the app for surveillance of the participants only and did not interact through the app unless there was a software update. Once participants in the wait-list group received the intervention, they were able to interact with other wait-list controls and intervention participants who were not done with the 12-week program. UP accounts were “friended” prior to the start of the study and participants were instructed to ignore friend requests from unknown users. The primary social features of the UP app at the time of the intervention included comments and “likes”. Regardless of their social engagement, participants received notifications from the app when they received a comment or a “like” from a peer. More details about the UP app features are available as a supplementary file.¹¹⁹

DATA ANALYSIS

The overall study included 40 participants but the analysis was limited to the 35 participants that used the UP app and were able to provide social support to other participants throughout the entire 12-weeks. Three wait-list control participants declined to use the UP24. Since enrollment was on a rolling basis, there were 2 participants that did not have peers to socialize with throughout the 12-weeks. NVivo 11 Pro (QSR International) was used for qualitative analysis and the Statistical Package for the Social Sciences (version 20) was used for quantitative analysis. Descriptive analyses were conducted using means and frequencies. Interquartile range (IQR) was used to identify superusers and lurkers. Participants above the 75th percentile in both social support categories (given “likes” and comments) were classified as superusers. Participants below the 25th percentile in both social support categories were classified as lurkers. A combination of direct and conventional qualitative content analysis was used to analyze the app comments.¹⁶⁴ Codes included emotional, informational, instrumental, appraisal support, and self-talk. Additional codes were developed from reading through the comments. Two investigators independently coded the comments and agreement was determined from the NVivo software. Disagreement was settled through discussion and joint review of the comments. Due to protocol restrictions, only the quantitative report and the coded qualitative themes are reported.

Results

DESCRIPTIVE INFORMATION

Table 3-1 displays the baseline characteristics of the participants that used the UP app and were able to receive social support from other participants (n=35). Most participants were female (82.9%), non-Hispanic White (57.1%), and college graduates (62.9%). Throughout the study, participants gave 3,153 “likes” and provided 1,759

comments. The most support given by one participant was 986 “likes” and 344 comments. The mean number of peers (other study participants) within the app over 12-weeks was eight with a minimum and maximum of four and 13, respectively. With rolling enrollment, the number of peers fluctuated throughout the 12-weeks. However, participants always had at least 1 peer to communicate with during the week. Three participants out of 35 did not receive a “like” or comment over the 12-weeks.

Table 3-1: Baseline Demographic Characteristics of Preliminary Study (n=35)

	Intervention (n=19)	Wait-list Control (n=16)	Total (n=35)
Female (%)	16 (84.21%)	13 (81.25%)	19 (82.90%)
Race			
Non-Hispanic White (%)	11 (57.89%)	9 (56.25%)	20 (57.10)%
Other (%)	8 (42.11%)	7 (43.75%)	15 (42.90%)
College graduate (%)	12 (63.16%)	10 (62.50%)	22 (62.86%)
Age (SD)	61.32 (5.13)	62.06 (6.60)	61.66 (5.77)
Body Mass Index, kg/m ² (SD)	29.99 (2.94)	30.80 (3.82)	30.36 (3.34)

The median number of “likes” given was two with a range of 0 to 986 and an IQR of 40. The median number of comments given was 14 with a range and IQR of 0 to 344 and 45, respectively. Twelve participants were above the 75th percentile for one or both of the social support categories. Among these individuals, four participants were above the 75th percentile in given “likes” and comments. These four superusers combined accounted for 2289 (72.6%) and 902 (51.3%) of the total “likes” and comments. Conversely, seven participants were below the 25th percentile for comments given. Of these, six participants can be classified as lurkers because they did not give any “likes” to other participants. The 25th percentile for “likes” given was 0, therefore no participants were below this threshold. The remaining 25 participants can be classified as contributors for falling within the IQR for “likes” or comments given. This group accounted for 864 (27.1%) likes and 857 (48.72%) comments.

COMMENT THEMES

The comments within the app mostly followed the major themes of social support theory.^{102,109,112} The only theme that was not prevalent was appraisal support. Some comments that were useful for self-evaluation were coded as a sub-theme of emotional support. In addition to emotional support, informational support, instrumental support, and self-talk there was an “other” major theme. Each major theme had additional subthemes. The intervention group gave more comments than the wait-list control group but the most prevalent themes were the same between the two groups. Agreement between the two coders ranged from 53.4 to 99.4% for each theme. The lowest agreement was with self-talk (67.9%) and emotional support (53.44%). **Table 3-2** displays the number of comments given by the participants by each major theme. Several comments were coded into numerous themes.

Table 3-2: Number of Comments by Themes

	Intervention (n=19)	Wait-list Controls (n=16)	Total (N=35)
	n (%)	n (%)	n (%)
Emotional support	475 (26.0)	596 (32.7)	1071 (58.7)
Concern	29 (1.6)	24 (1.3)	53 (2.9)
Gratitude	75 (4.1)	107 (5.9)	182 (10.0)
Motivating	317 (17.4)	420 (23.0)	737 (40.4)
<i>Compliments</i>	41 (2.2)	54 (3.0)	95 (5.2)
<i>Congratulatory</i>	53 (2.9)	60 (3.3)	113 (6.2)
<i>Encouragement</i>	75 (4.1)	89 (4.9)	164 (9.0)
<i>Impressed</i>	45 (2.5)	70 (3.8)	115 (6.3)
<i>Verbal Persuasion</i>	155 (8.5)	215 (11.8)	370 (20.3)
Sharing	92 (5.0)	80 (4.4)	172 (9.4)
Social norms	42 (2.3)	18 (1.0)	60 (3.3)
<i>Agreement</i>	13 (0.7)	5 (0.3)	18 (1.0)
<i>Comparison</i>	32 (1.8)	13 (0.7)	45 (2.5)
Informational support	64 (3.5)	18 (1.0)	82 (4.5)
Informative	23 (1.3)	2 (0.1)	25 (1.4)
Inquiry	40 (2.2)	17 (0.9)	57 (3.1)
Instrumental Support	48 (2.6)	11 (0.6)	59 (3.2)
Competition	20 (1.1)	0 (0)	20 (1.1)
Exercise companion	17 (0.9)	10 (0.5)	27 (1.5)
Participatory support	12 (0.7)	1 (0.1)	13 (0.7)
Self-Talk	220 (12.1)	188 (10.3)	408 (22.4)
Anecdote	83 (4.6)	85 (4.7)	168 (9.2)
Feelings	49 (2.7)	38 (2.1)	87 (4.8)
<i>Negative</i>	15 (0.8)	6 (0.3)	21 (1.2)
<i>Positive</i>	34 (1.9)	31 (1.7)	65 (3.6)
Planning	42 (2.3)	16 (0.9)	58 (3.2)
Reflection	98 (5.4)	78 (4.3)	176 (9.6)
Other	132 (7.2)	72 (3.9)	204 (11.2)
Correction	6 (0.3)	9 (0.5)	15 (0.8)
Greeting	23 (1.3)	24 (1.3)	47 (2.6)
<i>Salutatory</i>	10 (0.5)	11 (0.6)	21 (1.2)
<i>Welcome</i>	15 (0.8)	10 (0.5)	25 (1.4)
Health behaviors	52 (2.9)	22 (1.2)	74 (4.1)
<i>Diet</i>	7 (0.4)	0 (0)	7 (0.4)
<i>Sleep</i>	46 (2.5)	23 (1.3)	69 (3.8)
Technical problems	33 (1.8)	16 (0.9)	49 (2.7)
Unknown	6 (0.3)	3 (0.2)	9 (0.5)
Total*	939 (51.5)	885 (48.5)	1824
Major themes, sub-major themes, minor themes			
*Some comments were coded into several sub-major or minor themes. Therefore, the total depicts the total number of comments under the major themes			

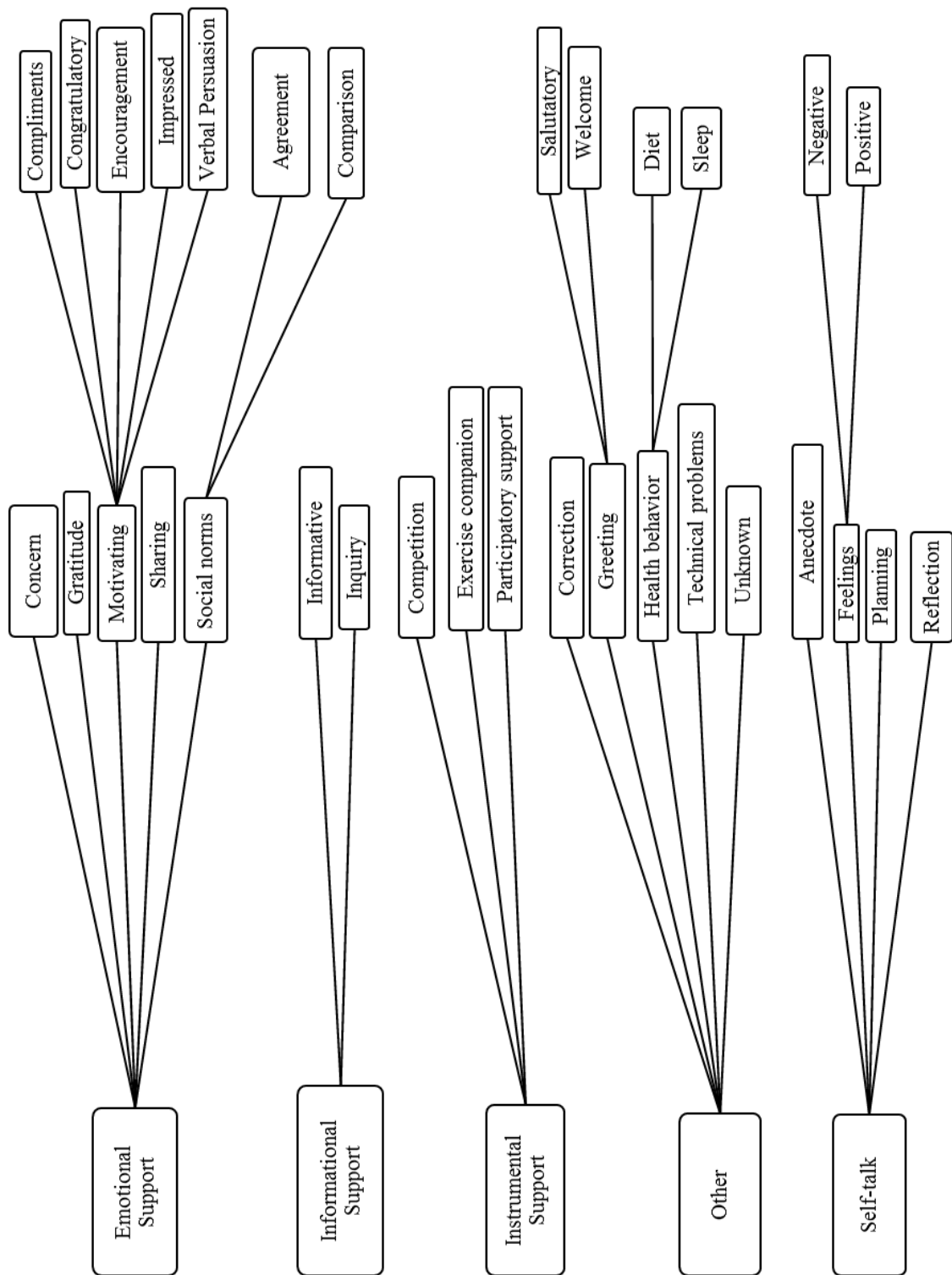
Emotional support, the most prevalent, made up 58.7% of all comments. It was further categorized as concern, gratitude, sharing, motivating, and social norms. “Concern” comments were those that expressed concern for their peer’s health and well-being and “gratitude” comments expressed thanks to fellow peers for their support. “Sharing” comments were conversation-like posts. “Motivating” comments were further categorized as congratulatory, encouragement, impressed, compliment, and verbal persuasion. “Verbal persuasion” were short, encouraging comments such as “woo-hoo” and “yay”. “Social norms” was further categorized as agreement and comparison [4]. Motivating comments accounted for 68.8% of all emotional support with verbal persuasion a prominent minor theme (50.2% of motivating comments).

Self-talk was the second most common, accounting for 22.4% of all comments. Sub-themes of self-talk included anecdote, feelings (positive and negative), planning and reflection. Anecdotes were comments that shared personal information or a personal story but were not directed to a peer. “Positive” or “negative” comments toward an individual’s own activity was coded as “feelings.” “Planning” comments were the result of an individual planning future PA. Comments where an individual would reflect on their past PA or other health behaviors were coded as “reflection”. Reflections (43.1%) and anecdotes (41.2%) were the most common type of self-talk.

Other themes, which made up 11.2% of all comments, were subcategorized as a correction, technical problems, greeting, health behavior, and unknown. Users cannot edit a previous comment within the app, therefore additional comments that fixed a previous comment were coded as a “correction”. Comments that expressed technical issues with the Up24 band or the app were coded as “technical problems”. “Greeting” comments were further subcategorized as welcome and salutation. Users have the option to also monitor their sleep and diet behavior which were the two subthemes for “health behavior”. Lastly, any other comments that could not be coded into the aforementioned themes were coded as “unknown”.

Informational support included informative and inquiry comments and made up 4.5% of all the comments. Informative support was the least prevalent comment type (3.2%). Informative comments educated peers on PA, the app, or the Up24 band and inquiry comments posed a question to peers. Instrumental support was further categorized as competition, exercise companion, and participatory support. Comments that mentioned an “exercise companion” differed from “participatory support” because the exercise companion was exercise with the individual’s friend or family member while participatory support came from discussing meeting for in-person exercise with their peers in the study. Participants were not expected to exercise with one another, but comments indicated that participants contacted one another and walked together on at least 12 occasions. All participatory support was organized in the app among the participants. Figure 3-1 illustrates the hierarchy of major and minor themes in the comments.

Figure 3-1: Social Support Themes



Discussion

The purpose of this study was to describe the social support patterns of older adults using a mobile app and to evaluate them within the context of social support theory. Giving social support was encouraged but not required as part of the overall intervention. Without being mandated to socialize with other participants, the 35 participants that used the app as part of the intervention produced a total of 1,759 comments and 3,153 likes over 12-weeks per participant. Four participants were classified as superusers because they were above the 75th percentile for all support categories (given likes and comments), while six participants were classified as lurkers for falling below the 25th percentile in given comments and not giving any likes. Comment themes followed social support theory with the most prevalent comments classified as emotional support followed by self-talk.

Our evaluation partially supports the 90-9-1 principle in that the smallest portion of participants were superusers,¹⁶² however, our sample did not follow the same distribution. We found that 11.4% (n=4) of participants were superusers while 17.1% (n=6) were lurkers and 71.4% (n=25) were contributors, making contributors the largest group which is contrary to the 90-9-1 principle.¹⁶² Despite the increase in superusers and contributors, their contribution in the app is similar to previous evaluations. Van Mierlo investigated the 90-9-1 principle in four digital health social networks. The author found that the superusers, the top 1%, accounted for 73.6% of posts while contributors accounted for 24.7% of posts.¹⁶² In our study, superusers and contributors accounted for a comparable 72.6% and 27.1% of likes, respectively. The larger proportion of superusers and contributors in our sample may be the result of the intimate nature and anonymity of the study. At any given time during the study, there were only 1 to 13 peers for a participant to interact with versus the possible hundreds of peers on a social networking site. Due to the small number of peers, participants may have felt inclined to give

support. Although previous research suggests that older adults are apprehensive to communicate with strangers,¹¹⁸ the anonymous nature of the team may have also contributed as individuals were known by their icon rather than their real name. Future research should investigate the effect of group size and icon personae on social interaction within apps or social networking sites.

Although the number of comments varied between intervention and wait-list control participants, the most prevalent comment themes remained the same. The rank of comments themes by prevalence were emotional support, self-talk, other, informational support, and instrumental support. In addition to the comments, “likes” could also be viewed as emotional support by acting as a virtual empathy tool.¹⁰⁸ Therefore, emotional support was overwhelmingly the most prevalent. It is documented that the type of support can vary based on the relationship between users¹⁰⁹ which suggests that participants predominately used the app as an emotional support system. This trend is similar to women that utilized Fitbit and its online social network.¹⁰⁷ The 20 women enrolled into a 6-week study were given a Fitbit Flex to monitor their activity as well as access to the online Fitbit system. Furthermore, they were assigned PA partners matched for starting PA level and age. The social features of the Fitbit system included a message board for communication and a leaderboard.¹⁰⁷ The author found the most prevalent comments were motivational (emotional support), followed by sharing PA ideas (informational support), and exercising with others (instrumental support). The author did not report self-talk or other types of comments. In addition to evaluating the comments, the author demonstrated that PA was highest during weeks of frequent social contact.¹⁰⁷

Social support is important in changing PA behavior for all ages.⁴⁰ Virtual support may be perceived as more inherent for young and middle-aged adults but older adults can gain further benefits from this type of support. Through virtual support, older adults can find new friend and learn tips for increasing exercise from their peers.¹¹⁸ Older adults may also be more engaged in social interaction as part of a PA intervention than their

younger counterparts. In a 12-week study among college-aged adults, participants that received incentives for social interaction produced 259 comments on a social networking website.¹⁰² This is far less than the 1,759 comments that our participants produced organically. Future research should investigate the differences in virtual social interactions between different age groups

IMPLICATIONS

Use of wearable activity monitors that have a social networking features, such as Jawbone or Fitbit, are on the rise both commercially and in research.^{77,107} However, to our knowledge, utilization of the social support features of these devices are seldom reported. Their features, like other social networking sites, require more scrutinized investigation;¹⁶³ however, they have the potential to make a widespread impact on PA promotion. The results of this investigation and previous investigations of other platforms suggest that, although individuals interact to varying degrees,¹⁶² social support provided in the apps for wearable devices follows theory.¹⁶⁴ Furthermore, the support is organic in that individuals can, at least in this program, naturally support each other emotionally without being prescribed as a part of an intervention. In combination with the other implemented behavioral change techniques,⁷⁹ this makes wearable activity monitors powerful intervention tools to encourage behavior change. Researchers and practitioners who provide these devices should encourage the use of the devices' social support features to promote PA of the individual and the population. However, despite efforts to keep a social group private as part of an intervention, other unidentified individuals can be "friended" unknowingly by the participant and personal information may be shared. This raises ethical concerns including, but not limited to, data security and bystander privacy.¹⁶⁵ Researchers and policy makers should work together to support data sharing legislature that fosters virtual social support and protects the security of the user.

LIMITATIONS

The informed consent document did not ask for clearance to share comments from the app, as we did not expect social support to be so prevalent. Therefore, this study is limited to a description. A description cannot investigate the impact of social interaction on PA change. Preliminary results from Arigo¹⁰⁷ suggest that most virtual social interaction results in more PA but these findings are not exclusive to older adults. More research is needed to evaluate if increased virtual support results in increased PA among older adults. This brief report does not provide a network analysis of the relationship between lurkers, contributors, and superusers. The majority of our participants were female which may not be generalizable to older adults that use these technologies. Future research should include a more diverse sample. Finally, due to the intervention's methodology and the inclusion of wait-list controls, the current study did not investigate the effect of social support on PA levels. The strength of this study includes a thorough description of how older adults support their unknown peers in a mobile app and evidence of the acceptability of anonymous social support via an app.

Conclusion

In the current study, participants provided a total of 3,153 likes and 1,759 comments over a 12-week intervention. Illustrating that older adults are willing to use social tools in a PA app to communicate with unknown, anonymous peers. Contrary to the 90-9-1 principle, most participants were contributors (71.4%) with only 11.4% superusers and 17.1% lurkers. Most of the comments follow social support theory, with the most prevalent type of support being emotional support. The use of these social support features within a mobile app that connects to a wearable activity monitor give these devices great potential to enhance PA promotion. Researchers and practitioners who utilize these monitors may want to encourage social support through the device. However, they should also take care to ensure privacy and security.

CHAPTER 4: THAT'S MY MEDICAL AND THIS IS MY HEALTH: THE FEASIBILITY OF A PRAGMATIC, TECHNOLOGY-BASED, PRIMARY CARE, PHYSICAL ACTIVITY INTERVENTION

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Background: Conducting 5 A's counseling in clinic and utilizing technology-based resources are recommended to promote physical activity but little is known about how to implement such an intervention. This investigation aimed to determine the feasibility and acceptability, using the RE-AIM framework, of a pragmatic, primary care-based intervention that incorporated 5 A's counseling and self-control through an activity monitor. **Methods:** Primary care patients (n=40) 55-74 years of age were recruited and randomized to receive a pedometer or an electronic activity monitor (EAM), Jawbone UP24, to monitor activity for 12-weeks. Participants were also invited to a focus group after completing the intervention. Stakeholders (n=36) were also recruited to provide feedback. **Results:** The intervention recruitment rate was 24.7%. The attrition rate was 20% with a significantly higher rate for the pedometer group (p=0.02). The EAM group increased their minutes of physical activity by 11.1 mins/day while the pedometer maintained their activity (0.2 min/day), with no significant group difference. EAM participants liked using their monitor and would continue wearing it while the pedometer group was neutral to these statements (p<0.05). Over the 12-weeks there were 490 comments and 1,094 likes given to study peers in the corresponding application for the UP24 monitor. Some EAM participants enjoyed the social interaction feature while others were uncomfortable talking to strangers. Participants stated they would want

counseling from a counselor and not their physician or a nurse. Other notable comments included incorporating multiple health behaviors, more in-person counseling with a counselor, and having a funding source for sustainability. **Conclusions:** Overall, the study was well-received but the results raise a number of considerations. Practitioners, counselors, and researchers should consider the following before implementing a similar intervention: 1) utilize PA counselors, 2) target multiple health behaviors, 3) form a social support group, 4) identify a funding source for sustainability, and 5) be mindful of concerns with technology.

