THE IMPACT OF A LOW-INTENSITY PHYSICAL ACTIVITY INTERVENTION ON HEALTH BEHAVIOR CHANGE IN PEDIATRIC CANCER SURVIVORS

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Abstract: *Objective*: To assess the FitBit Flex^{TM} as a low-intensity, low cost physical activity (PA) intervention for pediatric cancer survivors (PSCs). Additionally, we aimed to assess the impact of social support (SS) for PA on moderate to vigorous physical acticity (MVPA), and the feasibility/acceptability of survivors wearing a FitBit Flex^{TM}. It was hypothesized that wearing a FitBit Flex^{TM} and increased SS would increase rates of MVPA/step count and that survivors and their families would report high feasibility/acceptability of FitBit Flex^{TM} use. *Methods*: Utilizing an N-of-1 design, participants and one of their parents were randomized by day for 30 days to wear or not wear the FitBit Flex^{TM}. SS for PA was measured using the Social Support for Exercise Survey. Acceptability and feasibility were assessed using a Feedback Questionnaire and examining protocol compliance. *Results*: Twelve PCSs (M_{age} = 13.6 years; 33% male; 67% Caucasian) completed the study. Participants engaged in less MVPA than recommended. Additionally, the FitBit Flex^{TM} intervention negatively impacted rates of MVPA and step counts. SS did not have an impact on rates of MVPA. Participants were adherent to wear time and study protocol. Acceptability and feasibility were high. *Conclusions*: Rates of PA are a concern among PCSs and interventions are needed to promote positive behavior change. Future research should aim to better understand the role that electronic devices and SS can play within this specific population to help promote increased PA.

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CHAPTER I

INTRODUCTION

The American Cancer Society (2017) has estimated that 10,270 children in the United States would be diagnosed with cancer in 2017 alone, with incidence rates slowly continuing to rise since 1975. Among children recently diagnosed with cancer, approximately 83 percent will survive at least 5 years past their diagnosis date (American Cancer Society, 2014). Although these children survive their diagnosis, many are at risk to experience significant cancer- and treatment-related side effects, including impairment in cardiovascular and lung functioning (Hochberg, Cairo, & Friedman, 2014), bone growth abnormalities (Paulino, 2004), muscle and tissue atrophy (Paulino, 2004), increased rates of obesity (Zhang, Kelly, Saltzman, Must, Roberts, & Parsons, 2014), increased risk for endocrine and metabolic disorders (Tonorezos, Hudson, Edgar, Kremer, Sklar, Wallace, & Oeffinger, 2015; Rosen, Nguyen, & Shaibi, 2013), and neurocognitive problems (e.g., deficits in attention, concentration, executive functioning, processing speed, and working memory; Olson & Sands, 2015). Additionally, adult pediatric cancer survivors are 3 times more likely to develop a chronic illness compared to their siblings (Oeffinger et al., 2006) and about 8 times more likely to die prematurely compared to matched controls (Mertens, 2008).

These side effects inevitably result in significant increases in health care utilization (Rebholz et al., 2011). It has been estimated that at least one late-onset therapy-related complication will occur in about 67 percent of pediatric cancer cases requiring frequent follow-up care (American Academy of Pediatrics, 2009), resulting in increased health care costs. For example, research has shown that pediatric cancer survivors have increased rates of both out- and in-patient hospital visits and speak with their physicians more frequently than the general population (Rebholz et al., 2011). Furthermore, these rates are highest among survivors who have a history of neuroblastoma, Wilms tumor, Hodgkin's lymphoma, bone sarcomas, and central nervous system tumors (Rebholz et al., 2011). Among radiated acute lymphoblastic leukemia survivors, research demonstrates increased rates of hospital visits and increased days inpatient compared to matched controls (Holmqvist et al., 2014). In order to combat adverse cancer- and treatment-related side effects, research has progressed toward identifying protective behaviors. Through this work, physical activity has been identified as a critical intervention for improving the general health of pediatric cancer survivors (Gilliam et al., 2013).

Although the literature is limited in child studies, there is preliminary research that supports a link between increased rates of physical activity and decreased health care utilization among adults with a chronic illness. A meta-analysis of the Chronic Disease Self-Management Program, which encouraged adults with a chronic illness to increase their physical activity, found a relation between increases in physical activity and decreases in the amount of time spent in-patient in the hospital (Brady et al., 2013). Among adults with diabetes, participating in physical activity has been correlated with about 41 percent less health care costs than matched controls (Nguyen et al., 2007). Although rates of health care utilization have not specifically been assessed as outcomes in physical activity interventions among pediatric cancer survivors, research with other disease populations is promising.

Importantly, several studies suggest a number of positive outcomes related to physical activity in pediatric cancer. Outcomes from physical activity interventions with pediatric cancer survivors ages 16 to 30 years old include improvements in fasting plasma insulin, homeostasis model of assessment-insulin resistance, supine diastolic blood pressure, metabolic syndrome, peak oxygen uptake, and maximal workload (Järvelä, 2012). Furthermore, pediatric cancer survivors who had higher physical activity endurance also had better cardiometabolic profiles (Slater et al., 2015). Preliminary research has also found a promising link between participation in physical activity and neurocognitive improvements in pediatric brain tumor survivors (Riggs et al., in press). As a result of these improvements, the American Cancer Society (2015) recommends that children and adolescent cancer survivors participate in at least 1 hour of moderate to vigorous physical activity (MVPA) per day. Furthermore, these children and adolescents are specifically encouraged to participate in vigorous physical activity at least 3 times per week. Additionally, the National Institutes of Health suggest that 60 minutes of MVPA translates to approximately 10,000 to 11,700 steps per day (Tudor-Locke et al., 2011).

Although physical activity has been identified as improving the health of pediatric cancer survivors, the adverse cancer- and treatment-related side effects these children and adolescents experience appear to negatively impact their rates of physical activity. When comparing rates of physical activity, pediatric cancer survivors participate in fewer minutes of strenuous, moderate, and mild physical activity than their healthy peers (Hocking, 2013; Stolley, 2010). Furthermore, less than 50 percent of pediatric cancer survivors participate in the recommended amount of physical activity (Badr et al., 2013; Denmark-Wahnefried, 2005). Previous research has also found pediatric cancer survivors to have less exercise capacity than their healthy siblings (Miller et al., 2013). As a result of these findings, researchers have begun to develop interventions based on theoretical models that have been successful in other populations (e.g., pediatric obesity) to target behavior change in pediatric cancer survivors (see Riggs et al., in press; Keats & Culos-Reed, 2008; Li, 2013).

One such theory, Control Theory, postulates that self-management and behavioral control are achieved through goal setting, goal reviewing, monitoring behavior, and receiving feedback on behavior (Carver & Scheier, 1982). This theory suggests that individuals manage their behavior based on a negative feedback loop (see Figure I). The negative feedback loop is used to reduce deviation from a perceived comparison value. In this model, the input function represents the individual's perception of their current state. The individual's current state is then compared to a reference value.

If there is a discrepancy between the current state and the comparator, the individual will engage in a behavior, the output function, to try and reduce the discrepancy. This behavior then has an impact on the environment, which impacts the individual's perception of their current state (Carver & Schier, 1982). A recent meta-analysis exploring health behavior change found that interventions that included self-monitoring and at least one of the four other self-regulatory techniques from control theory were significantly more effective than interventions without these methods (Michie et al., 2009).

There are a number of interventions implemented with other populations, including healthy adults to reduce second hand smoke exposure in children and obese children to increase physical activity and reduce sedentary behaviors, that have used Control Theory techniques to aid in behavior change (i.e., Hovell & Hughes, 2009; Kalarchian, 2009; Steele et al., 2012). Although there are several interventions that utilize these methods with pediatric cancer survivors (i.e., Keats & Culos-Reed, 2008; Li, 2013), the majority of interventions with this population do not utilize Control Theory methods (i.e., goal setting, goal reviewing, monitoring behavior, and receiving feedback on behavior; Sharkey et al., 1993). Furthermore, only a handful of studies investigating the impact of physical activity interventions have been completed with pediatric cancer survivors, making this an important area of research.

When asked about preferred health-behavior change interventions, pediatric cancer survivors have expressed interest in interventions that focus on increasing physical activity compared to weight management or dieting (Badr et al., 2013; Denmark-Wahnefried, 2005). Pediatric cancer survivors have also identified a preference for less invasive opposed to more invasive interventions (i.e., mail- or computer-based interventions, where intervention information about physical activity is mailed to individuals or completed via the internet, rather than clinic-, camp-, or classroom-based interventions; Badr et al., 2013; Denmark-Wahnefried, 2005). Unfortunately, the majority of interventions to improve physical activity in pediatric cancer survivors involve more invasive and time-consuming approaches (i.e. Keats & Culos-Reed, 2009; Li, 2013; Sharkey et al., 1993; Takken, 2009). In addition, a number of interventions aimed at improving physical activity in pediatric cancer survivors are implemented when survivors reach adulthood (i.e., Blaauwbroek, 2009; Jarvela et al., 2013; Miller, 2013). However, there may be added benefits to implementing interventions focused on increasing physical activity in child and adolescent pediatric cancer survivors, as research has shown that readiness to exercise decreases with age (Denmark-Wahnefried, 2005).

Stemming from Bronfenbrenner's (1977) social-ecological model, family and friend social support is another key construct that influences rates of physical activity and sedentary behavior. Within the general population, social support has been identified as the most important predictor of engaging in physical activity (Dowda et al., 2009). Consistent with these findings, previous research has found that pediatric cancer survivors who reported higher social support for physical activity were more likely to participate in physical activity (Gilliam et al., 2012).

Thus, the overarching goal of the current study was to implement a less burdensome intervention focused on promoting behavior change in pediatric cancer survivors through the lense of Control Theory (Carver & Scheier, 1982) and the social-ecological model (Bronfenbrenner, 1977). Therefore, this study protocol incorporated social support for physical activity by having a parent also wear a FitBit Flex™ and by assessing daily social support for physical activity. In this N-of-1 randomized control trial, pediatric cancer survivors were randomized by day to wear or not wear a FitBit Flex™ activity monitor. This randomization resulted in each patient experiencing 15 Intervention days and 15 Control days. They also wore an Actigraph on their hip throughout the 30 days of the protocol, which tracked the outcome variables (MVPA and step count). Within the context of Control Theory (Carver & Scheier, 1982), the goal of steps per day was the reference value, number of steps taken was the comparator, taking more steps was the output function, steps counted by the FitBit Flex™ was the impact on environment, and self-monitoring of steps acted as the input function (see Figure II). The N-of-1 design therefore allowed us to examine ***for whom*** the intervention produced behavior change and, with the daily evaluation of social support, ***why*** the intervention had an impact.

In light of the current literature, the aims of this study were to: (1) assess the impact that wearing a FitBit Flex™ has on rates of MVPA and step count in pediatric cancer survivors; (2) assess the impact that social support for physical activity had on rates of MVPA in pediatric cancer survivors; and (3) assess the feasibility and acceptability of pediatric cancer survivors wearing a FitBit Flex™ over an extended period of time.

CHAPTER II

METHODS

Participants

Pediatric cancer survivors, along with one of their parents, who presented to the University of Oklahoma Health Sciences Center (OUHSC) and owned a smartphone were eligible for the study. Pediatric cancer survivors were identified as all children with a past diagnosis of cancer who were off treatment for at least one day at the time of enrollment. Children and parents who were not English speaking, who had a concomitant medical or psychological diagnosis, or who were currently enrolled in another physical activity or weight loss intervention were excluded from the study. Demographic information is presented in Table I.

Procedure

Child-parent dyads were recruited by a research assistant during their regularly-scheduled appointment to the pediatric oncology clinic. At enrollment, families completed all study measures. Additionally, both the child and parents received a FitBit Flex™ and children were given an ActiGraph. Children and parents were then randomized by day for a 30-day period to either wear (i.e., Intervention day) or not wear (i.e., Control day) the FitBit device. This allowed for 15 Intervention and 15 Control days over the 30 day study period. All participants and parents received a randomization text-message in the morning. Furthermore, children received a text message each evening with a link to the Social Support for Physical Activity Questionnaire. A home visit was also completed approximately 2-weeks from baseline to collect the ActiGraph and provide the family with another fully-charged ActiGraph. Finally, a 30-day home visit was completed in order to collect all study materials. At this time the child and parent completed a Feedback Form. This study was approved by the Institutional Review Board at OUHSC.

Materials

The *FitBit Flex^{TM}* is a consumer-available activity monitor, which is worn on the wrist. The FitBit Flex^{TM} tracks steps, distance traveled, and calories burned and automatically downloads this information to a smartphone application. Using the application, participants were able to set daily goal for steps and then track progress towards that goal by tapping directly on the FitBit Flex^{TM} device or by accessing the FitBit Application on their smartphone. The FitBit Flex^{TM}, in conjunction with the application, allowed for participants to engage in a number of activities that are consistent with Control Theory (Carver & Scheier, 1982) and believed to encourage behavior change, including goal setting, goal review, and self-monitoring. Of particular importance, the utilization of the FitBit Flex^{TM} allowed children and parents to engage in these activities on a minute-to-minute feedback loop. Step data were collected from the FitBit Application to assess adherence to randomization. However, as the FitBit was the independent variable, any additional data that may have been tracked by the FitBit device was not used in data analysis.

