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# Enhancing Parent-Child Communication and Promoting Physical Activity and Healthy Eating Through Mobile Technology: A Randomized Trial

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Enhancing Parent-Child Communication and Promoting Physical Activity and  
Healthy Eating Through Mobile Technology: A Randomized Trial

by

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Bachelor of Arts  
Stanford University, 2008

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Submitted in Partial Fulfillment of the Requirements

For the Degree of Doctor of Philosophy in

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University of South Carolina

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## Dedication

I dedicate this dissertation to my mom, Delores Schoffman, for her unwavering support, pure love, and unending confidence in my ability to persevere, even when I doubt myself the most. Thank you, mom, for all you have sacrificed to cheer me on through this long journey. I am so grateful for you. And, to my love, Bryan Jake-Schoffman, thank you for joining me during the process of my doctoral education and showing me how wonderful life can be with a partner. Here's to the rest of our lives together!

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## Abstract

### *Background*

Although rates of pediatric and adult obesity remain high in the U.S., finding scalable and engaging ways to disseminate obesity prevention and treatment for families has been challenging. The purpose of the Motivating Families with Interactive Technology (mFIT) study was to test the feasibility, acceptability, and effectiveness of two remotely-delivered family-based health promotion programs for improvements physical activity (PA), healthy eating, and parent-child communication and relationship quality.

### *Methods*

Parent-child (child age 9-12 years) dyads enrolled in a 12-week mobile intervention to increase physical activity and healthy eating, which included weekly email newsletters and the use of pedometers. Dyads were randomly assigned to one of two family-based programs, one of which utilized a mobile website and program materials that emphasized the importance of family interactions for health behavior changes. At baseline and 12 weeks, height and weight were measured by research staff, and participants completed web-based questionnaires about their dietary intake, family dynamics (e.g., parent-child communication), and experiences in the study.

## *Results*

Dyads (n=33) were randomized (parents: 43±6 years, 88% female, 70% white, BMI 31.1±8.3 kg/m<sup>2</sup>; children: 11±1 years, 64% female, 67% white, BMI 77.6±27.8 percentile) and 31 (93.9%) provided complete follow-up data. Overall, there were no significant between-group differences in PA or dietary outcomes, but families significantly increased their average daily steps and servings of fruit during the intervention (marginally significant decrease in sugar-sweetened beverages) and had excellent adherence to self-monitoring protocols. Family functioning indicators were all high at baseline and most did not change significantly over time; none of the family dynamics variables were significant predictors of changes in average daily steps. Almost all parents (97%) and children (86%) said that they would recommend the mFIT program to a friend.

## *Conclusions*

Dyads in the present study had high scores on family functioning variables at baseline, from both parent and child perspectives. Further research is needed to develop domain-specific measures of family dynamics, as well as to test family-based research with samples of families with more diverse baseline scores on family dynamics variables. Overall, the mFIT program showed excellent feasibility and acceptability as a low-cost, remotely delivered family intervention for physical activity and healthy eating promotion, and could serve as a dissemination model for similar public health interventions.

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## Chapter 1: Introduction

Recent reports estimate that 16.9% of children in the U.S. are obese and almost 30% of children are overweight or obese by age 5,<sup>1,2</sup> putting them at risk for health complications and future weight gain.<sup>3,4</sup> At present, few adults or children come close to reaching their recommended daily intake of fruits or vegetables<sup>5</sup> and physical activity (PA) is low among all Americans.<sup>6</sup> Among the goals of Healthy People 2020 are targets for increased PA as well as increased fruit and vegetable intake in all age groups.<sup>7,8</sup> Among the actions recommended by pediatric obesity experts are the promotion of PA and healthy eating (HE),<sup>9,10</sup> as well as including the whole family in treatment.<sup>11</sup> However, finding scalable and innovative ways to disseminate obesity treatment and prevention programs for children has been challenging.

Mobile applications (apps) are an engaging way to involve children in health behavior changes, capitalizing on the portability and affordability of delivering health information via mobile devices and the opportunity to use gaming to make health information entertaining.<sup>12,13</sup> While most children do not own their own mobile device (e.g., smartphone, tablet), children have increasing access to apps (e.g., through use of family tablets, their parent's smartphone, etc.).<sup>14,15</sup> Seventy two percent of parents with children ages 0 to 8 years old report that their child has used a mobile device for some type of media activity, including using apps.<sup>14</sup> Adults with children report that 30% of the apps on their

smartphones are for their children.<sup>15</sup> Smartphones and tablets also offer an opportunity to extend health interventions to traditionally underserved groups, including African Americans and Latinos, as mobile device ownership among these groups is growing faster than that of whites.<sup>14,16</sup>

Many health promotion apps are currently available. We completed the first systematic review<sup>17</sup> of mobile apps for the prevention and treatment of pediatric obesity (children/teens <18) through weight loss, PA, and HE to determine if expert-recommended strategies and behavioral targets were promoted.<sup>16</sup> Similar to other studies that examined the content of apps for adult weight loss<sup>18</sup> and smoking cessation,<sup>19</sup> we found the apps for children to be lacking in the use of theory or evidence-informed practices. Further, a pilot study by our team tested the effectiveness of the highest-scoring apps from the review as well four as PA monitoring devices (e.g., FitBit) for increasing the PA and HE of parent-child dyads; the results suggested that there are deficiencies in the HE apps and that no single PA device was significantly effective for the dyads. Taken together, the review of apps and pilot results demonstrated that additional levels of support and encouragement are needed to aid in behavior change for parent-child dyads; an enhanced intervention is presented here.

In addition to the promotion of PA and HE, mobile technologies can potentially encourage improved and increased family communication. Recently, researchers have explored the idea of encouraging bi-directional family communication,<sup>20</sup> as opposed to the traditional view of top-down communication (where the parent confers all information to the child). Further investigation into

the impact of mobile technologies on family communication is needed. Thus, there exists a need for more effective family interventions for obesity prevention as well as evidence-based interventions using mobile technologies. The present study built upon the previous work of the research team to deliver a mobile-based family intervention for the promotion of PA, HE and parent-child communication about health behaviors.

### *1.1 Present Study*

The aims of present study were to test the effectiveness of using commercially available apps and a PA monitoring device (Tech) compared to the apps and PA device plus a mobile website and theory-based family intervention that encourages increased parent-child communication about PA and HE and family behavior change (Tech+). The two programs were administered remotely via email, mobile apps, and a mobile website to parent-child dyads (child 9-12 years old) over a 3-month intervention period. Parent-child dyads were randomized to the two behavioral interventions: Tech (16 dyads) or Tech+ (17 dyads).

The study was guided by the Environmental Research framework for weight Gain prevention (EnRG),<sup>21</sup> Family Systems Theory,<sup>22</sup> Family Systems Theory framework related to youth health behaviors,<sup>23</sup> the model of bidirectional processes in parent-child relationships,<sup>24</sup> the model of social context in health behavior interventions,<sup>25</sup> Social Cognitive Theory,<sup>26</sup> and the Theory of Planned

Behavior.<sup>27</sup> Further details about the conceptual model are presented below in Section 2.6.

**\*Specific Aim 1:** Test the effectiveness of an evidence-based mobile intervention with enhanced parent/child communication (Tech+) versus commercially available products alone (Tech) for improvements in child's average minutes of moderate- to vigorous-intensity physical activity (MVPA) per day [*primary outcome*], changes in the parent's average minutes of MVPA per day, changes in self-monitored PA (average daily steps from pedometer), and improvements in dietary quality as measured by meeting HE targets (e.g., increased fruit and vegetable consumption) [*secondary outcomes*].

**Hypothesis1a:** *Improvements in both primary and secondary outcomes will be significantly greater in participants randomized to the Tech+ program relative to participants randomized to the Tech control program.*

**\*Specific Aim 2:** Examine the impacts of evidence-based family intervention on parent-child relationship quality and communication about PA and HE [*secondary outcomes*].

**Hypothesis2a:** *Improvements in parent-child relationship quality and communication will be significantly greater in participants randomized to the Tech+ program relative to participants randomized to the Tech control program.*

**Hypothesis2b:** *Increasing levels of utilization of the responsive design website (e.g., more frequent logging of steps, use of the goal and reward*

*systems) will be associated with greater frequency and quality of parent-child communication.*

## *1.2 Justification for the Research*

The present research adds to what is currently known about family-based health promotion by testing two low-cost remotely delivered interventions. The study provides evidence about the feasibility, acceptability, and effectiveness of: the recruitment strategies and materials, the study delivery method, the study-designed website functionality, the use of commercial apps as part of a larger program, and the content of the two family-based interventions. The present research attempts to address currently defined needs in health promotion using tools that have been designed and built by the research team with formative research.



## Chapter 2: Background and Significance

While obesity, physical inactivity, and unhealthy dietary intake are persistent problems in the U.S., the impact of few public health initiatives has been limited.<sup>28</sup> First, we outline the patterns of weight status, PA, and dietary eating in the U.S. Second, we describe some of the expert recommendations for tackling these health issues as well as past intervention strategies that have been tested. Third, we discuss the promising area of Family Systems-Based Research, and specifically examine how parent-child communication and relationship quality could be important factors in health promotion research. Fourth, we examine the use of mobile technology in health behavior interventions, including our pilot research with families.

### *2.1 Obesity, Physical Inactivity, and Unhealthy Eating in the U.S.*

Recent reports estimate that 16.9% of children in the U.S. are obese and almost 30% of children are overweight or obese by age 5,<sup>1,2</sup> putting them at risk for health complications and future weight gain.<sup>3,4</sup> Rates of obesity among adults in the U.S. continue to be alarmingly high at 34.9%, despite growing public awareness and willingness to support public interventions to help reverse the trend.<sup>29,30</sup> Obesity rates in South Carolina (S.C.) are among the highest in the U.S.; 31.6% of South Carolinians are classified as obese, and the state ranks 7<sup>th</sup> in most obese residents in the U.S.<sup>31</sup> Among the actions recommended by

pediatric obesity experts are the promotion of PA and HE,<sup>9,10</sup> as well including the whole family in treatment.<sup>11</sup> However, consumption of fruits and vegetables and levels of PA are low among children and adults, with few individuals meeting their recommended daily targets for either behavior.

Beyond its role in weight loss, the health benefits of PA are well known and supported by extensive observational and clinical trial evidence.<sup>32-35</sup> PA is included among the recommendations for behavioral strategies for the prevention and control of many chronic diseases, including diabetes, cardiovascular disease, and cancer.<sup>36-39</sup> In addition to the health benefits of PA, children who are physically active are more likely to be successful in their schoolwork and have less behavioral problems in school.<sup>40,41</sup> Few Americans currently reach the levels of PA recommended by national standards for a typical week.

Recommendations mandate that adults engage in a minimum of 150 minutes per week of moderate intensity PA or 75 minutes of vigorous PA and at least two days of strength training a week and children get a minimum of 60 minutes per day of moderate-intensity PA most days, with vigorous activity on at least 3 days per week.<sup>42</sup> However, self-report estimates say that 60% of adults<sup>43</sup> and 50% of children<sup>44</sup> meet these recommendations, while objective monitors estimate that less than 5% of adults and less than 8% of adolescent children meet these recommendations.<sup>6</sup> Healthy People 2020 calls for increased PA for all age groups in the U.S., and underscores the importance of focusing on increasing the activity of children.<sup>8</sup>

While girls of all ages tend to be less active than boys, there is a marked decline in PA for all children during the important transitional period of adolescence (ages 12-19 years).<sup>45</sup> Estimates of the longitudinal PA trends estimated from the Growing Up Today Study, a cohort of 12,812 boys and girls in the U.S., showed that PA tended to increase until early adolescence and they decline after age 13 for boys and girls.<sup>46</sup> Given these trends in PA declines, experts have recommended that interventions to increase PA should begin before this decline and the transition to adolescence (i.e., age 12 and below).<sup>46,47</sup> Additionally, research has shown that there have been some improvements in recent years in the PA levels of white children between the ages of 6 to 11 years but no corresponding improvement in Hispanic or black children of the same age, signaling the potential for a growing racial disparity in children's PA rates.<sup>45</sup> The different trends and influences on PA for different racial and ethnic groups points to the need for interventions that can be disseminated to a large section of the population, not limited to those groups traditionally represented in university-based research.

In addition to low PA levels, the average dietary intake for adults and children in the U.S. falls short on average of health standards and recommended daily servings of healthy foods (e.g., fruits and vegetables) and exceeds recommended daily servings of unhealthy foods (e.g., sugar-sweetened beverages and fast food).<sup>48,49</sup> S.C. and other regions of the southern U.S. are also behind the already low national average on some dietary indicators, such as percentage of adults who report that they consume fruits and vegetables less

than one time per day (fruit: S.C. 44.4% vs. U.S. 37.7%; vegetables: S.C. 27.3% vs. U.S. 22.6%); similar trends are seen for adolescents (fruit: S.C. 50.6% vs. U.S. 36.0%; vegetables: S.C. 47.8% vs. U.S. 37.7%).<sup>50</sup> Additionally, regional variations in dietary intake are associated with the regional variations in blood pressure and stroke mortality, where the southern region has higher consumption of salt and saturated fatty acids and also the highest rates of stroke mortality and high blood pressure in the U.S.<sup>51</sup> Thus, while nutritional improvements merit national attention, there is a very pressing need to find solutions in the south, including S.C.

## *2.2 Expert Recommendations and Past Intervention Strategies*

In 2007, Expert Committee for Pediatric Obesity Prevention (ECPOP) published a set of guidelines for the prevention and treatment of pediatric obesity, including 8 strategies for intervention and 7 behavioral targets.<sup>9</sup> The ECPop was made of representatives from 15 national health care organizations, including the American Medical Association and the Centers for Disease Prevention and Control; a steering committee appointed scientists and clinicians to three writing groups that subsequently reviewed the existing literature and provided recommendations for the prevention and treatment of pediatric obesity.<sup>9</sup> In 2007, the ECPop published a set of recommendations for the prevention and treatment of pediatric obesity that build off the original ECPop suggestions from 1995, incorporating evidence-based research as well as supplemental recommendations from clinical practice experiences where evidence-based

research was unavailable.<sup>9</sup> Among the actions recommended by pediatric obesity experts are the promotion of PA and HE,<sup>9,10</sup> as well as including the whole family in treatment.<sup>11</sup> (See Appendix A for complete list of recommended strategies and behavioral targets recommended by the ECPOP.)

There have been many approaches taken to intervene and improve levels of children's PA, including programs centered at schools, in neighborhoods/communities, and in family settings.<sup>52</sup> The Community Preventive Task Force, a collaborative team of researchers organized by the Centers for Disease Control and Prevention (CDC), maintain a report and database (The Community Guide) where they report on the effectiveness of strategies to promote lifestyle behaviors.<sup>53</sup> The Community Guide on "Increasing Physical Activity: Behavioral and Social Approaches" has rated individually-adapted health behavior-change programs, social support interventions in community settings, and school-based physical education, as having sufficient evidence to recommend for future use.<sup>52</sup> However, among the intervention approaches rated with "insufficient evidence" on which to judge are family-based social support interventions. The Community Guide<sup>52</sup> and other reviews of family-based PA interventions,<sup>54</sup> have concluded that family-based interventions hold promise for future effectiveness, but there have been methodological quality issues with the studies conducted to date that make it difficult to fully understand what components of the interventions are most helpful. Additionally, there have been a number of family-based interventions that have had null results in terms of improvement in accelerometer-based PA,<sup>54-57</sup> despite the intensive resources

required to conduct them, leaving some skeptical about the effectiveness of family-based approaches to intervention. Nevertheless, more research is needed to understand if this approach can be used for PA, and using a remotely-delivered intervention, such as the proposed study, could help to minimize costs associated with intervening.<sup>58</sup>

### 2.2.1 Physical Activity Interventions

Research has also shown that wearing a pedometer or other monitoring device can lead to increases in PA and enhanced weight loss during behavioral interventions.<sup>59,60</sup> In our pilot work we found that pedometers were the only PA monitoring device that was associated with increased steps in children (as compared to baseline steps). Qualitative feedback supplemented our quantitative findings by teaching us that the children in the pilot study preferred the immediate feedback that the pedometer offered (as opposed to having to sync to an app with the other devices tested, e.g., FitBit). Our results are in line with other past research, which found that pedometers had the potential to motivate children to increase their PA, largely because of the screen display they provided with instantaneous step information.<sup>61-63</sup> Pedometers are also an appealing method for PA monitoring because they are relatively low cost,<sup>64</sup> have been used extensively in behavioral research with parents and children, and are highly correlated with directly observed PA ( $r = 0.95$ ) among 12-yr-old children.<sup>65,66</sup>

### 2.2.2 Children's Obesity Prevention

Obesity prevention and treatment programs for children have had similarly mixed success.<sup>67</sup> A recent review of 57 randomized controlled trials in elementary and secondary school children with a school component, focused on increasing healthy eating and PA, found that only 4 studies reported both statistically and clinically significant differences between the intervention and control groups in their respective outcomes (increased HE, reduced physical inactivity, increased PA, increased HE and PA).<sup>67</sup> From the studies reviewed, 19 targeted HE (1 significant result), 4 targeted reduced physical inactivity (1 significant result), 9 targeted increased PA (1 significant result), and 25 targeted HE and PA (1 significant result).<sup>67</sup> Among the common approaches to PA and HE promotion are interventions where children attend weekly classes to receive instructional materials at a university setting, or receive educational trainings in their schools, then return home to continue with the skills they learned.<sup>67</sup> The authors concluded that the modest and mixed results are due to multiple factors including a lack of implementation monitoring (for dose of program received by participants) and an explicit theoretical basis for the intervention or interpretation of the trial results.<sup>67</sup>

### 2.2.3 Parental Involvement in Children's Obesity Prevention and Treatment

A growing body of research recognizes that parents play an important role in the health behaviors of children, and several reviews have highlighted the importance of incorporating the family in efforts to reduce obesity.<sup>68,69</sup> Thus,

researchers began to test the combinations of family elements needed to create meaningful change in obesity risk factors through interventions, examining the impact of child-only interventions versus parent and child interventions, and most recently parent-only interventions versus parent-child interventions. The findings from child-only versus parent and child show that involving a parent is very helpful for the achievement of better outcomes.<sup>70</sup> However, the results for parent-only versus parent and child interventions for obesity prevention are less straight forward. A recent meta-analysis of parent-only versus parent-child (family-focused) interventions concluded that there was a lack of high quality evidence on which to judge the relative impact of both approaches.<sup>71</sup>

Another factor to consider when evaluating the effectiveness of family-based interventions for obesity prevention is the true method in which they are delivered. Traditional “family” interventions have been delivered in a top-down fashion, where the parent receives all intervention materials and knowledge and is charged with disseminating the intervention to their family.<sup>72</sup> However, more interventions have moved toward a family-based model where parents *and* children are directly involved in the intervention,<sup>73</sup> and more research is needed to better understand the impacts of such interventions on future health outcomes. Therefore, it is still worthwhile to continue to investigate family-based research programs, especially those with potential to reduce the average cost of intervention, such as a mobile-delivered program

Researchers have examined what strategies are most motivating to encourage sustainable behavior change in children. This research revealed that



children respond best to positively-framed health messages (i.e., increasing healthy behaviors as opposed to focusing on reductions in unhealthy behaviors).<sup>74</sup> As such, the proposed research will focus on the main health behavior targets of increasing time spent in MVPA and increasing consumption of fruits and vegetables (other secondary goals include decreasing sugar-sweetened beverage and fast food consumption).