Keywords: physical activity, technology, older adults, activity monitor, RE-AIM

Introduction

Habitual physical activity (PA) can reduce risk for cardiovascular diseases (CVD),^{6,10,12,18,166,167} but most older adults fall far below the recommended 30 minutes of moderate intensity PA at least 5 times a week.²⁵⁻²⁷ There are several reasons why older adults do not get enough PA including social influences, competing priorities, personal beliefs and motivation.³² The American Heart Association encourages the implementation of individual clinical and population-level strategies to target these barriers and reduce physical inactivity.⁵⁵ One such strategy is to implement 5 A's counseling within the primary care clinic.⁵⁵

Five A's counseling was developed by the United States Preventive Services Task Force to provide brief counseling within the primary care setting.⁷¹ This form of counseling is recommended over comprehensive counseling because it is short in duration and more feasible for a busy clinic.^{33,55,59,60,65,66} The 5 A's stand for assess, advise, agree, assist, and arrange.^{55,71} The assist component is particularly impactful because the clinician provides behavioral change techniques, such as problem solving and social support, that aid in changing PA behavior.⁶³ Shaping knowledge and providing

feedback through counseling are effective behavioral strategies⁴⁰ but the addition of technology is recommended to enhance counseling for individuals at moderate risk for CVD.⁵⁵

Activity monitors have the potential to enhance primary care interventions by motivating individuals to change their PA behaviors⁷⁹ while lessening the burden on clinical staff.^{55,61} Two types of activity monitors are commonly used for PA promotion: pedometers and electronic activity monitors (EAMs). Pedometers are low-tech devices that provide immediate feedback on PA and have been shown to be feasible and acceptable within primary care interventions.^{82,87,88} Conversely, EAMs are high-tech devices that can provide PA feedback, individualization, and behavior change techniques.^{77,79} There is preliminary evidence that these monitors are feasible in community interventions.⁷⁷ EAMs have potential in primary care because they offer effective behavior change techniques that may be overlooked in clinic-based counseling and they facilitate social support.¹⁰⁸ Social interaction further promotes PA because it provides emotional support^{106,109}, it allows older adults to learn PA tips from their peers,¹¹⁸ and it is associated with long term behavior maintenance.¹⁶⁸

The American Heart Association recommends a 2-tiered approach to promote lifestyle changes, like PA, in the healthcare system. The first tier is to provide low-intensity 5 A's counseling and the second tier is to utilize technology-based resources.⁵⁵ However, the adoptability of a primary care-based intervention that incorporates counseling and activity monitoring has not been studied in depth. There is also limited information on how to successfully combine and implement these types of interventions in a real world setting.¹⁶⁹

To increase the likelihood that research findings will be utilized in the clinic, interventions need to be pragmatic^{56,160,170,171} and they should be assessed for their impact on the population-level.¹⁷² The pragmatic nature of a study can be illustrated with the Pragmatic Explanatory Continuum Indicator Summary (PRECIS) tool.^{56,160,170,171}

Population-level impact can be assessed through RE-AIM indicators.¹⁷³ RE-AIM is a public health framework that describes the reach, effectiveness, adoption, implementation, and maintenance of a program.¹⁷² The purpose of the current study was to determine the feasibility and acceptability of the TAME health (Testing Activity Monitors' Effect on health) intervention within the RE-AIM framework using dimension indicators outlined by Harden et. al.¹⁷³ TAME health is a pragmatic, primary care-based intervention that incorporates 5 A's counseling and self-control through an activity monitor. Furthermore, we aimed to compare feasibility and acceptability results between two types of activity monitors: pedometer (Digi-walker CW-700/701, YAMAX, San Antonio, TX) and EAM (UP24 by Jawbone, San Francisco, CA).

Methods

The methodology for this study has been previously described in-depth,¹¹⁹ and the study is registered online at clinicaltrials.gov (NCT02554435). The methodology related to feasibility and acceptability outcomes is described briefly below.

RECRUITMENT

Study participants (N=40) were recruited from two primary care clinics affiliated with The University of Texas Medical Branch (UTMB). Clinic patients were recruited by direct solicitation from the clinic lobby and flyers posted throughout the clinic. Patients were screened for eligibility in person or over the phone. Patients were deemed eligible if the following criteria were met: age (55-74 years), physically inactive (less than 60 min/week of PA), body mass index between 25-35, in good health measured by the PA Readiness Questionnaire Plus (Par-Q+)¹²⁴ and access to a smart device. After participants were deemed eligible an initial assessment was scheduled.

In an effort to assess adoptability, stakeholders (n=36) were also recruited. Stakeholders were staff and faculty members of the medical institution who could

provide input on clinic-based practice. They were recruited via email and through an Institutional email list to take part in a focus group meeting.

INTERVENTION PROCEDURES

All study participants underwent 5 A's counseling from a counselor during their first assessment prior to randomization. The counselor was trained in exercise physiology and motivational interviewing. An example of the counseling guide is available in **Appendix A**. After counseling, participants were randomized to the pedometer group or the EAM group using a random number generator.¹²⁸

Participants in the pedometer group received the Digi-Walker CW-700/701 digital pedometer (YAMAX, San Antonio, TX). The participants also received an activity log to record their daily steps, activity time, and distance walked measured by the pedometer.

Participants randomized to the EAM group received an UP24 wearable device manufactured by Jawbone. They were instructed to install the corresponding UP application (app) to their smart device and wear the bracelet monitor daily. The UP24 was chosen for the intervention due to its popularity and its high implementation of behavior change techniques.^{79,130} In addition to monitoring PA behavior, the UP24 also measures sleep and the app allows for participants to track their diet and weight. All participants were given an anonymous UP app account and encouraged to socialize with other participants in the group through the app.

ASSESSMENT PROCEDURES

Feasibility was operationalized through evaluation of attrition, the number of days logged for activity, reported adverse events, report of technical difficulties, and social interactions in the UP app. Logged days of activity were taken from the pedometer log and from the Jawbone online data file. The effectiveness of the intervention to increase minutes of PA was measured with a SenseWear Armband. Participants were instructed to

wear the armband for a 7-day period at baseline and at 12-weeks. The effectiveness of the participants to self-regulate their behaviors was measured by the Exercise Goal-Setting Scale and Exercise Planning and Scheduling Scale.¹⁵⁴ Both scales are self-report and were administered at baseline and at 12-weeks.

Acceptability was determined through questionnaires and focus groups. Questionnaires allowed participants to answer on a range from 1 to 5 for each acceptability statement. Score 1 to 5 reflected the participant strongly disagreed, disagreed, neutral, agreed, or strongly agreed, respectively. Statements were modeled on items previously developed by Vandelanotte et. al.¹³³ Focus groups were chosen over exit-interviews to allow the opportunity for EAM participants to meet their peers that they interacted with through the app. Participant focus groups were open to 2-8 individuals within the same study group and lasted for approximately 1 hour. The focus group structured guide was developed by ZHL and EJJ (**Appendix E**). The discussions were led by two trained, blinded Masters-level interns who were well-versed on the study protocol and the study activity monitors. Focus groups were broken up by intervention group and clinic location.

Additional focus groups were conducted with stakeholders (**Appendix F**). These discussions were led by the principal investigator, ZHL. During the focus group, stakeholders were prompted to fill out two brief quantitative surveys. After the focus group, stakeholders had the opportunity to test the UP24 monitor for 4-weeks and provide feedback on usability.

Feasibility and acceptability results were organized into dimensions of RE-AIM.¹⁷³ Indicators of Reach included the recruitment rate, participant characteristics, and focus group participation rates. Effectiveness included follow-up results of PA and self-regulation, percent attrition, rates of adverse events, and quantitative acceptability results. Qualitative comments about the delivery of the interventions were used as indicators of Adoption. Implementation indicators included the report of technical difficulties, number

of logged activity days, and participant perceptions of the intervention. Maintenance was divided into individual and organizational. Indicators of individual maintenance included quantitative and qualitative results of monitor usability. Stakeholder perceptions of the intervention were used as an indicator of potential organizational maintenance.

STATISTICAL ANALYSES

The Statistical Package for the Social Sciences (SPSS, version 20) and NVivo 11 Pro (QSR International) were used to perform the quantitative and qualitative analyses, respectively. The α -level was set at 0.05. Descriptive statistics across intervention groups were calculated by means, medians, and frequencies. Comparisons between groups for feasibility and acceptability were analyzed by an Independent T-Tests and Chi-Square tests. PA, exercise goals, and exercise planning was assessed with an analysis of covariance using the intent-to-treat principle and controlled for baseline values of the dependent variable.

Thematic analyses¹⁵⁹ were conducted to analyze data from the focus groups. We chose thematic analysis because we wanted to describe participant and stakeholder perspectives of the main study components. Initial codes were developed prior to the focus groups and new codes were added based on new data. All focus groups were audio-recorded and data transcripts were written out by the principal investigator. The moderators were asked to verify any inaudible segments.

PRAGMATIC EVALUATION

The PRECIS-2 figure was used to illustrate the explanatory and pragmatic components of a study.^{170,171} Each study component was rated on a 1-5 scale with 5 being the most pragmatic. The figure of a mostly pragmatic study will be closer to the outside circle. The study components included: eligibility, recruitment, setting, organization, flexibility-delivery, flexibility adherence, follow-up, primary outcome, and primary

analysis.^{170,171} The PRECIS-2 figure for the TAME health study was rated by Principle Investigator and is available in **Appendix J** and illustrates that this intervention was largely pragmatic.

Results

Complete demographic information is illustrated in **Table 4-1**. Feasibility and acceptability results are described below by each dimension of the RE-AIM framework.^{172,173} Complete quantitative results are presented in **Tables 4-2 and 4-3**. Feedback from the focus groups was centered around 4 major themes: TAME health, self-monitoring, social support on the UP app, and counseling from the counselor or from a health care provider. Example quotes from the focus groups are presented in **Table 4-4**.

Table 4-1: Participant demographic information (n=40)

	EAM	Pedometer	All
	n (%)		
Age, years; mean (SD)	64 (5.1)	63.2 (5.7)	63.6 (5.3)
Body mass index, kg/m ² ; mean (SD)	30.0 (3.2)	30.6 (3.1)	30.3 (3.1)
Female	17 (85)	13 (65)	30 (75)
Hispanic	3 (15)	2 (10)	5 (12.5)
Black/ African American	4 (20)	3 (15)	7 (17.5)
Other	1 (5)	1 (5)	2 (5)
Non-Hispanic White	12 (60)	14 (70)	26 (65)
College or Graduate/Professional school	10 (50)	12 (60)	22 (55)
Some college or technical school	8 (40)	7 (35)	15 (37.5)
High school diploma/General education development	2 (10)	1 (5)	3 (7.5)

Table 4-2: Feasibility results

	Pedometer (n=20)	Electronic activity monitor (n=20)
Days of recorded step data, mean (SD) [▽]	71.4 (11.5)	73.1 (21.5)
Attrition rates, n (%) [*]	7 (35)	1 (5)
Moderate/high adverse events, n (%)	1 (0.05)	3 (15)
Report of technical difficulties, n (%)	10 (50)	13 (65)
UP app usage		
Likes given through the UP app, median (IQR)		0.0 (38)
Likes on user's own activity, median (IQR)		3.5 (31)
Comments given through the UP app, median (IQR)		0.0 (15)
Comments on user's own activity, median (IQR)		0.0 (4)
app: application; IQR: Inter-quartile range; SD: Standard deviation		
*p<0.05		
[▽] The reported means and standard deviations are based on participants with complete step data (pedometer, n=9; electronic activity monitor, n=19). Pedometer step data was based on returned physical activity logs. Electronic activity monitor step data was retrieved from an online server.		

Table 4-3: Acceptability results from the follow-up questionnaire

	Pedometer (n=12)	Electronic activity monitor (n=19)	Stakeholder (n=6)
Feelings about the study	Mean (SD)		
I felt the counseling was motivational	3.8 (1.2)	4.1 (0.7)	
The exercise prescription was helpful	3.8 (0.8)	3.8 (1.0)	
I would prefer if there were more counseling sessions	3.0 (1.0)	3.5 (1.3)	
Feelings on the activity monitor			
It was easy to remember to wear the monitor	3.5 (1.6)	4.5 (0.8)	3.2 (1.33)
I felt that the monitor was comfortable	4.2 (1.2)	4.1 (1.0)	4.2 (1.0)
I would continue to wear the monitor*	3.5 (1.5)	4.4 (0.9)	3.7 (1.2)
The monitor was motivating	3.7 (1.1)	4.4 (1.0)	3.5 (0.8)
I liked using the monitor**	3.0 (1.4)	4.4 (1.0)	4.0 (0.6)
I thought the pedometer was helpful	3.3 (1.4)		
I would prefer to use another type of monitor	3.1 (1.3)	2.4 (1.3)	2.0 (0.9)
I have a better understanding on my physical activity level	3.8 (1.1)	4.4 (1.1)	3.5 (1.0)
Feeling on the Jawbone UP application			
It was convenient for me to use the UP application		4.6 (0.8)	4.2 (0.8)
The UP application encouraged me to view my steps		4.7 (0.7)	4.2 (0.8)
I would like to continue using the UP application		4.5 (1.1)	3.8 (0.8)
I think the application is user-friendly		4.3 (1.2)	3.8 (0.8)
I enjoyed the social interaction		3.7 (1.0)	N/A
Comments and smiles from my “friends” in the application were motivating		3.9 (1.2)	2.7 (0.8)
I think the information is interesting		4.6 (0.5)	4.0 (0.6)
I think the information is relevant		4.5 (0.6)	3.8 (0.4)
I think the tips and advice are specific to me		4.0 (0.9)	3.8 (0.8)
I am going to use the advice		4.4 (0.7)	3.3 (0.5)
*p<0.05, **p≤0.01, Significantly different between pedometer and Electronic activity monitor group			

Table 4-4: Example quotations from study groups

	Electronic activity monitor	Pedometer	Stakeholder
TAME health study	<i>It's a good idea. I think, I would really advise it for anybody that wants to try and get themselves going. I think belonging to something like this is a really good idea. Female, 73</i>	<i>That was an education for me. Just to wear it and to see how much I actually did in a day's time. Female, 72</i>	<i>Even though people dropped out and there was damage with some of the monitors, just the fact that every group increased their activities and their steps. I think you can definitely tell that this encouraged and motivated them to be more active than they usually would have been.</i>
Self-Monitoring	<i>I even would like to get one for myself and my husband so we can both keep track of our activity. Female, 73</i>	<i>I would probably go out and buy one because I think it's really good psychologically, to have something that you can actually see. Female, 72</i>	<i>If we didn't have it to give to them, they couldn't afford it.</i> <i>There's certain patients that you know are going to be engaged in that way and others that if you told them that was an additional step that would maybe turn them away from it.</i>
Pedometer		<i>I like the convenience of knowing how active I've been or how inactive that I've been, and what time frame. Female, 72</i> <i>It also irritated my belly, you know that's where I had it sitting. Female, 66</i>	<i>The belt clip ones, well relatively, they're the ones that are bound to go in the toilet or dropped.</i>

	Electronic activity monitor	Pedometer	Stakeholder
		<i>You had to have it in a certain position on your waist or it wouldn't read. I had a week where it didn't read for a few days. Male, 56</i>	
UP24	<p><i>I liked the Jawbone because it was comfortable. I would put it on in the morning and I never felt it again. It didn't bother me at all, and it's not awful looking. Female, 55</i></p> <p><i>No complaints except that they're going out of business. That's why I didn't buy one. Female, 68</i></p> <p><i>My neighbor was in the program also, ahead of me... She was energized and she had the iPad, which is more conducive or complimentary with it. I have an [Android] tablet. So the interface for me was not as gratifying as hers. It worked again me which I didn't need. Female, 68</i></p>		<p><i>I think that recommending this to someone who is comfortable with technology. Otherwise, if you go bombard them with all these types of data and statistics, they may not know exactly what it is they're looking at.</i></p> <p><i>I would think something like this for most people in this room works. We all have smartphones, but in terms of the patients we see. I would say maybe one out of every 10 have a smartphone. A good portion of them don't have Internet at home so connecting to an app or something like this is pretty... even though it's prettier and great for us it may not be useful for an older population.</i></p>
Social support on UP app	<i>I was on there maybe a week when I met cowboy. She kept hitting goal and she had a small goal because she [had] knee surgery and I said 'do you want to meet to walk?' I just assumed everybody was in Galveston.</i>		<i>Even for me as an adult. I have friends that we do like that challenges that you can do. Even as adults that's something we do very regularly. So see who can win.</i>

	Electronic activity monitor	Pedometer	Stakeholder
	<p><i>Well she wasn't, she was in League City. So we met in Texas City. Female, 64</i></p> <p><i>If I saw that somebody had done a lot that day I would give them a thumbs up and stuff like that... and then other people would encourage me and I didn't know who they were either but their icon. Female, 68</i></p> <p><i>I understand the rationale for the anonymity but I'm just sitting here thinking now, that for me, probably if I met everybody I would have been much more social. Female, 61</i></p>		
Counseling from the counselor	<p><i>I think that's good to have somebody else that maybe is a little more informed than your family or your friends or even reading about it. It is good just to have a face to face. Female, 73</i></p>	<p><i>[I felt] very, very comfortable. It was not like that she was speaking above my head and I'm going 'I don't have any idea what she's talking about'... like I said, she was always very supportive and I think that made the big difference too. Female, 72</i></p>	
Counseling from health care provider	<p><i>No. I've got a great primary care physician here but I love that it was separate from that. Ya know, because that's my medical and this is my health. Female, 61</i></p>	<p><i>It's just like those two things seem to be separate in my mind. I just feel like they, everybody in the doctor's office is so busy. With [the counselor], I felt that she had all the time in the world to deal with me. Female, 66</i></p>	<p><i>It just depends...if there was a part of the process that said, hey the social worker can go in and do the counseling for this [patient] versus taking away a MA or a nurse that would be maybe triaging or</i></p>