The *ActiGraph accelerometer* is a device used to collect information about minutes of mild, moderate, and vigorous physical activity, step count, and minutes of sedentary behavior. The ActiGraph has been identified as a reliable and valid device when measuring these constructs in children (Choi, 2010; Guinhouya, 2009; Ridgers, 2012). MVPA and step count collected with actigraphy was used as the dependent variable in this study. ActiGraph accelerometers were programmed and data was abstracted using the ActiLife Lifestyle Monitoring System software (V.3.2.11).

Measures

Demographics. A demographic form was completed by the primary caregiver inquiring about child and parent age, gender, date of birth, race/ethnicity, child diagnosis, diagnosis date, and date of cancer treatment discontinuation, household income, and parent marital status.

Severity of Illness Scale. The Severity of Illness Scale (SOIS; Young-Saleme & Prevatt, 1999) is a 6-item, physician-report, Likert-type response measure used to assess the medical severity of symptoms associated with pediatric cancer. Item responses range from 1 to 7 and a Total Score is calculated by tallying each item response. Total Scores range from 6-42, with higher scores indicating increased severity. This measure has been shown to have good interrater reliability, test-retest reliability, and validity (Young-Saleme & Prevatt, 1999). Baseline SOIS total scores can be seen in Table I.

Intensity of Treatment Rating Scale 2.0. The Intensity of Treatment Rating Scale 2.0 (ITR-2; Werba, Hobbie, Kazak, Ittenbach, Reilly, & Meadows, 2007) is a physician-report scale used to assess the intensity of pediatric cancer treatments. Physicians identify the presence or absence of four treatment modalities (e.g., surgery, chemotherapy, radiation, and transplantation) for each patient. In addition, they rate treatment intensity based on a Likert-type scale ranging from 1 to 4. Level 1 treatments are identified as the "Least Intensive Treatments" and Level 4 treatments are classified as the "Most Intensive Treatments". Therefore, higher scores indicate higher intensity of treatment. Additional information is provided for each specific Level to help physicians classify treatment intensity (e.g., Level 1: "Surgery Only – Excluding all brain tumors, Germ Cell Tumors – Surgery Only, Neuroblastoma – Surgery Only, Retinoblastoma – Enucleation (unilateral disease) without chemotherapy, Wilms' Tumor (Stages 1, 2)" (Werba et al., p. 675, 2007). The ITR-2 has been shown to have good reliability and validity (Werba et al., 2007). Baseline ITR-2 scores can be seen in Table I.

Pediatric Symptom Checklist/Pediatric Symptom Checklist-Youth Report. The Pediatric Symptom Checklist (PSC) and the Pediatric Symptom Checklist-Youth Report (Y-PSC) are 35-item parent- and child-report measures, respectively, used to assess behavior problems and psychological functioning in children (Jellinek, Murphy, & Burns, 1986). Item options include "Never" (0), "Sometimes" (1), and "Often" (2). A measure total score is calculated by adding each item score, with total scores of 28 or greater suggesting psychological impairment for the PSC and a total score of 30 or greater suggesting psychological distress in the Y-PSC. For the PSC, a cutoff of 28 has 0.95 sensitivity and 0.68 specificity (Jellinek, Murphy, Robinson, Feins, Lamb, & Fenton, 1988). Additionally, the PSC has been shown to have good reliability and validity (Jellinek, Murphy, & Burns, 1986). These measures were included to assess baseline psychosocial functioning. Baseline scores for the PSC and Y-PSC can be seen in Table II. It is important to note that although reliability statistics would normally be documented, due to the small sample size of this pilot study they were not included.

Social Support and Exercise Survey. The Social Support and Exercise Survey (SSES) is a 13-item self-report questionnaire assessing both family and friend social support for engaging in physical activity (Sallis et al., 1987). Responses are presented in a Likert-type manner ranging from 1 (None) to 5 (Very often). Respondents can also select a "does not apply" option. Item scores are tallied, omitting questions 7 to 9, to develop total scores for both family and friends (e.g., Family Participation and Friend Participation), with higher scores representing more social support for physical activity. An additional Family Reward and Punishment subscale can also be calculated. Reliability and validity for the SSES are acceptable (Sallis et al., 1987). Again, due to the small sample size, reliability statistics were not included.

Feedback Form. A Study Feedback Form, a 4-item questionnaire, was completed by all participating children and parents in order to obtain feedback about the feasibility and acceptability of the study protocol. Participants were asked to identify elements of the study they liked, disliked, and what they would change for a future study. Questions were open-ended to encourage qualitative responses.

Overview of Analyses

Statistics. All data were entered and analyzed using Statistical Analysis System (SAS) 9.4. Descriptive statistics were run for patient demographic information and to evaluate baseline psychosocial functioning, as measured by the PCS and Y-PCS, and disease characteristics, as measured by the SOIS and ITR-2. In order to assess the treatment effect for MVPA and then step count for each participant, multiple degree-of-freedom *F*-tests were completed. In this analysis, participant 9 was used as the reference participant as they were the only participant with outcome data for all 30 days of enrollment. In order to evaluate for carryover effects from Intervention to Control days, a binary predictor variable was created to identify if the previous day was an Intervention or Control day. This variable was then added to the previous model to assess for an interaction effect. For more information about this statistical analysis, see Cushing, Walters, and Hoffman (2013).

Missing Cases. Of 360 MVPA data points, 73 were missing (20.3%) and of 360 step count data points, 68 were missing (18.8%). This was largely due to participants failing to wear the actigraph (42 missing data points for both MPVA and step count), incomplete data due to the battery running out on the actigraph device (26 missing data points for both MPVA and step count), or engaging in too few minutes of wear time to validate data (5 missing data points for MVPA only). Using SAS 9.4, missing data were analyzed and it was determined they were missing at random (MAR). Therefore, multiple imputation procedures using regression with predictive mean matching were used to deal with missing MVPA, step count, and SSES data. Multiple imputations have been used to reconcile missing data in other, similar N-of-1 design studies with similar percentages of missing data (see Nyman et al., 2016). The participants were divided into three separate datasets and a total of five imputations were completed, with treatment type (intervention or control), protocol day (1 through 30), and the three SSES subscales used as auxiliary variables. Due to a smaller number of nonmissing values for SSES for participant 14, a separate multiple imputation procedures using the Monte Carlo method was completed. All datasets were then combined and parameter estimates were examined and determined to be comparable.

CHAPTER III

RESULTS

Acceptability and Feasibility

Of the 20 eligible pediatric cancer survivors receiving follow-up care in the Jimmy Everest Center who were approached for the study, 70.00% enrolled in this pilot study. Of those participants, one participant (7.14%) discontinued the study early due to a slow internet connection that did not allow the FitBit device and phone application to communicate. One additional participant was not included in data analysis due to an irreconcilable protocol deviation (e.g., wearing only the FitBit Flex™ on Intervention days and only the Actigraph on Control days). Figure III displays detailed enrollment information.

Actigraph monitor compliance was relatively high (79.72% over 30 days), which is consistent with wear-time for other studies that used waist-worn accelerometers in children and adolescents (see Audrey et al., 2012; Tarasenko et al., 2015). Participants were adherent to randomization (e.g., wearing or not wearing their FitBit Flex™) 76.67% of the time, which is similar to or slightly below expectation when compared to similar studies in adult populations (see Cadmus-Bertram et al., 2015; Choi et al., 2016).

Qualitative information provided on the Study Feedback Form suggested that participants generally enjoyed using the FitBit Flex™. For example, several participants noted that they "liked wearing the FitBit", while another stated that the protocol was "fun" and that they "enjoyed the step counting." When asked to identify aspects of the study they disliked or would change, participants even noted that they "didn't like not wearing the FitBit" and were "greatly disappointed when not wearing FitBit." Conversely, participants generally reported less favorability towards wearing the actigraph daily. Specifically, participants noted that the "belt [which held the actigraph] bothered [their] waist" and identified dislikes of the study as having "to wear the actigraph."

Related to completing the daily online SSES questionnaire, participants were compliant 71.20% of the time. Futhermore, they were slightly more likely to complete the questionnaire on Intervention (73%) compared to Control days (69%), although this difference was not statistically significant. On the study feedback form, specifically related to the SSES participants noted that they "didn't like surveys" and also did not appreciate "answering the same [questions] everyday."

Descriptive Statistics

Examination of participant descriptive statistics revealed that participants engaged in an average of 21.02 (SD = 21.67) minutes of MPVA daily on Intervention days compared to 22.63 (SD = 25.27) minutes on Control days. Additionally, participants engaged in approximately 5173 (SD = 3666) steps on Intervention days and 5429 (SD = 3667) steps on Control days. Importantly, the American Cancer Society (2015) suggests that pediatric cancer survivors engage in at least 60 minutes of MVPA daily. Thus, these results indicate that participants engaged in far less physical activity than recommended. See Figure IV for estimated daily MVPA by participant on Intervention and Control days and Figure V for daily rates of MVPA by participant. For step count by participant on Intervention and Control days see Figure VI and see Figure VII for daily step count by participant.

Examination of Treatment Effect for Each Participant: MVPA

The heterogeneous variance model with multiple degree-of-freedom F-tests revealed an intervention effect, $F(11,1776) = 4.76$, $p = <.0001$, with a significant difference in minutes of

MVPA from Intervention (*M* = 20.93; *SD* = 13.45) to Control days (*M* = 23.06; *SD* = 14.63). An effect size estimate indicated that the intervention effect accounted for 0.25% of the variability in minutes of MVPA, suggesting a very small effect. Interestingly, these results indicated that rates of MVPA decreased when participants wore a FitBit Flex™ compared to when they did not wear a FitBit Flex™. Individual participant MVPA on Intervention and Control days can be seen in Table III.

Results identifying who revealed significant change specifically were requested through post-estimation commands and showed that participants 2, 3, 4, 6, 11, and 13 experienced a significant difference in MVPA from Intervention to Control days. Further examination of these results reveal that participants 2, 3, 6, and 13 engaged in fewer minutes of MVPA on Intervention days (M = 6.92, 10.24, 12.31, and 35.13 minutes, respectively) versus Control days (M = 10.25, 17.87, 21.63, and 51.04 minutes, respectively), suggesting an opposite effect than hypothesized. Additionally, participants 4 and 11 engaged in more minutes of MVPA from Intervention (M = 37.59 and 7.72 minutes, respectively) to Control days (M = 28.54 and 6.34 minutes, respectively). Therefore, while the intervention did not produce behavior change in 50% of participants, the intervention resulted in decreased rates of MVPA for 33.3% of participants and in increased rates for 16.7% of participants. A homogeneous variance model was also completed to assess for better fit. In this model, the heterogeneous variance model fit better than the homogeneous variance model, $-2\Delta LL(11) = 15492.1 - 13380.1 = 2112$, $p < .001$.

Examining for Carryover Effects for MVPA

Due to the potential for a carryover of the intervention effect from Intervention to Control days, an omnibus *F*-test was run to assess for the presence of a carryover effect. Results indicated the absence of such an effect, $F(11,1692) = 0.48$, $p = .92$, suggesting no difference from Control days that followed a Control day from Control days that followed an Intervention day.

Examination of Treatment Effect for Each Participant: Step Count

A heterogeneous variance model with multiple degree-of-freedom *F*-tests revealed no intervention effect, $F(11,1776) = 8.32$, $p = <0.0001$, with a significant difference in number of steps from intervention ($M = 4850.27$; $SD = 2534.78$) to control days ($M = 5230.91$; $SD = 2786.00$). An effect size estimate indicated that the intervention effect accounted for 0.30% of the variability in step count, indicating a very small effect. These results again indicated that participants took fewer steps when they wore a FitBit Flex™ compared to when they did not wear a FitBit Flex™. Individual participant step counts on Intervention and Control days can be seen in Table IV.

Furthermore, results identifying who revealed significant change specifically were requested through post-estimation commands and showed that participants 2, 3, 4, 5, 9, and 13 experienced a significant difference in step count from Intervention to Control days. However, further examination of results reveal that participants 2, 3, 9, and 13 engaged in fewer steps on Intervention days (M = 2230.06, 2564.26, 1902.06, and 5302.26, respectively) versus Control days (M = 3919.97, 5397.69, 2207.93, and 7005.12, respectively), suggesting an opposite effect than hypothesized. Conversely, participants 4 and 5 engaged in more steps on Intervention days (M = 8533.85 and 8834, respectively) compared to Control days (M = 7017.92 and 6697.64, respectively). Again, step count data suggests that although the intervention did not impact step counts for 50% of participants, 33.3% of participants engaged in fewer steps on Intervention days and 16.7% of participants engaged in more steps in Intervention days. Finally, a homogeneous variance model was also completed to assess for better fit. In this model, the heterogeneous variance model fit better than the homogeneous variance model, $-2\Delta LL(11) = 33426.2 – 32904.4 = 521.8$, $p < .001$.