### *2.3 Promise of Family Systems-Based Research*

There is a growing consensus that family-based research holds promise for obesity prevention and treatment research.<sup>9,11,75</sup> Recently more studies have begun to utilize Family Systems Theory,<sup>22</sup> a theoretical framework that emphasizes the interconnectedness of the family dynamics and the importance of addressing the entire “system” of a family in order to impact meaningful changes. Many of these interventions have been successful in promoting healthy behaviors associated with the prevention and treatment of obesity by focusing on elements of a warm, cohesive family environment, and parenting styles that promote positivity and structured but flexible rules (i.e., authoritative parenting).<sup>23,76</sup>

### *2.4 Parent-Child Communication and Relationship Quality*

One important element of promoting a healthy family environment is the quality and quantity of parent-child communication. Positive family communication has been linked with higher rates of PA,<sup>20</sup> less time in sedentary

behaviors,<sup>73</sup> and reduced health risk factors.<sup>77,78</sup> Additionally, overall positive relationships with parents have been associated with more PA and lower participation in risk behaviors (e.g., tobacco usage).<sup>20,79</sup>

Researchers have also begun to investigate and model the ways in which parent-child communication are truly reciprocal; that is that each party is exchanging ideas and exerting influence on the other.<sup>24,80</sup> Reciprocal communication describes parent-child interactions in the context of their present relationship, past interactions, and future interactions.<sup>24</sup> Therefore, it moves beyond the way that parenting interventions have focused almost solely on the methods through which parents deliver information and support to children, and interventions that focus solely on child disposition and reception to information.<sup>24,80,81</sup> Learning to view both of these components in a dynamic and interactive system is crucial to the advancement of family-based health promotion. However, measurement of this interaction has proven difficult and little work has been completed to advance this area of research.<sup>24,80,81</sup>

One way in which parent-child interactions can be measured in more of a real life dynamic context is with the use of mobile technology. Technology allows for more real-time collection of data, such a nightly check-ins on goal progress. Informed by research on the promotion of healthy family communication and Family Systems Theory, the present study aimed to increase the quality and frequency of communication between parents and children, as well as facilitate family group activities. The proposed study aimed to fill this measurement void by providing objectively measured data on parent-child communication through the

user statistics of a mobile website (see Chapter 3 for more details on mobile website functionality).

### *2.5 Use of Mobile Technology in Health Behavior Interventions*

Finding scalable and engaging ways to disseminate obesity treatment and prevention for children has been challenging. Apps are an engaging way to involve children in health behavior changes, capitalizing on the portability and affordability of delivering health information via mobile devices and the opportunity to use gaming to make health information entertaining.<sup>12,13</sup> While most children do not own their own mobile device (e.g., smartphone, tablet), children have increasing access to apps (e.g., through use of family tablets, their parent's smartphone, etc.).<sup>14,15</sup> Seventy two percent of parents with children ages 0 to 8 years old report that their child has used a mobile device for some type of media activity, including using apps.<sup>14</sup> Adults with children report that 30% of the apps on their smartphones are for their children.<sup>15</sup> Additionally, smartphone and tablet ownership among teens is growing, (37% of teens aged 12-17 own a smartphone and 23% own a tablet), and smartphone ownership is likely to increase in younger children as mobile companies begin to offer smartphones for free phone upgrades.<sup>82-84</sup> Smartphones and tablets also offer an opportunity to extend health interventions to traditionally underserved groups, including African Americans and Latinos, as smartphone ownership among these groups is growing faster than that of whites.<sup>14,16</sup>

Mobile technologies can be used to encourage obesity prevention through the promotion of PA and HE, as well as the potential to encourage improved and increased communication between parents and children. Research has shown that many aspects of the parent-child relationship are crucial for fostering the development of healthy behaviors in adolescence (e.g., increased PA, HE).<sup>85,86</sup> Many health promotion apps are currently available. We recently completed the first systematic review<sup>17</sup> of mobile apps for the prevention of pediatric obesity (children/teens <18) through weight loss, PA, and HE to determine if expert-recommended strategies and behavioral targets were promoted,<sup>9</sup> and we found the apps for children to be lacking in the use of theory or evidence-informed practices. Using data from a pilot study of the commercially available apps and follow-up focus groups, developed a responsive-design mobile website for parents and children to support PA, HE, weight loss, and increased communication within the family unit.

Building upon extensive research about the strategies promoted in a clinical setting for pediatric obesity prevention, the mFIT study examines the translation of clinical obesity solutions to a mobile platform that engages parents and children in changing their health behaviors. The present study tests the effectiveness of the mobile website in a randomized trial of parent-child dyads to facilitate PA, HE, and parent-child communication about health behaviors.

## *2.6 Summary of the Current Status of Problem*

The present research study will address the previously described challenges by testing two family-based health promotion interventions, both designed to promote PA and HE using low-cost remote delivery methods. Both interventions will also make use of mobile technology including apps for children's PA and HE to further engage children in making health behavior changes. Further, the intervention condition will use a variety of strategies to encourage positive parent-child communication about PA and HE, including weekly suggestions for family activities, a messaging feature on the study website, and the layout of the study website such that parents and children can view each other's progress.

The goals of the present study are two-fold. The first goal of the study is to test the effectiveness of an evidence-based mobile intervention with enhanced parent/child communication (Tech+) versus commercially available products alone (Tech) for improvements in child's average minutes of MVPA per day [primary outcome], changes in the parent's average minutes of MVPA per day, changes in self-monitored PA (average daily steps from pedometer), and improvements in dietary quality as measured by meeting HE targets (e.g., increased fruit and vegetable consumption) [secondary outcomes]. The second goal is to examine the impacts of evidence-based family intervention on parent-child relationship quality and communication about PA and HE [secondary outcomes].

The conceptual model, shown in Figure 2.1, is adapted from the Environmental Research framework for weight Gain prevention (EnRG),<sup>21</sup> Family Systems Theory,<sup>22</sup> family systems theory framework related to youth health behaviors,<sup>23</sup> the model of bidirectional processes in parent-child relationships,<sup>24</sup> the model of social context in health behavior interventions,<sup>25</sup> Social Cognitive Theory,<sup>26</sup> and the Theory of Planned Behavior.<sup>27</sup> The intervention was designed to target multiple levels of influence on health behaviors, including cognitive factors at the individual level (e.g., self-efficacy), as well as the social context, including family-level factors (e.g., cohesion) and parent-child interactions. The model emphasizes the importance and influence of moderators, broken down here into person factors (social class, ethnicity, etc.) and behavior factors (interactions and counteractive control strategies). These moderators act on the multiple levels of factors (environmental and individual), as well as acting on health behaviors and directly on health outcomes. Items in bold are main foci of the intervention; items in italics will be measured but not acted directly upon.

The intervention targeted three main areas: family environment (e.g., cohesion, warmth), parent-child interpersonal factors (e.g., communication, support) and individual factors. The family environmental factors were targeted through tenets of Family Systems Theory, which describes the dynamic interactions within the family unit, including the variety of interconnected dimensions through which family functioning may impact the well-being of each family member, including the level and quality of family support, relationship satisfaction between family members, and the emotional cohesion of the family

members.<sup>87</sup> Elements of Family Systems Theory have been applied to a range of health behaviors related to the targets of the proposed research, such as nutrition,<sup>88</sup> obesity treatment,<sup>23</sup> and PA.<sup>20,89</sup>

On an interpersonal level, the intervention targeted the quality and frequency of parent-child communication. The conceptual model for the study describes the reciprocal nature of parent-child interactions and communication, and views them in the context of the broader parent-child relationship.<sup>24</sup> Therefore, it moves beyond the way that parenting interventions have focused almost solely on the methods through which parents deliver information and support to children, and interventions that focus solely on child disposition and reception to information.<sup>24,80,81</sup> Using the conceptual model as a framework, the study collected objective data on the interactions between parents and children in the Tech+ group, as recorded by the mobile website.

On an individual level, the intervention used aspects of the theory of planned behavior and social cognitive theory to impact decision making and self-efficacy for PA. Self-efficacy was operationalized with the definition of Bandura<sup>26</sup> from social cognitive theory. Social cognitive theory, which emphasizes the reciprocal relationship between the environment and internal beliefs and attitudes, has been used to help explain exercise adherence and actual participation in an exercise program.<sup>90</sup> One aspect of this framework, self-efficacy, been shown to have large influence on exercise behaviors. Self-efficacy is the confidence someone has in overcoming barriers to accomplish something—in this case, the confidence that he/she can engage in the targeted

behaviors on a regular basis. Studies have shown a strong relationship between self-efficacy for exercise and intention to start exercising as well as actual exercise levels, making it a useful construct to target interventions.<sup>90-92</sup> Additionally, self-efficacy has been shown to moderate the relationship between the common declines in the levels of PA achieved by adolescent girls and their perceived social support.<sup>93</sup>

The Theory of Planned Behavior explains that there are three main aspects of an individual's perceptions about a behavior that affect her intentions to carry out that behavior and her actual actions.<sup>27</sup> The three areas of conceptualization are attitudes, subjective norms, and perceived behavioral control as they relate to the specific behavior.<sup>27</sup> In the conceptual model for the present study, these factors were thought to act as individual mediators, or potential factors that can influence the uptake and success of individual participants in intervention activities. In addition to targeting an increase in self-efficacy for PA, intervention materials aimed to increase participants' perceived behavioral control of PA, as well as attempting to change the attitudes and subjective norms of the participants with respect to PA (changing the social environment).

See Appendix B for details about how the conceptual model was implemented in the in the research design and participant materials.



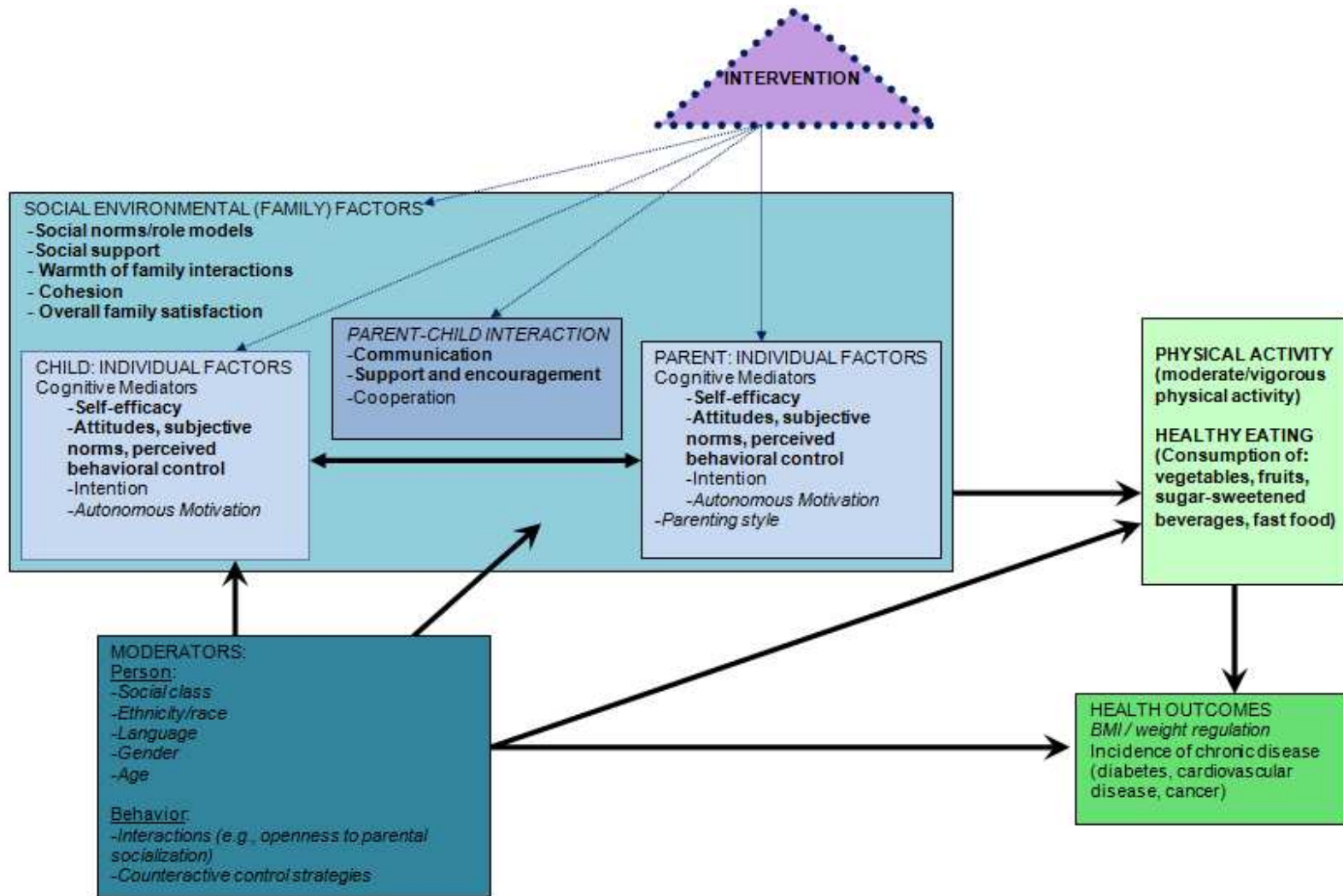


Figure 2.1: Conceptual Model for the mFIT Study

## Chapter 3: Methodology

### 3.1 Overview

The overall goal of the present study was to test the effectiveness of a standard family-based health promotion program versus an enhanced technology program for improvements in PA, HE, and parent-child communication. The intervention condition was designed to enhance parent-child communication and child engagement in health behavior changes, and made use of a newly designed mobile website. The *first specific aim* is to test the effectiveness of an evidence-based mobile intervention with enhanced parent/child communication (Tech+) versus a usual care “family-based” intervention focused on parents using available products (PA and HE apps, PA device) alone (Tech) for improvements in child’s minutes MVPA [*primary outcome*], improvements in the parent’s minutes of MVPA, changes in self-monitored PA (average daily steps from pedometer), and increased achievement of HE goals (e.g., increased fruit and vegetable consumption) [*secondary outcomes*]. The *second specific aim* was to examine the impacts of the evidence-based family intervention on parent-child relationship quality and communication about PA and HE.

The present study was conducted through a 12-week two-arm randomized trial; parent-child dyads were randomly assigned to the intervention condition (Tech+) or to a control group (Tech). Both groups underwent identical measurement procedures, including an online screening questionnaire, baseline

and post-program online assessment questionnaires, and baseline and post-program in-person assessment visits (to objectively measure height and weight). Additionally, dyads in both conditions used an accelerometer for one week at baseline and again for one week at post program to provide objective assessment of PA levels at both timepoints. The explicit goals of the intervention are to increase MVPA, increase vegetable consumption, increase fruit consumption, decrease sugar-sweetened beverage consumption, and decrease fast food consumption.

### *3.2 Sample Description and Sampling Procedures*

The present research took place in the Columbia, S.C. area at the University of South Carolina's Columbia campus. Columbia, S.C. was an ideal setting for the present study, given the relevance of the research to medically underserved and traditionally unrepresented populations in medical research, the high percentage of African American families living there (42.2% of residents as compared to 27.9% statewide), and the high rate of poverty (23.3% of residents as compared to 17.0% statewide), (see Table 3.1).<sup>94</sup> Thus, the portions of the population of Columbia are exposed to many of the risk factors which are playing a role in disparate health outcomes across the U.S.: low employment/income, and high percentage of minority racial groups, both of which can lead to poor medical care or lack of preventive health services.<sup>95</sup>

TABLE 3.1: Demographic characteristics of Columbia, S.C., and the U.S.

	<b>Columbia</b>	<b>S.C.</b>	<b>U.S.</b>
% African American	42.8%	28.0%	12.5%
% families with children under 18 years, below poverty in last 12 months	26.6%	20.4%	16.4%
% unemployed	6.4%	6.3%	5.6%
% Armed Forces	9.1%	1.0%	0.5%

Participants for the present research were parent-child dyads, where the parent was not adequately physically active, owned a smartphone or tablet, and the child was between 9-12 years old. See below for more details on specific inclusion/exclusion criteria and sampling procedures. The target sample for the proposed intervention did not include a body weight or BMI requirement for eligibility; instead, the criteria are based on level of PA and access to technology. While children who are overweight/obese have an increased risk of being overweight/obese as adults, under- and normal-weight children are also at risk for becoming overweight/obese and have been shown to have more severe health risks when they become overweight later in life than children who were overweight.<sup>67</sup> Therefore, all children, regardless of their weight status in childhood, can benefit from behavioral interventions that promote healthy lifestyles and prevent excessive weight gain.<sup>67</sup>

### 3.3 Inclusion/Exclusion Criteria:

- Parent/Guardian:

- Not currently meeting PA guidelines (participants were eligible if they engaged in aerobic activities <3 days/week for 30 minutes/day or strength training <2 days/week for ≥20 minutes/day)
  - Assessed with questions from the 2013 Behavioral Risk Factor Surveillance System (BRFSS), previously found to have adequate validity and test-retest reliability. questions)<sup>96,97</sup>
- Owned and used a smartphone and/or a tablet with a data plan (e.g., iPhone, iPad)
  - If they did not have a data plan for mobile device, required to have reliable WI-FI Internet access in their home
- Lived in the same household as the child
- Child:
  - Aged 9-12 years old
- Both:
  - Willing to be randomized to one of the two intervention groups
  - Willing and able to be physically active
  - Free of major chronic diseases, including: heart disease, cancer, diabetes, past incidence of stroke
  - Did not have a psychiatric disease, drug or alcohol dependency, or uncontrolled thyroid condition
  - Free of eating disorders

- Were not participating in a concurrent weight loss program or taking weight loss medications

### *3.4 Recruitment Strategy*

Parents-child dyads were recruited through a variety of community contacts. Low-cost methods included posting flyers in churches, afterschool programs, schools, and fitness centers, email announcements through university and community listservs, tabling at local health fairs, an informational blog post on a local parenting blog, a brief appearance on the local news, and posts on Craigslist ([www.craigslist.com](http://www.craigslist.com)). Additionally, a paid advertisement in a local newspaper was published two times in print (as well as on the newspaper's website) and a direct mail postcard campaign sent mailers to approximately 2000 families in the local area of the university. All recruitment materials also encouraged people to pass on the study information to friends and family who might be interested in participating and to encourage spread by word of mouth (see Appendix C for sample recruitment flyer).

### *3.5 Intervention Programs*

The mFIT study tested the effectiveness of two family-based theory-informed health promotion programs: the Tech program and the Tech+ program (see Appendix D for detailed comparison of programs). Intervention materials for both groups were informed by Social Cognitive Theory<sup>26</sup> and the Theory of Planned Behavior,<sup>27</sup> and offered overall information about setting small attainable

goals, identifying and overcoming obstacles to behavior change, and encouraging a shift in attitudes towards PA and healthy eating in the family unit. Materials in the Tech+ program also incorporated elements of Family Systems Theory<sup>87</sup> and conceptualized parent-child relationships in the context of reciprocal interactions.<sup>24</sup>

Dyads in both programs received a theory-based weekly email newsletter (see Appendix E for topics and Supplemental File: Example TECH+ Newsletter for sample), were asked to wear a study-provided pedometer daily, and were sent a link to a free, commercially available mobile app for PA and/or healthy eating to play each week. The five main behavioral goals of the study were: increase steps (to at least 10,000/day), increase servings of vegetables (parents: 5-7 servings/day, children: 3-5 servings/day), increase servings of fruit (parents: 2-3 servings/day, children: 1-2 servings/day), decrease servings of sugar-sweetened beverages (SSBs; work to decrease to 0-3 servings/week), and decrease servings of fast food (work to decrease to 0-3 servings/week). All participants were encouraged to self-monitor their progress toward study goals daily as well as to set weekly goals for incremental progress and to set rewards for reaching those goals. Study materials emphasized the need to set healthy rewards for healthy goals, such as earning a trip to the park or a new book, as opposed to earning sweets or large amounts of screen time.

Dyads randomized to the Tech program were asked to self-monitor via study-provided paper logs. Content in the Tech intervention focused on standard recommendations for PA and healthy eating, with messages delivered to parents

(top-down approach), and was based on standard obesity prevention and treatment messages (e.g., Diabetes Prevention Program; Centers for Disease Control and Prevention; *Let's Move!* campaign; *We Can!* campaign).<sup>34,98-100</sup>

Dyads randomized to the Tech+ were asked to self-monitor using a mobile responsive design website made for the mFIT study (see Appendix F for screen shots of the mobile website). The Tech+ mobile website was developed with input from parent-child dyads from formative research, and included features such as a single log-in for each family (parents and children could toggle to their information from within the same username/password), side-by-side graphs to show the daily progress of parents and children toward study goals, and a messaging feature where parents and children could send messages of support and encouragement to one another to help reinforce behavioral goals. Content in the Tech+ intervention focused on creating opportunities for parent-child communication about PA and healthy eating, as well as encouraging family activities (e.g., cooking together, exercising as a family). Additionally, the Tech+ intervention materials and website included sections directed to parents, separate sections for children, and a section for the family, to encourage collaboration.

### *3.6 Measures and Specification of Variables*

#### *3.6.1 Overview*

Measures were collected from participants at a multiple timepoints and through multiple methods. At baseline and the post-program (3-month



timepoint), participants came to the university research center for a short assessment visit; at baseline and post-program, participants also filled out an online assessment questionnaire. Sample copies of the questionnaire can be found in Supplemental Files: Example Parent Questionnaire and Example Child Questionnaire.