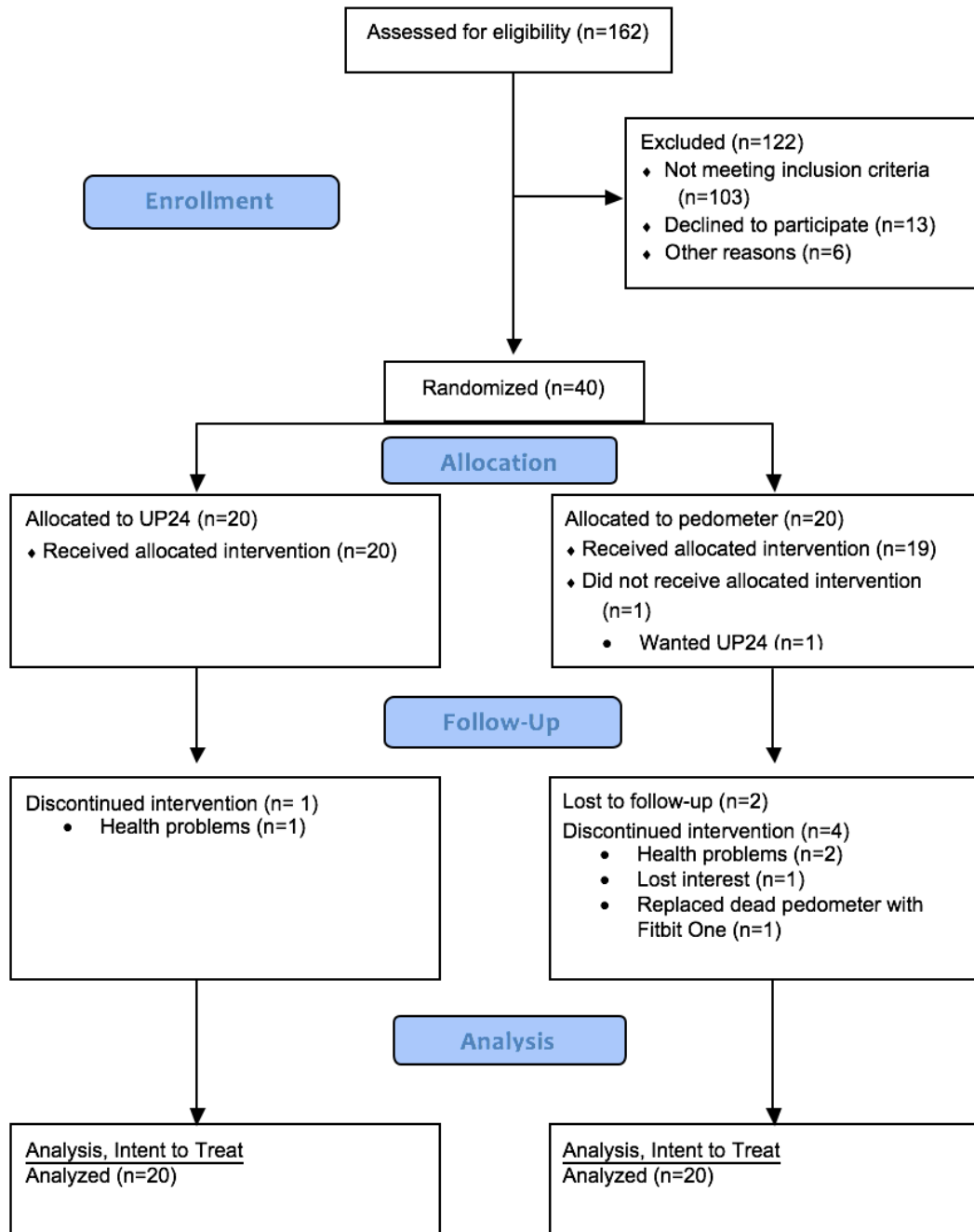
	Electronic activity monitor	Pedometer	Stakeholder
	<i>No, I don't think I would especially like that because I don't think the primary care physician has time enough. They're usually trying to take care of whatever your current problem is. They want to hit on several different things and I don't think exercise or diet is big in their specialty area. They just either don't take the time or don't know enough about it to individualize it for you. So I think it's better to have someone else do that. Female, 73</i>	<i>[My physician] takes care of my boobos and my ouches and ooze and 'what-the-heckes' kind of stuff. This other thing... I mean, they'll sit and tell you 'you need to exercise Hunny' but they don't' really give you a plan or that's just not their job. Female, 72</i> <i>In my opinion a nurse or a doctor, they're not... they're a doctor. They can give you some advice on how to... what you need to do but as far as how to get it done, that's not their area of study. Male, 56</i>	<i>drawing blood or doing something else.</i> <i>Would I tell my nurse to do that? Yes. Or would I ask my nurse to do that and would she participate in that, yes. I mean, I think I do have support staff that will do that. Do I think it's important? Absolutely.</i>
5A's structure	<i>You have to advise with assess. Without... looking at those numbers probably would not have meant as much. Female, 64</i> <i>I think with [the counselor] suggesting, well maybe you can start with at least 5000 [steps], it gave me something to work toward. So I eventually did get there and I even got up to where it was not unusual for me to get 10,000 steps. Female, 61</i>	<i>Maybe number 2 [advise]... If I was going to do this, I was going to do what I was told to do. Female, 72</i> <i>Agree, reach agreement, that helped too because you can set a goal then. Male, 56</i>	<i>I've actually done it without knowing it. It's pretty much what I do with patients.</i>
Exercise prescription	<i>It was [helpful]. I have a hard time remembering things and forming habits so this was up on my board. So</i>	<i>Everything I got was really [an] eye opener because of seeing it in writing, and it's just to you. It's not</i>	<i>To me it seems the prescription was almost more motivating in the sense that now they have something they</i>

	Electronic activity monitor	Pedometer	Stakeholder
	<i>I saw it every day. I would say 'Oh that's right my goal's 7000' what do I have, oh I only have 4 [thousand], I better go for a walk. That helped, but it was a starting point and it was necessary. Female, 64</i>	<i>the household or anything. IT's only up to you to do these things that are listed here. So that was a good prescription. A good incentive to look and see. Female, 72</i>	<i>received from a clinician that says, this is what I recommend to you.</i>

Reach

Recruitment rate is displayed in **Figure 4-1**. A total of 162 individuals were screened for eligibility over 8 months (October 2015- June 2016), and 42 were eligible. Two eligible participants dropped out before randomization due to care-giver responsibilities and work commitments. The resulting recruitment rate was 24.7%. Twenty-seven (67.5%) participants were recruited in-person at the clinic, 8 (20%) were recruited through flier postings, and 5 (12.5%) were referred by a friend or employee that heard of the study from the clinic. Eight (20%) participants were not clinic patients. Four of these individuals were referrals while 4 were recruited in-person while at the clinic with their family.

Figure 4-1: Recruitment flow diagram



At baseline participants had a mean age of 63.7 ± 5.3 years (EAM: 64 ± 5.1 , Pedometer: 63.2 ± 5.7). Most participants were female (total: 75%, EAM: 85%, Pedometer: 65%), non-Hispanic White (total: 65%, EAM: 60%, Pedometer: 70%), and

had a college degree (total: 55%, EAM: 50%, Pedometer: 60%). The EAM group and the pedometer group averaged 22.6 ± 24.5 and 40.0 ± 33.9 minutes of moderate or vigorous PA a day, respectfully. There were no significant group differences among these variables. Stakeholders were predominately clinical faculty and professors (33%). Other stakeholder positions included physician, nurse, social worker, graduate student, epidemiologist, researcher, research coordinator, post-doctoral fellow, and administration.

There were 6 scheduled focus group meetings for study participants. Of the 36 study participants that were invited to take part in a focus group, 11 participated (8 EAM, 3 Pedometer). Four participants were not invited because they ended the intervention several weeks after the majority of participants. Although focus groups were planned, several of the meetings (4 out of 6) resulted in a one-on-one interview due to low attendance. These interviews followed the same structured question guide. There were two scheduled stakeholder focus group meetings that reached 36 individuals.

Effectiveness

Over 12-weeks the EAM and pedometer group increased their minutes of moderate or vigorous PA by 11.1 and 0.2 minutes per day, respectively. The groups were not statistically different in their rate of PA at 12-weeks ($p=0.29$, $d=0.78$). Groups were significantly different in exercise goal-setting and planning scales ($p<0.01$). The EAM group increased 8.3 ± 9.8 and 3.6 ± 7.6 points in goal-setting and planning while the pedometer group increased by 1.7 ± 5.3 and 0.3 ± 4.1 points, respectively. The resulting effect size was large for goal-setting ($d=0.84$) and planning ($d=0.55$).

Overall attrition was 20%, which differed significantly between groups ($p=0.02$). Two participant (pedometer group) were lost to follow up and 6 participants (EAM: 1, Pedometer: 5) did not finish the intervention. The EAM participant dropped out due to physical health issues. Reasons for pedometer participants not completing the intervention included: randomized to the pedometer but wanted the EAM ($n=1$), physical

health issues (n=2), lost interest (n=1), and replaced broken pedometer with an EAM (n=1). Participants that dropped out had a significantly higher goal-setting score at baseline. In addition to the drop-outs, two participants (EAM: 1, Pedometer: 1) did not complete the final assessment but provided PA data and/or subjective data.

There were no moderate or severe adverse events related to the study. However, there were four moderate unrelated adverse events during the study. Two participants scheduled a knee replacement at the time of consent and their initial assessment was postponed until completion of physical therapy. The other events involved an emergency room visit for kidney stones and an adverse reaction to physician prescribed medication.

Only 7 stakeholders agreed to wear the UP 24 and all but 1 provided feedback. Of these, 3 only tested the monitor and did not take part in a focus group. Study participants and stakeholders agreed that the study and UP24 monitor were mostly acceptable. EAM users agreed that they liked using the monitor and that they would continue wearing it while pedometer users were neutral to these statements ($p < 0.05$).

Adoption

Participants felt that the doctor's office was too regimented, and this study is something they did for themselves, not for their doctor. Moreover, the participants expressed that PA is separate from primary care. As one participant stated "I've got a great primary care physician here but I love that it was separate from that... because that's my medical and this is my health (Female, 61)." The study participants enjoyed counseling from the counselor and would not want counseling from a health care provider. However, they would like if the counselor was part of the health care team and had access to their medical record. Participants wanted more in-person counseling sessions and counseling on other health behaviors. The EAM group found all of the 5A's components helpful while the pedometer group found "Advise" the most helpful. The exercise prescription after counseling was also helpful to participants.

Stakeholders liked the counseling format but stressed it would need to be individualized to the patient. Practitioners often use one of the 5A's components but do not recognize it as 5A's counseling. Stakeholders also commented that the physician would not have time to conduct the "arrange" call but it could be done by a clinical staff member. Like study participants, stakeholders liked the exercise prescription. They would alter the prescription to have more "I will..." language, more planning details, and prescribe both steps per day and minutes of PA.

Implementation

There were 28 reports of technical issues across 21 participants during the intervention. All broken or lost monitors were replaced and all other technical issues were resolved. Five pedometers were lost, 5 pedometers broke, and participants sought help from the research staff for assistance with getting data from the pedometer on 3 occasions. There were 2 reports that the UP24 would not hold a charge, 5 reports of UP24 Bluetooth connectivity issues, 3 reports that the UP24 would not record activity and 1 UP24 was lost. During the intervention 4 participants got a new phone or downloaded the UP app on a different device. Three of these participants sought assistance from the research staff while 1 participant created their own UP account and was no longer connected to the rest of the group. Over the 12-weeks participants logged an average of 72.6 days of activity. There was no difference between groups in logging at least 80% of activity days.

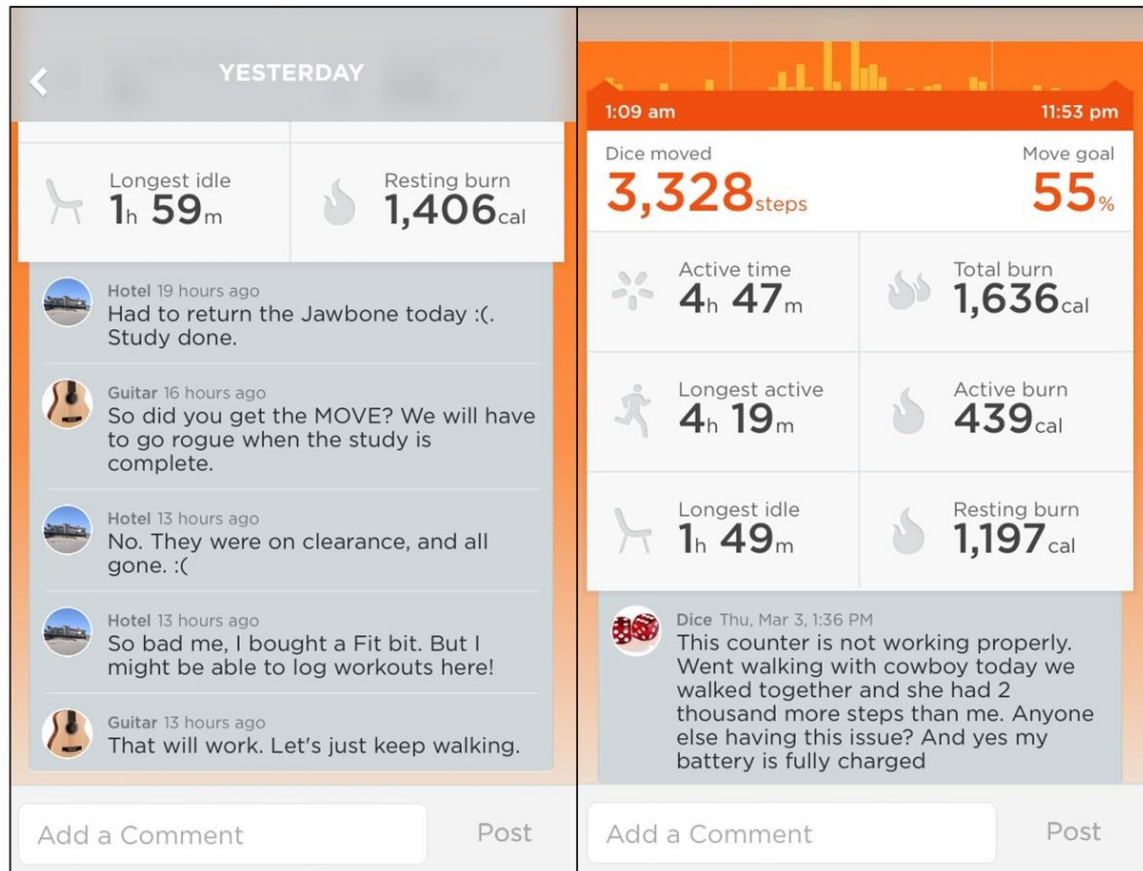
Overall participants reported liking the TAME health program. Participants found it educational to know how active they were in a day and the monitor they used (pedometer or EAM) became a part of them. One of the most motivational aspects that participants reported was having a goal in mind. Despite enjoying the program, participants wanted a multiple behavior change intervention that also targeted water consumption, diet, and sleep.

Maintenance: individual

Participants in both study groups questioned the accuracy of the devices and how they recorded the activity. Both monitors were admired for being easy to use, convenient, and discreet. Of the participants that used the UP app, some liked that it synced with another device while others wanted direct feedback on the monitor. The app was also user friendly for most. Both groups complained that the device could irritate the skin. EAM users disliked the number of technical and syncing issues, as well as the interface on Android versus Apple products. Furthermore, EAM users were confused by some of the biometrics presented in the UP app. In particular, participants didn't understand how "resting burn" (resting energy expenditure) could be more than "active burn" (active energy expenditure). Pedometer users disliked that the pedometer would only count steps when worn in a certain position. In the face of complications, participants would continue to use the type of device they wore.

Over the 12-week intervention there were 490 comments to study peers and 299 self-comment (comments on the user's own activity) on the UP app. There were 1,094 likes given and 104 likes on the user's own activity. Ten participants did not give any likes or comments to their peers and only 3 of these 10 had at least 1 self-comment. Despite this, every participant received at least 1 comment and 1 like from one of their peers. The most comments and likes given by a single participant was 315 and 434, respectively. During the 12-weeks, participants had 10 to 19 peers to interact with. Comment examples are presented in **Figure 4-2**. Some EAM participants reported enjoying the socializing features and interacted with others regularly. Others did not use any of the social support features, reporting that they did not know the other participants or their health status.

Figure 4-2: Social Interaction on the UP app



Stakeholders believed that self-monitoring may be very beneficial for some patients but not others. They were concerned with the cost of the monitors and their accuracy. For pedometers, stakeholders felt that it may work with an older population but pedometers have limitations. Some limitations cited by the stakeholders include: flimsy, bulky, sensitive to measurement, difficult to read, short battery life, and easy to lose. Stakeholders felt that the EAM is carefree, easy to wear, and it has some attractive features (i.e. competition, Smartcoach). However, there may be a technology barrier for use by patients.

Maintenance: organizational

Prior to the focus group presentation, 90.6% of stakeholders believed that counseling is effective to change behavior while 53.1% actually counselled patients on

becoming more physically active. Similarly, 84.8% of stakeholders believed that activity monitors can change behavior while 18.8% advised patients to use an activity monitor. After the presentation, stakeholders somewhat agreed that they would recommend an EAM over a pedometer for their patients (3.4 ± 1.2) and that the intervention can be implemented into their clinic (3.3 ± 1.1). Despite this, stakeholders had positive reactions to TAME health. They felt that counseling is already a part of practice behavior and the other aspects of the study can be implemented into the clinic if there was a funding source, like grants or insurance, to supply patients with monitors.

Discussion

The purpose of this study was to evaluate the feasibility and the acceptability of a pragmatic, primary care-based PA intervention within the context of the RE-AIM framework. Overall, the study was feasible with adequate retention, sufficient number of days of recorded activity, no study-related adverse events, and plentiful social interaction on the UP app. The study was reasonably acceptable for participants and stakeholders. Notable comments include incorporating multiple health behaviors, more in-person counseling with a counselor (not a health care provider), and having a funding source to supply activity monitors to patients. Based on the feasibility and acceptability scores, the EAM intervention appears to be more feasible and acceptable than the pedometer intervention on some indicators of reach, effectiveness, implementation, and maintenance.

Our reach, effectiveness, and implementation findings are comparable to other primary care-based studies and interventions that utilized an EAM. Our retention rate of 82.5% is within the 60.7 to 95% retention rate cited in other primary care-based studies^{82,174,175} and an EAM yields a lower attrition rate than health education alone.¹⁷⁶ Similar to a Fitbit-based intervention⁹⁸, we saw no adverse events related to the intervention. Only 1% of our participants had an unrelated event which is lower than the

2-19% reported in primary care-based studies.^{87,175} Like other study participants that used an EAM,^{98,101,177-181} EAM participants in the present study met the 80% recommended wear time. Reports of technical issues using activity monitors vary widely from 16%⁹⁸ to 90%.¹⁰¹ Approximately 50% of our participants reported an issue which is line with the 58% of chronically-ill patients that used an EAM system.¹⁶⁹

In terms of individual maintenance, there was less social interaction among TAME health participants compared to a previous evaluation of 35 community-dwelling adults aged 55 to 79 years using the UP app (see Chapter 3). Over a 12-week intervention, the thirty-five participants produced 1,759 comments and 3,153 likes. With the most likes and comments given by one participant was 986 and 344, respectively. In this evaluation, 31 out of 35 participants socialized with the app. In the present study, half of the participants that used the UP app did not give support to other participants but social interaction was still prevalent. Both the current study and previous investigation of adults 55 years of age and older found that older adults organically produce over 400 comments in 12-weeks, which is more than the reported 259 comments from college-aged adults over 12-weeks.¹⁰²

Other indicators of potential individual maintenance in our TAME health study were similar to other activity monitor interventions. We found that participants found the EAM more helpful and participants were more likely to purchase a similar EAM. Based on previous investigations, evidence suggests that older participants find a Fitbit EAM three times more helpful than a pedometer,⁹⁸ they would continue to use an EAM,¹⁸² and they would purchase an EAM over a pedometer.¹⁸³ Our participants also had similar sentiments in that the monitor made them more aware of their activity, the pedometer was enjoyable because it was simple, the EAM is easy to use and put on but can cause some irritation.^{101,183}

TAME health participants and stakeholders expressed opinions related to adoption and organizational maintenance that reflect known barriers and considerations

of behavioral counseling in primary care. It is suggested that counseling include multiple sessions and targets multiple health behaviors.^{33,56,184} Patients find advising helpful but they also value all constructs of 5A's counseling which are not often performed by practitioners.¹⁸⁵ Practitioners perceive self-monitoring effective to change behavior and easier than counseling.¹⁸⁶ Health care providers lack the time and skills necessarily to complete effective PA counseling.^{187,188}

CONSIDERATIONS FOR IMPLEMENTATION

Our results raise a number of considerations. PA counseling in primary care is incentivized under Patient Protection and the Affordable Care Act and obesity counseling is covered, with stipulations, under The Centers for Medicare and Medicaid Services.¹⁸⁷ However, TAME health participants overwhelmingly expressed that they would prefer counseling from a counselor over their primary care physician. The first consideration is to incorporate PA counselors in primary care. As we observed, recruiting and identifying individuals in the primary care clinic provides great reach to patients and caregivers alike and, therefore, primary care should continue to act as a platform to initiate behavioral counseling.^{61,63,67,189} Use of designated PA counselors in primary care is feasible and has been shown to produce favorable changes in body fat and PA.¹⁹⁰ Behavioral health providers are already members of the primary care team and consult with medical providers but they are underutilized for health behavior change.¹⁹¹ Alternatively, community health workers (e.g. allied health professionals) could undergo specialized training and be included as part of the routine primary care practice to promote PA.^{55,192} Moreover, targeting multiple health behaviors in counseling should be considered.^{33,56,184}

Practitioners, counselors, and researchers should also consider forming a support group where patients can meet. Social support is associated with PA maintenance among older adults⁴⁶ but some individuals may be apprehensive of virtual support.¹¹⁸ Our

participants expressed that if they met with fellow participants, they would have socialized in the app and would not feel hesitation.

Identifying a funding source that provides monitors and technical support to patients to sustain the intervention should also be considered. We found that some individuals are willing to buy their own monitor but a funding source may still be necessary to supply technical support. Similarly, practitioners, counselors, and researchers should be conscious of potential concerns using technology. Ease of use and offering a variety to patients should be considered in selecting technologies. Further, users must be mindful of the longevity of available technologies. The SenseWear armband and the Jawbone UP24 used in this study are no longer manufactured for commercial use. Other comparable monitors are available but the type should be based on available resources and patient needs.

STRENGTHS AND LIMITATIONS

The major strength of this study is that it assessed the feasibility and acceptability of a recommended intervention to prevent CVD. It was also a comparative evaluation of two common types of activity monitors that uses a mixed-methods approach. Furthermore, we presented the pragmatic nature of the intervention and presented the results within the RE-AIM framework which directly provide a foundation for optimizing future intervention implementation and adoption.

This study is limited to the reports from participants that completed the study. With one exception, there is no acceptability information from participants who dropped out or were lost to follow up. Based on inclusion criteria and recruitment strategy, the results are also not generalizable to all patients and potential stakeholders. Lastly, this is a short-term pilot study that was not able to objectively assess maintenance and should not be taken to indicate efficacy.