Examining for Carryover Effects for Step Count

Again, due to the potential for a carryover of the intervention effect from Intervention to Control days, an omnibus *F*-test was again run to assess for the presence of a carryover effect.

Results indicated the absence of such an effect, F (11,1692) = 0.34, p = .98, suggesting no difference from Control days that followed a Control day from Control days that followed an Intervention day.

Evaluating the Impact of Social Support for Physical Activity

Social support for physical activity scores across participants averaged 19.63 on Control days and 20.67 on Intervention days (see Table V for individual participant SSES scores). Additionally, Figures VIII, IX, and X show daily SSES scores by participant, while also identifying days where participants engaged in $\geq$ 60 minutes of MVPA. From these figures, there does not appear to be a strong relationship between social support, either from parents or from friends, and rates of MVPA. Specifically, on all three subscales of the SSES, Family Participation, Family Reward and Punishment, and Friend Participation, participants did not appear to report higher rates of social support on days when they engaged in higher levels of physical activity. However, due to small sample size inferential statistics could not be completed.

CHAPTER IV

CONCLUSIONS

This is the first N-of-1 design randomized control trial pilot study to assess the effect of a FitBit Flex™ on rates of physical activity among pediatric cancer survivors. The aims of the current study were to 1) assess the impact of wearing a FitBit Flex™ on rates of MVPA and step count in pediatric cancer survivors; 2) assess the impact of social support for physical activity had on rates of MVPA in pediatric cancer survivors; and 3) assess the feasibility and acceptability of pediatric cancer survivors wearing a FitBit Flex™.

Broadly, findings from this study are consistent with the extant literature showing that pediatric cancer survivors generally fail to meet the physical activity guidelines suggested by the American Cancer Society (2015). They also fail to meet step counts that correlate with these activity recommendations (Tudor-Locke et al., 2011). In combination with the potential health benefits of engaging in physical activity, this speaks to the importance of developing interventions to increase rates of physical activity among this population.

Furthermore, this pilot study identified that using a FitBit Flex™ as a low-impact physical activity intervention does not appear to have the desired impact on daily rates of MVPA or daily step counts. Rather than encouraging increases in physical activity, the use of a FitBit Flex™ appears to actually decrease activity or have no effect among the majority of participants.

These findings are consistent with a study by Le et al. (2016) who found nonsignificant differences from baseline to follow-up in a sample of young adult pediatric cancer survivors who were provided with a FitBit One™ for 6 months. However, these findings are inconsistent with a study by Hayes and Van Camp (2015), which found increases in both step-count and MVPA in school-aged children who wore a FitBit device during recess. Schoenfelder and colleagues (2017) also found that FitBit Flex™ devices increased step counts among adolescents with attention deficit hyperactivity disorder. Results are also inconsistent with other studies in the adult literature, which have shown increased MVPA in interventions using FitBit devices (Cadmus-Bertram et al., 2015 & Wang et al., 2015). However, the extant literature aimed at increasing step-counts through the use of FitBits is still inconclusive (e.g., Choi et al., 2016 & Valbuena, Miltenberger, & Solley, 2015).

One explanation for the differences in findings between this study and others is that several studies used FitBit devices to measure step-counts and MVPA (e.g., Hayes & Van Camp, 2015; Choi et al., 2016; Valbuena et al., 2015), which are not reliable or valid devices among adults (Sushames, Edwards, Thompson, McDermott, & Gebel, 2016). Additionally, there appears to be no research examining reliability and validity of FitBit devices among children and adolescents. These findings suggest further research is needed to examine the use of these types of devices in children and adolescents.

There are several other potential explanations for the opposite effect than hypothesized in this intervention. First, Control Theory (Carver & Scheier, 1982) is based on behavior modification resulting from a minute-to-minute feedback loop. Therefore, if the information provided in the feedback loop is inaccurate, it follows that behavior change could be variable. Unfortunately, as previously discussed, FitBit devices are not accurate in their step counts (Sushames et al., 2016). Thus, the current results may be a reflection of this lack of accuracy in the device. Additionally, by design, this protocol and the intervention by Le and colleagues (2016) included very low-impact interventions with minimal contact with or instruction from study personnel. This is contrary to typical physical activity interventions which pose a much larger burden on participant time and resources by requiring them to attend weekly sessions and engage in specific physical activities for specific durations of time during session (see Riggs et al., in press; Keats & Culos-Reed, 2009; Li, 2013; Sharkey et al., 1993; Takken, 2009). These results thus suggest the use of a FitBit Flex™ alone may not be enough to produce meaningful behavior change and may even produce decreases in physical activity. This is consistent with the extant literature, where pedometers are typically used in conjunction within a larger intervention protocol (e.g., Cadmus-Bertram et al., 2015 & Wang et al., 2015). Finally, since a baseline assessment of MVPA or step count was not completed, it is possible that an overarching intervention effect, beginning on the first day of the intervention and continuing throughout the 30 days, was missed.

Interestingly, two participants did increase MVPA and step count as a result of the FitBit Flex™ intervention. The ability to detect these outcomes is one of the specific benefits of completing an N-of-1 design; although the sample was too small to draw further conclusions about the success of the protocol in these two participants compared to other participants enrolled in the study. Future studies should aim to better understand the nuances of using electronic devices to promote behavior change.

Additionally, although inferential statistics could not be completed due to small sample size, visual representations of the data did not support a relationship between social support for physical activity and increases in MVPA or step count. This is inconsistent with previous research which has supported a relationship between these variables (Dowda et al., 2009; Gilliam et al., 2012) and within the broader theoretical social-ecological model (Bronfenbrenner, 1977). Future research should aim to identify socio-environmental stimuli that promote engagement in physical activity, such as social support from family and friends. These stimuli can then be infused into current behavioral protocols to help increase the likelihood of promoting positive behavior change.

Acceptability and feasibility data show that a physical activity intervention such as the one presented here is generally well-received. One major difficulty included enrollment rates, which were just slightly above 50%. This was likely due to the perceived burden of daily contact with the researcher through text messaging and the necessity of wearing the actigraph for 30 days. However, once enrolled participants were generally adherent to the study protocol, despite its complexity. Participants also reported being pleased with the protocol and provided positive feedback. Specifically, participants reported enjoying the use of the FitBit Flex™ and even noted disappointment on control days. However, participants did not appreciate wearing the actigraph daily or completing daily surveys on their smartphone. Thus, suggesting electronic devices that link with smartphone applications, such as FitBits, show promise as a tool for increasing interest in behavior change interventions. Additionally, although children and teens may not enjoy daily questionnaires or waist-worn actigraphy, they are still generally willing to utilize these mechanisms for an extended period of time.

There are several limitations for this pilot study. First, as this study had a small sample size and recruitment was completed at a single children's hospital in the Midwest, results may not be generalizable to all pediatric cancer survivors. Additionally, again due to the preliminary nature of this protocol, the researcher was not blinded to participant randomization. The SSES was completed on the participants' smartphone rather than a paper and pencil format. However, previous research has shown comparable validity to data collected in person versus online (Gosling, Vazire, Srivastava, & John, 2004). Finally, no baseline measure of MVPA or step count was completed. This may have resulted in the statistical analysis missing an effect that occurred at the start of the intervention and lasted throughout the study. Future protocols should aim to develop larger, double-blinded, randomized controlled trials, including a baseline assessment to study methods for instigating change in rates of physical activity among pediatric cancer survivors.

In sum, pediatric cancer survivors consistently fall below physical activity recommendations that could help to alleviate numerous late-effects of their diagnosis. Current protocols aimed at producing behavior change tend to require significant facility resources in space, time, and staff. Additionally, they pose a burden to patients (Denmark-Wahnefried, 2005). Therefore, though this specific protocol did not induce increases in physical activity, the field needs to continue to strive towards developing interventions that are clinically useful and benefit patients without undue hardships. Specifically, future research should strive to understand the patient-specific components that allow some patients to benefit from the use of electronic monitoring while others' behaviors are negatively affected.

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APPENDICES

Table I. Participant demographic information

Child Characteristics (*N = 12*)	**%***
Age; Mean (SD)	13.58 (2.15)
Male	33.33
Race/Ethnicity:	
Caucasian	66.67
Hispanic/Latino	16.67
Native American	8.33
Other	8.33
Diagnosis:	
Low grade glioma	16.67
Optic pathway germinoma	16.67
Intracranial germinoma	8.33
Wilms' tumor	8.33
Pre B acute lymphoblastic leukemia	8.33
Pilocytic astrocytoma spin	8.33
Burkitt's lymphoma	8.33
Intracranial germ cell tumor	8.33
Medulloblastoma	8.33
Soft tissue tumor	8.33
SOIS; Mean (SD)	15.00 (3.41)
ITR-2; Mean (SD)	2.27 (0.88)
Days off treatment; Mean (SD)	1391.56 (1289.39)
Parent Characteristics (*N = 12*)	**%***
Age; Mean (SD)	42.25 (6.03)
Male	8.33
Marital Status:	
Married	50.00
Divorced	41.67
Single/Never Married	8.33
Annual Household Income	
>$60,000	58.33
$50,000-41,000	0.0
$40,000-31,000	16.67
$30,000-21,000	8.33
$20,000-10,000	16.67

Note. * = unless otherwise specified; SD = standard deviation; SOIS = Severity of Illness Scale.

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Table II. PSC and Y-PSC baseline scores

Measure	Baseline Mean (SD)
PSC	17.45 (10.58)
Y-PSC	16.40 (9.01)

Note. SD = standard deviation; PSC = Pediatric Symptoms Checklist; Y-PSC = Pediatric Symptom Checklist-Youth Report.

Table III. ***Final Results Using Fixed-Effects Model with Constant (Heterogeneous) Variance: MPVA***

	Differences relative to participant 9				Unique effects for each participant			
Fixed effects	**Estimate**	***SE***	***t***	***p***	**Estimate**	***SE***	***t***	***p***
Intercept	6.82	0.17	-	-	-	-	-	-
Intervention day	0.30	0.23	1.25	0.21	-	-	-	-
Control day								
Participant 1	32.77	0.17	40.55	<0.05	39.59	2.07	19.12	<0.05
Participant 2	3.43	0.24	1.25	0.21	10.25	0.68	15.11	<0.05
Participant 3	11.05	2.08	15.77	<0.05	17.87	1.03	17.43	<0.05
Participant 4	21.72	0.70	4.91	<0.05	28.53	1.97	14.51	<0.05
Participant 5	27.19	1.04	10.64	<0.05	34.01	1.89	18.05	<0.05
Participant 6	14.81	1.97	11	<0.05	21.62	1.51	14.31	<0.05
Participant 7	27.01	1.89	14.37	<0.05	33.83	1.79	18.92	<0.05
Participant 9	--	--	--	--	6.82	0.17	40.55	<0.05
Participant 11	-0.48	0.43	-1.13	0.26	6.34	0.39	16.21	<0.05
Participant 13	44.22	5.61	7.89	<0.05	51.04	5.60	9.11	<0.05
Participant 14	10.53	1.89	5.57	<0.05	17.35	1.88	9.22	<0.05
Participant 15	2.602	0.70	3.7	<0.05	9.42	0.68	13.79	<0.05
Intervention day increase								
Participant 1	0.53	2.94	0.18	0.86	0.82	2.93	0.28	0.78
Participant 2	-3.6271	0.99	-3.67	<0.05	-3.33	0.96	-3.47	<0.05
Participant 3	-7.9297	1.47	-5.4	<0.05	-7.63	1.45	-5.27	<0.05
Participant 4	8.7453	2.79	3.13	<0.05	9.04	2.78	3.25	<0.05
Participant 5	2.942	2.68	1.1	0.27	3.24	2.67	1.22	0.23
Participant 6	-9.6192	2.15	-4.47	<0.05	-9.32	2.14	-4.36	<0.05
Participant 7	-3.3613	2.54	-1.32	0.19	-3.06	2.53	-1.21	0.23
Participant 9	-	-	-	-	0.30	0.24	1.25	0.21
Participant 11	1.082	0.60	1.8	0.07	1.38	0.55	2.5	<0.05
Participant 13	-16.2133	7.93	-2.05	0.04	-15.92	7.92	-2.01	<0.05
Participant 14	-2.1715	2.67	-0.81	0.42	-1.87	2.66	-0.7	0.48
Participant 15	0.6471	1.00	0.65	0.52	0.94	0.97	0.98	0.33
Model fit								
-2LL		133380.1				133380.1		

Note. SE = standard error; Participant 9 was used as the comparison variable and therefore the intercept estimate of 6.82 represents the mean minutes of MVPA for participant 9 on Control days. The intervention main effect shows that participant 9 had a nonsignificant increase to 7.13 minutes of MVPA on Intervention days (6.82 + 0.30 = 7.13). Control day main effects for all other participants identify the difference in MVPA on Control days compared to participant 9. For example, participant 1 averaged 32.77 more minutes of MVPA than participant 9 on Control days (e.g., 6.82 + 32.77 = 39.59). For participants except participant 9, Intervention day effects are intervention-by-participant interactions. As such, they identify the difference in the treatment effect between participant 9 and each individual participant. Therefore, the average increase in simulated MVPA on treatment days for participant 1 was 0.35 minutes greater than participants 9 (e.g., 0.30 + 0.35 = 0.65). Taken together, participant 1 would average 37.52 minutes of MVPA on Intervention days (e.g., 6.82 + 32.77 + 0.30 + 0.35 = 40.24).