### 3.6.2 Clinic Visit

At baseline and post-program, parents and children were measured at the university research center by a research assistant who was blind to group assignment. Using standard protocols, body weight (to the nearest 0.1 lbs) was measured with a calibrated research-quality digital scale (seca model #869) and height (to the nearest 0.25 inch) was measured with a research-quality stadiometer (seca model #213). Body mass index was calculated as  $\text{kg/m}^2$ , and BMI percentile was calculated for children.

### 3.6.3 Accelerometer Data: Planned Methods

At baseline and post-program, parents and children each wore an Actigraph GT1X accelerometer to objectively measure their PA level. Accelerometers were worn on a belt around the waist, with the monitor positioned above the right hip bone. Participants wore the accelerometers for a 7-day collection period, shown to be sufficient for estimation of the main outcome in the present study, the MVPA of the children.<sup>101</sup> Accelerometers stored the data in 1 second epochs that were combined later for analysis. A monitored hour was not considered valid if there are 60 or more consecutive minutes of 0 counts; participants were included in the analysis only if they had at least 4 days of

monitoring data with at least 10 hours/day of data.<sup>6</sup> Accelerometer data were processed using the Troiano cutpoints for adults<sup>6</sup> and Evenson cutpoints for children.<sup>102,103</sup>

#### 3.6.4 Accelerometer Data: Revised Methods

Due to insufficient device memory to store PA data at the specified 1second epochs indicated at initialization, accelerometers stored a maximum of 2 days of data during the 7-day data collection period. Therefore, analysis methods were revised accordingly and are reflected below.

Physical activity, accelerometry. At baseline and post-program, parents and children each wore a GT1X Actigraph accelerometer to objectively measure their PA level. Accelerometers were worn on a belt around the waist, with the monitor positioned above the right hip bone. Participants wore the accelerometers for a 7-day collection period, shown to be sufficient for estimation of the main outcome in the present study, the MVPA of the children.<sup>101</sup>

Accelerometers stored the data in 1 second epochs were combined during analysis. A monitored hour was not considered valid if there are 60 or more consecutive minutes of 0 counts. Due to insufficient memory in the devices, all devices stored only a maximum of 2 days of data. Therefore, participants were only included in the analysis if they had 2 days of monitoring data with at least 10 hours/day of data.<sup>6</sup>

#### 3.6.5 Self-Monitoring Records

Parents and children were all asked to wear a study-provided pedometer each day and to record their steps and food intake each night. Food intake

recorded each day included servings of: vegetables, fruits, sugar-sweetened beverages, and fast food. Additionally, parents and children set goals for all five behavioral targets and potential rewards for meeting those goals each week, which were recorded in their respective self-monitoring records. Records for the Tech group were kept on paper and collected at the end of the intervention; records for the Tech+ group were kept online and recorded in the study database instantaneously. Using participant-entered daily records, averages for daily steps and servings of the four food groups were calculated for weeks where at least three days of data were available for a given behavioral target (e.g., steps).

### 3.6.6 Online Questionnaires

Online questionnaires were administered at baseline and the end of the program. Questionnaires contained questions about participant demographics, technology experience, health behaviors, as well as a group of psychosocial questionnaires.

Demographic questions included standard questions: age, race/ethnicity, grade level in school (child), highest level of educational attainment (parent), marital status (parent), number of children under the age of 18 in the household (parent), birth order of child enrolled in study (parent), roster of other related family living in the household (parent).

Technology owned/used: A custom-designed set of 10 questions assessed whether individuals used and or owned a range of technologies (e.g., smartphone, iPod).

Social media used: A custom-designed set of 6 questions assessed whether individuals used a range of social media sites (e.g., Facebook, Twitter).

Rating of study website: At post-program, Tech+ participants were asked to rate the usability of the study website on criteria such as how easy it was to enter information.

Dietary consumption. To reduce participant burden of completing a long dietary questionnaire, usual dietary consumption was assessed for adults with items from the BRFSS 2013 questionnaire (8 questions) and for children with items from the Youth Risk Behavior Surveillance System 2011 questionnaire (7 questions). The questionnaires provided data on usual consumption of fruits, vegetables, and SSBs. A question was developed for the mFIT study that asked how many times the participant ate at a fast food restaurant in an average week during the past month.

Sedentary behavior: The Sedentary Behavior Questionnaire for adults was used to measure parent's sedentary behavior, on weekdays and weekend days.<sup>104</sup> Time spent in nine sedentary behaviors is measured in time per typical week day. The scale has been shown to have adequate validity and reliability.<sup>104</sup> The Sedentary Behaviors Scale from the "Active Where? Survey" was used to measure children's sedentary behavior<sup>105</sup> on weekdays and weekend days.<sup>105</sup> Time spent in nine sedentary behaviors was measured in time per typical week day. The scale has high test-retest reliability, acceptable ICCs for outcome measures, and moderate construct validity.<sup>105</sup>

Social support: The Ball and Crawford<sup>106</sup> revision of the original Sallis<sup>107</sup> social support for health behaviors questionnaires was used to assess social support, including recommended revisions from Kiernan et al.<sup>108</sup> These revisions help to match the number and type of questions asked between PA and HE. There were 8 questions about support or sabotage for HE and 9 questions for PA; the questions are asked in two sets—one about support from family and the second about support from friends. Internal consistency, discriminate validity, and content validity are adequate.<sup>108</sup>

Family cohesion: Family cohesion was measured with 9 questions about a range of family norms (e.g., “There is a feeling of togetherness in our family”).<sup>109</sup> Dichotomous response choices included: “Mostly False” and “Mostly True”. The scale has been shown to have adequate internal consistency reliability and stability over time as well as good content and face validity.<sup>109</sup>

Family closeness and communication: A communication scale developed by Dr. Dawn Wilson and colleagues (unpublished) was used to measure child perception of parent-child communication. The scale is adapted from the previously validated Health Care Climate Questionnaire (HCCQ), originally used in health care settings.<sup>110</sup> The measure was adapted to include “parent” in each of the question stems, and now contains only 9 of the original 15 questions.

Parent-child communication, family engagement, and family closeness. Scales measuring parent-child communication, parental engagement, and family engagement were administered to parents and children. The measures are from the surveys used in the National Longitudinal Study of Adolescent Health (Add

Health), and have been used previously to analyze parent-child relationship quality in relation to health behaviors.<sup>20,111,112</sup> The measures ask about typical interactions over the past 4 weeks, and includes 3 questions about parent-child communication, 6 questions about parental engagement, and 2 questions about family closeness.

Parental monitoring of media use: Parental monitoring of media use was measured with the Adult Involvement in Media Scale (AIM), designed to measure 3 facets of media that monitored children's television and video game habits: limit-setting on amount (5 items), limit-setting on content (4 items), and active discussion about media (2 items).<sup>113,114</sup>

Self-efficacy: Self-efficacy for PA was assessed with a 5-item scale that has been previously validated and has been shown to differentiate between adults at different stages of exercise behavior change.<sup>115</sup>

Data collected from mobile website: The back end of the mobile website allowed us to collect objective data about the amount and type of self-monitoring of health behaviors the participants engaged in. Additionally, we collected information about participant goal setting, goal achievement, and reward setting. Lastly, we collected information about parent-child communication (frequency, type (encouragement, congratulations)). This monitoring provides objective data allowed us to explore the reciprocal nature of the communication and its impact on health behaviors in a novel way.

Qualitative data were collected using open-ended questions on the post-program survey. Questions evaluated level of satisfaction with the intervention, including

communication from the study staff (emails, newsletters); feedback on using the pedometers (pros and cons of the devices); feedback on the commercial apps used; general questions about the way parents and children felt about their relationship with each other; and any other comments participants wanted to leave for the study staff.

### *3.7 Data Collection*

Data were collected from the participants at a number of timepoints through objective and self-report methods. Data collection began with the online screening questionnaire and continued through the post-program assessment. All data were stored on a password-protected computer, and hard copies were filed in a locked cabinet in a locked office. Participant privacy was ensured using randomly generated 3-digit ID numbers generated at the time of the baseline survey completion, and linked to participant names in one single file. The linking file was password protected and stored on a password protected computer. Study ID numbers were used for all study documents and questionnaires, but participant first names were used in study emails (to avoid linking both sources of information). Participants used their study ID and a unique investigator-generated password to log on to the secure server linked to the mobile website. All online questionnaires were administered through SurveyGizmo ([www.surveygizmo.com](http://www.surveygizmo.com)), a secure web portal.

### *3.8 Online Screening Questionnaire*

Parents filled out a brief online screening questionnaire in order to assess initial eligibility. The questionnaire asked about: age of child to participate, activity level of parent, if/what type of smartphone/tablet the parent owns, presence of any inhibitive chronic disease or mental health conditions in the parent or child, etc. For more information, see eligibility criteria in Section 3.3.

### *3.9 Online Assessment Questionnaire*

At baseline and post-program, parents and children each filled out a brief online assessment questionnaire. The questionnaire asked a range questions about use of technology, typical diet, parent-child communication, and a range of psychosocial constructs (described in Section 3.6.6).

### *3.10 Accelerometer Data*

At baseline and post-program, parents and children each wore an accelerometer to objectively measure their PA level. Dyads were instructed about how and when to wear the accelerometer at their assessment visits, and were asked to keep a log of any interruptions in wear time especially noting any long periods of non-wear. These logs were collected with the accelerometer units at the end of the week of wear. PA data were downloaded from accelerometer units and the data were stored on a secure, password protected computer.



### *3.11 Assessment Data*

At baseline and post-program, dyads had a brief in-person assessment visit at the university research center. During the session, a trained research assistant (blinded to condition assignment) measured each individual's height and weight using standard protocols (see Section 3.6.2). During the post-program visit, dyads filled out an assessment of the apps they tested during the study and filled out an assessment of the program and their participation level.

### *3.12 Consent/Assent*

All dyads that were deemed eligible for participation after the initial screening process were invited to attend an in-person orientation session. Upon confirming that they would attend a session, they were emailed further information about the study expectations, including an informed consent form (approved by the University of South Carolina Institutional Review Board USC IRB; see Appendix G for approval letter, Appendix H for consent form). At the end of the in-person orientation session, dyads were provided a paper version of the consent form and asked to review it and ask questions. Dyads that were not ready to commit to participation were told they could contact the research team to follow up at a later time; dyads that were ready to sign up were asked to provide consent. Parents were required to sign the consent form for themselves and their child; children also provided assent for participation. Participants were encouraged to ask questions about the consent/assent or the study in general; motivational interviewing techniques were used to ensure that participants fully

comprehended the commitment they were making to the study, and the implications of being randomized to a study condition. Dyads received a signed copy of the consent/assent form to keep in their program materials for their own record. The study copy of the form was kept in a locked filing cabinet in a locked office.

### *3.13 Data Quality Control*

Data input into the online questionnaires were directly downloaded into Excel files, read into SAS version 9.4 (Cary, NC), and checked for outlying responses (see Section 3.14). Data from surveys administered in person (study evaluation, apps evaluation) and height and weight measurements were input into Excel by a trained research assistant. All hand-input data were double checked with the original data source at least once to screen for data entry errors. Any inconsistencies were checked again and corrected in the Excel spreadsheets.

### *3.14 Analysis*

#### *3.14.1 Overview*

The overall goal of the mFIT study was to test the comparative effectiveness of two methods of family-based health promotion using mobile technology. The intervention condition (Tech+) was designed to enhance parent-child communication and child engagement in health behavior changes, and made use of a newly design mobile website. All analyses were conducted with

SAS version 9.4 (Cary, NC) and findings at  $p < .05$  were considered statistically significant.

**\*Specific Aim 1:** Test the effectiveness of an evidence-based mobile intervention with enhanced parent/child communication (Tech+) versus commercially available products alone (Tech) for improvements in child's average minutes of MVPA per day [*primary outcome*], changes in the parent's average minutes of MVPA per day, changes in self-monitored PA (average daily steps from pedometer), and improvements in dietary quality as measured by meeting HE targets (e.g., increased fruit and vegetable consumption) [*secondary outcomes*].

**Hypothesis 1a:** *Improvements in both primary and secondary outcomes will be significantly greater in participants randomized to the Tech+ program relative to participants randomized to the Tech control program.*

Descriptive statistics were calculated for parents and children. Linear mixed effects models were used to analyze MVPA, average daily steps, and average daily servings of vegetables, fruits, SSBs, and fast food. The mixed effects models allow for missing data for outcomes. A covariance structure was used that allows for three types of correlation: the covariance between repeated measures on an individual, covariance between measures on members of a dyad at the same timepoint, and covariance between measures on members of a dyad at different timepoints (e.g., parent MVPA at baseline and child MPVA at post-program). Fixed effects were included for time (baseline, post-program), intervention group (Tech, Tech+), a Group\*Time interaction, and a three-way

interaction between Group\*Time\*Parent, to estimate whether the pattern of Group\*Time change was different between parents and children (Model 1). If the three-way interaction was not significant, it was removed and a second model was run (Model 2); if the two-way interaction was not significant, it was removed and a final model was run to examine the effects of group and time without interactions (Model 3). All models controlled for child gender, child baseline age (years), parent race, parent educational attainment (college graduate and above versus all others), and season of measurement (summer or schoolyear).

Effect sizes were computed using Cohen's  $d$ , as  $d = (\text{post adjusted mean} - \text{baseline adjusted mean}) / (\text{unadjusted baseline standard deviation})$ . Effect sizes were interpreted using standard criteria for Cohen's  $d$ , where  $d=0.2$  was considered a small effect,  $d=0.5$  a medium effect, and  $d=0.8$  a large effect.<sup>116</sup>

**\*Specific Aim 2:** Examine the impacts of evidence-based family intervention on parent-child relationship quality and communication about PA and HE [*secondary outcomes*].

**Hypothesis2a:** *Improvements in parent-child relationship quality and communication will be significantly greater in participants randomized to the Tech+ program relative to participants randomized to the Tech control program.*

**Hypothesis2b:** *Increasing levels of utilization of the responsive design website (e.g., more frequent logging of steps, use of the goal and reward*

*systems) will be associated with greater frequency and quality of parent-child communication.*

Descriptive statistics were calculated for parents and children. Change in parent-child relationship quality and communication variables during the intervention were examined with t-tests for parents and children separately. A composite score of the dyad-level of each family dynamic was calculated as the mean score of parent and child at post-program.

Linear mixed effects models (PROC MIXED) were used to examine the impact of each of the four family dynamics variables on average daily steps during the intervention. The mixed effects models allow for missing data for outcomes. A covariance structure was used that allows for three types of correlation: the covariance between repeated measures on an individual, covariance between measures on members of a dyad at the same timepoint, and covariance between measures on members of a dyad at different timepoints (e.g., parent steps at baseline and child steps at post-program). Fixed effects were included for time (baseline, post-program), intervention group (Tech, Tech+), a group x time interaction, a family dynamic x time interaction, and a three-way interaction between family dynamic x time x parent, to estimate whether the pattern of family dynamic x time change differed between parents and children. Subsequent models tested a two-way interaction between family dynamic X time and then just family dynamic. All models controlled for child gender, child baseline age (years), parent race, parent educational attainment

(college graduate and above versus all others), and season of measurement (summer or schoolyear).

In order to more directly interpret the interaction term for different levels of time (Week 1 vs. Week 12) and parent (parent vs. child), contrasts were computed between time and parent at high (75<sup>th</sup> percentile) and low (25<sup>th</sup> percentile) values of the dyad-level family dynamics variables. The statistical significance of the change as well as Week 1 and Week 12 LSMEANS within each level of family dynamics stratum are presented.

## Chapter 4: Manuscripts

The mFIT (Motivating Families with Interactive Technology) Study:  
A Randomized Pilot to Promote Physical Activity and Healthy Eating through  
Mobile Technology<sup>1</sup>

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<sup>1</sup> Schoffman D.E., Turner-McGrievy G., Wilcox S., Hussey J.R., Moore J.B., Kaczynski A.T. To be submitted to *Journal of Behavioral Medicine*.

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**Keywords:** physical activity, family relations, parents, eHealth, mHealth, mobile apps

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## **Abstract**

The purpose of the Motivating Families with Interactive Technology (mFIT) study was to test the feasibility, acceptability, and effectiveness of two remotely-delivered family-based health promotion programs for improvements in physical activity (PA) and healthy eating (HE). Thirty-three parent-child (child age 9-12 years) dyads were randomized to one of two 12-week mobile interventions to increase PA and HE, which included weekly email newsletters and the use of pedometers; programs differed on focus of content (individual vs. family) and method of tracking (paper vs. mobile website). At baseline and 12 weeks height and weight were measured and participants completed questionnaires. Of the 33 randomized dyads (parents: 43±6 years, 88% female, 70% white, BMI 31.1±8.3 kg/m<sup>2</sup>; children: 11±1 years, 64% female, 67% white, BMI 77.6±27.8 percentile), 31 (94%) had follow-up data. There were no between-group differences for PA or HE, but there was an overall significant increase in average daily steps and servings of fruit during the intervention and excellent adherence to self-monitoring protocols. Most parents (97%) and children (86%) would recommend the program to a friend. The mFIT program showed excellent feasibility and acceptability as a low-cost, remotely delivered family intervention for PA and HE promotion, and could serve as a disseminable model for public health interventions.

## **Introduction**

Many parents and children in the U.S. do not currently meet recommendations for adequate daily physical activity (PA)(Troiano et al., 2008)

and dietary intake including daily servings of fruits and vegetables.(S. A. Kim et al., 2014; National Center for Chronic Disease Prevention and Health Promotion: Division of Nutrition, 2013) Consequences of these lifestyle behaviors include weight gain and risk of overweight/obesity as well as increased risk of other chronic diseases such as cardiovascular disease, and diabetes.(Freedman, Mei, Srinivasan, Berenson, & Dietz, 2007; Kelsey, Zaepfel, Bjornstad, & Nadeau, 2014; Singh, Mulder, Twisk, van Mechelen, & Chinapaw, 2008) Further, while children who are overweight or obese have an increased risk of being overweight or obese as adults, children at a normal body weight are also at risk for becoming overweight/obese and have been shown to have more severe health risks when they become overweight later in life than children who were overweight.(Thomas, 2006) Therefore, all children, regardless of their weight status in childhood, can benefit from behavioral interventions that promote healthy lifestyles and prevent excessive weight gain.(Thomas, 2006)

There is a growing consensus that family-based research holds promise for obesity prevention and treatment research.(Barlow & the Expert Committee, 2007; L. H. Epstein, Paluch, Roemmich, & Beecher, 2007; L. H. Epstein & Wrotniak, 2010) Indeed, the Expert Committee for Pediatric Obesity Prevention recommends “involve the whole family” in their list of eight behavioral strategies for the prevention, assessment, and treatment of child and adolescent overweight and obesity.(Barlow & the Expert Committee, 2007) A recent commentary on future directions for pediatric obesity research included a focus on both the demonstrated power of family-based programs but also the need to

continue to investigate the best ways to leverage family support to improve children's PA and eating behaviors.(L. H. Epstein & Wrotniak, 2010)

Finding scalable and engaging ways to disseminate obesity prevention and treatment for families has been challenging. Mobile applications (apps) are an engaging way to involve children in health behavior changes, capitalizing on the portability and affordability of delivering health information via mobile devices and the opportunity to use gaming to make health information entertaining.(Boushey et al., 2009; "The Health Educator's Social Media Toolkit," 2011) Previous research, including a systematic review(Schoffman, Turner-McGrievy, Jones, & Wilcox, 2013) of commercially available mobile apps for family weight loss, PA, and healthy eating, as well as an iterative feasibility study of commercially available apps and PA monitoring devices with parent-child dyads, revealed significant gaps in the available mobile tools. The review of mobile apps highlighted the lack of use of evidence-based recommendations or strategies in the apps.(Schoffman et al., 2013) The iterative study explored the feasibility and acceptability of using high scoring apps for PA and healthy eating from the review as well as four PA monitoring devices (e.g., FitBit) for increasing the PA and healthy eating of parent-child dyads; the study helped to uncover some deficiencies in the commercially available apps and as well as identify specific features of PA devices that were most motivating to children. Taken together, the review of apps and pilot results demonstrate that additional levels of support and encouragement are needed to aid in behavior change for parent-child dyads.