Conclusion

The TAME health study used the RE-AIM framework to evaluate the feasibility and acceptability of a pragmatic, primary care-based, PA intervention that incorporated 5 A's counseling and activity monitoring. Overall, the study was well-received but the Jawbone UP24 appears to be more feasible and acceptable in some respects than a pedometer. Practitioners, counselors, and researchers should consider the following before implementing a similar intervention: 1) utilize PA counselors, 2) target multiple health behaviors, 3) form a social support group, 4) identify a funding source for sustainability, and 5) be mindful of concerns with technology.

Appendices

Appendix A: 5 A-S counseling guide

Appendix E: Participant focus group guide

Appendix F: Stakeholder focus group guide

Appendix J: PRECIS-2 Figure

CHAPTER 5: EFFECT OF ELECTRONIC ACTIVITY MONITORS AND PEDOMETERS ON HEALTH: A PILOT RANDOMIZED PRAGMATIC TRIAL

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Background: Brief counseling and self-monitoring with a pedometer are common practice within primary care for physical activity promotion. It is unknown how high-tech electronic activity monitors compare to pedometers within this setting. This study aimed to compare the effectiveness of an electronic activity monitor and a pedometer to increase physical activity and decrease cardiovascular disease risk.

Method: Forty overweight, sedentary participants 55-74 years of age were randomized to wear a digital pedometer (Digi-walker CW-700/701) or an electronic activity monitor (Jawbone UP24) for 12-weeks. Physical activity was measured objectively for 7 days at baseline and follow-up by a SenseWear monitor and cardiovascular disease risk was estimated by the Framingham risk calculator. **Results:** The electronic activity monitor group increased their physical activity by 11.1 min/day and decreased their cardiovascular risk score by 0.12 points. The pedometer groups had modest changes in physical activity (0.2 min/day) and cardiovascular risk (0.03 points). Compared to the pedometer, the electronic activity monitor intervention produced a medium effect on waist-to-hip ratio ($d=0.45$) and physical function ($d=0.46-0.49$). There were no statistically significant differences between groups. **Conclusion:** The low-intensity nature of this study has the potential to impact the health of primary care patients but large-scale trials are needed to test its effectiveness on a population-level.

Key Words: cardiovascular, older adults, activity monitor, primary care, physical activity

Introduction

Cardiovascular disease (CVD) is the leading cause of death world-wide;¹ however, approximately 12% of CVD related deaths are attributed to physical inactivity.⁵ For primary and secondary prevention of CVD it is recommended that individuals take part in at least 150 minutes of moderate intensity physical activity (PA) a week.³ For older adults, who have an increased risk for CVD,³ this recommendation equates to 7,000 to 10,000 steps per day.²⁹ Unfortunately, older adults fall far below this recommendation.²⁵ Self-monitoring of behavior is an effective behavioral strategy to increase PA among inactive individuals.¹²³

Electronic activity monitors (EAMs) are commercially-available technologies that are recommended to self-monitor behavior.⁹² EAMs are operationally defined as “a wearable device that objectively measures lifestyle PA and can provide feedback, beyond the display of basic activity count information, via the monitor display or through a partnering application to elicit continual self-monitoring of activity behavior.⁷⁷” EAMs are growing in popularity, with approximately 3.3 million units sold in 2014.⁹³ They provide an adequate estimation of PA¹³² and they are proliferating in community-based PA interventions.⁷⁷ In addition to self-monitoring of behavior some EAM devices offer other behavioral change techniques such as: providing feedback, goal-setting, planning, social support, social comparisons, commitment, instructions on how to perform a behavior, and information on consequences.⁷⁹ There is evidence that EAMs can increase PA and improve CVD related outcomes⁷⁷ but evidence is lacking on their effectiveness in a primary care setting.⁹²

PA interventions through primary care are common in CVD prevention for they rely on the strong clinician-patient relationships and the longitudinal nature of primary care.⁶³ It is recommended that these interventions take a 2-tiered approach to promote PA

incorporating both brief behavioral counseling and technology-based resources.⁵⁵ Pedometers can be used as a technology resource to facilitate self-monitoring of PA.⁸⁷ Pedometers are low tech activity monitors that can significantly increase and maintain an individual's level of PA.⁸⁷ Despite their frequent utilization in primary care based interventions, pedometers have several limitations. Pedometers have been scrutinized for their inaccuracy⁵⁷ and their limited methods for motivating exercise.⁹⁰ Furthermore, they do not provide features that are central to preventing CVD such as providing education and customizability.⁷⁶ For these reasons, EAMs may be more successful for primary care interventions.

EAMs are attractive in primary care because they have the appeal of pedometers while having a potentially higher effectiveness. Even with a modest effect size, the potential reach of EAMs and brief counseling in primary care could produce a large public health impact. Therefore, we conducted the TAME health (Testing Activity Monitors' Effect on health) randomized controlled trial which aimed to compare the effectiveness of an EAM and a pedometer to increase PA and decrease CVD risk within the primary care setting. We hypothesized that individuals in the EAM group would demonstrate greater improvements in PA and CVD risk than the pedometer group. We also hypothesized that the EAM group would have greater improvements in secondary outcomes than the pedometer group.

Methods

The methodology of TAME health is described succinctly below, further details on methods have been previously published.¹¹⁹ This study was approved by the University's Institutional Review Board and is registered on clinicaltrials.gov (NCT02554435). This study also follows CONSORT reporting guidelines (**Appendix K**).

SAMPLE

Older primary care patients (N=40) were recruited to participate in the 12-week TAME health randomized controlled trial. Patients aged 55-74 years with a body mass index of 25-35 kg/m², fewer than 60 minutes of planned exercise a week, access to a smart device and in good health were eligible. Participants were recruited in person or through posted flyers at two clinics affiliated with a large university-based health care system. Recruitment was conducted from October 2015 to June 2016. Screening for eligibility was conducted in person and over the phone. Once an individual was deemed eligible, informed consent was promptly obtained and assessment visits were scheduled.

INTERVENTION

All participants received brief 5 A's counseling which is optimized for primary care.⁷¹ The counseling components included: assess, advise, agree, assist, and arrange. During the counseling a researcher with a background in exercise physiology and training in motivational interviewing reviewed the participant's PA levels, agreed on step goals, and taught behavioral change strategies. After counseling, the researcher provided an exercise prescription and randomized the participant. Due to the nature of the intervention, the participants and the assessor were not blinded to group assignment after randomization.

Participants were randomized to one of the two groups: pedometer or EAM group. Participants in the pedometer group were given a digital pedometer (Digi-walker CW-700/701, YAMAX, San Antonio, TX) and a PA log to record their daily steps, activity time, and distance walked. Participants in the EAM group were given an UP24 monitor by Jawbone (San Francisco, CA) and downloaded the corresponding UP app on their personal smartphones. The UP system offers an array of behavioral change techniques including: goal setting on behavior and health outcome, providing instructions

and information on consequences, as well as facilitating social support.⁷⁹ More detailed information on the specific features of the UP system is available elsewhere.¹¹⁹

MEASURES

The study consisted of two assessments conducted at baseline and at 12 weeks. All assessments were conducted at the two clinic locations. The primary outcome variables of interest were CVD risk and PA. CVD risk was measured using the Framingham non-laboratory risk equation¹³⁴ and from fitness measured by the six minute walk test.¹³⁵ Variables used in the Framingham equation included sex, age, treatment of hypertension (yes or no), smoking status (yes or no), diabetes diagnosis (yes or no), systolic blood pressure, and body mass index. PA was measured across a 7-day period prior to each assessment using a Sense Wear Armband (BodyMedia, Pittsburgh, PA).¹⁴³

Secondary outcome variables included: anthropometrics, body composition, blood pressure, resting pulse, health status and quality of life, and physical function. Anthropometric measurements included height (cm), weight (kg), and body mass index (kg/m^2) using a portable stadiometer (Seca Corp., Hamburg, Germany) and a portable, calibrated electronic scale (Tanita, Arlington Heights, IL). Body composition was estimated by measuring waist and hip circumference (cm) and calculating the waist-to-hip ratio. Blood pressure and resting pulse was taken using a portable sphygmomanometer (Omron BP742N, Lake Forest, IL). Physical function was measured objectively through a repeated chair stand and balance test, as defined by the Short Physical Performance Battery,¹⁵⁰ and an 8-foot up-and-go test, as outlined in the Senior Fitness Test.¹⁴⁰ Due to the known ceiling effect in generally healthy adults,¹⁹³ the gait speed assessment of the Short Physical Performance Battery was replaced with the validated 8 feet up-and-go.¹⁴⁰ The same equipment for objective measurement of outcomes was used at both clinical sites.

The remaining outcomes were assessed through self-reported questionnaires. Health status and quality of life were estimated from the Medical Outcomes Study Questionnaire Short Form 36 (SF-36).¹⁹⁴ Physical function was estimated from the PROMIS Short Form v1.2-Physical function 8b.¹⁵¹

STATISTICAL ANALYSIS

TAME health was primarily designed to test the feasibility of the intervention and estimate effect sizes; therefore, the analyses described in this paper are exploratory and no pre-specified power calculation was performed. Effect sizes were calculated from the mean change in study variables and were categorized as small (≤ 0.2), medium (0.5), and large (≥ 0.8) using Cohen's classification.¹⁵⁸ The Statistical Package for the Social Sciences (IBM-SPSS, version 20) was used and the α -level was set at 0.05. Analyses were conducted using the intent-to-treat principle by carrying baseline information to follow-up.

Descriptive analyses were conducted using means and frequencies of all study variables. Group differences at baseline were examined using independent samples t-tests for continuous variables and through Chi-Square tests for frequency variables. Little's Missing Completely at Random test was performed to determine whether outcome data were missing at random.¹⁹⁵ Post-intervention differences between groups were assessed using analysis of covariance (ANCOVA) for normally distributed variables and with Mann-Whitney U for non-normal data. Covariates in the analysis were baseline values of the dependent variable and any variables significantly different between groups at baseline. Analyses on the primary outcome variables (CVD risk, fitness, PA) were conducted by a blinded statistician. Following standard protocol, only days with a minimum of 10 hours of wear time from the SenseWear armband were included in the analysis.²⁵ Although physical activity goals were set in terms of steps per day, only PA

minutes were included in the analysis because the SenseWear armband is not a validated measure for steps.¹⁴³

Results

The CONSORT flow diagram is available in **Figure 5-1**. At baseline, the mean age and body mass index of the participants was 63.6 ± 5.3 years and 30.3 ± 3.1 kg/m², respectively. A total of 75% of the participants were female, 65% were non-Hispanic White, and 55% graduated college. The demographic information by study group is available in **Table 5-1**. The mean heart/vascular age of the participants were approximately 74 ± 11.2 years with a Framingham risk score of 18.9%. Participants averaged 31.3 ± 29.4 minutes of moderate-vigorous PA per day and 4204.8 ± 2199.8 steps per day. Groups only differed at baseline in systolic blood pressure. Participants were comparable on all other study variables. Characteristics were not different by clinical location. Participants that did not complete the study were not significantly different on the tested variables. However, the relationship between group and missingness was significant ($p=0.04$). The odds ratio for missingness was 0.103 (0.002, 0.956) which signifies that missingness was more likely in the pedometer group. There were no adverse events related to the intervention.

Figure 5-1: Consort flow diagram

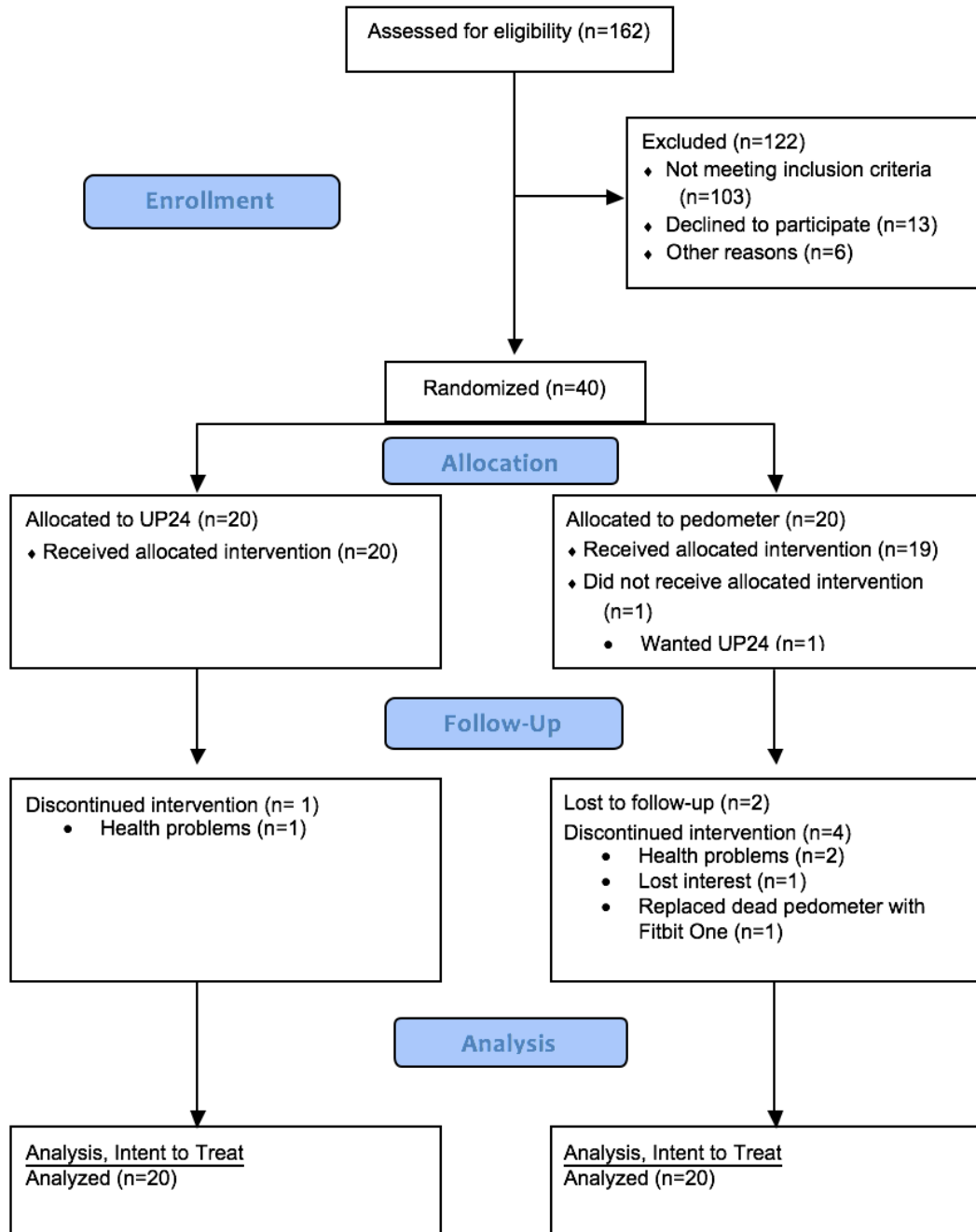


Table 5-1: Demographic information by study group (n=40)

	EAM	Pedometer	All
	n (%)		
Age, years; mean (SD)	64 (5.1)	63.2 (5.7)	63.6 (5.3)
Female	17 (85)	13 (65)	30 (75)
Non-Hispanic White	12 (60)	14 (70)	26 (65)
Hispanic	3 (15)	2 (10)	5 (12.5)
Black/ African American	4 (20)	3 (15)	7 (17.5)
Other	1 (5)	1 (5)	2 (5)

PRIMARY OUTCOMES

Baseline, follow-up values and the estimated effect size using the intent-to-treat principle for all study variables are outlined in **Table 5-2**. Group differences in primary outcomes were assessed with ANCOVA, controlling for baseline values and systolic blood pressure. There were no significant group differences at follow up in CVD risk ($p = 0.81$), fitness ($p = 0.73$), or PA ($p = 0.29$). The EAM intervention produced a large effect on minutes of PA.

Table 5-2: Baseline, follow-up values and effect sizes for tested variables

	EAM (n=20)		Pedometer (n=20)		Effect size α
	mean (SD)				
Primary Outcomes	Baseline	Follow-up	Baseline	Follow-up	
Framingham non-laboratory risk score	16.5 (12.2)	16.6 (13.2)	21.2 (13.6)	21.2 (12.6)	-0.01
Six minute walk, ft.	1487.4 (310.3)	1561.0 (353.6)	1568.4 (354.6)	1642.9 (287.3)	-0.01
Moderate/Vigorous Activity, minutes	22.6 (21.5)	33.8 (27.6)	40.0 (33.9)	40.2 (3.7)	0.78
Secondary Outcomes					
Heart/Vascular age, years	71.6 (11.3)	71.2 (11.3)	76.4 (10.9)	76.3 (10.5)	0.03
Weight, kg	81.7 (10.7)	81.9 (11.2)	94.1 (40.5)	86.8 (13.6)	0.22
BMI, kg/m ²	30.0 (3.2)	30.0 (3.5)	30.6 (3.1)	30.5 (3.1)	0.13
Waist to Hip ratio	0.8 (0.8)	0.8 (0.1)	0.9 (0.9)	0.84 (0.1)	0.45
Systolic blood pressure, mmHg*	125.0 (11.6)	125.0 (14.5)	134.8 (15.8)	134.3 (14.6)	-0.00
Diastolic blood pressure, mmHg	79.6 (10.5)	80.0 (9.8)	83.1 (9.0)	83.4 (10.0)	0.01
Resting pulse, bpm	69.4 (11.4)	69.1 (14.0)	76.3 (10.3)	76.5 (11.9)	-0.05
Chair stand, sec	12.8 (7.3)	14.7 (5.5)	15.0 (3.9)	14.2 (3.7)	0.49
Tandem balance, sec	7.9 (3.2)	9.1 (2.4)	9.1 (2.8)	9.2 (2.2)	0.46
8 feet up and go, sec	5.4 (3.1)	6.4 (3.0)	6.0 (1.3)	5.9 (1.4)	0.49
PROMIS Physical Function	28.4 (8.7)	29.2 (8.2)	33.2 (7.3)	33.8 (6.4)	0.07
SF-36: Physical functioning	59.5 (29.6)	62.3 (29.3)	73.8 (22.6)	73.1 (19.3)	0.27
SF-36: Physical health role limitations	64.4 (27.6)	67.9 (26.6)	69.4 (33.6)	72.2 (24.2)	0.26
SF-36: Emotional role limitations	58.8 (30.9)	75.8 (25.5)	68.1 (28.7)	71.3 (31.4)	0.20
SF-36: Energy/fatigue	70.4 (33.1)	53.1 (15.1)	72.1 (33.8)	58.1 (16.7)	-0.31
SF-36: Emotional well-being	67.5 (14.5)	70.0 (18.6)	71.0 (22.0)	76.3 (18.7)	-0.22
SF-36: Social functioning	47.8 (14.9)	66.3 (24.7)	48.4 (21.5)	69.4 (31.4)	0.08
SF-36: Pain	54.1 (29.1)	56.8 (29.1)	57.0 (28.5)	60.3 (26.1)	-0.04
SF-36: General health	62.1 (14.2)	63.9 (15.4)	60.7 (15.4)	58.8 (19.1)	0.39
BMI: Body Mass Index; EAM: Electronic Activity Monitor; PROMIS: Patient-Reported Outcomes Measurement Information System; SF-36: Medical Outcomes Study Questionnaire Short Form 36					
*significantly different between groups at baseline, p<0.05					
αCohen’s d for change in the tested variable between the electronic activity monitor					

SECONDARY OUTCOMES

Functional measures, health status, and heart age required the use of nonparametric tests. All other secondary outcomes were analyzed using ANCOVA, controlling for baseline values and systolic blood pressure. There were no significant group differences at 12-weeks on any secondary outcomes (Table 5-2). The EAM intervention produced a medium effect on waist-to-hip ratio, chair stand time, tandem balance time, and 8 feet up and go time. The EAM intervention also produced a small-to-medium effect on weight and SF-36 sub-scales, with the exception of social functioning and pain.

Discussion

This analysis of a pilot randomized controlled trial aimed to compare the effectiveness of an EAM to a pedometer for decreasing CVD risk, increasing PA, and improving secondary outcomes. Both groups increased their fitness and increased their minutes of PA. Due to the pilot nature of this study, statistical significance for these outcomes should be viewed with caution. However, the magnitude of change, which indicates potential clinical significance, was greater in the EAM group.