Table IV. ***Final Results Using Fixed-Effects Model with Constant (Heterogeneous) Variance: Steps***

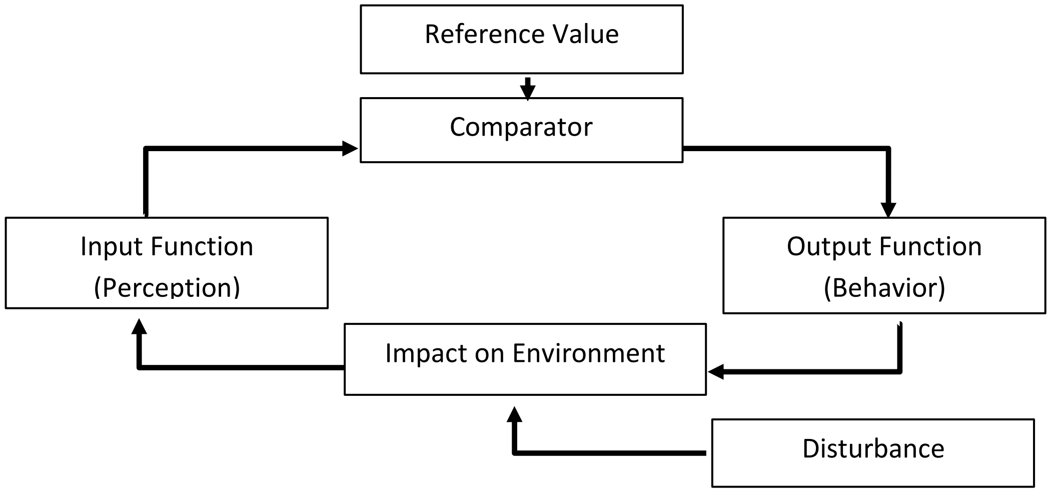
	Differences relative to participant 9				**Unique effects for each participant**			
Fixed effects	**Estimate**	***SE***	***t***	***p***	**Estimate**	***SE***	***t***	***p***
Intercept	2207.93	98.07	-	-	-	-	-	-
Intervention day	-305.87	138.69	-2.21	<0.05	-	-	-	-
Control day								
Participant 1	3071.72	335.29	9.16	<0.05	5279.65	320.63	16.47	<0.05
Participant 2	1712.04	248.34	6.89	<0.05	3919.97	228.15	17.18	<0.05
Participant 3	3189.76	291.35	10.95	<0.05	5397.69	274.35	19.67	<0.05
Participant 4	4809.99	446.41	10.77	<0.05	7017.92	435.5	16.11	<0.05
Participant 5	4985.6	333.4	14.95	<0.05	7193.53	318.65	22.58	<0.05
Participant 6	5333.8	557.55	9.57	<0.05	7541.73	548.86	13.74	<0.05
Participant 7	4200.77	273.57	15.36	<0.05	6408.71	255.39	25.09	<0.05
Participant 9	-	-	-	-	2207.93	98.0702	22.51	<0.05
Participant 11	2284.68	299.15	7.64	<0.05	4492.61	282.62	15.9	<0.05
Participant 13	4797.19	470.7	10.19	<0.05	7005.12	460.38	15.22	<0.05
Participant 14	-19.5467	227.35	-0.09	0.93	2188.39	205.11	10.67	<0.05
Participant 15	1909.75	311.69	6.13	<.05	4117.68	295.86	13.92	<0.05
Intervention day increase								
Participant 1	713.17	474.18	1.5	0.13	407.31	453.44	0.9	0.37
Participant 2	-1384.04	351.2	-3.94	<0.05	-1689.91	322.65	-5.24	<0.05
Participant 3	-2527.56	412.04	-6.13	<0.05	-2833.43	387.99	-7.3	<0.05
Participant 4	1821.8	631.32	2.89	<0.05	1515.93	615.89	2.46	<0.05
Participant 5	1947.27	471.5	4.13	<0.05	1641.4	450.64	3.64	<0.05
Participant 6	-1160.01	788.5	-1.47	0.14	-1465.88	776.21	-1.89	0.06
Participant 7	67.56	386.89	0.17	0.86	-238.31	361.17	-0.66	0.51
Participant 9	-	-	-	-	-305.87	138.69	-2.21	<0.05
Participant 11	877.08	423.07	2.07	<0.05	571.21	399.69	1.43	0.16
Participant 13	-1396.99	665.68	-2.1	<0.05	-1702.85	651.07	-2.62	<0.05
Participant 14	-226.29	321.52	-0.7	0.48	-532.16	290.07	-1.83	0.07
Participant 15	370.73	440.8	0.84	0.40	64.8667	418.42	0.16	0.88
Model fit								
-2LL		32904.4				32904.4		

Note. SE = standard error.

Table V. ***Social Support for Physical Activity Scale by Participant***

	Social Support for Exercise Survey					
	Family Participation		Family Reward and Punishment		Friend Participation	
	Intervention	Control	Intervention	Control	Intervention	Control
Participant 1	35.60	35.33	5.87	5.67	10.00	10.00
Participant 2	14.80	13.52	3.25	3.20	10.09	10.13
Participant 3	30.68	26.21	6.03	5.12	10.00	10.00
Participant 4	25.79	25.81	6.28	6.16	22.88	22.89
Participant 5	29.63	17.67	3.16	3.00	17.57	13.60
Participant 6	11.47	10.00	3.00	3.00	10.60	10.00
Participant 7	24.95	22.17	3.24	3.00	20.61	20.76
Participant 9	12.40	15.57	3.00	3.00	11.95	11.64
Participant 11	15.55	13.52	3.52	3.21	11.64	11.99
Participant 13	17.87	17.64	4.49	4.71	13.88	13.65
Participant 14	18.71	17.53	3.48	3.51	21.41	20.28
Participant 15	11.45	13.40	3.11	3.27	18.97	15.76
TOTAL	20.74	19.03	4.04	3.90	14.97	14.23

Figure I.



Note. From Carver & Schier, 1982.

Figure II.

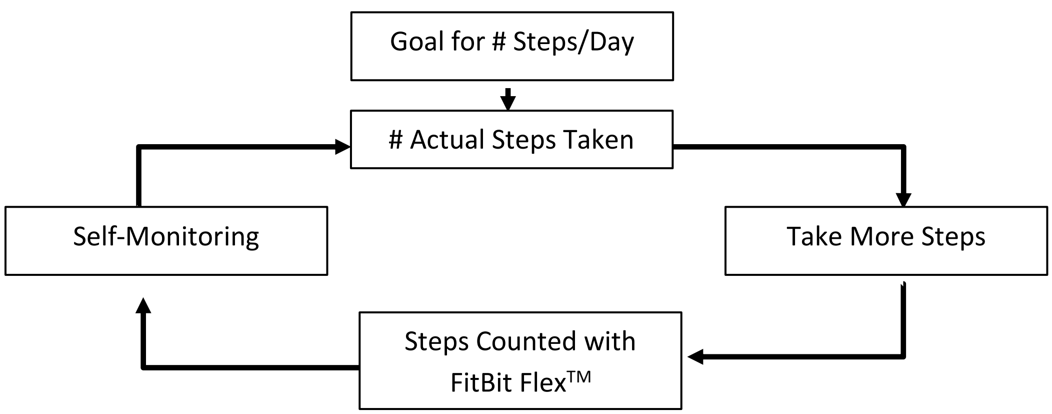
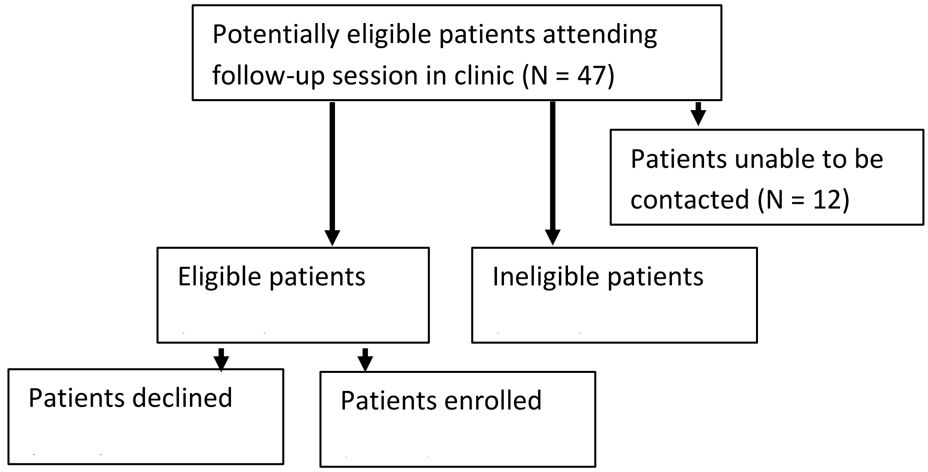
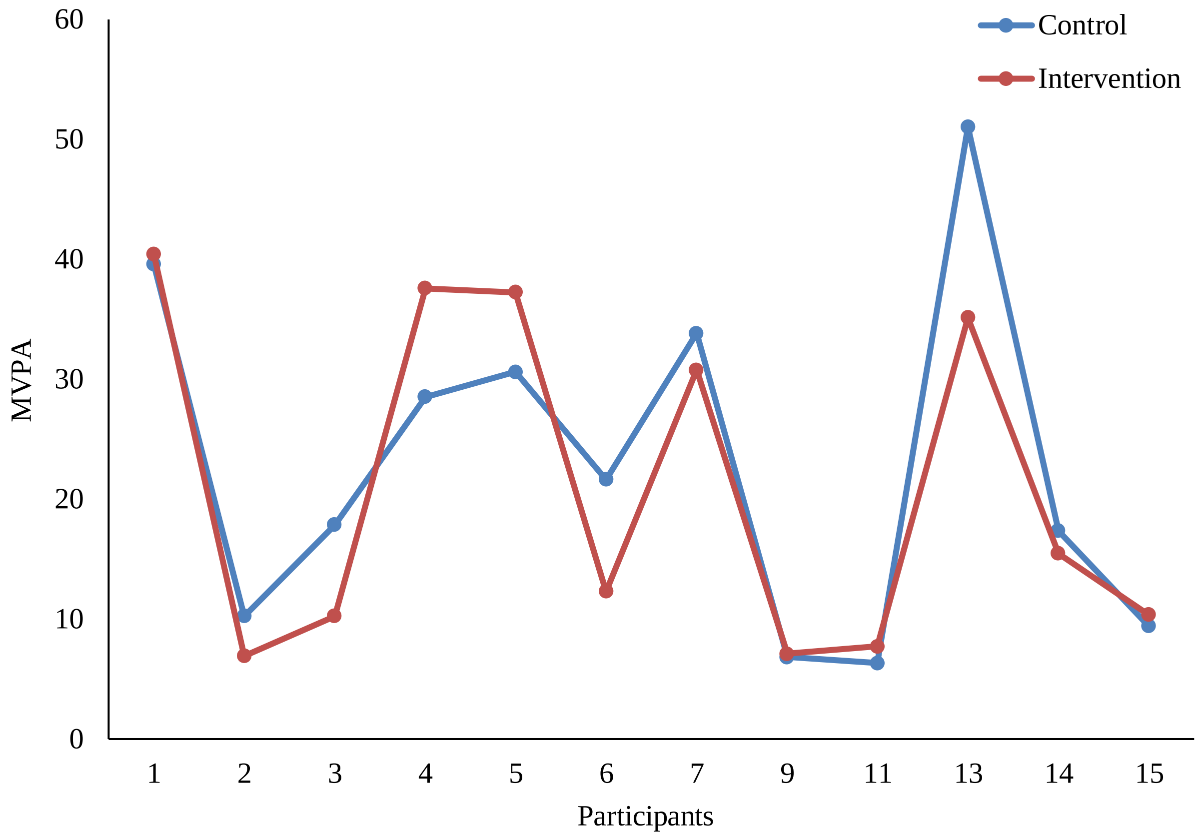


Figure III.



