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Feasibility of a Parent-Focused, Stress Management Intervention to Decrease Adolescent BMI, Reduce Stress, and Increase Well-Being Among African American Families

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FEASIBILITY OF A PARENT-FOCUSED, STRESS MANAGEMENT INTERVENTION TO DECREASE ADOLESCENT BMI, REDUCE STRESS, AND INCREASE WELL-BEING AMONG AFRICAN AMERICAN FAMILIES

by

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ABSTRACT

African American adolescents in the United States experience a higher prevalence of obesity as compared to their White counterparts. This health inequity presents a public health concern as consequences of weight-related chronic diseases often persist into adulthood and are increasingly problematic. As chronic stress has been found to be higher among African American youth compared to White adolescents, it presents as a potential barrier to participation for African American families in health promotion interventions. Additionally, it may be beneficial to target stress in health promotion programs as a modifiable factor in conjunction with health behaviors that may improve outcomes related to weight-related health. The current study evaluated the feasibility and implementation of the Project LEADS pilot trial ("Linking Exercise for Advancing Daily Stress Management"), a 10-week family-based intervention that integrates stress management and health behavior components to improve adolescent BMI and adolescent well-being by addressing parent and adolescent stress as a fundamental intervention essential element. The intervention incorporated stress management components using a relapse prevention framework with The Families Improving Together (FIT) for weight loss randomized controlled trial, which incorporated behavioral strategies and positive parenting techniques to reduce body mass index (BMI) and improve physical activity (PA) and diet in African American adolescents. Feasibility elements of acceptability, likability, comprehension, and engagement of adolescents and their caregivers were assessed using survey-based assessments. Additionally, process evaluation elements of

reach (proportion of intended audience receiving the intervention), dose (completeness of implementation), and fidelity (the extent to which essential elements were delivered as planned) were assessed. Results indicate preliminary support for the feasibility and acceptability of the LEADS behavioral health program. Caregiver and adolescent ratings indicated satisfaction with the unique intervention components (i.e., stress management, coping, racial socialization) and overall enjoyment of the virtual group atmosphere. High dose and fidelity indicate that the intervention was delivered as intended. A larger trial and a longer follow-up period would allow for adequate testing of the intervention efficacy on various health outcomes and an in-depth exploration of key theoretical mediators that may be successful in promoting health behavior change in this population. Furthermore, this research fosters innovative implementation processes for future intervention programs in medical and community settings to address health inequities among African American adolescents and their families.

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M	Denotes the mean value. The mean is the average of a set of numbers.
n	Represents the total number of individuals or observations in a sample; sample size.
SD	The standard deviation is the average amount of variability in a dataset. It denotes, on average, how far each value lies from the mean.

LIST OF ABBREVIATIONS

ACT.....Acceptance and Commitment Therapy

BMI..... Body Mass Index

CBSM .....Cognitive Behavioral Stress Management

CBT.....Cognitive Behavioral Therapy

FIT..... Families Improving Together

FST..... Family Systems Theory

LEADS.....Linking Exercise for Advancing Daily Stress Management

MBCT .....Mindfulness-based Cognitive Therapy

MBSR .....Mindfulness-based Stress Reduction

PA .....Physical Activity

RPM.....Relapse Prevention Model

SCT ..... Social Cognitive Theory

SDT .....Self-Determination Theory

CHAPTER 1

INTRODUCTION

The consequences of weight-related chronic diseases are increasingly troublesome, as the prevalence rate of individuals with overweight and obesity has risen above 40% in recent years (Hales et al., 2020). African American adolescents in the United States (US) experience a higher prevalence of obesity as compared to their White counterparts (Fryar et al., 2014; Hales et al., 2020; Ogden et al., 2016). This health inequity presents a public health concern as obesity is a significant risk factor for diabetes, cardiovascular disease, cancer, and depression contributing to higher morbidity and mortality (Byrd et al., 2018; Fox et al., 2008; Pi-Sunyer, 2009). Beyond the physical and psychological impact of weight-related problems, the economic burden to society through direct medical and productivity costs is becoming more apparent (Hammond & Levine, 2010). It is projected that indirect and direct costs of childhood obesity will be between $13 billion and $49 billion annually by 2050 (Ling et al., 2023). In order to mitigate the consequences of poor health associated with weight-related outcomes, many family-based health promotion programs and interventions have been developed to prevent and treat overweight and obesity, but African American youth are often underrepresented in these studies (Ash et al., 2017; Braxton, 2017; Lavie et al., 2018; Law, Wilson, St. George et al., 2020).

Parenting factors are crucial when considering which components to incorporate into family-based weight management interventions (Haines et al., 2016). Previous

randomized controlled trials (RCT) have sought to incorporate various parenting and behavioral skill components into culturally tailored weight management interventions for African American families. The Families Improving Together (FIT) for weight loss randomized controlled trial incorporated behavioral strategies (i.e., self-monitoring, goal setting) and positive parenting techniques (i.e., authoritative parenting style, communication skills, autonomy-support) in an effort to reduce body mass index (BMI) and improve physical activity (PA) and diet in African American adolescents (Wilson, Kitzman-Ulrich, Resnicow et al., 2015; Wilson, Sweeney, Van Horn et al., 2022). Many family-based interventions for adolescent obesity often target common factors like diet, exercise, and screen time (Ash et al., 2017). However, other related variables may be crucial to consider in order to promote better health outcomes among African American adolescents, in particular chronic stress, which may deplete resources associated with physical and psychological health (Clifton & Feeny, 2014; Parks et al., 2012, 2016).

Chronic stress, which refers to stress that is abnormally persistent due to constant demands embedded in daily living environments (Baum et al., 1999; Cohen et al., 1983; Lazarus, 1966), has been found to be higher among African American adolescents compared to other racial groups (Berge et al., 2017; Chae et al., 2011; Dunkel Schetter et al., 2013; Hurley et al., 2008). Furthermore, African Americans have been shown to exhibit higher levels of perceived chronic stress than Whites (Chae et al., 2011; Kim et al., 2009), stemming, in part, from systemic racial discrimination and prolonged marginalization (Dunkel Schetter et al., 2013; Ong et al., 2009). Due to socioeconomic adversity, marginalization, poverty, chronic stress and stigma, African American individuals are at higher risk for developing chronic diseases earlier in life, beginning in

young adulthood (Anderson & Armstead, 1995; Geronimus, 2001; Geronimus & Thompson, 2004), possibly due to an increased allostatic load, which refers to the physical wear and tear on the body associated with repeated and prolonged activation of stress systems in the body due to sympathetic nervous system activation (Baum et al., 1999; Geronimus et al., 2006).

As chronic stress may be a potential barrier for participation of African American families in health promotion interventions, this variable should be addressed and integrated into health promotion programs as a modifiable factor in conjunction to health behaviors that may improve outcomes related to weight-related health (Barr-Anderson et al., 2013; Richardson et al., 2015; Quattlebaum, Kipp, Wilson et al., 2021). Stress management approaches are more recently being integrated into health promotion programs to assist in weight management and improve overall wellbeing (Cox et al., 2012; Woods-Giscombe et al., 2019), but only to a limited degree. While evidence has been found to link parent and adolescent chronic stress to adolescent BMI (De Vriendt et al., 2009; Fahrenkamp & Sato, 2017; Isasi et al., 2017; Nguyen-Rodriguez et al., 2008), few health promotion programs for African American families have incorporated stress reduction as an essential element of family-based interventions for promoting adolescent healthy weight as the primary outcome (Cox et al., 2012). Additionally, the majority of research on the effectiveness of stress management interventions has often focused solely on mental health outcomes (Robinson et al., 2015). These interventions seem to be effective among predominantly White samples (Riley et al., 2017), however, further investigation is needed to understand the efficacy of integrating these stress management techniques into health promotion interventions for African American adolescents and

their families as they are often underrepresented. Thus, the present study evaluates the acceptability and feasibility as well as implementation effectiveness of the pilot LEADS trial ("Linking Exercise for Advancing Daily Stress Management"), an innovative family-based intervention that expands on previous literature by integrating stress management skills, positive parenting techniques, and health behavior components using a relapse-prevention framework to improve adolescent BMI and adolescent well-being by addressing parent and adolescent stress as a fundamental intervention essential element.

1.1 THEORETICAL FOUNDATIONS

The theoretical framework underlying the LEADS program incorporates elements from various stress and coping theories (Cohen et al., 2007; Lazarus & Folkman, 1984) and utilizes the Relapse Prevention Model (RPM; Marlatt & Gordan, 1985) to incorporate stress management techniques into the already existing FIT health promotion intervention for African American adolescents and their caregivers (Law, Wilson, St. George et al., 2020; Wilson, Kitzman-Ulrich, Resnicow et al., 2015, Wilson, Sweeney, Van Horn, et al. 2022). The FIT trial incorporated theoretical frameworks from Family Systems Theory (FST; Broderick, 1993), Self-Determination Theory (SDT; Ryan & Deci, 2000), Social Cognitive Theory (SCT; Bandura, 1986, 2004), which were also used to guide the development of the LEADS pilot intervention.

Current conceptual frameworks for stress and coping are based on the fundamental work by Lazarus and Folkman, specifically related to their transactional theory of stress and coping (Lazarus & Folkman, 1984). According to their work, stress is present when a person experiences a stressor that either matches or exceeds their ability to manage that situation. For the purposes of this study, the term "stress" is described as a

negative, adverse, or overwhelming experience (Glanz & Schwartz, 2008). A key element of stress is the individual's perspective and evaluation of potential harm (Cohen et al., 1997; Lazarus & Folkman, 1984). While Lazarus and Folkman argue that stress and coping is a dynamic process, others have argued that stress can be unpredictable, coming from situations beyond the control of the individual (Geronimus, 1992; Tomiyama et al., 2012). Chronic stress refers to ongoing demands that come from various life difficulties that threaten to exceed self-perceived resources and coping abilities (Braveman & Gottlieb, 2014; Dunkel Schetter et al., 2013). These demands often co-occur and accumulate, coming from various life areas including work, health, parenting, family, finances, housing, and marriage (Dunkel Schetter & Dolbier, 2011). While there are individual differences in perceptions of coping resources and capacities, it is important to note that an individuals' perceived chronic stress is often circumstantial and contextual, making it variable between individuals, and even within racial/ethnic groups (Kumanyika, 2008).

While stress is often characterized as a psychological phenomenon, it has long been associated with physical health outcomes and decreased engagement in health behaviors. Numerous theoretical pathways and mechanisms have been researched to provide clarity about how cognitive processes are used to appraise stressful situations and how physical health is affected by situations that exceed an individual's perceived coping ability (Gianaros & Wager, 2015). Stress can be measured psychologically, biologically, and behaviorally. This makes it a difficult factor to specifically pinpoint and develop consistent methods for analyzing its effects (Schneiderman et al., 2005). Nonetheless, collective research evidence suggests that stress, however measured or conceptualized,

can be a serious risk factor for physical health outcomes such as chronic disease (Brosschot et al., 2006). For example, chronic stress has been found to increase the risk of coronary heart disease, which is one of the leading causes of premature death in the United States (Wirtz & von Känel, 2017). Among African American individuals, psychological stress has been associated with higher risk of developing hypertension overtime (Spruill et al., 2019).

Psychological stress is also hypothesized to negatively affect health behaviors, such as PA and consumption of healthy foods, potentially (Cohen et al., 2007; Kim & Brown, 2018). Furthermore, behavioral health changes that serve as coping strategies to stressors, such as increased sedentary behavior and overeating, present as a potential pathway linking psychological stress to diseases like cardiovascular disease and some cancers (Cohen et al., 2007). When a situation/stressor is beyond the perceived coping level (e.g., perceiving a lack of adequate resources), individuals may experience negative emotions that could lead to unhealthy behavior, such as poor diet quality, physical inactivity, and prolonged screen time all of which contribute to obesity (Folkman et al., 1986; Hruby et al., 2016).

Within the context of stress and coping frameworks, perceived chronic stress has also been studied from a stress-buffering hypothesis perspective. The stress-buffering hypothesis purports that the presence of social support and resources helps to buffer, or shield, an individual from the negative effects of stress, but only under high stress conditions (Cohen & Wills, 1985). Furthermore, the buffering hypothesis holds that those with little or no social support, or resources, will have harmful effects on their health caused by health-related stressors, while these effects will be reduced for those with

higher levels of more effective social support (Baek et al., 2014; Cohen & McKay, 1984). This theory has been tested in various populations and with many different health outcomes, including diabetes, high blood pressure, and weight gain (Baek et al., 2014; Bowen et al., 2014; Darling et al., 2016, 2019). Given that parents can be a primary form of social support among African American adolescents (McMahon et al., 2011), their influence may act as a buffer against the negative effects of stress under high stress conditions. It has been shown that parents in high stress circumstances who implement inflexible parent feeding practices, such as pressure to eat, have adolescents with higher BMI (Berge et al., 2017; Burton et al., 2017; Kipp, Wilson, Sweeney et al., 2021). Thus, future research involving family-based health promotion programs should evaluate the integration of stress management components, as chronic stress may interfere with intervention engagement.

The Relapse Prevention Model (RPM) is a framework that utilizes the mastery of preemptive coping strategies to resist relapse in future high stress situations. The RPM was initially developed by Marlatt and Gordon as a behavioral maintenance program used among individuals undergoing treatment for addictive behaviors and is especially relevant to the proposed study given the focus on coping with high-risk stress as critical for health promotion (Marlatt & Gordan, 1985). The RPM is aimed at increasing overall coping capacity in high stress situations that may undermine health behavior change (Marlatt & George, 1998). With the RPM being based on social-learning theory (Bandura, 1978, 1986), it incorporates three main intervention themes: 1) behavioral skill-training, 2) cognitive therapy (e.g., reframing negative emotions), and 3) lifestyle rebalancing (Marlatt & George, 1998). Combining these different aspects of intervention

assists in the maintenance of behavior change targeted at specific relapse prevention or at general lifestyle change (See Methods section for detailed descriptions of these three components).

Marlatt and colleagues have discussed the importance of assessing high stress situations in the maintenance of positive health behavior changes, which they propose as a relapse taxonomy (Marlatt, 1996). They purport that the base assumption of this taxonomy is that as a person maintains a behavior change, they gain a sense of perceived control; the longer an individual is able to maintain that change, the greater perceived self-control (Marlatt & George, 1998). Moreover, when an individual is presented with a high-stress situation that threatens their self-control, there is increased risk of relapse or inability to maintain the behavior change (Marlatt & George, 1998). Through analysis of hundreds of relapse episodes, it was discovered that the three high stress situations that pose the highest threat to maintaining behavior change include negative emotional states (i.e. depression, anxiety, boredom, anger), interpersonal conflict (i.e. conflicts with romantic partners, employers, friends, family members), and social pressure (i.e. direct or indirect social influence not in line with the recent behavior change) (Marlatt, 1996; Marlatt & George, 1998).

The RPM is dynamic and flexible, being able to be applied to various situations and groups of individuals. Relapse prevention has been found to be successful as a program for many different types of addictive behaviors such as smoking, alcohol use, and abuse of other controlled substances (Hendershot et al., 2011). Additionally, various research has found evidence for utilization of the RPM in physical health related outcomes. For example, relapse prevention techniques integrated into behavioral

interventions for adults with obesity were found to improve adherence to intervention components and assisted with weight management and increased PA (Burgess et al., 2017; Dombrowski et al., 2012). Relapse prevention components have been used in a few weight-loss interventions for African American adolescents, but these interventions did not incorporate a fully integrated model for stress management skills attainment (Jacques-Tiura et al., 2019; Moore et al., 2019). A main component of relapse prevention techniques is identifying stressors and seeking ways to manage stress in order to prevent the extinction of health behavior changes (Menon & Kandasamy, 2018). Thus, using the RPM as a key theory driving the stress management components integrated into a health promotion program seems appropriate to integrate as a key stress management component. Furthermore, few studies have used the RPM as the underlying theoretical underpinning of the stress component in a health promotion intervention, nonetheless an integrated intervention for African American adolescents. In summary, the LEADS intervention proposed in this study, incorporates a fully integrated approach to addressing stress in the context of a health promotion program (see Table 1).

The LEADS program is also founded on a Family Systems Theory (FST) framework, which purports that instead of focusing on the individual in isolation, the family context should be considered when trying to understand and explain individual behavior (Broderick, 1993). Furthermore, FST proposes that a change in behavior of one member of the family will affect the behavior of the other members, as the family acts as an interrelated system (Bowen, 1978). FST additionally argues that family functioning is determined by the types of interactions among the members of the family (Broderick, 1993). During adolescence, teenagers may exhibit more autonomy in their decisions

regarding health-related behaviors but will still be highly influenced by their parents and caregivers (Dietz & Gortmaker, 2001; Gordon-Larsen et al., 2004; Lee et al., 2013). Thus, parents can be conceptualized as agents of change within the family system and are often made the target in family-based health promotion prevention and intervention to elicit behavioral changes for youth (Ball et al., 2012; Tucker, 2009; Zarrett & Eccles, 2009).