A previous pilot trial evaluation by Cadmus-Bertram et. al.⁹⁸ of an EAM also found no group differences among post-menopausal women. Participants were randomized to receive a Fitbit One EAM or a pedometer and were encouraged to become more physically active. After 16-weeks the EAM group increased their PA by 62 minute while the pedometer group increased by 13 minutes. Although the magnitude of change was greater in those that wore a Fitbit, the differences were not significant between groups in the small study,⁹⁸ likely due to low power inherent to pilot studies. The analyses from our TAME health study using a Jawbone EAM were similar. These

preliminary results may suggest that, regardless of the type of monitor used, self-monitoring behaviors in combination with brief counseling can increase PA among older adults. This concept aligns with the literature of clinic-based and technology-based PA interventions.^{86,196, 176}

The increased minutes of moderate and vigorous PA within our EAM group is consistent with the literature. Aittasalo et. al. found that providing 5As counseling in clinic can result in an 28 minute increase of moderate to vigorous PA a week after 2 months.⁸⁶ Similarly, among chronically ill patients the combination of 5As counseling administered over 4-6 months and an EAM system resulted in an 8.9 minute increase in exercise per day.¹⁹⁶ Activity monitoring with an EAM, Fitbit, for 3 months along with PA education increased PA by 11 minutes per day.¹⁷⁶ Participants using the UP24 monitor in our study had an increase of approximately 11 minutes of PA a day, whereas our pedometer group had an increase of less than 1 minute of PA a day.

The EAM group did have a greater increase in PA, however the pedometer group was greater at baseline. The difference was non-significant but it brings up some considerations. Two participants in the EAM group started the intervention after completing physical therapy post-knee replacement. Both participants had extremely low physical activity levels at baseline which could have contributed to the lower EAM group average. One of these participants dropped out of the study while the other participant increased their PA at a similar rate than other EAM group participants. Considering the pedometer group averaged approximately 40 minutes of PA a day at baseline, there may have been a ceiling effect in regards to PA activity. Future research should evaluate the PA capacity within this population. In addition, future research should consider blocking randomization based on baseline PA levels.

In terms of reducing CVD risk, we found modest increases in fitness among both groups which were comparable to providing physician advice and educational material in clinic.¹⁹⁷ Digital health interventions have shown to reduce the 10-year Framingham risk

score by 1.24%, systolic blood pressure by 2.12 mmHg, and weight by 1.52 kg.¹³⁸ We found more conservative changes in these outcomes in both study groups. Despite the modest difference, the EAM group had more favorable changes in CVD risk factors. This suggests that the low-impact nature of using an EAM in combination with counseling can result in greater improvements in health than use of a pedometer, but these effects are likely smaller than those for more intensive digital interventions.

Our results indicated that the EAM intervention produced a medium effect on waist-to-hip ratio, chair stand time, tandem balance time, and 8 feet up and go time. The increase in chair stand time and 8 feet up and go time among the EAM group suggest that their physical function did not improve. However, the EAM group had greater increases in physical functioning based on self-reported measures, PROMIS and SF-36. The EAM intervention produced a favorable small-to-medium effect in both of these measures. It is possible that the decline in objective physical function is the result of measurement error. Participants completed the assessments in the same location using the same equipment and instructions, but EAM participants may have been more cautious during the follow-up. However, more research is needed to investigate the effects of an EAM on physical function.

LIMITATIONS AND STRENGTHS

This study has limitations. TAME health was primarily designed to test the feasibility of the intervention. To that end, there were no blinded assessors or follow up assessments to assess maintenance. In addition, the study was not powered to detect small group differences. Based on our reported effect sizes, a group difference may be observed with a larger sample. There is also possible volunteer and selection bias in the study. Participants were volunteers and may be more intrinsically motivated to exercise than other individuals of the same age. Eligible participants were required to have regular

access to a smart device, therefore the results cannot be generalized to all older adults that do not own or have access to a smart device.

The major strength of this study is that it was a comparative effectiveness evaluation. This study adds to a small body of literature that directly compare low- and high-tech activity monitors.⁹⁸ Another strength of this study its ability to test the current recommendation for PA promotion in primary care.^{55,61}

IMPLICATIONS

The American Heart Association encourages healthcare providers to provide 5A's interventions and provide technology-based resources for individuals at moderate risk for CVD.^{55,61} Our results provide preliminary evidence that adhering to this recommendation results in clinically meaningful improvements in health among older adults. Although not statistically significant, our results also suggest that EAMs produce a small-to-medium effect over a low-tech pedometer. Healthcare systems have the potential to deliver disseminable interventions that can impact the health of their priority population if they routinely administer the low-intensity, low-impact 5A's counseling for all patients at risk and these patients regularly self-monitor their behavior.^{55,61} Large-scale, multi-site trials are needed to address the limitations of the current study and to determine the intervention's effectiveness on a population level.

Conclusions

PA promotion in primary care through 5A's counseling and self-monitoring is recommended for individuals at moderate risk for CVD. Our evaluation of sedentary, overweight adults aged 55-74 years of age suggested that a pedometer or an EAM (Jawbone UP24) can be used with 5A's counseling to improve health, and there is a

small-to-medium effect of the EAM intervention when compared to use of a pedometer on health outcomes. Because of its low-intensity and highly scalable nature, this intervention has the potential to be broadly disseminated by healthcare systems to positively impact the health of their priority population.

CHAPTER 6: BRIEF REPORT: WEARABLE ACTIVITY MONITOR USE AND MOTIVATION IN A PILOT TRIAL

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Background: Self-Determination Theory posits that targeting autonomy, competence, and relatedness fosters autonomous regulation of behavior, which is strongly associated with physical activity. Wearable physical activity monitors have the potential to facilitate autonomous motivation through goal-setting, feedback, and other behavior change techniques. Here, we report results of a pilot randomized controlled trial comparing the effects of pedometer use to electronic activity monitor use on Self-Determination Theory constructs. **Methods:** Participants (n=40) 55-74 years of age took part in a 12-week physical activity intervention. At enrollment, all participants took part in brief counseling. After counseling participants were randomized to use a Digi-walker pedometer or a Jawbone UP24 monitor. Jawbone users were instructed to use the corresponding UP application on their smart device. Analyses of covariance were conducted to determine group differences between sub-scales scores of the Behavioral Regulation in Exercise Questionnaire 2 and the Psychological Need Satisfaction in Exercise Scale. **Results:** Controlling for baseline scores, the wearable activity monitor group reported less amotivation, as well as greater intrinsic regulation, identified regulation, relatedness, competence and autonomy (all $p < 0.05$) compared to the pedometer group. **Conclusions:** Motivation for physical activity can be influenced by the type of activity monitor used. The UP application incorporates effective behavioral

change techniques which appear to successfully promote autonomous forms of motivation. Future research should explore the most impactful application features on motivation and their long-term effects.

Key words: motivation, physical activity, older adult, technology, activity monitor

Introduction

It is recommended that adults take part in at least 150 minutes of moderate physical activity (PA) a week to prevent disease and improve health,¹⁹ but only 5% of adults reach recommended amounts.²⁵ It is estimated that adults over 50 years of age on average participate in 5.4 to 25.3 minutes of moderate PA per day.²⁵ A recent review synthesized six major themes to explain older adults' activity patterns.³² Major themes included: social influences, physical limitations, competing priorities, access difficulties, personal benefits of physical activity, and motivation and beliefs.³² Some older adults clearly acknowledge the benefits of PA but lack the motivation to do the activity.³²

Self-Determination Theory (SDT) outlines several different forms of motivation on a continuum from fully internal to fully external.³⁷ Intrinsic motivation is fully internal: activities are performed because they are inherently enjoyable.³⁷ Extrinsic motivation involves the engagement of activities based on external factors at varying levels of personal integration.³⁷ From the most controlled to the most autonomous, the spectrum includes: external regulation, introjection, identification, and integration.⁵² Introjection is somewhat external because it embraces contingent consequences. Identification and integration are relatively autonomous because the behavior or its outcome is valued. An individual that is not regulated to complete a behavior, extrinsically or intrinsically, is amotivated.⁵² A number of studies have demonstrated the

importance of intrinsic motivation in predicting PA. Recent studies have also suggested that a combination of fully intrinsic motivation as well as autonomous forms of extrinsic motivation (integrated and identified regulation) may better predict activity than one or the other.¹⁹⁸ According to SDT, fulfillment of the basic psychological needs for autonomy, competence, and relatedness predicts these autonomous forms of motivation.^{37,38} Interventions that target these forms of motivation through technology may effectively overcome this critical barrier to physical activity among older adults.¹⁹⁹

Two types of activity monitors are commonly used in PA interventions: pedometers and electronic activity monitors (EAMs). Pedometers are small devices that provide real-time feedback to the wearer on their physical activity (i.e. steps per day, minutes of activity). A wearable EAM is operationally defined as “a wearable device that objectively measures lifestyle PA and can provide feedback, beyond the display of basic activity count information, via the monitor display or through a partnering application (app) to elicit continual self-monitoring of activity behavior.”⁷⁷ EAMs can offer behavior change techniques that pedometers cannot, such as social support, teaching to use prompts, and goal-setting. These techniques may better promote SDT constructs⁷⁹ compared to standard pedometers, which could lead to better activity outcomes.

This study compared motivational effects of pedometers and electronic activity monitors using data from a pilot randomized controlled trial. The purpose of the trial was to investigate the comparative effectiveness of a pedometer (Digi-walker CW-700/701, YAMAX, San Antonio, TX) and EAM (UP24 by Jawbone, San Francisco, CA) over a 12-week period. We hypothesized that the EAM group would demonstrate greater

improvements than the pedometer group in autonomous forms of motivation (intrinsic motivation and identified regulation).

Methods

A complete description of the TAME health methodology is available elsewhere.¹¹⁹ This section serves as a brief summary. TAME health was approved by the University's Institutional Review Board and Informed Consent was provided for all participants. The study is also registered online at clinicaltrials.gov (NCT02554435).

INTERVENTION

Participants were eligible if they were 55-74 years of age, had a body mass index of 25-35 kg/m², participated in fewer than 60 minutes of planned exercise a week, had access to a smart device, and were in good health. All participants received brief physical activity counseling following 5 A's procedures prior to randomization.⁷¹ The counseling topics briefly intervened on autonomy, competence and relatedness. After counseling, participants were encouraged to self-monitor their PA using the assigned activity monitor. Participants were randomly assigned to the pedometer group or the EAM group.

The pedometer group was given a digital pedometer (Digi-walker CW-700/701, YAMAX, San Antonio, TX) and a physical activity log to record their daily steps, activity time, and distance walked. The EAM group was given an UP24 monitor by Jawbone (San Francisco, CA) and downloaded the corresponding UP app. The UP app includes a Smartcoach that provided personalized feedback and behavior change techniques daily. Behavior change techniques included providing information on consequences of behavior and teaching to use prompts and cues. Participants in this

group were given anonymous UP accounts and were “friended” with other participants in the study group in order to facilitate social support and social comparison. Further details on the features of the UP app are available elsewhere as an appendix file.¹¹⁹

MEASURES

Assessments were conducted at baseline and at 12 weeks. The primary assessment measures were the Behavioral Regulation in Exercise Questionnaire 2 (BREQ—2)¹⁵² and the Psychological Need Satisfaction in Exercise Scale (PNSE).²⁰⁰ The BREQ—2 is a 19-item self-report questionnaire that includes amotivation, and intrinsic, identified, introjected, and external regulation sub-scales for exercise motivation.¹⁵² Items are scored on a scale of 0 to 4 and the sub-scale values are derived from the mean of item scores. The theoretically autonomous construct of integrated regulation is not included in this measure and thus was not analyzed in this study. The PNSE is an 11-item self-report questionnaire includes perceived competence, autonomy, and relatedness subscales.¹⁵³ Items were scored on a scale of 1 to 5 and mean values were used to calculate subscales. Demographic characteristics (age, gender, ethnicity, race, education) were assessed through self-report. Body mass index was calculated from the assessment height and weight using a portable stadiometer (Seca Corp., Hamburg, Germany) and a portable, calibrated electronic scale (Tanita, Arlington Heights, IL), respectively.

STATISTICAL ANALYSES

Analyses were completed using the Statistical Package for the Social Sciences (IBM-SPSS, version 20) with an α -level set at 0.05. Analyses were completed using the intent-to-treat principle for missing outcome data. Participants with missing outcome data

had a significantly higher baseline identified score than those that completed the intervention ($p=0.02$).

Descriptive analyses for baseline characteristics were completed using means and frequencies. Mean group differences were determined using independent samples t-tests and Chi-Square tests. Analyses of Covariance (ANCOVA) were performed to test the post-intervention difference between the two groups on BREQ—2 and PNSE subscales while controlling for baseline values. Effect sizes were also calculated from the change in BREQ—2 and PNSE subscale scores using the Cohen's d method.¹⁵⁸ The primary purpose of the TAME health study was to test feasibility and the current evaluation is exploratory in nature; therefore, no pre-specified power calculation was performed.

Results

The mean age and body mass index for participants was 63.6 years and 30.3 kg/m², respectively. Thirty (75%) participants were female, 5 (12.5%) were Hispanic, 31 (78%) were White, and 22 (55%) obtained a college or graduate-level degree. At baseline, the two groups differed on intrinsic regulation with the EAM group more intrinsically motivated.

The ANCOVA results and effect sizes are displayed in **Table 6-1**. Based on ANCOVA results, EAM participants had significantly less amotivation ($p = 0.04$; $d = -0.42$), and greater intrinsic regulation ($p < 0.01$; $d = 0.85$), identified regulation ($p = <0.01$; $d = 0.70$), relatedness ($p=0.02$; $d=0.59$), competence ($p < 0.01$; $d = 1.01$), and autonomy ($p < 0.01$; $d = 1.13$) at follow-up as compared to pedometer group participants, controlling for baseline values of each dependent variable. **Figure 6-1** illustrates

examples of how autonomy, relatedness, and competence were presented in the UP app by EAM users.

Table 6-1: ANCOVA results for between group differences in Self-Determination constructs

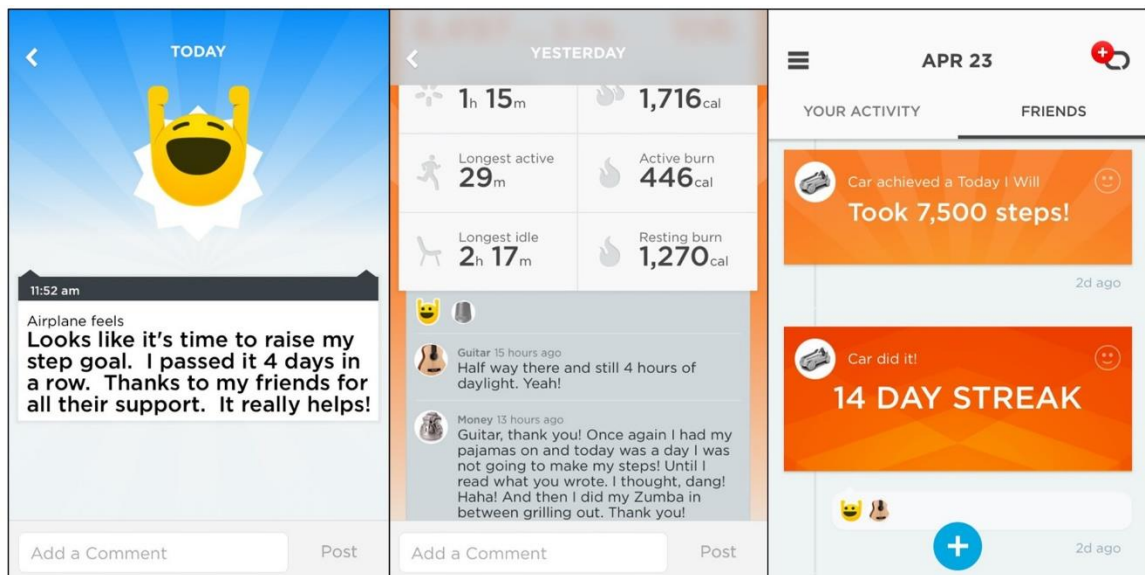
Electronic activity monitor			Pedometer		Effect size η^2
	Mean (SD)				
	Baseline	12-week	Baseline	12-week	
Behavioral Regulation in Exercise Questionnaire—2					
Intrinsic **	2.03 (1.02)	2.84 (0.77)	1.40 (0.95)	1.48 (1.00)	0.85
Identified **	2.36 (0.83)	2.92 (0.59)	2.30 (1.00)	2.24 (1.04)	0.70
Introjected	1.41 (1.07)	1.68 (0.88)	1.18 (1.04)	1.12 (1.06)	0.41
Extrinsic	0.42 (0.54)	0.51 (0.58)	0.54 (0.74)	0.49 (0.69)	0.26
Amotivation*	0.27 (0.49)	0.15 (0.38)	0.49 (0.83)	0.61 (0.78)	-0.42
Psychological Need Satisfaction in Exercise Scale					
Competence**	2.39 (0.96)	3.43 (0.95)	2.36 (0.87)	2.49 (0.94)	1.01
Autonomy**	3.14 (1.06)	4.01 (0.95)	3.03 (1.02)	3.16 (0.95)	1.13
Relatedness*	2.79 (1.38)	3.53 (1.03)	2.58 (1.39)	2.72 (1.33)	0.59

* Significantly different between groups at week 12, $p < 0.05$

** Significantly different between groups at week 12, $p < 0.01$

η^2 The calculated Cohen's d from the mean change in the variable of interest, for the effect of the electronic activity monitor group against the pedometers

Figure 6-1: Examples of autonomy, relatedness, and competence support in UP app



Discussion

This pilot study aimed to compare the effectiveness of a pedometer and an EAM on constructs of SDT. Though both groups received identical counseling, the EAM group received additional autonomy, competence, and relatedness support through the Smartcoach and social interaction features of the mobile app. After 12-weeks there was a significant difference in amotivation, intrinsic regulation, identified regulation, relatedness, competence, and autonomy scores between the two groups.

There was a greater impact on exercise motivation and regulation in the current study than some other previous evaluations. Older adults that took part in aerobic activity three days a week for 16 weeks did not have a significant change in autonomy, competence, or relatedness.²⁰¹ The addition of SDT-based counseling to an exercise intervention only significantly increased autonomy and competence measured by the PNSE but not relatedness or any BREQ—2 subscales after 12-weeks.²⁰² A study comparing individuals who were simply encouraged to exercise and those that received a one-time counseling session found no group differences in autonomous regulation.²⁰³ An investigation similar to this one did not find a significant difference in autonomous regulation between a group that received a pedometer with education and a group that received an EAM system that provided personalized feedback.²⁰⁴ There are several possible reasons why this study demonstrated a significant impact on motivation while many previous interventions did not.

First, participants in this study used PA goals that were based on competence and autonomy. All participants agreed on a personalized goal during their counseling session, but the EAM participants had the Smartcoach to encourage them to raise their goal. If the

wearer is consistently meeting their step goal, the Smartcoach will praise the wearer for their consistency and recommend a new step goal. The user has the choice to accept or decline the new goal. Other PA interventions set a workout or PA progression schedule.

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Secondly, a recent qualitative analysis by Kappen et. al. described the intrinsic motivators that older adults desire in mobile applications.²⁰⁵ Some noted intrinsic motivators include: describing the purpose of exercise, customization of the exercise routine, independence, ability to form relationships, and being able to share information about exercise.²⁰⁵ The UP app allows for all of these motivators. The Smartcoach provides information about the benefits of exercise and the app allows for the wearer to plan their own exercise routine. The social interaction features within the app allow for users to form relationships and to share information about their exercise. Lastly, the Jawbone UP system was chosen for the intervention due to its inclusion of many behavior change techniques that are known to promote physical activity.⁷⁹ Therefore, the unique features of the UP app may have potentially influence the autonomous regulation in this study.

STRENGTHS AND LIMITATIONS

The major strength of this study is that all of the participants received the same supportive counseling and differed on the type of activity monitor used for self-control. However, maintenance of motivation changes after 12 weeks was not assessed. This study is also limited in that, since the start of this study, the Jawbone company is no longer producing commercial activity monitors and it is unknown how long they will support the UP app. Despite this limitation, our results can still inform future technology-

based interventions aimed to promote motivation. The key behavior change techniques and potentially influential features of the UP app described should be investigated further in emerging technologies. Researchers interested in increasing motivation for PA should either develop mobile technologies or select commercially-available options that incorporate these features. Future studies need to explore which app features have the biggest impact on autonomous motivation and regulation and which features correlate with prolonged enhancement in intrinsic motivation.

In conclusion, our study aimed to investigate the comparative effectiveness of a pedometer and the Jawbone UP24 EAM on SDT constructs. After 12-weeks of self-monitoring, the EAM group significantly increased their autonomy, competence, relatedness, intrinsic regulation and identified regulation while significantly decreasing autonomous regulation compared to the pedometer group. The Up app that incorporated multiple behavioral change techniques may have potentially influenced the SDT constructs. Researchers should continue to identify similar mobile technologies and explore the most impactful features on motivation.

Chapter 7: Implications of findings, lessons learned, and future research

This project aimed to describe the impact of a primary care, technology-based intervention through the investigation of a mobile app, RE-AIM indicators, CVD related outcomes, and SDT constructs. Results were from a preliminary study (Chapter 3) and the TAME health intervention (Chapters 4-6). A summary of the key results and implications are discussed below by each chapter.

