

**The Role of Mobile Health in Individually Tailored Self-Management Interventions to
Promote Adherence to an Exercise Program for Older Adults
with Osteoarthritis of the Knee and Hypertension**

by

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Management Interventions to Promote Adherence to an Exercise Program for Older
Adults with Osteoarthritis of the Knee and Hypertension**

Taya Irizarry, PhD, RN

University of Pittsburgh, 2017

Little is known about how individually tailored self-management interventions (ITSMIs) and mobile health technology (mHealth) might work together to promote adoption and maintenance of exercise among people living with chronic conditions that impede physical functioning. The objective of this mixed-method study was to generate a contextually rich assessment of how adoption and maintenance of an exercise routine were supported within a mHealth-ITSMI designed specifically for older adults with osteoarthritis of the knee and hypertension. Quantitative and qualitative data from the intervention arm of the Staying Active with Arthritis (STAR) trial (R01 NR010904, PI Schlenk) were utilized in this mixed-method study. Latent trajectories of tailoring and adherence of lower extremity exercises (LEE) and fitness walking (FW) over the 24-week intervention period were identified using group based trajectory modeling. Bivariate associations between identified tailoring and adherence trajectory groups were evaluated. Multivariable multinomial logistic regression was used to identify predictors of adherence trajectory groups. Purposive sampling was performed based on adherence and tailoring trajectory group membership. Actor Network Theory was used to scaffold the descriptive analysis of transcribed audio-recorded participant-interventionist interactions to examine the role the eDiary played in tailoring and exercise adherence. Three distinct trajectories were identified for LEE adherence and tailoring; four were identified for FW adherence and

tailoring. A moderate association was observed between LEE and FW adherence trajectories ($p < .001$), between LEE and FW tailoring trajectories ($p = .001$), and between LEE tailoring and adherence trajectories ($p = .007$), but not between FW tailoring and adherence trajectories ($p = .12$). The LEE “remained highly tailored” trajectory group had greater odds of belonging to the “quick decline” (OR=16.89) and “steady decline” (OR=3.74) adherence trajectory groups. The FW “slight rise/remained highly tailored” trajectory group had greater odds of belonging to the “quick/steady decline” adherence trajectory group (OR=5.65). The eDiary played a role in the participant-interventionist relationship, decision-making, and motivation to exercise. Motivation was explained by concepts from social cognitive theory, self-determination theory, and goal-setting theory. The degree of individual fit between how a goal was defined and the way it was measured via the eDiary impacted participants’ overall sense of accomplishment, thereby directly impacting one’s motivation to initiate and sustain an exercise routine.

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PREFACE

The study was supported through funding from the Nightingale Award of Pennsylvania, the J. Wiggins Memorial Scholarship, and the Technology T32 2NR008857 (PI: Erlen, Co-I Devito Dabbs). In addition, I would like to recognize the funding sources for the parent study (5 R01 NR010904, PI Schlenk) the National Institute of Health and National Institute of Nursing Research. I would like to acknowledge the individual contributions of my dissertation chair Annette De Vito Dabbs and committee Elizabeth Schlenk, Susan Sereika, and Karen Drenkard. Finally, I would like to thank my family, friends, and furry babies for their patience and support.

1.0 INTRODUCTION

Adopting a regular exercise routine is necessary to achieve and maintain an optimal state of wellness (Nelson *et al.*, 2007). However, this task is especially difficult for people managing chronic conditions that impede physical function. Individually tailored self-management interventions (ITSMIs) and mobile health technology (mHealth) are two promising and potentially complementary approaches to improve patients' long-term adherence to an exercise routine (Friedberg *et al.*, 2015; D. Jones *et al.*, 2016; van der Weegen *et al.*, 2015). However, the current lack in understanding of the dynamic mechanisms of action of mHealth functionality within the context of on-going intervention tailoring and exercise adherence reduces the ability to optimize the design, implementation, and evaluation of mHealth-ITSMIs for chronic conditions (Michie *et al.*, 2017).

1.1 PURPOSE AND SPECIFIC AIMS

The purpose of this mixed-method study was to generate a contextually rich theory-driven assessment of adherence promotion via an mHealth-ITSMI targeting exercise and designed specifically for older adults with hypertension and osteoarthritis of the knee. Findings from this study fills gaps in our understanding of: 1) the ways in which individually tailored self-management interventions (ITSMIs) promote adherence and 2) how mHealth functionality can

aid the process. Ultimately, this knowledge can help guide targeted mHealth technology design and identify effective methods of translation of mHealth-ITSMIs into practice. The primary research questions of this mixed-methods study were: 1) What is the relationship between the extent of tailoring and patterns of adherence over the STAR study the 24-week intervention period? 2) What role might mHealth technology play in the process of tailoring and supporting adherence?

The quantitative aims were to first identify trajectories of the extent of tailoring of lower extremity exercise and fitness walking goals, and second, to identify trajectories of adherence to lower extremity exercise and fitness walking over weeks 3-24 of the STAR study intervention. Third was to determine the association between tailoring trajectory and adherence trajectory group membership. Fourth was to explore possible associations between baseline self-efficacy, outcome expectancy, and select sample characteristics with exercise adherence trajectory group membership.

The qualitative aims were to compare and contrast when, why and how participants who differ in adherence trajectory group membership used the eDiary during interactions with the interventionist to inform tailoring and aid conversations about potential barriers to exercise adherence.

The final aim was to combine findings from the quantitative and qualitative aims into a contextually rich theory driven assessment of the association between extent of tailoring and adherence to self-management interventions and the role mobile technology plays in the process.

1.2 BACKGROUND AND SIGNIFICANCE

Of the over 9 million Americans who have symptomatic osteoarthritis of the knee (OAK), half are diagnosed with hypertension (HBP), a prevalent risk factor for cardiovascular disease (Eymard *et al.*, 2015). Total treatment costs in the United States are estimated to be billions of dollars (Bauer *et al.*, 2014). Clinical trials targeting people with OAK and HBP have shown that physical activity has tremendous benefits; however, adherence to physical activity recommendations remains low (Fransen *et al.*, 2015). Knee pain and functional limitations associated with OAK have been identified as major barriers to exercise self-management regimen adherence (Wallis *et al.*, 2013), and thus contribute to accelerating morbidity and escalating healthcare costs.

Individually tailored self-management interventions (ITSMIs) are a promising alternative to standardized interventions because they seek to engage participants and motivate adherence by incorporating personal preferences and addressing unique barriers to adherence (Friedberg *et al.*, 2015; Hawkins *et al.*, 2008). Bandura's social cognitive theory (SCT) is a common underlying foundation of tailored interventions, especially those that focus on increasing physical activity (Richards *et al.*, 2007), because SCT incorporates perceived self-efficacy, a critical activity-specific behavioral determinant (Bandura, 1989). Self-efficacy is defined as "the personal belief in one's own ability to accomplish a certain task or succeed in a specific situation" and outcome-expectancy is defined as "a person's estimate that a given behavior will lead to certain outcomes" (Bandura, 1977, p.193). Stronger self-efficacy and positive outcome expectancy purportedly increase targeted behavior whereas lower self-efficacy and negative outcome expectancy decrease targeted behavior (Bandura, 1977).

Unfortunately, while self-efficacy theory is incorporated into many tailored intervention studies that aim to increase physical activity, it is seldom measured. Additionally, most studies did not quantify the extent of personal goal tailoring compared to an ideal exercise goal and only measure adherence at two or three time points over the course of 6 or 12 months (Plow *et al.*, 2016). Thus, the temporal relationship between the extent of exercise goal tailoring and adherence remains unclear, as does the role of self-efficacy and outcome-expectancy and potentially influential covariates such as age, functional status, pain, body mass index (BMI), etc.

The Staying Active with Arthritis (STAR) (R01 NR010904, PI Schlenk) is the first clinical trial to investigate a self-efficacy model (Bandura, 1997) as part of an ITSMI to promote exercise adherence in older adults with the comorbid conditions of OAK and HBP. The STAR study included self-efficacy and outcome expectancy measures and used an evidence-based ideal goal for lower extremity exercise and fitness walking intervention (Misso *et al.*, 2008). Participants were given a Smartphone with a custom application, the STAR Study eDiary, and an electronic pedometer. Daily adherence of lower extremity exercise goals, minutes walked, and pedometer steps taken were manually recorded by the participants in the eDiary. Precise definitions and measures of the extent of tailoring and multiple time point measurements of adherence allow for more complex analysis including the investigation of trends in the extent of intervention tailoring over time and its association to exercise adherence. Precise measurement of tailoring also permits researchers to identify and more deeply understand the association among and between potentially important predictors (such as self-efficacy and outcome expectancy).

Presently, little is known about the longitudinal relationship between the extent of individual tailoring of exercise goals and patterns of adherence, while considering baseline self-

efficacy and outcome expectancy as well as other empirically supported characteristics that may influence exercise adherence including age, functional status, pain, BMI, and duration of OAK and HBP diagnoses (Courneya *et al.*, 2014; Shang *et al.*, 2012). Individually tailored self-management interventions (ITSMIs) are defined as ‘any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment’ (Kreuter *et al.*, 1999)(pg. 276). ITSMIs are a promising approach for improving adherence because they incorporate selected patient characteristics (e.g., beliefs, preferences, physical and/or cognitive limitations, etc.) into a plan of care with the aim of increasing knowledge, ability and motivation, while addressing both practical and psychological barriers to adherence (Hawkins *et al.*, 2008).

Because chronic conditions are longitudinal as opposed to episodic, ITSMIs for chronic conditions are distinct from other ITSMIs in that there is more than one assessment phase. Information gathered at each assessment is incorporated into an individual’s plan of care and is intended to be re-assessed and re-tailored at multiple time points with the goal of adopting and maintaining condition specific motivational and self-regulatory behaviors over the course of one’s lifetime (Bandura, 2005). The process of re-assessment and re-tailoring requires setting goals and monitoring progress towards those goals with repeated measures related to the outcome of interest (Kruglanski *et al.*, 2002).

The ubiquity of mobile phones in today’s society makes them an especially well-suited method to capture individual level repeated measures related to the outcome of interest while simultaneously providing a convenient vehicle for interventions targeting motivational and self-regulatory health behavior change (Free *et al.*, 2013). The high and ever increasing availability of mobile phones across diverse populations means that mHealth has the potential to reach

traditionally vulnerable and medically underserved groups who are more likely to suffer from poorly managed chronic illness (Klonoff, 2013; Ricciardi *et al.*, 2013).

This secondary analysis includes quantitative and qualitative data from a randomized controlled trial of Staying Active with Arthritis (STAR), a home-based ITSMI designed specifically for older adults with hypertension and osteoarthritis of the knee (R01 NR010904, PI Schlenk). The STAR Study data are ideal to examine the relationship between ITSMIs, mHealth and exercise adherence for the following reasons: 1) tailoring of the intervention was based on an ideal exercise goal, making it possible to measure the unique extent of intervention tailoring each participant received; 2) participants used a smartphone with a custom eDiary application to self-monitor and report exercise adherence over the course of the intervention; 3) the tailored approach was based on social cognitive theory targeting self-efficacy and outcome expectancy (Bandura, 1989), two modifiable behavioral variables that add explanatory power in regard to the relationship between tailoring and adherence; 4) audio-recordings of all participant-interventionist interactions were available, allowing for qualitative analysis of conversations referencing eDiary use.

ANT challenges assumptions of separation between material (e.g., technology) and human (e.g., social interaction) worlds (Hanseth *et al.*, 2004). Instead of treating a mobile app as a material object that simply holds information, it is viewed as an active participant in a dynamic social network of actors (e.g., patient, clinician, mHealth app). The primary tenet of ANT suggests that recognizing and addressing the interrelationship between actors (human and non-human) and their roles within a social network can help to optimize the design of materials (e.g., eDiary), improve execution of actions (e.g., tailoring) and positively impact targeted outcomes (e.g., sustained adherence) (Cresswell *et al.*, 2010). Thus, a rich multi-dimensional description of

mHealth use within the context of tailoring and promoting adherence is made possible by fusing the focus on material (the eDiary) and human worlds (participant-interventionist interactions).

Actor Network Theory (ANT) guided this study in the following ways: 1) to scaffold qualitative analysis of audio-recorded participant-interventionist interactions, thereby focusing the thematic coding on technological functionality (i.e., the eDiary) playing an active role in intervention tailoring and adherence, and 2) to inform the inclusion criteria and structure of the final integrated conceptual model which synthesized the quantitative findings of adherence and tailoring trajectory groups with the qualitative findings from the audio-recordings of the participant-interventionist interactions.

1.3 PRELIMINARY STUDY MANUSCRIPT: INDIVIDUAL TAILORING TO PROMOTE ADHERENCE TO SELF-MANAGEMENT INTERVENTIONS FOR CHRONIC CONDITIONS: AN INTEGRATIVE REVIEW OF RANDOMIZED CONTROL TRIALS

1.3.1 Abstract

Background: Individually tailored self-management interventions (ITSMIs) are a promising approach to improve adherence to chronic disease management regimens. However, there is a lack of scientific evidence to support this claim.

Objectives: To describe the characteristics of ITSMIs for chronic conditions and to examine their mechanisms of action and efficacy for promoting adherence.

Research Design: This integrative review includes randomized control trials of ITSMIs for chronic conditions that included at least one re-assessment and re-tailoring session and one measure of adherence. Between-group effect sizes were calculated for each study.

Results: Eleven studies met the inclusion criteria. Populations, study designs, tailoring strategies, and adherence measures were diverse. Four studies included social determinants of health in the analyses. Four of the five studies targeting self-identified poor-adherers reported moderate or strong effect sizes for at least one adherence measure.

Conclusions: ITSMIs for chronic condition management may be effective in populations already identified as poor adherers. Considering ITSMIs require more healthcare resources than standard evidenced-based interventions, development of methods for identifying “at risk” for poor adherence is warranted. Findings suggest several future steps to effectively evaluate efficacy: 1) develop a formal taxonomy of tailoring intervention strategies specifically for chronic condition self-management, 2) include social determinants of health in the analyses, and 3) measure time-variant moderators and time-dependent mediators that may explain the mechanism of effects in the analysis of tailoring and adherence at multiple time points in order to gain an understanding of intra-individual change and inter-individual differences in intra-individual change over time.

1.3.2 Introduction

A growing aging population and increasing number of people living with multiple comorbidities (Bauer et al., 2014) make managing chronic conditions increasingly more complex and costly than ever before. Individually tailored self-management interventions (ITSMIs) defined as ‘any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from

an individual assessment'(Kreuter et al., 1999) (p. 276) are thought to be superior to standard evidenced-based interventions for improving adherence to chronic disease self-management regimens. However, the scientific evidence to support the claim is lacking and several reviews have reported mixed results.

Two reviews that focused on ITSMIs for chronic conditions (Plow et al., 2016; Radhakrishnan, 2012) speculated that the mixed results were due to variations between studies in (a) intervention dose (number and length of tailoring sessions), (b) tailoring strategies, (c) comparison conditions, (d) variability in characteristics within the samples (e.g., demographics, severity of health condition, etc.). These discrepancies and omissions made it difficult to make comparisons and draw conclusions about the impact of ITSMIs between studies. In addition to the reasons listed by the authors, failure to specify outcome measures for proximal intended behaviors (e.g., adherence) and distal health outcomes (e.g. blood pressure) do not allow a direct correlation between tailoring and improvements in the intended behavior.

Adherence is broadly defined as the degree to which patient behaviors coincide with the recommendations of health-care providers (Vitolins *et al.*, 2000). Adherence to chronic condition management behaviors is unique because behaviors must be sustained on a regular basis for an indefinite period, as compared to maintaining adherence to short-term behaviors such as a ten-day round of anti-biotics or completing a once-a-year preventative screening (Schwarzer *et al.*, 2011). Therefore, the aim of this integrative review was to explore the relationship between ITSMIs and adherence within the context of chronic condition management by including only RCTS of ITSMIs with iterative assessments and re-tailoring at multiple time points with a minimum of one adherence measure.

1.3.3 Methods

1.3.3.1 Data Sources and Search Strategy

The search covered peer-reviewed English language literature published within the last 10 years (January 1, 2006 to December 31, 2016) including e-publications ahead of print. A medical librarian assisted with search of records in PubMed, PsycINFO, and CINAHL and Medline databases. The list of subheadings (MeSH) and text words used in the search strategy in PubMed were title and abstract “Patient Compliance” OR “patient adherence” OR “medication compliance” OR “medication adherence” AND “tailored” OR “personalized” OR “individualized” OR “Patient-Centered” OR “Patient Preference”. These terms were combined with the filter for controlled trials of interventions. The last search was performed on March 3, 2017.

1.3.3.2 Study Selection

Included were all randomized controlled trials (RCTs) of ITSMIs for chronic condition management where tailoring was informed by an individual assessment; tailoring occurred more than one time and outcome measures included at least one measure of adherence. Studies were excluded if they did not focus on a chronic clinical condition (e.g., preventative behaviors such as smoking cessation, weight loss, etc.); the intervention was tailored based on population specifics (e.g., race, gender, culture), otherwise known as segmentation (Hawkins et al., 2008); only one assessment occurred, thus no re-tailoring took place; and only distal health outcome measures were included without a proximal related adherence measure of the targeted behavior.

1.3.3.3 Data Analysis

Information regarding the study characteristics of interest were extracted from selected articles on the basis of standardized definitions (Harrington & Noar, 2011) and further expanded based upon topics discussed in previous reviews of tailored interventions (Hawkins et al., 2008; Lustria *et al.*, 2009; Plow et al., 2016; Richards et al., 2007; P. Ryan & Lauver, 2002).

Due to significant heterogeneity in study designs, chronic conditions studied, and measures of adherence, a robust meta-analysis was not possible. However, between-group treatment effects were examined for each individual study at each outcome measurement time point for each adherence outcome. Effect sizes were calculated from data reported in the article using appropriate formulas (Rosenthal, 1991) and converted to Pearson r coefficients using the formula provided in (Sánchez-Meca *et al.*, 2003). Minimal intervention was chosen as the reference group for effect size calculation over usual care control groups where possible. Results were interpreted as small ($r < 0.3$), moderate ($r = 0.3-0.5$), or large ($r > 0.5$) effects from a behavioral science perspective (J Cohen, 1988).

1.3.4 Results

Of the 404 articles identified in the initial search, 9 articles met all inclusion criteria. Two additional studies were identified in the subsequent review of selected study references; a single study published in 2004 was included because it met all other criteria aside from the publishing date (refer to figure1). Table 1 presents a brief overview of the 11 included studies (i.e., chronic condition, sample, goal(s) for adherence, individual tailoring assessment, tailoring strategies, delivery mode intervention dose, measures of adherence, and calculated effect sizes).