FST promotes characteristics of authoritative parenting style (demonstrated by building nurturing and supportive parent-adolescent interactions), which has been associated with many desirable youth health outcomes, including healthy weight status and increased PA (Biglan et al., 2012; Kitzman-Ulrich et al., 2010; Loncar, Wilson, Sweeney et al., 2021; Parletta et al., 2012; Wilson, Sweeney, Kitzman-Ulrich et al., 2017). However, African American families are often underrepresented in weight-related interventions that incorporate parenting practices and some research suggests that cultural variations in parenting characteristics may be important to consider when designing family-based interventions for African American populations (Loncar et al., 2021; Tamis-LeMonda et al., 2008). Additionally, few family-based studies that have included FST components have been successful at retaining participants and achieving significant weight-related reductions among African American youth (Berry et al., 2014; Boutelle et al., 2017; Jones et al., 2014; Moore et al., 2019).

Some family-based treatment programs for African Americans designed to affect adolescent weight-status have found success in helping to support parents' application of authoritative parenting skills and other positive parenting techniques (Burnet et al., 2011; Kitzman-Ulrich et al., 2011; Law, Wilson, St. George et al., 2020; Sacher et al., 2019;

Wilson, Kitzman-Ulrich, Resnicow et al., 2015). However, few programs designed to incorporate parent training have considered the role of chronic stress among African American families (Moore et al., 2019). A recent study conducted by Kipp and colleagues found that pressure to eat (parent feeding practice) moderated the relationship between parent stress and adolescent BMI among African American families; parents that exhibit higher pressure to eat, parent stress was positively associated with higher adolescent BMI (Kipp, Wilson, Sweeney et al., 2021). This finding shows preliminary evidence that parenting factors may exacerbate the effects of chronic stress on weight-related outcomes, and due to the mixed findings regarding family-based health promotion programs in African Americans, it is important to consider the role of chronic stress as a barrier and modifiable risk factor in interventions (Kipp, Wilson, Sweeney et al., 2021; Loncar, Wilson, Sweeney et al., 2021; Parks et al., 2016). For instance, higher perceived stress among adolescents has been associated with lower fruit and vegetable intake, more snacking, higher waist circumference, and higher BMI (Cartwright et al., 2003; van Jaarsveld et al., 2009). Chronic stress may act as a substantial barrier to engagement in health promoting behaviors among African American adolescents, thus contributing to the racial health inequities observed (Jackson et al., 2010; Quattlebaum, Kipp, Wilson et al., 2021; Kipp, Wilson, Brown, et al., 2023).

Two other theoretical frameworks that are influential to the LEADS program are Social Cognitive Theory (SCT) and Self-Determination Theory (SDT), which each provide specific mechanisms for behavior change. Within the supportive context of FST, motivational aspects of SCT and SDT are more likely to be adopted and utilized in the context of behavioral health change. According to SCT, relationships between social-

environmental factors (e.g., parent and family social support) and personal cognitive factors (e.g., self-efficacy, motivation) are important predictors of positive health outcomes across the lifespan (Bandura, 2004). SDT suggests intrinsically motivated behavior changes, facilitated by supporting an individual's autonomy (i.e., feeling of having choice and control over one's own behavior), competence (i.e., feeling that one has proper skills to engage in a specified behavior), and belongingness (i.e., feeling valued and cared for by others), will be sustained longer and have more of an impact than extrinsically motivated behaviors (Ryan & Deci, 2000). When combined into health promotion programs for families, complimentary elements from FST, SCT, and SDT promote a positive social environment that supports the development of youth health behavior changes (See Table 1.1; essential elements table for the proposed study), leading to improvements in youth weight-related outcomes and overall well-being (Law et al., 2020; St. George et al., 2013; Wilson et al., 2015, 2017, 2022).

However, when considering the role of chronic stress among African American adolescents, it is argued that sustained uptake of intervention components based on FST, SCT, and SDT will be more successful when stress is addressed in a fully integrated manner. Reducing parent and adolescent stress and increasing their coping abilities is theorized to be a key mechanism to impact adolescent BMI and well-being (See Figure 1.1). Thus, successful integration of the RPM components to mitigate chronic stress is likely to occur within the context of the other guiding theories (FST, SCT, SDT), especially among African American adolescents and their caregivers.

1.2 PREVIOUS LITERATURE

Association of Stress and BMI in African American Youth. Researchers have increasingly been interested in investigating the relationship between perceived chronic stress and adolescent BMI (Tomiyama, 2019). While some studies have found a relationship between perceived chronic stress and adolescent BMI, the findings have been mixed and a majority of the studies have not investigated this relationship among African American families. While adolescent perceived stress is important to consider when developing health promotion interventions, parent perceived stress is also critical as their level of stress may have an impact on the health behavior development of their children (Kipp, Wilson, Sweeney, et al., 2021).

Previous findings suggest that there is a positive relationship between parental report of perceived stress and adolescent obesity (Kipp et al., 2021; Wilson & Sato, 2014; Zeller et al., 2012). One longitudinal study found that after controlling for age and sex of participants, perceived stress in parents at baseline was associated with an increase in predicted child BMI attained by age 10 as well as child BMI trajectory over a 4-year period (Shankardass et al., 2013). However, only about 3% of the sample included African American youth. In a study of primarily African American adolescents, the number of parent stressors was directly related to youth obesity and parent-perceived stress was directly related to youth fast food consumption, which has been associated with obesity risk (Davis & Carpenter, 2009; Parks et al., 2012). However, one cross-sectional study did not find a relationship, such that parenting stress was not significantly associated with youth BMI in a sample of approximately 50% African American adolescents (Guilfoyle et al., 2010).

Along with parent perceived stress, the stress of the adolescent may be an important factor to investigate when attempting to understand the mechanisms of adolescent obesity. Lohman and colleagues (2009), in their cross-sectional study which included about 40% African American adolescents (10-13 years old), found that increased levels of adolescent stress, but not maternal or family stress, was associated with a greater likelihood of being overweight or obese (Lohman et al., 2009). This relationship has also been investigated longitudinally. Van Jaarsveld and colleagues measured BMI, waist circumference, and perceived stress for 5 consecutive years in an adolescent sample (ages 11-16) from the United Kingdom, with approximately 25% Black individuals (van Jaarsveld et al., 2009). Although they did not find evidence that higher perceived stress was associated with greater weight gain over the 5 years, they reported that BMI and waist measurements were significantly higher among adolescents that reported moderate to high stress compared to those that reported lower stress over the 5-year period.

In a national longitudinal study that included African American (52%) and White (48%) female adolescents (ages 10-19), it was found that higher levels of perceived stress during the 10 years predicted significantly greater increases in BMI over time compared to lower levels of stress (Tomiyama et al., 2012). Additionally, this relationship was significantly stronger for African American compared to White adolescents. These findings suggest that perceived stress has the potential to impact adolescent BMI and may be a modifiable mechanism of change among African American adolescents. Furthermore, these findings highlight the need to incorporate stress management

components into health promotion programs for African American youth and their caregivers/parents.

Integrated Stress Management and Health Promotion Programs. While many stress management techniques have been deemed effective to treat varying physical and psychological outcomes, the research is lacking on investigating the effectiveness of integrated interventions targeting weight-related health outcomes among youth, and among African American youth and their families in particular. Furthermore, very few of these types of studies have utilized process evaluation techniques to evaluate intervention implementation and dose (Seral-Cortes et al., 2021; Wilson, Kitzman-Ulrich, Resnicow et al., 2015). Stress reduction interventions and techniques that have been extensively researched include, but are not limited to, Mindfulness-based Stress Reduction (MBSR, Kabat-Zinn, 2006; Spears et al., 2017), Cognitive Behavioral Stress Management (CBSM, Gaab et al., 2003; McGregor et al., 2015), acceptance and commitment based therapies (ACT, Hayes & Hofmann, 2017; Wicksell et al., 2015), and general lifestyle approaches that incorporate behavioral coping skills and other common stress management skills (Rose et al., 2013; Schellenberg et al., 2013). When considering what type of stress component to integrate into a health promotion program it is important to note that while stress reduction might be the ultimate goal, some argue that this end is never fully attainable because stressors will always be present in daily life (Wersebe et al., 2018). Reducing stress is possible, but it may be more appropriate to learn specific techniques to manage the stress that will inevitably be present. These strategies may be personally tailored techniques to mitigate the effects of life stressors or shaping one's lifestyle and environment to minimize the number of stressors. In addition,

conceptualizing stress as something that can be managed may be more appropriate for African American youth and their caregivers, as they experience higher levels of chronic stress (Chae et al., 2011; Dunkel Schetter et al., 2013; Ong et al., 2009).

There is preliminary evidence to support the integration of stress management and health promotion to improve weight-related outcomes among varying adult populations (e.g., weight loss, BMI, and waist-to-hip ratio). A number of studies have reported significant improvements for weight-related outcomes when integrating stress management and health behavior change components (Alamout et al., 2020; Asadollahi et al., 2015; Block et al., 2015; Christaki et al., 2013; Corsica et al., 2014; Forman et al., 2013; Hébert et al., 2013; Webber et al., 2016; Woods-Giscombe et al., 2019; Xenaki et al., 2018). Among these studies, the type of stress intervention component and the sample size varied. Two intervention studies that integrated Mindfulness-based Cognitive Therapy (MBCT) into a diet related therapy intervention for adults reported significant reductions in weight-related outcomes (i.e., weight loss, BMI) for interventions groups when compared to control groups (Alamout et al., 2020; Asadollahi et al., 2015).

Corsica and colleagues (2014) included 53 women with overweight in an intervention that combined stress eating/ diet components with Mindfulness-based Stress Reduction (MBSR) and observed significantly greater reductions in weight for individuals in the integrated intervention compared to the diet alone control group (Corsica et al., 2014). Another RCT that integrated Acceptance and Commitment Therapy (ACT) components into a health promotion program that included 128 adults with overweight or obesity found significantly higher weight loss for individuals in the integrated intervention compared to standard behavioral treatment at post-treatment and

6-month follow-up (Forman et al., 2013). Additionally, a fully integrated health promotion intervention that utilized common stress management techniques (i.e., progressive muscle relaxation, deep breathing, guided visualization) and included 45 adults with obesity found significantly larger reductions in BMI for the stress management and health condition compared to the health only control group (Xenaki et al., 2018).

However, of the studies mentioned above, only a few integrated intervention studies included African American participants (Forman et al., 2013). A church-based RCT, which used a delayed-intervention arm as a control group, integrated diet and PA behavioral skills with personalized stress management suggestions (Hébert et al., 2013). Significant reductions in waist-to-hip ratio were observed at 3 months and 1 year, but no differences in BMI were observed in the intervention group compared to the control. A feasibility RCT with 68 African American adults with prediabetes that incorporated MBSR with diet and PA components found reductions in BMI for adults in the intervention group, but this study was not powered to test efficacy (Woods-Giscombe et al., 2019). Few other integrated interventions have included full or partial samples of African Americans (Bernstein et al., 2014; Chang et al., 2017; Cox et al., 2012; Steinhardt et al., 2009).

Two pilot studies that included less than 50 African American participants and incorporated common stress management components (e.g., deep breathing, mediation, life balance) found no significant differences in weight-related outcomes between intervention and control groups (Bernstein et al., 2014; Cox et al., 2012). Steinhardt and colleagues (2009) observed significant reductions in BMI in their pilot effectiveness

study that included African American adults, however sample size was low (N =16) and they did not include a comparison group (Steinhardt et al., 2009). A large technology based RCT (N = 619; 80% African American adults) that incorporated DVD intervention segments on healthy diet, PA, and stress management skills found no significant differences in weight between intervention and control groups (Chang et al., 2017). While attempts have been made to include stress management components into health promotion programs, few studies have fully integrated stress and coping (e.g., relapse prevention) as a primary element of intervention to increase engagement and improve outcomes.

Among children and adolescents, few studies evaluating integrated interventions targeting weight-related outcomes have been conducted, and even rarer are studies that focus on African American youth. A handful of studies have found significant improvements for weight-status among children and adolescents (Emmanouil et al., 2018; Jastreboff et al., 2018; Melnyk et al., 2015) and others have found improvements for PA or sedentary behavior, both associated with weight-status (Händel et al., 2017; Weigensberg et al., 2014). One integrated stress management and health promotion program that included 36 children and adolescents with overweight or obesity found significant reductions of waist-to-hip ratio (but not BMI) for the intervention group compared to health promotion alone (Emmanouil et al., 2018). Another pilot RCT testing the effects of MBSR combined with a nutrition and PA intervention found that the control group, but not the intervention group was associated with significant increases in BMI during treatment, noting the added benefit of MBSR for weight maintenance (Jastreboff et al., 2018).

While some integrated interventions for children and adolescents have included racial/ethnic minority populations (Melnyk et al., 2015; Weigensberg et al., 2014), very few have included adequately representative samples of African American adolescents aligned with national averages (Moore et al., 2019; U.S. Census Bureau, 2019). An RCT testing the efficacy of the COPE/Healthy Lifestyles teen program (68% Latinx) that incorporated cognitive techniques and life balance to manage stress into a health promotion program found that in the COPE program had a significantly lower BMI at 12 months then the control group (Melnyk et al., 2015). Additionally, there was a significant decrease in the proportion of teens with overweight or obesity from baseline to 12 months. Another RCT that included predominantly Latinx adolescents with obesity and incorporated common stress management techniques into a lifestyle health promotion program demonstrated significant reductions in sedentary behavior along with increases in moderate PA (Weigensberg et al., 2014). Moore and colleagues (2019) included 360 adolescents (~ 80% African American) in a 3 group RCT comparing a family-based health promotion program with stress components, a broad level system change intervention and a treatment as usual control group. The results showed that BMI increased over time for all groups and when an intent-to-treat analysis was conducted, no significant differences were found in adjusted BMI slopes between the tested interventions (Moore et al., 2019). In summary, there is mixed support for the integration of stress management techniques into health promotion programs, but few studies have fully integrated the stress management essential elements as proposed in the current study (see Table 1). Using the RPM, stress management elements were integrated into every phase of the intervention as a way to improve engagement and improve health behaviors,

which has not been conducted or evaluated in past studies among African American families.

1.3 INTERVENTION PROCESS EVALUATION

Novel process evaluation approaches have been utilized in health promotion programs tailored for African American communities to evaluate feasibility and implementation (Alia et al., 2015; Brownson et al., 2009; Moore et al., 2021; Pate et al., 2003; Saunders et al., 2022; St George et al., 2016; Sweeney, Wilson, Zarrett et al., 2020; Wilson et al., 2009, 2022). Process evaluation is an important part of evaluating the completeness of program implementation and sets the foundation for successful translation of the intervention to community settings (Breitenstein et al., 2010; Saunders et al., 2005). However, given that the current study is integrating stress management using the RPM into a family-based intervention, process evaluation processes have not been developed or utilized to evaluate the stress management components in health promotion interventions. Comprehensive, theory-based process evaluation is essential for accurate interpretation of study outcomes as it reduces the risk of type III errors, concluding an intervention is not effective when in fact it was not implemented with fidelity (Brownson et al., 2009; Moore et al., 2015; Pearson et al., 2020; Seral-Cortes et al., 2021). One of the key aspects of process evaluation is to assess dose and fidelity, which is to evaluate the extent to which the essential elements of the program were delivered in terms of completeness and as intended (Breitenstein et al., 2010; Couturier et al., 2021). Past studies have demonstrated the utility of process evaluation in intervention implementation among African American families, paving the way to develop and utilize a novel process evaluation approach for assessing integrated stress interventions like the

current study (Alia, Wilson, McDaniel, 2015; Law et al., 2020; Wilson et al., 2009, 2017, 2022).

Integration of stress-related and health promotion techniques may be an effective strategy to alleviate the rising prevalence of weight-related chronic health disorders, however few studies have targeted African American adolescents and their families. Furthermore, few have utilized process evaluation techniques to assess intervention implementation and the feasibility of a fully integrated health promotion and stress management program. Thus, the purpose of this study is to assess the feasibility and acceptability of the LEADS pilot intervention designed to fully incorporate stress management components, using the RPM, and health promotion skills over 10 weeks with African American dyads of overweight adolescents and their caregivers. A second aim of this study is to assess the dose and fidelity of implementation of the LEADS pilot intervention, using novel process evaluation, in order to evaluate if the addition of the RPM components would not reduce the fidelity of the other health promotion components in the program.