SUMMARY OF FINDINGS AND IMPLICATIONS BY CHAPTER

Chapter 3: Social support patterns of older adults within a physical activity mobile application: A brief report

- Participants (N = 35) gave 3,153 “likes” and provided 1,759 comments over 90 days.
- The median number of “likes” and comments were 2 (IQR=40) and 14 (IQR=45), respectively.
- The most prevalent comment themes were emotional support (58.7%), self-talk (22.4%), other (11.2%), informational (4.5%), and instrumental (3.2%).
- Contrary to the 90-9-1 principle, we found contributors to be the largest group (71.4%).
- A previous investigation of digital health social networks found that superusers accounted for 73.6% of posts while contributors accounted for 24.7% of posts.¹⁶² Our results are comparable with superusers accounting for 72.6% of comments and contributors accounting for 27.1% of comments.
- The high rate of contributors may be due to the intimate or anonymous nature of the support group.

- Our ranking of comment themes coincides with a previous study using Fitbit.¹⁰⁷ The authors found the most prevalent comments were motivational (emotional support), followed by sharing PA ideas (informational support), and exercising with others (instrumental support).
- EAMs are powerful intervention tools because they allow for organic support that follows social support theory.
- Researchers and practitioners who provide these devices should encourage the use of these features. In addition, researchers and policy makers should support legislature that fosters virtual support while protecting the security of the user.

Chapter 4: That's my medical and this is my health: The feasibility a pragmatic, technology-based, primary care, physical activity intervention

Reach

- The recruitment rate was 24.7% while 20% of enrolled participants were not clinic patients.

Effectiveness

- Over 12-weeks the EAM and pedometer group increased their minutes of moderate or vigorous PA by 11 and 0.2 minutes per day, respectively.
- The EAM group increased 8.3 and 3.6 points in goal-setting and planning while the pedometer group increased by 1.7 and 0.3 points, respectively ($p<0.01$).
- Overall attrition was 20%, with 5% in the EAM group and 35% in the pedometer group ($p=0.02$).
- EAM users agreed that they liked using the monitor and that they would continue wearing it while pedometer users were neutral to these statements ($p<0.05$).
- There were no adverse events related to the intervention.

Adoption

- Participants felt a doctor's office was too regimented for the intervention.
- Participants preferred counseling from the counselor but they wanted more in person sessions and counseling on multiple health behaviors.
- Stakeholders liked the counseling but wanted it more individualized to the patient.
- Stakeholders felt they could implement the study with assistance from the clinical staff.

Implementation

- There were 28 reports of technical issues across 21 out of 40 participants during the intervention.
- Overall, participants liked the intervention and found having a goal in mind the most motivational aspect.

Maintenance

- Both monitors were admired for being easy to use, convenient, and discreet, but participants questioned the accuracy of the device.
- The EAM was criticized for technical and syncing issues, and participants didn't like that the pedometer would only record steps if worn in a certain position.
- Twenty TAME participants in the EAM group produced 789 comments and 1,198 "likes" over 12 weeks.
- Stakeholders felt self-monitoring can be beneficial for patients, but they were concerned about the cost and accuracy of the device.
- Stakeholders had positive reaction to TAME health and felt it can be implemented if there was a funding source.

Implications

- Compared to other primary care-based and EAM studies, our reported attrition rate, reported adverse events, wear time, and reported technical issues were comparable.^{82,87,98,101,174,175,177-181}
- TAME health participants interacted less on the UP app than previous participants but both studies observed over 400 comments in total in 12-weeks, which is more than the reported 259 comments from college-aged adults in the same time.¹⁰²
- Our results support previous investigations that found that older participants find an EAM three times more helpful than a pedometer,⁹⁸ they would continue to use an EAM,¹⁸² and they would purchase an EAM over a pedometer.¹⁸³
- TAME health participants and stakeholders expressed opinions that reflect known barriers and considerations of behavioral counseling in primary care including: target multiple health behaviors,^{33,56,184} patients value all constructs of 5A's counseling which are not often performed by practitioners,¹⁸⁵ and health care providers lack the time and skills necessarily to complete effective PA counseling.^{187,188}
- Practitioners, counselors, and researchers should consider the following before implementing a similar intervention: 1) utilize PA counselors, 2) target multiple health behaviors, 3) form a social support group, 4) identify a funding source for sustainability, and 5) be mindful of concerns with technology.

Chapter 5: Effect of electronic activity monitors and pedometers in a pilot randomized trial

- There were no significant group differences in study variables.

- The EAM group produced a moderate effect size on PA ($d=0.78$), waist-to-hip ratio ($d=0.45$), chair stand time ($d=0.49$), tandem balance time ($d=0.46$), and 8 feet up and go time ($d=0.49$) over the pedometer group.
- Our results coincide with another pilot study that compared a Fitbit One to a pedometer.⁹⁸ These preliminary results may suggest that self-monitoring behaviors in combination with brief counseling can increase PA among older adults regardless of the type of device used.
- The increase in PA observed by the EAM group is within the reported ranges of previous studies (approximately 2 to 11 minutes per day).^{86,176,196}
- There were conservative changes in CVD risk outcomes compared to previous studies.^{138,197}
- The small-to-medium effect produced by the EAM on study variables highlights the potential of these devices within the clinical setting.
- Healthcare systems have the potential to deliver disseminable interventions that can impact the health of their priority population if they routinely administer the low-intensity, low-impact 5A's counseling for all patients at risk and these patients regularly self-monitor their behavior.^{55,61}

Chapter 6: Brief report: Wearable activity monitor use and motivation in a pilot trial

- We found significant group differences in intrinsic regulation ($d=0.85$), identified regulation ($d=0.70$), amotivation regulation ($d=-0.42$), competence ($d=1.01$), autonomy ($d=1.13$), and relatedness ($d=0.85$).
- We found significant group differences across BREQ-2 and PNSE subscales where previous PA investigations among older adults and an EAM system did not.^{201,202,204}
- There are several possible reasons why our study demonstrated a significant impact on motivation: PA goals were based on competence and autonomy; the Smartcoach incorporated intrinsic motivators that older adults desire in a

mobile app;²⁰⁵ and the UP app has a high number of behavior change techniques.

IMPLICATIONS WITHIN SELF-DETERMINATION THEORY

TAME health is based on SDT, which posits that autonomous motivations are derived from a person's need for competence, autonomy, and relatedness. The most meaningful design difference between the two study groups was the relatedness theoretical construct (see Table 1-1).

Social interaction among older adults using mobile apps is important to increase intrinsic motivation for PA.²⁰⁵ When a part of a PA study, we found that adults 55 years of age or older organically and abundantly supported one another. Participants in both evaluated studies produced over a mean of 400 comments in a 12-week period. This is more than the 259 reported comments from college-aged adults in the same time period.¹⁰² Although not all participants gave social support, everyone in the EAM group received support and the overall contribution was more than expected. More than 50% of participants, in both studies, contributed to some degree in the virtual community. The 90-9-1 principle suggests that this should be 10%.¹⁶² Moreover, participants embraced the social group. The anonymity of the study likely facilitated the group identity, suggested by participants' many puns based on each other's code names. For example, "Purrfect Cat" and "Full steam ahead Battleship!!!"

Autonomy and competence were targeted to a lesser degree through the UP app. The UP app supported these constructs through the Smartcoach and through the social features. The Smartcoach is a feature that is available to all users but not utilized by all participants. If the participant did not pay attention to the Smartcoach they would not have gained information on consequences, learned to use prompts,⁷⁹ or have been exposed to other internal motivators valued by older adults.²⁰⁵ Competence was also targeted through self-talk, which was unanticipated. Self-talk, which occurs when an

individual supports him or herself^{112,113} is an effective behavior change technique than can enhance competence.²⁰⁶ Although it was a prevalent comment theme, self-talk was not utilized by everyone.

It is known that intrinsic motivation specifically and autonomous regulation, more generally, are correlated with PA.^{207,208} Despite the significant differences in SDT constructs the difference in PA between the two conditions was non-significant. The null findings could be the result of the conceptual pathway in which autonomy support impacts physical health.²⁰⁹ In a meta-analysis, Ng et. al. constructed a conceptual pathway representing how autonomy support affects physical health. The pathway suggests that competence, autonomy, and relatedness act through autonomous self-regulation (intrinsic, identified, introjected) for the biggest effect on physical health. Of these constructs, competence can also directly affect physical health without the mediation of autonomous self-regulation.²⁰⁹ The results of this meta-analysis found that competence, intrinsic regulation, and identified regulation are the most strongly correlated with exercise compared to other measures of motivation and regulation. Moreover, competence has a higher correlation with intrinsic and identified regulation than autonomy and relatedness.²⁰⁹ We hypothesize that a larger effect in competence is necessary to elicit a significant difference in PA. Competence could be further enhanced with an EAM if the wearer was encouraged to use the Smartcoach, or a similar personalized coaching feature, and to use self-talk within the app. Some EAMs can also enhance competence by offering virtual rewards if the wearer reaches certain milestones.⁷⁹ Conceivably, further enhancement of competence in addition to the relatedness and autonomy features could produce significant PA changes.

IMPLICATIONS FOR USE OF ACTIVITY MONITORS

In the previous section we highlighted how SDT was targeted with the Jawbone UP24 and we suggested how these features could lead to changes in PA between the

tested monitors. Along with PA there were small-to-moderate effects for other physiological outcomes (e.g. waist-to-hip ratio $d=0.45$, chair stand time $d=0.49$, tandem balance time $d=0.46$, 8 feet up and go time $d=0.49$). Large-scale interventions are necessary to test whether these effect sizes elicit significant group differences. Although the current study was not powered to detect small effects, we found both activity monitors can be used for self-control. However, the type of activity monitor used may impact the usability and the public health impact.

There were pros and cons in using a high-tech EAM over a basic pedometer. The major con was that EAMs experienced more technical and connectivity issues than pedometers and required more technical support. Other studies reported that 58-90% of participants had technical issues with an EAM system.^{101,169} Beyond technical issues, EAMs can break down or get lost and need to be replaced. This can result in higher long-term cost associated with the EAM for support and possible replacement. Long-term use of the device is also affected by its commercial availability. Jawbone is no longer producing commercially available activity monitors. In lieu of relying on commercial devices, researchers and interventionists can develop their own EAM but this requires greater development and maintenance resources than are typically available. The pro of the EAM was that it resulted in greater engagement in the intervention. There were more Jawbone participants that participated in the focus group, there was a lower attrition rate in the Jawbone group, and there were more logged days of PA in the EAM group. Sedentary individuals starting an exercise program are likely to relapse within 6 months;²¹⁰ the greater engagement resulting from EAM use may be able to combat relapse and lead to maintained behavior change.

Another aspect of usability is participant characteristics and preferences. We found that participants somewhat disagreed to somewhat agreed that they would continue using their monitor or they would prefer a different monitor. If someone is only interested in how active they are and does not want additional behavioral support, a basic

pedometer may be appropriate. Otherwise, a participant may require another type of monitor. The EAM tested in this study was well equipped to increase intrinsic motivation for exercise under SDT. Other commercially available EAMs also incorporate behavior change techniques that support other behavioral theories, such as Social Cognitive Theory.⁷⁹ Social Cognitive Theory aims to change health behavior by increasing self-efficacy.²¹¹ If someone lacks self-efficacy they may benefit from a commercial EAM that has rewards, like Fitbit or Misfit. If they lack motivation they may benefit from a Striiv, Withings, or Jawbone monitor that provide prompts and allow for action planning.⁷⁹ Beyond behavioral needs, the participant's preference may be based on the ability to monitor other health outcomes, whether the device is water proof, the appearance of the device, how feedback is displayed, and where the device must be worn. There is evidence that younger and older adults have different preferences in PA apps and websites,^{205,212} so there is reason to believe that different groups of people will prefer information to be displayed in a certain way.

In addition, how social support is integrated in the EAM should be considered. Jawbone is unique in that the social comparison and interaction appear on the same page as PA feedback. Other monitors have social support in a separate section of the app that may not be intuitive to the users. Moreover, some devices require the use of separate website to facilitate social support. If the user is interested in the social aspect, they should select a monitor that makes it easy. For these reason, it is necessary to offer a variety of monitors to participants and patients.

Another option to self-monitor PA behavior is to use a mobile app. All participants in the TAME health study were required to have access to a smart device and most smart devices are equipped with pedometer-like apps. Newest versions of Apple iPhones and iPod Touches are pre-installed with the Health App which will automatically track the wearer's steps per day, when the device is worn. In addition, Apple and Android products have a plethora of free tracking apps available for download. A review of 51

free mobile PA apps available on Apple and Android products in 2013 found that they incorporate, on average, 5 behavioral techniques used in interventions.²¹³ Some of the apps in the review have a corresponding EAM but can also be used with the accelerometer built into the smart device (e.g. Withings, Fitbit). The smart device based apps can be an alternative for individuals who want more features than a pedometer but do not have the resources to buy an EAM. The downside of these apps is that the device must be worn in order to record activity.

IMPLICATION FOR PRIMARY CARE

The current recommendation from the AHA was the inspiration to conduct this study within primary care. The AHA recommends a 2-tiered approach to promote PA in the health care system. The first tier is to provide low-intensity 5 A's counseling and the second tier is to utilize technology-based resources.⁵⁵ In particular, there is potential of EAM technology.⁶¹ TAME health reflects this recommended study design and we found that the study was feasible within the RE-AIM framework. Brief 5 A's counseling and providing a regular pedometer, or an EAM, does produce a positive result and might be a cost-effective way to improve health. Providers could also suggest use of a free phone-based pedometer app for their patients who have smartphones. If this is done routinely and on a large scale, the intervention may improve health on individual and population levels. However, we suggest that the intervention should be refined with the pre-stated considerations: 1) utilize PA counselors, 2) target multiple health behaviors, 3) form a social support group, 4) identify a funding source for sustainability, and 5) be mindful of concerns with technology.

In assessing feasibility, we found that stakeholders and patients had different perspectives on a clinic-based intervention. Clinical staff reported that implementing the intervention was possible and the clinical staff could be used to conduct counseling. Patients overwhelmingly stated they wouldn't want counseling from their physician or a

nurse, but they still were willing to go to their primary care clinic for the intervention. We suggest that there should be a designated counselor (e.g. PA counselor,¹⁹⁰ behavioral health provider,¹⁹¹ community health worker^{55,192}) that is based out of primary care to work with patients. We found that patients prefer a counselor over a physician or nurse because they don't have the time or the authority to counsel on exercise, which are previously cited barriers to physician-lead PA counseling.³³ Moreover, many participants believe exercise is separate from medicine and primary care. As one participant stated, "that's my medical and this is my health" (see Table 4-3). Therefore, a designated counselor with a background in exercise and fitness is preferred. These counselors should be integrated into primary care because it is a good platform to reach the community, not just patients. Eight TAME health participants (20%) were not patients but, per protocol, they were recruited through the clinic. They were recruited into the study because they were at the clinic with a family member or friend, they were a contract employee, or they were referred by a friend who saw the flyer in the clinic during their appointment. If the intervention were implemented on a larger scale and open to everyone, it would have the potential to intervene beyond the clinic population.

Stakeholders expressed the need of a funding source to supply monitors to the patients. One stakeholder stated that "If we didn't have it to give to them, they couldn't afford it" (see Table 4-3). Whereas, a number of TAME participants intended to buy their own monitor once the study was over. While some patients may not have the resources to buy their own monitor, there is a portion of primary care patients that are willing to buy their own. A funding source will still be necessary to supply technical support to patients, which was a potential barrier expressed by stakeholders and participants.

It must be noted that these implications only apply to externally regulated individuals. Participants with higher identified regulation and goal-setting scores dropped out of the current study. Furthermore, all but 1 of the 7 participants that dropped out or were lost to follow up were in the pedometer group. The two study groups were not

different at baseline for identified regulation and goal-setting and yet participants that scored high in these areas discontinued using the pedometer. This suggests that a pedometer is not enough to engage autonomously regulated individuals. These individuals may need an activity monitor with more behavior change techniques to prevent a relapse or they may need additional support from a designated counselor.

PRACTICAL LESSONS LEARNED

A number of practical lessons emerged from this study. First, we learned that primary care is an effective mode for recruitment. Although time consuming, recruiting through the primary care clinic yielded a 24.7% recruitment rate over 8 months for a specific patient population. This falls within the higher range of recruitment rates among walking interventions (0.8 to 39%).²¹⁴ Furthermore, an in-person recruitment approach is associated with higher quality metric scores for recruitment planning and implementation among walking interventions.²¹⁴ Based on what we experienced, active recruitment through the primary care clinic may also be a viable option for community-based interventions.

As noted previously, we learned that EAMs produce a high volume of technical issues. In the preliminary study there were 49 comments about technical issues and there were 13 reported technical issues in the TAME health study. The technical issues did not cause any participants to drop out of the study, but we learned that technical education and support should be an integral aspect of the intervention.

We also learned that PA education should be more in-depth. During the brief counseling session, all participants were taught the difference between resting energy expenditure and total energy expenditure while assessing their PA. However, participants made comments within the UP app and during the final assessment that they did not understand how they could burn more calories at rest than during activity. Also during the counseling sessions, participants were given an initial step goal (e.g. 5,500 steps, 3

days a week) and were advised to increase this to at least 7,000 steps at least 5 days a week at their own pace. At the final assessment, some participants admitted to never increasing their goal. This experience taught us that some modifications should be made. First, the exercise prescription should be explicit with the long-term step goal and it should be supplemented with a brochure or pamphlet that reiterates the principles of PA. Alternatively, the designated counselor can follow up over the phone or through an app to encourage increasing the goal and answer any questions or concerns.

FUTURE RESEARCH

There are several areas that should be investigated in-depth before implementing a similar intervention into a clinic. We believe that several study designs are needed for further investigation.

Observational studies are necessary to examine patient use of EAMs and the behavioral content of EAMs and mobile apps. Considering EAMs are commercially available, there are many patients who are already actively using these devices. Epidemiological and qualitative-based studies should survey these patients to gauge their preferences. Furthermore, these studies can discover why certain patients chose certain EAMs, what features they like, and their intended use of the device. These types of studies are necessary to make EAM use patient-centered and not clinic-driven. Longitudinal observational studies are also necessary to examine organic changes in EAM use and motivational changes overtime. Updated content analysis reviews are also necessary. Technology is rapidly changing and the last content analyses on EAMs and mobile apps were conducted in 2014.^{79,213} Although this information is helpful, it is likely out of date.

Quasi-experimental and pilot randomized trials are necessary for further refinement of the TAME health intervention. Researchers should investigate methods to further enhance social support. Some areas of investigation may include: having

participants meet in person at the beginning or throughout the intervention; testing effect of varying group sizes on the contribution of virtual support; and experimenting with different anonymous personae that elicit communication between participants within a virtual community. Researchers should also find effective strategies to further enhance competence. Such strategies may include encouraging all participants to self-talk within an app, urging use of the Smartcoach or other similar feature, or utilizing external rewards within the EAM system. If rewards are used they must be used mindfully.^{215,216} In an effort to maintain intrinsic motivation verbal rewards, task non-contingent rewards, and rewards of glory (i.e. achievements, badges) should be utilized.²¹⁷

Similarly, future research should test other EAMs that incorporate other behavior change techniques such as biofeedback, non-specific rewards, and situation-specific rewards within a quasi-experimental or pilot randomized trial.⁷⁹ There is also a need to evaluate a comprehensive intervention that targets multiple health behaviors on CVD risk. EAMs have the ability to monitor multiple behaviors but TAME health participants were provided minimal guidance or education on these behaviors. Some health behaviors cited by participants include diet, strength-training, sleep, and water intake. Lastly, researchers should investigate maintenance of behavior change from this type of intervention.

Once all of the aforementioned studies are conducted and the most effective interventions are identified, then large-scale, multi-site randomized controlled studies should be conducted. These studies should include multiple intervention groups to test them simultaneously. This can be done using the Multiphase Optimization Strategy (MOST) or Sequential Multiple Assignment Randomized Trial (SMART).²¹⁸ Both strategies use adaptable protocols that allow for systematic intervention refinement. Use of either of these strategies will result in a more potent technology-based intervention.²¹⁸

CONCLUSIONS

We found that the TAME health intervention is feasible and acceptable. Compared to the pedometer, the EAM produced small-to-moderate effect sizes on PA, waist-to-hip ratio, and physical function. Furthermore, the EAM significantly improved constructs of SDT. The results of this study have implications within SDT, on use of activity monitors, and on primary care. Overall, our findings imply that brief 5 A's counseling and providing a regular pedometer, or an EAM, does produce a positive result and might be a cost-effective way to improve health. These results suggest that, on a larger scale, the intervention may improve health at individual and population levels. Moreover, we learned that recruitment through primary care is a possible strategy to target the community, EAMs produce a high volume of technical issues, and participants need additional educational tools to understand the principles of PA. Future research should update a review on the behavior change techniques within an EAM, observe patient's use of EAMs, investigate methods to enhance social support and competence, test other behavior change techniques, incorporate counseling on multiple health behaviors, and evaluate long-term maintenance of behavior change.