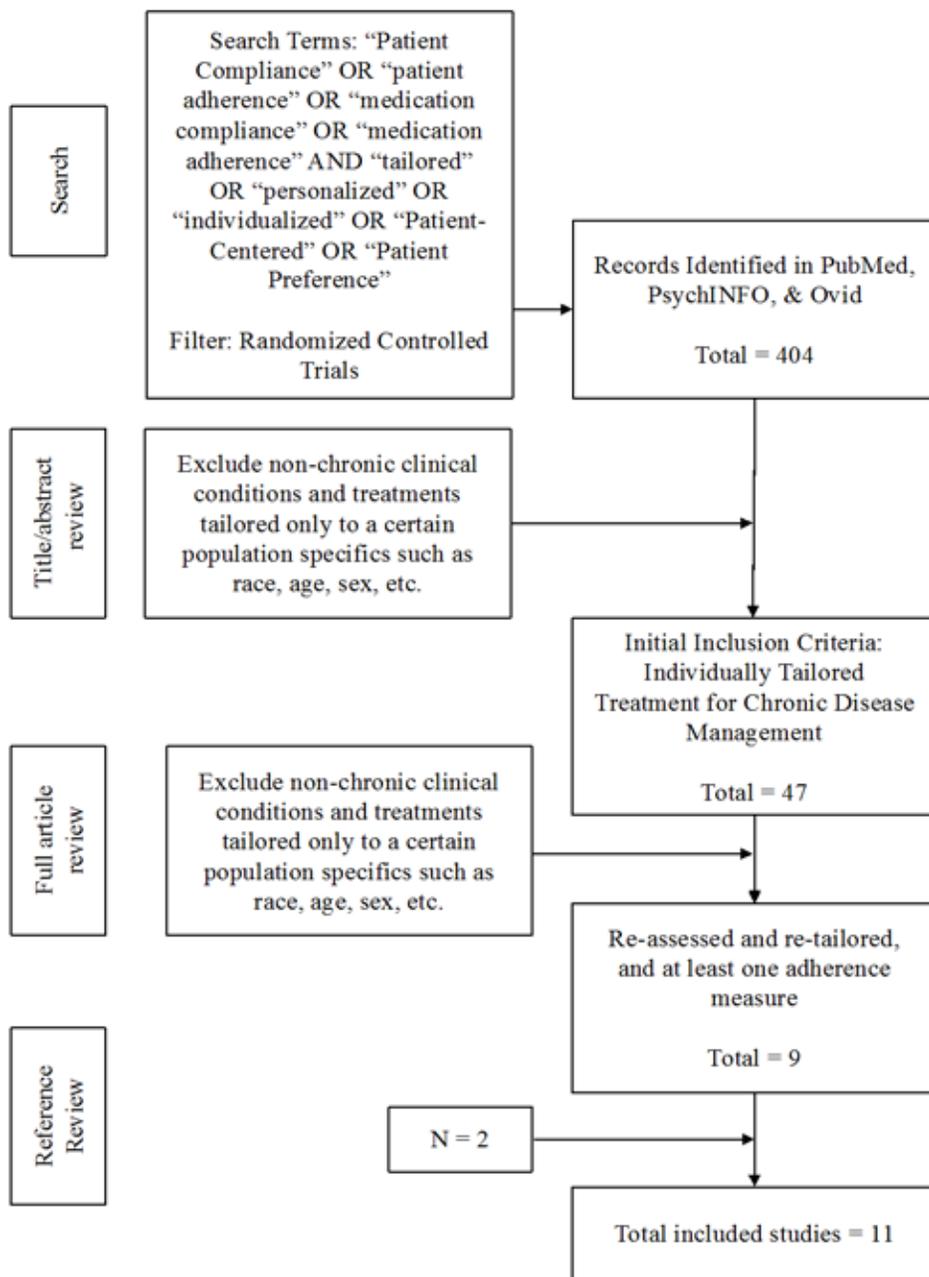


Figure 1. ITSMIs Literature Review Flow Chart

Table 1. Description of Studies and Effect Sizes for Strength of the Relationship between the ITSMI and Adherence

RCT	Chronic Condition	Sample	Goal(s) for Adherence	Individual Tailoring				Measures of Adherence	Effect Size (r)
				Assessment	Strategies	Delivery Mode	Dose		
Alexopoulos et al., 2014	COPD Major depression	<input type="checkbox"/> N=138 <input type="checkbox"/> Adults (54-86yrs) <input type="checkbox"/> Admitted for acute respiratory inpatient rehab unit	<input type="checkbox"/> Exercise <input type="checkbox"/> Medication	Self-report Questionnaires: <input type="checkbox"/> Depressive Symptoms <input type="checkbox"/> Functional Status <input type="checkbox"/> Medical Burden	<input type="checkbox"/> Forming alliance <input type="checkbox"/> Explore barriers to engagement <input type="checkbox"/> Goal setting <input type="checkbox"/> Clinical state feedback <input type="checkbox"/> Shared adherence record with PCP	<input type="checkbox"/> Social worker <input type="checkbox"/> Home visits	<input type="checkbox"/> 1 30-min session prior to discharge <input type="checkbox"/> 8 30-min sessions at wk 3, 4, 8, 12, 16, 20, 24, & 26	<input type="checkbox"/> Pharmacy refill records <input type="checkbox"/> Cross referenced with self-report	5.5 Mob: CRAFT $r=0.22$ Pharmacy refills $r=0.21$
Clark et al., 2004	DM type 2 Obesity	<input type="checkbox"/> N=100 <input type="checkbox"/> Adults (40-70 yrs) <input type="checkbox"/> BMI >25 <input type="checkbox"/> Insulin dependent <input type="checkbox"/> Self-reported sub-optimal control	<input type="checkbox"/> Exercise <input type="checkbox"/> Diet	Self-report Questionnaires: <input type="checkbox"/> Dietary habits <input type="checkbox"/> Physical activity level <input type="checkbox"/> Stages of change <input type="checkbox"/> Barriers <input type="checkbox"/> Self-efficacy	<input type="checkbox"/> Motivational interviewing <input type="checkbox"/> Goal setting <input type="checkbox"/> Strategies for overcoming barriers <input type="checkbox"/> Strategies to increase self-efficacy <input type="checkbox"/> Final follow-up focused on coping skills and relapse	<input type="checkbox"/> Clinician <input type="checkbox"/> Baseline face-to-face in clinic <input type="checkbox"/> Follow-up phone calls <input type="checkbox"/> Final intervention session face-to-face	<input type="checkbox"/> Baseline clinic visit (variable time) <input type="checkbox"/> 3 10-min calls at wk 1, 3, 7, 12 <input type="checkbox"/> Final clinic visit at 24 wks <input type="checkbox"/> Variable time	Self-report: <input type="checkbox"/> Dietary habits <input type="checkbox"/> Physical activity	3 Mob: FHQs $r=0.25$ FHQm $r=0.25$ FHQb $r=0.07$ PACE $r=0.17$ SDQD $r=0.21$ SDQA $r=0.24$ 12 Mo: FHQs $r=0.25$ FHQm $r=0.25$ FHQb $r=0.07$ PACE $r=0.17$ SDQD $r=0.21$ SDQA $r=0.23$
Ellis et al., 2012	DM type 1 & type 2	<input type="checkbox"/> N=146 <input type="checkbox"/> Adolescents (10-18yrs) <input type="checkbox"/> Chronic poor metabolic control <input type="checkbox"/> Insulin dependent	<input type="checkbox"/> Medication	Manualized diagnostic interview: Risk factors (individual, family, peer, school, community)	<input type="checkbox"/> Cognitive behavioral therapy <input type="checkbox"/> Skill building <input type="checkbox"/> Goal setting <input type="checkbox"/> Action plan <input type="checkbox"/> Accompanied to medical appointments	<input type="checkbox"/> Therapist <input type="checkbox"/> Home visits <input type="checkbox"/> School visits <input type="checkbox"/> Phone calls	<input type="checkbox"/> Variable time (15 minutes to 2 hours) <input type="checkbox"/> Variable session number <input type="checkbox"/> Treatment terminated when goals were met	Self-report: Diabetes Management Scale	6 Moc: Parent DMS $r=0.63^*$ Youth DMS $r=0.56^*$ 12 Mo: Parent DMS $r=0.66^*$ Youth DMS $r=0.64^*$

RCT	Chronic Condition	Sample	Goal(s) for Adherence	Individual Tailoring				Measures of Adherence	Effect Size (r) *
				Assessment	Strategies	Delivery Mode	Dose		
Foster et al., 2014	Asthma	<input type="checkbox"/> N=143 <input type="checkbox"/> Adults (32-75yrs) <input type="checkbox"/> Suboptimal asthma control	<input type="checkbox"/> Medication	Self-Report Questionnaires: <input type="checkbox"/> Personal barriers to controller inhaler use	<input type="checkbox"/> Goal setting <input type="checkbox"/> Action plan <input type="checkbox"/> Strategies for overcoming barriers <input type="checkbox"/> Customized electronic reminders <input type="checkbox"/> Computer-based adherence feedback <input type="checkbox"/> Shared adherence record with PCP monthly	<input type="checkbox"/> PCP <input type="checkbox"/> Clinic <input type="checkbox"/> Follow-up phone calls <input type="checkbox"/> Custom electronic Inhaler monitor	<input type="checkbox"/> Baseline clinic visit <input type="checkbox"/> 4 calls at wk 1, 8, 16, 24 <input type="checkbox"/> Variable time	Self-report to independent rater: Medication adherence 6 Moc: MARS-A r=0.01	
Friedberg et al., 2015	HTN	<input type="checkbox"/> N=533 <input type="checkbox"/> Older adult veterans (65-85yrs) <input type="checkbox"/> Sub-optimal BP control	<input type="checkbox"/> Exercise <input type="checkbox"/> Diet <input type="checkbox"/> Medication	Semi-structured interview: <input type="checkbox"/> Stages of change <input type="checkbox"/> Self-efficacy	<input type="checkbox"/> Strategies for overcoming barriers <input type="checkbox"/> Generated pros/cons to adherence <input type="checkbox"/> Strategies to enhance confidence in ability to adhere	<input type="checkbox"/> Psychologist or social worker <input type="checkbox"/> Phone	<input type="checkbox"/> Baseline clinic visit <input type="checkbox"/> 6 monthly phone calls <input type="checkbox"/> Variable time	Self-report: <input type="checkbox"/> Exercise adherence <input type="checkbox"/> Medication non-adherence <input type="checkbox"/> Dietary habits 6 Moc: Exercise adherence r=0.70* Morisky r=0.18 DASH score r=0.45*	
Hedegaard et al., 2015	HTN	<input type="checkbox"/> N=516 <input type="checkbox"/> Adults (52-68yrs) <input type="checkbox"/> HTN &/or lipid-lowering medication	<input type="checkbox"/> Medication	Semi-structured interview: <input type="checkbox"/> Medication side-effect review <input type="checkbox"/> Standard Medication Adherence Questionnaire	<input type="checkbox"/> Motivational interviewing <input type="checkbox"/> Goal setting <input type="checkbox"/> Action plan <input type="checkbox"/> Strategies for overcoming barriers <input type="checkbox"/> Written summary of goals & action plan	<input type="checkbox"/> Pharmacist <input type="checkbox"/> Baseline face-to-face in clinic <input type="checkbox"/> Follow-up phone calls	<input type="checkbox"/> Baseline semi-structured interview <input type="checkbox"/> Phone calls at 1 & 6 months <input type="checkbox"/> Additional follow-up calls if necessary <input type="checkbox"/> Variable time	Pharmacy refill records 12 Moc: MPR composite r=0.05	

RCT	Chronic Condition	Sample	Goal(s) for Adherence	Individual Tailoring				Measures of Adherence	Effect Size (r)*
				Assessment	Strategies	Delivery Mode	Dose		
Holzemer et al., 2006	HIV/AIDS	<input type="checkbox"/> N=180 <input type="checkbox"/> Adults (31-50yrs)	<input type="checkbox"/> Medication	<input type="checkbox"/> Self-report Questionnaire: <input type="checkbox"/> Knowledge of medication taking <input type="checkbox"/> Reasons for missed medications <input type="checkbox"/> Use of reminders <input type="checkbox"/> Self-reported adherence <input type="checkbox"/> Medication issues <input type="checkbox"/> Role performance <input type="checkbox"/> Client-provider relationship	<input type="checkbox"/> Skill building based on established thresholds in areas of most need <input type="checkbox"/> RN <input type="checkbox"/> Baseline face-to-face in clinic <input type="checkbox"/> Follow-up phone calls	<input type="checkbox"/> Baseline interview <input type="checkbox"/> 3 calls in 1 st wk <input type="checkbox"/> Time raged 6 min to 3 hours <input type="checkbox"/> 15-min clinic visits at 1 & 3 months	<input type="checkbox"/> Pill count <input type="checkbox"/> MEMS cap <input type="checkbox"/> Pharmacy refill records <input type="checkbox"/> Self-report: Pharmacy refills <input type="checkbox"/> Medication non-adherence <input type="checkbox"/> AIDS Clinical Trial Group-Revised Total Score	6 Mob. Pill count $r = 0.09$ MEMS cap $r = 0.01$ Pharmacy refills $r = 0.48^*$ Morisky $r = 0.05$ ACTG-rev $r = 0.10$	
Hommel et al., 2011 (Pilot Study)	Crohn's or ulcerative colitis	<input type="checkbox"/> N=14 <input type="checkbox"/> 10 girls and 4 boys (12-16yrs) <input type="checkbox"/> Parent-teen dyads	<input type="checkbox"/> Medication	<input type="checkbox"/> Semi-structured discussion about adherence with parent & teen <input type="checkbox"/> Self-report Questionnaires: <input type="checkbox"/> Disease severity <input type="checkbox"/> Medication adherence	<input type="checkbox"/> Psychologist <input type="checkbox"/> Face-to-face in clinic	<input type="checkbox"/> 4 wkly 60-75 min sessions	<input type="checkbox"/> Pill count conducted by study personnel	5wks: Pill count $r = 0.27$	
Janson et al., 2009	Asthma	<input type="checkbox"/> N=84 <input type="checkbox"/> Adults (27-50yrs) <input type="checkbox"/> Moderate-severe daily symptoms	<input type="checkbox"/> Medication	<input type="checkbox"/> Daily symptom self-monitoring (diary) <input type="checkbox"/> Environmental control strategies for relevant allergen and irritant exposures <input type="checkbox"/> Daily spirometry readings compared to personal best	<input type="checkbox"/> Face-to-face in clinic with respiratory therapist <input type="checkbox"/> Follow-up in clinic with APRN	<input type="checkbox"/> 3 30-minute identical sessions at 0, 2, 4wks <input type="checkbox"/> Daily diary <input type="checkbox"/> Clinic visits at 8, 12, 16wks	<input type="checkbox"/> Electronic device monitoring metered-dose inhaler use	4 Mod. Meter dose $r = 0.62^*$ 6 Mo: $r = 0.29$	

RCT	Chronic Condition	Sample	Goal(s) for Adherence	Individual Tailoring				Measures of Adherence	Effect Size (r) ^a
				Assessment	Strategies	Delivery Mode	Dose		
Schlenk et al., 2011 (Pilot Study)	OAK & HTN	<input type="checkbox"/> N=26 <input type="checkbox"/> Adults (50-75yrs) <input type="checkbox"/> Over-weight or obese <input type="checkbox"/> Inactive	<input type="checkbox"/> Exercise <input type="checkbox"/> Medication	<input type="checkbox"/> Evaluation of physical function <input type="checkbox"/> Self-reported goal achievement	<input type="checkbox"/> Goal setting based on established thresholds <input type="checkbox"/> Strategies to increase self-efficacy <input type="checkbox"/> Performance feedback <input type="checkbox"/> Strategies for overcoming barriers <input type="checkbox"/> Written summary of goals <input type="checkbox"/> Self-monitoring with daily physical activity (diary)	<input type="checkbox"/> Face-to-face in clinic with physical therapist <input type="checkbox"/> Phone with RN	<input type="checkbox"/> 6 1-hr w/ky sessions <input type="checkbox"/> 9 15-30 min phone calls at 8, 10, 12, 14, 16, 18, 20, 22, 24wks <input type="checkbox"/> Daily diary	Self-report Exercise adherence: LEE and FW 6 Mo: LEE r=0.47* FW r=0.01 12 Mo: LEE r=0.53* FW r=0.02	
Staring et al., 2010	Schizophrenia	<input type="checkbox"/> N=95 <input type="checkbox"/> Adults (27-50yrs)	<input type="checkbox"/> Medication	<input type="checkbox"/> Semi-structured interview to identify determinants of non-adherence. <input type="checkbox"/> Determinants dictate which module to employ	3 modules: <input type="checkbox"/> Motivational interviewing <input type="checkbox"/> Medication optimization <input type="checkbox"/> Behavioral training	<input type="checkbox"/> Psych RN <input type="checkbox"/> Face-to-face in clinic	<input type="checkbox"/> Variable time <input type="checkbox"/> Variable session number <input type="checkbox"/> Treatment terminated when goals were met	Semi-structured interview by independent rater 6 Mo: Medication adherence r=0.21 12 Mo: r=0.14	
Adherence per intervention assignment b Compared to usual care c Compared to attention control d Compared to minimal intervention ACTG-rev = AIDS Clinical Trial Group-Revised total score APRN = advanced practice registered nurse BP = blood pressure CRAFT = COPD Rehabilitation and Activity Follow-up Talley DM = diabetes mellitus FHQs = Food Habits Questionnaire: substitute healthy foods FHQm = Food Habits Questionnaire: modify meats			FHQb = Food Habits Questionnaire: block fat screener FW = fitness walking HTN = hypertension DASH = Dietary Approaches to Stop Hypertension DMS = Diabetes Management Scale HBP = high blood pressure LEE = lower extremity exercise MARS-A = Medication Adherence Report Scale for Asthma MEMS = Medication Event Monitoring System MI = motivational interviewing Mo = month Morisky = self-report validated scale designed to estimate the risk of medication non-adherence MPR = Medication possession ratio measure	Mo = months OAK = osteoarthritis of the knee PACE = Physical Activity Scale for the Elderly PDC = proportion of days covered PCP = primary care practitioner RN = registered nurse SDQD = Summary of Diabetes Self-care Activities Questionnaire: Dietary SDQA = Summary of Diabetes Self-care Activities Questionnaire: physical activity Wk = week Yr = year * Indicates intervention compared to control with a moderate (r=0.3 to 0.5) or strong effect (r=0.5 or higher) (Cohen, 1988)					

1.3.4.1 Sample

Chronic conditions.

Chronic conditions included asthma (n=2) (J. M. Foster *et al.*, 2014; Janson *et al.*, 2009), hypertension (n=2) (Friedberg *et al.*, 2015; Hedegaard *et al.*, 2015), diabetes (n=2) (Clark *et al.*, 2004; Ellis *et al.*, 2012), and single studies focused on HIV/AIDS (Holzemer *et al.*, 2006), schizophrenia (Staring *et al.*, 2010), and bowel disorders (Hommel *et al.*, 2011). Two studies focused on co-morbid conditions, COPD with major depression (Alexopoulos *et al.*, 2014) and osteoarthritis of the knee with hypertension (Schlenk *et al.*, 2011).

Aside from the primary chronic condition(s) targeted in the intervention, three studies report prevalence of other chronic conditions. Friedberg *et al.* (2015) and Hedegaard *et al.* (2015) both targeted hypertension and reported diabetes in 45% and 92% of the sample and dyslipidemias in 30% and 81% of the sample, respectively. The sample of persons with COPD and depression (Alexopoulos *et al.*, 2014) included participants with mild cognitive-impairment because it is common among people living with COPD; however, they did not report prevalence in the sample.

Demographics and other characteristics.

Age, sex, and race were the three demographic variables reported in all studies. Four studies included adults 50 years and older (Alexopoulos *et al.*, 2014; Friedberg *et al.*, 2015; Hedegaard *et al.*, 2015; Schlenk *et al.*, 2011), five had a wide age range of adults (range 25-50 years). Two studies focused on adolescent-parent dyads where the adolescents' ages ranged from 10-18 years (Ellis *et al.*, 2012) and 12-16 years (Hommel *et al.*, 2011). The proportion of females was more than 50% in most studies, except Friedberg *et al.* (2015) where the population was 98% male

veterans. Holzemer et al. (2006) and Staring et al. (2010) included 65% and 77% males, respectively. Most samples were predominantly white except two studies where the samples were mostly black (Holzemer et al. (2006) and Ellis et al. (2012) both at 72%.

Four studies purposively targeted predominantly underserved populations. Friedberg et al. (2015) reported sample race at 40% black and 17% hispanic with 50% of the sample having a highschool level education. Foster et al. (2014) described 50% as “low social economic status”. Holzemer et al.’s (2006) sample was 72% black, 75% unemployed, 53% uninsured with 65% educated at or below high school and 27% health literacy comparable to a 6th grade reading level. Foster et al. (2014) reported 51% living in a socially disadvantage area and 37% speaking another language other than English in the home.

Refer to Table 2 for a matrix of all demographic and other characteristics reported in each study (aside from age, sex and race). No study reported statistically significant differences between the intervention and control arms.

1.3.4.2 Study Designs

Sample size and attrition.

Sample sizes for the nine full-scaled RCTs ranged from 95-180 participants, except for Friedberg et al. (2015) and Hedegaard et al. (2015) which had sample sizes over 500 because they were designed for comparison among two active intervention arms in addition to a control arm. Samples for the two pilot studies were 14 and 26. All studies used an intent-to-treat approach and reported attrition from 0% to 26%. No study reported significant differences in attrition between the control and intervention groups.

Table 2. Reported Demographics and Other Characteristics Included per Study

Characteristics	Alexopoulos et al., 2014	Clark et al., 2004	Ellis et al., 2012	Foster et al., 2014	Friedberg et al., 2015	Hedegaard et al., 2015	Holzner et al., 2006	Hommel et al., 2011	Janson et al., 2009	Schlenk et al., 2011	Staring et al., 2010
Alcohol consumption						X					
Anxiety				X							
Baseline adherence		X	X	X		X	X		X		
BMI		X			X	X				X	
Cognitive ability	X										
Depression	X			X							
Duration of diagnosis	X	X	X					X	X	X	X
Education					X		X	X	X	X	X
Employment status					X		X		X	X	X
Engagement with health services									X		
Functional status	X			X	X					X	
Health literacy							X				
Income								X		X	
Insurance status							X		X		
English as 2 nd language				X							
Living in a socially disadvantaged area				X							
Marital status			X		X			X		X	
Medical burden	X		X								
Neuroticism	X										
Number of medications		X				X					
Other chronic		X			X	X				X	
Quality of life									X		
Self-efficacy										X	
Smoking status					X	X					
Social network	X										
Social support	X										

Recruitment.

Four studies recruited participants from clinical settings primarily based on the presence of the chronic condition of interest. Seven studies limited enrollment to participants with evidence of poor adherence to medication (based on self-report, biomarkers, or limited involvement in programs to promote health behaviors) (Alexopoulos et al., 2014; Clark et al., 2004; Ellis et al., 2012; J. M. Foster et al., 2014; Friedberg et al., 2015; Janson et al., 2009; Lustria et al., 2009; Schlenk et al., 2011).

Study length.

Duration of intervention and follow-up periods varied among studies with intervention periods ranging from 1 to 6 months and post intervention follow-up ranging from 1 week (Alexopoulos et al., 2014; J. M. Foster et al., 2014; Friedberg et al., 2015) to 6 months (Clark et al., 2004; Ellis et al., 2012; Hedegaard et al., 2015; Hommel et al., 2011; Schlenk et al., 2011).

Comparison groups.

No study reported significant baseline differences between the intervention and control arms(s). Seven studies compared a ITSMI to usual care (Alexopoulos et al., 2014; Clark et al., 2004; Hedegaard et al., 2015; Holzemer et al., 2006; Hommel et al., 2011; Schlenk et al., 2011; Staring et al., 2010). Ellis et al. (2012) and Friedberg et al. (2015) compared the intervention to an attention control group, which consisted of the same number of sessions and mode of contact with standard education related to chronic condition management and healthy lifestyle tips. Foster et al. (2014) compared tailored adherence coaching plus automated feedback and reminders, a group that received only feedback and reminders, and a group that received tailored adherence coaching with no reminders or feedback. Janson et al. (2009) compared self-

monitoring alone to self-monitoring plus tailored adherence coaching.

1.3.4.3 Effect Size

Nine studies were full-scale RCTs with reported sample size estimation to detect a moderate effect. The two pilot studies were designed to collect preliminary efficacy data for the design of future studies. Observed effect sizes were moderate or large for at least one of the adherence measures in 4 of the 5 studies that targeted poor adherers. All of the studies that used a convenience sample had small effect sizes, apart from Holzemer et al. (2006) who had a moderate effect size for one of the five medication adherence measures used (i.e., pill count).