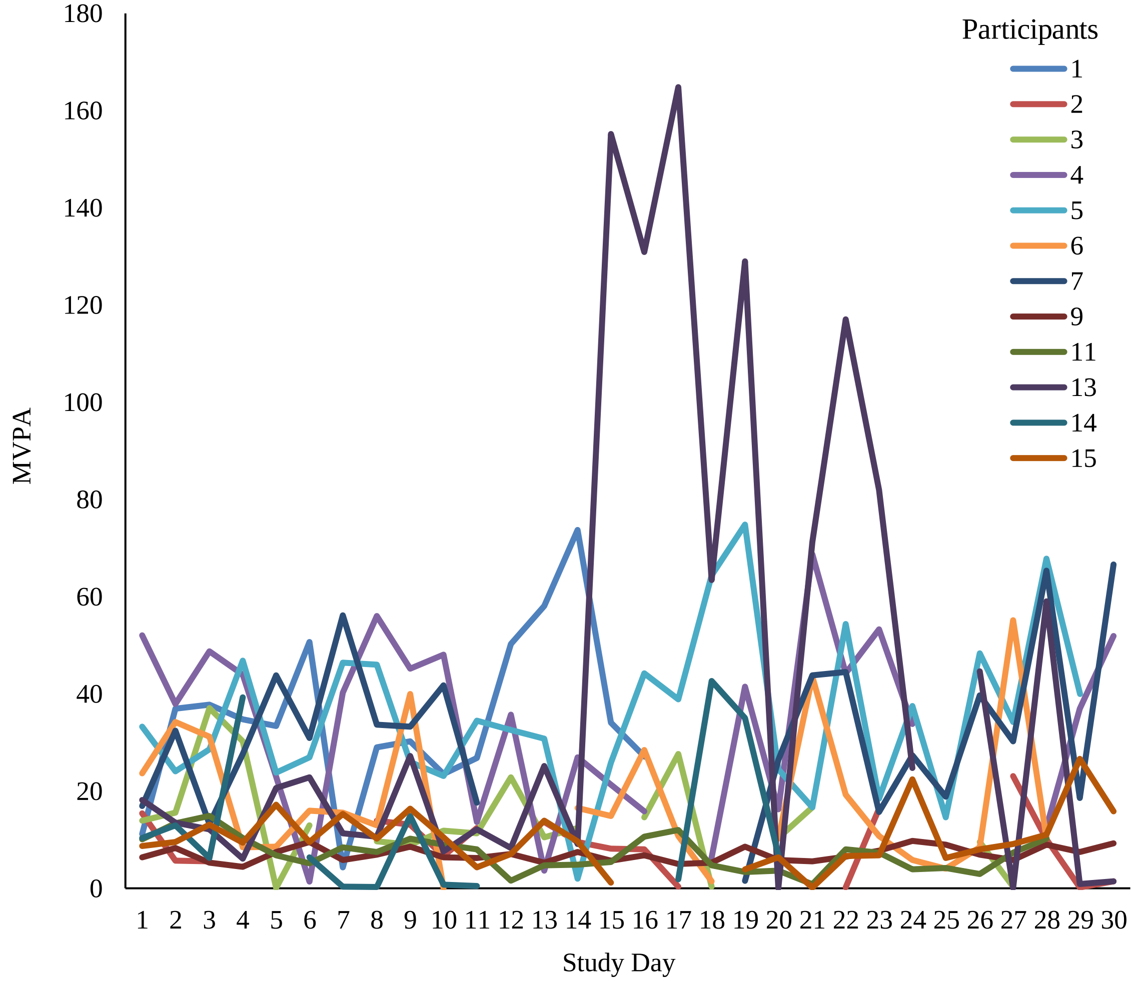
Note. N = number of patients.

Figure IV. Estimated MVPA on Intervention and Control Days by Participant



Note. MVPA = moderate to vigorous physical activity.

Figure V. Daily MVPA by Participant



Note. MVPA = moderate to vigorous physical activity.

Figure VI. Estimated Step Count on Intervention and Control Days by Participant

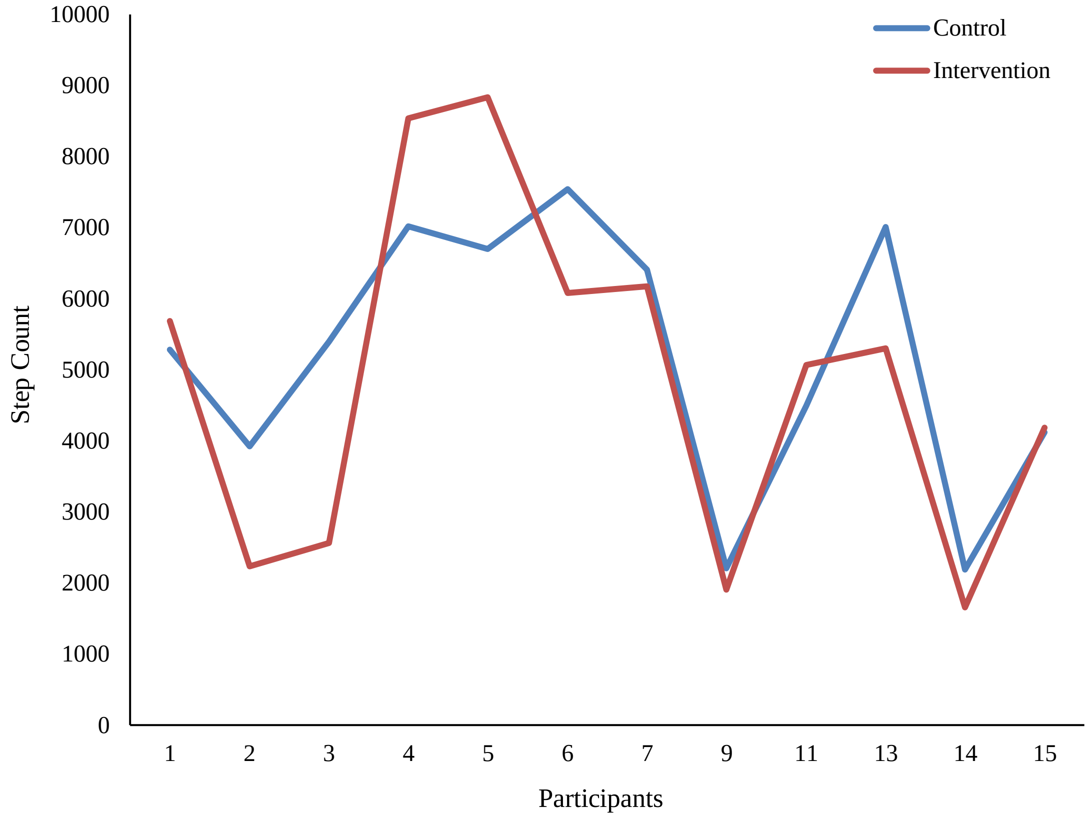


Figure VII. Daily Step Count by Participant

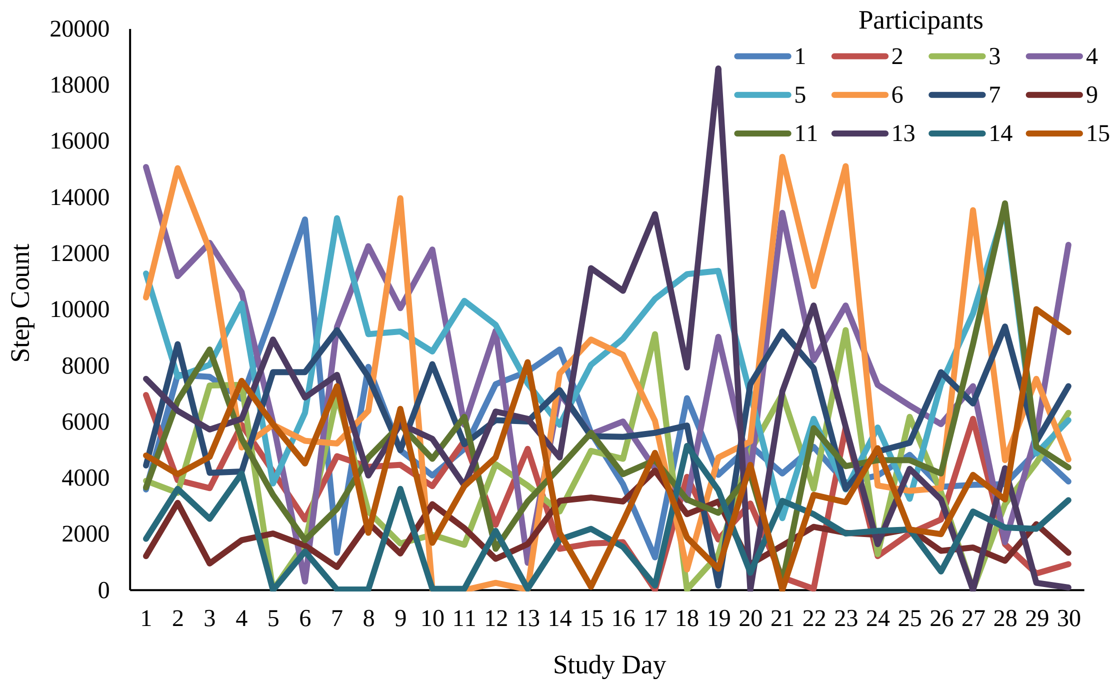
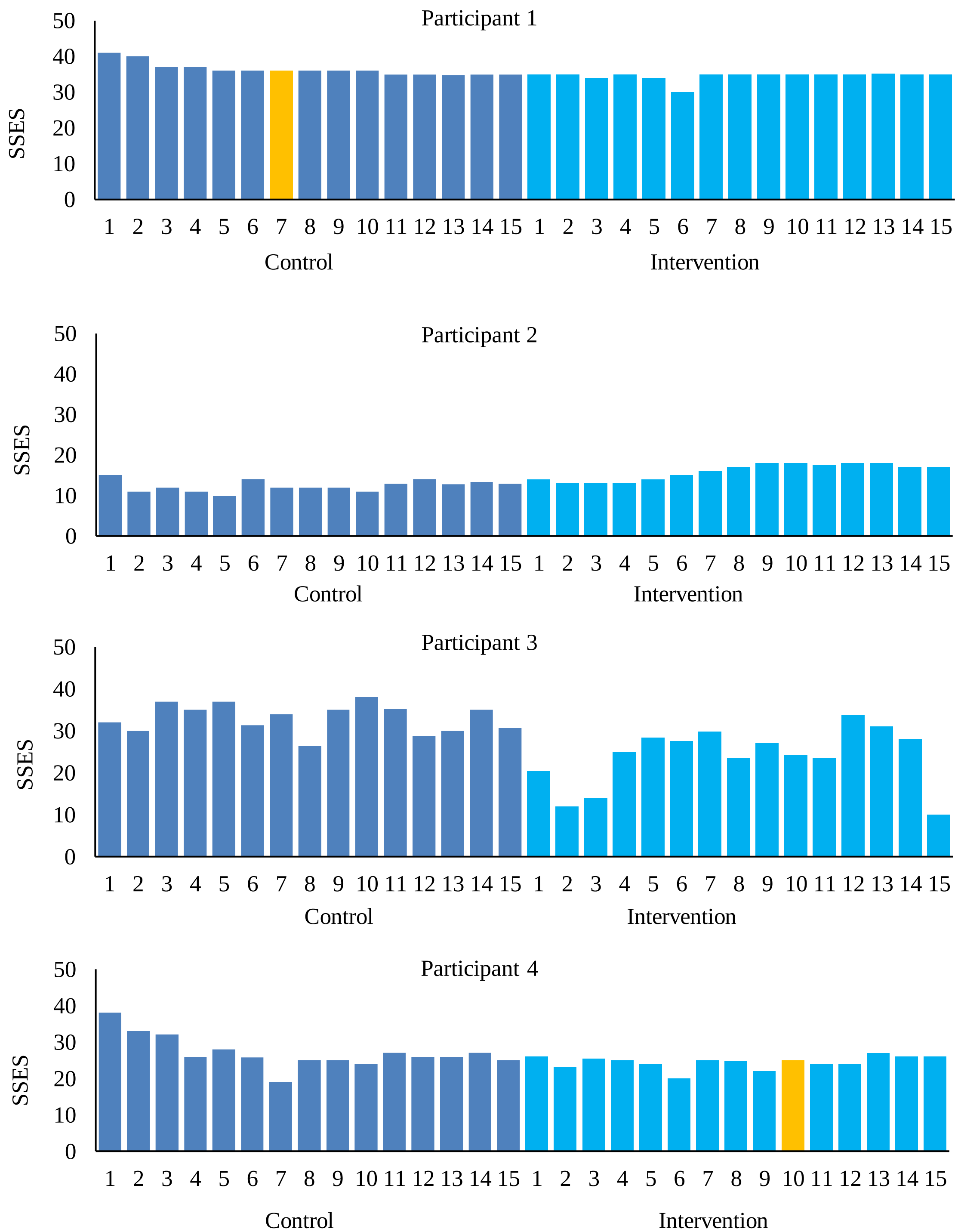
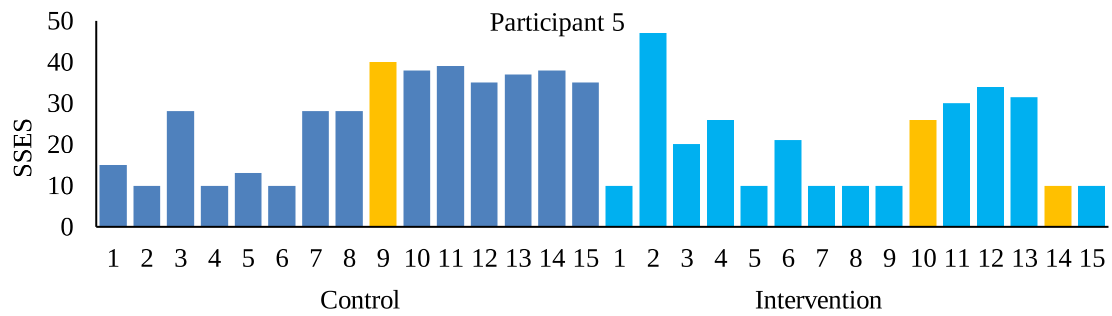
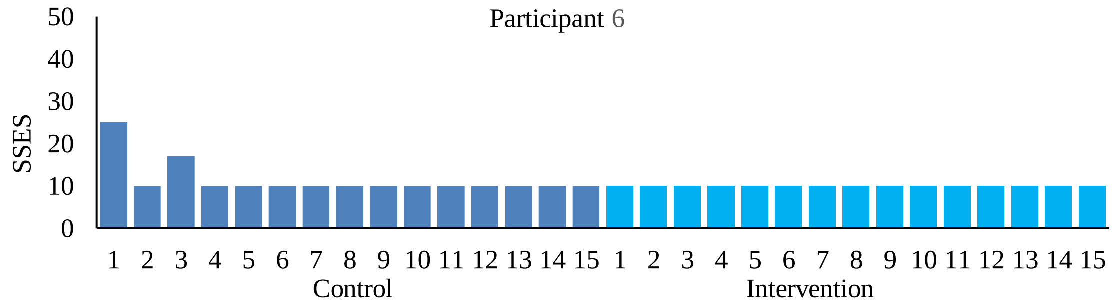
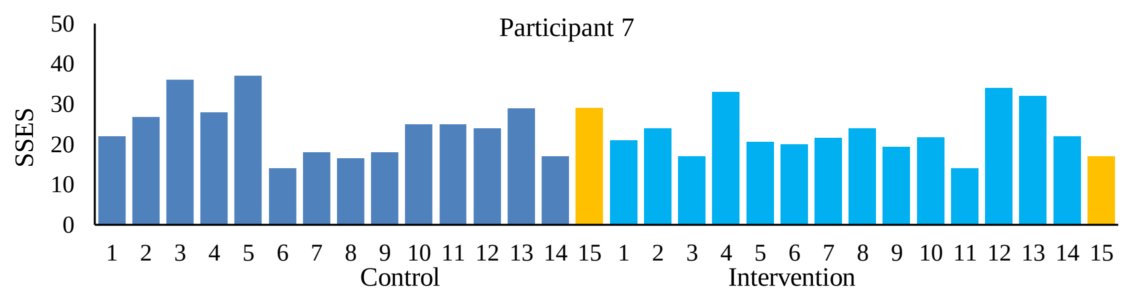