Appendices

Appendix A: 5 A-S counseling guide

Brief Counseling Guide

1. Assess- ask about/ asses behavioral health risk

Start by reviewing the participant's physical activity from the armband. Assess the participant's physical activity in terms of steps per day and minutes per day

2. Advise- advise participant to increase their physical activity to meet healthy levels

Based on your physical activity we measured this past week, you are currently active for _____ minutes a week and about _____ steps a week. The public health guideline is at least 150 minutes of moderate or vigorous activity a week. Moderate activity is any activity that may produce sweat and heavy breathing, one example of moderate activity is a brisk walk. If you're doing vigorous activity, it will be difficult to carry a conversation. An example of this is running a 12-minute mile. About 7,000 steps a day for your age group corresponds with the public health guideline. Physical activity is important because it can help prevent cardiovascular disease and other chronic conditions. If you're not physically active on a regular basis, your health can suffer. You can meet this goal by ... [based on their activity, suggest increasing frequency or duration of physical activity to meet healthy levels].

3. Agree- reach agreement with the participant about appropriate weekly physical activity goal and a long term goal

Now, let us agree on a physical activity goal for the three months. When creating a step goal, we want it to be clear and measureable. An example of a goal is to reach 7,000 steps a day. What is a realistic goal for you? [discuss with the participant on a clear,

measurable goal that is reasonable for them based on their baseline physical activity]

GREAT! Your step goal is _____

To reach this goal, let's make a plan.

Which days do you plan to exercise? S M T W R F S

How many exercise sessions per day? _____

How many minutes per session? _____ minutes/session

In the long-term, by the end of the intervention, what is your physical activity goal? This goal does not have to be as specific as your short-term goal.

4. Assist- teach behavior change strategies

Now we are going to come up with different strategies to help you meet your goals.

First we are going to discuss social support. Research shows that social support is key in helping people adopt a program of regular exercise. There are some different types of social support that can help motivate you to walk and help you stick to your walking program. Let's identify people who could possibly provide each in your life, and in the upcoming weeks you can try to enlist their help.

- Participatory support (e.g. a waling "buddy") _____
- Technical Support (resource for increasing exercise knowledge, radio or people)

- Motivational Support (encouragement) _____
- Practical Support (helping around the house so you have more free time to walk)

I want you to think about some areas where you need support. Pick one area you need help and ask for assistance.

Next, we are going to use something called the IDEA process to examine ways to overcome possible barriers to exercise. The IDEA process stands for Identify, Develop, Evaluate, and Analyze. Let's choose one barrier you might have with physical activity and problem-solve that barrier.

Identify problem _____

Develop creative solutions. What are some possible solutions? (brainstorm as many as you possibly can _____

Evaluate the solutions and select the one you are most likely to implement and develop a specific plan to implement. _____

After implement, analyze how well it worked and revise if necessary.

5. Arrange- arrange a follow-up appointment to assess progress and any issues that arise.

Let's arrange a time for me to call you next week so we can talk about your progress.

Now, let's arrange a time for your 12-week visit

Appendix B: Exercise prescription

Exercise Prescription

You have a goal of _____ steps, _____ days a week.

Remember your long term goal of

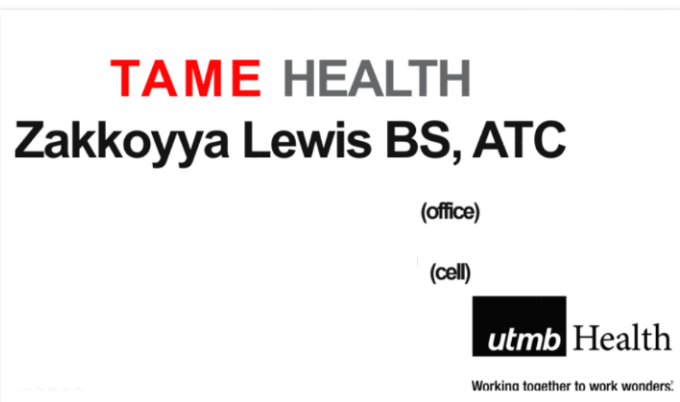
Here are some tips to help meet this goal:

- Take 5-10 minute walking breaks
- Walk while you're on the phone
- Take the stairs
- Park your car further away
- Take an evening walk after dinner

We came up with these additional tips:

Remember to enlist **support** from _____.
If _____ is a **barrier** for you, remember your **plan** to

Our next meeting is scheduled for _____



Appendix C: Baseline questionnaire

ID: _____ Date: _____

BASELINE QUESTIONNAIRE

Background questions

Please write in your answer or check the box that describes you best.

1. What is your age?

_____ years old

2. What is your data of birth?

_____/_____/_____

3. Are you

☐

Male

☐

Female

4. Are you Hispanic or Latino?

☐

Yes

☐

No

5. Which one or more of the following would you say is your race?

American Indian or Alaska Native

☐

Asian

☐

Black or African American

☐

Native Hawaiian or Other Pacific Islander

☐

White

☐

Other race

☐

6. What is the highest grade of school you completed?

Some high school

☐

High school graduate or GED

☐

Some college or technical school

☐

College graduate

☐

Graduate or professional school

☐

7. Are you currently receiving treatment for hypertension?

☐

Yes

☐

No

ID: _____ Date: _____

BASELINE QUESTIONNAIRE

8. Have you ever been diagnosed with diabetes?

☐ Yes☐ No

9. What medications do you currently take, and for what condition?

Exercise Regulations

Using the scale below, please indicate to what extent each of the following items is true for you. Please note that there are no right or wrong answers and no trick questions. We simply want to know how you personally feel about exercise.

		Not true		Sometimes true		Very true
1	I exercise because other people say I should	0	1	2	3	4
2	I feel guilty when I don't exercise	0	1	2	3	4
3	I value the benefits of exercise	0	1	2	3	4
4	I exercise because it's fun	0	1	2	3	4
5	I don't see why I should have to exercise	0	1	2	3	4
6	I take part in exercise because my friends/family/partner say I should	0	1	2	3	4
7	I feel ashamed when I miss an exercise session	0	1	2	3	4
8	It's important to me to exercise regularly	0	1	2	3	4
9	I can't see why I should bother exercising	0	1	2	3	4
10	I enjoy my exercise sessions	0	1	2	3	4
11	I exercise because others will not be please with me if I don't	0	1	2	3	4
12	I don't see the point in exercising	0	1	2	3	4
13	I feel like a failure when I haven't exercised in a while	0	1	2	3	4
14	I think it is important to make the effort to exercise regularly	0	1	2	3	4
15	I find exercise a pleasurable activity	0	1	2	3	4
16	I feel under pressure from my friends/family to exercise	0	1	2	3	4
17	I get restless if I don't exercise regularly	0	1	2	3	4
18	I get pleasure and satisfaction from participating in exercise	0	1	2	3	4
19	I think exercising is a waste of time	0	1	2	3	4

Page 2 of 8

ID: _____ Date: _____

BASELINE QUESTIONNAIRE

Psychological feelings about exercise. The following sentences refer to your overall experiences in exercise as opposed to any particular situation. Using the 1-5 scale below, please indicate the extent to which you agree with these statements by circling one number for each statement.

		I don't agree at all	I agree a little bit	I somewhat agree	I agree a lot	I complete- ly agree
1.	I feel I have made a lot of progress in relation to the goal I want to achieve	1	2	3	4	5
2.	The way I exercise is in agreement with my choices and interests	1	2	3	4	5
3.	I feel I perform successfully the activities of my exercise program	1	2	3	4	5
4.	My relationship with the people I exercise with are very friendly	1	2	3	4	5
5.	I feel that the way I exercise is the way I want to	1	2	3	4	5
6.	I feel exercise is an activity which I do very well	1	2	3	4	5
7.	I feel I have excellent communication with the people I exercise with	1	2	3	4	5
8.	I feel that the way I exercise is a true expression of who I am	1	2	3	4	5
9.	I am able to meet the requirement of my exercise program	1	2	3	4	5
10.	My relationship with the people I exercise with are close	1	2	3	4	5
11.	I feel that I have the opportunity to make choices with regard to the way I exercise	1	2	3	4	5

ID: _____ Date: _____ **BASELINE QUESTIONNAIRE**
Exercise goal-setting and planning

The following questions refer to how you set exercise goals and plan exercise activities. Please indicate the extent to which each of the statements below describes you.

		Does not describe me		describes moderately		Describes completely
1	I often set exercise goals	1	2	3	4	5
2	I usually have more than one major exercise goal	1	2	3	4	5
3	I usually set dates for achieving my exercise goals	1	2	3	4	5
4	My exercise goals help to increase my motivation for doing exercise	1	2	3	4	5
5	I tend to break more difficult exercise goals down into series of smaller goals	1	2	3	4	5
6	I usually keep track of my progress in meeting my goals	1	2	3	4	5
7	I have developed a series of steps for reaching my exercise goals	1	2	3	4	5
8	I usually achieve the exercise goals I set for myself	1	2	3	4	5
9	If I do not reach an exercise goal, I analyze what went wrong	1	2	3	4	5
10	I make my exercise goals public by telling other people about them	1	2	3	4	5
11	I never seem to have enough time to exercise	1	2	3	4	5
12	Exercise is generally not a high priority when I plan my schedule	1	2	3	4	5
13	Finding time for exercise is difficult for me	1	2	3	4	5
14	I schedule all events in my life around my exercise routine	1	2	3	4	5
15	I schedule my exercise at specific times each week	1	2	3	4	5
16	I plan my weekly exercise schedule	1	2	3	4	5
17	When I am very busy, I don't do much exercise	1	2	3	4	5
18	Everything is scheduled around my exercise routine—both classes and work	1	2	3	4	5
19	I try to exercise at the same time and same day each week to keep a routine going	1	2	3	4	5
20	I write my planned activity session in an appointment book or calendar	1	2	3	4	5

ID: _____ Date: _____

BASELINE QUESTIONNAIRE

Health Survey

Please take the time to read and answer each question carefully by marking or circling the answer that best represents your response about your health.

1. In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

2. Compared to one year ago, how would you rate your health in general now?

☐ Much better than one year ago ☐ Somewhat better now than one year ago ☐ About the same as one year ago ☐ Somewhat worse now than one year ago ☐ Much worse now than one year ago

3. The following questions are about activity you might do during a typical day. Does your health now limit you in these activity? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several hundred yards	1	2	3
i. Walking one hundred yards	1	2	3
j. Bathing or dressing yourself	1	2	3

ID: _____ Date: _____ **BASELINE QUESTIONNAIRE**

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Were limited in the kind of work or other activities	1	2	3	4	5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Did work or other activities less carefully than usual	1	2	3	4	5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

7. How much bodily pain have you had during the past 4 weeks?

☐ None ☐ Very mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

ID: _____ Date: _____

BASELINE QUESTIONNAIRE

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. did you feel full of life?	1	2	3	4	5
b. have you been very nervous?	1	2	3	4	5
c. have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. have you felt calm and peaceful?	1	2	3	4	5
e. did you have a lot of energy?	1	2	3	4	5
f. have you felt downhearted and depressed?	1	2	3	4	5
g. did you feel worn out?	1	2	3	4	5
h. have you been happy?	1	2	3	4	5
i. did you feel tired?	1	2	3	4	5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (life visiting friends, relative, etc.)?

☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time

11. How TRUE or FALSE is each of the following statement for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as health as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

ID: _____ Date: _____

BASELINE QUESTIONNAIRE**Physical Function**

Please respond to each question by marking or circling the answer that best represents your response.

	Unable to do	With much difficulty	With some difficulty	With a little difficulty	Without any difficulty
1. Are you able to do chores such as vacuuming or yard work?	1	2	3	4	5
2. Are you able to go up and down stairs at a normal pace?	1	2	3	4	5
3. Are you able to go for a walk of at least 15 minutes?	1	2	3	4	5
4. Are you able to run errands and shop?	1	2	3	4	5
	Cannot do	Quite a lot	Somewhat	Very little	Not at all
5. Does your health now limit you in doing two hours of physical labor?	1	2	3	4	5
6. Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?	1	2	3	4	5
7. Does your health not limit you in lifting or carrying groceries?	1	2	3	4	5
8. Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?	1	2	3	4	5

This is the end of the questionnaire, thank you for participating.

Appendix D: Follow-Up questionnaire

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE

Background questions

Please write in your answer or check the box that describes you best.

1. Are you currently receiving treatment for hypertension?

☐ Yes

☐ No

2. Have you ever been diagnosed with diabetes?

☐ Yes

☐ No

3. What medications do you currently take, and for what condition?

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE

Exercise Regulations

Using the scale below, please indicate to what extent each of the following items is true for you.

Please note that there are no right or wrong answers and no trick questions. We simply want to know how you personally feel about exercise.

		Not true		Sometimes true		Very true
1	I exercise because other people say I should	0	1	2	3	4
2	I feel guilty when I don't exercise	0	1	2	3	4
3	I value the benefits of exercise	0	1	2	3	4
4	I exercise because it's fun	0	1	2	3	4
5	I don't see why I should have to exercise	0	1	2	3	4
6	I take part in exercise because my friends/family/partner say I should	0	1	2	3	4
7	I feel ashamed when I miss an exercise session	0	1	2	3	4
8	It's important to me to exercise regularly	0	1	2	3	4
9	I can't see why I should bother exercising	0	1	2	3	4
10	I enjoy my exercise sessions	0	1	2	3	4
11	I exercise because others will not be please with me if I don't	0	1	2	3	4
12	I don't see the point in exercising	0	1	2	3	4
13	I feel like a failure when I haven't exercised in a while	0	1	2	3	4
14	I think it is important to make the effort to exercise regularly	0	1	2	3	4
15	I find exercise a pleasurable activity	0	1	2	3	4
16	I feel under pressure from my friends/family to exercise	0	1	2	3	4
17	I get restless if I don't exercise regularly	0	1	2	3	4
18	I get pleasure and satisfaction from participating in exercise	0	1	2	3	4
19	I think exercising is a waste of time	0	1	2	3	4

ID: _____ Date: _____ **END OF STUDY QUESTIONNAIRE**

Psychological feelings about exercise The following sentences refer to your overall experiences in exercise as opposed to any particular situation. Using the 1-5 scale below, please indicate the extent to which you agree with these statements by circling one number for each statement.

		I don't agree at all	I agree a little bit	I somewhat agree	I agree a lot	I complete- ly agree
1.	I feel I have made a lot of progress in relation to the goal I want to achieve	1	2	3	4	5
2.	The way I exercise is in agreement with my choices and interests	1	2	3	4	5
3.	I feel I perform successfully the activities of my exercise program	1	2	3	4	5
4.	My relationship with the people I exercise with are very friendly	1	2	3	4	5
5.	I feel that the way I exercise is the way I want to	1	2	3	4	5
6.	I feel exercise is an activity which I do very well	1	2	3	4	5
7.	I feel I have excellent communication with the people I exercise with	1	2	3	4	5
8.	I feel that the way I exercise is a true expression of who I am	1	2	3	4	5
9.	I am able to meet the requirement of my exercise program	1	2	3	4	5
10.	My relationship with the people I exercise with are close	1	2	3	4	5
11.	I feel that I have the opportunity to make choices with regard to the way I exercise	1	2	3	4	5

ID: _____ Date: _____ **END OF STUDY QUESTIONNAIRE**
Exercise goal-setting and planning

The following questions refer to how you set exercise goals and plan exercise activities. Please indicate the extent to which each of the statements below describes you.

		Does not describe me		describes moderately		Describes completely
1	I often set exercise goals	1	2	3	4	5
2	I usually have more than one major exercise goal	1	2	3	4	5
3	I usually set dates for achieving my exercise goals	1	2	3	4	5
4	My exercise goals help to increase my motivation for doing exercise	1	2	3	4	5
5	I tend to break more difficult exercise goals down into series of smaller goals	1	2	3	4	5
6	I usually keep track of my progress in meeting my goals	1	2	3	4	5
7	I have developed a series of steps for reaching my exercise goals	1	2	3	4	5
8	I usually achieve the exercise goals I set for myself	1	2	3	4	5
9	If I do not reach an exercise goal, I analyze what went wrong	1	2	3	4	5
10	I make my exercise goals public by telling other people about them	1	2	3	4	5
11	I never seem to have enough time to exercise	1	2	3	4	5
12	Exercise is generally not a high priority when I plan my schedule	1	2	3	4	5
13	Finding time for exercise is difficult for me	1	2	3	4	5
14	I schedule all events in my life around my exercise routine	1	2	3	4	5
15	I schedule my exercise at specific times each week	1	2	3	4	5
16	I plan my weekly exercise schedule	1	2	3	4	5
17	When I am very busy, I don't do much exercise	1	2	3	4	5
18	Everything is scheduled around my exercise routine—both classes and work	1	2	3	4	5
19	I try to exercise at the same time and same day each week to keep a routine going	1	2	3	4	5
20	I write my planned activity session in an appointment book or calendar	1	2	3	4	5

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE

Health Survey

Please take the time to read and answer each question carefully by marking or circling the answer that best represents your response about your health.

1. In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

2. Compared to one year ago, how would you rate your health in general now?

☐ Much better than one year ago ☐ Somewhat better now than one year ago ☐ About the same as one year ago ☐ Somewhat worse now than one year ago ☐ Much worse now than one year ago

3. The following questions are about activity you might do during a typical day. Does your health now limit you in these activity? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several hundred yards	1	2	3
i. Walking one hundred yards	1	2	3
j. Bathing or dressing yourself	1	2	3

ID: _____ Date: _____ **END OF STUDY QUESTIONNAIRE**

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Were limited in the kind of work or other activities	1	2	3	4	5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Did work or other activities less carefully than usual	1	2	3	4	5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

7. How much bodily pain have you had during the past 4 weeks?

☐ None ☐ Very mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. did you feel full of life?	1	2	3	4	5
b. have you been very nervous?	1	2	3	4	5
c. have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. have you felt calm and peaceful?	1	2	3	4	5
e. did you have a lot of energy?	1	2	3	4	5
f. have you felt downhearted and depressed?	1	2	3	4	5
g. did you feel worn out?	1	2	3	4	5
h. have you been happy?	1	2	3	4	5
i. did you feel tired?	1	2	3	4	5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (life visiting friends, relative, etc.)?

☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time

11. How TRUE or FALE is each of the following statement for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as health as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE

Physical Function

Please respond to each question by marking or circling the answer that best represents your response.

	Unable to do	With much difficulty	With some difficulty	With a little difficulty	Without any difficulty
1. Are you able to do chores such as vacuuming or yard work?	1	2	3	4	5
2. Are you able to go up and down stairs at a normal pace?	1	2	3	4	5
3. Are you able to go for a walk of at least 15 minutes?	1	2	3	4	5
4. Are you able to run errands and shop?	1	2	3	4	5
	Cannot do	Quite a lot	Somewhat	Very little	Not at all
5. Does your health now limit you in doing two hours of physical labor?	1	2	3	4	5
6. Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?	1	2	3	4	5
7. Does your health not limit you in lifting or carrying groceries?	1	2	3	4	5
8. Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?	1	2	3	4	5

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE
Feeling about the study

Please answer the following question by circling the answer that is closest to how you feel. The first section asks about your opinion on the counseling.

		Strongly disagree		Neutral		Strongly agree
1	I felt the counseling was motivational	1	2	3	4	5
2	The counseling was helpful	1	2	3	4	5
3	I felt the counseling was too short	1	2	3	4	5
4	The exercise prescription was helpful	1	2	3	4	5
5	I would prefer if there were more counseling sessions	1	2	3	4	5
6	I would prefer counseling from a physician or nurse	1	2	3	4	5
7	I enjoyed the counseling	1	2	3	4	5

These next sets of questions covers your feelings on your activity monitor.

		Strongly disagree		Neutral		Strongly agree
1	It was easy to remember to wear the monitor	1	2	3	4	5
2	I felt that the monitor was comfortable	1	2	3	4	5
3	I would continue to wear the monitor	1	2	3	4	5
4	I was embarrassed for people to see the monitor	1	2	3	4	5
5	The monitor was motivating	1	2	3	4	5
6	I liked using the monitor	1	2	3	4	5
7	I though the pedometer was helpful	1	2	3	4	5
8	I would prefer to use another type of monitor	1	2	3	4	5
9	I have a better understanding on my physical activity level	1	2	3	4	5

ID: _____ Date: _____ END OF STUDY QUESTIONNAIRE
 These questions ask about your feelings about the Up application overall. **JAWBONE GROUP ONLY.**

		Strongly disagree		Neutral		Strongly agree
1	It was convenient for me to use the Up application	1	2	3	4	5
2	The Up application encouraged me to view my steps	1	2	3	4	5
3	I would like to continue using the Up application	1	2	3	4	5
4	I think the application is user-friendly	1	2	3	4	5
5	I think the application is conveniently arranged	1	2	3	4	5
6	I think the application is good choice for this intervention	1	2	3	4	5
7	I have problems with the colors used in the application	1	2	3	4	5
8	I have problems with the presentation of the application	1	2	3	4	5
9	I have problems with the styling used in the application	1	2	3	4	5
10	I enjoyed the social interaction	1	2	3	4	5
11	Comments and smiles from my "friends" in the application were motivating	1	2	3	4	5

ID: _____ Date: _____ **END OF STUDY QUESTIONNAIRE**
 These questions are about the information (including facts, advice, tips, and feedback) provided by the Up application on your Up feed. **JAWBONE GROUP ONLY.**

		Strongly disagree		Neutral		Strongly agree
1	I think the information is credible	1	2	3	4	5
2	I think the information is interesting	1	2	3	4	5
3	I think the information is relevant	1	2	3	4	5
4	I think the tips and advice are specific to me	1	2	3	4	5
5	I think the information has taught me new things	1	2	3	4	5
6	I am going to use the advice	1	2	3	4	5
7	I think the information is correct	1	2	3	4	5
8	I think the information is too long	1	2	3	4	5
9	I think the information is confusing	1	2	3	4	5
10	I think the app gives too much information	1	2	3	4	5

This is the end of the questionnaire, thank you for participating.