1.3.4.4 Integration of Findings

Operationalizing tailoring and adherence.

Generally, tailoring involves one or both of two types of processes: 1) enhancing cognitive pre-conditions needed to assimilate information effectively (e.g., contextualizing health information based on individual characteristics), and 2) modifying behavioral determinants of goal outcomes (e.g., addressing unique motivators and barriers) (Hawkins et al., 2008). Therefore, operationalization of tailoring is directly related to outcome goal(s). Outcome goals of included studies were focused on adherence to either medication, exercise, diet, or a combination. The ITSMIs of 7 studies in this review focused on promoting adherence to a single behavior, such as medication-taking (Ellis et al., 2012; J. M. Foster et al., 2014; Gangestad & Snyder, 2000; Holzemer et al., 2006; Hommel et al., 2011; Janson et al., 2009; R. M. Ryan & Deci, 2000; Staring et al., 2010) or exercise (Schlenk et al., 2011). The ITSMIs of Alexopoulos et al. (2014),

Clark et al. (2004), and Friedberg et al. (2015) focused on medication-taking, exercise, and/or diet.

Individual tailoring for chronic condition self-management. As previously stated in the introduction, ITSMIs are defined as ‘any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment’ (Kreuter et al., 1999)(p. 276). The unique feature of ITSMIs for chronic conditions is iterative assessments and subsequent re-tailoring with the intention of adopting and maintaining self-regulatory behaviors specific to the chronic condition one must manage. All studies used a combination of enhancing cognitive pre-conditions and modifying behavioral determinants based off the initial assessment as well as re-assessments.

Assessment. The first step in ITSMIs is to assess individual pre-conditions and/or current state of modifiable behavioral determinants. All included study assessments used self-report data collected in three different ways: 1) using standard questionnaires administered by a clinician interventionist, 2) questionnaires completed by participants, or 3) gathered through semi-structured interviews. The initial assessment questionnaires or manualized interview (with additional physical assessment in some cases) was used to inform tailoring of educational information, define goals, and serve as a starting point for in-depth conversations about intrinsic and extrinsic motivators as well as physical, psychological, social, and practical barriers to adherence. The follow-up sessions were designed to re-educate and re-assess comprehension, discuss progress towards goals, and device action plans to reduce the impact of barriers to adherence. The most comprehensive questionnaire included 71 items on topics such as reasons

for missing medication, currently utilized memory aids, self-rated adherence, side effects, barriers to adherence, and patient-provider relationship (Holzemer et al., 2006).

Tailoring strategies. Tailoring strategies employed by the interventionists varied from completely driven by clinical judgement to entirely manualized. Theoretically-based methods employed were: motivational interviewing (Friedberg et al., 2015; Hommel et al., 2011), cognitive behavioral therapy (CBT) (Ellis et al., 2012), adapting information based on stages of readiness to change (Clark et al., 2004; Hedegaard et al., 2015), and strategies to address self-efficacy and outcome expectancy (Clark et al., 2004; Foster et al., 2014; Schlenk et al., 2011). Holzemer et al. (2006) referred to previously published work validating an empirical theoretical model encompassing complexity of treatment regimen, client-provider relationship, clinical setting, and condition status (Ickovics & Meisler, 1997). Staring et al. (2010) and Janson et al. (2009) both stated that the intervention was “theory-based” but did not identify a specific theory. Alexopoulos et al. (2014) was the only entirely atheoretical intervention; it focused more on practical barriers to treatment including things like misconceptions about condition and treatment, scheduling visits and access to care, transportation, and finances.

Self-monitoring, defined as ‘the active process of being aware of ones’ actions, emotions, attitudes and/or behaviors’ (Gangestad & Snyder, 2000), is the first step towards self-regulation of behavior. Self-monitoring most likely occurred in every study due to the need to communicate progress towards goals and experiences managing barriers at each re-assessment session. However, only two studies incorporated self-monitoring as a formal strategy; Janson et al. (2009) required a daily symptom self-monitoring diary and Schlenk et al. (2011) had participants use a daily physical activity diary. Hedegaard et al. (2015) used a written summary of goals and action plan but did not explicitly describe utilizing it as a tool for self-monitoring.

Feedback involves presenting individuals with information about themselves obtained during assessments. Hawkins et al. (2008) describes three main types: descriptive, comparative, and evaluative. Seeing that all included studies assessed and re-tailored goals, all studies naturally included at least some form of feedback. None of the studies incorporated comparative feedback (i.e., comparing an individual to those of others). Alexopoulos et al. (2014) incorporated evaluative feedback based on results from a depressive symptoms questionnaire. Schlenk et al. (2011) used evaluative feedback of exercise performance by the physical therapist interventionist. Janson et al. (2009) included daily spirometry readings compared to a personal best. Several studies incorporated descriptive feedback as a part of motivational interviewing or CBT, meaning the interventionist mirrored what the participants were communicating with the aim of assisting them to gain greater insight about beliefs, behaviors, and/or barriers related to the outcome of interest.

The term accountability refers to expectations (implicit or explicit) of an individual to justify his or her actions or inactions; the central aim is to enforce commitment to the targeted behavior (Lerner & Tetlock, 1999). The underlying drivers of enforced commitment may be a combination of the formation of a therapeutic bond with the clinician interventionist and/or the perception of legitimacy of the role of the clinician as possessing expertise or “knowing best” (Mohr *et al.*, 2011). Since included studies incorporated re-assessment with a clinical interventionist, they naturally included some form of accountability. However, explicit accountability was used as a strategy in four studies. Ellis et al. (2012) had interventionists accompany participants to medical appointments and work with them to build communication skills needed to communicate personal goals and action plans with their primary care providers (PCP). Alexopoulos et al. (2014) and Foster et al. (2014) shared adherence data with PCPs.

Schlenk et al. (2011) required participants to share information from the exercise diary with the interventionist at each encounter as a formal part of the re-tailoring assessment.

Tailoring mode. All studies relied on face-to-face encounters with a clinical professional (e.g., social worker, nurse, psychologist, primary care physician) to personally contextualize information and address unique motivators and barriers based on an initial assessment and follow-up assessments. Only Foster et al. (2014) utilized participants' regular primary care providers as data collectors. Five studies used a combination of face-to-face baseline assessments and variable numbers of follow-up phone calls, with some on a weekly basis and others monthly. Ellis et al.'s (2012) interventionists met with the adolescent-parent dyads in the home and the adolescents' school and primary care appointments in addition to phone calls. Schlenk et al. (2011) included in-clinic sessions with a physical therapist to learn exercises and gain confidence before transitioning to bi-weekly phone calls with a registered nurse. Aside from the first baseline assessment in a hospital setting at discharge, Alexopoulos et al. (2014) employed in-home intervention sessions. Janson et al. (2009) and Hommel et al. (2011) included in-clinic sessions only.

Tailoring dose. Several previous reviews have used the term "tailoring dose" to refer to the length and number of intervention sessions (Noar *et al.*, 2007; P. Ryan & Lauver, 2002). Length of sessions ranged from 6 minutes to 3 hours. Number of sessions ranged from 4 weekly sessions to an unlimited number over the course of 6 months. Few studies provided a rationale for decisions regarding the length of the intervention in terms of time per session, number of sessions, or intervention duration. Only Alexopoulos et al. (2014) and Schlenk et al. (2011) explicitly defined length and number of sessions to simulate clinical practice resources and time constraints in real-world settings. In three studies (Ellis et al., 2012; Holzemer et al., 2006;

Staring et al., 2010) the number of sessions was driven by the achievement of pre-set treatment targets such as medication adherence sustained for a given period or achievement of behavioral goals. None of the three studies reported the variability in dose between participants.

Adherence. While patients are routinely classified as being either adherent or non-adherent (as they were in all included studies), adherence is not inherently a dichotomy. There is no gold standard for what defines “satisfactory” versus “poor” adherence across health behaviors. Definitions of adherence are directly related to the type of adherence of interest. Appropriate adherence is situational, and therefore defined parameters of satisfactory adherence are most often explicitly delineated and appropriate to the medication regimen or health behavior under study. For example, medication for HIV is clinically effective at a 95% adherence rate. Holzemer et al. (2006) operationalized adherence medication as 96% and above as adherent, those at 95% and below as non-adherent. In contrast, Janson et al. (2009) cited previous research showing that 50% adherence rate is the norm among asthma sufferers and subsequently used 60% as the adherence cut-off point.

Measuring Adherence. Four of the nine studies that measured medication adherence used multiple objective techniques such as pill count, pharmacy refill records or electronic meter dose inhaler readings, alone or in combination with self-report. The remaining medication adherence studies (Ellis et al., 2012; J. M. Foster et al., 2014; Friedberg et al., 2015; Staring et al., 2010) relied solely on self-report. The two studies targeting adolescent-parent dyads and medication adherence included collateral adherence measures for both adolescents and parents. Staring et al. (2010) used semi-structured interviews of patients in addition to clinician ratings of perceived adherence. Adherence to diet and exercise were self-reported in all four studies.

Other factors that may impact the relationship between the ITSMIs and adherence.

The term social determinants of health (SDOH) broadly refers to any nonmedical factors influencing health (Raphael, 2006). (Braveman *et al.*, 2011) differentiate SDOH such as health-related knowledge, attitudes, beliefs, or behaviors (referred to as “downstream determinants”) from “upstream determinants” such as economic status, social resources, and physical environment, which play a more fundamental causal role in one’s ability to achieve and maintain health.

Two studies included analyses of a downstream SDOH. Schlenk *et al.* (2011) evaluated the possible impact of the ITSMI on self-efficacy at the end of the 6-month intervention period and at the end of the 6-month follow-up. Group differences analyses showed a trend toward increase in exercise self-efficacy in the intervention group from baseline to the end of the 6-month follow-up (23.7% gain), whereas the control group decreased (27.7% loss). Staring *et al.* (2010) conducted an efficacy analyses of hypothesized mediating variables- insight, stigma, recovery style and therapeutic alliance measures; there were no effects of intervention group on any of the measures.

Two studies included a mix of downstream and upstream determinants in analyses. Friedberg *et al.*’s (2015) sample size ($n = 481$) allowed for sub-group analyses and found that participants who were older, not working, and not obese had slightly higher odds of having BP under control, and participants who were married and without a cardiovascular disease diagnosis had twice the odds of having blood pressure under control in the tailored intervention group compared with usual care. Alexopoulos *et al.* (2014) conducted exploratory moderator analyses with age, education, dyspnea related disability, anxiety, overall cognitive impairment, response

inhibition, initiation-perseveration, neuroticism, social support network, and social interaction at baseline. None of the variables moderated the difference in adherence between invention and control groups.

1.3.5 Discussion

This integrative review is the first to systematically examine ITSMIs for promoting adherence to chronic disease management regimens. ITSMIs for chronic conditions are distinct from other forms of ITSMIs in that information gathered in the assessment phase is incorporated into an individual's plan of care and is intended to be re-assessed and re-tailored at multiple time points with the goal of adopting and maintaining condition specific regulatory-behaviors indefinitely. Included studies used a multi-dimensional interpersonal approach to assess and tailor interventions on an individual basis. Therefore, the impact on motivation and behavior were a function of both intervention content and the interpersonal style in which the content was delivered. Thus, the ITSMIs relied heavily on the patient-provider relationship and clinical judgment in combination with manualized procedures and formal methods, such as motivational interviewing, to identify goals and formulate an action plan that addressed individual abilities, motivating factors, and barriers.

Gaps in our understanding of mechanisms of actions are due to several inter-dependent factors including: 1) the lack of formal classification of tailoring assessment and evaluation measures, 2) lack of social determinants in analyses, 3) limited measurement of theory-based time-variant behavioral moderators and mediators at multiple time points, and 4) minimal use of longitudinal data analysis strategies that would allow for the simultaneous analysis of intra-individual change and inter-individual differences in intra-individual change over time (Fralely &

Hudson, 2014). Current work is underway to isolate and classify both relational techniques and content elements aimed at changing health-related motivation and behavior in several related areas including: a hierarchal taxonomy of health behavior change techniques (Michie *et al.*, 2013), a classification system of motivational interviewing components (Hardcastle *et al.*, 2017), common data elements in chronic condition self-management (Moore *et al.*, 2016) and a framework of methods and processes of tailored interventions (Hawkins *et al.*, 2008). Adopting elements from existing classification systems and including theory-driven behavioral mediators and moderators measured at multiple points throughout the intervention and follow-up phases would present researchers with the necessary elements to clearly test the main and interactive effects of ITSMIs strategies on health behavior change over time and would ultimately advance the science and speed of translation into practice (MacKinnon, 2011; Noar *et al.*, 2007).

Advances in and proliferation of personal computing technology may be a solution for collecting time-variant measures at multiple time points and could also function as an additional mode of intervention delivery (Moller *et al.*, 2017; Riley *et al.*, 2011). Specifically the popularity and convenience of mobile phones has led to high and increasing ownership, thus there is great potential to incorporate mobile phones into ITSMIs for chronic conditions across diverse populations, most notably traditionally vulnerable and medically underserved groups who often face more barriers and experience poorly managed chronic conditions (Hamine *et al.*, 2015).

Despite variable study designs and intrinsic limitations in the measurement of both tailoring and adherence, 4 of 5 studies targeting poor adherers reported moderate to large effect sizes for at least one adherence measure. These findings suggest that ITSMIs for chronic conditions may be most effective in populations most at risk for poor adherence. This finding may also have implications for translation into practice. The Radhakrishnan's (2012) review of

10 chronic condition ITSMIs (type 2 diabetes, hypertension, and heart disease) concluded that tailored interventions may not be superior to non-tailored interventions when cost and resource utilization are considered. Because iterative assessments and tailoring of interventions in the context of chronic condition self-management requires greater intensity and implementation costs, it is important to consider real-world practice limitations in research design. Future research should document resource consumption, including cost effectiveness, and build evaluation methods that capture long-term outcomes such as healthcare utilization and sustained behavior change.

1.3.5.1 Limitations

This integrative review has several limitations. The included studies were limited to RCTs; including a wider range of study designs may offer a more comprehensive picture of the state of the science regarding the impact and mechanisms of chronic condition ITSMIs on adherence. Also, other RCTs may have tested personally tailored interventions; however, without explicitly stating as such in the title, abstract, or key words RCTs where personally tailored interventions may have been omitted. This is particularly true of computer-based and mobile phone delivered interventions, which often include individual tailoring strategies such as self-monitoring and feedback. However, few have incorporated the core components of ITSMIs (initial comprehensive assessment, barrier identification, and goal setting with iterative assessments and re-tailoring), and do not identify themselves as such (Free et al., 2013; Hanlon *et al.*, 2017). Finally, the variation in study designs, as well as the diversity in definition and measurement of both tailoring and adherence makes it difficult to compare outcomes across studies despite comparable effect size calculations.

1.3.5.2 Conclusions

ITSMIs for chronic condition management may be effective in populations already identified as poor adherers. Considering ITSMIs require more healthcare resources than standard evidenced-based interventions, development of methods for identifying “at risk” for poor adherence is warranted. Reports of ITSMIs for chronic conditions lacked the details required to compare results and identify explanatory mechanisms. To strengthen the efficacy of ITSMIs for chronic conditions, a better understanding of the characteristics and mechanisms of action of tailoring (assessment methods, tailoring strategies, modes of delivery, and dose) and evaluation of their efficacy to impact adherence is warranted. Findings suggest several future steps: 1) develop a formal taxonomy of tailoring intervention strategies specifically for chronic condition self-management, 2) include social determinants of health in analyses, and 3) measure time-variant behavioral mediators and moderators that may explain mechanism of effects in the analysis of tailoring and adherence at multiple time points over the course of the intervention and maintenance phases in order to gain an understanding of intra-individual change and interindividual differences in intra-individual change over time.

2.0 RESEARCH METHODS

The following sections first describe the parent study, including sample, recruitment, assignment, inclusion and exclusion criteria, followed by a description of the additional eligibility criteria for this mixed-method study. The measures section includes only a description of measures used in this secondary analysis. Access to the data for the purposes of secondary analysis was covered under the STAR study IRB protocol approved by the University of Pittsburgh.

2.1.1 Parent Study Design

The STAR study (R01-NR010904, PI E. Schlenk) is the first clinical trial to investigate a self-efficacy model to promote exercise adherence in older adults with the comorbid conditions of osteoarthritis of the knee and hypertension. Self-efficacy theory hypothesizes that self-efficacy and outcome expectancy are inter-related concepts. Self-efficacy is defined as “the personal belief in one's own ability to accomplish a certain task or succeed in a specific situation” and outcome-expectancy is defined as “a person's estimate that a given behavior will lead to certain outcomes” (Bandura, 1977, p.193). Stronger self-efficacy and positive outcome expectancy purportedly increase targeted behavior whereas lower self-efficacy and negative outcome expectancy decrease targeted behavior (Bandura, 1977).

Four self-efficacy principles form the foundation of the STAR study: modeling, mastery, physiological feedback, and social persuasion (Bandura, 1977). Together these strategies aim to enhance the belief that physical activity is possible in the presence of knee pain, knee instability, and high blood pressure by supporting behavior to adopt and maintain physical activity in the form of lower extremity exercise and fitness walking. Mastery (or performance achievement) is the central self-efficacy strategy employed for achieving exercise adherence and is operationalized by gradually increasing lower extremity exercise and fitness walking goals toward an ideal goal over the course of the 24-week intervention period. This gradual increase of goals based on individual ability and limitations is also known as personal intervention tailoring (Hawkins et al., 2008).

The intervention ideal goal was consistent with the American College of Sports Medicine (ACSM) (Nelson et al., 2007), the American Geriatrics Society (AGS) (American Geriatrics Society, 2001), and the American Heart Association (AHA) (Williams *et al.*, 2007). For the first six sessions, each participant met face-to-face with a physical therapist (PT) interventionist on a weekly basis in order to gain confidence in performing the new exercise routine. The remaining sessions were nine biweekly telephone-counseling sessions lead by a registered nurse (RN) interventionist. Thus, the 24-week intervention period consisted of 15 interactive sessions with an interventionist.

The STAR intervention began with an initial physical function assessment performed by the PT-interventionist to guide development of an individually tailored regimen for minutes of fitness walking (FW) and the number of sets, repetitions, and amount of ankle weight for lower extremity exercises (LEE). All participants received a smartphone with a custom smartphone eDiary application to manually record daily progress toward LEE and FW goals as well as to

record other physical activity performed and pedometer step-count. Data collected via the eDiary were uploaded to a secure server and reviewed during the sessions with the PT and RN interventionists. The general rule was that goals were advanced if 75% adherence to the previous goal was achieved. If the goal was not achieved the interventionist and participant discussed the specific problems being encountered and decided whether to keep the goal the same or lower it.

2.1.2 Parent Study Sample

2.1.2.1 Recruitment

Participants were recruited from the three following registries at the University of Pittsburgh: Pittsburgh Pepper Center Registry, University Center for Social and Urban Research Gerontology Program Research Registry, and the University of Pittsburgh Clinical and Translational Science Institute Registry. Public domain mailing lists from a variety of vendors were also utilized.

2.1.2.2 Inclusion Criteria for STAR Study

The following were parent study inclusion criteria:(1) age ≥ 50 years 2) community-dwelling; 3) diagnosed with OAK and defined as knee pain lasting at least a month within the previous year; 4) prescribed pharmacological treatment for high blood pressure (HBP); 5) able to complete questionnaires, use a 7-day eDiary, and wear an ActiGraph accelerometer at the waist for 7 days; 6) able to provide informed consent; and 7) physicians' written permission to participate.

2.1.2.3 Exclusion Criteria for STAR Study

The following were parent study exclusion criteria: 1) currently meets minimum intervention exercise goal (i.e., performing lower extremity exercises ≥ 2 times/week and/or participating in fitness walking ≥ 90 minutes/week); 2) is incapable of managing own treatment regimen; 3) self-reported unstable medical condition that restricts activity; 4) inability or unwilling to use a telephone; 5) receipt of cortisone or Synvisc injections in the knee, angioplasty, stents, or a pacemaker in the past 6 months; 6) has resting BP $\geq 160/100$ mm Hg; 7) OA of the hip, spinal stenosis, inflammatory arthritis, foot drop, diabetes treated with insulin, diabetic complications, major depression, or knee conditions, such as meniscus tears or knee ligament ruptures; 8) major surgery scheduled in the next 13 months; or 9) enrolled in another intervention study that may result in bias, such as a drug study or a psycho-education study.

2.1.3 Mixed-Method Study Design

A mixed-method design was chosen for the purpose of complementarity (Sandelowski *et al.*, 2006), meaning findings from the quantitative inquiry and qualitative inquiry were integrated in a complementary fashion to produce an integrated and more complete understanding of the phenomena of interest. The aims and methods for each of the inquiries are presented sequentially to demonstrate how findings from each stage of inquiry were used to inform the subsequent stage and ultimately the integration of findings.

2.1.3.1 Mixed-Method Study Selection Criteria

This study includes participants in the intervention arm only. The single additional eligibility criterion was participants had to have followed the intervention protocol (i.e., regular weekly and bi-weekly meetings) and have sufficient data to be able to apply the longitudinal statistical analysis methods. Eighty-five of the 91 STAR study intervention arm participants met the additional criterion.

2.1.4 Measures

Demographic, behavioral, and biological measures used in this secondary analysis were assessed at baseline only. Tailoring and adherence measures were assessed over weeks 3-24 of the intervention because week 3 was the first week participants were assigned FW and LEE exercise goals. References of reliability and validity for all measure are sited with each measure description.

Demographic variables. The Sociodemographic Questionnaire Short Form developed at Center for Research in Chronic Disorders (CRCD) of the University of Pittsburgh was used to describe sample demographics including age (years), race (white, other), sex (male, female), education (Grade/High School/GED, Vocational/Associates Degree, Four Year College, Graduate Education), and income (\$0-29,999, \$30,000-59,999, \$60,000-99,999, \geq \$100,000).