The purpose of the Motivating Families with Interactive Technology (mFIT) study was to test the feasibility, acceptability, and effectiveness of two remotely-delivered family-based health promotion programs for improvements in parent-child dyad's PA and healthy eating. One program (Tech+) was hypothesized to result in larger improvements in PA and healthy eating goals, due to the enhanced family-based content and dyads' use of a specially designed mobile website for tracking and family encouragement.

## **Methods**

### *Subjects*

Due to past difficulty recruiting parent-child dyads, eligibility criteria were left as inclusive as possible. There were no weight requirements for parents or children, and because children often have higher PA levels than adults, there was no include a cap on child PA at enrollment. Parent-child dyads were eligible to participate if the parent was not sufficiently physically active at baseline (assessed by Behavioral Risk Factor Surveillance System (BRFSS) 2013 questions), the parent owned a smartphone or tablet and had internet access at home, and the child was between 9 and 12 years old at baseline. Other criteria included: dyad must live in same household, both must be free of major chronic disease (e.g., heart disease, cancer, diabetes), free of eating disorders, and not currently participating in a weight loss program or taking weight loss medications. Human subjects' approval was obtained from the institutional review board at [removed for blind review].

### *Recruitment*

Parent-child dyads were recruited from the community via a range of methods. Low-cost methods included posting flyers in churches, afterschool programs, schools, and fitness centers, email announcements through university and community listservs, tabling at local health fairs, an informational blog post on a local parenting blog, a brief appearance on the local news, and posts on Craigslist ([www.craigslist.com](http://www.craigslist.com)). Additionally, a paid advertisement in a local newspaper was published three times and a direct mail postcard campaign sent mailers to approximately 6,000 families in the local area of the university. All recruitment materials also encouraged people to pass on the study information to friends and family who might be interested in participating, to encourage spread by word of mouth.

### *Procedures*

All recruitment materials and communications directed interested parents to complete a web-based eligibility questionnaire. Parents answered a series of screening questions about themselves and the child with whom they wished to enroll and participate. Study staff followed up with participants via phone and email where needed to clarify responses and determine eligibility. Parents in eligible dyads were contacted to schedule an in-person orientation session at the university research center; parent-child dyads were required to attend together. After signing up to attend one of the in-person orientation sessions, parents were emailed further information about the mFIT study, including details about the time

commitment involved in participating, expectations for study visits and questionnaires, and information about the self-monitoring required during the study (e.g., logging steps daily). They were also emailed a copy of the informed consent and assent form for review with their child before the orientation session.

Interactive in-person orientation sessions lasted approximately one hour and included a presentation about the mFIT study, including the background of the research team, scientific rationale for the study, and details about the expectations for participants. Additionally, sessions included discussion of the importance of retention and the impact of attrition on overall study quality and results. Sessions were modeled on a framework of orientation sessions (Goldberg & Kiernan, 2005) found to be successful in other interventions facing difficult retention situations. (Kiernan et al., 2013; R. E. Lee et al., 2011) Sessions used motivational interviewing to engage participants and encourage them to consider both pros and cons of enrollment as well as the full commitment of enrolling. At the end of the session, dyads had the chance to speak privately with the PI about remaining questions, as well as sign and turn in their informed consent/assent forms if they chose. Dyads were also given the opportunity to return the forms at a later time. Details on study enrollment are shown in Figure 4.1.

After submitting informed consent, dyads were given Actigraph GT1X accelerometers (see below, *Measures*) to wear for seven days, and sent links to online questionnaires to complete at home (parents and children had separate questionnaires). Upon completing their online questionnaires, dyads were randomized to an intervention group and scheduled to attend an in-person

information session about their program; group assignment was not revealed until dyads were at the program visit. At this visit, dyads also had their heights and weights taken by research staff using standard protocols; measurement staff were blinded to participant group assignment. After having height and weight taken, group assignment was revealed to dyads, they received a pedometer, and learned about their program and the general behavioral goals of the mFIT program (e.g., steps and servings of vegetables). The remainder of program materials and correspondence during the 12-week study took place via email for both intervention groups and both groups received weekly newsletters.

After the 12-week intervention, dyads returned to the university research center to have their height and weight measured, answer questionnaires about their impressions of the study and the commercial apps they tested, and received accelerometers to wear for one week (along with their pedometers). After the post-program visit, dyads were emailed a final set of online questionnaires to complete. Upon completion of the online questionnaires and seven days of accelerometry, dyads returned briefly to turn in their accelerometers and pick up a gift card incentive for the child.

### *Intervention Programs*

The present study tested the effectiveness of two family-based theory-informed health promotion programs: the Tech program and the Tech+ program (see Table 4.1 for detailed comparison of programs). Intervention materials for both groups were informed by Social Cognitive Theory (Bandura, 1989) and the

Theory of Planned Behavior,(Icek, 1991) and offered overall information about setting small attainable goals, identifying and overcoming obstacles to behavior change, and encouraging a shift in attitudes towards PA and healthy eating in the family unit. Materials in the Tech+ program also incorporated elements of Family Systems Theory(Bowen, 1993) and conceptualized parent-child relationships in the context of reciprocal interactions.(Lollis & Kuczynski, 1997)

Dyads in both programs received a theory-based weekly email newsletter (see Table 4.1 for details), were asked to wear a study-provided pedometer daily, and were sent a link to a free, commercially available mobile app for PA and/or healthy eating to play each week. The five main behavioral goals of the study were: increase steps (to at least 10,000/day), increase servings of vegetables (parents: 5-7 servings/day, children: 3-5 servings/day), increase servings of fruit (parents: 2-3 servings/day, children: 1-2 servings/day), decrease servings of sugar-sweetened beverages (SSBs; work to decrease to 0-3 servings/week), and decrease servings of fast food (work to decrease to 0-3 servings/week). All participants were encouraged to self-monitor their progress toward study goals daily as well as to set weekly goals for incremental progress and to set rewards for reaching those goals. Study materials emphasized the need to set healthy rewards for healthy goals, such as earning a trip to the park or a new book, as opposed to earning sweets or large amounts of screen time.

Dyads randomized to the Tech program were asked to self-monitor via study-provided paper logs. Content in the Tech intervention focused on standard recommendations for PA and healthy eating, with messages delivered to parents



(top-down approach), and was based on standard obesity prevention and treatment messages (e.g., Diabetes Prevention Program; Centers for Disease Control and Prevention; *Let's Move!* campaign; *We Can!* campaign).(Centers for Disease Control and Prevention, 2014; "The Diabetes Prevention Program (DPP): description of lifestyle intervention," 2002; "Learn the Facts," 2012; "We Can! NHLBI, NIH," 2014)

Dyads randomized to the Tech+ were asked to self-monitor using a mobile responsive design website made for the mFIT study (see Figure 4.2 for screen shots of the mobile website). The Tech+ mobile website was developed with input from parent-child dyads from formative research, and included features such as a single log-in for each family (parents and children could toggle to their information from within the same username/password), side-by-side graphs to show the daily progress of parents and children toward study goals, and a messaging feature where parents and children could send messages of support and encouragement to one another to help reinforce behavioral goals. Content in the Tech+ intervention focused on creating opportunities for parent-child communication about PA and healthy eating, as well as encouraging family activities (e.g., cooking together, exercising as a family). Additionally, the Tech+ intervention materials and website included sections directed to parents, separate sections for children, and a section for the family, to encourage collaboration.

### *Measures*

Demographics. Demographic questions included standard questions for measuring: age, race/ethnicity, grade level in school or on summer vacation (child), highest level of educational attainment (parent).

Physical activity, accelerometry. At baseline and post-program, parents and children each wore a GT1X Actigraph accelerometer to objectively measure their PA level. Accelerometers were worn on a belt around the waist, with the monitor positioned above the right hip bone. Participants wore the accelerometers for a 7-day collection period, shown to be sufficient for estimation of the main outcome in the present study, the moderate- to vigorous-intensity physical activity (MVPA) of the children.(Trost, Pate, Freedson, Sallis, & Taylor, 2000) Accelerometers stored the data in one second epochs that were combined during analysis. A monitored hour was not considered valid if there are 60 or more consecutive minutes of zero counts. Due to insufficient memory in the devices, all devices stored only a maximum of two days of data. Therefore, participants were only included in the analysis if they had two days of monitoring data with at least 10 hours/day of data.(Troiano et al., 2008) Accelerometer data were processed using the Troiano cutpoints for adults(Troiano et al., 2008) and Evenson cutpoints for children.(Evenson, Catellier, Gill, Ondrak, & McMurray, 2008; Y. Kim, Beets, & Welk, 2012)

Physical activity, self-monitoring. To provide further context for the accelerometer-derived estimates of PA, average daily step counts from self-monitoring logs in weeks 1 and 12 (final) of the intervention were also analyzed for changes in PA during the intervention. An average steps per day was

calculated for both weeks for participants who self-monitored for at least three days during that week.

Dietary consumption. To reduce participant burden of completing a long dietary questionnaire, usual dietary consumption was assessed for adults with items from the BRFSS 2013 questionnaire (8 questions) and for children with items from the Youth Risk Behavior Surveillance System 2011 questionnaire (7 questions). The questionnaires provided data on usual consumption of fruits, vegetables, and SSBs. A question was developed for the mFIT study that asked how many times the participant ate at a fast food restaurant in an average week during the past month.

Self-monitoring data. During the 12-weeks of the mFIT intervention, participants self-monitored their daily steps and servings of vegetables, fruits, SSBs, and fast food. A week was considered monitored if there were three or more days of non-missing data logged; weekly averages for non-missing data during these weeks are presented.

Feedback on and Engagement in the mFIT program. Participant satisfaction with the mFIT program was assessed at post-program with a question to assess whether they would recommend the program to a friend. Participants also indicated how many of the 12 weekly newsletters they read during the program.

## *Statistical Analyses*

All analyses were conducted with SAS version 9.4 (Cary, NC) and findings at  $p < .05$  were considered statistically significant. Descriptive statistics were calculated for parents and children. Linear mixed effects models were used to analyze MVPA, average daily steps, and average daily servings of vegetables, fruits, SSBs, and fast food. The mixed effects models allow for missing data for outcomes. A covariance structure was used that allows for three types of correlation: the covariance between repeated measures on an individual, covariance between measures on members of a dyad at the same timepoint, and covariance between measures on members of a dyad at different timepoints (e.g., parent MVPA at baseline and child MPVA at post-program). Fixed effects were included for time (baseline, post-program), intervention group (Tech, Tech+), a Group\*Time interaction, and a three-way interaction between Group\*Time\*Parent, to estimate whether the pattern of Group\*Time change was different between parents and children (Model 1). If the three-way interaction was not significant it was removed and a second model was run (Model 2); if the two-way interaction was not significant, it was removed and a final model was run to examine the effects of group and time without interactions (Model 3). All models controlled for child gender, child baseline age (years), parent race, parent educational attainment (college graduate and above versus all others), and season of measurement (summer or schoolyear).

Effect sizes were computed using Cohen's  $d$ , as  $d = (\text{post adjusted mean} - \text{baseline adjusted mean}) / (\text{unadjusted baseline standard deviation})$ . Effect

sizes were interpreted using standard criteria for Cohen's  $d$ , where  $d=0.2$  was considered a small effect,  $d=0.5$  a medium effect, and  $d=0.8$  a large effect. (Cohen, 1988)

## Results

A total of 33 dyads were enrolled and randomized to the Tech (n=16 dyads) or Tech+ (n=17 dyads) group; 31 dyads (94%) returned for post-program assessment visits. The flow of participants through the recruitment and intervention periods is shown in Figure 4.1. As shown in Table 4.2, on average parents were female (87.9%),  $43\pm 5.8$  years old, obese (BMI:  $31.1\pm 8.3\text{kg/m}^2$ ), college graduates (72.7%), and White (69.7%). On average, children were female (63.6%),  $11\pm 0.9$  years old, normal weight (BMI percentile  $77.6\pm 27.8$ ), and White (66.7%). Although parents and children of all body weights were eligible to participate, over 70% of parents and over 60% of children were overweight or obese at baseline.

Table 4.3 shows the adjusted baseline and post-program means for minutes of MVPA (accelerometer) for parents and children by intervention group, from Model 1: Tech parents decreased 4.1 min, Tech+ parents decreased 5.0 min, Tech children decreased 16.6 min, and Tech+ children increased 3.9 min, although the Group\*Time\*Parent interaction was not significant. Additionally, in Model 2, there was no significant Group\*Time interaction, and in Model 1 there were no significant group or time effects.

Table 4.4 shows the adjusted Week 1 and Week 12 mean daily step estimates for parents and children by intervention group from Model 1; Tech parents increased 1502 steps, Tech+ parents increased 424 steps, Tech children increased 789 steps, and Tech+ children increased 2575 steps, although the Group\*Time\*Parent interaction was not significant. Additionally, in Model 2, there was no significant Group\*Time interaction. However, there was a significant time effect in Model 3, where the overall mean daily steps (for parents and children in both intervention groups combined) increased by 1408 steps ( $p=0.04$ ). The effect size for the change in mean daily steps was  $d = 0.40$ .

Table 4.5 shows adjusted baseline and post-program estimates for average servings per day of vegetables, fruits, SSBs, and fast food. Overall, baseline intake of vegetables, fruits, SSBs and fast food was low. There were no significant changes in intake of vegetables or fast food. There were no Group\*Time\*Parent or Group\*Time interactions, or group or time effects for fruit or SSBs, although there was a significant change over time in fruit (increase in 0.3 servings/day,  $p=0.02$ ; Cohen's  $d=0.24$ ) and marginally significant in SSBs (decrease in 0.2 servings/day,  $p=0.05$ ; Cohen's  $d=0.20$ ).

There was high adherence to self-monitoring protocols, with parents keeping step and food logs for an average of  $9.4 \pm 3.7$  weeks (median: 12.0 of 12 weeks), and children keeping step and food logs an average of  $9.0 \pm 3.9$  weeks (median: 11.5 of 12 weeks). Additionally, there was moderately high utilization of program materials. In a post-program survey, parents reported reading an average of  $8.5 \pm 3.0$  of the 12 weekly newsletters, while children read an average

of 5.2<sub>±</sub>4.3. Families also reported downloading an average of 5.7<sub>±</sub>3.1 of the 12 apps sent with the weekly newsletters, with 88.5% of families downloading the week 1 app and rates declining as the intervention progressed. Families rated the program favorably overall, with 97% of parents and 86% of children stating that they would recommend the mFIT program to a friend.

## **Discussion**

The present study demonstrates the feasibility and acceptability of a remotely-delivered family-based and theory-informed intervention for the promotion of PA and healthy eating. While the small sample size makes it difficult to infer statistically significant outcomes for all behavioral indicators examined, the findings indicate that the data are trending in the desired direction. Further, the high levels of retention, participant engagement, and enthusiasm for the program overall show that it could serve as a model for future research.

While there were no significant differences between the groups in MVPA or self-monitored steps, there were increases in self-monitored steps for both groups as well as trends towards improvements in dietary intake (i.e., increased vegetables and fruits, decreased SSBs and fast food). The increase in mean steps per day (1408 steps) represents a clinically significant increase, with a small to medium effect size ( $d = 0.40$ ). These positive trends in health behavior changes for both parents and children suggest that some aspects of the two remotely delivered interventions hold promise as a model for future programs. Participants had limited contact with study staff and all intervention materials

(newsletters, apps) were delivered via email. The similar results overall for changes in PA and eating goals suggest that perhaps the differences between Tech and Tech+ (i.e., paper vs. online self-monitoring, focus on individual vs. focus on family) did not significantly impact behavioral changes. These results are similar to a recent study that tested the impact on sedentary time and PA in children when a family-based weight-gain prevention program was delivered via the internet or paper workbooks.(Catenacci et al., 2014) The results showed that there were similar (non-significant) changes in sedentary time in both groups, and the researchers concluded that the internet delivery method holds promise for future interventions to reach more children than the workbook method.(Catenacci et al., 2014)

Another explanation for the lack of between-group differences in outcomes relates to baseline characteristics of the sample. As described elsewhere in detail families had very high scores on family functioning variables at enrollment into the mFIT study, limiting the potential impact of the enhanced techniques used in the Tech+ program. It is possible that in a sample of more diverse family functioning scores at baseline, there would be more differences seen between the impact of the Tech and Tech+ programs on PA and healthy eating via improvements in parent-child communication, etc.

It is also important to note the somewhat contradictory findings of steps and MVPA could signal difficulties in promoting the same PA goals for parents and children. While there was a significant increase in steps overall, there was a non-significant decrease in MVPA for all groups except Tech+ children. It is



possible that promoting increased steps for children may have encouraged them to engage in less MVPA than they would have otherwise, replacing that time with walking with their parents. While the benefits of walking for adults are well documented,(I. M. Lee & Buchner, 2008) less is known about promoting walking and specifically step counts for children, and future research should examine the potential impact of such interventions in more detail (including possible replacement of more vigorous activities).

As this study aimed to examine many new program elements and delivery methods, dietary self-monitoring was simplified to reduce participant burden. However, it is possible that monitoring diet in a more detailed manner for adults, such as tracking calories or fat grams would have yielded greater results. Future research could look at incorporating other methods of low burden dietary intervention such as the traffic light diet(Leonard H. Epstein et al., 2001; L. H. Epstein, Wing, & Valoski, 1985) for children using a similar mobile platform and delivery package as mFIT. Further, intake of the unhealthy food group targets was lower at baseline in the present sample than anticipated, leaving less room for significant change during the intervention.

We observed very high levels of self-monitoring with step and food logs and engagement with the study materials (measured as newsletters read) during the mFIT program. This suggests that participants enjoyed the format and delivery of the materials, which is significant given that it was a low cost and low intensity intervention without face-to-face contact during the 12 weeks of the intervention period. This is contrasted with the usual care model that has been

tested many times and includes a least weekly in-person meetings with an interventionist, even in studies that are reportedly testing mobile-enhanced interventions.(Rhee et al., 2016; Sze, Daniel, Kilanowski, Collins, & Epstein, 2015)

Despite a small sample of randomized dyads, the mFIT study had excellent retention at the 12-week follow-up visits (94%), especially for an intervention that was entirely remotely-delivered. The high retention may be attributable to the format and content delivered of the orientation session, the weekly contact from study staff (to mail program materials), and the high engagement of participants with study materials (as evidenced by high rates of self-monitoring).

The results of the present research should be interpreted in the context of a few limitations. First, the small sample size limited the statistical power of the analyses and the ability to detect differences between groups and over time. Second, the device memory issue with the accelerometry protocol limits the validity of those data, although they are still important and can be interpreted conservatively as has been done in the present analysis. Third, the reliance on self-reported dietary intake via online questionnaire limits the precision of our measure and ability to detect changes over time. However, the self-reported questionnaire also decreased the participant burden over other methods (e.g., 24-hour recall) and this may have also aided in our high retention rates.

## Conclusion

The mFIT study tested two low-cost, low-burden remotely delivered family interventions, and results of the two programs showed similarly promising increases in pedometer-measured steps and modest dietary improvements. Future research might test a more intensive family-based intervention (e.g., more contact with interventionists, more extensive dietary counseling and monitoring) compared to a similar program to Tech or Tech+ to examine what (if any) factors are associated with larger dietary improvements. Overall, the results of the mFIT program demonstrate promise in the area of remotely-delivered family-based programs, a cost-effective and disseminable model for public health interventions.