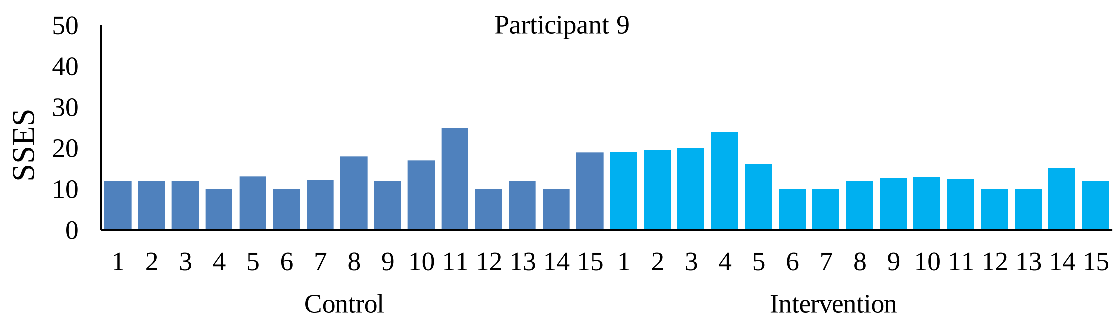
Figure VIII. SSES by Participant: Family Participation Subscale

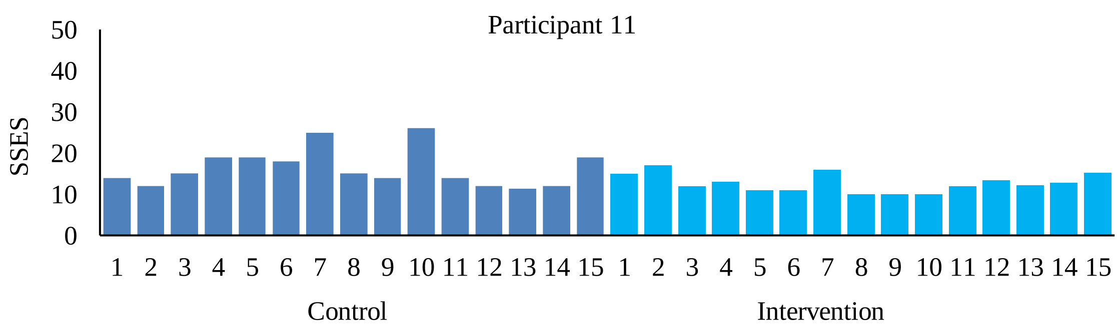


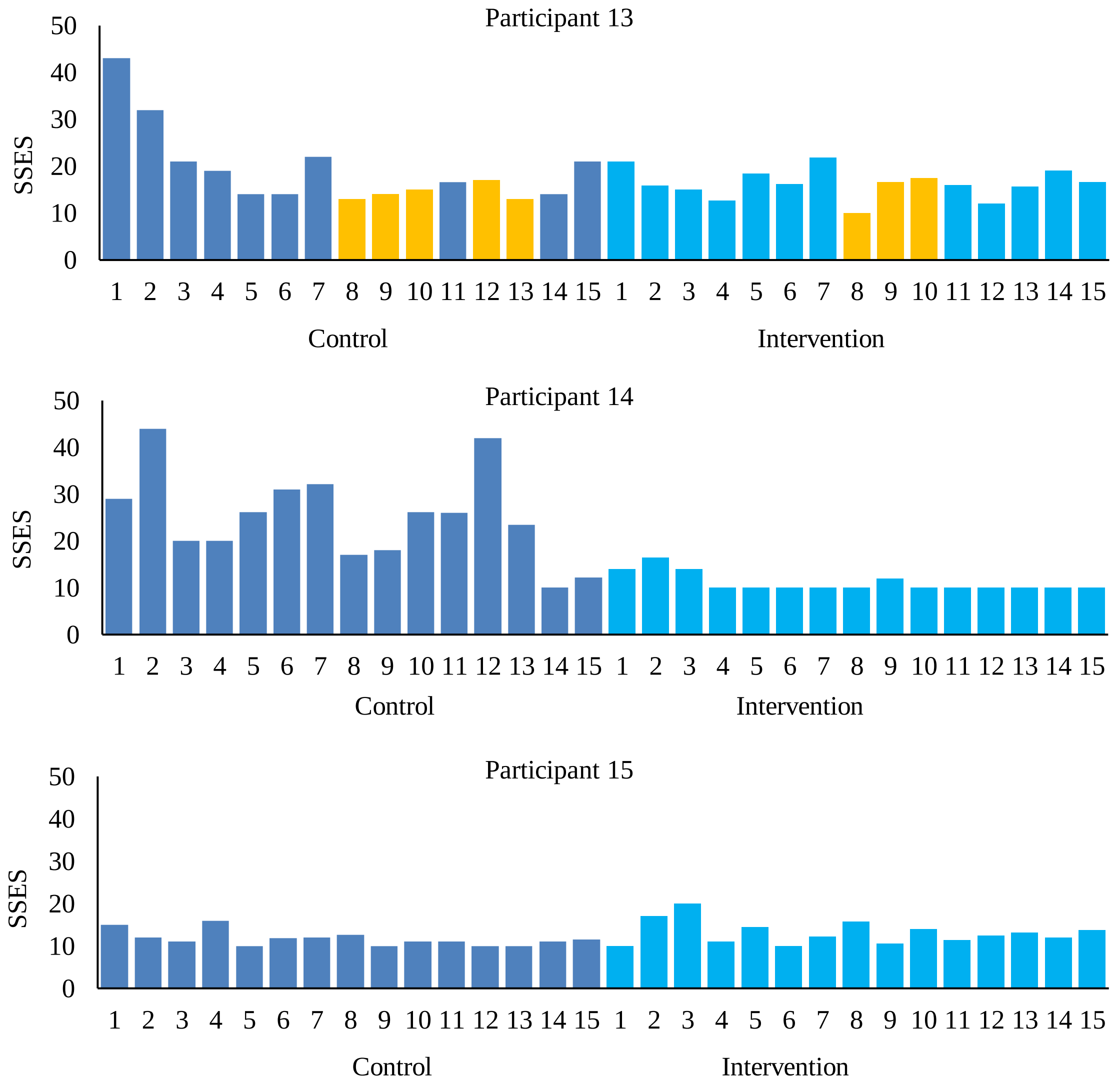

Participant 5
SSES
0 10 20 30 40 50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention


Participant 6
SSES
0 10 20 30 40 50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention


Participant 7
SSES
0 10 20 30 40 50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

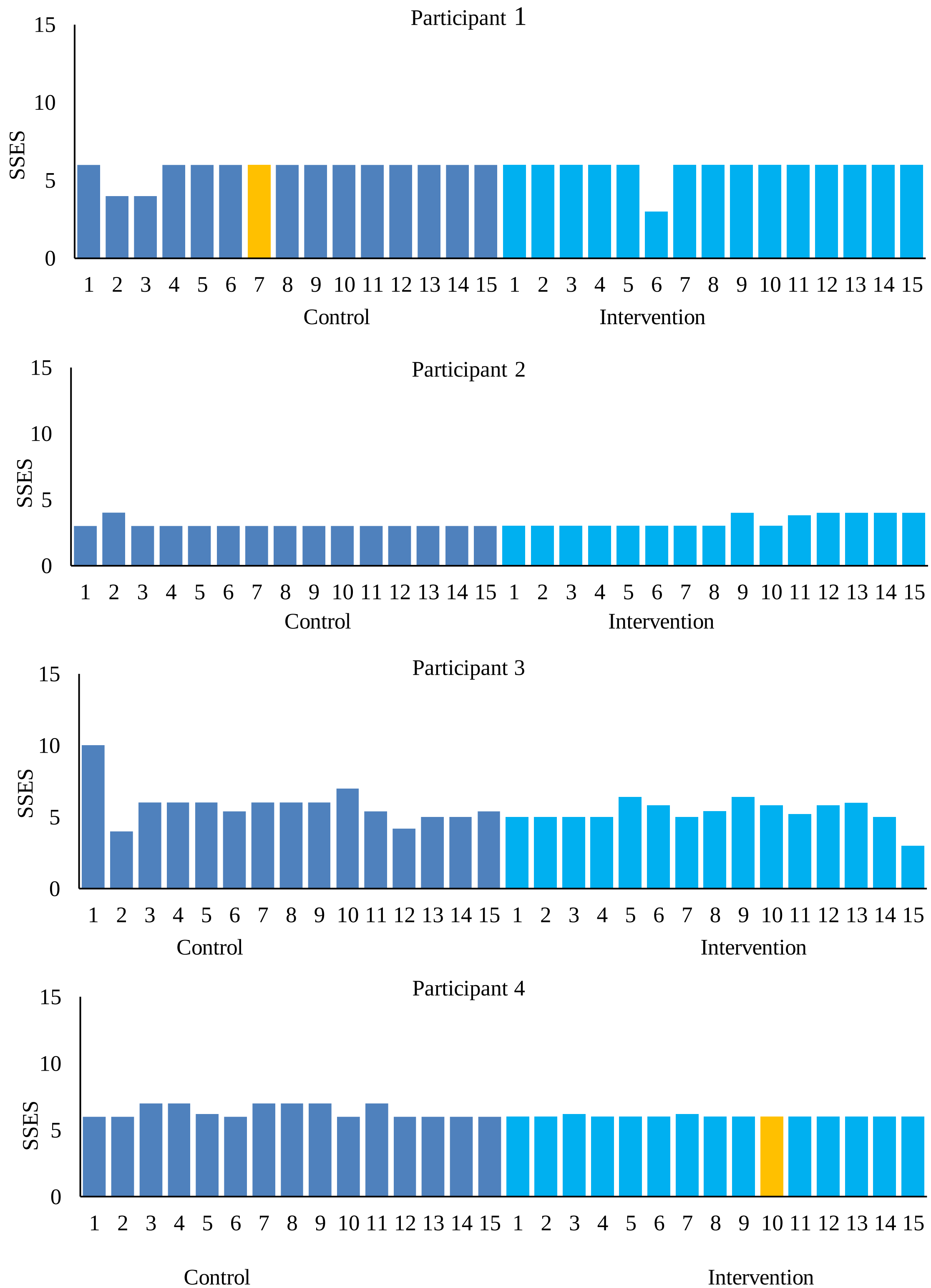

Participant 9
SSES
0 10 20 30 40 50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