1.4 STUDY PURPOSE AND HYPOTHESES

The main objective of the proposed study was to assess the feasibility and acceptability of a randomized controlled pilot study of the LEADS program that fully integrates stress management components (behavioral coping skills, cognitive reframing, life balance) from an RPM perspective (see Table 1.1 for essential elements) into an already existing family-based health promotion intervention that incorporates FST, SCT, and SDT; FIT (Law, Wilson, St. George et al., 2020; Wilson, Kitzman-Ulrich, Resnicow et al., 2015, Wilson, Sweeney, Van Horn, et al. 2022). As African American families are

more likely to experience higher levels of chronic stress, it is essential to incorporate stress management components in order to maintain health behavior changes during high stress situations. The specific aims and hypotheses for this study were:

1. To assess feasibility and acceptability of the LEADS pilot trial, an integrated stress management (RPM) and health promotion program, by examining aspects of acceptability, likability, comprehension, and engagement of adolescents and their caregivers included in the LEADS program using survey-based assessments.
2. To evaluate the implementation of the LEADS pilot trial using summative process evaluation elements of reach (proportion of intended audience receiving the intervention), dose (completeness of implementation) and fidelity (extent to which essential elements were delivered as planned) to determine if stress management components from the RPM can be successfully integrated with other health promotion components. Formative process evaluation was also conducted throughout the program to ensure implementation success.

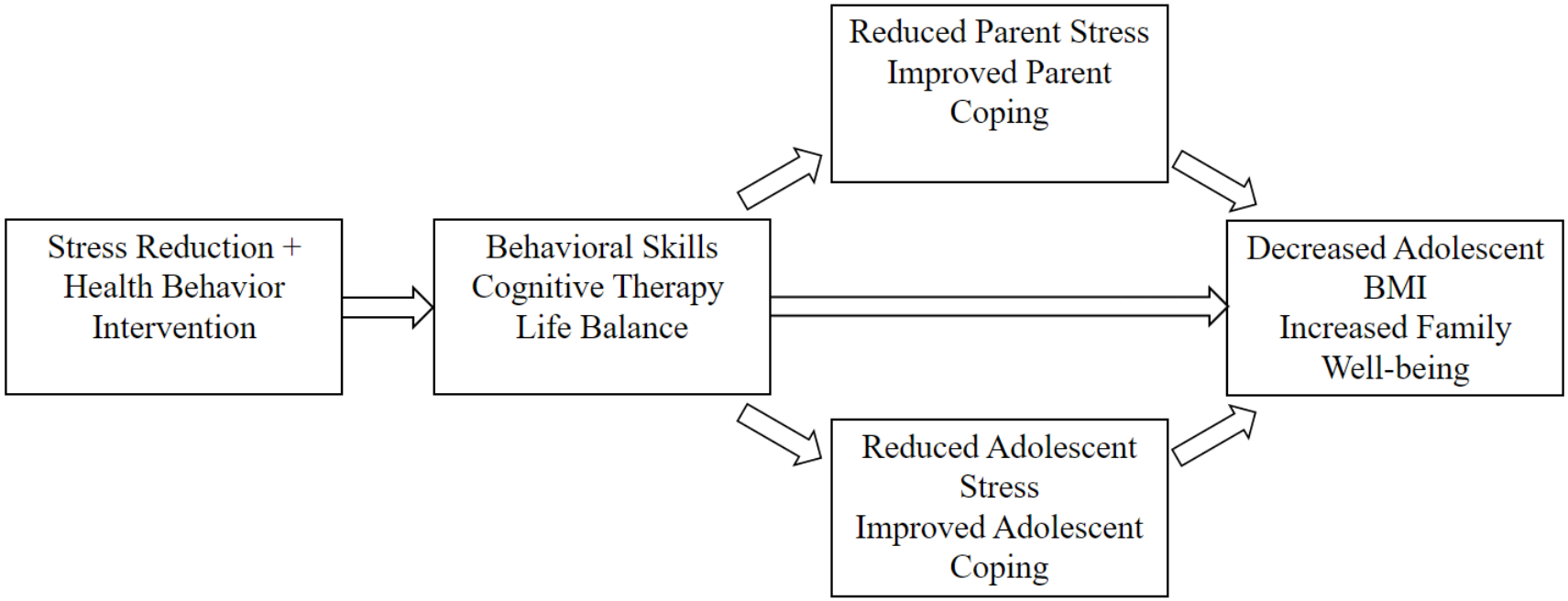

Figure 1.1 LEADS Project Proposed Model of Change

Table 1.1 LEADS Intervention Essential Elements

Theory	Essential Element	Description
RPM	Stress Coping Strategies	Parents and adolescents learn and implement interactive behavioral skills to reduce daily stress (e.g., meditation, mindfulness, progressive muscle relaxation, spirituality/prayer).
RPM	Cognitive Reframing	Parents and adolescents learn skills to reduce the impact of negative thoughts and overwhelming emotions related to daily stress.
RPM	Life Balance	Parents and adolescents learn to cooperatively structure daily routines to incorporate health behaviors, stress management skills, and family time.
Cultural Tailoring	Adaptation to Cultural Issues	Families develop action plans for resolving cultural barriers to health behavior change and parenting skill development as appropriate. Families develop goals in context of personal spiritual practice.
Cultural Assets	Racial Identity and Cultural Tradition	Families discuss the role of racial identity in their family relationships and develop coping strategies in line with their cultural traditions and racial identity.
SCT and RPM	Self-Monitoring	Parents and adolescents monitor their daily health behaviors related to stress using a tool of their choice.
SCT	Goal Setting	Parents and adolescents set specific health behavior goals together weekly, including stress reduction, dietary intake, physical activity, and sedentary behavior goals.
SCT	Self-Regulation Skills	Parents and adolescents learn to identify personal barriers, substitute healthier alternatives, and provide positive reinforcements.
FST	Parental Monitoring and Limit Setting	Parents monitor and track adolescent self-monitoring and goals, set limits with adolescents around health behaviors, and monitor implementation of family rules and rewards for adhering to health-related behaviors.
SDT and FST	Communication Skills	Parents and adolescents use positive communication strategies, including reflective listening, problem-solving, and shared decision-making, to discuss health behaviors.
SCT, SDT, and FST	Social Support	Adolescents use strategies for eliciting social support for health behaviors from parents. Parents provide adolescents with social support for health behaviors.
SDT	Autonomy Support	Adolescents have choices and are provided with opportunities to give input. Parents seek input from adolescents and negotiate rules and behavior changes together. Families engage in shared decision-making.

SCT	Self-Efficacy	Adolescents and parents have opportunities to practice and successfully master health behavior strategies.
SDT	Motivation	Families provide input and build confidence in changing health behaviors.

Note. Relapse Prevention Model (RPM); Social Cognitive Theory (SCT); Self-determination Theory (SDT); Family Systems Theory (FST)

CHAPTER 2

METHOD

2.1 PARTICIPANTS

Participants were 23 dyads of African American adolescents and their caregivers. 23 families enrolled in the study and were randomized to either the LEADS Intervention (n = 12) or a comprehensive health education (CHE) program (n = 11) over three cohorts. 25 eligible families were recruited, but two families were lost during the 2-week run-in period before the program sessions began. Of the 23 families enrolled in the study, 5 were lost to follow-up; one family moved out of state, one caregiver had complications due to a cancer diagnosis and the other three did not respond to multiple contacts. Thus, pre- and post- intervention measures were obtained from 18 dyads. See Table 2.1 for sample details and Figure 2.1 for CONSORT flow diagram.

Families were considered eligible if: 1) there was an African American adolescent between the ages of 11 and 17 years old, 2) the adolescent was overweight or obese, defined as having a $\geq 80^{th}$ and $<99^{th}$ percentile for age and sex, 3) at least one parent or caregiver living in the household was willing to participate, 4) could attend Tuesday or Thursday evening virtual group meetings, and 5) the family had internet access and video chat capabilities on their devices. Exclusion criteria included the presence of a medical or psychiatric condition that would interfere with PA or dietary behaviors, they were already participating in a weight-loss program or taking medication that could interfere with weight loss.

All participants signed informed consent and were compensated a total of $90 for their participation in the LEADS pilot trial distributed across measurement time points; $20 for completing the baseline measures and $70 for completing the post-intervention measurements. The study was approved by the University of South Carolina Institutional Review Board (IRB) prior to recruitment and consent procedures.

2.2 RECRUITMENT

Families were recruited through community partnerships with pediatric clinics (e.g., Eau Claire Cooperative Health Clinics, Joseph Woffard, Ph.D.), local community events, community centers (e.g., Newton Family Life Center, Barney Gadson), culturally relevant radio ads, study brochures, word-of-mouth similar to our previous studies (Law, Wilson, Kitzman, et al. 2016). See Table 2.2 and Figure 2.1 for complete details regarding recruitment methods, number of participants attempted to be reached by study staff, and participant allocation details. At these events and locations, study staff described the LEADS program as a fun, interactive, and family-based program focused on improving physical health and overall well-being for African American families and their children. If a family expressed interest, they were called at a later time and screened for eligibility using a standardized protocol by trained staff members. Eligible families were then invited to a "welcome" visit to collect baseline data and introduce them to the format of the virtual program.

Partnerships were made with local medical clinics and physicians to provide direct contact with members of the designated populations, where physicians would invite eligible patients to participate in the study. Print brochures were distributed in the local community, including at community centers and community events. Participants

that had participated in other research projects (i.e., the Families Improving Together [FIT] for Weight Loss randomized controlled trial [Dawn Wilson, Ph.D.] and the Developing Real Incentives and Volition for Exercise Project [DRIVE; Allison Sweeney, Ph.D.]) were also contacted and invited to participate in the LEADS program. Participants that enrolled were asked to provide referrals for family members and friends that might be interested and eligible to participate.

A total of 338 total attempted phone contacts were made by staff after having received the information from the above-mentioned recruitment methods. A large proportion (46%) were unable to be reached, meaning they did not answer the phone, did not return phone calls, the call went straight to voicemail, or the numbers were not functioning after multiple attempts. Of the families reached (184), 13% were eligible families that enrolled in the program, 34% were found to be ineligible, 38% were not interested, and 15% did not show up for their scheduled welcome visit. Regarding method of recruitment, a large number of attempted contacts came from referrals from participants (19%) and referrals from another research study (47%; FIT and DRIVE). Similar numbers of contacts were received from community centers and medical clinics (11%).

2.3 STUDY DESIGN AND PROCEDURE

The current study was a pilot randomized group cohort trial which aimed to assess the feasibility and acceptability of an integrated stress management and health promotion intervention (LEADS) for African American families compared to a comprehensive health education (CHE) control group (see Figure 1.1). Recruited families first participated in a 2-week run-in (orientation phase) which was designed to allow

participants to learn more about the program, complete baseline measures, and identify families with barriers to participating in the full program. Families who successfully completed run-in were then randomized to one of two weekday evenings (Tuesday or Thursday). After the run-in phase, evenings were then randomized to a treatment condition (intervention or a comprehensive health education program). Both the intervention and comparison programs were conducted online over 10 weeks (weekly 1.5-hour sessions) using the Zoom online video conferencing platform. The study included 3 cohorts, which comprised of one intervention group and one comparison group. Group sizes on average were between three and four parent-child dyads per condition. A team of trained measurement staff (blind to randomization) collected baseline measures prior to the start of the intervention and immediately post-intervention for all participants. Measures collected included demographics, objectively measured anthropometric data (height and weight), 7-day accelerometry estimates (Acticals), three 24-hour randomized dietary recalls, and psychosocial surveys. Fitbit tracking activity data was also collected throughout the course of the program but was not considered a baseline measure. Confidentiality of participant responses was emphasized prior to completion of psychosocial measures to decrease social desirability response bias.

2.4 LEADS INTERVENTION DESCRIPTION

The curriculum for the LEADS trial integrated stress management components, using the Relapse Prevention Model, into the previously conducted Families Improving Together (FIT) for Weight Loss randomized controlled trial intervention (Marlatt & Gordan, 1985; Wilson et al., 2015). The FIT intervention integrated Social Cognitive Theory, Self-Determination Theory, and Family Systems Theory with cultural tailoring

strategies to target weight-related outcomes in African American youth. Essential elements included autonomy, parent social support, communication skills, parental monitoring, goal setting, self-monitoring, and behavioral skills (non-bolded aspects of Table 1.1 & 2.3). Project FIT used these components to specifically target: 1) increasing fruit and vegetable intake (FVI), 2) decreasing fast food and junk food intake, 3) decreasing sugar sweetened beverages, 4) increasing physical activity, and 5) decreasing screen time (see Wilson et al., 2015; Alia, Wilson, McDaniel et al., 2015 for a published description of the FIT intervention).

Expanding on elements of the FIT intervention mentioned above, three new stress management components related to a relapse prevention framework were added to the curriculum to target reductions in stress (parents and teens) and adolescent BMI in addition to improvements in adolescent wellbeing (see bolded aspects of Tables 1.1 & 2.3). The intervention incorporated the following three components from the RP model aimed at increasing overall coping capacity in high stress situations that may undermine health behavior changes and parental skill attainment (Lazarus & Folkman, 1984; Marlatt & Gordan, 1985).

Behavioral Coping Skill Training. These activities were designed to teach the families to recognize high-stress situations that might prevent continued health behavior change and implement behavior coping skills to management feelings of stress. Additionally, the families identified unproductive coping strategies and determined alternative coping strategies to implement in high-stress situations. Stress coping training activities (e.g., exercise as stress relief, deep breathing, meditation, mindfulness, progressive muscle relaxation) were presented to the group each week but coping strategy

implementation was unique to each family. Weekly goal setting was integrated for stress reduction in combination with health behavior change goals.

Cognitive Reframing. Using aspects of traditional cognitive therapy, cognitive reframing procedures are designed to provide the families with alterative and flexible cognitions regarding the nature of health behavior change, for example viewing it as a learning process. The intervention team implemented specific strategies that helped the participants identify and dispute negative thoughts and emotions during stressful situations that could lead to diminished health behavior change. Additionally, activities and strategies related to acceptance and self-compassion were incorporated to further strengthen participant self-efficacy. In particular, negative emotions and avoidant coping were addressed as these have been shown to lead to poor health outcomes.

Life Balance. Recent qualitative work with African American families conducted by Kipp and colleagues (Quattlebaum, Kipp, Wilson et al., 2021; Kipp, Wilson, Brown, et al., 2023) indicated that lack of time and multiple caregiver/work responsibilities contributed profoundly to chronic stress and limited heath behavior change. Thus, it was essential to include activities designed to help the families implement balance life to reduce the impact of stressors and to teach them balance and time management skills. These strategies included work-life balance planning, determining priorities, pre-planning a family schedule, scheduling time for relaxation and meditation practices, and prioritizing health behaviors. Primarily, families undertook lifestyle rebalancing to combat high stress situations and understand the value of relaxation as a coping strategy.

During each of the 10 weeks, 3-4 families met for 1.5 hours with the facilitators in virtual groups (using Zoom). The LEADS intervention was delivered by two-three

facilitators, both African American and Caucasian, for each cohort. Discussion topics included stress management (behavioral coping skills, cognitive reframing, life balance) in addition to positive parenting and communication skills, self-monitoring and goal setting, dietary considerations and portion sizes, physical activity and sedentary behavior, and relapse prevention (see Table 2.3 for curriculum matrix). A supportive, interactive group environment was emphasized, and facilitators modeled autonomy supportive communication and empowered families to make choices around setting weekly health behavior goals and stress management goals. Parents were encouraged to provide choice to their child and engage in shared decision making as in our past studies (Law et al., 2020; Wilson et al., 2015, 2022). At the end of each session, family bonding activities were described which were designed to encourage positive parenting skills and reinforce behavioral changes. Families also received two individualized feedback during the program (Weeks 3 and 8) for approximately 15 minutes that emphasized personalized and family goal setting, self-assessment of health behavior changes and stress management skill development, discussion of self-monitoring, and problem-solving barriers. Make-up sessions were available using Zoom or by phone and included essential components of the intervention.

The LEADS group facilitators received training and were certified on their ability to communicate behavioral skills, relapse prevention, stress management, positive parenting communication strategies, motivational interviewing, and cultural competency. In order to minimize group effects, each cohort (i.e., one intervention group and one comparison group) were led by the same intervention facilitators. Intervention facilitators were graduate and advanced undergraduate students in clinical psychology with

counseling and practicum training. One lead facilitator was responsible for delivering weekly content, and 1 co-facilitator was responsible for assisting the lead facilitator in managing the group (e.g., taking attendance, managing the group chat, materials, video/audio recording group sessions). During each intervention session, facilitators followed a structured facilitator guide detailing key topics, discussion points, and activities. To ensure the intervention was implemented with high fidelity, facilitators received on-going feedback at weekly intervention meetings based on formative process evaluation measures led by the primary mentor (Wilson).