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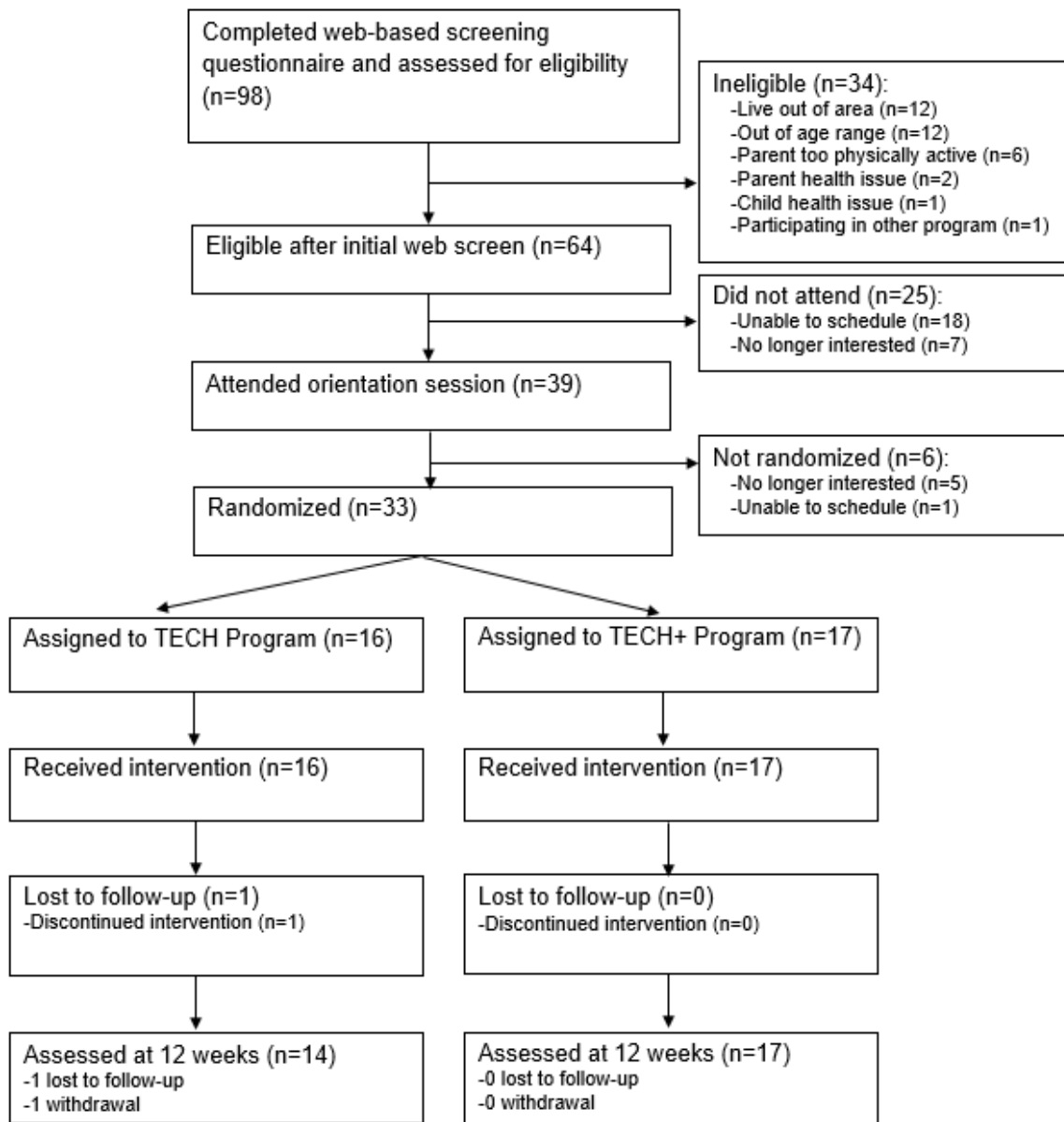
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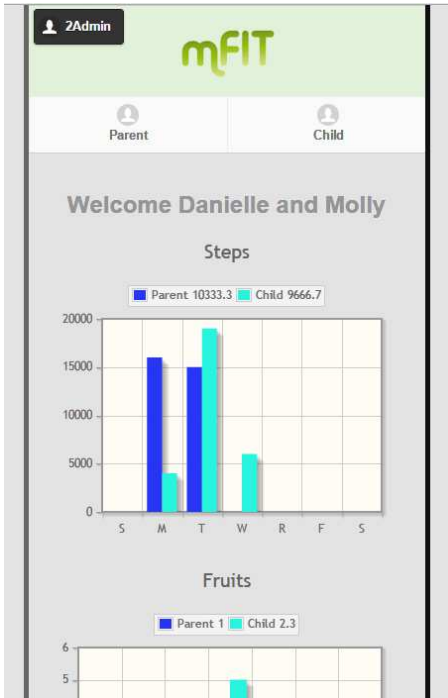
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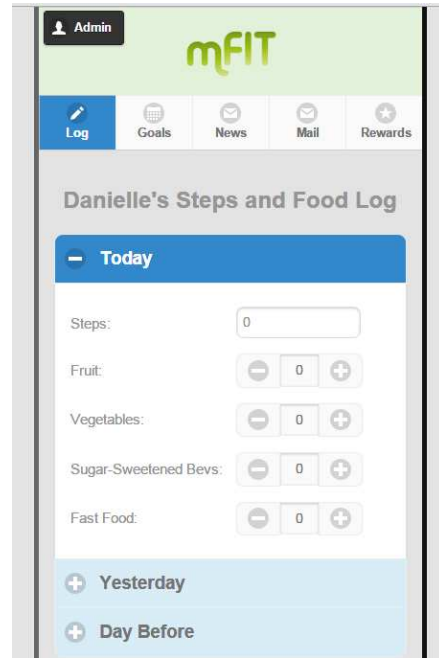




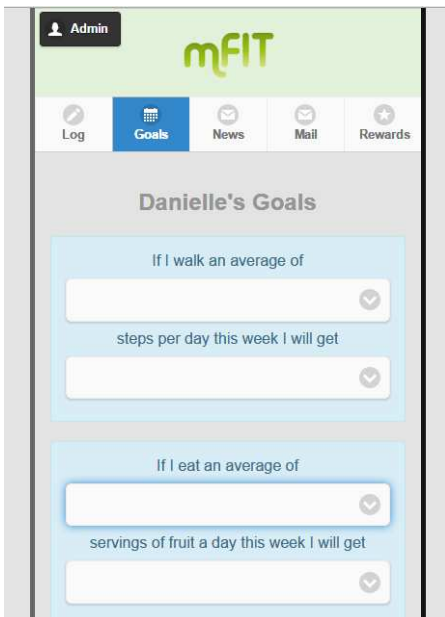
**Figure 4.1: mFIT CONSORT: Participant (Dyad) Flow**



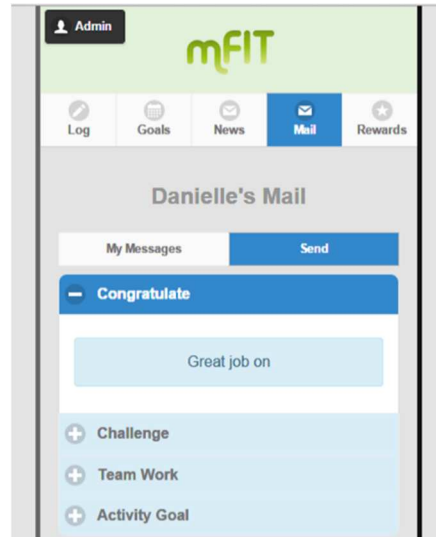
Family Comparison Graphs:



Step and Food Logs:



Weekly Goal and Reward Setting:



Family Messaging:

Figure 4.2: Screenshots of mFIT website (for example user)

**Table 4.1: Comparison of mFIT Intervention Program Components**

	<b>Tech</b>	<b>Tech+</b>
<b>Program Content</b>	<ul style="list-style-type: none"> <li>• Based on standard individual recommendations (e.g., Diabetes Prevention Program<sup>34</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>• Emphasizing family-based activities, family collaboration</li> </ul>
<b>Newsletter Framing</b>	<ul style="list-style-type: none"> <li>• Separate sections for parents and children</li> <li>• All content individually framed</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences) and Theory of Planned Behavior<sup>27</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Separate sections for parents, children, and the whole family</li> <li>• All content emphasized ways to work together and increase parent-child communication about PA and healthy eating</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences, social modeling), Family Systems Theory<sup>87</sup> (e.g., family cohesion,</li> </ul>

		problem-solving, support), and Reciprocal Family Communication <sup>24</sup> (e.g., quality and frequency of communication)
<b>Physical Activity Self-Monitoring</b>	<ul style="list-style-type: none"> <li>• ACCUSPLIT AX2720 pedometers</li> </ul>	
<b>Food and Step Logs</b>	<ul style="list-style-type: none"> <li>• Individual paper records</li> </ul>	<ul style="list-style-type: none"> <li>• mFIT website, including family comparison graphs</li> </ul>
<b>Goals and Rewards</b>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> </ul>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> <li>• Notified by mFIT website about goals met/rewards earned each week</li> </ul>
<b>Family Communication</b>	<ul style="list-style-type: none"> <li>• No content provided</li> </ul>	<ul style="list-style-type: none"> <li>• Messaging function on mFIT website for sending messages of encouragement and</li> </ul>

		support between parents and children
<b>Commercial Apps</b>	<ul style="list-style-type: none"><li>• Weekly recommendation for free PA or healthy eating app to download</li><li>• Android and iPhone versions included each week</li></ul>	

**Table 4.2: Participant Demographic Characteristics at Baseline by Condition**

	Intervention (Tech+) Mean(SD) or % (n)	Control (Tech) Mean(SD) or % (n)	Full Sample Mean(SD) or % (n)
Sample size, dyads	n=17	n=16	n=33
Parent Gender, % female	76.5 (13)	100.0 (16)	87.9 (29)
Parent Age, years	41 (6.1)	44 (5.4)	43 (5.8)
Parent Weight Status			
Mean BMI, kg/m <sup>2</sup>	31.4 (8.5)	30.7 (8.3)	31.1 (8.3)
% Underweight/Normal Weight, BMI<25.0 kg/m <sup>2</sup>	29.4 (5)	31.3 (5)	30.3 (10)
% Overweight, BMI 25.0- 29.9 kg/m <sup>2</sup>	17.4 (3)	12.5 (2)	15.2 (5)
% Obese, ≥30.0 kg/m <sup>2</sup>	52.7 (9)	56.3 (9)	54.5 (18)
Parent Race/Ethnicity			
% White	76.5 (13)	62.6 (10)	69.7 (23)
% Black	17.7 (3)	37.5 (6)	27.3 (9)
% Asian	5.9 (1)	0.0 (0)	3.0 (1)
% Hispanic	5.9 (1)	6.3 (1)	6.1 (2)
Parent Highest Level of Education			

% High school	12.5 (2)	0.0 (0)	6.1 (2)
% Some college	12.5 (2)	29.4 (5)	21.2 (7)
% College degree	25.0 (4)	41.2 (7)	33.3 (11)
% Graduate degree	50.0 (8)	29.4 (5)	39.4 (13)
Child Gender, female	47.1 (8)	75.0 (12)	63.6 (21)
Child Age, years	11 (0.9)	11 (0.9)	11 (0.9)
Child Weight Status			
Mean percentile	74.9 (29.6)	80.5 (26.2)	77.6 (27.8)
% Underweight/Normal Weight, <85th percentile	41.2 (7)	37.5 (6)	39.9 (13)
% Overweight, 85th - <95th percentile	57.1 (4)	6.3 (1)	15.2 (5)
% Obese, ≥ 95th percentile	35.3 (6)	56.3 (9)	45.5 (15)
Child Race/Ethnicity			
% White	76.5 (13)	56.3 (9)	66.7 (22)
% Black	17.7 (3)	37.5 (6)	27.8 (9)
% Asian	5.9 (1)	6.3 (1)	6.1 (2)
% Hispanic	5.9 (1)	12.5 (2)	9.1 (3)

**Table 4.3: Mixed Model Estimates of MVPA by Parent/Child and Intervention Group**

	Model 1 Estimates: Tech			Model 1 Estimates: Tech+			Model 1 <sup>a</sup>	Model 2 <sup>b</sup>		Model 3 <sup>c</sup>		
	Baseline <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Post- Program <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Change <sup>a</sup>	Baseline <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Post- Program <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Change <sup>a</sup>	p-value for group* time* parent	p- value for group* time	p-value for parent	p-value for group	p-value for time	p-value for parent
Parent MVPA <sup>d</sup>	28.5 (8.2)	14.4 (20.5)	-14.1	24.5 (7.5)	19.5 (8.1)	-5.0	0.69	0.11	0.01	0.74	0.21	0.01
Child MVPA <sup>d</sup>	37.8 (8.2)	21.2 (10.1)	-16.6	34.1 (7.7)	38.0 (7.7)	3.9						

NOTE: all models adjusted for parent race, parent education level, child gender, child age (at baseline), season

<sup>a</sup>Model 1 included three-way interaction (group\*time\*parent) and two-way interaction (group\*time)

<sup>b</sup>Model 2 included two-way interaction (group\*time)



<sup>c</sup>Model 3 included no interaction terms

<sup>d</sup>accelerometer-based moderate- to vigorous-intensity physical activity (MVPA)

**Table 4.4: Mixed Model Estimates of Average Steps from Self-Monitoring Logs by Parent/Child and Intervention Group**

	Model 1 Estimates: Tech			Model 1 Estimates: Tech+			Model 1 <sup>a</sup>	Model 2 <sup>b</sup>		Model 3 <sup>c</sup>		
	Week 1 <i>LS Mean</i> ( <i>SE</i> ) <sup>a</sup>	Week 12 <i>LS Mean</i> ( <i>SE</i> ) <sup>a</sup>	Change <sup>a</sup>	Week 1 <i>LS Mean</i> ( <i>SE</i> ) <sup>a</sup>	Week 12 <i>LS Mean</i> ( <i>SE</i> ) <sup>a</sup>	Change <sup>a</sup>	p-value for group* time* parent	p-value for group* time	p-value for parent	p-value for group	p-value for time	p-value for parent
Parent Steps <sup>d</sup>	5694 (1611)	7196 (1744)	1502	5492 (1376)	5916 (1520)	424	0.73	0.76	<0.01	0.50	0.04	<0.01
Child Steps <sup>d</sup>	10379 (1608)	11168 (1856)	789	8749 (1380)	11324 (1456)	2575						

NOTE: all models adjusted for parent race, parent education level, child gender, child age (at baseline), season

<sup>a</sup>Model 1 included three-way interaction (group\*time\*parent) and two-way interaction (group\*time)

<sup>b</sup>Model 2 included two-way interaction (group\*time)

<sup>c</sup>Model 3 included no interaction terms

<sup>d</sup>daily average from one week of self-monitoring logs

**Table 4.5: Mixed Model Estimates of Average Dietary Intake by Parent/Child and Intervention Group**

	Model 1 Estimates: Tech			Model 1 Estimates: Tech+			Model 1 <sup>a</sup>	Model 2 <sup>b</sup>			Model 3 <sup>c</sup>	
	Baseline <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Post- Program <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Change <sup>a</sup>	Baseline <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Post- Program <i>LS</i> <i>Mean</i> <i>(SE)<sup>a</sup></i>	Change <sup>a</sup>	p-value for group* time* parent	p- value for group* time	p-value for parent	p-value for group	p-value for time	p-value for parent
Parent Veg <sup>d</sup>	2.5 (0.5)	2.6 (0.5)	0.1	2.5 (0.5)	2.6 (0.5)	0.1	0.53	0.71	0.0008	0.89	0.49	<0.01
Child Veg <sup>d</sup>	1.7 (0.5)	1.5 (0.5)	-0.2	1.7 (0.5)	1.2 (0.5)	-0.5						
Parent Fruit <sup>d</sup>	1.7 (0.5)	2.4 (0.5)	0.7	2.2 (0.5)	2.6 (0.5)	0.4	0.28	0.12	0.04	0.53	0.02	0.04
Child Fruit <sup>d</sup>	1.4 (0.5)	1.8 (0.5)	0.4	1.8 (0.5)	1.6 (0.5)	-0.2						

Parent SSB <sup>d,e</sup>	0.7 (0.3)	0.3 (0.3)	0.4	0.3 (0.3)	0.1 (0.3)	-0.2	0.81	0.17	0.25	0.41	0.05	0.25
Child SSB <sup>d,e</sup>	0.3 (0.3)	-0.0 (0.3)	-0.3	0.1 (0.3)	0.1 (0.3)	0.0						
Parent FF <sup>d,f</sup>	1.4 (0.5)	1.1 (0.4)	-0.3	1.1 (0.4)	1.3 (0.4)	0.2	0.94	0.16	0.96	0.65	0.54	0.97
Child FF <sup>d,f</sup>	1.5 (0.5)	1.2 (0.5)	-0.3	1.1 (0.4)	1.1 (0.4)	0.0						

82 NOTE: all models adjusted for parent race, parent education level, child gender, child age (at baseline), season

<sup>a</sup>Model 1 included three-way interaction (group\*time\*parent) and two-way interaction (group\*time)

<sup>b</sup>Model 2 included two-way interaction (group\*time)

<sup>c</sup>Model 3 included no interaction terms

<sup>d</sup>daily average from web-based questionnaires

<sup>e</sup>sugar-sweetened beverages (SSBs)

<sup>f</sup>fast food (FF)

All in the Family: Parent-Child Dynamics and Family Communication During the  
mFIT (Motivating Families with Interactive Technology) Study<sup>2</sup>

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<sup>2</sup> Schofman D.E., Turner-McGrievy G., Wilcox S., Hussey J.R., Moore J.B., Kazcynski A.T.. To be submitted to *Childhood Obesity*.

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## **Abstract**

### **Background**

Parent-child communication and relationship quality are predictors of the adoption and maintenance of health behaviors in childhood; however, the impact of targeting these factors on health behaviors is unknown.

### **Methods**

Parent-child (child age 9-12 years) dyads enrolled in a 12-week mobile intervention to increase physical activity and healthy eating, which included weekly email newsletters and the use of pedometers. Families were randomly assigned to one of two family-based programs, one of which utilized a mobile website and program materials that emphasized the importance of family interactions for health behavior changes. At baseline and 12 weeks, height and weight were measured by research staff, and participants completed questionnaires including validated measures of family communication, engagement, closeness, and cohesion. A dyad-level measure of each of the four family function indicators (three-way interaction between time X parent X family dynamic variable) was used in multilevel models to examine associations with changes in average daily steps during the intervention.



## Results

Thirty-three families were randomized (parents: 43+6 years, 88% female, 70% white, BMI 31.1+8.3 kg/m<sup>2</sup>; children: 11+1 years, 64% female, 67% white, BMI 77.6+27.8 percentile) and 31 (93.9%) had complete follow-up data. Overall, family functioning indicators were all high at baseline and most did not change significantly over time. None of the three-way interaction terms were significant predictors of steps during the intervention.

## Conclusions

Families in the present study had high scores on family functioning variables at baseline, from both parent and child perspectives. Further research is needed with a sample that has lower parent-child relationship and communication scores at baseline.

## Introduction

There is a growing consensus that family-based research holds promise for obesity prevention and treatment research.<sup>1-3</sup> Recently more studies have begun to utilize Family Systems Theory,<sup>4</sup> a theoretical framework that emphasizes the interconnectedness of the family dynamics and the importance of addressing the entire “system” of a family in order to impact meaningful changes. Many of these interventions have been successful in promoting healthy behaviors associated with the prevention and treatment of obesity by focusing on

elements of a warm, cohesive family environment, and parenting styles that promote positivity and structured but flexible rules (i.e., authoritative parenting).<sup>5,6</sup>

One important element of promoting a healthy family environment is the quality and quantity of parent-child communication. Positive family communication has been linked with higher rates of physical activity (PA)<sup>7</sup>, less time in sedentary behaviors<sup>8</sup>, and reduced health risk factors.<sup>9,10</sup> Additionally, overall positive relationships with parents have been associated with more PA and lower participation in risk behaviors (e.g., tobacco usage).<sup>7,11</sup>

Researchers have also begun to investigate and model the ways in which parent-child communication are truly reciprocal; that is that each party is exchanging ideas and exerting influence on the other.<sup>12,13</sup> Reciprocal communication describes parent-child interactions in the context of their present relationship, past interactions, and future interactions.<sup>12</sup> Therefore, it moves beyond the way that parenting interventions have focused almost solely on the methods through which parents deliver information and support to children, and interventions that focus solely on child disposition and reception to information.<sup>12-14</sup> Learning to view both of these components in a dynamic and interactive system is crucial to the advancement of family-based health promotion. However, measurement of this interaction has proven difficult and little work has been completed to advance this area of research.<sup>12-14</sup>

Additionally, little is known about the impact of parent-child relationship quality from the parent perspective, and whether parent perceptions of relationship quality and communication with their children can also impact their

own health behaviors. One arm of the present randomized intervention was informed by Family Systems Theory<sup>15</sup> Reciprocal Family Communication<sup>12</sup> designed to increase the quantity and quality of parent-child communication about health behaviors (here PA and healthy eating), while measuring parent-child relationship variables from the parent and child perspective. In the present analysis, we aimed to first examine if participation in a family-based intervention led to changes in parent-child relationship and communication factors, and second, if the higher levels of family functioning were associated with more average daily steps.

## **Methods**

Data for the present analysis come from the Motivating Families with Interactive Technology (mFIT) study, described elsewhere in detail.