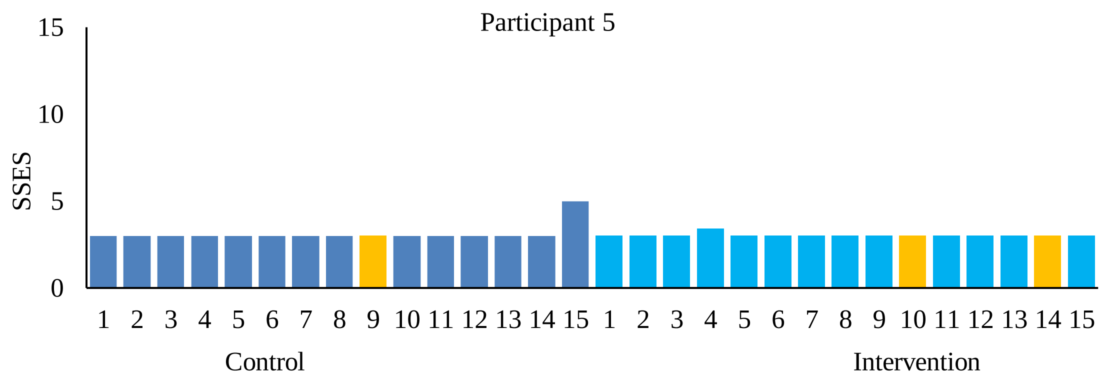

Participant 11
SSES
0 10 20 30 40 50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

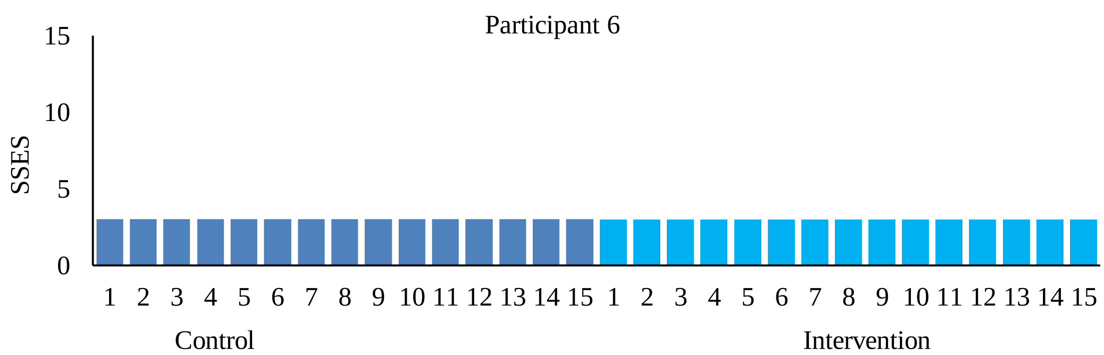


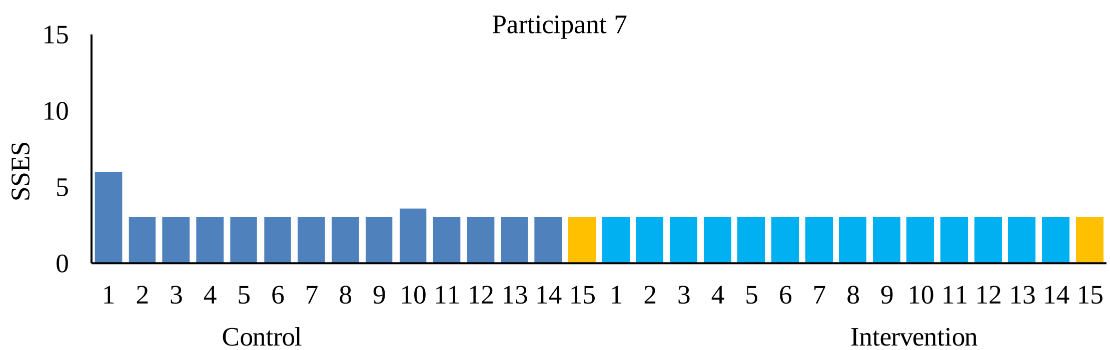
Note. Orange = days where participants met the recommended 60 minutes of MVPA per day.

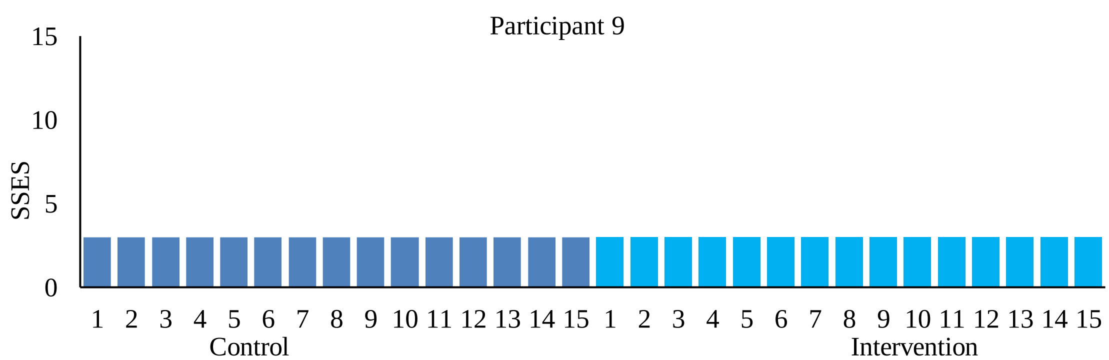
Figure IX. SSES by Participant: Family Reward and Punishment Subscale