Duration of osteoarthritis of the knee and hypertension diagnoses. Each of these variables was measured in self-reported years since diagnosis.

Comorbidities. Comorbidities were measured as a total count of diagnosed comorbid conditions/diseases with the brief version of the self-report Comorbidity Questionnaire developed at the CRCD of the University of Pittsburgh. Possible scores range is 0-47, however

since all participants had OAK and HBP, the possible score for the study participants was 2-47 (Sereika & Engberg, 2006).

Functional status. Functional status score was calculated by summing scores from a performance-based Short Physical Performance battery consisting of: (1) repeated chair-stands test of lower body strength, (2) 4-meter walk of usual gait speed, and (3) standing balance test of static balance. Possible scores ranged between 0-13 (Guralnik *et al.*, 1994).

Pain. Pain was measured by the self-report 5-item, 5-point Likert pain subscale of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, which assesses ratings of knee joint pain for the past 48 hours. Possible scores ranged between 0-25 (Bellamy *et al.*, 1988).

Body mass index. Height and weight were obtained on a balance beam scale with height rod. BMI was calculated as weight in kilograms divided by height in meters squared (Romero-Corral *et al.*, 2008).

Exercise self-efficacy. The baseline score from the self-report self-efficacy scale for exercise, a 12-item, 11-point Likert scale was used to measure level of self-efficacy for performing exercise on a regular basis over the next 6 months. Possible scores ranged between 0-1200 (McAuley, 1992).

Outcome expectancy. Outcome expectancy was measured as a baseline score from the self-report exercise and arthritis version of the Perceived Therapeutic Efficacy Scale (PTES), a 10-item, 11-point Likert scale survey. Possible scores ranged between 0-100 (Dunbar-Jacob *et al.*, 2006).

Tailoring of fitness walking goals. This tailoring variable was measured by self-report via the eDiary and defined as a proportion of the number of minutes prescribed by the

interventionist per week relative to the upper time limit of the target goal defined in the STAR study.

Tailoring of lower extremity exercise goals. This tailoring variable was measured by self-report via the eDiary and defined as the average proportion of the total number of repetitions and sets prescribed by the interventionist relative to the upper limit of the target goal for the following exercises: 3 range of motion/flexibility exercises, 6 lower extremity-strengthening exercises, and 4 standing balance exercises.

Adherence to lower extremity exercise. This adherence variable was measured by self-report via the eDiary and defined as a proportion of the reported number of lower extremity exercise sets and repetitions performed relative to the number of lower extremity exercise sets and repetitions prescribed by the interventionist. If the participant met 75% of the goal for the day they were considered adherent. Overall adherence was summarized over a 7-day period.

Adherence to fitness walking. This adherence variable was measured by self-report via the eDiary and defined as a proportion of total minutes of walking per day performed relative to the total minutes of walking per day prescribed by the interventionist. If the participant met 75% of the goal for the day they were considered adherent. Overall adherence was then summarized over a 7-day period.

2.1.5 Analysis

IBM SPSS[®] Statistics (version 24.0, IBM Corp., Armonk, NY) was used for descriptive analysis, data summarization, and data screening including: 1) variable distributions, 2) amount and pattern of missing data, and 3) potential violation of assumptions necessary for the planned analyses. Distribution of continuous variables was summarized using frequencies, means, and

standard deviations. Frequency counts, percentages, and ranges were calculated for nominal variables. Randomness of missing data was investigated using information on participant characteristics to discern patterns and possible missing data mechanisms.

2.1.5.1 Quantitative Analysis Plan for Aim 1

Aim 1: Identify latent trajectories of lower extremity exercises, fitness walking adherence and tailoring over weeks 3-24 of the STAR study intervention period. Group-based trajectory modeling (GBTM) was used for principal analyses of temporal patterns of tailoring and adherence of lower extremity exercise and fitness walking with the statistical software SAS (v.9.4, SAS Institute, Cary, NC) PROC TRAJ. GBTM uses objective statistical criterion to identify the best fitting model for the data, specifically the most appropriate number of groups of individuals following similar trajectories of a given outcome over time (B. L. Jones *et al.*, 2001).

The primary fit statistic used is the Bayesian Information Criterion (BIC) value, which is generated for each model. BICs from competing models are used to approximate a Bayes factor, which is a statistical index that quantifies the evidence for one model being a better fit when compared to another. Per Jeffrey's scale of evidence of Bayes factor reported in (Wasserman, 2000), a score less than 1/10 or greater than 10 is considered strong evidence for one model over another. Thus, starting with the simplest model (one latent group), groups were added until the difference in BIC values between the more complex model and the simpler model that preceded it yielded a Bayes factor score between 1/10 and 10, at which point the last added group was removed.

Once the optimal number of trajectory groups was determined, the best fitting trajectories' shape (e.g., linear, quadratic, etc.) were identified by adding higher order terms to each trajectory's polynomial function until the highest order term was no longer statistically

significant based on the Wald test statistic (D. Nagin, 2005). Once the highest order statistically significant terms were identified, each model was retested using the same BIC comparison method previously described. This process of comparing the fit of a more complex model to the fit of the simpler model that preceded it continued until there was no substantial evidence for improvement in model fit.

To further assess model fit, each group was expected to meet the following criteria outlined by (B. L. Jones & Nagin, 2007): (1) average posterior probabilities of assignment (APPA) greater than 0.7, (2) odds of correct classification (OCC) of at least 5.0, and (3) an acceptable correspondence between the probability of assignment and the proportion actually assigned to each group (i.e., mismatch) where perfect correspondence is equal to zero. Finally, the substantive importance of the groups (e.g., parsimony, group size, and standard errors) was considered.

2.1.5.2 Quantitative Analysis Plan for Aim 2

Aim 2: Identify associations between adherence and tailoring trajectory group membership. Upon identification of the adherence and tailoring trajectory groups for both LEE and FW, associations between adherence and tailoring trajectory groups were determined using chi-square test of independence for LEE and Fischer's Exact test for FW (due to small cell counts). Additional associations between tailoring of LEE and tailoring of FW, as well as adherence of LEE and adherence to FW were performed using Fischer's Exact tests. Alpha was set at ≤ 0.05 for all analyses. Post-hoc testing using adjusted standardized Pearson residuals was performed to determine the source of any significant result using a threshold of ± 2 (Agresti, 1996).

2.1.5.3 Qualitative Analysis Plan for Aim 3

Aim 3: Compare and contrast when, why, and how interventionists and participants who differed in extent of tailoring and adherence trajectory group membership used the eDiary in the tailoring process and its impact adherence. Purposive sampling was applied in a variety of ways. First, a representative sample of participants was chosen primarily based upon LEE and FW adherence and tailoring trajectory group membership. After identifying participants based upon a combination of adherence and tailoring trajectory group membership, other pertinent participant characteristics were considered to assure the qualitative sample characteristics resembled those of the full intervention sample as much as possible. Second, four participant-interventionist interactions per participant spread out across the 24-week intervention period were selected (refer to table 1); session three, the first session when participation in both fitness walking and knee exercise began; session six, the final face-to-face session with the physical therapist interventionist; session nine, the third session when the RN-interventionist covered the topic of setbacks from situational factors; session thirteen, where participants explored personal challenges and persuasive things they may be able to do or say to themselves to motivate themselves to perform physical activity. Third, selected time points of the audio-recordings included the beginning and end of each session when the eDiary was most often referred to and goal setting took place. Three additional recordings per person were reviewed to ensure data saturation was reached. All audio-recorded qualitative data was transcribed verbatim and transferred from a word processing program to Atlas.ti[®] (version 7.5 Scientific Software Development GmbH) to organize and manage qualitative data analysis for aim 3.

With ANT as the lens, qualitative description was used (Sandelowski, 2000) to systematically expose content related to the interplay between all the actors (human and non-

human) within the context of individual tailoring to promote exercise adherence. The analysis of qualitative data was initiated by a lead coder who used open coding and thick description to identify and describe instances in which the eDiary was referenced in the discussions of self-reported eDiary adherence data and tailoring of subsequent goals.

2.1.5.4 Synthesis Plan for Aim 4

Aim 4: Integrate findings from qualitative and quantitative aims to generate a contextually rich theory driven assessment of the relationships between tailoring and adherence and the role mobile technology played in the process. Conceptual triangulation (Sandelowski et al., 2006) was used to integrate quantitative results from aim 1 and 2 with qualitative findings from aim 3. First, data was analyzed within method in order to identify pertinent results and investigate their credibility (e.g., threats to rigor and strength of support for findings) (R. L. Foster, 1997). Additionally, the strength of support for findings in the literature, both empirical and theoretical, as well as within the study itself, was reflexively investigated. The process of identifying pertinent findings and assessing their credibility culminated in an integrated conceptual model.

Trustworthiness was achieved in the pursuit of the qualitative aims by incorporating a second coder in the review of initial codes and holding discussions among the research team members regarding interpretation and conceptualization throughout the course of the study's analysis phase (Erlandson, 1993).

2.2 POTENTIAL LIMITATIONS

Limitations of this study are primarily due to the fact that it is a secondary analysis and thus relies on previously collected STAR Study data. The limited sample size was not ideal for the multivariable analysis. A larger sample would improve sensitivity and specificity of the analysis. Adherence was measured by self-report only. Including an objective activity measure may provide a different result. The trajectories only represent the intervention period and do not address the likely declines afterward. In addition, potential association of trends in behavioral measures that may further explain the relationship between individual tailoring and adherence (such as self-efficacy and outcome expectancy) could not be explored via trajectory modeling because they were only measured at baseline, 6, and 12 months in the parent study. Also, the qualitative analysis included only transcriptions of recorded patient-interventionist interactions; the inclusion of follow-up semi-structured interviews would have been helpful for confirmation and further exploration, however the duration of time since the parent study participants actively used the eDiary was too long for accurate recall.

2.3 ALTERNATIVE APPROACHES

The competing statistical methodology of Random Coefficient Modeling was considered. This methodology would allow the interpretation of how much an individual change would deviate from the population mean. However, it would not allow for the distinction of groups, therefore it lacks explanatory power at the individual level. GBTM is the chosen method of analysis because it quantifies group membership as a probability and therefore provides a rich statistical snapshot

of the key characteristics and behaviors of individuals following distinctive trajectories(D. S. Nagin & Odgers, 2010).

Among the various alternative approaches available to meet qualitative aim 2 (e.g., grounded theory, qualitative description), thematic analysis was chosen because its primary goal is to describe how people feel, think, and behave within a particular context related to specific phenomena of interest (Guest *et al.*, 2012). Grounded theory shares a similar process, but aims to produce a substantive theoretical model (Robrecht, 1995). Consequently, grounded theory may be a better choice for future studies because there will be further elucidation of actors' motivations relative to the core phenomena.

Conceptual triangulation is the chosen method of synthesis because the ultimate goal of the proposed study is integration of findings from aim 1 and 2 (as opposed to aggregation which would require quantifying qualitative data or vice versa). Conceptual triangulation preserves the integrity and unique contributions of qualitative and quantitative research, and is designed to achieve a more complete and contextually rich description of the phenomenon of interest (R. L. Foster, 1997).

2.4 PROTECTION OF HUMAN SUBJECTS

2.4.1 Potential Risks for Proposed Secondary Analysis

Since there is no direct contact with human subjects, there is no direct risk, but rather a minimal risk of vulnerable personal health information. All STAR study participants were assigned a

unique identification number, under which all data, including audiotapes, are stored. The unique identifier limits the potential risks of loss of privacy of personal health information.

2.4.2 Procedures for Protection Against Risk

To minimize the risks of breach of confidentiality, all participants were assigned a unique identification number, under which all data, including audiotapes, is stored. Paper copies of data and audiotapes will continue to be stored in locked file cabinets accessible only to the STAR study PI and project staff, and myself. Data and audiotapes were kept separate from the consent forms, which were stored in a locked case. The code sheet linking subjects' names and identification numbers was stored in another locked case. Data was kept secured through the use of password protection. Review of data and preparation of reports used identification numbers and not subjects' names. Myself, and all project staff were required to complete the online courses offered by the University of Pittsburgh, Internet-Based Studies in Education and Research, as well as to sign a confidentiality agreement prior to contact with data.

2.5 STUDY SUMMARY

The purpose of this mixed-method study is to generate a contextually rich assessment of adherence promotion via a personally tailored exercise self-management intervention that employs an mHealth self-monitoring system and is designed specifically for older adults with hypertension and osteoarthritis of the knee. The results of the quantitative specific aims are

presented in section 3.0. The results of the qualitative specific aims and synthesis are presented in section 4.0

2.6 PROPOSAL CHANGES

The single change to the original proposal was to the purposive sampling strategy. Initially, 2 recordings of 20 participants was proposed. However, upon thorough investigation of the audio-recordings, it was determined that more recordings of fewer participants would offer more information in the sense of change in adherence over the course of the invention period. Therefore, the purposive sample consisted of 4 recordings from 12 participants.

3.0 QUANTITATIVE MANUSCRIPT: TEMPORAL PATTERNS IN INDIVIDUALIZED INTERVENTION TAILORING AND EXERCISE ADHERENCE AND THEIR CORRELATES AMONG OLDER ADULTS WITH OSTEOARTHRITIS OF THE KNEE AND HYPERTENSION

3.1 ABSTRACT

Background: Little is known about the relationship between extent of individual tailoring of exercise goals and trends in adherence among older adults with osteoarthritis of the knee and hypertension (OAK/HTN).

Objectives: 1) Identify trajectory groups for extent of tailoring of exercise goals, adherence to lower extremity exercise (LEE), and adherence to fitness walking (FW); 2) Determine the associations between tailoring and exercise trajectory groups; 3) Explore sample characteristics (e.g., demographics, self-efficacy, outcome expectancy, extent of tailoring) as potential predictors of exercise adherence trajectory groups.

Methods: Group-based trajectory modeling was used to identify trajectory groups. Associations between tailoring and adherence trajectories were evaluated using Chi-square or Fisher's exact tests. Multivariable multinomial logistic regression was used to identify predictors of adherence trajectory groups.

Results: Three distinct trajectories were identified for LEE tailoring and adherence; four were identified for FW tailoring and adherence. A moderate association was observed between tailoring and exercise adherence trajectories for LEE ($p=.007$), but not FW ($p=.12$). The LEE “remained highly tailored” trajectory group had greater odds of belonging to the “quick decline” (OR=16.89) and “steady decline” (OR=3.74) adherence trajectory groups. The FW “slight rise/remained highly tailored” trajectory group had greater odds of belonging to the “quick/steady decline” adherence trajectory group (OR=5.65).

Conclusions: Stratification based upon extent of intervention tailoring and progression towards an ideal goal may be an effective way to target those least likely to remain adherent. More work is needed to identify additional tailored supportive techniques to improve efficacy of OAK/HTN exercise interventions.

Keywords: self-efficacy, self-management strategies, osteoarthritis of the knee, hypertension, personalized intervention tailoring, predictors of exercise adherence

Clinical Messages

- Refining methods to identify trends in extent of exercise tailoring and subsequent adherence can inform interventions by targeting individuals least likely to experience sustained adherence.
- New strategies and tools are needed to identify, measure, and support individuals’ unique motivators and barriers to adherence as they change over time.

3.2 INTRODUCTION

Of the over 9 million Americans who have symptomatic osteoarthritis of the knee (OAK), half are diagnosed with hypertension (HBP), a prevalent risk factor for cardiovascular disease (Eymard et al., 2015). Total treatment costs in the United States are estimated to be billions of dollars (Bauer et al., 2014). Clinical trials targeting people with OAK and HBP have shown that physical activity has tremendous benefits; however, adherence to physical activity recommendations remains low (Fransen et al., 2015). Knee pain and functional limitations associated with OAK have been identified as major barriers to exercise self-management regimen adherence (Wallis et al., 2013), and thus contribute to accelerating morbidity and escalating healthcare costs.

Individually tailored self-management interventions (ITSMIs) are a promising alternative to standardized interventions because they seek to engage participants and motivate adherence by incorporating personal preferences and addressing unique barriers to adherence (Friedberg et al., 2015; Hawkins et al., 2008). Bandura's social cognitive theory (SCT) is a common underlying foundation of tailored interventions, especially those that focus on increasing physical activity (Richards et al., 2007), because SCT incorporates perceived self-efficacy, a critical activity-specific behavioral determinant (Bandura, 1989). Self-efficacy theory hypothesizes that self-efficacy and outcome expectancy are inter-related concepts; stronger self-efficacy and positive outcome expectancy increase targeted behavior, whereas lower self-efficacy and negative outcome expectancy decrease targeted behavior (Bandura, 1997).

Unfortunately, while self-efficacy theory is incorporated into many tailored intervention studies that aim to increase physical activity, it is seldom measured. Additionally, most studies did not quantify the extent of personal goal tailoring compared to an ideal exercise goal and only

measure adherence at two or three time points over the course of 6 or 12 months (Plow et al., 2016). Thus, the temporal relationship between the extent of exercise goal tailoring and adherence remains unclear, as does the role of self-efficacy and outcome-expectancy and potentially influential covariates such as age, functional status, pain, body mass index (BMI), etc.

The Staying Active with Arthritis (STAR) (R01 NR010904, PI Schlenk) is the first clinical trial to investigate a self-efficacy model (Bandura, 1997) as part of an personally tailored intervention to promote exercise adherence in older adults with the comorbid conditions of OAK and HBP. The STAR study included self-efficacy and outcome expectancy measures and used an evidence-based ideal goal for lower extremity exercise and fitness walking intervention (Misso et al., 2008). Participants were given a Smartphone with a custom application, the STAR Study eDiary, and an electronic pedometer. Daily adherence of lower extremity exercise goals, minutes walked, and pedometer steps taken were manually recorded by the participants in the eDiary. Precise definitions and measures of the extent of tailoring and multiple time point measurements of adherence allow for more complex analysis including the investigation of trends in the extent of intervention tailoring over time and its association to exercise adherence. Precise measurement of tailoring also permits researchers to identify and more deeply understand the association among and between potentially important covariates (such as self-efficacy and outcome expectancy).

3.2.1 Study Aims

Presently, little is known about the longitudinal relationship between the extent of personal tailoring of exercise goals and patterns of adherence, while considering baseline self-efficacy and outcome expectancy as well as other empirically supported characteristics that may influence

exercise adherence including age, functional status, pain, BMI, and duration of OAK and HBP diagnoses (Courneya et al., 2014; Shang et al., 2012). Fully understanding the temporal relationship between tailoring, adherence, and role of related covariates can inform future efforts to refine the tailoring process and ultimately increase the odds of adherence. Therefore, the aims of this study were to: 1) identify latent trajectories of the extent of tailoring of lower extremity exercise and fitness walking goals, 2) identify latent trajectories of adherence to lower extremity exercise and fitness walking over the course of the STAR study intervention; 3) determine the association between identified tailoring trajectory and adherence trajectory group membership; and 4) explore possible associations between baseline self-efficacy and outcome expectancy, tailoring trajectory group membership, and select sample characteristics with adherence trajectory group membership.

3.3 METHODS

3.3.1 Parent Study Intervention

This secondary analysis includes quantitative longitudinal data from the intervention arm of a randomized controlled trial of Staying Active with Arthritis (STAR) (R01 NR010904, PI Schlenk). Four self-efficacy principles form the foundation of the STAR study: modeling, mastery, physiological feedback, and social persuasion (Bandura, 1977). Together these strategies aim to enhance the belief that physical activity is possible in the presence of knee pain, knee instability, and high blood pressure by supporting behavior to adopt and maintain physical activity in the form of lower extremity exercise and fitness walking. Mastery (or performance

achievement) is the central self-efficacy strategy employed for achieving exercise adherence and is operationalized by gradually increasing lower extremity exercise and fitness walking goals toward an ideal goal over the course of the 24-week intervention period. This gradual increase of goals based on individual ability and limitations is also known as personal intervention tailoring (Hawkins et al., 2008).

The STAR intervention included a total of 15 interactive sessions with an interventionist. Each participant met face-to-face with a physical therapist interventionist on a weekly basis over the first six weeks of the intervention period. Participants then transitioned to nine biweekly telephone-counseling sessions lead by a registered nurse during weeks seven to twenty-four. Lower extremity exercise and fitness walking was carried out at home between sessions.

The daily self-reported lower extremity exercise and fitness walking adherence data collected via the eDiary was uploaded to a secure server and reviewed during the sessions with the physical therapist and nurse interventionists to aid discussions about adherence to the goals from the previous week(s) and to inform tailoring of knee exercise and fitness walking goals for the subsequent weeks. Each participant's intervention regimen was systematically tailored in terms of time (of fitness walking) and of number of sets and repetitions, and amount of ankle weight (of lower extremity exercise) based on the ideal goal of 150 minutes of walking per week and 2 sets of 15 repetitions with 2 lbs. ankle weights for selected exercises. The lower extremity exercises recommendations are consistent with the American College of Sports Medicine (ACSM) (Nelson et al., 2007), the American Geriatrics Society (AGS) (American Geriatrics Society, 2001), and the American Heart Association (AHA) (Williams et al., 2007). The fitness walking program is consistent with the ACSM/AHA (Nelson et al., 2007) recommendations. The

goals were advanced if 75% adherence to the previous goal was achieved. If not, the goal remained the same.

Access to STAR study intervention data was covered under the STAR study IRB protocol at the University of Pittsburgh. The following sections first describe the parent study sample, recruitment, inclusion and exclusion criteria followed by additional criteria of this secondary analysis. The measures section includes only those measures used in this secondary analysis.