### *Subjects*

Parent-child dyads were eligible to participate if the parent was not sufficiently physically active at baseline (assessed by Behavioral Risk Factor Surveillance System (BRFSS) 2013 questions), the parent owned a smartphone or tablet and had internet access at home, and the child was between 9 and 12 years old at baseline. Other criteria included: dyad must live in same household, both must be free of major chronic disease (e.g., heart disease, cancer, diabetes), free of eating disorders, and not currently participating in a weight loss

program or taking weight loss medications. Human subjects' approval was obtained from the institutional review board at [removed for blind review].

### *Recruitment*

Parent-child dyads were recruited from the community via a range of methods including posted flyers, announcements on email listservs, and direct mail postcards. All recruitment materials also encouraged people to pass on the study information to friends and family who might be interested in participating, to encourage spread by word of mouth.

### *Procedures*

All recruitment materials and communications directed interested parents to complete a web-based eligibility questionnaire. Parents answered a series of screening questions about themselves and the child with whom they wished to enroll and participate. Study staff followed up with participants via phone and email where needed to clarify responses and determine eligibility. Parents in eligible dyads were contacted to schedule an in-person orientation session at the university research center; parents and the child with whom they would participate were required to attend together. After signing up to attend one of the in-person orientation sessions, parents were emailed further information about the mFIT study, including details about the time commitment involved in participating, expectations for study visits and questionnaires, and information about the self-monitoring required during the study (e.g., logging steps daily).

They were also emailed a copy of the informed consent and assent form for review with their child before the orientation session.

Interactive in-person orientation sessions lasted approximately one hour and included a presentation about the mFIT study, including the background of the research team, scientific rationale for the study, and details about the expectations for participants. At the end of the session, dyads had the chance to speak privately with the PI about remaining questions, as well as sign and turn in their informed consent/assent forms if they chose. Dyads were also given the opportunity to return the forms at a later time.

After submitting informed consent, dyads sent links to online questionnaires to complete at home (parents and children had separate questionnaires). Upon completing their online questionnaires, dyads were randomized to one of two groups and scheduled to attend an in-person information session about their program. At this visit, dyads also had their heights and weights taken by research staff using standard protocols; measurement staff were blinded to participant group assignment. After having height and weight taken, group assignment was revealed to dyads, they received a pedometer, and learned about their program and the general behavioral goals of the mFIT program (e.g., steps and servings of vegetables).

After the 12-week intervention, dyads returned to the university research center to have their height and weight measured, answer questionnaires about their impressions of the study and the commercial apps they tested, and receive accelerometers to wear for one week (along with their pedometers). After the

post-program visit, dyads were emailed a final set of online questionnaires to complete. Upon completion of the online questionnaires, dyads returned briefly to pick up a gift card incentive for the child.

### *Intervention Programs*

The present study tested the effectiveness of two family-based theory-informed health promotion programs: the Tech program and the Tech+ program (see Table 4.6 for detailed comparison of programs and theoretical basis for materials). Intervention materials for both groups were informed by Social Cognitive Theory<sup>16</sup> and the Theory of Planned behavior,<sup>17</sup> and offered overall information about setting small attainable goals, identifying and overcoming obstacles to behavior change, and encouraging a shift in attitudes towards PA and healthy eating in the family unit. Materials in the Tech+ program also incorporated elements of Family Systems Theory<sup>15</sup> and conceptualizes parent-child relationships in the context of reciprocal interactions.<sup>12</sup>

Dyads in both programs received a weekly email newsletter, were asked to wear a study-provided pedometer (ACCUSPLIT AX2720) daily, and were sent a link to a free, commercially available mobile app for PA and/or healthy eating to play each week. There were five main behavioral goals of the study, although in the present analysis we focus on the goal of increased steps (i.e., increase to at least 10,000/day). All participants were encouraged to self-monitor their progress toward study goals daily as well as to set weekly goals for incremental progress and to set rewards for reaching those goals. Study materials emphasized the

need to set healthy rewards for healthy goals, such as earning a trip to the park or a new book, as opposed to earning sweets or large amounts of screen time.

Materials in the Tech program emphasized standard obesity prevention and treatment messages (e.g., Diabetes Prevention Program; Centers for Disease Control and Prevention; *Let's Move!* campaign; *We Can!* campaign).<sup>18-21</sup> Dyads randomized to the Tech program were asked to self-monitor via study-provided paper logs. Content in the Tech intervention was delivered to parents (top-down approach).

Materials in the Tech+ program were informed by Family Systems Theory<sup>15</sup> (e.g., family cohesion, problem-solving, support), and Reciprocal Family Communication<sup>12</sup> and designed to encourage interaction within dyads, including increased frequency and quality of communication about health behaviors. Content in the Tech+ program focused on creating opportunities for parent-child communication about PA and HE, as well as encouraging family activities (e.g., cooking together, exercising as a family). Dyads randomized to the Tech+ were asked to self-monitor using a mobile responsive design website made for the mFIT study. The Tech+ mobile website was developed with input from parent-child dyads from formative research, and included features such as a single log-in for each family (parents and children could toggle to their information from within the same username/password), side-by-side graphs to show the daily progress of parents and children toward study goals, and a messaging feature where parents and children could send messages of support and encouragement to one another to help reinforce behavioral goals. Additionally, the Tech+

intervention materials and website included sections directed to parents, separate sections for children, and a section for the family, to encourage collaboration.

### *Measures*

Demographics. Demographic questions included standard questions for measuring: age, race/ethnicity, grade level in school or on summer vacation (child), highest level of educational attainment (parent).

Family cohesion. Family cohesion was measured with 9 questions about a range of family norms (e.g., “There is a feeling of togetherness in our family”).<sup>22</sup> Dichotomous response choices included: “Mostly False” and “Mostly True.” The scale has been shown to have adequate internal consistency reliability and stability over time as well as good content and face validity.<sup>22</sup>

Parent-child communication, family engagement, and family closeness. Scales measuring parent-child communication, parental engagement, and family engagement were administered to parents and children. The measures are from the surveys used in the National Longitudinal Study of Adolescent Health (Add Health), and have been used previously to analyze parent-child relationship quality in relation to health behaviors.<sup>7,23,24</sup> The measures ask about typical interactions over the past 4 weeks, and includes 3 questions about parent-child communication, 6 questions about parental engagement, and 2 questions about family closeness.



Physical activity, self-monitoring. During the 12-week intervention, parents and children monitored their daily steps (as measured by their pedometer); Tech families monitored on paper logs, Tech+ families monitored on the mFIT website. Average daily step counts from self-monitoring logs in weeks 1 and 12 (final) of the intervention were analyzed for changes in PA during the intervention. An average steps per day was calculated for each week for participants who self-monitored for at least 3 days during that week.

mFIT Website Messages. The mFIT website offered four types of messages that parents and children could send to each other, each about either PA or healthy eating topics: congratulations on doing well with a goal; encouragement to “pick up the pace” and do more towards a goal (e.g., get more steps); a suggestion of a team goal to help each other reach a goal (e.g., set our step goals together next week); and a suggestion for a joint activity to go together to reach goals (e.g., go to a new park together). Families were encouraged to send a minimum of two messages per week to each other. Messaging information from the mFIT website was downloaded and analyzed to categorized the frequency and type of messages sent.

### *Statistical Analyses*

All analyses were conducted with SAS version 9.4 (Cary, NC) and findings at  $p < .05$  were considered significant. Descriptive statistics were calculated for parents and children. Change in parent-child relationship quality and communication variables during the intervention were examined with t-tests for

parents and children separately. A composite score of the dyad-level of each family dynamic was calculated as the mean score of parent and child at post-program.

Linear mixed effects models (PROC MIXED) were used to examine the impact of each of the four family dynamics variables on average daily steps during the intervention. The mixed effects models allow for missing data for outcomes. A covariance structure was used that allows for three types of correlation: the covariance between repeated measures on an individual, covariance between measures on members of a dyad at the same timepoint, and covariance between measures on members of a dyad at different timepoints (e.g., parent steps at baseline and child steps at post-program). Fixed effects were included for time (baseline, post-program), intervention group (Tech, Tech+), a group x time interaction, a family dynamic x time interaction, and a three-way interaction between family dynamic x time x parent, to estimate whether the pattern of family dynamic x time change differed between parents and children. Subsequent models tested a two-way interaction between family dynamic X time and then just family dynamic. All models controlled for child gender, child baseline age (years), parent race, parent educational attainment (college graduate and above versus all others), and season of measurement (summer or schoolyear).

In order to more directly interpret the interaction term for different levels of time (Week 1 vs. Week 12) and parent (parent vs. child), contrasts were computed between time and parent at high (75<sup>th</sup> percentile) and low (25<sup>th</sup>

percentile) values of the dyad-level family dynamics variables. The statistical significance of the change as well as Week 1 and Week 12 LSMEANS within each level of family dynamics stratum are presented.

## Results

A total of 33 dyads were enrolled and randomized to the Tech (n=16 dyads) or Tech+ (n=17 dyads) group; 31 dyads (94%) returned for post-program assessment visits. The flow of participants through the recruitment and intervention periods is shown in Figure 4.3. As shown in Table 4.7, on average parents were female (87.9%), 43±5.8 years old, obese (BMI: 31.1±8.3kg/m<sup>2</sup>), college graduates (72.7%), and White (69.7%). On average, children were female (63.6%), 11±0.9 years old, normal weight (BMI percentile 77.6±27.8), and White (66.7%). Although parents and children of all body weights were eligible to participate, over 70% of parents and over 60% of children were overweight or obese at baseline. Overall, parents and children significantly increased their average daily steps during the mFIT study (no significant differences between groups; data not shown).

There was limited use of the messaging feature on the mFIT website, limiting our ability to use it as a predictor of change within the Tech+ group. Within the Tech+ program, 25/34 individuals (comprising n=17 dyads) sent at least one message, the mean messages sent was 6.2±4.4 (range 1.0-20.0; data not shown) for a total of 155 messages sent. Of these messages, 66 were congratulations for doing well with steps or a healthy eating goal, 33 were

encouragement to “pick up the pace”, 31 were suggestions for activities to do together, and 25 were suggestions for setting a joint goal for an area. About half of the messages (54%, n=84) were about PA and the others (46%, n=71) were about healthy eating.

Baseline unadjusted means for all measures of parent-child communication and engagement were high and most did not change significantly during the 12-week intervention (see Table 4.8). One exception was a significant decrease in family closeness for Tech+ children ( $p=0.03$ ) (although Tech children also decreased in family closeness though it was not significant). Therefore, we compared post-program unadjusted means between groups for all family measures and found no significant differences (see Table 4.8). Therefore, subsequent analyses controlled for group but did not specifically examine between-group differences), and all models used a combined dyad-level variable using post-program means for the family measures (see Table 4.8).

Overall, none of the three-way interactions between family dynamics variables X parent X time were significant (see Table 4.9), meaning that none of the family dynamics variables significantly impacted the change in average daily steps over time for parents or children. One contrast change was significant, where children with a high dyad-level score for engagement had a significant change in steps over time ( $p=0.01$ ), indicating that for this subgroup (children, high rating of family engagement), there was a significant relationship between engagement and steps during the intervention. Additionally, none of the two-way

interactions between family dynamics variables and time, or the family dynamics variables in models without the interaction terms were significant.

## **Discussion**

The present study examined parent-child relationship and communication factors to examine first if participation in a family-based intervention leads to changes in these factors, and second, if the higher levels of family functioning were associated with more average daily steps. Baseline levels of the parent-child relationship and communication factors were high in both the Tech and Tech+ groups and did not change significantly during the intervention, with the exception of a decrease in family closeness for Tech+ children. There were also no significant relationships between any of the family dynamics variables at the dyad level and average daily steps during the 12-week intervention.

One contributing factor to the results of the present study was that at baseline, the families already reported high scores on general parent-child relationship quality as measured by family cohesion, closeness, engagement, and parent-child communication. While we might have expected that families could be higher on these measures than the average family, by virtue of them being willing to enter the study, scores for both parents and children were higher with less variability than expected. In fact, the present sample reported much higher scores on the parent-child communication and engagement scores than other samples, such as the nationally representative survey where the questions were derived from.<sup>7</sup> In the Add Health sample, researchers found that the same

communication and engagement scores were predictive of moderate- to vigorous-intensity PA.<sup>7</sup> Perhaps using the mFIT materials and techniques (especially from the Tech+ group) in a sample with more variation of relationship quality at baseline would have yielded more robust change and relationship to PA than what was seen in the present study.

Another contributing factor to the lack of significant findings might have been the strength of the materials and intervention elements targeting parent-child communication and relationship quality. Based on pilot research, the mFIT website was built to streamline family logging of health behaviors (e.g., steps) and also make it easier to keep track of the family member's progress through side-by-side progress graphs. Unfortunately, the website analytics did not allow us to analyze the number of times participants viewed views these joint graphs or how use of this feature related to use of other website features, limiting our ability to assess the impact of the graphs on logging and family support. Additionally, despite study recommendations to send each other at least two messages per week, parents and children rarely utilized this feature of the mFIT website (average of 6 messages over the 12 weeks). Future research could use a more sophisticated messaging platform that pushes the messages to the recipient in real time to see if this can lead to greater engagement with the messaging tool and a subsequently greater impact on perceptions of communication and relationship quality. It is possible that despite the efforts of the Tech+ program to increase parent-child communication and team work, families did not end up

interacting as much as intended and the materials in both the Tech and Tech+ groups were used more for an individual than family-based approach.

The mFIT study also adds to a growing conversation about the most effective areas of the parent-child relationship to target in health promotion efforts. The debate centers around whether it is most effective to target general parenting and relationship quality within the scope of health promotion interventions, or whether we should target more specific parenting to the health behaviors themselves (e.g., modeling of PA and healthy eating).<sup>14</sup> Given that the families that entered the mFIT study tended to have high levels of general relationship quality and communication at baseline, future research might have more of an impact with this population if it focuses on developing family interaction skills that are specific to health practices.

Additionally, the mFIT study draws attention to the need for more precise and domain-specific measures of family functioning in the context of specific health behaviors. A recent family-based study for adolescent health behavior changes developed a new set of communication measures specific to PA and healthy eating, although these were only measured from the parent perspective.<sup>8</sup> Given a need to better understand and measure the true reciprocal nature of communication and relationship quality, we believe that measures are needed that are not only specific to health behaviors but also allow for responses from both the parent and child perspective. It is likely that the measurement tools used in the present study were not able to truly measure the motivation and encouragement that was experienced both by parents and children from their

family partner within the mFIT study. Further, qualitative research might be an effective means of gathering more information to inform future research on the complex interactions between parents and children.

This study has several other limitations. First, the sample size was relatively small and this limits the generalizability of the findings. Second, the analysis relies on self-reported pedometer steps which could be subject to recall or other biases. Third, the study does not represent a diverse mixture of parent and child genders (majority mothers and daughters) and it is possible that there could be different parent-child factors at play in a sample of different gender composition.

## **Conclusion**

Parent-child communication and relationship quality have been found to influence health behaviors for the child, resulting in protection against unhealthy behaviors and support of the establishment of healthy behaviors.<sup>7-11</sup> While the materials in the present intervention targeting parent-child communication and relationship quality did not appear to impact PA, important insights were learned about the characteristics of the study sample and the need for more testing more targeted intervention materials.



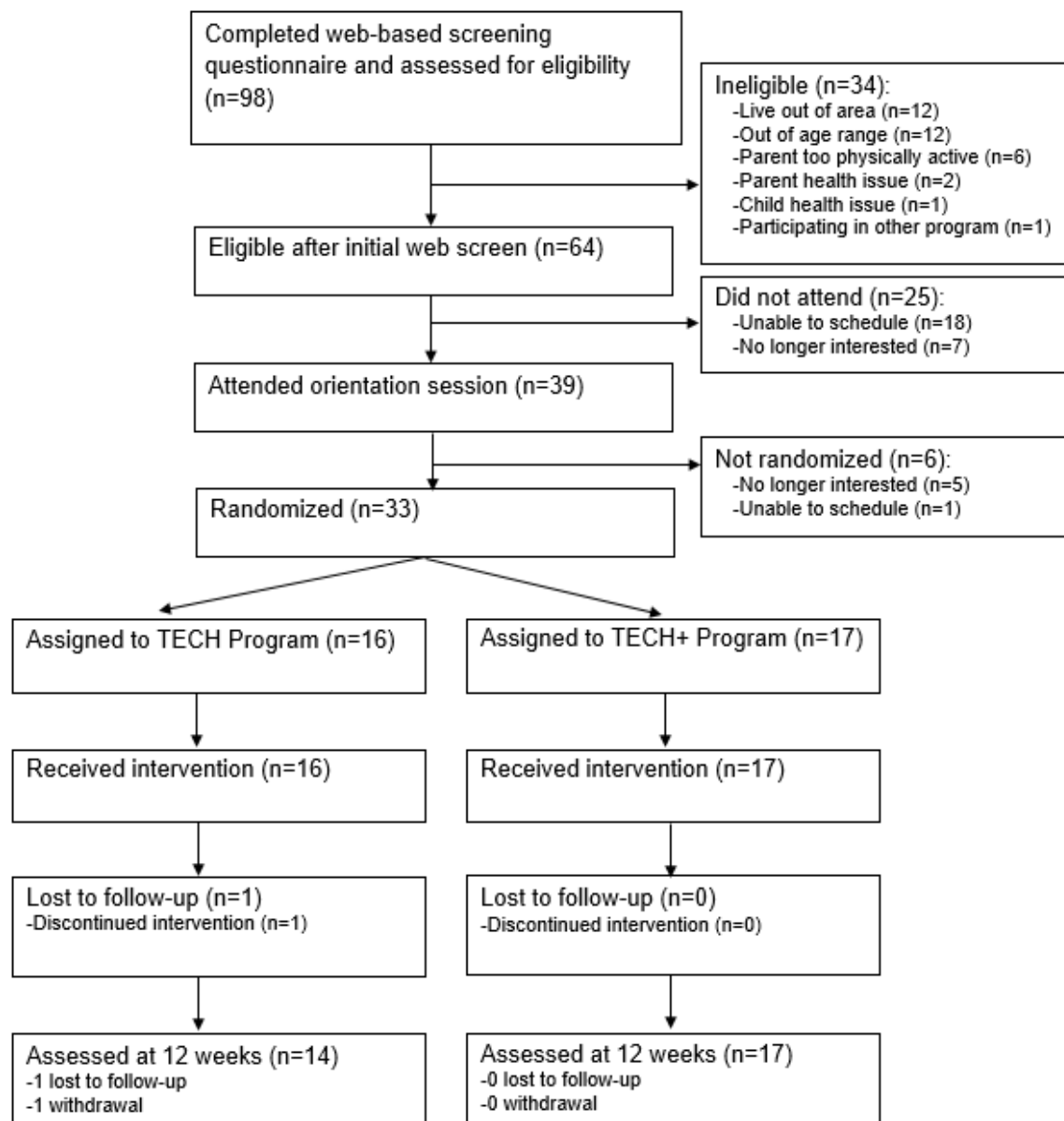
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**Figure 4.3: mFIT CONSORT: Participant (Dyad) Flow**

**Table 4.6: Comparison of mFIT Intervention Program Components**

	<b>Tech</b>	<b>Tech+</b>
<b>Program Content</b>	<ul style="list-style-type: none"> <li>• Based on standard individual recommendations</li> </ul>	<ul style="list-style-type: none"> <li>• Emphasizing family-based activities, family collaboration</li> </ul>
<b>Newsletter Framing</b>	<ul style="list-style-type: none"> <li>• Separate sections for parents and children</li> <li>• All content individually framed</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences) and Theory of Planned Behavior<sup>27</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Separate sections for parents, children, and the whole family</li> <li>• All content emphasized ways to work together and increase parent-child communication about PA and healthy eating</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences, social modeling), Family Systems Theory<sup>87</sup> (e.g., family cohesion, problem-solving,</li> </ul>

		support), and Reciprocal Family Communication <sup>24</sup> (e.g., quality and frequency of communication)
<b>Physical Activity Self-Monitoring</b>	<ul style="list-style-type: none"> <li>• ACCUSPLIT AX2720 pedometers</li> </ul>	
<b>Food and Step Logs</b>	<ul style="list-style-type: none"> <li>• Individual paper records</li> </ul>	<ul style="list-style-type: none"> <li>• mFIT website, including family comparison graphs</li> </ul>
<b>Goals and Rewards</b>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> </ul>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> <li>• Notified by mFIT website about goals met/rewards earned each week</li> </ul>
<b>Family Communication</b>	<ul style="list-style-type: none"> <li>• No content provided</li> </ul>	<ul style="list-style-type: none"> <li>• Messaging function on mFIT website for sending messages of encouragement and</li> </ul>

		support between parents and children
<b>Commercial Apps</b>	<ul style="list-style-type: none"><li>• Weekly recommendation for free PA or healthy eating app to download</li><li>• Android and iPhone versions included each week</li></ul>	