2.5 COMPREHENSIVE HEALTH EDUCATION PROGRAM DESCRIPTION

Groups sessions for the comprehensive health education (CHE) control group were similar to the FIT intervention and also took place online using Zoom for 1.5 hours weekly for 10 weeks. Topics included diabetes, hypertension, stress, cancer, media literacy, metabolism, positive self-concept, and sleep. The CHE curriculum did not include stress management skills development, parenting skills, or behavioral components. Weekly feedback occurred at the intervention meetings to ensure that the control group was receiving the correct information and behavioral goals/stress management techniques were not highlighted in the group session.

2.6 MEASURES

Demographics. Demographic data were collected from adolescents and their caregivers at baseline and included items such as date of birth, education level (for parents), household income, and total number of family members living in the household (Appendix A).

Midpoint Interview and Survey Questions. At week 5 of the intervention, facilitators scheduled individual Zoom meetings with each family outside of the normally scheduled group time. These were conducted to review and develop further individual/family goals and gather preliminary feedback data about feasibility and acceptability of the LEADS program with each cohort. These individualized feedback sessions involved discussing the families progress with making SMART goals, Fitbit utilization and adherence, acceptability of stress-management skills outside of the group meetings, and development of family communication strategies. In addition, preliminary interview questions about acceptability and engagement were asked including question like "How understandable is the program so far?", "What parts of the program have been difficult to understand?", and "What has been your favorite aspect of the program up to this point?". Additionally, participants each filled out a survey assessing these same aspects during these interview appointments. The survey presented at midpoint consisted of 15 statements scored on a 5-point Likert scale (1 = "Never", 2 = "Rarely", 3 = "Sometimes", 4 = "Often", 5 = "Always"). Sample items included "The LEADS program has been easy for me to understand", "I enjoyed talking about family cultural traditions.", "Focusing on stress management was important to me", and "I like that the program is virtual". See Appendix B for full list of interview questions and the survey used at midpoint.

Post-Intervention Interview and Survey Questions. At week 10 of the intervention, facilitators met with group members at the end of the scheduled Zoom meetings to conduct post-intervention group feedback. While this group interview was very similar to the midpoint individual interviews, further discussion about feasibility and

acceptability of the LEADS program overall was conducted with each cohort. Interview questions about feasibility, acceptability, and engagement were asked again similar to the midpoint questions with some additional prompts, including questions like “What was your favorite aspect of the program?”, “How did you feel talking about stress management and coping throughout the program?”, and “What skills and strategies will you continue to use of the program?”. Additionally, participants each filled out a survey assessing these same aspects of the program as they did at midpoint, with a number of additional items. The survey presented at the end of the program consisted of 22 statements scored on a 5-point Likert scale (1 = “Never”, 2 = “Rarely”, 3 = “Sometimes”, 4 = “Often”, 5 = “Always”). Sample items included “The Fitbit group goal setting has been useful”, “I enjoyed talking about family cultural traditions”, “I would recommend the program to other families I know”, and “I like that the program is virtual”. See Appendix B for full list of interview questions and the survey used at the end of the program.

2.7 PROCESS EVALUATION

A major component of assessing feasibility was gaining valuable insight from the families participating in the intervention. The feasibility and acceptability of the integrated intervention was assessed using (1) qualitative feedback using semi-structured interview questions (midpoint and post-intervention), (2) survey-based objective participant report (midpoint and post-intervention), and (3) formative observation of key issues using recordings of sessions. Brief individualized interviews with the adolescents and their caregivers were conducted to measure perceptions of intervention feasibility and acceptability at midpoint. Similar group feedback was conducted during the final

week of the intervention. Only post-intervention results were presented as most of the questions at midpoint are encompassed in the post-questions and the midpoint questions were primarily used for formative process evaluation. During these interviews, the participants were given the survey-based questionnaires to assess aspects related to acceptability, likability, comprehension, and engagement (See Appendix B). The qualitative feedback gathered in these interviews is not presented in this study and will be analyzed and prepared for a future publication; only the survey-based questionnaire data is presented in the current study.

To assess the adequacy of intervention implementation, the process evaluation elements of reach, dose, and fidelity were examined in the present study. Similar to the process evaluation approach taken in the FIT intervention trial (Wilson et al., 2015; Wilson et al., 2022; Alia et al., 2015), quantitative checklists and rating scales designed to capture how well intervention facilitators characterized a positive, autonomy-supportive social climate based on study essential elements were developed for the present study. In addition, the dose and fidelity of the behavioral and family skills, stress related coping strategies, cognitive reframing, life balance strategies, and cultural components were assessed. The LEADS process data was assessed for summative purposes and was collected by trained, independent process evaluators using systematic observation of virtual recorded group sessions. Inter-rater reliability reached a Kappa coefficient of 0.85, which is high in comparison to past studies among adolescents and families (Cargo et al., 2015). Once inter-rater reliability was established, evaluators worked independently scoring the recorded sessions but still met to discuss any disagreements until consensus was met regarding the final scoring or each group session.

Reach. Reach was assessed using participant recruitment, attendance, and retention data. Reach is traditionally defined as the proportion of eligible individuals that participated in a particular intervention and is often shown though response rate of participants (Balasubramanian et al., 2015). However, given the restricted nature of a pilot study, components of attendance and retention rate were classified as elements of reach in this study in order to more fully capture participant involvement. An apriori goal for participant response rate was set at 50% which is similar to past studies involving African American families (Durant et al., 2011). The apriori goal for attendance was 70% of families to attend 6 or more total intervention sessions including make-up sessions. Although this represents less sessions than our past studies, more concise virtual interventions may increase retention and involvement as African American families experience various stressors that make attending the gold standard 12-14 sessions difficult (Johnson et al., 2021). Retention rate was analyzed as well with a goal to retain 70% of the participating families as in past studies (Wilson et al., 2008; 2022). Although the importance of attending in-person virtual sessions was emphasized, if extenuating circumstances prevented families from attending sessions, make-up sessions were permitted. Attendance was calculated both including and excluding the completion of make-up sessions similar to the FIT intervention procedures.

Dose. A trained, independent process evaluator systematically observed all one-and-a-half-hour weekly intervention sessions to assess both dose delivery and intervention fidelity using facilitator guides which outlined the intervention content in detail (See Appendix C for sample process evaluation forms). Dose was assessed using yes/no response options around key session content. Percentages of "yes" responses was

used to summarize results. Achieving adequate dose was defined as ≥75% of the intended intervention delivered to each cohort, which is a similar benchmark as past studies (Robbins et al., 2016; Saunders et al., 2005; Young et al., 2007).

Fidelity. Ratings for fidelity assessed the extent to which families were provided with opportunities to be actively engaged in their health behavior change (i.e., set goals, self-monitor, receive feedback), stress management skill building (behavioral coping skills, cognitive reframing, life balance), cultural tailoring (e.g., coping with racial stress, family cultural traditions), and the extent to which the social environment fosters positive communication, social support, and autonomy support. Ratings for fidelity were made on each of five components (behavioral skills, stress coping skills, communication skills, social support, and autonomy support) using a 4-point scale ranging from 1=low implementation to 4=high implementation (See Appendix C). These ratings were made for both facilitator implementation and group interactions separately during each session. An overall average as well as an average for each individual component was calculated across all study cohorts. Achieving fidelity was defined as a value of ≥3 for each essential element as seen in past studies (Wilson et al., 2009 & 2022; Saunders et al., 2022).

2.8 DATA ANALYSIS

Survey-based Feasibility and Acceptability. The first aim of the study was to assess feasibility and acceptability of the LEADS trial, which incorporated RPM components with health promotion elements, by examining aspects of acceptability, likability, comprehension, and engagement of adolescents and their caregivers included in the LEADS program using survey-based assessments. Means and standard deviations

were calculated for each individual question on the survey using a 5-point Likert scale score and are summarized by group condition.

Process Evaluation. The second study aim examined the process evaluation elements of reach, dose, and fidelity of the LEADS trial, which incorporated RPM components with health promotion elements. Recruitment response rate, weekly session attendance, and retention data were used to assess reach. Response rate was a percentage calculated of eligible families contacted by phone that eventually enrolled in the study. Participant attendance at weekly sessions was coded as either 0 = family not in attendance or 1 = family in attendance (at least one member of the dyad), and a sum was calculated for each family. The percentage of families attending either sessions post randomization was subsequently calculated including and excluding make-up sessions. Frequencies and means were calculated to assess the external evaluator's dose and fidelity ratings, respectively. Similar to the FIT intervention, the dose criteria were based on the percentage of core activities that the facilitator completed during the sessions, and it was determined that the minimum acceptable level was 75% completion. In addition, it was determined that the minimal acceptable level of fidelity is a mean of 3 on a 1–4 scale.

Table 2.1 Summary of LEADS Sample by Cohort

	Cohort 1	Cohort 2	Cohort 3	Total
Participants Recruited	10	7	8	25
Participants Randomized	9	6	8	23
Participants at Post Measures	8	4	6	18
Retention Rate	89%	67%	75%	78%

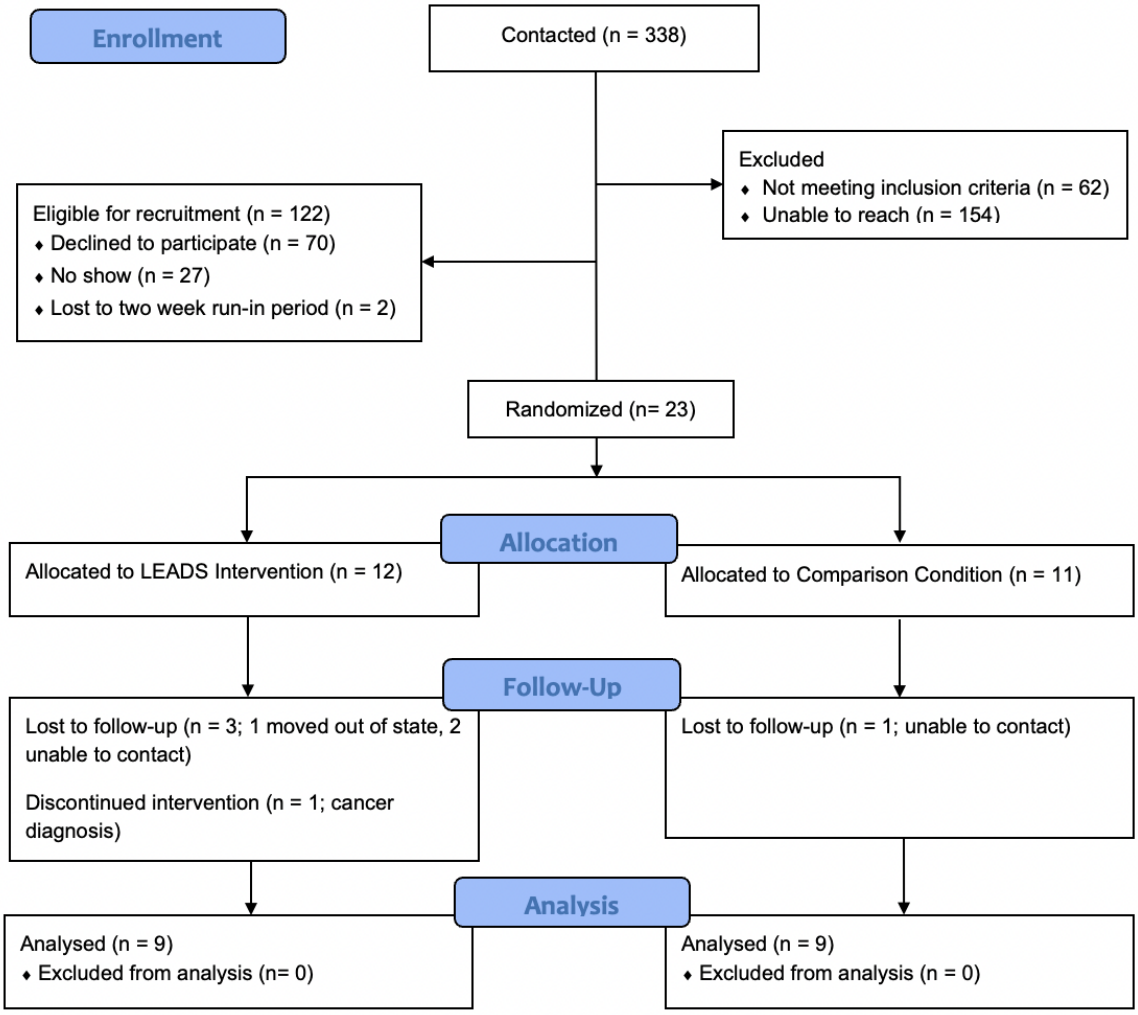

Figure 2.1 Participant flow diagram based on the Consolidated Standards for Reporting Trials 2010 (CONSORT)

Table 2.2 LEADS Recruitment Methods

Method	Participant Status (No., %)					
	Enrolled	Unable to Reach	Ineligible	Not Interested	No Show	Total*
Local community event	2 (9%)	7 (30%)	8 (35%)	4 (17%)	2 (9%)	23 (7%)
Medical Clinic	5 (14%)	12 (33%)	3 (8%)	9 (25%)	7 (19%)	36 (11%)
Community center	2 (5%)	14 (37%)	13 (34%)	6 (16%)	3 (8%)	38 (11%)
Participant Referral	5 (8%)	23 (37%)	12 (19%)	16 (25%)	7 (11%)	63 (19%)
Multimedia (brochure, website, radio)	1 (25%)	1 (25%)	2 (50%)	0	0	4 (1%)
Referral from another research study	10 (6%)	87 (54%)	22 (14%)	33 (21%)	8 (5%)	160 (47%)
Other	0	10 (71%)	2 (14%)	2 (14%)	0	14 (4%)
Total*	25 (7%)	154 (46%)	62 (18%)	70 (21%)	27 (8%)	338 (100%)

Table 2.3 LEADS Intervention Curriculum Matrix

Week	Theory	Key Content and Core Activities	Tailored Text Messages
1	RPM, SDT, FST	Group ground rules Positive communication *Family bonding* – planning a family activity *Stress coping exercise* – Deep Breathing	Welcome to group! **Coping:** using positive communication, using deep breathing as a technique, linking activities to PA
2	RPM, SCT, CT, FST	Identify stressors (chronic, cultural) Self-monitoring and goal setting Group Fitbit Goal *Family bonding* - positive communication *Stress coping exercise* – Body Scan	**Coping:** identify stressors and plan ahead with deep breathing and other coping strategies, practice monitoring and goal setting for PA **Socialization:** identify racial stressors and use positive communication skills, link these activities to family history of health and PA
3	RPM, SCT, FST, SDT	SMART Goals Cognitive reframing Self-affirmations Personalized and Group Fitbit goal *Family bonding* – family PA goal setting and tracking *Stress coping exercise* - PA for stress management	**Coping:** coping with negative emotions through cognitive reframing, PA as a tool for stress management **Socialization:** affirmations related to racial identity, link these activities to PA
4	RPM, FST, SDT, SCT	Life balance, family routine, lifestyle health behavior changes Energy In/Energy Out Group Fitbit goal *Family bonding* – building family routines *Stress coping exercise* – Guided Imagery Group PA video	**Coping:** using guided imagery and developing family routines about life balance and linking to PA, proactive monitoring of caloric balance **Socialization:** using spirituality as a coping strategy and building cultural pride and family routines, linking to PA

5	RPM, SDT, FST, SCT	Portions, Hunger and Satiety, Mindful eating, Autonomy, Emotional eating Cognitive reframing	**Coping:** using mindful eating and proactive planning for healthy eating and linking to PA **Socialization:** linking eating to spirituality and cultural traditions and to PA
		Personalized and Group Fitbit goal *Family bonding* – healthy meal preparation, tracking emotions, overeating *Stress coping exercise* – Mindful Eating Group PA video	
6	RPM, FST, SCT, SDT	PA (lifestyle, barriers, coping, communication, support)	**Coping:** integrating lifestyle PA into daily routines, using PA as a coping strategy **Socialization:** autonomy-supportive discussions about PA and building cultural pride
		Group Fitbit goal *Family bonding* – PA and support *Stress coping exercise* – Beginner Yoga Group PA video	
7	RPM, CA, SDT, SCT	Racial discrimination, health/well-being, and coping Autonomy support for adolescent health behavior	**Coping:** using mindfulness activity to address stressors and developing skills for coping with racism, linking to PA **Socialization:** coping with discrimination through autonomy-supportive communication and continuing to reinforce daily PA
		Group Fitbit goal *Family bonding* – communication for health behaviors *Stress coping exercise* – Mindfulness 5 Senses Activity Group PA video	
8	RPM, SCT, FST	Sedentary behavior Screen time and junk food	**Coping:** using progressive muscle relaxation for coping, integrating more activity in place of sedentary behavior, continue PA lifestyle **Socialization:** use of shared decision-making for cultural activities that link to PA and healthy eating
		Group Fitbit goal *Family bonding* – screen time and junk food *Stress coping exercise* – Progressive Muscle Relaxation Group PA video	

9	CA, SCT, RPM, SDT, FST	Cultural pride and family coping traditions (e.g., family tree, SC calendar) Communication, Active listening and Self-monitoring Barriers to stress and exercise	**Coping:** use of family routines and cultural history to address stress and improve PA, intention-setting for health behaviors and stress coping **Socialization:** importance of family tree and active listening for building resilience/traditions to cope with racism/stress and integrate daily PA
		Group Fitbit goal *Family bonding* – family rules *Stress coping exercise* – Intention Setting Meditation Group PA video	
10	RPM, FST, SCT	Relapse prevention Recap life balance/family routine plan, cognitive reframing, stress coping strategies	**Coping:** review of stress management techniques, goal-setting, and proactive coping **Socialization:** importance of family culture, routines, and traditions, planning for future stressors and overcoming barriers to PA
		Stress and Health toolbox Testimonials	

CHAPTER 3

RESULTS

3.1 DEMOGRAPHIC AND PSYCHOSOCIAL DATA

Participant demographic and psychosocial data are provided in Table 3.1, and show similar descriptive data across groups as baseline indicating that randomization was successful. A total of 23 adolescent-caregiver dyads participated over 3 cohorts, with 12 dyads in the intervention (LEADS pilot program) group and 11 dyads in the control (CHE program) group. A majority of adolescents were female (57%). On average, adolescents were 13.72 ± 1.98 years old. Adolescents were above the 85th percentile for BMI, with the majority being above the 95th percentile (~92%). All caregivers were female and on average were 49.13 ± 9.09 years of age. A majority of caregivers had a BMI ≥ 30 with an overall average of 39.76 ± 7.10 for the entire sample.