3.3.2 Sample

A convenience sample was recruited from existing registries and public domain mailing lists for the parent study. In addition to the parent study's eligibility criteria, the participants in this study were randomized to the intervention arm, followed the intervention protocol (i.e., regular weekly and bi-weekly meetings), and had sufficient data to be able to apply the longitudinal statistical analysis methods. Eighty-five of the 91 STAR Study intervention arm participants met the additional criteria for this secondary analysis.

3.3.3 Measures

The parent STAR study assessed all measures of interest at baseline, at the end of intervention at six months, and six months after the end of intervention at twelve months. Demographic, behavioral, and biological measures used in this secondary analysis were from baseline only. Tailoring and adherence measures include weeks 3-24 of the intervention because week 3 was

the first week participants were assigned both fitness walking goal and lower extremity exercise goal.

Demographic variables. Age (years), race (white, other), sex (male, female), education (Grade/High School/GED, Vocational/Associates Degree, Four Year College, Graduate Education), and income (\$0-29,999, \$30,000-59,999, \$60,000-99,999, \$100,000-over) were collected using the Sociodemographic Questionnaire Short Form developed at Center for Research in Chronic Disorders (CRCD) of the University of Pittsburgh.

Duration of osteoarthritis and hypertension diagnoses. Each of these variables was measured in years since diagnosis.

Comorbidities. Comorbidities were measured as a total score from the brief version of the Comorbidity Questionnaire developed at the CRCD of the University of Pittsburgh. It is comprised of a self-report of comorbid conditions. It covers 47 potential comorbid conditions (possible range is 0-47).

Functional status. Functional status was measured objectively as a total score from a performance-based Short Physical Performance battery consisting of (1) repeated chair-stands test of lower body strength, (2) 4-meter walk of usual gait speed, and (3) standing balance test of static balance. Possible total score range is 0-13 (Guralnik et al., 1994).

Pain. Pain was measured by the self-administered 5-item, 5-point Likert pain subscale of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, which collects information about knee joint pain for the past 48 hours. Possible total score range is 0-25 (Bellamy et al., 1988).

BMI. Height and weight were obtained on a balance beam scale with height rod. BMI was calculated as weight in kilograms divided by height in meters squared.

Exercise self-efficacy. Exercise self-efficacy was measured as a baseline score from the self-administered Self-Efficacy scale for exercise, a 12-item, 11-point Likert scale that measures self-efficacy to exercise on a regular basis over the next 6 months. The total score range is 0-1200 (McAuley, 1992).

Outcome expectancy. Outcome expectancy was measured as a baseline score from the self-administered exercise and arthritis version of the Perceived Therapeutic Efficacy Scale (PTES) (Dunbar-Jacob et al., 2006). This is a 10-item survey with 11-point Likert scale. The total score range is 0-100.

Tailoring of fitness walking goals. This tailoring variable was measured by self-report via the eDiary and defined as a proportion of the number of minutes prescribed by the interventionist per week relative to the upper time limit of the target goal defined in the STAR study.

Tailoring of lower extremity exercise. This tailoring variable was measured by self-report via the eDiary and defined as the average proportion of the total number of repetitions and sets prescribed by the interventionist relative to the upper limit of the target goal across the following exercises: 3 range of motion/flexibility exercises, 6 lower extremity-strengthening exercises, and 4 standing balance exercises.

Adherence to fitness walking goals. This adherence variable was measured by self-report via the eDiary and defined as a proportion of total minutes of walking per day performed relative to the total minutes of walking per day prescribed by the interventionist. If the participant met 75% of the goal for the day they were considered adherent. Adherence was then summarized over a 7-day period.

Adherence to lower extremity exercise goals. This adherence variable was measured by self-report via the eDiary and defined as proportion of the reported number of lower extremity exercise sets and repetitions performed relative to the number of lower extremity exercise sets and repetitions prescribed by the interventionist. If the participant met 75% of the goal for the day they were considered adherent. Adherence was summarized over a 7-day period.

3.3.4 Analysis

IBM SPSS[®] Statistics (version 24.0, IBM Corp., Armonk, NY) was used for descriptive analysis, data summarization, and data screening including: 1) variable distributions, 2) amount and pattern of missing data, and 3) potential violation of assumptions necessary for the planned analyses. Distribution of continuous variables was summarized using frequencies, means, and standard deviations. Frequency counts, percentages, and ranges were calculated for nominal variables. Randomness of missing data was investigated using information on participant characteristics to discern patterns and possible missing data mechanisms.

3.3.4.1 Group-based Trajectory Modeling

Group-based trajectory modeling (GBTM) was used for principal analyses of temporal patterns of tailoring and adherence of lower extremity exercise and fitness walking with the statistical software SAS (v.9.4, SAS Institute, Cary, NC) PROC TRAJ. GBTM uses objective statistical criterion to identify the best fitting model for the data, specifically the most appropriate number of groups of individuals following similar trajectories of a given outcome over time (B. L. Jones et al., 2001).

The primary fit statistic used is the Bayesian Information Criterion (BIC) value, which is

generated for each model. BICs from competing models are used to approximate a Bayes factor, which is a statistical index that quantifies the evidence for one model being a better fit when compared to another. Per Jeffrey's scale of evidence of Bayes factor reported in (Wasserman, 2000), a score less than 1/10 or greater than 10 is considered strong evidence for one model over another. Thus, starting with the simplest model (one latent group), groups were added until the difference in BIC values between the more complex model and the simpler model that preceded it yielded a Bayes factor score between 1/10 and 10, at which point the last added group was removed.

Once the optimal number of trajectory groups was determined, the best fitting trajectories' shape (e.g., linear, quadratic, etc.) were identified by adding higher order terms to each trajectory's polynomial function until the highest order term was no longer statistically significant based on the Wald test statistic (D. Nagin, 2005). Once the highest order statistically significant terms were identified, each model was retested using the same BIC comparison method previously described. This process of comparing the fit of a more complex model to the fit of the simpler model that preceded it continued until there was no substantial evidence for improvement in model fit.

To further assess model fit, each group was expected to meet the following criteria outlined by (B. L. Jones & Nagin, 2007): (1) average posterior probabilities of assignment (APPA) greater than 0.7, (2) odds of correct classification (OCC) of at least 5.0, and (3) an acceptable correspondence between the probability of assignment and the proportion actually assigned to each group (i.e., mismatch) where perfect correspondence is equal to zero. Finally, the substantive importance of the groups (e.g., parsimony, group size, and standard errors) was considered.

3.3.4.2 Associations Between Tailoring and Adherence Trajectory Group Membership

Upon identification of the adherence and tailoring trajectory groups for both lower extremity exercise and fitness walking, IBM SPSS[®] Statistics (version 24.0, IBM Corp., Armonk, NY) was used to perform the subsequent quantitative analysis with p values ≤ 0.05 considered statistically significant throughout, unless otherwise stated. The associations between adherence and tailoring trajectory groups were assessed using chi-square test of independence for lower extremity exercise and Fischer's Exact test for fitness walking (due to small cell counts). Post-hoc testing using adjusted standardized Pearson residuals was used to determine the source of any significant result using a threshold of ± 2 (Agresti, 1996).

3.3.4.3 Predictors of Adherence Trajectory Group Membership

Demographic characteristics, durations of OAK and HBP, functional status, pain, BMI, self-efficacy, outcome expectancy, and tailoring trajectory group membership were screened in a bivariate manner using a p -value of .20 to identify candidate predictor variables of lower extremity exercise and fitness-walking adherence group membership for inclusion in multivariable analyses (Tabachnick & Fidell, 2012). Candidate predictors of adherence group membership that met screening criteria were considered jointly in a multivariable multinomial logistic regression analysis. Then a manual backward step-wise process was conducted where predictor variables were removed one at a time. Criterion for removal was $p \geq .1$ across all adherence groups.

The multinomial logistic regression assumption of a linear relationship between the continuous independent variables and the logit transformation of the dependent variable was tested with the Box-Tidwell approach (Li *et al.*, 2001). Variance inflation factors (VIF) were

inspected to detect possible multicollinearity (Mansfield & Helms, 1982). Studentized residuals larger than ± 3 were investigated for potentially influential outliers (Selst & Jolicoeur, 1994).

3.4 RESULTS

3.4.1 Sample Characteristics

The average age of participants was 64.8 (SD \pm 8.36) years old. Seventy-five percent were female, and 74% were white, with adequate representation of educational attainment and income levels. The average duration of OAK was 11.53 (SD \pm 9.92) years and the average duration of HBP was 14.20 (SD \pm 9.59) years. The average comorbidities score was 8.41 (SD \pm 3.55) and BMI was 33.86 (SD \pm 6.21) kg/m². The average functional status was high at 10.95 (SD \pm 1.75). While the range of participant pain scores was wide (0-20), the average score was moderately low at 5.64 (SD \pm 3.79). Average exercise self-efficacy score was moderate at 859.41 (SD \pm 339.68), as was the average outcome-expectancy score of 68.36 (SD \pm 24.17). Refer to Table 3 for a summary of all descriptive statistics of the intervention group overall, as well as by adherence trajectory group membership for lower extremity exercise. Refer to Table 4 for descriptive statistics by fitness walking adherence trajectory group.

Table 3. Sample Characteristics by Lower Extremity Exercise Adherence Trajectory Group

Membership

Participants Characteristics	Total Group N=85	Lower Extremity Exercise Adherence		
		Quick Decline N=16	Steady Decline N=37	Consistently Adherent N=32
Age (years) Mean (SD)	64.81 (±8.36)	61.69 (±6.75)	62.81 (±7.07)	68.69 (±9.17)
Gender (Female) n (%)	64 (75.3%)	12 (75%)	29 (78.4%)	23 (71.9%)
Race (White) n (%)	63 (74.1%)	10 (62.5%)	28 (75.7%)	25 (78.1%)
Education n (%)				
High School Degree/GED	17 (20.0%)	1 (6.3%)	6 (16.2%)	10 (31.3%)
Vocational/Associates	18 (21.2%)	5 (31.2%)	8 (21.6%)	5 (15.6%)
Four-year College	21 (24.7%)	4(25%)	10 (27.0%)	7 (21.9%)
Graduate Education	29 (34.1%)	6 (37.5%)	13 (35.1%)	10 (31.3%)
Income n (%)				
0-\$29,999	19 (22.4%)	5 (31.3%)	5 (13.5%)	9 (28.1%)
\$30,000-\$59,999	23 (27.1%)	5 (31.3%)	10 (27.0%)	8 (25.0)
\$60,000-\$99,999	15 (17.6%)	0 (0%)	8 (21.6%)	7 (21.9%)
\$100,000 and over	15 (17.6%)	4 (24%)	7 (18.9%)	4 (12.5%)
Refused	13 (15.3%)	2 (12.5%)	7 (18.9%)	4 (12.5%)
Duration of OAK (years) Mean (SD)	11.53 (±9.92)	9.69 (±9.38)	11.84 (±10.52)	12.09 (±9.67)
Duration of HBP (years) Mean (SD)	14.20 (±9.59)	10.41 (±8.97)	14.76 (±8.69)	15.09 (±10.28)
Comorbidities Score Mean (SD)	8.41 (±3.55)	9.06 (±5.88)	8.05 (±2.86)	8.50 (±3.84)
Functional Status (score 3.5-13) Mean (SD)	10.95 (±1.75)	10.94 (±1.95)	11.40 (±1.30)	10.44 (±1.99)
Pain (score 0-20) Mean (SD)	5.64 (±3.79)	6.22 (±3.33)	5.45 (±3.96)	5.56 (±3.88)
Body Mass Index Mean (SD)	33.86 (±6.21)	34.87 (±5.88)	34.15 (±6.35)	33.01 (±6.29)
Exercise Self-Efficacy (score 0-1200) Mean (SD)	859.41 (±339.68)	781.88 (±365.46)	917.30 (±43.53)	831.25 (±398.35)
Exercise/Arthritis Outcome-Expectancy (score 0-100) Mean (SD)	68.36 (±24.17)	59.69 (±25.81)	69.41 (±24.03)	71.50 (±23.22)
HBP: Hypertension OAK: Osteoarthritis of the Knee SD: Standard Deviation				

Table 4. Sample Characteristics by Fitness Walking Adherence Trajectory Group Membership

Participants Characteristics	Fitness Walking Adherence			
	Gradual Decline N=10	Steady Decline N=15	Steady Increase N=12	Consistently Adherent N=48
Age (years) Mean (SD)	65.10 (+6.47)	64.47 (+8.65)	62.08 (+ 8.16)	65.54 (+18.75)
Gender (Female) n (%)	6 (60%)	12 (80%)	9 (75%)	37 (77.1%)
Race (White) n (%)	8 (80%)	13 (86.7%)	8 (66.7%)	34 (70.8%)
Education n (%)				
High School Degree/GED	1 (10%)	2 (13.3%)	2 (16.7%)	12 (25.0%)
Vocational/Associates	0 (0%)	4 (26.7%)	3 (25.0%)	11 (22.9%)
Four-year College	3 (30%)	5 (33.3%)	4 (33.3%)	9 (18.8%)
Graduate Education	6 (60%)	4 (26.7%)	3 (25.0%)	16 (33.3%)
Income n (%)				
\$0-\$29,999	2 (20%)	2 (13.3)	4 (33.3%)	11 (22.9%)
\$30,000-\$59,999	4 (40%)	1 (6.7%)	4 (33.3%)	14 (29.2%)
\$60,000-\$99,9999	0 (0%)	5 (33.3%)	1 (8.3%)	9 (18.8%)
\$100,000 and over	2 (20%)	4 (26.7%)	2 (16.7%)	7 (14.6%)
Refused	2 (20%)	3 (20%)	1 (8.3%)	7 (14.6%)
Duration of OAK (years) Mean (SD)	12.80 (+10.38)	12.93 (+12.02)	10.67 (+8.96)	11.04 (+9.59)
Duration of HBP (years) Mean (SD)	16.30 (+10.61)	16.86 (+ 9.35)	12.92 (+7.48)	13.55 (+9.77)
Comorbidities Score Mean (SD)	10.30 (+4.0)	7.67 (+3.52)	8.17 (+3.51)	8.31 (+3.45)
Functional Status (score 3.5-13) Mean (SD)	11.50 (+1.27)	10.13 (+2.42)	11.58 (+1.51)	10.94 (+1.58)
Pain (score 0-20) Mean (SD)	5.85 (4.01%)	4.13 (+3.66)	7.04 (+4.04)	5.71 (+3.68)
Body Mass Index Mean (SD)	36.42 (+7.84)	32.99 (+5.66)	36.87 (+7.55)	32.84 (+5.42)
Exercise Self-Efficacy (score 0-1200) Mean (SD)	687.00 (+343.67)	783.33 (+364.57)	872.50 (+405.95)	915.83 (+306.53)
Exercise/Arthritis Outcome-Expectancy (score 0-100) Mean (SD)	61.80 (+27.32)	68.60 (+29.69)	69.67 (+225.91)	69.33 (+21.69)
HBP: Hypertension OAK: Osteoarthritis of the Knee SD: Standard Deviation				

3.4.2 Group-Based Trajectory Modeling

Refer to Table 5 for a complete overview of all model parameters, BIC scores, APPAs, OCCs, mismatch differences, and group sizes. All APPAs were greater than 0.7. OCCs were all at least 5.0, and correspondence between the probability of assignment and the proportion actually assigned to each group (i.e., mismatch) were acceptable.

3.4.2.1 Tailoring of Lower Extremity Exercise

A three-group trajectory model best fit lower extremity exercise tailoring (see Table 3 and Figure 2). Twenty-four participants (28.2%) were assigned to a trajectory group (named “slight rise/remained highly tailored”) with a linear trend in which participants started at 27% of ideal goal to an increase of 35% of ideal goal over the 24-week intervention. Twenty-six (30.6%) were assigned to a trajectory group (named “slow rise to partial goal”) with a quadratic trend in which participants started at 25% of ideal the goal to an increase of 50% of the ideal goal over the 24-week intervention. Thirty-five (41.2%) of participants were assigned to a trajectory group (named “steady rise to near goal”) with a quadratic trend in which participants started at approximately 32% of the ideal goal to an increase of approximately 60% of the ideal goal over the 24-week intervention.

Table 5. Group-based Trajectory Modeling Statistics

Tailoring Trajectory Group Membership							
Lower Extremity Exercise	Parameter	β(SE)	BIC	APPA	OCC	MM	N (%)
Slight Rise/Remained Highly Tailored	Intercept	0.266 (0.001)	2085.20 (N=1661)				24
	Linear	0.005 (0.001)	2101.55 (N=85)	0.97	83.56	0.32	(28.2%)
Slow Rise to Partial Goal	Intercept	0.179 (0.01)					26
	Linear Quadratic	0.029 (0.002) -0.001 (0.0001)		0.98	109.58	0.33	(30.6%)
Steady Rise to Near Goal	Intercept	0.20 (0.01)					35
	Linear Quadratic	0.05 (0.002) -0.001 (0.0001)		0.99	141.29	0.01	(41.2%)
Fitness Walking	Parameter	β(SE)	BIC	APPA	OCC	MM	N (%)
Slight Rise/Remained Highly Tailored	Intercept	0.24 (0.01)	1018.36 (N=1623)				27
	Linear	0.004 (0.001)	1036.06 (N=85)	0.97	70.64	0.42	(31.8%)
Steady Rise Goal Achievers	Intercept Linear	0.33 (0.01) 0.02 (0.001)		0.97	58.24	0.44	30 (35.3%)
Steady Rise to Partial Goal	Intercept Linear	0.38 (0.02) 0.03 (0.001)		0.97	139.65	0.03	16 (18.8%)
Quick Goal Achievers	Intercept Linear	0.67 (0.02) 0.02 (0.001)		0.99	603.13	0.01	12 (14.1%)
Adherence Trajectory Group Membership							
Lower Extremity Exercise	Parameter	β(SE)	BIC	APPA	OCC	MM	N (%)
Quick Decline	Intercept	2.74 (0.67)					16
	Linear	-0.65 (0.13)	-662.71 (N=1713)				(18.8%)
	Quadratic	0.02 (0.01)	-650.70 (N=85)	0.95	84.83	0.47	
Steady Decline	Intercept Linear	2.47 (0.25) -0.09 (0.01)		0.97	41.15	0.54	37 (43.5%)
Consistently Adherent	Intercept	4.73 (0.57)		0.97	164.30	0.03	32 (37.6%)
Fitness Walking	Parameter	β(SE)	BIC	APPA	OCC	MM	N (%)
Gradual Decline	Intercept	1.97 (0.77)					10
	Linear	-0.52 (0.15)	-797.80 (N=1713)				(11.8%)
	Quadratic	0.02 (0.01)	-779.28 (N=85)	0.91	72.77	0.70	
Steady Decline	Intercept Linear	2.62 (0.41) -0.15 (0.03)		0.89	34.50	1.41	15 (17.6%)
Steady Increase	Intercept Linear	-0.21 (0.52) 0.08 (0.04)		0.82	23.22	2.32	12 (14.1%)
Consistently Adherent	Intercept	2.51 (0.18)		0.91	9.19	4.08	48 (56.5%)
BIC: Bayesian Information Criterion APPA: Average Posterior Probabilities of Assignment MM: Mismatch OCC: Odds of Correct Classification SE: Standard Error							

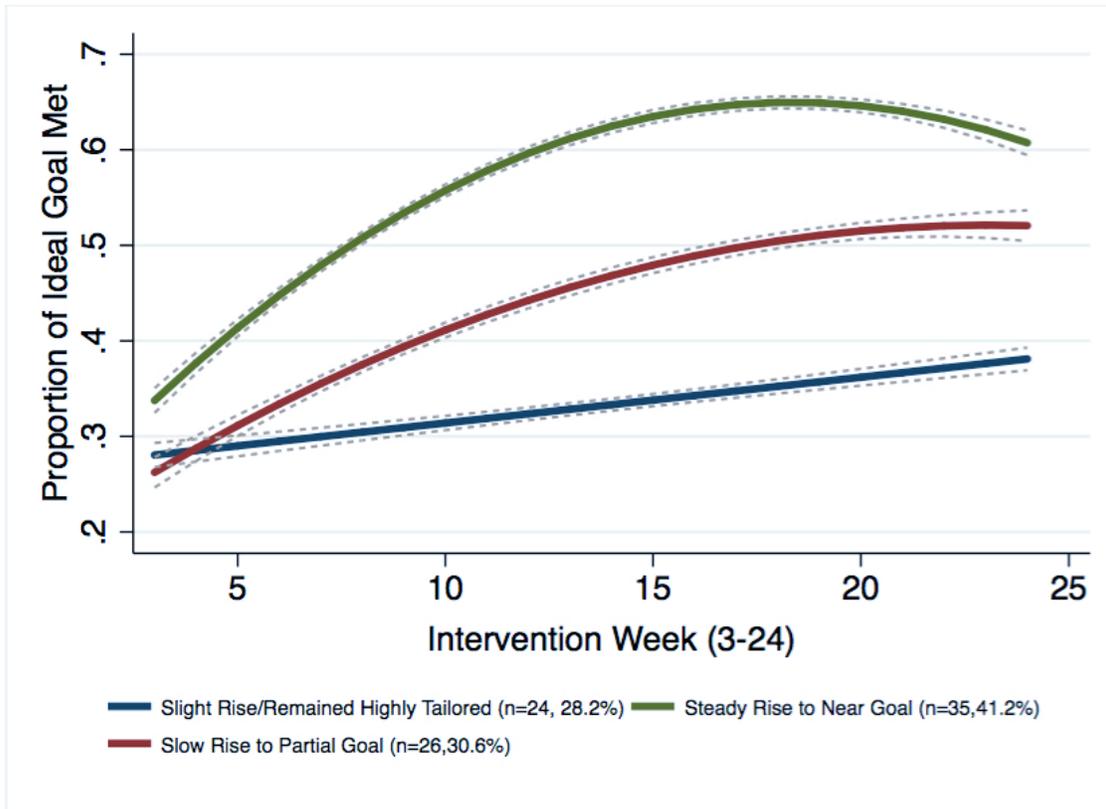


Figure 2. Lower Extremity Exercise Tailoring Trajectory Groups

3.4.2.2 Adherence to Lower Extremity Exercise

A three-group trajectory model best fit lower extremity exercise adherence (see Table 3 Figure 3). Sixteen participants (18.8%) were assigned to a trajectory group (named “quick decline”) with a quadratic trend in which adherence quickly declined to less than approximately 20% over the first 10 weeks of the intervention with a slight rise to 30% between weeks 20-24. Thirty-seven (43.5%) were assigned to a trajectory group (named “steady decline”) with a linear trend in which adherence steadily declined from approximately 90% to 50% over the 24-week intervention. Thirty-two (37.6%) participants were assigned to a trajectory group (named “consistently adherent”) with a constant trend at 100% adherent.