**Table 4.7: Participant Demographic Characteristics at Baseline by Condition**

	Intervention (Tech+) Mean(SD) or % (n)	Control (Tech) Mean(SD) or % (n)	Full Sample Mean(SD) or % (n)
Sample size, dyads	n=17	n=16	n=33
Parent Gender, % female	76.5 (13)	100.0 (16)	87.9 (29)
Parent Age, years	41 (6.1)	44 (5.4)	43 (5.8)
Parent Weight Status			
Mean BMI, kg/m <sup>2</sup>	31.4 (8.5)	30.7 (8.3)	31.1 (8.3)
% Underweight/Normal Weight, BMI<25.0 kg/m <sup>2</sup>	29.4 (5)	31.3 (5)	30.3 (10)
% Overweight, BMI 25.0- 29.9 kg/m <sup>2</sup>	17.4 (3)	12.5 (2)	15.2 (5)
% Obese, ≥30.0 kg/m <sup>2</sup>	52.7 (9)	56.3 (9)	54.5 (18)
Parent Race/Ethnicity			
% White	76.5 (13)	62.6 (10)	69.7 (23)
% Black	17.7 (3)	37.5 (6)	27.3 (9)
% Asian	5.9 (1)	0.0 (0)	3.0 (1)
% Hispanic	5.9 (1)	6.3 (1)	6.1 (2)
Parent Highest Level of Education			

% High school	12.5 (2)	0.0 (0)	6.1 (2)
% Some college	12.5 (2)	29.4 (5)	21.2 (7)
% College degree	25.0 (4)	41.2 (7)	33.3 (11)
% Graduate degree	50.0 (8)	29.4 (5)	39.4 (13)
Child Gender, female	47.1 (8)	75.0 (12)	63.6 (21)
Child Age, years	11 (0.9)	11 (0.9)	11 (0.9)
Child Weight Status			
Mean percentile	74.9 (29.6)	80.5 (26.2)	77.6 (27.8)
% Underweight/Normal Weight, <85th percentile	41.2 (7)	37.5 (6)	39.9 (13)
% Overweight, 85th - <95th percentile	57.1 (4)	6.3 (1)	15.2 (5)
% Obese, ≥ 95th percentile	35.3 (6)	56.3 (9)	45.5 (15)
Child Race/Ethnicity			
% White	76.5 (13)	56.3 (9)	66.7 (22)
% Black	17.7 (3)	37.5 (6)	27.8 (9)
% Asian	5.9 (1)	6.3 (1)	6.1 (2)
% Hispanic	5.9 (1)	12.5 (2)	9.1 (3)

**Table 4.8: Unadjusted Means of Family Functioning Variables at Pre- and Post-Intervention by Group and Parent/Child**

	Intervention (Tech+)			Control (Tech)			Difference between groups (Post)	Dyad Combined <sup>d</sup>
	Pre	Post	t (p) <sup>a</sup>	Pre	Post	t (p) <sup>b</sup>	t (p) <sup>c</sup>	Post
Family Engagement, Parent	4.59 (0.80)	4.82 (1.01)	0.81 (0.43)	4.38 (0.96)	4.64 (1.22)	1.24 (0.24)	-0.45 (0.66)	8.39 (3.08)
Family Engagement, Child	4.00 (1.17)	4.18 (1.38)	0.51 (0.62)	4.13 (1.20)	4.29 (1.82)	0.25 (0.81)	0.19 (0.85)	
Family Cohesion, Parent	5.41 (1.28)	5.53 (1.50)	0.34 (0.74)	5.38 (1.36)	5.29 (1.20)	-0.20 (0.84)	-0.49 (0.63)	11.19 (2.06)
Family Cohesion, Child	5.12 (1.73)	5.76 (1.09)	1.78 (0.09)	5.06 (1.48)	5.71 (1.20)	1.39 (0.19)	-0.12 (0.90)	
Family Closeness, Parent	9.53 (1.07)	9.47 (0.94)	-0.37 (0.72)	9.44 (0.81)	9.42 (0.85)	0.00 (1.00)	-0.13 (0.90)	18.68 (1.45)

Family Closeness, Child	9.76 (0.44)	9.12 (1.32)	-2.39 (0.03)	9.50 (1.03)	9.36 (0.93)	-0.29 (0.78)	0.57 (0.57)	
Family Communication, Parent	2.41 (0.71)	2.53 (0.51)	1.00 (0.33)	2.63 (0.50)	2.79 (0.43)	1.38 (0.19)	1.49 (0.15)	4.32 (1.23)
Family Communication, Child	2.06 (0.75)	1.88 (0.86)	-1.14 (0.27)	1.43 (1.22)	1.43 (1.22)	-0.37 (0.72)	-1.21 (0.24)	

<sup>a</sup>t-test of change in unadjusted means of family variables from pre- to post-intervention for Tech+

<sup>b</sup>t-test of change in unadjusted means of family variables from pre- to post-intervention for Tech

<sup>c</sup>t-test of difference in between-group unadjusted means of family variables at post-intervention

<sup>d</sup>unadjusted means of combined dyad-level variable for each of the family dynamics indicators (sum of parent and child values at post-program)

**Table 4.9: Mixed Model Estimates of Average Daily Steps by Parent/Child and Dyad Level of Family Dynamics Variable<sup>a</sup>**

	Parents				Children						
	Week 1 LS Mean (SE) <sup>b</sup>	Week 12 LS Mean (SE) <sup>b</sup>	Change <sup>b</sup>	t (P) for diff (0-12 wk) <sup>b</sup>	Week 1 LS Mean (SE) <sup>b</sup>	Week 12 LS Mean (SE) <sup>b</sup>	Change <sup>b</sup>	t (P) for diff (0-12 wk) <sup>b</sup>	F(P) 3-Way Interaction <sup>b</sup>	F(P) 2-way Interaction <sup>c</sup>	F(P) Family Variable <sup>d</sup>
<b>Low Engagement<sup>e</sup></b>	4445 (1475)	4966 (1648)	522	-0.46 (0.64)	9091 (1492)	9746 (1594)	654	-0.63 (0.53)	0.89 (0.42)	3.60 (0.08)	1.12 (0.30)
<b>High Engagement<sup>f</sup></b>	6174 (1395)	7716 (1632)	1542	-1.10 (0.28)	8927 (1366)	13617 (1778)	4690	-2.96 (0.01)			
<b>Low Cohesion<sup>e</sup></b>	5631 (1382)	5774 (1620)	143	-0.11 (0.91)	8858 (1395)	11249 (1633)	2391	-1.90 (0.06)	0.95 (0.40)	0.01 (0.93)	0.79 (0.38)
<b>High Cohesion<sup>f</sup></b>	5602 (1447)	7077 (1576)	1475	-1.32 (0.20)	10279 (1427)	11586 (1576)	1307	-1.17 (0.25)			
<b>Low Closeness<sup>e</sup></b>	4690 (1816)	4412 (1861)	-278	0.23 (0.82)	9371 (1791)	10798 (1774)	1167	-1.22 (0.23)	1.23 (0.31)	2.23 (0.16)	0.55 (0.47)

<b>High Closeness<sup>f</sup></b>	5803 (1416)	8023 (1562)	2220	-1.82 (0.08)	9135 (1401)	11490 (1580)	2355	-1.90 (0.07)			
<b>Low Communication<sup>e</sup></b>	5431 (1467)	7426 (1533)	1995	-1.76 (0.09)	9712 (1476)	11140 (1528)	1429	-1.28 (0.21)	1.33 (0.28)	0.46 (0.51)	0.11 (0.75)
<b>High Communication<sup>f</sup></b>	5817 (1710)	4708 (1947)	-1109	0.72 (0.47)	9147 (1712)	11992 (2053)	2845	-1.75 (0.09)			

NOTE: all models adjusted for parent race, parent education level, child gender, child age (at baseline), season

<sup>a</sup>daily average from one week of self-monitoring logs

<sup>b</sup>Model 1 included three-way interaction (time\*parent\*family dynamics variable) and two-way interactions (time\*family dynamics variable, and time\*family dynamics variable)

<sup>c</sup>Model 2 included two-way interaction (time\*family dynamics variable)

<sup>d</sup>Model 3 included no interaction terms (looked at impact of family dynamics variable alone in adjusted model)

<sup>e</sup>assessed at the 25<sup>th</sup> percentile of distribution

<sup>f</sup>assessed at the 75<sup>th</sup> percentile of distribution

## Chapter 5: Conclusions and Implications

The mFIT study was a randomized study of two remotely-delivered family-based programs to promote PA and HE with parent-child dyads. The study demonstrates the feasibility and acceptability of the intervention and the remote-delivery method for this population. While the small sample size makes it difficult to infer statistically significant outcomes for all behavioral indicators examined, the findings indicate that the data are trending in the desired direction, demonstrating the potential of this kind of intervention to improve PA and HE among both parents and children. Further, the high levels of retention, participant engagement, and enthusiasm for the program overall show that it could serve as a model for future research.

While there were no significant differences between the groups in MVPA or self-monitored steps, there were increases in self-monitored steps for both groups as well as trends towards improvements in dietary intake (i.e., increased vegetables and fruits, decreased SSBs and fast food). These positive trends in health behavior changes for both parents and children suggest that some aspects of the two remotely-delivered interventions hold promise as a model for future programs. Participants had limited contact with study staff and all intervention materials (newsletters, apps) were delivered via email. The similar results overall for changes in PA and eating goals suggest that perhaps the differences between Tech and Tech+ (i.e., paper vs. online self-monitoring, focus

on individual vs. focus on family) did not significantly impact behavioral changes, or that the interventions were not sufficiently intensive to produce behavior changes. These results are similar to a recent study that tested the impact on sedentary time and PA in children when a family-based weight-gain prevention program was delivered via the internet or paper workbooks.<sup>55</sup> The results showed that there were similar (non-significant) changes in sedentary time in both groups, and the researchers concluded that the internet delivery method holds promise for future interventions to reach more children than the workbook method.<sup>55</sup>

As this study aimed to examine many new program elements and delivery methods, dietary self-monitoring was simplified to reduce participant burden. However, it is possible that monitoring diet in a more detailed manner for adults, such as tracking calories or fat grams would have yielded greater results. Additionally, future research could look at incorporating other methods of low burden dietary intervention such as the traffic light diet<sup>74,123</sup> for children using a similar mobile platform and delivery package as mFIT. Further, intake of the unhealthy food group targets was lower at baseline in the present sample than anticipated, leaving less room for significant change during the intervention.

We observed very high levels of self-monitoring with step and food logs and engagement with the study materials (measured as newsletters read) during the mFIT program. This suggests that participants enjoyed the format and delivery of the materials, which is important given that it was a low cost and low intensity intervention without face-to-face contact during the 12 weeks of the



intervention period. This is contrasted with the usual care model that has been tested many times and includes a minimum of one weekly in-person meeting with an interventionist, even in studies that are reportedly testing mobile-enhanced interventions.<sup>124,125</sup>

The modest findings of the mFIT study in terms of PA and HE trends follow trends in other remotely-delivered interventions, such as a recent review of behavior modification interventions found that Internet-delivered interventions tended to produce about two thirds of the weight change for adults as standard in-person treatments.<sup>126</sup> Thus, it is not uncommon for technology-assisted interventions to produce smaller effects than might be expected from intensive in-person programs. It will be a goal of future iterations of the mFIT study and similar programs to continue to strive for larger changes in behaviors such as steps and healthy eating.

It is also important to note the somewhat contradictory findings of steps and MVPA could signal difficulties in promoting the same PA goals for parents and children. While there was a significant increase in steps overall, there was a non-significant decrease in MVPA for all groups except Tech+ children. It is possible that promoting increased steps for children may have encouraged them to engage in less MVPA than they would have otherwise, replacing that time with walking with their parents. While the benefits of walking for adults are well documented,<sup>122</sup> less is known about promoting walking and specifically step counts for children, and future research should examine the potential impact of

such interventions in more detail (including possible replacement of more vigorous activities).

The mFIT study also examined parent-child relationship and communication factors to see first if participation in a family-based intervention lead to changes in these factors and second if the higher levels of family functioning were associated with more average daily steps. Baseline levels of the parent-child relationship and communication factors were high in both the Tech and Tech+ groups and did not change significantly during the intervention, with the exception of a decrease in family closeness for Tech+ children. There were no significant relationships between any of the family dynamics variables at the dyad level and average daily steps during the 12-week intervention.

One contributing factor to the results of the present study was that at baseline, the families already reported high scores on general parent-child relationship quality as measured by family cohesion, closeness, engagement, and parent-child communication. While we might have expected that families could be higher on these measures than the average family, by virtue of them being willing to enter the study, scores for both parents and children were higher with less variability than expected. In fact, the present sample reported much higher scores on the parent-child communication and engagement scores than other samples such as the nationally representative survey where the questions were derived from.<sup>20</sup> In the Add Health sample, researchers found that the same communication and engagement scores were predictive of moderate- to vigorous-intensity PA.<sup>20</sup> Perhaps using the mFIT materials and techniques

(especially from the Tech+ group) in a sample with more variation of relationship quality at baseline would yielded more robust change and relationship to PA than what was seen in the present study.

Another contributing factor to the lack of significant findings might have been the strength of the materials and intervention elements targeting parent-child communication and relationship quality. Based on our pilot results, we built the mFIT website to streamline family logging of health behaviors (e.g., steps) and also make it easier to keep track of the family member's progress through side-by-side progress graphs. Unfortunately, the website analytics did not allow us to analyze the number of views to these joint graphs, so their impact on logging and family support cannot be directly assessed. We also hoped that the messaging feature built into the mFIT website would help to both encourage parents and children to stay connected to each other about each other's progress, but could also provide us with more objective data about the reciprocal nature of the communication. However, despite study recommendations to send each other at least two messages per week, parents and children rarely utilized this feature of the mFIT website, with only an average of only six messages over the entire 12-week intervention. One explanation for the low use of the messaging feature is that the mFIT website could not push notifications to users and thus they had to go to that tab of the website to send and receive messages. It is possible that the extra steps involved in sending and retrieving messages may have deterred participants from using this feature and it required that they take conscious actions to engage with the feature. In the future, a few simple

additions could be made to this feature. First, more explicit reminders could be sent to families, especially in the beginning of the study when habits for the use of the website are being set, for parents and children to utilize this feature. Second, the messages were pre-populated with drop down menus of message stems and text to ensure that study-approved messages were sent and to simplify the programming of the website. It is possible that the content that was available in the messages did not resonate with some of the families, and if the messages were able to be more customizable, this could increase use of the website feature.

The mFIT study also adds to a growing conversation about the most effective areas of the parent-child relationship to target in health promotion efforts. The debate centers around whether it is most effective to target general parenting and relationship quality within the scope of health promotion interventions, or whether we should target more specific parenting to the health behaviors themselves (e.g., modeling of PA and HE).<sup>81</sup> The present study suggests that at least in the context of a family-based intervention that targeted the health behaviors of both parents and children, perhaps general relationship quality is already at a high enough level that more effort should be placed on developing skills and practices specific to health practices.

Additionally, the mFIT study draws attention to the need for more precise and domain-specific measures of family functioning in the context of specific health behaviors. A recent family-based study for adolescent health behavior changes developed a new set of communication measures specific to PA and

HE, although these were only measured from the parent perspective.<sup>73</sup> Given a need to better understand and measure the true reciprocal nature of communication and relationship quality, we believe that measures are needed that are not only specific to health behaviors, but also allow for responses from both the parent and child perspective. It is likely that the measurement tools used in the present study were not able to truly measure the motivation and encouragement that was experienced both by parents and children from their family partner within the mFIT study. Additionally, there remains immense potential for mobile technology to both facilitate and capture parent-child communication in real time, and this area merits further investigation.

Despite a small sample of randomized dyads, the mFIT study had excellent retention at the 12-week follow-up visits (94%), especially for an intervention that was entirely remotely-delivered. The high retention may be attributable to the format and content delivered of the orientation session, the weekly contact from study staff (to mail program materials), and the high engagement of participants with study materials (as evidenced by high rates of self-monitoring).

### *5.1. Limitations*

The results of the present research should be interpreted in the context of a few limitations. First, the small sample size and lack of statistical power may have limited our ability to detect significant findings. Second, the lack of racial/ethnic and gender diversity limits our ability to generalize the findings to other populations. Third, the memory issue with the accelerometry protocol limits

the validity of those data, although they are still important and can be interpreted conservatively as has been done in the present analysis. Four, the reliance on self-reported dietary intake via online questionnaire limits the precision of our measure and ability to detect changes over time. However, the self-reported questionnaire also decreased the participant burden over other methods (e.g., 24-hour recall) and this may have also aided in our high retention rates.

## *5.2. Future Research*

The results of the mFIT study suggests a few different directions for future research, including additions and changes to the intervention delivery, content, and possibly participants. In terms of delivery of the intervention, future research could use a more sophisticated messaging platform that pushes the messages to the recipient in real time to see if this can lead to greater engagement with the messaging tool and a subsequently greater impact on perceptions of communication and relationship quality. Using a an app- versus web-based system would also allow participants to receive notifications on their phones to remind them to use the self-monitoring features, as well as tell them when they had received a message from their family member. However, the benefits of an app-based delivery (as opposed to a mobile website such as the one used in mFIT) must be weighed with the costs, including monetary and time investments in the development of the app and limiting the sample to users of a particular type of device (e.g., Android users).

Additionally, there is much to be learned about using mobile technology as a measurement tool for communication, especially in capturing complex systems of communication (as with parents and children). Unlike static questionnaires assessed at pre- and post-intervention, mobile technology-based measures of communication could provide real-time data in the *context* of health behavior decisions and other important points of intervention. Other iterations of a platform similar to mFIT might also include more tools for real-time communication and conversation that could provide important insights for further assessment of reciprocal communication.

In terms of the content of the future interventions, future research might test a more intensive family-based intervention (e.g., more contact with interventionists, more extensive dietary counseling and monitoring) compared to a similar program to Tech or Tech+ to examine what (if any) factors are associated with larger dietary improvements. Additionally, content focused on parent-child relationship quality and communication could be bolstered to more explicitly target these areas, as opposed to the way it was approached more discretely in the mFIT study. Likewise, more work is needed to develop better measures to capture the reciprocal nature of the parent-child communication and motivation that occurs within the context of a family-based intervention such as mFIT.

A next iteration of the mFIT study might include enhanced features for both participant engagement and data capture. Participant engagement could include tools to request more frequent input and interaction from participants,

such as weekly check-in dialogue chats where participants report on challenges or barriers they are facing and receive some simple feedback from an interventionist. Additionally, as described above, using more push notifications could help to add contact with participants. There could also be specific weekly communication activities for parents and children where they are prompted by study materials to send each other messages about specific topics or activities. In terms of data capture, future iterations of the mFIT website could include more sophisticated logging of participant use of features, such as number of times viewing joint progress graphs, messaging, etc. Additionally, future website iterations could track participant navigation on the website in response to messages (i.e., does a note of encouragement lead to higher engagement with viewing progress and tracking?). Another useful feature would be to integrate the PA tracking devices used by participants into the mFIT website to increase accuracy and frequency of monitoring. This could also potentially allow for the tracking of PA that parents and children engage in *together*, a research area of recent interest.<sup>127,128</sup>

In terms of future study populations to work with, it would be informative to test the mFIT intervention in a (larger) sample of families with more diversity of baseline scores on the family dynamics variables of interest. Future research might focus on recruiting a sample that represents a range of baseline scores on family variables, likely including some of these measures as screening tools. Or perhaps a future study could limit enrolled to just include families that are below a certain score on the family measures.



Additionally, the general mFIT study design could be used in other populations where more than one individual is working on health behavior changes with a family member or other partner. For example, spouses or significant others could use a modified version of the mFIT website to encourage accountability and increased communication in the context of a weight loss intervention. It would also be interesting to test the mFIT platform with partner pairs where the two members do not live in the same household. Perhaps the communication tools and open sharing of information in terms of goal attainment would be more impactful where daily casual conversation is less likely to occur outside the context of the website (e.g., chatting at the kitchen table about progress).