Appendix E: Participant focus group guide

Focus group guide

Before you started the program, how did you feel about exercise?

What prevented you from getting as much exercise as you wanted?

Do you think that your attitude towards exercise has changed?

Thinking about the monitor you used, what did you like about it?

What didn't you like about it?

Do you think you'll continue using a monitor like this (be honest!)?

Do you think you'll use any activity monitor after the study is over (be honest!)?

Provide a copy of the brief counseling sheet.

Of the counseling components (assess, advise, agree, assist, arrange), which did you value the most?

Did you like receiving counseling from a counselor? Why or why not?

Would you prefer the counseling done by your primary care physician? Why or why not?

Would you prefer the counseling done by a nurse, physician assistant, or anyone else who worked with your doctor? Why or why not?

Provide a copy of the exercise prescription.

Did you find the written prescription helpful? Why or why not?

For the intervention group only.

Did you like the social aspects of this study? For example: the leaderboard, the comments, smileys, and duels. How often did you communicate with other participants?

Do you think you'd use some of these social tools with your friends and family?

Appendix F: Stakeholder focus group guide

Stakeholder Focus group guide

The 5 A's counseling is brief counseling that has been adopted by the United States Preventive Services Task Force to promote behavioral change during a doctor's visit. Have you done 5 A's counseling in your clinic?

Here is a copy of the counseling done in our study along with a supplementary exercise prescription. Please look it over.

Do you like the counseling? Why or why not?

Would you use this counseling with your patients?

Using technology to self-monitor PA is an effective method to change behavior. Do you currently advise your patients to monitor their activity?

We gave half of our participants this pedometer to self-monitor behavior. Would you recommend your patients to use this pedometer? Why or why not?

The other half of our participants were given this Up24 to self-monitor behavior. This monitor pairs with an app on a smart device to give feedback on behavior. This is an example of the feedback it provides.

Would you recommend your patients to use this monitor? Why or why not?

In our study we compared the effectiveness of the two devices. *Present preliminary results.*

What are your thoughts about the study?

Is this study something you can implement in your clinic?

What would you change about the study?

Appendix G: Stakeholder first focus group questionnaire

Group Number: _____ Date: _____

1

Background questions

What is your position?

Please circle yes or no to the following questions

Do you counsel patients on how to be more physically active?	yes	no
Do you provide written material on how to be more physically active?	yes	no
Have you heard of 5 A's counseling?	yes	no
Have you used 5 A's counseling?	yes	no
Do you believe counseling is effective to change behavior?	yes	no
Do you currently advise patients to use an activity monitor?	yes	no
Do your patients ask your recommendation for an activity monitor?	yes	no
Do you believe activity monitors are effective to change behavior?	yes	no

Appendix H: Stakeholder last focus group questionnaire

Group Number: _____ Date: _____

1

Follow-up questions

What is your position? _____

Based on the materials from the study and the preliminary results, please answer the following questions. Using the 1-5 scale below, please indicate the extent to which you agree with these statements by circling one number for each statement.

		I don't agree at all	I agree a little bit	I somewhat agree	I agree a lot	I completely agree
1.	I like the format of 5 A's counseling	1	2	3	4	5
2.	I like the questions in 5 A's counseling	1	2	3	4	5
3.	I believe this counseling would be beneficial for my patients	1	2	3	4	5
4.	I would use 5 A's counseling with my patients	1	2	3	4	5
5.	I think pedometers are effective to increase physical activity	1	2	3	4	5
6.	I would recommend a pedometer to my patients	1	2	3	4	5
7.	I think an electronic activity monitor is effective to increase physical activity	1	2	3	4	5
8.	I would recommend an electronic activity monitor to my patients	1	2	3	4	5
9.	For my patients, I would recommend an electronic activity monitor rather than a pedometer	1	2	3	4	5
10.	This intervention would be beneficial for my patients	1	2	3	4	5
11.	It would be feasible to implement this intervention in my clinic	1	2	3	4	5

Appendix I: Stakeholder UP24 questionnaire

ID: _____ Date: _____ Stakeholder Monitor Questionnaire

Feeling about the study

What is your position? _____

Please answer the following question by circling the answer that is closest to how you feel. The first section asks about your opinion on the activity monitor.

		Strongly disagree		Neutral		Strongly agree
1	It was easy to remember to wear the monitor	1	2	3	4	5
2	I felt that the monitor was comfortable	1	2	3	4	5
3	I would continue to wear the monitor	1	2	3	4	5
4	I was embarrassed for people to see the monitor	1	2	3	4	5
5	The monitor was motivating	1	2	3	4	5
6	I liked using the monitor	1	2	3	4	5
7	I thought the pedometer was helpful	1	2	3	4	5
8	I would prefer to use another type of monitor	1	2	3	4	5
9	I have a better understanding on my physical activity level	1	2	3	4	5

ID: _____ Date: _____ Stakeholder Monitor Questionnaire

These questions ask about your feelings about the Up application overall.

		Strongly disagree		Neutral		Strongly agree
1	It was convenient for me to use the Up application	1	2	3	4	5
2	The Up application encouraged me to view my steps	1	2	3	4	5
3	I would like to continue using the Up application	1	2	3	4	5
4	I think the application is user-friendly	1	2	3	4	5
5	I think the application is conveniently arranged	1	2	3	4	5
6	I think the application is good choice for this intervention	1	2	3	4	5
7	I have problems with the colors used in the application	1	2	3	4	5
8	I have problems with the presentation of the application	1	2	3	4	5
9	I have problems with the styling used in the application	1	2	3	4	5
10	I enjoyed the social interaction	1	2	3	4	5
11	Comments and smiles from my "friends" in the application were motivating	1	2	3	4	5

ID: _____ Date: _____ Stakeholder Monitor Questionnaire

These questions are about the information (including facts, advice, tips, and feedback) provided by the Up application on your Up feed.

		Strongly disagree		Neutral		Strongly agree
1	I think the information is credible	1	2	3	4	5
2	I think the information is interesting	1	2	3	4	5
3	I think the information is relevant	1	2	3	4	5
4	I think the tips and advice are specific to me	1	2	3	4	5
5	I think the information has taught me new things	1	2	3	4	5
6	I am going to use the advice	1	2	3	4	5
7	I think the information is correct	1	2	3	4	5
8	I think the information is too long	1	2	3	4	5
9	I think the information is confusing	1	2	3	4	5
10	I think the app gives too much information	1	2	3	4	5

ID: _____ Date: _____ Stakeholder Monitor Questionnaire

In the lines provided, please write any additional comments you have about the following app features:

Activity monitoring (e.g. Stopwatch mode, idle alert, activity alert)

Diet monitoring

Weight monitoring

Sleep monitoring (e.g. sleep tracking, power nap, smart alarm)

ID: _____ Date: _____

Stakeholder Monitor Questionnaire

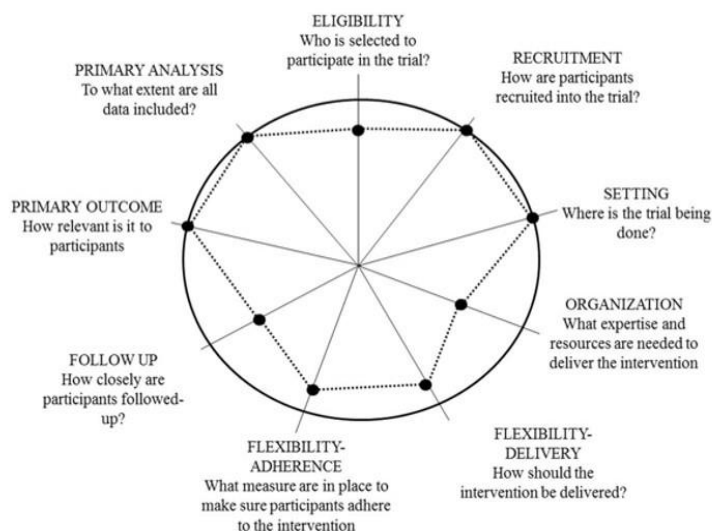
Smart Coach

Reminders (e.g. bedtime, workout, meal, pill, custom)

Socialization (e.g. leaderboard, duels, feelings)

This is the end of the questionnaire, thank you for participating.

Appendix J: PRECIS-2 Figure



Component	Score	Rationale
Eligibility	4	Participants are essentially identical to those in usual care because they are primary care patients, with some exclusion criteria to identify the moderate risk patients
Recruitment	5	The study design targeted recruitment to occur through the usual primary care appointment
Setting	5	The trial was conducted in the participant's normal primary care setting
Organization	3	The trial would not require additional staff however clinicians and/or nurses would need additional training to administer 5 A's counseling
Flexibility -Delivery	4	5 A's counseling is already a standard in primary care, however clinicians would need further instruction
Flexibility -Adherence	4	Compliance is only required for baseline assessments. Participants were not excluded for non-compliance with the activity monitor or with follow-up assessments.
Follow up	3	The visits are longer than expected to assess study outcomes but with minimal additional visits
Primary Outcome	5	Physical activity is important to the participants that volunteer to be a part of a physical activity intervention
Analysis	5	The primary analysis of the study outcomes used the intent-to-treat principle

Appendix K: CONSORT checklist



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	94
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	94
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	95-96
	2b	Specific objectives or hypotheses	96
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	97-98
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	97
	4b	Settings and locations where the data were collected	97-98
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	97-98
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	98-99
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	99
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	previously reported, reference on page

	8b	Type of randomisation; details of any restriction (such as blocking and block size)	96 previously reported, reference on page 96
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	previously reported, reference on page 96
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	previously reported, reference on page 96
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	97, 99
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	99
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	101
	13b	For each group, losses and exclusions after randomisation, together with reasons	101
Recruitment	14a	Dates defining the periods of recruitment and follow-up	97
	14b	Why the trial ended or was stopped	100
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	102
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	104
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	104
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	100
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	107
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	107-108
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	105-108
Other information			
Registration	23	Registration number and name of trial registry	96-97
Protocol	24	Where the full trial protocol can be accessed, if available	96
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	96

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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217. Lewis ZH, Swartz MC, Lyons EJ. What's the Point?: A Review of Reward Systems Implemented in Gamification Interventions. *Games Health J*. 2016.
218. Collins LM, Murphy SA, Strecher V. The Multiphase Optimization Strategy (MOST) and the Sequential Multiple Assignment Randomized Trial (SMART) - New methods for more potent eHealth interventions. *American Journal of Preventive Medicine*. 2007;32(5):S112-S118.

Vita

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COMMITTEE RESPONSIBILITIES:

National

Student Co-Chair (2015-2016), Behavioral Informatics and Technology Special Interest Group, Society of Behavioral Medicine

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MEMBERSHIP IN SCIENTIFIC SOCIETIES/PROGRESSIONAL ORGANIZATIONS:

American Heart Association	2015-present
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American College of Sports Medicine	2011-present
National Athletic Trainers Association	2011-present
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HONORS:

Peyton and Lydia Schapper Endowed Scholarship Fund	2016
Don W. Micks Scholarship in Preventive Medicine and Community Health	2015
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Excellence in Student Research: Minority Health/ Health Disparities Annual Forum on Aging	2015
Clinical Science Poster Award Center for Interdisciplinary Research in Women's Health poster session	2015
Research Excellence Poster Award Clinical & Translational Research Forum	2014
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PUBLISHED:

A. PUBLICATIONS IN PEER-REVIEWED JOURNALS:

1. Lyons, E.J., Lewis, Z.H., Mayrsohn, B., & Rowland, J. (2014). *Behavior change techniques implemented in electronic lifestyle activity monitors: a systematic content analysis*. Journal of medical internet research, 16(8),e192. Available at: [Http://www.jmir.org/2014/8/e192/](http://www.jmir.org/2014/8/e192/)
2. Lewis, Z.H., Lyons, E.J., Jarvis, J., Baillargeon, J. (2015) *Using an electronic monitor system as an intervention modality: A Systematic Review*. BMC Public Health, 15, 585.
3. Almstedt, H.C., Lewis, Z. (2015) *Intermittent Pneumatic Compression and Bone Mineral Density: An Exploratory Study*. Journal of Sport Rehabilitation.
4. Lewis, Z., Swartz, M.C., Lyons, E.J. (2016) *What's the point?: A Review of Reward Systems Implemented in Gamification Intervention*. Games for Health Journal, 5(2).
5. Lyons, E.J., Baranowski, T., Basen-Engquist, K.M., Lewis, Z.H., Swartz, M.C., Jennings, K.J., Volpi, E. (2015) *Testing the effects of narrative and play on physical activity among breast cancer survivors: study protocol for a randomized controlled trial*. BMC Cancer.
6. Lewis, Z., Markides, K.S., Ottenbacher, K.J., Al Snih, S. (2015) *The Role of Physical Activity and Physical Function on the Risk of Falls in Older Mexican Americans*. Journal of Aging and Physical Activity.
7. Lewis, Z.H., Ottenbacher, K.J., Fisher, S.R., Jennings, K., Brown, A.F., Swartz, M.C., Lyons, E.J. (2016) *Testing Activity Monitors' Effect on health (TAME health): Study protocol for a randomized controlled trial among older primary care patients*. JMIR RES PROTOC, 5(2):E29. doi:10.2196/resprot.5454
8. Lewis, Z.H., Hay, C.C., Graham, J., Lin, Y., Karmarkar, A., Ottenbacher, K.J. (2016) *Social support and actual versus expected length of stay in inpatient rehabilitation facilities*. Archives of Physical Medicine and Rehabilitation.

B. OTHER:

C. ABSTRACTS:

1. Lewis, Z., Swartz, M., Lyons, E. (2016). *What types of incentives elicit weight control in adults?: A systematic review of behavioral interventions*. Annals of Behavioral Medicine, 50 (Suppl 1), S25.

2. Lewis, Z., Swartz, M., Nowakowski, S., Lyons, E. (2016). *Are personal characteristics correlated with measurement error in wearable activity monitors?*. Annals of Behavioral Medicine, 50 (Suppl 1), S319.
3. Lewis, Z.H., Hay, C.C., Lin, Y., Graham, J. (2015). *Not as Expected! Length of Stay in Inpatient Rehabilitation Facilities*. Archives of Physical Medicine and Rehabilitation, 96(10), e43.
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6. Almstedt, H., & Lewis-Powell, Z. (2012). College-age dancers have greater bone mass than runners and controls despite low energy availability. Medicine & Science in Sports & Exercise, 44(5), 517-518.

PRESENTED:

CONFERENCE/CONVENTION:

- Lewis, Z.H., Lyons, E.J., Nowakowski, S., Swartz, M.C. (2016) *Are personal characteristics correlated with measurement error in wearable activity monitors?* Presented at the Society of Behavioral Medicine annual meeting, March 30-April 2, Washington D.C.
- Lewis, Z.H., Swartz, M.C., Lyons, E.J. (2016). *What types of incentives elicit weight control in adults?: A systematic review of behavioral interventions*. Presented at the Society of Behavioral Medicine annual meeting, March 30-April 2, Washington D.C.
- Lewis, Z.H., Markides, K.S., Ottenbacher, K., Al Snih, S. (2015). *The Role of Physical Activity and Physical Function on the Risk of Falls in Older Mexican Americans*. Presented at the Gerontological Society of America's Annual Scientific Meeting, November 18-22, Orlando, FL.
- Lewis, Z.H. & Lyons, E.J. (2015). *The Walking Dead: Is implementation of a zombie running game feasible among adult women?* Presented at the Society of Behavioral Medicine annual meeting, April 22-25, San Antonio, CA.
- Lewis, Z.H. & Lyons, E.J. (2014). *Activity monitor-based mhealth intervention increases fitness in older adults: a pre-experimental pilot study*. Presented at the International Society for Behavioral Nutrition and Physical Activity annual meeting, May 21-24, San Diego, CA.
- Lyons, E.J. & Lewis-Powell, Z.H. (2014). *An activity monitor and mobile device intervention is feasible among older adults*. Presented at Translational Science 2014, April 9 – 11, Washington, DC.
- Lewis, Z.H. & Almstedt, H. (2012). *Intermittent pneumatic compression may improve bone mineral density at the hip*. Presented at the Southwest American College of Sports Medicine annual meeting, October, Newport Beach, CA.
- Almstedt, H. & Lewis-Powell, Z.H. (2012). *College age dancers have stronger bones than runners and controls, despite low energy availability*. Presented at the ACSM annual meeting, May, San Francisco, CA.
- Almstedt, H. & Lewis-Powell, Z.H. (2011). *College age dancers have stronger bones than runners and controls, despite low energy availability*. Presented at

the annual biomedical research conference for minority students, November, St. Louis, MO.

LOCAL:

- Lewis, Z.H., Markides, K.S., Ottenbacher, K., Al Snih, S. (2016). *The Impact of 10-year Physical Activity Changes on 7-year Mortality in Older Mexican Americans*. Presented at the Public Health Symposium at the University of Texas Medical Branch, April, Galveston, TX.
- Lewis, Z.H., Markides, K.S., Ottenbacher, K., Al Snih, S. (2015). *The Role of Physical Activity and Physical Function on the Risk of Falls in Older Mexican Americans*. Presented at the Annual Forum on Aging at the University of Texas Medical Branch, October, Galveston, TX.
- Lewis, Z.H., Markides, K.S., Ottenbacher, K., Al Snih, S. (2015). *The Activity Paradox: Relationship Between Physical Ability and Falls in Older Mexican Americans*. Presented at the Public Health Symposium at the University of Texas Medical Branch, April, Galveston, TX.
- Lewis, Z.H., Lyons, E.J., Jarvis, J.M., Baillargeon, J.G. (2015). *Using an electronic activity monitor system as an intervention modality: A systematic review*. Presented at the Public Health Symposium at the University of Texas Medical Branch, April, Galveston, TX.
- Lewis, Z.H. & Lyons, E.J. (2015). *The Walking Dead: Is Implementation of a Zombie Running Game Feasible Among Adult Women?* Presented at the Center for Interdisciplinary Research in Women's Health poster session at the University of Texas Medical Branch, March, Galveston, TX.
- Lewis, Z.H. & Lyons, E.J. (2015). *The Walking Dead: Is Implementation of a Zombie Running Game Feasible Among Adult Women?* Presented at the Clinical & Translational Research Forum at the University of Texas Medical Branch, March, Galveston, TX.
- Lewis, Z.H. & Lyons, E.J. (2014). *Activity Monitor-Based Health Intervention Increases Fitness in Older Adults: A Pre-experimental Pilot Study*. Presented at the Public Health Symposium at the University of Texas Medical Branch, February, Galveston, TX.
- Lewis, Z.H. & Lyons, E.J. (2014). *Activity Monitor-Based Health Intervention Increases Fitness in Older Adults: A Pre-experimental Pilot Study*. Presented at the Clinical & Translational Research Forum at the University of Texas Medical Branch, February, Galveston, TX.
- Lewis, Z.H. & Almstedt, H. (2013). *Intermittent Pneumatic Compression May Improve Bone Mineral Density at the Hip*. Presented at the Undergraduate Research Symposium at Loyola Marymount University, March, Los Angeles, CA.
- Lewis, Z.H. & Almstedt, H. (2012). *Intermittent Pneumatic Compression May Improve Bone Mineral Density at the Hip*. Presented at the Sigma Xi Student Symposium at Loyola Marymount University, October, Los Angeles, CA.
- Lewis, Z.H. & Almstedt, H. (2012). *Intermittent Pneumatic Compression May Improve Bone Mineral Density at the Hip*. Presented at the Summer Undergraduate Research Symposium at Loyola Marymount University, July, Los Angeles, CA.
- Almstedt, H. & Lewis-Powell, Z.H. (2012). *College Age Dancers Have Stronger Bones than Runners and Controls, Despite Low Energy Availability*. Presented at the Undergraduate Research Symposium at Loyola Marymount University, March, Los Angeles, CA.

Almstedt, H. & Lewis-Powell, Z.H. (2011). *College Age Dancers Have Stronger Bones than Runners and Controls, Despite Low Energy Availability*. Presented at the ACE & Honors Research Symposium at Loyola Marymount University, November, Los Angeles, CA.