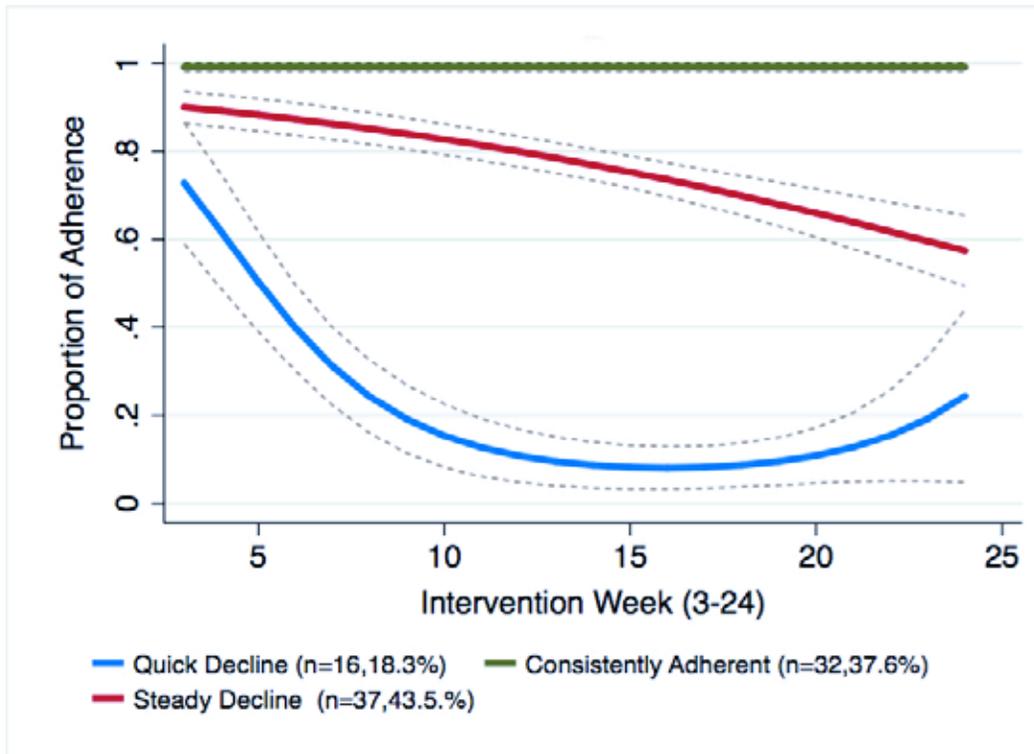


Figure 3. Lower Extremity Exercise Adherence Trajectory Groups

3.4.2.3 Tailoring of Fitness Walking

A four-group trajectory model best fit tailoring of fitness walking (see Table 4 and Figure 4). Twenty-seven (31.8%) participants were assigned to a trajectory group (named “slight rise/remained highly tailored”) with a linear trend in which participants started at approximately 25% of ideal goal to an increase of approximately 30% of ideal goal over the 24-week intervention. Thirty (35.3%) participants were assigned to a trajectory group (named “steady rise goal achievers”) with a linear trend in which participants started at approximately 25% of the ideal goal to an increase of approximately 95% of the ideal goal by week 22 of intervention. Sixteen (18.8%) participants were assigned to a trajectory group (named “steady rise to partial goal”) with a linear trend in which participants started at approximately 37% of the ideal goal to an increase of approximately 60% of the ideal goal over the 24-week intervention. Twelve

(14.1%) participants were assigned to a trajectory group (named “quick goal achievers”) with a linear trend in which participants started at approximately 57% of the ideal goal to an increase of 100% of the ideal goal by week 13 of the study intervention.

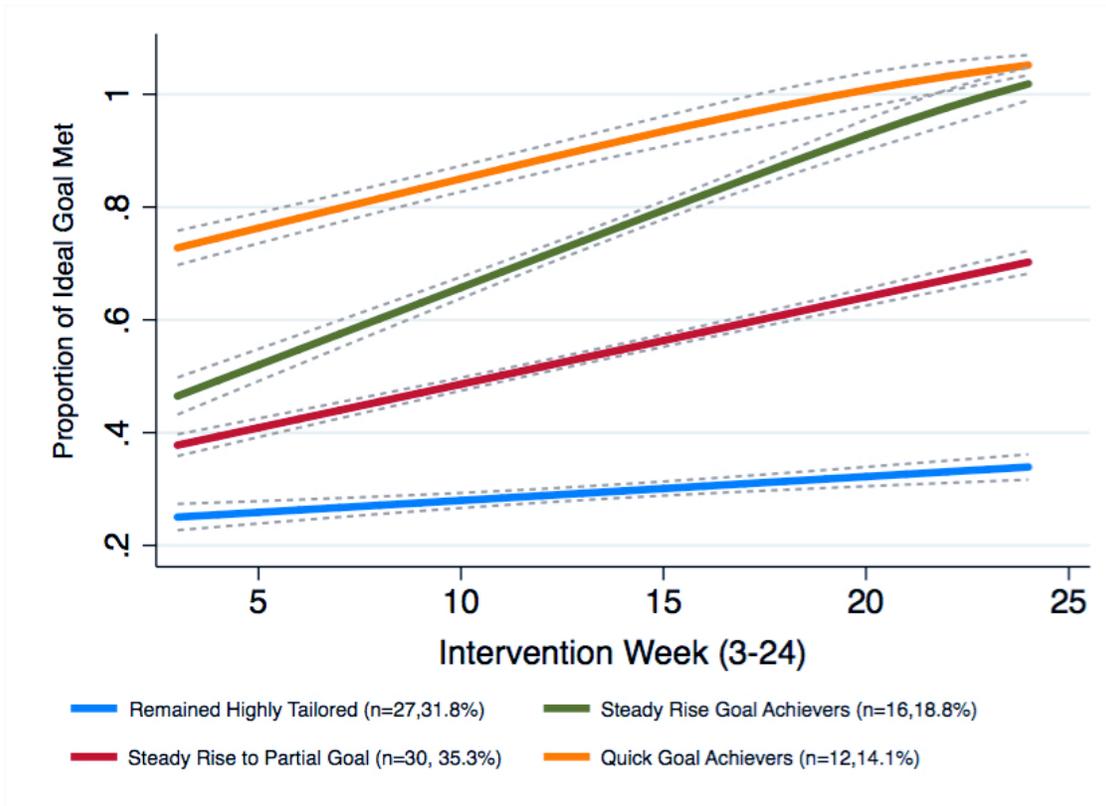


Figure 4. Fitness Walking Tailoring Trajectory Groups

3.4.2.4 Adherence to Fitness Walking

A four-group trajectory model best fit fitness walking adherence (see Figure 5). Ten participants (11.8%) were assigned to a trajectory group (named “quick decline”) with a quadratic trend in which adherence declines to less than approximately 10% over the first 13 weeks of the intervention and slight rise to 20% in weeks 20-24. Fifteen (17.6%) participants were assigned to a trajectory group (named “steady decline”) with a linear trend in which adherence steadily declined from approximately 90% to 20% over the 24-week intervention. Twelve (14.1%)

participants were assigned to a trajectory group (named “steady increase”) with a linear trend steadily increasing from approximately 50% to 80% over the 24-week intervention. Forty-eight (56.5%) were assigned to a trajectory group (named “consistently adherent”) with a constant trend at 100% adherent.

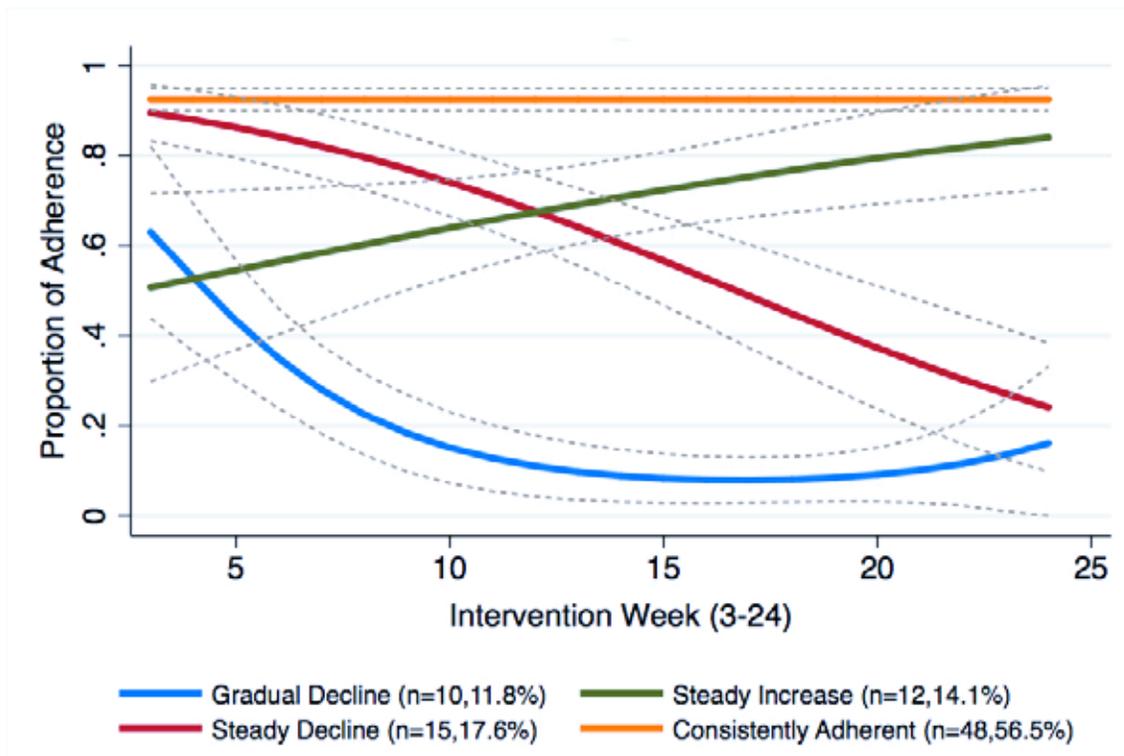


Figure 5. Fitness Walking Adherence Trajectory Groups

3.4.3 Associations Between Tailoring and Adherence Group Membership

3.4.3.1 Association Between Lower Extremity Exercise Tailoring and Adherence Trajectory Groups

A moderate association was observed between trajectory group membership for LEE tailoring and adherence group memberships ($\chi^2(4) = 13.92, p=.008$); Cramer's V = .29. Post hoc testing indicated more participants in the “quick decline” adherence group were members of “slight

rise/remained highly tailored” tailoring group than would be expected by chance (adjusted Pearson residual 2.7),

Table 6. Cross Tabulation of Tailoring Trajectory Groups and Adherence Trajectory Groups

Lower Extremity Exercise Adherence Trajectory Groups	Slight Rise/Remained Highly Tailored	Slow Rise to Partial Goal	Steady Rise to Near Goal	
Quick Decline n (%)	9 (56.2%)	4 (25.0%)	3 (18.8%)	
Steady Decline n (%)	10 (27.8%)	14 (38.9%)	12 (33.3%)	
Consistently Adherent n (%)	5 (15.6%)	7 (21.9%)	20 (62.5%)	
Fitness Walking Adherence Trajectory Groups				
	Slight Rise/Remained Highly Tailored	Steady Rise Goal Achievers	Steady Rise to Partial Goal	Quick Goal Achievers
Gradual Decline n (%)	6 (60.0%)	2 (20.0%)	2 (20.0%)	0 (0.0%)
Steady Decline n (%)	4 (26.7%)	8 (53.3%)	3 (20.0%)	0 (0.0%)
Steady Increase n (%)	6 (45.5%)	4 (36.4%)	0 (0.0%)	2 (18.2%)
Consistently Adherent n (%)	11(22.9%)	16 (33.3%)	11 (22.9%)	10 (20.8%)
^a $\chi^2(4) = 13.92, p < .007$ ^b $\chi^2(9) = 13.42, p = .12$				

and more participants in the “adherence to goals” adherence group were members of the “steady rise to near goal” tailoring group than would be expected by chance (adjusted Pearson residual 3.0). Refer to Table 6 for joint frequency distributions between group memberships for LEE tailoring and adherence.

3.4.3.2 Association Between Fitness Walking Tailoring and Adherence Trajectory Groups

There was not a significant association between trajectory group membership for FW tailoring and trajectory group membership for FW adherence ($\chi^2(9) = 13.42, p = .12$). Refer to Table 6 for joint frequency distributions between group memberships for FW tailoring and adherence.

3.4.3.3 Association between Lower Extremity Exercise and Fitness Walking Adherence Trajectory Groups

A moderate association was observed between trajectory group membership for LEE adherence and FW adherence group membership ($\chi^2(6) = 21.86, p < .001$); Cramer's $V = .41$. Post hoc testing indicated more participants in the LEE “quick decline” adherence group were members of the FW “gradual decline” adherence group than would be expected by chance (adjusted Pearson residual 4.4), and more participants in the LEE “steady decline” adherence group were members of the FW “steady decline” adherence group than would be expected by chance (adjusted Pearson residual 2.6). Also, more participants in the LEE “consistently adherent” adherence group were members of the FW “consistently adherent” adherence group than would be expected by chance (adjusted Pearson residual 3.1). Refer to Table 7 for joint frequency distributions between LEE adherence group memberships and FW adherence group memberships.

3.4.3.4 Association between Lower Extremity Exercise and Fitness Walking Tailoring Trajectory Groups

A statistically significant association was observed between trajectory group membership for LEE tailoring and FW tailoring ($\chi^2(6) = 21.29, p = .001$). The association was moderately strong (Jacob Cohen, 1992), Cramer's $V = .36$. Post hoc testing indicated more participants in the LEE “slight rise/remained highly tailored” group were members of the FW “slight rise/remained

highly tailored” group than would be expected by chance (adjusted Pearson residual 3.3), and more participants in the LEE “steady rise to near goal” tailoring group were members of the FW “steady rise to partial goal” tailoring group than would be expected by chance (adjusted Pearson residual 3.1). Also, fewer participants in the LEE “steady rise to near goal” tailoring group were members of the FW “slight rise/remained highly tailored” group than would be expected by chance (adjusted Pearson residual -3.4). Refer to Table 7 for joint frequency distributions between LEE tailoring group memberships and FW tailoring group memberships.

Table 7. Cross Tabulations of LEE with FW Adherence Trajectory Groups and LEE and FW Tailoring Trajectory Groups

Lower Extremity Exercise Adherence Trajectory Groups	Fitness Walking Adherence Trajectory Groups			
	Gradual Decline	Steady Decline	Steady Increase	Consistently Adherent
Quick Decline n (%)	7 (43.8%)	2 (12.5%)	1 (6.3%)	6 (37.5%)
Steady Decline n (%)	2 (5.4%)	7 (18.9%)	11 (29.7%)	17 (45.9%)
Consistently Adherent n (%)	1 (3.1%)	3 (9.4%)	3 (9.4%)	25 (78.1%)
Lower Extremity Tailoring Trajectory Groups	Fitness Walking Tailoring Trajectory Groups			
	Slight Rise/Remained Highly Tailored	Steady Rise Goal Achievers	Steady Rise to Partial Goal	Quick Goal Achievers
Slight Rise/Remained Highly Tailored n (%)	14 (58.3%)	8 (33.3%)	1 (4.2%)	1 (4.2%)
Slow Rise to Partial Goal n (%)	9 (34.6%)	11 (42.3%)	3 (11.5%)	3 (11.5%)
Steady Rise to Near Goal n (%)	4 (11.4%)	11 (31.4%)	12 (34.3%)	8 (22.9%)
^a $\chi^2(6) = 21.86, p < .001$ ^b $\chi^2(6) = 21.29, p = .001$				

3.4.4 Predictors of Adherence Trajectory Group Membership

The following 8 out of 10 possible predictors were included in both multivariable multinomial logistic regression analyses for lower extremity exercise and fitness walking adherence based on the bivariate screening criteria of $p=0.20$: age, BMI, duration of HBP, functional status, pain, exercise self-efficacy, outcome expectancy, and tailoring group membership (refer to Table 8).

Separate multivariable multinomial logistic regression analyses were performed to ascertain the effects of included measures on the likelihood of participants' membership in the high adherence group for 1) lower extremity exercise and 2) fitness walking. The “steady rise to goal” and “quick rise to goal” tailoring groups and the “Gradual Decline” and “Steady Decline” adherence groups were combined in the fitness walking adherence analysis due to a combination of small group membership and lack of clinical relevance.

The assumption of no multi-collinearity among independent variables was confirmed by variance inflation factors (VIF) of less than 2 for all measures. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell (Box & Tidwell, 1962) procedure and a Bonferroni correction was applied using all terms in each model (Tabachnick & Fidell, 2012). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable for both lower extremity exercise and fitness walking. All studentized residuals were less than 3 for fitness walking adherence; however, there were 3 studentized residuals with a standard error greater than 3 for lower extremity exercise adherence. The outcomes of the analyses performed with and without the three cases were similar; therefore, all cases were included the final analysis.

3.4.4.1 Lower Extremity Exercise Adherence

The final multivariable multinomial logistic regression model of lower extremity exercise adherence included self-efficacy, outcome expectancy, tailoring, and age. All other variables were excluded in the manual backward stepwise process described in the methods section. The model was statistically significant, $\chi^2(10)= 29.50$, $p= 0.001$, Nagelkerke R^2 0.34. This finding suggests that the added variables statistically significantly improved the model compared to the intercept alone.

Table 8. Group Differences Bivariate Screening Analysis

	Lower Extremity Exercise Adherence	Fitness Walking Adherence
Potential Predictor Variables		
Age	$F(2,82)=6.32, p=0.003^a$	$F(3,81) 0.55, p=0.65$
BMI	$F(2,82)=0.54, p=0.58$	$F(3,81) 2.12, p=0.11^a$
Duration of OAK	$F(2,82)=0.22, p=0.81$	$F(3,81) 0.22, p=0.88$
Duration of HBP	$F(2,82)=1.89, p=0.16^a$	$F(3,81) 0.69, p=0.56$
Functional Status	$F(2,82)=2.26, p=0.11^a$	$F(3,81)1.77, p=0.16^a$
Pain	$F(2,82)=0.24, p=0.79$	$F(3,81) 1.37, p=0.26^a$
Number of Comorbidities	$F(2,82)=0.46, p=0.63$	$F(3,81) 1.21, p=0.31$
Exercise Self-efficacy	$F(2,82)=0.47, p=0.63$	$F(3,81) 1.75, p=0.16^a$
Outcome Expectancy	$F(2,82)=1.47, p=0.24^a$	$F(3,81) 0.26, p=0.86$
Tailoring	$\chi^2(4)=13.92, p<.007^a$	$\chi^2(9)=13.42, p=.12^a$
^a Initially included in the full multivariate multinomial model BMI: Body Mass Index HBP: Hypertension OAK: Osteoarthritis of the Knee SD: Standard Deviation		

The classification accuracy rate was 60.0%. Of the 4 predictor variables included in the multivariable model, only two were statistically significant: age and tailoring group membership (as shown in Table 9). Younger participants had 1.16 (95% CI 1.04 - 1.29) times the odds of belonging to the “quick decline” trajectory group for lower extremity exercise adherence, Wald

$c^2(1)= 6.92$, $p<0.001$, and 1.09 (95% CI 1.01 – 1.17) times more likely of belonging to “steady decline” trajectory group, Wald $c^2(1)= 6.51$, $p= 0.01$. In addition, participants in the “slight rise/remained highly tailored” trajectory group were 16.89 (95% CI 2.82 - 100.9) times more likely to be assigned to the “quick decline” trajectory group for lower extremity exercise adherence, Wald $c^2(1)= 9.59$, $p=0.002$. Also, participants in the “slight rise/remained highly tailored” were 3.74 (95% CI 0.97 - 14.46) times more likely to belong to the “steady decline” adherence group for lower extremity exercise, Wald $c^2(1)= 3.65$, $p=0.05$, and the “slow rise to partial goal” trajectory groups members were 3.59 (95% CI 1.02 - 12.69) times more likely to belong to the “steady decline” adherence group for lower extremity exercise, Wald $c^2(1)= 3.96$, $p= 0.04$.