Most of the caregivers were mothers (83%), with a smaller percentage participating that were grandmothers (17%). Most caregivers were either married (39%) or in an unmarried relationship (9%), and some were widowed (13%) and divorced (17%). Some of the families reported graduating college (8.7%) but the majority of participants did not graduate from college (~60%). A large majority of caregivers were working part- or full-time (86.4%), with a small number being retired, students, or not working. The average household consisted of 3.91(1.04) individuals, including the

adolescent participating in the program. The majority of families had a household yearly income under $40,000 per year (60.8%), while a small percentage had an income level above $70,000 (12.9%).

3.2 PROCESS EVALUATION: FEASIBILITY AND ACCEPTIBILITY

Data related to feasibility and acceptability of the LEADS intervention are presented in Table 3.2. While survey-based data was collected at midpoint and post-intervention, only post-intervention results are presented as most of the questions at midpoint are encompassed in the post- questions and the midpoint questions were primarily used for formative process evaluation. Feedback topics included questions related to the following categories: 1) General (likability and acceptability), 2) group climate, 3) RPM elements, 4) behavioral skills, 5) family skills, and 6) cultural topics. Survey question responses were on a 5-point Likert scale score (1 = “Never”, 2 = “Rarely”, 3 = “Sometimes”, 4 = “Often”, 5 = “Always”).

General. A majority of caregivers indicated that they enjoyed attending the LEADS group sessions often with a rating of 4.8 ± 0.66 and that they would recommend the program to other families (4.6 ± 1.00). Adolescents reported a slightly lower overall enjoyment of LEADS group session with an average rating of 3.7 ± 1.6 but indicated a similar probability of recommending the program to other families. Caregivers had ratings about being able to understand the program (4.6 ± 0.7) and learning new things in the group sessions (4.3 ± 0.66) that were similar to adolescents (4.0 ± 0.92, 4.3 ± 0.70), respectively. Both caregivers and adolescents indicated on average, that they often enjoyed the program being virtual (4.4 ± 0.70 and 4.3 ± 1.03).

Group Climate. Caregivers on average, indicated they felt highly respected by group facilitators (4.9 ± 0.33). They also indicated that they enjoyed having more than two group facilitators throughout the session (4.8 ± 0.43). Adolescents on average, indicated they felt highly respected by group facilitators (4.9 ± 0.35) and always enjoyed having more than two group facilitators (4.9 ± 0.35). Both caregivers (4.1 ± 1.05) and adolescents (4.0 ± 1.07) noted they often felt support from other families in the LEADS groups sessions.

RPM Components. Regarding the stress managements components of the program, both caregivers (4.5 ± 0.71) and adolescents (4.1 ± 1.12), on average, indicated they were often able to understand the stress management lessons throughout the program. However, there was a difference noted between caregivers and adolescents regarding their desire to focus on stress management in the program (4.5 ± 0.71 vs. 3.7 ± 1.16) respectively, with adolescents noting they wanted to focus on stress sometimes. Both caregivers and adolescents, on average, highly endorsed plans to use the stress management skills in the future (4.9 ± 0.33 versus 4.3 ± 0.70, respectively). Caregivers indicated they often found the cognitive reframing skills useful (4.5 ± 0.71) while adolescents found these skills sometimes useful, on average (3.6 ± 1.40). Regarding the usefulness of life balance/time management skills, caregivers again indicated that these skills were often useful in the program (4.6 ± 0.70) with adolescents indicating them being useful only sometimes, on average (3.7 ± 1.16).

Behavioral Skills. Caregivers indicated that they often found the SMART goals/tracking skills (4.6 ± 0.35) and the Fitbit group goal setting (4.6 ± 0.35) to be

useful. Adolescents also indicated that they often found the SMART goals/tracking skills (4.0 ± 0.93) and Fitbit group goal setting (3.9 ± 1.12) useful throughout the program.

Family Skills. Both caregivers and adolescents indicated that they use more positive language with their families since beginning the program (4.1 ± 1.05; 3.9 ± 0.83). Caregivers also indicated that the communication skills in the program were often found to be useful in the program (4.3 ± 0.97). Adolescents indicated they found the communication skills sometimes useful (3.9 ± 1.12). When asked whether family members were more supportive in their home since beginning the program, caregivers and adolescents indicated that this was often the case (4.5 ± 0.50 versus 4.1 ± 0.99), respectively.

Cultural Topics. Caregivers and adolescents, on average, indicated that they often enjoyed speaking about racial discrimination/coping (4.5 ± 1.00; 4.3 ± 0.88). Additionally, both caregiver and adolescents noted that they often found the discussions about family cultural traditions enjoyable and useful (4.6 ± 0.70, 4.1 ± 0.83).

3.3 PROCESS EVALUATION: EFFECTIVENESS OF IMPLEMENTATION

Reach. Refer to Figure 2.1 and Table 2.2 for detailed information on recruitment and reach. Recruitment data indicates that out of the 338 attempted contacts, 154 participant families were unable to be reached and 62 participants were not eligible. Of the remaining 122 families that were eligible for recruitment, 23 families enrolled in the study resulting in a response rate of 19%. The apriori goal of ≥70% of families attending at least 6 sessions was met for both study conditions with make-up session included (See Table 3.3). Specifically, 75% of families in the LEADS intervention groups attended $\underline{\geq}$ 6 virtual group sessions, while about 92% of families in the comparison group attended $\underline{\geq}$ 6

virtual group sessions. Families were retained if they completed post measures. The overall retention rate over the three cohorts was 78% (see Table 2.1). The highest retention rate was observed in Cohort 1 (89%).

Dose. Adequate dose was defined apriori as ≥75% of the intended intervention delivered to each cohort. (See Table 3.4 for information on dose delivered by cohort). Elements of dose were key content topics presented and discussed in the intervention, including health behavior skills, family skills, cultural assets, and relapse prevention skills (i.e., stress coping behaviors, cognitive reframing, and life balance). Overall, all key session content was delivered with high dose. The dose for health behavior skills was 100%, and for both family skills and cultural assets the dose was >90%. The dose was also 100% for relapse prevention topics, across all skills, including stress coping skills, cognitive reframing skills, and life balance skills.

Additional program-related dose items were analyzed, including if the facilitators reviewed group ground rules, conducted group feedback, conducted group goal setting, facilitated a group physical activity, assigned the "Family Bonding Activity", and included a summary/closure of the session. Of note, the majority of these program-related elements were delivered with 100% dose, including all key content, interactive activities, and stress coping activities for each session over the three cohorts. Dose for facilitators providing a summary or closure to the session was also adequate at 93% dose delivered. However, the apriori cut point for facilitators displaying or reviewing ground rules established by the participants (63%) did not meet cut-point of 75% or higher.

Fidelity. Adequate level of fidelity was a mean of 3 on a 1–4 scale (1-2 = low; 2-3 = moderate; 3-4 = high). Overall fidelity scores are summarized below, and cohort-

specific fidelity scores for the LEADS intervention can be found in Table 3.5. Across the three cohorts analyzed, all fidelity measures were found to have a mean >3 overall which met the apriori goal. Fidelity scores were compiled to rate the fidelity of implementation of the program by the facilitators. For the key content areas, each component was rated on how well the topic was acknowledged by the facilitator in addition to how well it was reinforced in the groups session. All key program essential elements received a rating of 3.4 or higher; health behavior skills (3.80), family skills (3.74), cultural assets (3.4), stress coping (3.82), cognitive reframing (4.00), and life balance (3.67). Facilitator communication skills (e.g., answering participant questions, encouraging meaningful verbal interactions, providing clear, descriptive praise, reflective listening) were received with high fidelity (3.94). For social support (i.e., positive atmosphere, reinforcing positive interaction between and within families) and self-efficacy (i.e., elicit and reinforce participant success around skill development) high fidelity was observed (>3.5). The highest average fidelity scores were associated with facilitator autonomy support (3.98) which assesses whether the facilitators provide the participants with choices and if they elicit and reinforce participant input in the group meetings.

In addition to facilitator scores, participant group level scores were also analyzed and compiled in Table 3.5. to evaluate the group climate. The overall group climate was rated above the apriori cut point (3.74) and included sharing personal stories, working as a group, making decisions as a group. The highest fidelity score observed was seen in the group level communication scores (3.85), which assesses the level at which families engaged in reciprocal communication with one another and encourage one another to follow the agreed upon ground rules. The lowest average of all fidelity scores, although

still reaching the apriori cut point of >3.0, was observed for participant/family interactions (3.11) which assesses the level with which families provide feedback and encouragement on personal and group goals and helping each other identify and overcome barriers to goal attainment.

3.4 FORMATIVE PROCESS EVALUATION AND CHANGES

During the pilot implementation of the LEADS intervention, facilitators and collaborators met weekly to discuss implementation barriers and make appropriate adjustments to programmatic elements. As pilot studies are intended to prepare the study design and concepts for future testing and implementation, slight adjustments were made during the implementation of the first three cohorts of the LEADS program (Eldridge et al., 2016; Pearson et al., 2020). These adjustments are summarized in Table 3.6. While these adjustments were made during the first three cohorts of the pilot study, no changes were made to key essential elements, measurement, or study design of the program. At the beginning of cohort two in response to the amount of content being presented in the group meetings, it was decided to conduct participant individualized feedback (i.e., personalized discussion about health behavior goals and stress management skills) in separate meetings with families twice during the programs outside of the scheduled group time. Physical activity was reprioritized as a high priority at the beginning of cohort two, which lead to integrating weekly exercise videos in the group sessions in addition to prioritizing the group Fitbit goal setting by moving it to the second session instead of later in the fourth session.

Through formative process evaluation discussions, it was also determined early on in implementation that the families were responsive to discussing racial

discrimination, how it related to stress and coping, and cultural values and traditions. Therefore, a full session was dedicated to racial socialization and family cultural traditions in addition to these aspects being integrated into more stress and behavioral components throughout the intervention. Beginning in cohort three, slight adjustments to the placement and presentation of the cognitive reframing and life balance skills with the adolescent participants were made. For example, reframing was referred to as replacing positive thoughts for negative thoughts. This allowed the adolescents to practice these more complex components separated from their caregivers with breakout rooms and understand these components at a more appropriate pace.

To increase the dose of the stress and racial socialization components of the program without adding more content to the group meetings, tailored text messages were sent daily beginning in cohort three. Examples messages included "Take time this week to continue to talk with your family about tracking stressors throughout your daily routine and develop a plan for your family to cope" and "Take time this week to think of ways you can continue to use the support of your family to maintain your family routine." While participants reported that they enjoyed the tailored text messages and recommended that this continue in future cohorts, it is unknown how of this component of the intervention will impact implementation and study outcomes until more data is collected from later cohorts. These alterations to the pilot study were implemented after careful collaboration with program facilitators, mentors, and collaborators with lived experiences similar to our families. After listening to participant feedback and reviewing the session recordings during process evaluation, these adjustments progressively improved the implementation of the LEADS program across the preliminary cohorts.

Table 3.1 Participant Demographics at Baseline (*n*=23)

Variable	Intervention	Control	Total
Sample Size	12 (52%)	11 (48%)	23 (100%)
Adolescent Sex (Female/Male)	8 (67%)/ 4 (33%)	5 (45%)/ 6 (55%)	13 (57%)/10 (43%)
Adolescent Age (years)	13.27 (1.54)	14.18 (2.25)	13.72 (1.98)
Adolescent Body Mass Index (BMI)	32.64 (7.11)	36.66 (8.00)	34.56 (7.95)
Adolescent Weight Status			
Normal Weight (< 85th %ile)	0 (0%)	0 (0%)	0 (0%)
Overweight (85th %ile - < 95th %ile)	2 (8.33%)	0 (0%)	2 (8.33%)
Obese (≥ 95th %ile)	10 (91.67%)	11 (100%)	21 (91.67%)
Caregiver Sex (Female/Male)	12 (100%)	11 (100%)	23 (100%)/ 0 (0%)
Caregiver Age (years)	50.72 (10.29)	47.55 (7.38)	49.13 (9.09)
Caregiver Body Mass Index (BMI)	39.21 (5.54)	40.38 (8.44)	39.76 (7.10)
Caregiver Weight Status			
Underweight (BMI < 18.5)	0 (0%)	0 (0%)	0 (0%)
Normal Weight (BMI 18.5 – 24.0)	0 (0%)	1 (9.09%)	1 (4.35%)
Overweight (BMI 25.0 – 29.9)	1 (9.09%)	0 (0%)	1 (4.35%)
Obese (BMI ≥ 30.0)	11 (90.91%)	10 (90.91%)	21 (91.30%)
Caregiver Relationship to Adolescent			
Mother	10 (83.3%)	9 (81.8%)	19 (82.6%)
Grandmother	2 (16.6%)	2 (18.2%)	4 (17.4%)
Caregiver Relationship Status*			
Married	5 (45.5%)	4 (36.4%)	9 (39.1%)
Widowed	2 (18.2%)	1 (9.1 %)	3 (13.0%)
Divorced	3 (27.3%)	1 (9.1 %)	4 (17.4%)
Separated	0 (0.0%)	0 (0.0%)	0 (0.0%)
Never married	1 (9.1 %)	3 (27.3%)	4 (17.4%)
In an unmarried couple	0 (0.0%)	2 (18.2%)	2 (8.7%)

Caregiver Education*			
Some High School	0 (0.0%)	0 (0.0%)	0 (0.0%)
High School Degree or GED	0 (0.0%)	1 (9.1 %)	1 (4.3%)
Some College	3 (27.3%)	5 (45.5%)	8 (34.8%)
Associate Degree (2 yrs.)	3 (27.3%)	2 (18.2%)	5 (21.7%)
Bachelor's Degree (4 yrs.)	2 (18.2%)	0 (0.0%)	2 (8.7%)
Graduate Training or Professional Degree	3 (27.3%)	3 (27.3%)	6 (26.1%)
Caregiver Employment Status*			
Working	8 (72.7%)	11 (100%)	19 (86.4%)
Not working	1 (9.1 %)	0 (0.0%)	1 (4.3%)
Retired	1 (9.1 %)	0 (0.0%)	1 (4.3%)
Student	1 (9.1 %)	0 (0.0%)	1 (4.3%)
Household Yearly Income*			
< $10,000	0 (0.0%)	0 (0.0%)	0 (0.0%)
$10,000 to $19,999	2 (18.2%)	1 (9.1 %)	3 (13.0%)
$20,000 to $29,999	3 (27.3%)	2 (18.2%)	5 (21.7%)
$30,000 to $39,999	2 (18.2%)	4 (36.4%)	6 (26.1%)
$40,000 to $49,999	1 (4.3%)	3 (27.3%)	4 (17.4%)
$50,000 to $59,999	1 (4.3%)	1 (4.3%)	2 (8.7%)
$60,000 to $69,999	0 (0.0%)	0 (0.0%)	0 (0.0%)
$70,000 to $79,999	0 (0.0%)	1 (4.3%)	1 (4.3%)
$80,000 to $89,999	1 (4.3%)	0 (0.0%)	1 (4.3%)
$90,000 to $99,999	0 (0.0%)	0 (0.0%)	0 (0.0%)
$100,000 to $149,999	0 (0.0%)	0 (0.0%)	0 (0.0%)
> $150,000	1 (4.3%)	0 (0.0%)	1 (4.3%)
Household Size (# people)	4.27 (0.96)	3.55 (0.99)	3.91 (1.04)

*Note. One participant dyad did not complete baseline measures for these variables, thus data for 22 participants is presented here.