### *5.3. Conclusions*

The mFIT study tested two low-cost, low-burden remotely delivered family interventions, and results of the two programs showed similarly promising increases in pedometer-measured steps and modest dietary improvements. Overall, the results of the mFIT program demonstrate promise in the area of remotely-delivered family-based programs, a cost-effective and disseminable model for public health interventions.

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## Appendix A: ECPOP Recommended Strategies and Behavioral Targets for Pediatric Obesity Treatment

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### Strategies for Pediatric Obesity Treatment<sup>a</sup>

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Calculate / plot BMI over time

Assess motivation to make changes

Use motivational interviewing to help create and sustain behavior changes

Tailor strategies and timing of interventions to the specific case (depending on child's weigh status)

Set goals/limits (e.g., screen time limits)

Need to focus beyond individual behaviors to look at environmental influences

Involve the whole family

Combine multiple behavior changes for larger impact (e.g., physical activity and diet)

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### Behavioral Targets for Pediatric Obesity Treatment<sup>a</sup>

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Reduce sugar-sweetened beverages with goal of completely eliminating

Consume  $\geq 9$  servings of fruits and vegetables every day

Decrease TV time to  $< 2$  h/d

Eat breakfast every day

Prepare more meals at home instead of purchasing restaurant food

Eat meals at the table together as a family

Be physically active for >1 h/d

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<sup>a</sup>Recommendations from: Barlow SE. 2007. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity- summary report.<sup>9</sup>

## Appendix B: Examples of Application of Theoretical Model to mFIT Intervention Elements

Guiding Theory	Construct	Intervention Element Addressing Theory	Example
Family Systems Theory <sup>87</sup>	Communication	Communication tools built into mobile website; study activities to encourage communication and feedback	Feedback graphs showing progress of parent and child displayed side-by-side on website to allow for quick review of each other's progress; tools provided to "push" messages of congratulations or encouragement to other member of dyad
	Cohesion	Study activities designed for dyad to complete together; setting and working towards family goals	Physical activity challenges to take as a dyad (e.g., scavenger hunt activity at local park); setting step goals to achieve together as a family; encouragement of eating dinner and

			other meals together as a family
	Problem-solving	Progress reports and activities to evaluate progress, identify barriers to success, and troubleshoot for the future	Mid-study progress report; families will discuss their progress, goals, and rewards to date, then discuss new goals moving forward
	Support	Support from dyad, participating in all intervention activities as a team; communication tools built into mobile website	Tools provided to “push” messages of congratulations or encouragement to other member of dyad
Self-Efficacy (Social Cognitive Theory) <sup>26</sup>	Mastery experiences	Setting small, attainable goals	Weekly goal setting for steps and dietary targets of study
	Social modeling	Working in dyadic teams towards individual goals (and family goals)	Monitoring progress of each individual on the mobile website and acknowledging each other’s progress
	Social persuasion	Support from dyadic team	Ability to “push” messages and encouragement between parent and child on the mobile website



Reciprocal parent-child communication <sup>24</sup>	Quality and frequency of communication	Use of mobile website and structure for regular communication about health behavior goals between dyad	Schedule of brief daily check-ins to log progress toward behavior goals; weekly goal and reward setting together as a dyad; ability to “push” messages and encouragement between parent and child on the mobile website
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## Appendix C: Sample mFIT Recruitment Flyer



UNIVERSITY OF  
**SOUTH CAROLINA**  
Arnold School of Public Health



**Interested in learning about using smartphone apps to help your family get more physical activity and eat healthier?**

Researchers in the Arnold School of Public Health at the University of South Carolina seek healthy parent/guardians and children (9-12 years old) for a research study to find out how apps and monitoring devices can help support families in getting more physical activity and eating healthy.

One parent/guardian and one child from each family will enroll in the 3-month study, which will include 2 brief assessment visits and testing apps and physical activity monitors.

Parents/guardians must have a web-enabled phone or tablet, and parent/guardians and children must be willing and able to participate in physical activity. There is no charge for the program, and children will receive a small gift card incentive for their time.

To determine if you are eligible to participate, please visit [mobilefamilyresearch.com](http://mobilefamilyresearch.com) to take a brief screening questionnaire. You can also contact the study staff at [mobilefamilyresearch@gmail.com](mailto:mobilefamilyresearch@gmail.com) with questions.



## Appendix D: Comparison of Tech and Tech+ Programs

	Tech	Tech+
<b>Program Content</b>	<ul style="list-style-type: none"> <li>• Based on standard individual recommendations (e.g., Diabetes Prevention Program<sup>34</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>• Emphasizing family-based activities, family collaboration</li> </ul>
<b>Newsletter Framing</b>	<ul style="list-style-type: none"> <li>• Separate sections for parents and children</li> <li>• All content individually framed</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences) and Theory of Planned Behavior<sup>27</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Separate sections for parents, children, and the whole family</li> <li>• All content emphasized ways to work together and increase parent-child communication about PA and healthy eating</li> <li>• Guided by Social Cognitive Theory<sup>26</sup> (e.g., mastery experiences,</li> </ul>

		social modeling), Family Systems Theory <sup>87</sup> (e.g., family cohesion, problem-solving, support), and Reciprocal Family Communication <sup>24</sup> (e.g., quality and frequency of communication)
<b>Physical Activity Self-Monitoring</b>	<ul style="list-style-type: none"> <li>• ACCUSPLIT AX2720 pedometers</li> </ul>	
<b>Food and Step Logs</b>	<ul style="list-style-type: none"> <li>• Individual paper records</li> </ul>	<ul style="list-style-type: none"> <li>• mFIT website, including family comparison graphs</li> </ul>
<b>Goals and Rewards</b>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> </ul>	<ul style="list-style-type: none"> <li>• Set weekly PA and healthy eating goals</li> <li>• Set weekly healthy rewards</li> <li>• Notified by mFIT website about goals met/rewards earned each week</li> </ul>

<p><b>Family Communication</b></p>	<ul style="list-style-type: none"> <li>• No content provided</li> </ul>	<ul style="list-style-type: none"> <li>• Messaging function on mFIT website for sending messages of encouragement and support between parents and children</li> </ul>
<p><b>Commercial Apps</b></p>	<ul style="list-style-type: none"> <li>• Weekly recommendation for free PA or healthy eating app to download</li> <li>• Android and iPhone versions included each week</li> </ul>	

## Appendix E: mFIT Newsletter Topics

Tech+					
Week	Topic	Child Target	Parent Target	Family Target	App to try
1	Welcome; using your pedometer; using the mobile website	Increased steps	Increased steps		NFL Play60
2	Setting goals and rewards	Learn to set goals and rewards	Learn to set goals and rewards	Setting rewards that can be enjoyed together as a family	Easy Eater
3	Checking in with each other	Learn to encourage and support parent	Learn to encourage	Increased communication	Smash Your Food

			and support parent		
4	Get active as a family	Leading by example/ encouraging the family	Leading by example/ encouraging the family	Family activity— try to involve other family members	Move-And-Eat-O-Matic
5	Adding more fruits and vegetables	Suggestions of new fruits and vegetables to try; tasty new snacks that incorporate more fruits and vegetables	Suggestions of new fruits and vegetables to try; tasty new snacks that incorporate more fruits and	Try one new fruit and one new vegetable together this week; prepare a new dish for the family using these ingredients	Veg-Out

			vegetables; ways to sneak more fruits and vegetables into family dishes		
6	Sneaking in physical activity	Fun games and other ways to get more steps in the day	Strategies for finding small physical activity breaks that can add up to large activity increases	Try one of the suggested strategies for increasing physical activity together (e.g., hula hooping during	TreznrHunt free



				commercial breaks of your favorite TV show)	
7	Mid-program check-in	Reflection on progress in first half of the program; setting goals for the second half	Reflection on progress in first half of the program; setting goals for the second half	Review each other's progress together and discuss goals for the second half of the program	HyperAnt
8	Cooking together	Help parent in the kitchen and learn about source of foods	Work with child to learn about the preparation of	Cook a healthy meal together for the family	WeCookit

		(e.g., gardening and cooking activity)	one of their favorite healthy meals		
9	Limit TV (<2 hrs/day)	Limit TV viewing to one day this week	Limit TV viewing to one day this week	Have a family game night or other activity together that does not involve the TV	MotionMaze
10	Try something new	Try at least one new food or physical activity from the provided list	Try at least one new food or physical activity from the provided list	Try at least one new food or physical activity from the provided list	Food Find

				together as a family	
11	<i>National challenges (Let's Move, Fit Family)</i>	Join one of the national challenges and learn about what other kids are doing	Join one of the national challenges and learn about what other parents are doing	Find a local fitness or nutrition event and sign up or attend together	Family Cart
12	Wrapping it up	Review progress and achievement of goals over past 12 weeks; set goals for the	Review progress and achievement of goals over past 12 weeks; set	Review each other's progress and set goals together as a family for the future	Pop & Dodge

		future, after the intervention ends	goals for the future, after the intervention ends		
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<b>Tech</b>				
Week	Topic	Child Target	Parent Target	Apps to try
1	Welcome; using the pedometers	Increased steps	Increased steps	NFL Play60
2	Activity recommendations	Information about the national standards for physical activity	Information about the national standards for physical activity	Easy Eater
3	Food recommendations (MyPlate)	Understanding food groups and recommendations	Understanding food groups and recommendations	Smash Your Food
4	Portion sizes	Guide to understanding portion distortion	Guide to understanding portion distortion	Move-And-Eat-O-Matic

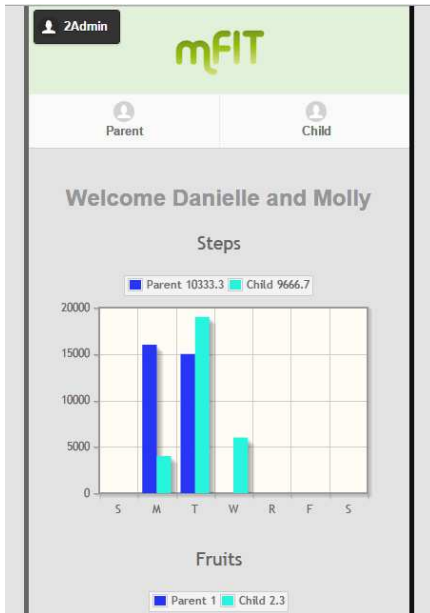
5	Limit TV (<2 hrs/day)	Tips for reducing TV time	Tips for reducing TV time	Veg-Out
6	Eat breakfast every day	Ideas for healthy breakfasts before school; the importance of eating breakfast to start the day right	Ideas for quick breakfasts for parents on the move	TreznrHunt free
7	Sneaking in physical activity	Suggestions about fun ways to get more physical activity	Guidelines about ways to get more activity (e.g., park further away from the store entrance; take the stairs)	HyperAnt

8	Cook at home	Recipes for easy kid-friendly meals to help prepare	Tips for eating more meals at home; benefits of eating at home versus restaurants	WeCookit
9	Reduce SSBs	“Rethink your drink” information about sugar equivalents in beverages	“Rethink your drink” information about sugar equivalents in beverages	MotionMaze
10	Eat at the table	Tips on eating meals at the table, not in front of a screen	Tips on eating meals at the table, not in front of a screen	Food Find
11	Limit fast food	Information about the nutritional content of fast food as compared	Information about the nutritional content of fast food as	Family Cart

		to home-cooked meal equivalents; time in physical activity to burn off calories in popular fast foods	compared to home-cooked meal equivalents; time in physical activity to burn off calories in popular fast foods	
12	Wrapping it up	Reflection on progress with physical activity and healthy eating goals since beginning of study	Reflection on progress with physical activity and healthy eating goals since beginning of study	Pop & Dodge



## Appendix F: Screen Shots of mFIT Mobile Website (for example user)



Family Comparison Graphs:

Admin mFIT

Log Goals News Mail Rewards

Danielle's Steps and Food Log

Today

Steps: 0

Fruit: 0

Vegetables: 0

Sugar-Sweetened Bevs: 0

Fast Food: 0

Yesterday

Day Before

Step and Food Logs:

Admin mFIT

Log Goals News Mail Rewards

Danielle's Goals

If I walk an average of

steps per day this week I will get

If I eat an average of

servings of fruit a day this week I will get

Weekly Goal and Reward Setting:

Admin mFIT

Log Goals News Mail Rewards

Danielle's Mail

My Messages Send

Congratulate

Great job on

Challenge

Team Work

Activity Goal

Family Messaging:

## Appendix G: IRB Approval Letter



OFFICE OF RESEARCH COMPLIANCE

### INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH APPROVAL LETTER for EXPEDITED REVIEW

This is to certify that the research proposal: **Pro00038855**

Entitled: *Enhancing Parent-Child Communication and Promoting Physical Activity and Healthy Eating Through Mobile Technology: A Randomized Trial*

Submitted by:

Principal Investigator: Danielle Schoffman  
College: Arnold School of Public Health  
Department: Health Promotion, Education & Behavior  
Address: 921 Assembly Street, First Floor  
Columbia, SC 29208

was reviewed and approved by the University of South Carolina Institutional Review Board (USC IRB) by **Expedited** review on **10/13/2014** (category **4 & 7**).

Approval is given for a one-year period from **10/13/2014** to **10/12/2015**. When applicable, approved consent /assent documents are located under the "Stamped ICF" tab on the Study Workspace screen in eIRB.

### PRINCIPAL INVESTIGATORS ARE TO ADHERE TO THE FOLLOWING APPROVAL CONDITIONS

- The research must be conducted according to the proposal/protocol that was approved by the USC IRB
- Changes to the procedures, recruitment materials, or consent documents, must be approved by the USC IRB prior to implementation

- *If applicable*, each subject should receive a copy of the approved date stamped consent document
- It is the responsibility of the principal investigator to report promptly to the USC IRB the following:
  - Unanticipated problems and/or unexpected risks to subjects
  - Adverse events effecting the rights or welfare of any human subject participating in the research study
- Research records, including signed consent documents, must be retained for at least (3) three years after the termination of the last IRB approval.
- No subjects may be involved in any research study procedure prior to the IRB approval date, or after the expiration date. For continued approval of the research study, an update of the study is required prior to the expiration date. The PI is responsible for initiating the Continuing Review process. At the time a study is closed, a Continuing Review report form is to be used for the final report to the USC IRB in order to formally close the research study.

The Office of Research Compliance is an administrative office that supports the University of South Carolina Institutional Review Board. If you have questions, contact Arlene McWhorter at [arlenem@sc.edu](mailto:arlenem@sc.edu) or (803) 777-7095.

Sincerely,

Lisa M. Johnson



IRB Manager

## Appendix H: Informed Consent/Assent Form



UNIVERSITY OF  
**SOUTH CAROLINA**

**CONSENT FORM**

### *Things You Should Know Before You Agree to Take Part in this Research*

---

IRB Study # Pro00038855

Title of Study: A Randomized Trial to Promote Physical Activity, Healthy Eating, and  
Parent-Child Communication with Mobile Technology

People in charge of study: Danielle E. Schoffman, Doctoral Candidate  
Gabrielle Turner-McGrievy, PhD, MS, RD

Where they work: University of South Carolina, Arnold School of Public Health

Study contact phone numbers: (803) 777-2830 & (803) 777-3932

Study contact email address: Ms. Schoffman: [schoffmd@email.sc.edu](mailto:schoffmd@email.sc.edu)  
Dr. Turner-McGrievy: [brie@sc.edu](mailto:brie@sc.edu)

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Researchers at the University of South Carolina study ways to make people's lives better. This research study is about what kinds of tools help families improve their eating and physical activity habits. For example, eating more fruits and vegetables and exercising more. We also are interested in how parents and children communicate about healthy behaviors. We will examine a variety of tools, including mobile apps, websites, and paper materials.

You (meaning you and your child) are invited to participate in a study of the effectiveness of tools to help families adopt healthy eating and physical activity habits.

**For IRB Staff Use Only**  
University of South Carolina  
IRB Number: Pro00038855  
Date Approved 10/13/2014  
Version Valid Until: 10/12/2015

### **What is the purpose of this research study?**

The reason for doing this research is to learn more about the kinds of tools that help families improve their eating and physical activity habits, like eating more fruits and vegetables and going for more walks.

### **Why am I being asked to be in this research study?**

We are asking you to take part in this research because you are the parent/guardian of a child between the ages of 9 and 12, and you have access to a smartphone or tablet.

### **How many people will take part in this study?**

A total of 100 children and 100 parents/guardians will take part in this study.

### **What will I be asked to do in this study?**

Part of this study will take place at the University of South Carolina, and part of it will be done through online surveys.

If you agree to be in the study, you will be asked to:

- Answer a set of online questionnaires at home or on a computer of your choosing, including questions about what you usually eat and drink, questions about your physical activity, your use of technology, and how your family communicates about health.
- Come to the University of South Carolina, where you will have your height and weight measured and you will be given a small device to wear that will track your physical activity (an accelerometer) for one week.
- You will be assigned randomly (by chance) to one of two groups, you will not have a choice about which group you are assigned, and each group will be a 12-week program.
  - In both groups, you will be asked to do the following:
    - You will be asked to test a series of apps, including some for healthy eating and physical activity (accessed on your mobile device)
    - You and your child will each receive a pedometer to wear to track your steps.
    - You will be asked to set goals for increasing your physical activity, and eating healthy (like eating more fruits and vegetables).
    - You will also receive an email newsletter with tips about new foods and physical activities to try.
  - If you are randomly assigned to the website group, you will be asked to use a new website to set goals and track your progress.
  - If you are randomly assigned to the paper group, you will be asked to use paper records to set goals and track your progress.

- Answer another set of online questionnaires at home, or on a computer of your choosing, including a dietary recall of everything you ate and drank, and questions about your physical activity, your use of technology, and how your family communicates about health.
- Come back to the University of South Carolina to have your height and weight measured again and wear the activity tracking device for another week.

**Where and when will participation occur?**

<b>Time/Task</b>	<b>Location</b>
Enrollment questionnaires	On a computer from your home or other location of your choosing
Baseline assessment and orientation to your assigned group	University of South Carolina
Following intervention guidelines and using apps	Using your mobile device and over email
Follow-up questionnaires	On a computer from your home or other location of your choosing
Follow-up assessment	University of South Carolina

**How will my privacy and confidentiality be protected?**

The researchers will use the answers to your survey and the information from your group discussions to learn more about how to help families make healthy lifestyle changes, and we may share what we learn with other researchers. Your answers and information will be coded so that no one will know which information came from you. Your answers and information will be combined with those of other participants, and no one will know your name or which part of the results came from you.

You will not be told your child’s answers on the surveys and interviews and your child will not be told your answers.

**Will I benefit from this research study?**

There are no guaranteed benefits for being in this study; however, you may learn about ways to improve your family’s health and well-being. What we learn will help us develop ways to better educate families about improving their health.

**Are there any risks associated with this being in this study?**

Risks of participation in this study are low. The main risk associated with participating in the study is loss of confidentiality. Other risks are no different than participating in moderate-intensity walking programs.

**What are the costs of participating in this research study?**

Other than parking or gas expenses, there are no costs to you for participating in this study.

**Will I get any money or gifts for being in this research study?**

Each family who completes both of the visits to the University of South Carolina (before and after the study) as well as the physical activity monitoring with the accelerometer, will receive a \$10 gift card for their child.

**Whom should I ask if I have any questions?**

If you have questions about this research study contact one of the persons listed on the first page of this consent form.

Questions about your rights as a research subject are to be directed to, Lisa Marie Johnson, IRB Manager, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-7095 or email: [LisaJ@mailbox.sc.edu](mailto:LisaJ@mailbox.sc.edu). The Office of Research Compliance is an administrative office that supports the University of South Carolina Institutional Review Board (USC IRB). The Institutional Review Board consists of representatives from a variety of scientific disciplines, non-scientists, and community members for the primary purpose of protecting the rights and welfare of human subjects enrolled in research studies.

I agree to participate in this study. I have been given a copy of this form for my own records.

*If you wish to participate, you should sign below.*

\_\_\_\_\_

Name of Adult Participant

\_\_\_\_\_

Signature of Parent/Legal Guardian

\_\_\_\_\_

Date

**Consent for Minors 9-12 Years of Age**

My participation in this research study has been explained to me and all of my questions have been answered. I am willing to participate.

\_\_\_\_\_

Name of Child Participant

\_\_\_\_\_

Signature

\_\_\_\_\_

Date of Birth