Table 9. Multivariate Multinomial Logistic Regression of Lower Extremity Adherence Groups

Predictors	Lower Extremity Adherence Trajectory Groups ^a					
	Quick Decline			Steady Decline		
	p	OR	95% CI	p	OR	95% CI
Age (years)	<.001	1.16	1.04 - 1.29	0.01	1.09	1.01 - 1.17
Exercise Self-efficacy ^b	0.92	0.97	0.91 - 1.08	0.58	0.98	0.92 - 1.04
Outcome Expectancy ^b	0.08	1.38	0.96 - 1.99	0.43	1.19	0.84 - 1.48
Tailoring Trajectory ^c						
Slight Rise/Remained Highly Tailored	0.002	16.89	2.82 - 100.9	0.05	3.74	0.97 - 14.46
Slow Rise to Partial Goal	0.18	3.66	0.54 - 24.68	0.04	3.59	1.02 - 12.69
^a Reference group is Consistently Adherent ^b Square root transformation applied ^c Reference tailoring group is Quick Goal Achievers OR: odds ratio (adjusted) CI: confidence interval p<.05 (significant predictors are in bold)						

3.4.4.2 Fitness Walking Adherence

The final multinomial logistic regression model for fitness walking adherence included only tailoring and was not statistically significant, $\chi^2(21) = 34.62, p < .031$. This finding suggests that the added variables did not statistically significantly improve the model compared to the intercept alone. Only “slight rise/remained highly tailored” trajectory group was statistically significant, Wald $\chi^2(1) = 3.96, p = 0.04$ (as shown in Table 10). Participants in the “slight rise/remained highly tailored” trajectory group were nearly 6 times more likely to belong to the “gradual decline” adherence group for fitness walking (OR = 5.65, 95% CI 1.03 - 31.07).

Table 10. Multivariate Multinomial Logistic Regression of Fitness Walking Adherence Groups

Predictors	Fitness Walking Adherence Trajectory Groups ^a					
	Gradual Decline			Steady Decline		
	p	OR	95% CI	p	OR	95% CI
Tailoring Trajectory ^b						
Slight Rise/ Remained Highly Tailored	0.04	5.65	1.03 – 31.07	.93	0.94	0.25 – 3.58
Slow Rise to Partial Goal	0.31	2.91	0.37 – 23.20	.91	1.09	0.25 – 4.86

^a Reference group is consolidated Steady Increase/Consistently Adherent
^b Reference tailoring group is consolidated Steady Rise/Quick Goal Achievers
OR: odds ratio (adjusted)
CI: confidence interval
p < .05 (significant predictors are in bold)

3.5 DISCUSSION

Group-based trajectory modeling revealed distinct temporal patterns in tailoring and exercise adherence that have not been previously explored in exercise interventions designed specifically for older adults with OAK and HBP. Differences were observed between lower extremity

exercise and fitness walking (for both tailoring and adherence) in terms of number of groups, trajectory shape, and proportion of people who met the ideal exercise goals. Two fitness walking groups met the ideal goals completely (one gradually and one quickly), while no participants met the lower extremity exercise goals completely with 41.2% meeting 65% of the goal and another 30.6% meeting 50% of goal by the end of the intervention period. More participants' adherence declined for lower extremity exercise (18.8% quickly and 43.5% steadily) than with fitness walking where only 11.8% declined gradually and 17.6% declined steadily. A significant moderate bivariate association between lower extremity exercise tailoring and for lower extremity exercise adherence was observed, but not for fitness walking. Also, age was significant in the bivariate analysis, as well as being a significant predictor in the multinomial multivariable regression analysis, where younger participants had increased odds of being the least adherent to lower extremity exercise, but not for fitness walking adherence. These findings suggest that the least physically able older adults were less likely to adhere to lower extremity exercise interventions even when the regimen was tailored to meet their personal ability and limitations.

Despite the aforementioned differences, there were also a number of commonalities. First, multinomial logistic regression analysis for both lower extremity exercise and fitness walking indicated that participants whose adherence declined over the course of the intervention had increased odds of exercise goals remaining highly tailored. Second, neither baseline self-efficacy nor outcome expectancy, or the other physiological baseline measures, were statistically significant predictors of either the lower extremity exercise or fitness walking adherence models.

While the STAR intervention addressed many common physical and behavioral barriers to exercise throughout the intervention period, tailoring was principally informed by current physical ability and adherence to previous weeks' goal. This approach may improve adherence

for older adults who can progress towards an ideal goal, but may not be effective for individuals who do not (or cannot) progress towards an ideal goal. Stratification of groups based upon extent of intervention tailoring and pace of progression towards an ideal goal may be an effective way to target those least likely to remain adherent. Alternative methods of adherence support should be explored to effectively meet the needs of individuals who remain highly tailored and do not progress towards the ideal exercise goal.

3.5.1 Limitations

Limitations of this study are primarily due to the fact that it is a secondary analysis and thus relies on previously collected STAR Study data. The limited sample size impacted the multivariable analysis as evidenced by the large confidence intervals. A larger sample would improve sensitivity and specificity of the analysis. Adherence was measured by self-report only. Including an objective activity measure may provide a different result. The trajectories only represent the intervention period and do not address the likely declines afterward. In addition, potential association of trends in behavioral measures that may further explain the relationship between individual tailoring and adherence (such as self-efficacy and outcome expectancy) could not be explored via trajectory modeling because they were only measured at baseline, 6, and 12 months in the parent study.

3.5.2 Conclusions

The extent of exercise tailoring and pace towards reaching the ideal goal are significant factors in sustained adherence. Future work should build on the methodology of this study to include a

larger sample size and greater measurement frequency of empirically supported measures related specifically to physical symptoms and behavioral factors. Refining methods to identify patterns of characteristics within the target population in relationship to trends in extent of tailoring and adherence may ultimately contribute to intervention refinement by helping to identify those individuals who are least likely to experience sustained adherence and designing strategies and tools to support their unique and dynamic needs as they change over time.

4.0 MIXED-METHOD MANUSCRIPT: THE ROLE OF MOBILE HEALTH IN INDIVIDUALLY TAILORED SELF-MANAGEMENT INTERVENTIONS TO PROMOTE ADHERENCE TO AN EXERCISE PROGRAM FOR OLDER ADULTS WITH OSTEOARTHRITIS OF THE KNEE AND HYPERTENSION

4.1 ABSTRACT

Background: Little is known about how individually tailored self-management interventions (ITSMIs) and mobile health technology (mHealth) might work together to promote adoption and maintenance of routine exercise among people living with chronic conditions that impede physical functioning.

Objectives: To generate a contextually rich theory driven assessment of the ways in which the adoption and maintenance of an exercise routine were supported within a mHealth-ITSMI designed specifically for older adults with osteoarthritis of the knee and hypertension.

Methods: Quantitative and qualitative data from the intervention arm of the Staying Active with Arthritis (STAR) trial (R01 NR010904, PI Schlenk) were utilized. Latent trajectories of tailoring and adherence of lower extremity exercises (LEE) and fitness walking (FW) over the 24-week intervention period were identified using group based trajectory modeling. Purposive sampling was performed based on adherence and tailoring trajectory group membership in addition to empirically supported participant characteristics. Actor Network Theory was used to scaffold the

qualitative descriptive analysis of transcribed audio-recorded participant-interventionist interactions to examine the role the eDiary played in intervention tailoring and exercise adherence.

Results: Participants were purposively sampled based upon their membership in one of the identified three distinct LEE adherence and LEE tailoring trajectory groups in combination with one of the four distinct FW adherence and tailoring trajectory groups. The eDiary played a role in the participant-interventionist relationship, decision-making, and motivation. Motivation to adopt and maintain routine exercise was explained by concepts from social cognitive theory, self-determination theory, and goal-setting theory. The degree of individual fit between how a goal was defined and the way it was measured via the eDiary impacted participants' overall sense of accomplishment, thereby directly impacting their motivation to initiate and sustain an exercise routine.

Conclusions: mHealth supported ITSMIs could further encourage the initiation and maintenance of an exercise routine by offering more individually tailored ways of defining goals and measuring achievement. Further evaluation of mHealth-ITSMIs should include identifying the ideal frequency of goal re-assessments and how mHealth functionality could be used to automate some or all the tailoring process including goal setting and goal progress. Further exploration of mHealth functionality that could help people to form a daily routine, assist with contingency planning, and enhance both extrinsic and intrinsic motivation is warranted.

4.2 INTRODUCTION

Adopting a regular exercise routine is necessary to achieve and maintain an optimal state of wellness (Nelson et al., 2007). However, this task is especially difficult for people managing chronic conditions that impede physical function. Individually tailored self-management interventions (ITSMIs) and mobile health technology (mHealth) are two promising and potentially complementary approaches to improve patients' long-term adherence to an exercise routine (Friedberg et al., 2015; D. Jones et al., 2016; van der Weegen et al., 2015).

Individually tailored self-management interventions (ITSMIs) are defined as 'any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment' (Kreuter et al., 1999)(pg. 276). ITSMIs are a promising approach for improving adherence because they incorporate selected patient characteristics (e.g., beliefs, preferences, physical and/or cognitive limitations, etc.) into a plan of care with the aim of increasing knowledge, ability and motivation, while addressing both practical and psychological barriers to adherence (Hawkins et al., 2008).

Because chronic conditions are longitudinal as opposed to episodic, ITSMIs for chronic conditions are distinct from other ITSMIs in that there is more than one assessment phase. Information gathered at each assessment is incorporated into an individual's plan of care and is intended to be re-assessed and re-tailored at multiple time points with the goal of adopting and maintaining condition specific motivational and self-regulatory behaviors over the course of one's lifetime (Bandura, 2005). The process of re-assessment and re-tailoring requires setting goals and monitoring progress towards those goals with repeated measures related to the outcome of interest (Kruglanski et al., 2002).

The ubiquity of mobile phones in today's society makes them an especially well-suited method to capture individual level repeated measures related to the outcome of interest while simultaneously providing a convenient vehicle for interventions targeting motivational and self-regulatory health behavior change (Free et al., 2013). The high and ever increasing adoption of mobile phones among older adults and their growing interest in utilizing mHealth applications underscores the potential to reach this traditionally vulnerable population who are more likely to experience poorly managed chronic illness (Kampmeijer *et al.*, 2016; Kuerbis *et al.*, 2017). However, the current lack in understanding of how mHealth functionality might support ongoing intervention tailoring and motivation of exercise adherence reduces the ability to optimize the design and evaluation of mHealth-ITSMIs for chronic conditions (Michie et al., 2017).

This secondary analysis includes quantitative and qualitative data from a randomized controlled trial of Staying Active with Arthritis (STAR), a home-based ITSMI designed specifically for older adults with hypertension and osteoarthritis of the knee (R01 NR010904, PI Schlenk). The STAR Study data are ideal to examine the relationship between ITSMIs, mHealth and exercise adherence for the following reasons: 1) tailoring of the intervention was based on an ideal exercise goal, making it possible to measure the unique extent of intervention tailoring each participant received; 2) participants used a smartphone with a custom eDiary application to self-monitor and report exercise adherence over the course of the intervention; 3) the tailored approach was based on social cognitive theory targeting self-efficacy and outcome expectancy, two modifiable behavioral variables that add explanatory power in regard to the relationship between tailoring and adherence; 4) audio-recordings of all participant-interventionist interactions were available, allowing for qualitative analysis of conversations referencing eDiary use.

The purpose of this mixed-method study was to generate a contextually rich theory-driven assessment of adherence promotion via an mHealth-ITSMI targeting exercise and designed specifically for older adults with hypertension and osteoarthritis of the knee. The primary research questions of this mixed-methods study were: 1) What is the relationship between the extent of tailoring and patterns of adherence over the STAR study the 24-week intervention period? 2) What role might mHealth technology play in the process of tailoring and supporting adherence?

Actor Network Theory (ANT) guided this study in the following ways: 1) to scaffold qualitative analysis of audio-recorded participant-interventionist interactions, thereby focusing the thematic coding on technological functionality (i.e., the eDiary) playing an active role in intervention tailoring and adherence, and 2) to inform the inclusion criteria and structure of the final integrated conceptual model which synthesized the quantitative findings of adherence and tailoring trajectory groups with the qualitative findings from the audio-recordings of the participant-interventionist interactions.

ANT challenges assumptions of separation between material (e.g., technology) and human (e.g., social interaction) worlds (Hanseth et al., 2004). Instead of treating a mobile app as a material object that simply holds information, it is viewed as an active participant in a dynamic social network of actors (e.g., patient, clinician, mHealth app). The primary tenet of ANT suggests that recognizing and addressing the interrelationship between actors (human and non-human) and their roles within a social network can help to optimize the design of materials (e.g., eDiary), improve execution of actions (e.g., tailoring) and positively impact targeted outcomes (e.g., sustained adherence) (Cresswell et al., 2010). Thus, a rich multi-dimensional description of

mHealth use within the context of tailoring and promoting adherence is made possible by fusing the focus on material (the eDiary) and human worlds (participant-interventionist interactions).

4.3 METHODS

The following sections first describe the parent study. The measures section includes only a description of measures used in this secondary analysis. Access to the data for the purposes of secondary analysis was covered under the STAR study IRB protocol approved by the University of Pittsburgh.

4.3.1 Description of the Parent Study

The STAR study (R01-NR010904, PI E. Schlenk) is the first clinical trial to investigate a self-efficacy model to promote exercise adherence in older adults with the comorbid conditions of osteoarthritis of the knee and hypertension. Self-efficacy theory hypothesizes that self-efficacy and outcome expectancy are inter-related concepts. Self-efficacy is defined as “the personal belief in one's own ability to accomplish a certain task or succeed in a specific situation” and outcome-expectancy is defined as “a person's estimate that a given behavior will lead to certain outcomes” (Bandura, 1977, p.193). Stronger self-efficacy and positive outcome expectancy purportedly increase targeted behavior whereas lower self-efficacy and negative outcome expectancy decrease targeted behavior (Bandura, 1977).

Mastery, also referred to as performance achievement, was a primary self-efficacy strategy employed in the STAR study. It was operationalized by gradually increasing leg

exercise and fitness walking goals towards an ideal goal over the 24-week intervention period. The intervention ideal goal was consistent with the American College of Sports Medicine (ACSM) (Nelson et al., 2007), the American Geriatrics Society (AGS) (American Geriatrics Society, 2001), and the American Heart Association (AHA) (Williams et al., 2007). For the first six sessions, each participant met face-to-face with a physical therapist (PT) interventionist on a weekly basis in order to gain confidence in performing the new exercise routine (refer to Figure 6). The remaining sessions were nine biweekly telephone-counseling sessions lead by a registered nurse (RN) interventionist. Thus, the 24-week intervention period consisted of 15 interactive sessions with an interventionist.

The STAR intervention began with an initial physical function assessment performed by the PT-interventionist to guide development of an individually tailored regimen for minutes of fitness walking (FW) and the number of sets, repetitions, and amount of ankle weight for lower extremity exercises (LEE). All participants received a smartphone with a custom smartphone eDiary application to manually record daily progress toward LEE and FW goals as well as to record other physical activity performed and pedometer step-count. Data collected via the eDiary were uploaded to a secure server and reviewed during the sessions with the PT and RN interventionists. The general rule was that goals were advanced if 75% adherence to the previous goal was achieved. If the goal was not achieved the interventionist and participant discussed the specific problems being encountered and decided whether to keep the goal the same or lower it.

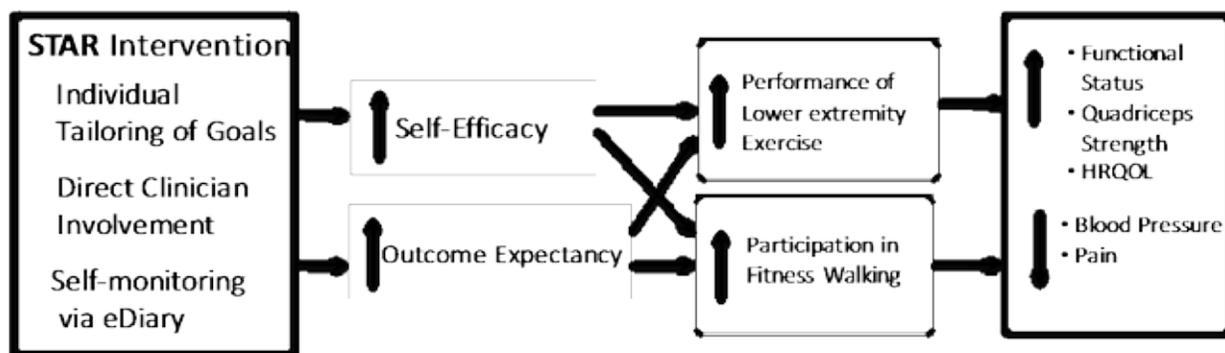


Figure 6. STAR Study Intervention Theoretical Model

4.3.1.1 Mixed-method Study Design

A mixed-method design was chosen for the purpose of complementarity (Sandelowski et al., 2006), meaning findings from the quantitative inquiry and qualitative inquiry were integrated in a complementary fashion to produce an integrated and more complete understanding of the phenomena of interest. The aims and methods for each of the inquiries are presented sequentially to demonstrate how findings from each stage of inquiry were used to inform the subsequent stage and ultimately the integration of findings.

4.3.1.2 Sample

A convenience sample was recruited from existing registries and public domain mailing lists for the parent study. In addition to the parent study's eligibility criteria, the participants in this study were randomized to the intervention arm, followed the intervention protocol (i.e., regular weekly and bi-weekly meetings), and had sufficient data to be able to apply the longitudinal statistical analysis methods. Eighty-five of the 91 STAR Study intervention arm participants met the additional criteria for this secondary analysis.

4.3.2 Measures

Refer to section 4.3.3 for a complete detail of all measures.

4.3.3 Analysis

Refer to section 4.3.1.4 for a full description of the quantitative analyses.

4.3.3.1 Quantitative Analysis Plan for Aim 1

Aim1: Identify latent trajectories of lower extremity exercises, fitness walking adherence and tailoring over weeks 3-24 of the STAR study intervention period. Group based trajectory modeling (GBTM) was the principal analyses technique used to identify temporal patterns of tailoring and adherence of leg exercises and fitness walking.

4.3.3.2 Quantitative Analysis Plan for Aim 2

Aim2: Identify associations between adherence and tailoring trajectory group membership. Upon identification of the adherence and tailoring trajectory groups for both LEE and FW, associations between adherence and tailoring trajectory groups were determined using chi-square test of independence for LEE and Fischer's Exact test for FW (due to small cell counts). Additional associations between tailoring of LEE and tailoring of FW, as well as adherence of LEE and adherence to FW were performed using Fischer's Exact tests.

4.3.3.3 Qualitative Analysis Plan for Aim 3

Aim 3: Compare and contrast when, why, and how interventionists and participants who differed in extent of tailoring and adherence trajectory group membership used the eDiary in the tailoring process and its impact adherence. Purposive sampling was applied in a variety of ways. First, a representative sample of participants was chosen primarily based upon LEE and FW adherence and tailoring trajectory group membership. After identifying participants based upon a combination of adherence and tailoring trajectory group membership, other pertinent participant characteristics were considered to assure the qualitative sample characteristics resembled those of the full intervention sample as much as possible. Second, four participant-interventionist interactions per participant spread out across the 24-week intervention period were selected (refer to Table 11); session three, the first session when participation in both fitness walking and knee exercise began; session six, the final face-to-face session with the physical therapist interventionist; session nine, the third session when the RN-interventionist covered the topic of setbacks from situational factors; session thirteen, where participants explored personal challenges and persuasive things they may be able to do or say to themselves to motivate themselves to perform physical activity.

Table 11. STAR Study Participant Schedule with Purposively Sampled Sessions in Bold.

Session	Activities & Topics Covered
1	BP check. Education on OA of the knee and <i>HBP</i> . PT evaluation. E-diary.
2	BP check. Review e-diary. Goal setting. DVD. Diagrams and demo of lower extremity exercise. Joint performance.
3	BP check. Review e-diary. Goal setting. Demo fitness walking. Medication side effects. Joint performance.
4	BP check. Review e-diary. Goal setting. Pain management. Joint performance.
5	BP check. Review e-diary. Goal setting. Use of heat and cold. Joint performance.
6	BP check. Review e-diary. Goal setting. Normal body signals vs. warning signs. Joint performance.
7	Review e-diary. Goal setting. Scheduling physical activity.
8	Review e-diary. Goal setting. Unpleasant sensations with exercise.
9	Review e-diary. Goal setting. Setbacks from situational factors.
10	Review e-diary. Goal setting. Avoiding risks of exercise.
11	Review e-diary. Goal setting. Support from others for physical activity changes
12	Review e-diary. Goal setting. Motivational and persistence techniques.
13	Review e-diary. Goal setting. Self-persuasion.
14	Review e-diary. Goal setting. Generalizing to other physical activities.
15	Review e-diary. Goal setting. Review and closure.

Third, selected time points of the audio-recordings included the beginning and end of each session when the eDiary was most often referred to and goal setting took place. Three additional recordings per person were reviewed to ensure data saturation was reached.

With ANT as the lens, qualitative description was used (Sandelowski, 2000) to systematically expose content related to the interplay between all the actors (human and non-human) within the context of individual tailoring to promote exercise adherence. The analysis of qualitative data was initiated by a lead coder who used open coding and thick description to identify and describe instances in which the eDiary was referenced in the discussions of self-reported eDiary adherence data and tailoring of subsequent goals. All audio-recorded qualitative

data was transcribed verbatim and transferred from a word processing program to Atlas.ti © (version 7.5 Scientific Software Development GmbH) to organize and manage qualitative data analysis for aim 3.

4.3.3.4 Synthesis Plan for Aim 4

Aim 4: Integrate findings from qualitative and quantitative aims to generate a contextually rich theory driven assessment of the relationships between tailoring and adherence and the role mobile technology played in the process. Conceptual triangulation (Sandelowski et al., 2006) was used to integrate quantitative results from aim 1 and 2 with qualitative findings from aim 3. First, data was analyzed within method in order to identify pertinent results and investigate their credibility (e.g., threats to rigor and strength of support for findings) (R. L. Foster, 1997). Additionally, the strength of support for findings in the literature, both empirical and theoretical, as well as within the study itself, was reflexively investigated. The process of identifying pertinent findings and assessing their credibility culminated in an integrated conceptual model.

Trustworthiness was achieved in the pursuit of the qualitative aims by incorporating a second coder in the review of initial codes and holding discussions among the research team members regarding interpretation and conceptualization throughout the course of the study's analysis phase (Erlandson, 1993).