Table 3.2 Post Intervention Feedback for LEADS Intervention Group

	Parents (n = 8)		Adolescents (n = 7)	
	M	SD	M	SD
General				
The LEADS program has been easy to understand for me.	4.6	0.70	4.0	0.92
The LEADS program has been useful for me.	4.4	0.70	4.1	0.83
I enjoy the LEADS group sessions.	4.8	0.66	3.7	1.16
I learned new things in the LEAD group sessions.	4.3	0.66	4.3	0.70
I would recommend the program to other families I know.	4.6	1.00	4.4	0.49
I liked that the program is virtual.	4.4	0.70	4.3	1.03
Group Climate				
I feel respected by the group leaders.	4.9	0.33	4.9	0.35
I liked having more than 2 group leaders/facilitators.	4.8	0.43	4.9	0.35
I feel supported by other families in the LEADS group sessions.	4.1	1.05	4.0	1.07
RPM Components				
I understood the stress management lessons of the LEADS program.	4.5	0.71	4.1	1.12
Focusing on stress management was important to me.	4.5	0.71	3.7	1.16
I plan to use the stress coping strategies I learned in the future.	4.9	0.33	4.3	0.70
It was useful to learn about cognitive reframing.	4.5	0.71	3.6	1.40
It was useful to learn about life balance/time management.	4.6	0.70	3.7	1.16
Behavioral Skills				
I have found the SMART goals and tracking useful.	4.6	0.70	4.0	0.93
The Fitbit group goal setting has been useful.	4.6	0.70	3.9	1.12
Family Skills				
Since the LEADS program, I use more positive language with my family.	4.1	1.05	3.9	0.83

The positive communication skills are useful for me.	4.3	0.97	3.9	1.12
Since the LEADS program, I am more supportive of my family.	4.5	0.50	4.1	0.99
Cultural Topics				
Talking about racial discrimination and coping was useful for me.	4.5	1.00	4.3	0.88
I enjoyed talking about family cultural traditions.	4.6	0.70	4.1	0.83

Note. All items scored on a 5-point scale (1 = Never, 5 = Always)

Table 3.3 Participant Attendance by Condition

	LEADS Intervention (n = 12)	CHE Comparison (n = 11)
Virtual group sessions attended		
Make-up not included		
Attended ≥ 6 sessions, *n* (%)	6 (50.0%)	10 (91.7%)
Average number of sessions attended per family, *M* (*SD*)	6.33 (3.34)	7.73 (2.09)
Make-up included		
Attended ≥ 6 sessions, *n* (%)	9 (75.0%)	10 (91.7%)
Average number of sessions attended per family, *M* (*SD*)	7.66 (3.09)	9.09 (1.44)

Note. CHE = Comprehensive Health Education
A priori criteria for group-based attendance was set at ≥ 70%, make-up sessions included

Table 3.4 Dose Delivered by Cohort

	Cohort			
	1	2	3	Total
Ground rules displayed/reviewed	40%	57%	90%	63%
Session objectives reviewed	100%	100%	100%	100%
Group feedback conducted	100%	100%	100%	100%
Group goal setting conducted (i.e., Fitbit)	100%	100%	100%	100%
Workbook pages displayed	100%	100%	100%	100%
Key content reviewed	100%	100%	100%	100%
Key topics/skills demonstrated	100%	100%	100%	100%
Participants engaged in interactive activity	100%	100%	100%	100%
Stress coping activity completed	100%	100%	100%	100%
Physical activity completed	100%	100%	100%	100%
"Family Bonding Activity" assigned	100%	100%	100%	100%
Summary/closure	90%	86%	100%	93%
Session Content				
Health Behavior Skills	100%	100%	100%	100%
Family Skills	100%	100%	90%	95%
Cultural Assets	100%	100%	88%	92%
Relapse Prevention Content				
Stress Coping Skills	100%	100%	100%	100%
Cognitive Reframing	100%	100%	100%	100%
Life Balance	100%	100%	100%	100%

Note. Percentage calculation = skills delivered/skills intended
A priori criteria for session content dose was set at $\geq$ 75%,

Table 3.5 Intervention Fidelity Scores by Cohort

	Cohort			
	1	2	3	Total
Facilitator Level, *M*(*SD*)				
Health Behavior Skills	3.81 (0.39)	3.63 (0.70)	3.81 (0.39)	3.80 (0.47)
Family Skills	3.79 (0.41)	3.93 (0.26)	3.55 (0.67)	3.74 (0.51)
Cultural Assets	3.50 (0.50)	3.00 (0.82)	3.37 (0.70)	3.40 (0.67)
Stress Coping Skills	3.83 (0.37)	3.75 (0.43)	3.88 (0.37)	3.82 (0.39)
Cognitive Reframing Skills	4.00 (1.00)	4.00 (1.00)	4.00 (1.00)	4.00 (1.00)
Life Balance Skills	3.50 (0.50)	4.00 (1.00)	3.50 (0.50)	3.67 (0.50)
Communication skills	3.95 (0.21)	3.94 (0.25)	3.94 (0.25)	3.94 (0.23)
Social support	3.57 (0.53)	3.63 (0.48)	3.50 (0.50)	3.55 (0.51)
Autonomy support	3.96 (0.18)	3.95 (0.21)	4.00 (1.00)	3.98 (0.16)
Self-efficacy	3.79 (0.40)	3.80 (0.40)	3.62 (0.49)	3.73 (0.45)
Group Level, *M*(*SD*)				
Participant/Family Interactions	3.32 (0.63)	2.88 (0.70)	3.04 (0.62)	3.11 (0.66)
Communication Skills	3.82 (0.39)	3.90 (0.39)	3.85 (0.35)	3.85 (0.38)
Group Climate	3.79 (0.41)	3.58 (0.70)	3.78 (0.42)	3.74 (0.50)

Note. Fidelity items rated on a 1-4 likert scale, 1 = none to 4 = all; all *M* and *SD* were rounded
A priori criteria were set at $\geq$ 3 for fidelity

Table 3.6 Changes Made to LEADS Pilot Study using Formative Process Evaluation

Timepoint	Adjustment
Cohort 2	Prioritized Fitbit group goal setting by moving it up in the intervention timeline.
Cohort 2	Moved individualized feedback sessions to separate meetings. Provided more group time and allowed for more focused individual goal setting.
Cohort 2	Included more discussion about racial stress, discrimination, and racial socialization.
Cohort 2	Included more in-session group exercise videos.
Cohort 3	Simplified discussion around cognitive reframing and life balance with adolescent participants in order to increase uptake and understanding.
Cohort 3	Introduction of tailored text messaged to increase dose of intervention and participation outside of group session.

CHAPTER 4

DISCUSSION

The current study assessed the feasibility, dose, and fidelity of implementation of the LEADS randomized controlled pilot intervention. The LEADS intervention integrated stress management and family-based health promotion components to improve adolescent weight outcomes, decrease stress, and increase well-being among African American families. Novel process evaluation was utilized to assess the addition of the RPM components, and specifically whether this addition reduced the fidelity of the other health promotion components in the program that were based on the previous FIT trial. Dose and fidelity of essential program elements were assessed, including behavioral skills, family skills, cultural tailoring, positive group climate, and the addition of the relapse prevention components (i.e., stress coping, cognitive reframing, life balance). Participants indicated that they enjoyed the program overall with high ratings on a 1-5 scale, noting a positive group climate and usefulness of the program skills and activities. Other than reviewing and displaying group ground rules, it was found that dose met the apriori goal of ≥75% of the intended intervention delivered. Fidelity to essential intervention components met the apriori goal of mean scores >3. It is noted that high fidelity was observed with all program essential elements and the addition of RPM components did not appear to reduce the fidelity of other health promotion elements. Overall, this study provides preliminary support for the usefulness and implementation of

the LEADS intervention and that the program can be delivered with adequate dose, fidelity, and acceptability in a larger effectiveness RCT.

4.1 FEASIBILITY OUTCOMES

A major aim of the current study was to assess if the participants, namely African American families with adolescents, would enjoy intervention content and what aspects of the program were more useful over others. In general, caregiver ratings indicated that they enjoyed the program overall and would recommend the program to other families. While adolescent ratings of overall enjoyment were somewhat lower than their caregivers, it was still relatively high when considering that many of the intervention elements were geared toward caregivers. Parental involvement in health promotion interventions has long been supported and may explain differences in adolescent and caregiver ratings as caregivers may be more equipped to uptake intervention skills and strategies (Tomayko et al., 2021). Related to this, differences in rating of certain RPM components were seen, with caregivers rating the usefulness of cognitive reframing skills and life balance/time management higher than the adolescent participants. It is noted that cognitive reframing and life balance skills are higher-level concepts and can be difficult for younger participants to grasp, and this was noticed in the second cohort of the intervention. Adjustments were made in placement and presentation of these skills in the latter cohort in order to increase uptake and understanding (See Table 3.6). These concepts were explained more in detail using simplified language and break-out groups were formed in order to allow the adolescents to understand and practice cognitive skills with individuals at their developmental level. Yet differences in ratings of enjoyment of these components may indicate the need for higher doses of certain RPM components

with adolescents and less focus on others. For example, although adolescents indicated difficulty with cognitive reframing skills, they expressed that they understood the stress coping skills and planned to use these skills in the future. Tailored preference of intervention components, with specific adaptation for caregivers and adolescents, may be a manner to increase participation and ensure fidelity to intervention essential elements (Napolitano et al., 2021; Sweeney, Wilson, Van Horn et al., 2022).

Both caregiver and adolescent participants indicated that they found talking about racial discrimination and coping to be useful and that they enjoyed discussing family cultural traditions. Previous studies have shown that when parents of African American adolescents are able to promote racial socialization and foster cultural assets (parent support of racial bias, foster cultural pride), benefits are seen in adolescent well-being and self-regulation among other positive outcomes (Anderson et al., 2018; Brody et al., 2004). While the LEADS study incorporated these racial socialization and discrimination coping techniques into primarily one session during the program, participants rated these components to be highly enjoyable and useful. It may be effective to tailor more of the intervention to include these components with higher dose which we are currently doing in subsequent cohorts. After the first three cohorts of the LEADS program were completed, more participants were recruited, and a "high cultural" intensity program was developed which incorporated more discussion and activities about racial socialization, racial coping, and family cultural traditions. This will be compared against the RPM approach with relatively "low cultural" intensity of tailoring. It is anticipated that by incorporating a higher dose of cultural assets and racial socialization within the frame of

the RPM, greater improvements will be seen for adolescent well-being, levels of overall stress, and various physical health outcomes.

Creating a positive group atmosphere in health promotion programs for adolescents and their caregivers has long been a strategy employed to improve group participation and facilitate positive behavior change (Smith et al., 2017; Weihrauch-Blüher et al., 2018). Both caregiver and teens in the LEADS program indicated with very high ratings that they felt respected by the group facilitators, and they enjoyed having more than 1 group leader in the sessions. Not only does this aspect foster a positive group climate but assists in making the environment safe for families to discuss difficult topics such as chronic stress and racial discrimination. Throughout the LEADS program it was also important to include at least one facilitator with African American heritage as this has been found in past research to be an important aspect in family-based health interventions tailored for African American families (Wang et al., 2022; Wilson, Kitzman-Ulrich, Williams et al., 2008). Participants also indicated that they felt supported by other families in the LEADS group sessions. As seen in past studies, utilizing a family group structure allows for more group support, family-based learning and bonding, and improved health behavior outcomes (Sweeney, Wilson, Loncar et al., 2019; Wang et al., 2022).

While the intervention was delivered virtually for various reasons (i.e., reducing transportation difficulties, flexibility, COVID-19 safety), it was unknown how this adaptation would affect the group climate aspect of the program. Past research regarding virtually delivered health promotion programs for families has resulted in promising outcomes, but results have been mixed and few have adequately assessed differences in

group climate when delivered virtually versus in person (Nuss et al., 2022; Popescu et al., 2022). Much of the research has focused on digital media including websites, texting, and videos while very few have assessed the implementation of family-based group meetings held over virtual meeting platforms like Zoom (Archibald et al., 2019; Chai et al., 2022). Various challenges have been discovered when implementing intervention group meetings online including distractibility of participants, technical difficulties, less group cohesion, and decreased group participation (Lopez et al., 2020; Weinberg, 2021). Despite these concerns, families in the LEADs program indicated that they felt supported by other families in the program and noted that they enjoyed that the program was virtual. They also provided high ratings for the program being virtual. Further research is needed to determine best practices when administering a group-based health promotion intervention in a virtual setting, especially among ethnic minority populations.

4.2 IMPLEMENTATION OUTCOMES

High dose and fidelity were observed in the implementation of the LEADS intervention using comprehensive process evaluation methods. All but one of the dose indicators met the apriori goal of ≥75%. Display and review of group ground rules occurred at 63%. Group ground rules are utilized in family-based interventions to encourage respectful communication and foster a positive group environment (e Cunha et al., 2022; Sweeney et al., 2022; Wilson et al., 2022). One noticeable difficulty with displaying ground rules was the virtual nature of the program and the challenge of not displaying the ground rules continually throughout the group sessions. Group ground rules are an important part of the intervention process and should be utilized with higher dose in future. Practical solutions for future implementation could be to have the group ground rules displayed on the screen when group members enter the virtual environment

or to send the rules in the chat at the beginning of the group session. All essential intervention components met the apriori fidelity goal of mean scores >3. Comprehensive and theory-based process evaluation indicators are essential for accurate interpretation of study outcomes, as interventions may have limited effects due to improper implementation (Brownson et al., 2009; Moore et al., 2015; Saunders et al., 2005, 2022). Implementation data is highly useful for pilot and feasibility studies as this information can be invaluable when planning next steps for larger-scale RCT's (Pearson et al., 2020; Saunders et al., 2022). Novel process evaluation approaches have been utilized in health promotion programs tailored for African American communities to evaluate dose and fidelity of implementation (Alia et al., 2015; Moore et al., 2021; Pate et al., 2003; Saunders et al., 2022; St. George et al., 2016; Sweeney et al., 2020; Wilson et al., 2009, 2022). The current study builds upon previous process evaluation strategies by developing and implementing a novel protocol for evaluating the integration of stress management components using the RPM (See Appendix C).

While it is important to assess the overall implementation effectiveness of a pilot intervention, process evaluation is also useful to assess the overall group climate. As done in our past studies, the facilitator level of dose and fidelity was assessed along with the family group level related to group climate (Sweeney et al., 2019; Wilson et al., 2009, 2022). Past studies have demonstrated that a positive group climate provides support during the group but can also provide secondary benefits in health promotion programs for families and their children, such as improved family communication and self-efficacy (Kurock et al., 2022; Sweeney et al., 2019). Fostering a positive and nurturing environment was a key intervention component, and process evaluation data in this study

indicated that apriori goals for a positive social climate were met at both the facilitator and group levels (Wilson et al., 2017). Families rated the group climate highly and families were very receptive to the stress management components of the intervention based on the RPM which could have an effect on group climate and group cohesiveness. Facilitators in the program consistently modeled a nurturing and supportive environment demonstrating high fidelity for implementation of behavioral skills, family skills, stress management skill, communication skills, social support, and autonomy support. Furthermore, a positive group climate was observed at the family group level across cohorts demonstrating that the families worked on activities and made decision as a group in addition to sharing personal stories about their progress in the program. Capturing the climate at both the facilitator and family group level is an important approach that will inform the implementation of the intervention moving forward.

Along with aspects of fidelity and dose, reach was assessed for the intervention with response rate, attendance, and retention rate. Past research suggests that recruitment of ethnic minority populations for intervention research may be difficult due to barriers associated with lower availability and utilization of formal services and historical distrust of the medical system (Brannon et al., 2013; Brown et al., 2014). In the feasibility and acceptability questions, most of the families indicated that they found the virtual aspect of the program convenient. However, the 10-week program requires a large commitment for families in the context of previously mentioned barriers known among African American families. Additionally, African American families may experience other barriers to recruitment including study language literacy, multiple caregiver responsibilities, lack of transportation and childcare, and lack of time to participate (Haley et al., 2017;

Quattlebaum et al., 2021). Recruitment in the current study yielded a 19% response rate which is relatively low compared to other studies (Durant et al., 2011; Guagliano et al., 2021; Law et al., 2020). Recruitment strategies that are targeted at cultural events and already existing cultural institutions have demonstrated success in the past and this preliminary study shows the importance of continuing to build these partnerships in the community (Brookman-Frazee et al., 2016; D'Alonzo, 2010; Wilson et al., 2015). Furthermore, an effort to engage in culturally tailored recruitment would assist in the translation of evidenced-based treatments into community-based services (Law et al., 2020).

Attendance rates have also been shown to be lower in interventions recruiting ethnic minority families due to barriers mentioned above in addition to the possibility that programs do not adequately address important cultural factors that affect behavioral outcomes (St. George et al., 2018; Williams et al., 2010; Williams et al., 2017). Incorporating cultural components and the virtual aspect of the program addressed some of these barriers and allowed for more flexibility for families to attend sessions which assisted in meeting the apriori goal of ≥70% session attendance with makeup sessions included. While virtual implementation of family-based interventions using video platforms (e.g., Zoom) is relatively new and little data is available, some studies have demonstrated comparable attendance and completion rates when comparing in-person and virtual program (Nuss et al., 2022; Williams et al., 2010). This study provides preliminary support of the transition of group-based health promotion programs to online platforms. The high study retention rate of 78% is comparable to other similar studies (Mazzeo et al., 2019; Wilson et al., 2022) and suggests that once families were

randomized, they tended to complete the study and engage in post intervention measurement activities. Furthermore, this study implemented a 2-week run-in phase which has been found useful in retaining participant families in past studies by randomizing families that show a commitment to the program and allow time to address socio-cultural barriers to engagement (Laursen et al., 2019; Ulmer et al., 2008). Although the sample size is low in relation to the retention rate, this process evaluation data provides preliminary evidence that families are willing to continue in the program despite barriers and program length.

4.3 STUDY LIMITATIONS AND STRENGTHS

There were several study limitations, which should be considered when interpreting the results. Despite having a relatively high retention rate of participants (78%), the response rate of potentially eligible participants was low (~20%). This has been observed in past behavioral health intervention studies for African American families. Although precautions were made to increase participant engagement (i.e., having virtual sessions, shortening the number of sessions compared to other programs, making survey measures electronic), it remains an ongoing challenge to increase methods for reach for African American families. Yet, few studies have tested the implementation of a virtual stress coping plus behavioral health intervention among this population and this study adds to the literature specifically by integrating a relapse prevention model that incorporates stress management techniques and life balance. Further research is needed such as a large scale RCT before definite conclusions and comparisons can be made.

Another limitation of the current study is that reasons for dropping out were not assessed, meaning we cannot make firm conclusions about the reasons for participants dropping out of the program or failing to provide post-intervention measures. While some

families had health problems or deaths in their families no systematic system documented all the reasons for dropping out. Although the sample size in this study is comparable to other pilot studies of this type, it is acknowledged that implementation barriers will most likely increase with a larger sample size in a larger efficacy trial. However, with more specific cultural recruitment strategies (e.g., partnerships with African American churches and organizations, African American recruiters) and tailoring, barriers can be overcome to increase reach, engagement, and retention. Despite the promising preliminary implementation and feasibility data, it is unknown how these aspects could generalize to a larger sample or other racial/ethnic groups. The sample has limited variability, as it included a small sample of AA adolescents with overweight or obesity in the Southern United States, limiting applicability to families of non-AA descent or families with normal-weight adolescents.

Despite these limitations, this study also presents many unique strengths and is a preparatory step in furthering the research evidence base on this topic. The sample is a consistently understudied and underserved population, namely African American adolescents with obesity and their caregivers (Tomiyama et al., 2012). Many researchers have called for incorporating culturally tailored intervention components into health promotion program in order to mitigate health disparities unique to African American families (Kumanyika et al., 2014). With chronic stress being a possible mechanism in addressing health disparities among ethnic minority families, this is one of few studies to assess the implementation of an intervention that incorporates stress coping strategies (i.e., RPM), racial socialization, and cultural tailoring into a behavioral health

intervention to improve health behaviors related to weight outcomes among African American adolescents (Berge, 2009; Parks et al., 2016).

This study provides preliminary evidence with regard to utilizing various technological and media-based mediums, including virtual group meetings, electronic communication, and text message intervention elements. This is an important strength of the current study as the need for adaptive, virtual interventions is growing and more families can be reached with these tailored and flexible interventions (Partridge & Redfern, 2018; Whitley & Yahia, 2021). Finally, this study provides feasibility and fidelity evidence for a larger efficacy trial to obtain statistical power in order to adequately measure the efficacy of study outcomes and evaluate mechanisms of change.

4.4 CONCLUSION AND IMPLICATIONS

Given that African American adolescents experience high rates of obesity in the United States (~40%), they are at risk for numerous chronic diseases, including type 2 diabetes and high blood pressure. Additionally, African American adolescents are exposed to high levels of chronic stress from social and environmental circumstances. The present study is one of the first to assess the feasibility and fidelity of a randomized controlled pilot study that integrated stress management and family-based health promotion components to improve adolescent weight outcomes, decrease stress, and increase well-being among African American families. Study results indicate preliminary support for the feasibility and acceptability of the LEADS behavioral health program. High dose and fidelity indicate that the intervention can also be delivered in the designated session length and in a virtual group format. Additionally, caregiver and adolescent rating of program elements and key content indicate satisfaction with the intervention and overall enjoyment of the virtual group atmosphere.

Of note, both caregivers and adolescents in the program rated the stress coping and racial socialization components highly, noting the need to address chronic stress as a barrier to intervention participation and maintenance of health behavior goals. Despite these favorable ratings, it was observed that certain stress management components were rated to be less understood and useful by adolescents (i.e., cognitive reframing, life balance). This indicates the possible usefulness of a developmentally tailored delivery system to be used in future trials, which could act as a way to deliver this content in a way that was developmentally appropriate and appealing to youth.

A larger trial and a longer follow-up period would allow for adequate testing of the intervention efficacy on various health outcomes and in-depth exploration of key theoretical mediators that may be successful in promoting health behavior change alleviating health disparities among this population. As few integrated stress management and health promotion programs have been developed and utilized among African American families, the implementation evidence results from the current study inform subsequent research about the utility of including these components into future programs. Furthermore, this research fosters innovative implementation processes for future intervention programs in medical and community settings to address health inequities among African American adolescents and their families.

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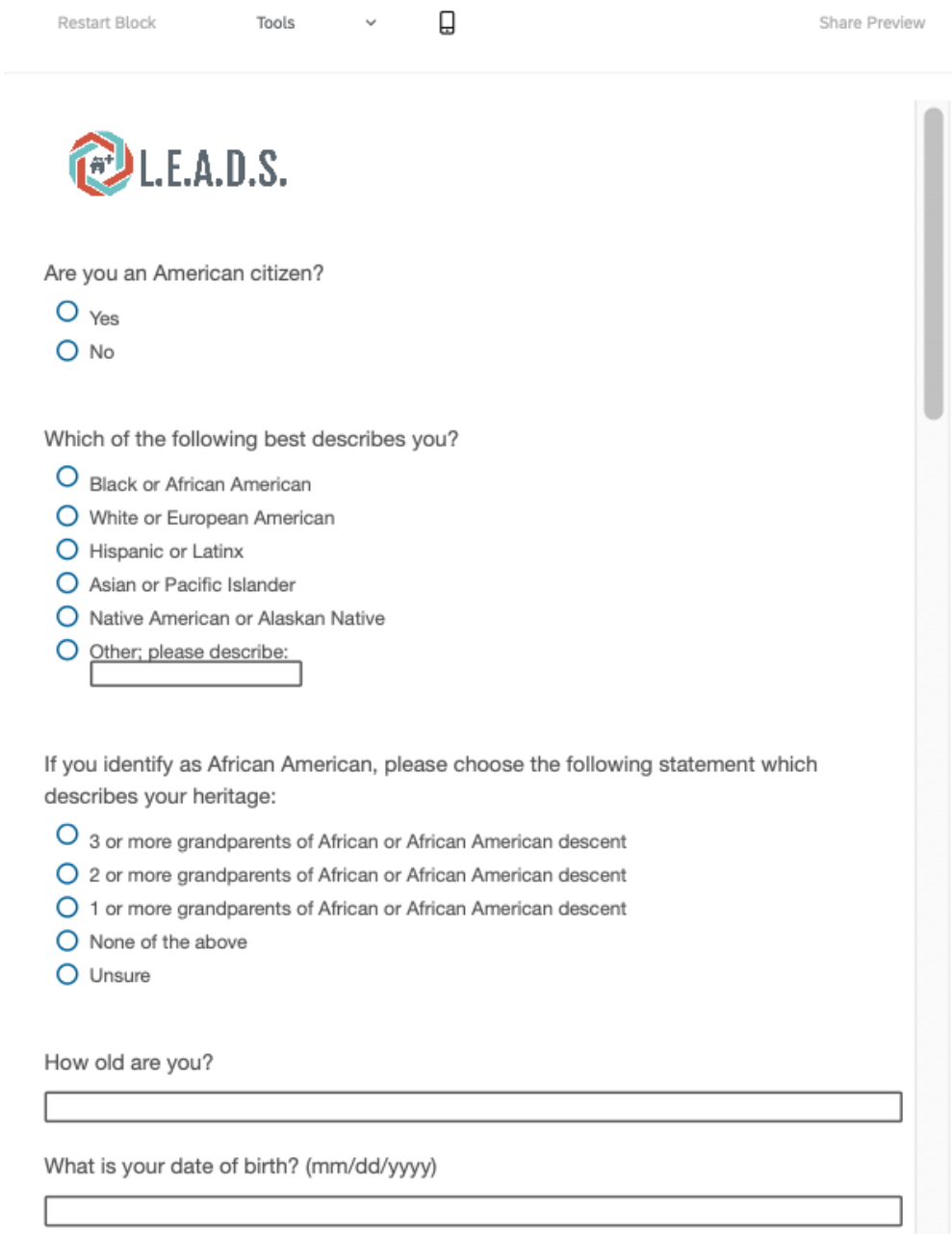
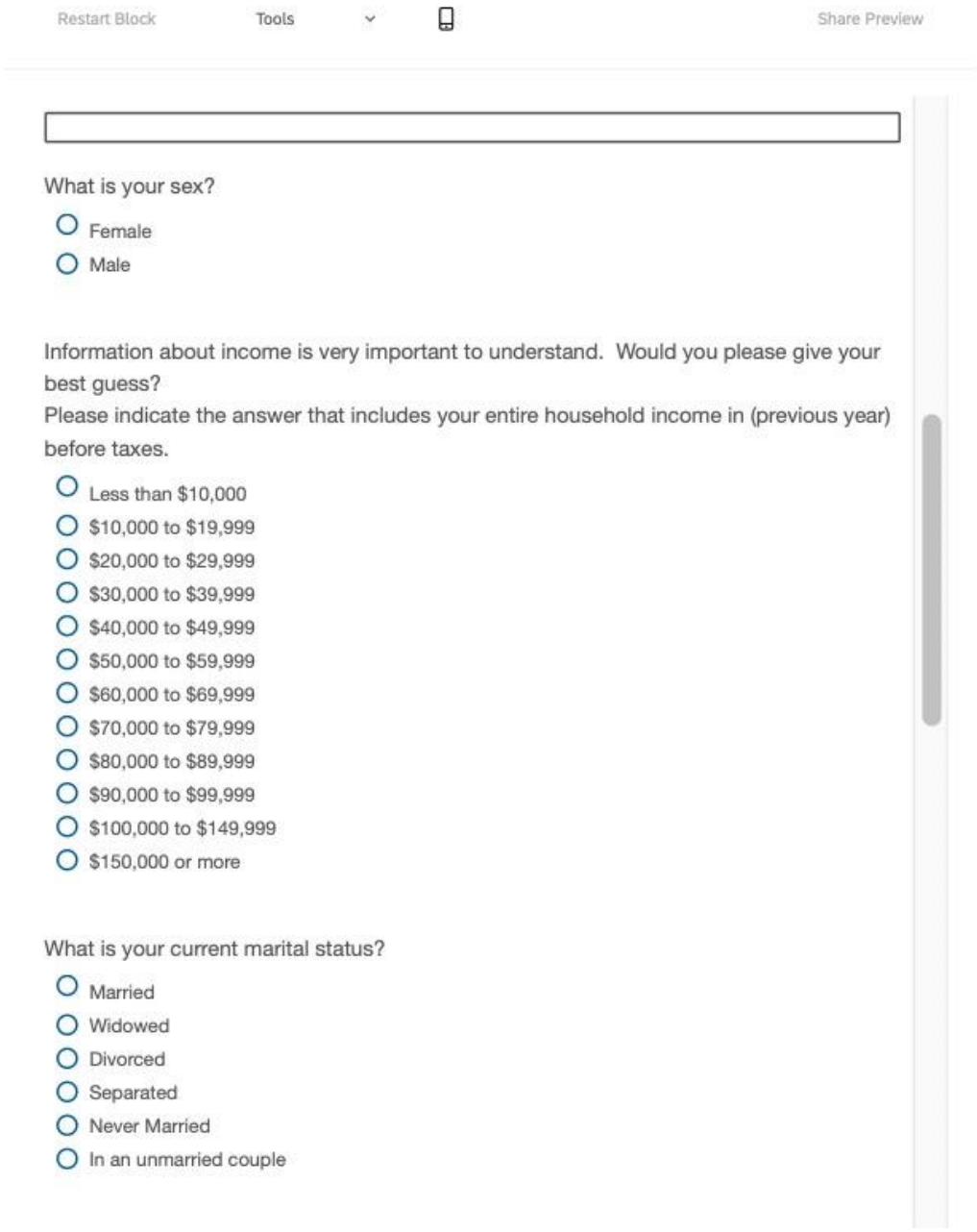
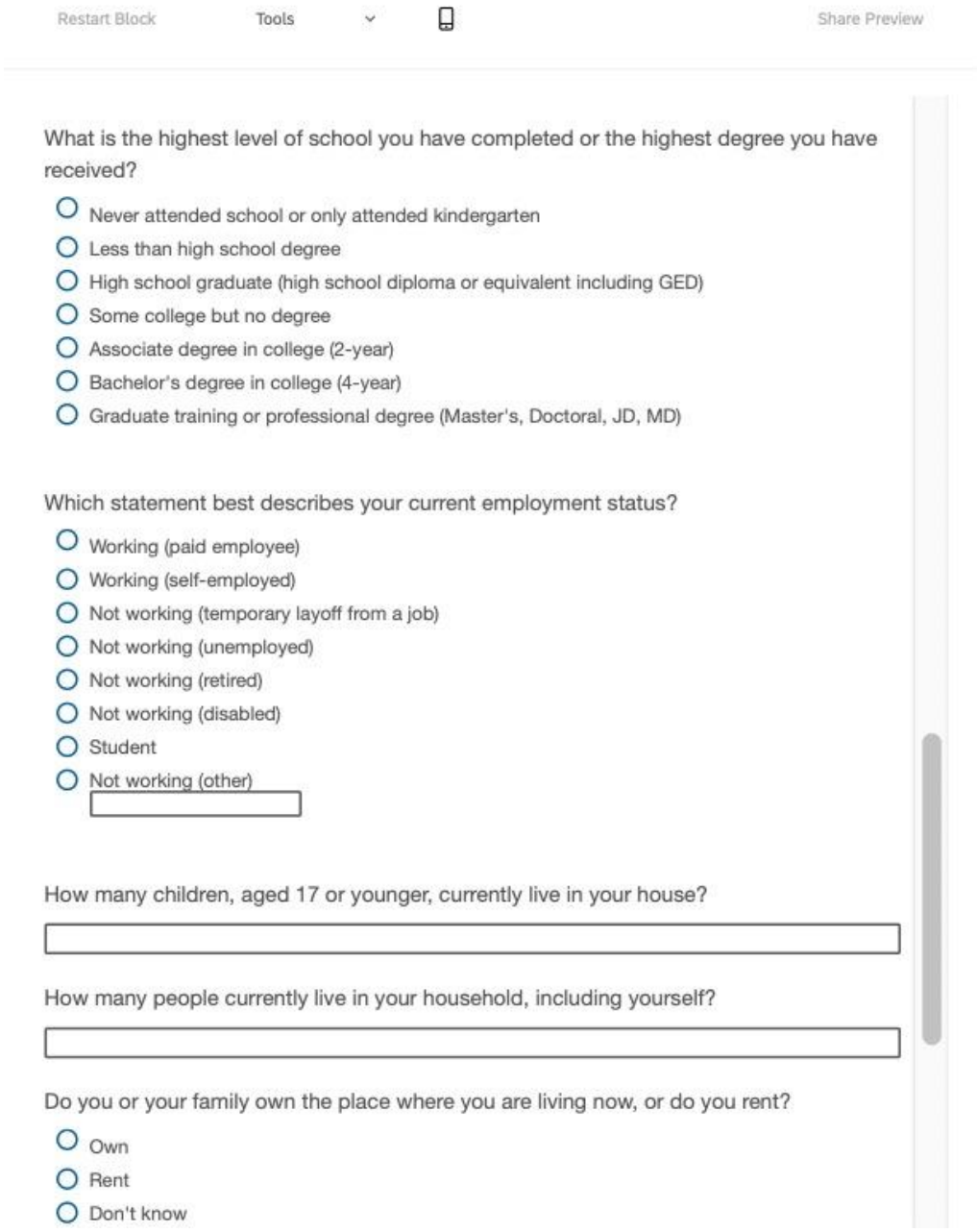
APPENDIX A

FOCUS GROUP QUESTIONS




Restart Block
Tools
Share Preview
What is your sex?
Female
Male
Information about income is very important to understand. Would you please give your best guess?
Please indicate the answer that includes your entire household income in (previous year) before taxes.
Less than $10,000
$10,000 to $19,999
$20,000 to $29,999
$30,000 to $39,999
$40,000 to $49,999
$50,000 to $59,999
$60,000 to $69,999
$70,000 to $79,999
$80,000 to $89,999
$90,000 to $99,999
$100,000 to $149,999
$150,000 or more
What is your current marital status?
Married
Widowed
Divorced
Separated
Never Married
In an unmarried couple


Restart Block
Tools
Share Preview
What is the highest level of school you have completed or the highest degree you have received?
Never attended school or only attended kindergarten
Less than high school degree
High school graduate (high school diploma or equivalent including GED)
Some college but no degree
Associate degree in college (2-year)
Bachelor's degree in college (4-year)
Graduate training or professional degree (Master's, Doctoral, JD, MD)
Which statement best describes your current employment status?
Working (paid employee)
Working (self-employed)
Not working (temporary layoff from a job)
Not working (unemployed)
Not working (retired)
Not working (disabled)
Student
Not working (other)
How many children, aged 17 or younger, currently live in your house?
How many people currently live in your household, including yourself?
Do you or your family own the place where you are living now, or do you rent?
Own
Rent
Don't know

What is your relationship to the adolescent participating?