4.4 RESULTS

4.4.1 Quantitative

4.4.1.1 Sample Characteristics

Refer to section 4.4.1 and Table 3 for a complete overview of the full sample.

4.4.1.2 Quantitative Results

Refer to sections 3.4.2 through 3.4.4.2 for results to quantitative aims.

4.4.2 Qualitative

4.4.2.1 Sample Characteristics

Six of the 12 participants were members of declining adherence groups for both LEE and FW, 3 were members of one declining and one increasing or consistently adherent trajectory group, and 2 were members of consistently adherent trajectory groups for both LEE and FW. Ten different combinations of goal tailoring trajectories were represented. Refer to Table 13 for a complete list of all 12 participants' individual trajectory group memberships and select sample characteristics.

The average age of the qualitative purposive sample was 65.75 (SD=11.72) years old. Eight were female (66.7%), and 75% were white with a similar representation of educational attainment and income levels as the full intervention sample. The average duration of OAK was 9.92 (SD=8.83) years and the average duration of HBP was 17.83 (SD=8.58) years. BMI was slightly higher than the full sample (BMI mean=36.82 kg/m², SD=6.62) with number of multiple comorbidities also slightly higher (mean number= 9.58, SD=3.55). The average functional status

was nearly the same at 10.13 (SD=2.63). The average pain score was a little more than two points higher at 7.83 (SD=3.34). Average exercise self-efficacy score was slightly higher at 929.17 (SD=252.68) and the average outcome-expectancy score was nearly the same at 67.00 (SD=20.68). Refer to Table 12 for a complete description of sample characteristics in comparison to the full sample.

4.4.2.2 Qualitative Results

The eDiary played a central role in the ITSMI to self-report exercise adherence. Thus, much attention was given to participants' understanding of the proper way to input data. Participants' issues and questions related to navigating the eDiary were addressed in the first six weeks of face-to-face meetings with the PT-interventionist. No participants experienced major difficulties using the eDiary. The following qualitative description of the ways in which the eDiary played a role in goal tailoring and adherence are discussed within three overarching categories: relationship dynamics, decision-making, and behavior change. Concepts from social cognitive theory, self-determination theory, and goal-setting theory were used to frame the findings.

Relationship Dynamics

Each participant-interventionist session began with a review of the self-reported adherence data supplied by the eDiary. The interventionist repeated out-loud the details of what had been accomplished on each day and congratulated participants who met their individual goals for the week(s). If the participant did not meet the goals, the eDiary data was referred to as a guide to discuss possible patterns of non-adherence (e.g., which days were missed, how many days in a row, etc.). Numerous participants made statements like, "Knowing that you're going to look at this [eDiary] makes me do it". This alludes to the act of self-reporting adherence via the eDiary as

Table 12. Qualitative Sample Characteristics

N=12	Adherence		Tailoring		Exercise Self-Efficacy (range 0-1200)	Outcome expectancy (range 0-100)	BMI	Pain (range 0-20)	Physical Function (score 3.5-15)	Comorbidities (range 0-47)	Age (yrs)	Sex
	Leg Exercise	Fitness Walking	Leg Exercise	Fitness Walking								
1	Quick Decline	Gradual Decline	Slow Rise to Partial Goal	Steady Rise Goal Achievers	640.00	38.00	48.00	9.00	9.0	15.00	57	F
2	Quick Decline	Gradual Decline	Remained Highly Tailored	Quick Goal Achievers	1080.00	85.00	36.56	12.00	11.0	10.00	69	F
3	Quick Decline	Steady Decline	Slow Rise to Partial Goal	Quick Goal Achievers	960.00	67.00	42.09	3.00	11.0	10.00	54	F
4	Steady Decline	Gradual Decline	Steady Rise to Near Goal	Steady Rise Goal Achievers	500.00	51.00	46.07	9.50	10.0	9.00	68	M
5	Steady Decline	Steady Decline	Slow Rise to Partial Goal	Steady Rise Goal Achievers	960.00	63.00	28.73	3.00	10.0	4.00	53	F
6	Steady Decline	Steady Decline	Slow Rise to Partial Goal	Remained Highly Tailored	990.00	75.00	33.00	9.00	12.0	10.00	54	F
7	Steady Decline	Steady Increase	Remained Highly Tailored	Steady Rise to Partial Goal	1200.00	77.00	35.81	8.00	13.0	12.00	57	M
8	Steady Decline	Consistently Adherent	Slow Rise to Partial Goal	Steady Rise Goal Achievers	960.00	72.00	29.08	7.50	12.0	12.00	84	F
9	Consistently Adherent	Steady Decline	Remained Highly Tailored	Remained Highly Tailored	500.00	23.00	35.36	12.00	3.5	14.00	82	M
10	Consistently Adherent	Steady Increase	Steady Rise to Near Goal	Quick Goal Achievers	1200.00	97.00	27.67	8.00	13.0	4.00	81	M
11	Consistently Adherent	Consistently Adherent	Steady Rise to Near Goal	Remained Highly Tailored	1200.00	77.00	39.75	2.50	8.0	8.00	59	F
12	Consistently Adherent	Consistently Adherent	Remained Highly Tailored	Steady Rise Goal Achievers	960.00	79.00	39.68	10.50	9.0	7.00	71	F

Table 13. Participant Characteristics

Participants Characteristics	Total Intervention Group n= 85	Qualitative Sample n= 12
Age (years) Mean (SD)	64.81 (8.36)	65.75 (11.72)
Gender (Female) n (%)	64 (75.3%)	8 (66.7%)
Race (White) n (%)	63 (74.1%)	9 (75%)
Education n (%)		
High school degree/GED	17 (20.0%)	4 (33.3%)
Vocational/Associates	18 (21.2%)	0 (0%)
Four-year College	21 (24.7%)	4 (33.3%)
Graduate Education	29 (34.1%)	4 (33.3%)
Income n (%)		
0-\$29,999	19 (22.4%)	3 (25%)
\$30,000-59,999	23 (27.1%)	4 (33.3%)
\$60,000-99,999	15 (17.6%)	3 (25%)
\$100,000-over	15 (17.6%)	1 (8.3%)
Refused	13 (15.3%)	1 (8.3%)
Duration of OAK (years) Mean (SD)	11.53 (9.92)	9.92 (8.83)
Duration of HBP (years) Mean (SD)	14.20 (9.59)	17.83 (8.58)
Number of Comorbidities Mean (SD)	8.41 (3.55)	9.58 (3.48)
Functional Status (score 3.5-13) Mean (SD)	10.95 (1.75)	10.13 (2.63)
Pain (score 0-20) Mean (SD)	5.64 (3.79)	7.83 (3.34)
Body Mass Index Mean (SD)	33.86 (6.21)	36.82 (6.62)
Exercise Self-Efficacy (score 0-1200) Mean (SD)	859.41 (339.68)	929.17 (252.68)
Exercise/Arthritis Outcome-Expectancy (score 0-100) Mean (SD)	68.36 (24.17)	67.00 (20.68)

a form of accountability to the PT/RN interventionist. Self-determination theory (SDT) describes this form of behavioral motivation as “extrinsic”, meaning the motivation arises from outside the individual and is driven by external rewards (praise in this case)(Fortier *et al.*, 2012).

Decision-Making

While the initial exercise goals were tailored based on the physical assessment performed with the PT-interventionist, each proceeding session included a time when the participant and interventionist would discuss whether to lower the goals, keep the goals the same, or increase the

goals. This goal re-assessment discussion included referencing patterns in eDiary adherence data by both the interventionist and the participant. The interventionists used the data as convincing evidence to increase the goals in the case that a participant had consistently met the goals.

In cases where the goals were not met, and it was determined that there was no major issue impeding adherence, the discussion turned to identifying strategies for fitting exercise into a person's daily routine. In instances where little to none of the goal had been met, the decision to keep the goals the same or lower them was the impetus for deeper conversations about physical symptoms from a short-term illness, increased pain or other physical discomfort, or an unexpected life event (e.g., extra hours at work, sick family member, etc.) that prevented a person from reaching the goal. In these cases, it was often determined that lowering the goal would be most appropriate because it had been so long since he or she had exercised.

Even when goals were met, some participant chose to keep the goals the same. The most common reason for doing so was because the goals were still challenging or because the participant felt they couldn't commit any more time to exercise than they already were. This behavior is consistent with goal-setting theory; one is more motivated to strive towards a goal he or she believes they can meet (Kruglanski et al., 2002).

The data supplied by the eDiary was the central player in starting the goal-setting conversation and supplying evidence for the decision-making process, but ultimately the goal-setting decision was up to the participant. Formally placing the decision in the hands of the participant instead of the PT/RN interventionist naturally created a social environment that promoted participant autonomy. Within SDT, when individuals are more autonomously motivated (also referred to as 'being self-determined'), they are more likely to experience intrinsic motivation where behaviors (e.g., exercise) are performed for their own inherent

rewards, such as a sense of accomplishment from meeting a personally meaningful challenge (R. M. Ryan & Deci, 2000).

Behavior Change

Participants' experience utilizing the eDiary as part of adopting a new exercise routine took several forms. The most practical was following along with the eDiary data entry fields as part of the performance of the numerous lower extremity exercises. The eDiary input-fields served as a way for participants to learn the sequence of the complex leg exercise routine, thereby confirming competence in performance achievement (Kwasnicka *et al.*, 2016).

The most adherent participants used the eDiary as a way of recording their accomplishments (i.e., performance achievement), which intrinsically motivated them to continue to exercise and input the outcome in the eDiary (Richard *et al.*, 1997). Participants described inputting their accomplishments in the eDiary as "giving themselves credit" for the little bits of exercise they would fit in throughout the day such as parking farther away from a destination and walking the extra-long distance as quickly as possible or performing calf raises while waiting in line at the grocery store.

Interestingly, some participants who were only moderately adherent to LEE and FW, talked about becoming more motivated to adopt other forms of exercise and used the eDiary to input other exercise accomplishment such group exercise classes. Similarly, the most physically limited participants who felt they could not walk fast enough for it to be considered fitness walking focused instead on increasing step-count. In both cases participants steered the conversation with the PT/RN interventionist away from the formal LEE and FW goals and measures towards the eDiary data that showed what they had accomplished in terms of other exercise and step-count. Unfortunately, the perception of the eDiary as re-enforcing a sense of

accomplishment was not the same for everyone. Participants who had the hardest time initiating exercise were demotivated by having to report non-adherence and consequently avoided the eDiary because it re-enforced the feeling of failure.

According to social cognitive theory, the satisfaction one feels with performance achievement is a primary intrinsic motivator in the adoption and long-term maintenance of the behavior of interest (Bandura, 1989). For those participants who regularly adhered to the exercise goals, the eDiary acted a source of evidence that they were in fact achieving what is they set out to achieve. The more frequent and regular the act of achievement the more intrinsically motivated they were to continue. However, without an initial achievement to start the positive feedback loop, the eDiary only re-enforced the desire to abandon the goal entirely (Kluger & DeNisi, 1996).

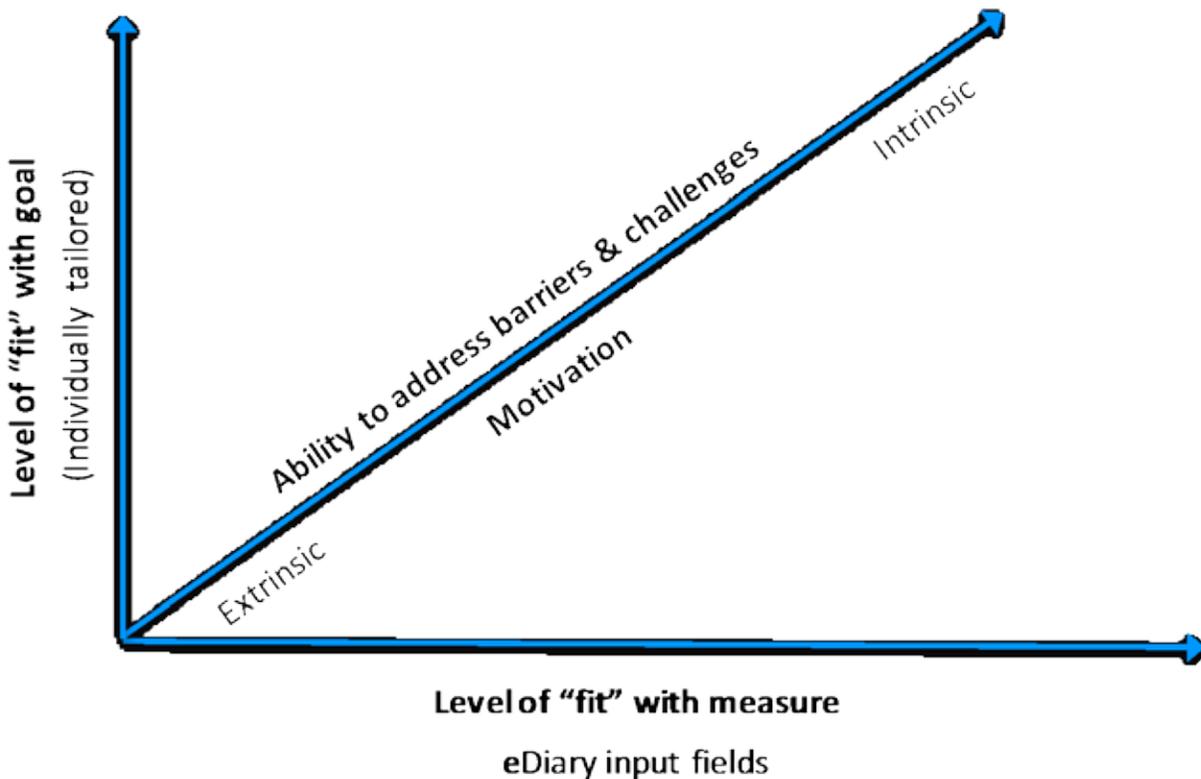


Figure 7. Integrated Conceptual Model

4.4.3 Synthesis of Quantitative and Qualitative Results

Four interrelated concepts accounted for most of the differences between participants who were the least and most adherent (refer to the integrated conceptual model in Figure 7). One, participants' personal level of "fit" with the goal. Participants who felt that the interventions goal (either LEE, FW, or both) was a good fit with his or her interests, lifestyle, and physical capabilities increased or remained adherent. This was true for participants whose goals remained highly tailored and those that met the ideal goal by the end of the intervention period. Participants who were more interested in other physical activity goals such as increasing step-count or attending more group exercise classes were less adherent to the intervention goals.

Two, participants' personal level of "fit" with the way the goal was measured. Participants who felt more of a sense of accomplishment by recording daily step-count than they did recording the number of minutes of FW were considered non-adherent based on formal study measure of adherence, yet they were still motivated to increase their physical activity. In contrast, participants who perceived filling in each and every data entry field as form of "giving themselves credit" developed a routine that perfectly matched the goals and measures of the intervention.

Three, degree of extrinsic and intrinsic motivation. Participants who had the hardest time getting started would often apologize to the interventionist when asked about non-adherence and would jokingly ask if they were in trouble, which points to participants' being fully external motivated and thus unable to sustain the effort needed to prioritize exercise among the daily many demands (Richard et al., 1997). Other participants who were at least moderately adherent over the course of the 24-weeks were both pleased with being congratulated for succeeded

(extrinsic motivation), and mentioned experiencing fewer symptoms, feeling more stable, or walking faster; these statements are signs of intrinsic motivation (Schwarzer et al., 2011).

Four, ability to address barriers and challenges (both expected and unexpected). Participants whose adherence gradually declined over the intervention period most often suffered from unexpected physical setbacks (e.g., a severe cold, deterioration in physical ability due to joint pain, etc.) and/or unexpected life events (e.g., extra hours at work, a family member in need of care, etc.) that got them off track on more than one occasion. Participants who had the hardest time getting started cited lack of ability to plan ahead, not having a routine, and being constantly interrupted at home as the major reasons why they couldn't fit exercise in despite how much they said they wanted to do it or believed they could physically perform the exercise itself. Alternatively, when interventionists asked the most consistently adherent participants about how they handled setbacks, they mentioned having contingency plans that worked within a relatively stable daily routine.

4.5 DISCUSSION

This mixed-methods study provides a theory-driven assessment of the dynamic interplay between individual tailoring of exercise goals, self-monitoring via a custom mHealth application and the impact on both extrinsic and intrinsic motivation within the context of an ITSMI designed specifically for older adults with osteoarthritis of the knee and hypertension. Ultimately, the extent to which an individual perceived the goal to be a good fit with his or her ability and interest in combination with the suitability of the measurement of progress towards the goal influenced a participant's overall sense of accomplishment and directly impacted their

motivation to adopt and maintain an exercise routine. External factors such as the degree to which a participant was able to plan ahead, make contingency plans, and maintain a daily routine were also important factors that impacted adherence.

Implications

Intervention. All the participants in the parent study were generally inactive, overweight, and experienced physical limitations, factors that make it difficult to initiate an exercise routine. Therefore, having an initial period of one-on-one sessions with the PT-interventionist was helpful for building self-efficacy in their ability to perform LEE and FW. Exercise self-efficacy was encouraged by tailoring exercise goals in terms of time of FW and sets, weights and reps of LEE. However, the STAR study did not tailor the types of exercises offered or the ways in which goal achievement was measured. Participants may be more committed to adopt and maintain an exercise routine if they are offered a wider range of types of exercises to choose from in addition to more ways to measure goal achievement. By offering a wider range of exercises and goal achievement measures, participants could choose the exercises they feel is most appropriate for their lifestyle and physical ability. Employing a trained professional, such as a physical therapist, to guide such choices could support confidence and motivation among participants with little previous exercise experience.

The STAR study was designed to address physical barriers to exercise by teaching participants how to manage common side-effects such as pain and stiffness and promoting strength and stamina with gradual increase in time of FW and weight and reps with LEE. The STAR study also addressed psychological barriers to exercise with the focus on building self-efficacy and outcome-expectancy through gradual goal increases. However, while practical barriers to exercise such as inability to maintain a routine or plan ahead were discussed, there

was no formal intervention to address such issues. Participants who had the most difficulty with adherence may have benefited from a direct focus on the skills needed to build and maintain a daily routine and form contingency plans.

The STAR study supported participants' extrinsic motivation in the form of accountability over the course of the 24-week intervention period with 6-weeks of face-to-face time with a PT-interventionist and 9 bi-weekly calls with an RN-interventionist. Some of the most adherent participants mentioned enjoying fitting more exercise in and noticing the positive physical benefits, thus demonstrating the intrinsic motivation needed to maintain exercise adherence (Richard et al., 1997). However, little attention was placed on systematically helping all participants to recognize and articulate intrinsic motivators. Supporting extrinsic motivation throughout the initial adoption phase via accountability is an important first step, additional attention to identify and encourage the unique intrinsic motivation of participants could support maintenance of an exercise routine beyond the adoption phase.

mHealth design. The primary purpose of the eDiary was to self-report exercise adherence. However, the eDiary played several other roles. The eDiary supported the ITSMI in practical ways such as helping to reinforce the sequence of the complex LEE routine and encouraged exercise adherence via extrinsic motivation in the form of accountability and intrinsic motivation by providing evidence of goal achievement.

Participants who benefited most from the intrinsic motivator of goal achievement perceived a good fit with the study's measure of goal achievement. This was most evident in the case of fitness walking where the formal adherence measure was minutes walked yet some participants preferred to measure walking in terms of step count and were therefore considered non-adherent. Including other measures of goal achievement that could be incorporated into

mHealth design such as distance or pace (distance/time) in addition to minutes and step count would offer participants more options and increase the odds of a good fit between the goal and the measure of goal achievement thus encouraging intrinsic motivation.

While functionality currently exists to track exercise achievement in terms of distance, pace, step count, etc. what is often lacking is a visual display of progress towards a predetermined goal. The addition of a visual display of personal goals and goal achievement could support both extrinsic motivation e.g., sharing progress with interventionist with the expectation of receiving feedback about their exercise performance and intrinsic motivation e.g., providing evidence of progress in achieving their personal exercise goals.

mHealth functionality could further support adoption and maintenance of routine exercise by complementing the focus on goal achievement with tools that address external factors that directly impact adherence such as tools that help participants plan ahead, make contingency plans, and maintain a daily routine. An approach that works with existing technology such as calendar applications in combination with geospatial intelligence are features that could help participants to build organizational and problem solving skills needed to maintain routine exercise while adjusting for changes in health status, physical ability, life events, and environmental considerations.

4.5.1 Limitations

This was a secondary analysis, and thus limited to data previously collected in the parent study. The small sample size may have impacted the sensitivity and specificity of the quantitative analyses and did not allow for more in-depth intra-individual analysis. Potential association of temporal trends in behavioral measures (such as self-efficacy and outcome expectancy) and

physical symptoms (such as pain and physical function) that may further explain the relationship between goal tailoring and adherence could not be explored via trajectory modeling because they were only measured at baseline, 6, and 12 months in the parent study. Adherence and tailoring trajectories represent the intervention period and do not address likely post-intervention decline in adherence. Adherence was measured by self-report only; including objective physical activity measures may have provided a different result. Also, the qualitative analysis included only transcriptions of recorded patient-interventionist interactions; the inclusion of follow-up semi-structured interviews would have been helpful for confirmation and further exploration, however the duration of time since the parent study participants actively used the eDiary was too long for accurate recall.

4.5.2 Conclusions

mHealth-ITSMIs for chronic conditions could further encourage the initiation and maintenance of routine health behaviors by offering a wider range of potential goals to choose from in combination with more options for measuring goal achievement via mHealth functionality. Further evaluation of mHealth-ITSMIs should include identifying the ideal frequency of goal reassessments and how mHealth functionality could be used to automate some or all the tailoring process including goal setting and goal progress. Further exploration of mHealth functionality that could help people to form a daily routine, assist with contingency planning, and enhance both extrinsic and intrinsic motivation is warranted.

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