- ○ Mother
- ○ Father
- ○ Grandmother
- ○ Grandfather
- ○ Aunt
- ○ Uncle
- ○ Other relation (cousin, sibling, etc.)
- ○ Not-related (nanny, babysitter, godparent, etc.)

→

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APPENDIX B

MIDPOINT & POST-INTERVENTION FEASIBILITY SURVEYS

Welcome to the LEADS Mid-Point Survey!

We are interested in learning more from you about how the program is going so far.

The following questions ask about different aspects of the program. We appreciate your honest feedback so we can improve the program

This survey should take about 10 minutes to complete.

Please answer the following questions regarding various aspects of the LEADS group sessions. Rate on a scale of 1-5 how often you experience the following statements.

Never	Rarely	Sometimes	Often	Always
1	2	3	4	5

1. The LEADS program has been easy to understand for me.
2. The LEADS program has been useful for me.
3. I feel respected by the group leaders.
4. I feel supported by other families in the LEADS group sessions.
5. Since the LEADS program, I use positive language with my family.
6. I enjoy the LEADS group sessions.
7. I understand the stress management lessons of the LEADS program.
8. I have found the SMART goals and tracking useful.
9. The Fitbit group goal setting has been fun.
10. I am learning new things in the LEAD group sessions.
11. Since the LEADS program, I am supportive of my family.
12. I like that the program is virtual.
13. I would recommend the program to other families I know.
14. I have found the exercise videos during the group sessions enjoyable.
15. I enjoy receiving customized text messages daily.

What have you liked most about the LEADS program?

What could we do better?

Welcome to the LEADS Post-Intervention Final Survey!

We are interested in learning more from you about how the program is going so far.

The following questions ask about different aspects of the program. We appreciate your honest feedback so we can improve the program

This survey should take about 10 minutes to complete.

Please answer the following questions regarding various aspects of the LEADS group sessions. Rate on a scale of 1-5 how often you experience the following statements.

Never	Rarely	Sometimes	Often	Always
1	2	3	4	5

1. The LEADS program has been easy to understand for me.
2. The LEADS program has been useful for me.
3. I enjoyed the LEADS group sessions.
4. I felt respected by the group leaders.
5. I liked having more than 2 group leaders/facilitators.
6. I feel supported by other families in the LEADS group sessions.
7. Since the LEADS program, I use positive language with my family.
8. The positive communication skills are useful for me.
9. Since the LEADS program, I am more supportive of my family.
10. I understand the stress management lessons of the LEADS program.
11. Focusing on stress management was important to me.
12. I plan to use the stress coping strategies I learned in the future (I.e. deep breathing, progressive muscle relaxation).
13. It was useful to learn about cognitive reframing.
14. It was useful to learn about life balance/time management.
15. I have found the SMART goals and tracking useful.
16. The Fitbit group goal setting has been fun.
17. I am learned new things in the LEAD group sessions.
18. I would recommend the program to other families I know.
19. Talking about racial discrimination and coping was useful for me.
20. I enjoyed talking about family cultural traditions.
21. I like that the program is virtual.
22. I have found the exercise videos during the group sessions enjoyable.

What have you liked most about the LEADS program?

What could we do better?

APPENDIX C

LEADS PROCESS EVALUATION FORMS

DOSE	No	Yes	NA
Session Content			
1. Facilitators start session on time (or no more than 5-7 minutes past the scheduled time)	0	1	____
2. Trivia Question	0	1	____
3. Reminder about Gift Card Raffles	0	1	____
4. Ground rules reviewed	0	1	____
5. Session objectives reviewed with participants	0	1	____
6. Group feedback conducted	0	1	____
7. Group goal setting conducted (i.e. FitBit)	0	1	____
8. Reminder about Tailored Text Messages	0	1	____
9. Workbook pages displayed/used by facilitators	0	1	____
10. Most (≥75%) of the key content reviewed (see facilitators guide for list of key content)	0	1	____
11. Most (≥75%) of the key topics/skills demonstrated (or examples provided/elicited from participants)	0	1	____
12. Most (≥75%) of the families engage in interactive activity (brainstorm, role play, etc.)	0	1	____
13. Most (≥75%) of the families had their cameras turned on for at least part of the session.	0	1	____
14. Most (≥75%) of the families remained logged in for the full session	0	1	____
15. Most (≥75%) of the families did not experience technology challenges (e.g., camera issues, sound, internet dripping, etc.)	0	1	____
16. Stress coping activity completed	0	1	____
17. Physical activity completed	0	1	____
18. "Family Bonding Activity" assigned	0	1	____
19. Cultural Assets discussed	0	1	
20. Summary/closure	0	1	____

Health Behavioral Skills

1. Behavioral Skill discussed during session as highlighted in the facilitators guide. Name Behavioral skill:_____ 0 1 ____
2. Behavioral Skill discussed during session as highlighted in the facilitators guide. Name Behavioral skill:_____ 0 1 ____
3. Behavioral Skill discussed during session as highlighted in the facilitators guide. Name Behavioral skill:_____ 0 1 ____

Family Skills

1. Family Skill discussed during session as highlighted in the facilitators guide. Name Family skill:_____ 0 1 ____
2. Family Skill discussed during session as highlighted in the facilitators guide. Name Family skill:_____ 0 1 ____
3. Family Skill discussed during session as highlighted in the facilitators guide. Name Family skill:_____ 0 1 ____

Cultural Assets

1. Cultural topic discussed during session as highlighted in the facilitators guide. Name Cultural topic:_____ 0 1 ____
2. Cultural topic discussed during session as highlighted in the facilitators guide. Name Cultural topic:_____ 0 1 ____
3. Cultural topic discussed during session as highlighted in the facilitators guide. Name Cultural topic:_____ 0 1 ____

Stress Coping Skills

4. Stress Coping Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____
5. Stress Coping Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____
6. Stress Coping Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____

Cognitive Reframing Skills

4. Cognitive Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____
5. Cognitive Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____
6. Cognitive Skill discussed during session as highlighted in the facilitators guide. Name skill:_____ 0 1 ____

Life Balance

4. Life Balance discussed during session as highlighted in the facilitators guide. Name topic:_____ 0 1 ____
5. Life Balance discussed during session as highlighted in the facilitators guide. Name topic:_____ 0 1 ____
6. Life Balance discussed during session as highlighted in the facilitators guide. Name topic:_____ 0 1 ____

Group Session – Facilitator Implementation

FIDELITY *(observe facilitation of all facilitators)*	None	Some	Most	All	NA
Session Content					
1. Facilitators covered key content as outlined in the facilitator's guide	1	2	3	4	____
2. Participants engaged in interactive activity as outlined in the facilitator's guide	1	2	3	4	____
3. Facilitators explained and assigned "Family Bonding Activity" as outlined in the facilitator's guide	1	2	3	4	____
Group Feedback Sessions/Group Goal Setting					
1. Facilitators reinforce national recommendations for target health behaviors	1	2	3	4	____
2. Facilitators reinforce use of health behavior skills	1	2	3	4	____
3. Facilitators reinforce use of stress management skills	1	2	3	4	____
4. Facilitators provide feedback on use of self-monitoring tools (e.g., Fitbits, logs, tracking systems)	1	2	3	4	____
5. Facilitators provide feedback on weekly short term goals (group or personal) related to health behavior and stress management	1	2	3	4	____
6. Facilitators aid families in linking short term goals to long term goals	1	2	3	4	____
7. Facilitators aid participants in identifying and overcoming barriers towards skill development and goal attainment	1	2	3	4	____
a. Identify Barriers	1	2	3	4	____
b. Identify strategies for overcoming barriers					
8. Facilitators acknowledge and reinforce progress (based on individual/family goals) towards skill development and goal attainment					
a. Acknowledge	1	2	3	4	____
b. Reinforce	1	2	3	4	____
9. Facilitators aid participants in developing an action plan for achieving personal/family goals.	1	2	3	4	____
10. Facilitators encourage families to support one another in setting/meeting goals through comments or questions	1	2	3	4	____

Behavioral Skills

1. Facilitators acknowledge and reinforce use of behavioral skill as highlighted in facilitators guide. Name Behavioral skill:_____
   a. Acknowledge 1 2 3 4 _____
   b. Reinforce 1 2 3 4 _____
2. Facilitators acknowledge and reinforce use of behavioral skill as highlighted in facilitators guide. Name Behavioral skill:_____
   c. Acknowledge 1 2 3 4 _____
   d. Reinforce 1 2 3 4 _____
3. Facilitators acknowledge and reinforce use of behavioral skill as highlighted in facilitators guide. Name Behavioral skill:_____
   e. Acknowledge 1 2 3 4 _____
   f. Reinforce 1 2 3 4 _____

Family Skills

1. Facilitators acknowledge and reinforce use of family skill as highlighted in facilitators guide. Name family skill:_____
   a. Acknowledge 1 2 3 4 _____
   b. Reinforce 1 2 3 4 _____
2. Facilitators acknowledge and reinforce use of family skill as highlighted in facilitators guide. Name family skill:_____
   a. Acknowledge 1 2 3 4 _____
   b. Reinforce 1 2 3 4 _____
3. Facilitators acknowledge and reinforce use of family skill as highlighted in facilitators guide. Name family skill:_____
   a. Acknowledge 1 2 3 4 _____
   b. Reinforce 1 2 3 4 _____

Cultural Assets

1. Facilitators acknowledge and reinforce cultural assets as highlighted in facilitators guide. Name skill:_____
   c. Acknowledge 1 2 3 4 _____
   d. Reinforce 1 2 3 4 _____
2. Facilitators acknowledge and reinforce cultural assets as highlighted in facilitators guide. Name skill:_____
   c. Acknowledge 1 2 3 4 _____
   d. Reinforce 1 2 3 4 _____

3. Facilitators acknowledge and reinforce cultural assets as highlighted in facilitators guide. Name skill:_____

c. Acknowledge	1	2	3	4	____
d. Reinforce	1	2	3	4	____

Stress Coping Skills

4. Facilitators acknowledge and reinforce use of stress coping skill as highlighted in facilitators guide. Name skill:_____

e. Acknowledge	1	2	3	4	____
f. Reinforce	1	2	3	4	____

5. Facilitators acknowledge and reinforce use of stress coping skill as highlighted in facilitators guide. Name skill:_____

e. Acknowledge	1	2	3	4	____
f. Reinforce	1	2	3	4	____

6. Facilitators acknowledge and reinforce use of stress coping skill as highlighted in facilitators guide. Name skill:_____

e. Acknowledge	1	2	3	4	____
f. Reinforce	1	2	3	4	____

Cognitive Reframing Skills

1. Facilitators acknowledge and reinforce use of cognitive skill as highlighted in facilitators guide. Name skill:_____

g. Acknowledge	1	2	3	4	____
h. Reinforce	1	2	3	4	____

2. Facilitators acknowledge and reinforce use of cognitive skill as highlighted in facilitators guide. Name skill:_____

g. Acknowledge	1	2	3	4	____
h. Reinforce	1	2	3	4	____

3. Facilitators acknowledge and reinforce use of cognitive skill as highlighted in facilitators guide. Name skill:_____

g. Acknowledge	1	2	3	4	____
h. Reinforce	1	2	3	4	____

Life Balance

1. Facilitators acknowledge and reinforce use of life balance topic as highlighted in facilitators guide. Name skill:_____

i. Acknowledge	1	2	3	4	____
j. Reinforce	1	2	3	4	____

2. Facilitators acknowledge and reinforce use of life balance skill as highlighted in facilitators guide. Name skill:_____
    i. Acknowledge 1 2 3 4 ____
    j. Reinforce 1 2 3 4 ____

Communication Skills

1. Facilitator reviews session objectives with all participants 1 2 3 4 ____
2. Facilitator asks if participants have questions 1 2 3 4 ____
3. Facilitator fully answers participants' questions or promises to get back to them 1 2 3 4 ____
4. Facilitators ensure participants follow ground rules 1 2 3 4 ____
5. Facilitators have meaningful verbal interaction with participants:
    a. Calling participants by name 1 2 3 4 ____
    b. Tone of voice 1 2 3 4 ____
    c. Using developmentally appropriate language 1 2 3 4 ____
6. Facilitators engage in reciprocal communication with participants:
    a. Listen 1 2 3 4 ____
    b. Verbally respond when prompted 1 2 3 4 ____
    c. Respond with reflective listening statements 1 2 3 4 ____
7. Facilitators use clear, descriptive praise when providing participants with feedback. 1 2 3 4 ____

Social Support

1. The atmosphere set by facilitators is welcoming, upbeat and positive
    a. Small talk 1 2 3 4 ____
    b. Upbeat, enthusiastic 1 2 3 4 ____
2. Facilitators acknowledge and reinforce positive interactions within families
    a. Acknowledge 1 2 3 4 ____
    b. Reinforce 1 2 3 4 ____
3. Facilitators acknowledge and reinforce positive interactions between families
    a. Acknowledge 1 2 3 4 ____
    b. Reinforce 1 2 3 4 ____

Autonomy Support

1. Facilitators provide participants with choices 1 2 3 4 ____
2. Facilitators elicit and reinforce participant input
    a. Elicit 1 2 3 4 ____
    b. Reinforce 1 2 3 4 ____

Self-Efficacy

1. Facilitators elicit and reinforce participants' personal successes around behavioral skill development.					
a. Elicit	1	2	3	4	____
b. Reinforce	1	2	3	4	____
2. Facilitators elicit and reflect upon participants' personal successes around parenting skill development.					
a. Elicit	1	2	3	4	____
b. Reinforce	1	2	3	4	____

Group Session – Group Participant Interactions

FIDELITY *(observe group participants)*	None	Some	Most	All	NA
Participant/Family Interactions					
1. Families provide one another with feedback on use of self-monitoring tools.	1	2	3	4	____
2. Families provide one another with feedback on use of stress management skills.	1	2	3	4	____
3. Families provide one another with feedback on weekly short term group goals and assignments.	1	2	3	4	____
4. Families help one another identify strategies for overcoming barriers to health behavior and stress management goals.	1	2	3	4	____
5. Families provide one another with encouragement and positive reinforcement towards achieving personal/family goals.	1	2	3	4	____
Communication Skills					
1. Families follow ground rules.	1	2	3	4	____
2. Families encourage one another to follow ground rules.	1	2	3	4	____
3. Families engage in reciprocal communication with one another:					
a. Listen	1	2	3	4	____
b. Verbally respond when prompted	1	2	3	4	____
c. Positive tone of voice	1	2	3	4	
Group Climate					
1. Families share personal stories related to working on health behavior goals.	1	2	3	4	____
2. Families share personal stories related to working on family skills.	1	2	3	4	____
3. Families work on activities as a group.	1	2	3	4	____
4. Families make decisions as a group.	1	2	3	4	____