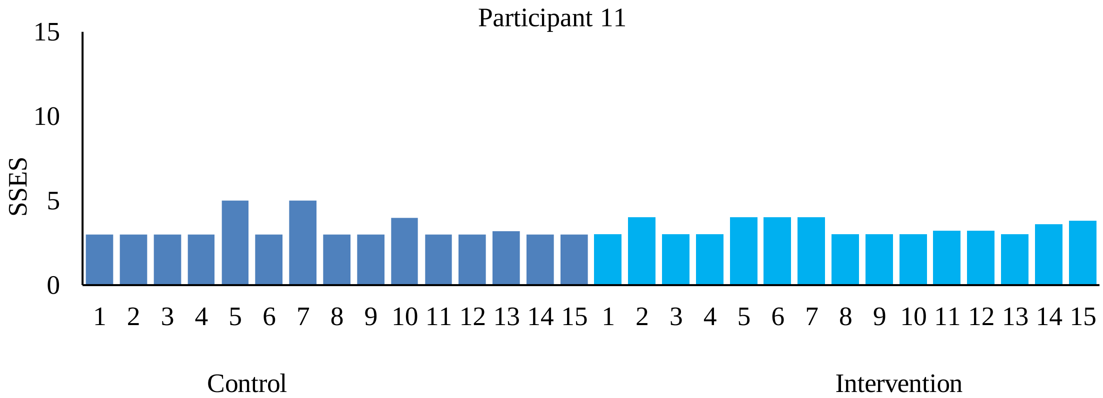


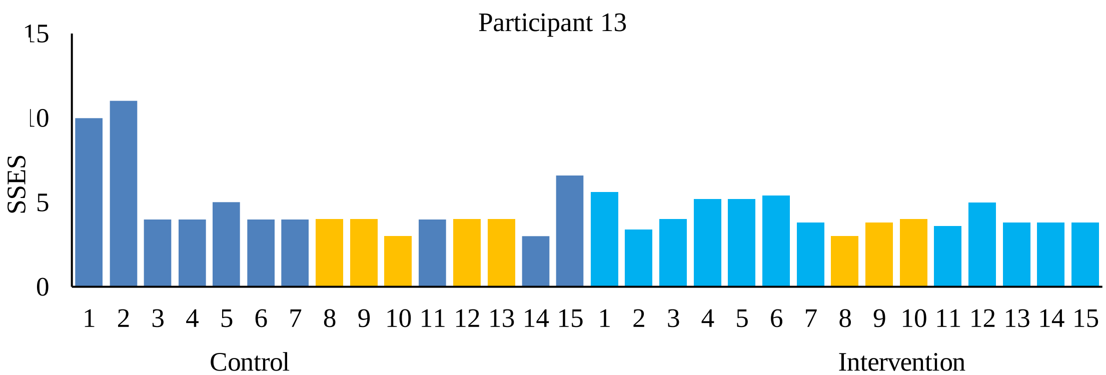

Participant 5
SSES
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

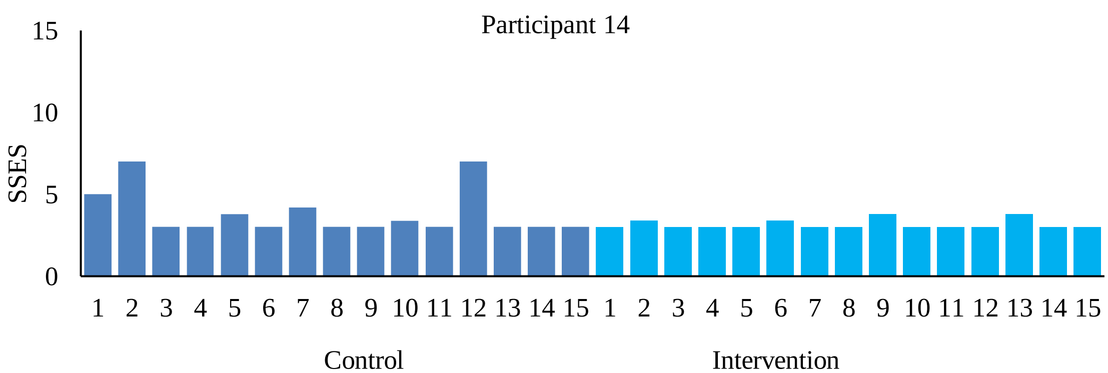

Participant 6
SSES
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

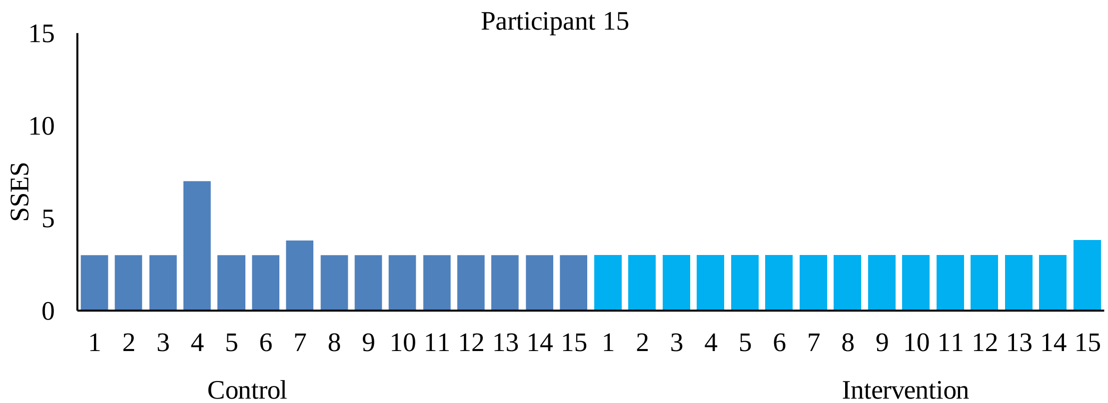

Participant 7
SSES
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention


Participant 9
SSES
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention



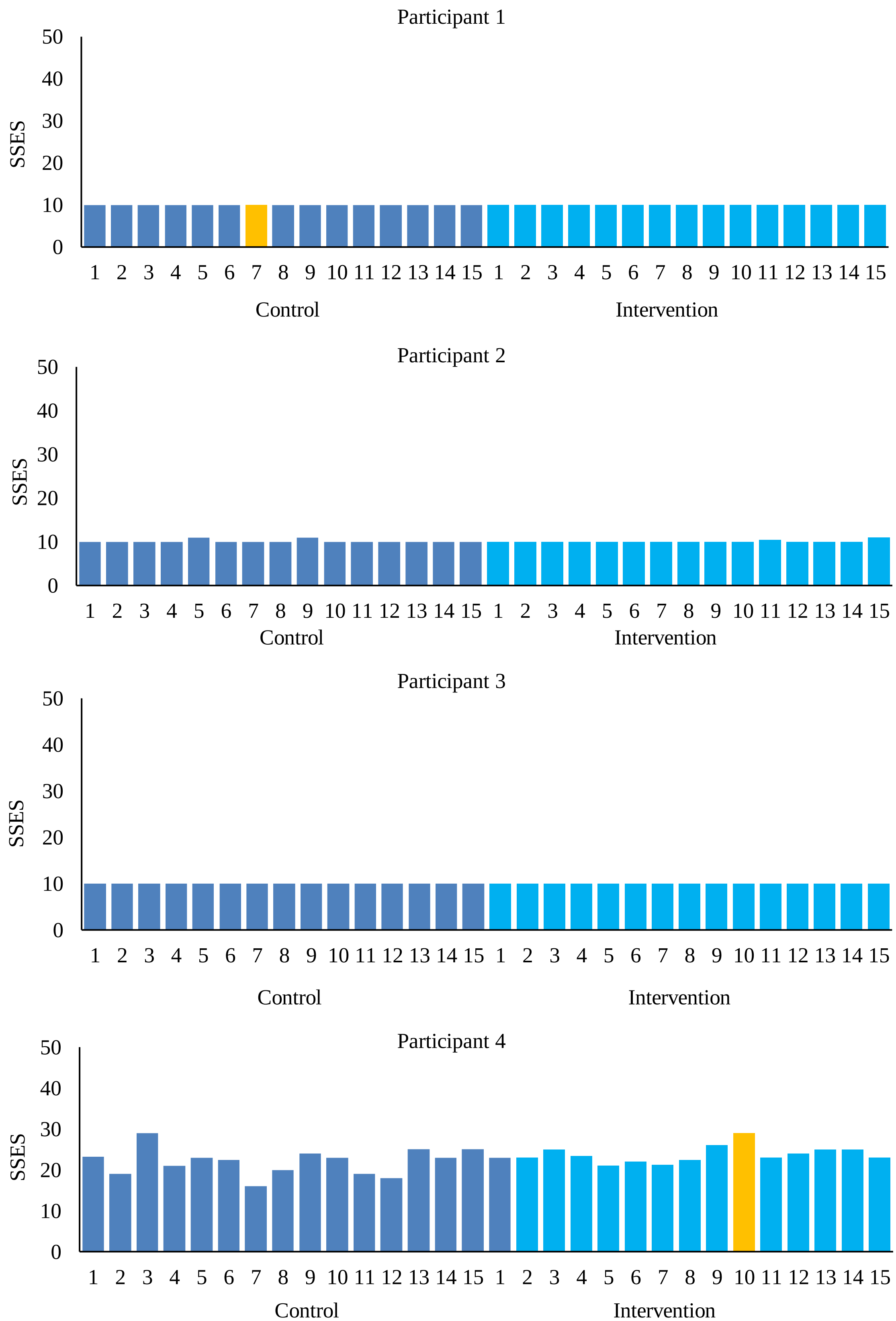


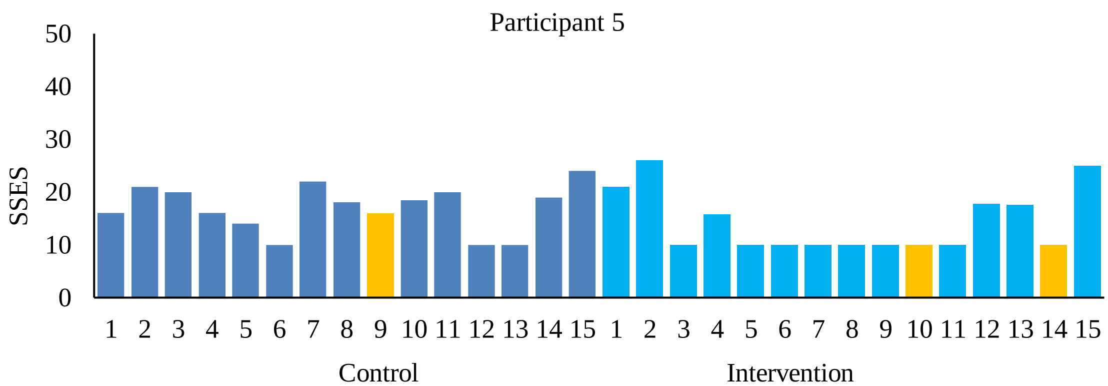


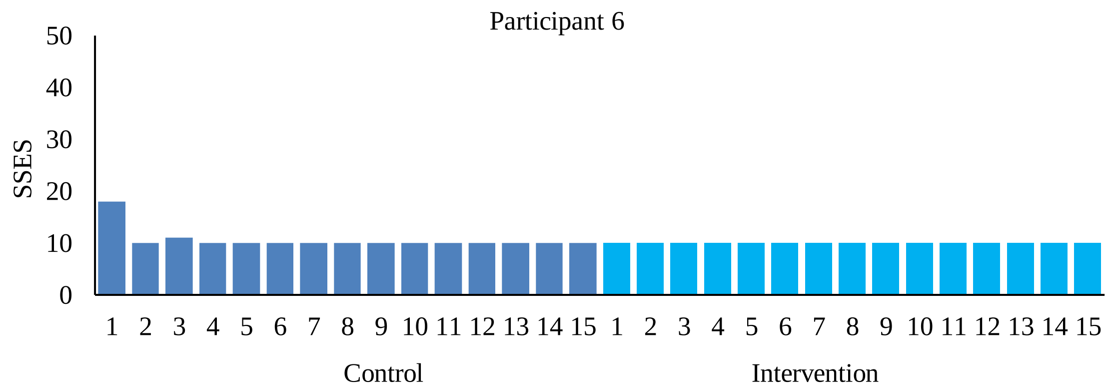


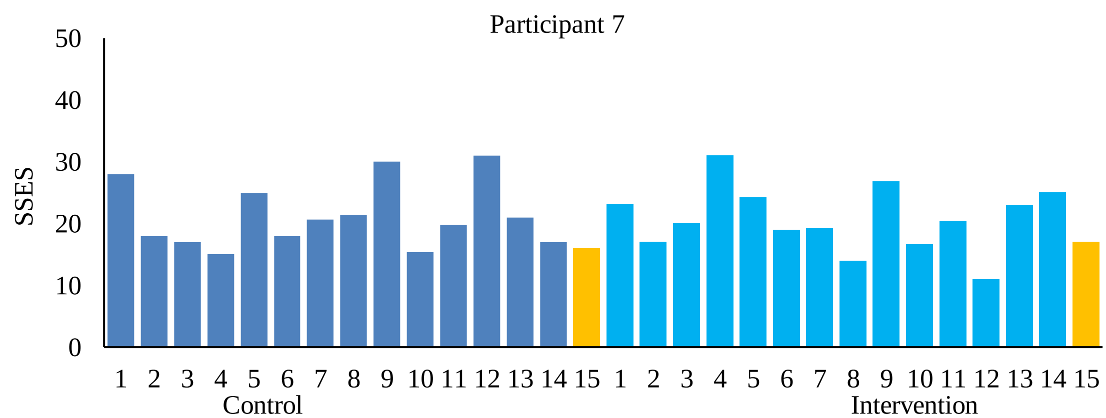
Note. Orange = days where participants met the recommended 60 minutes of MVPA per day.

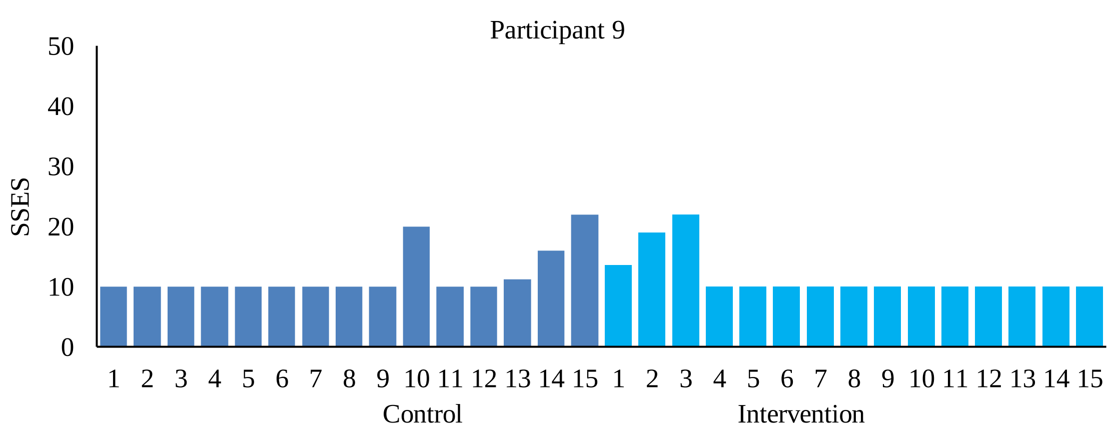
Figure X. SSES by Participant: Friend Participation

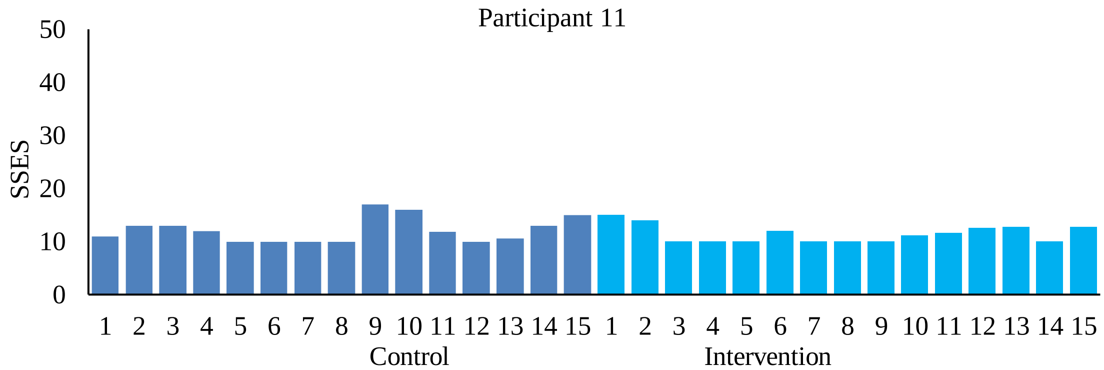


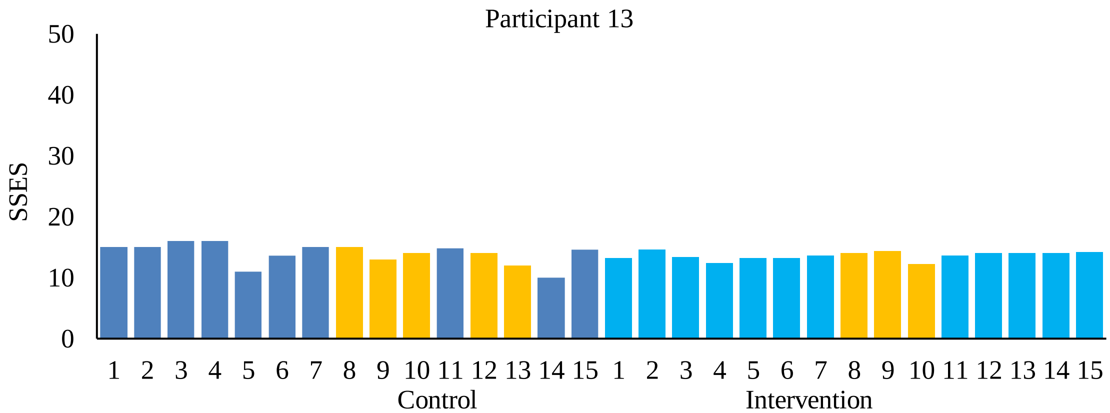

Participant 5
SSES
0
10
20
30
40
50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

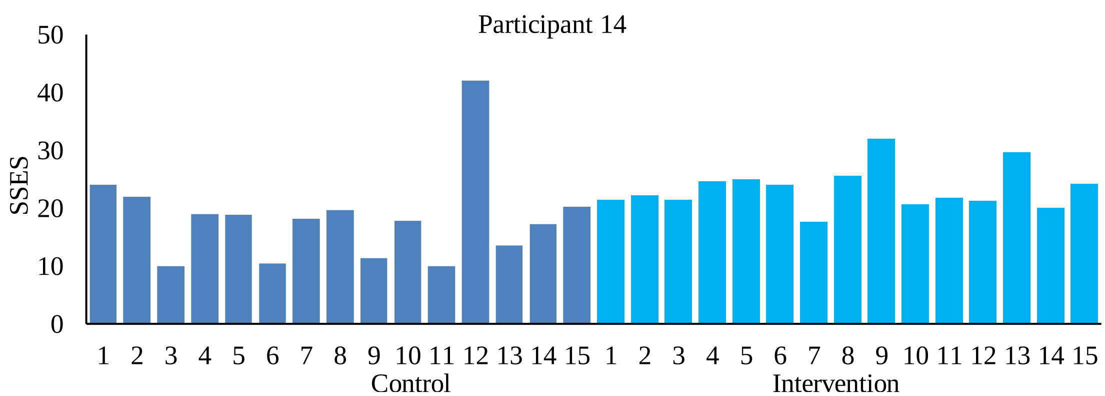

Participant 6
SSES
0
10
20
30
40
50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention

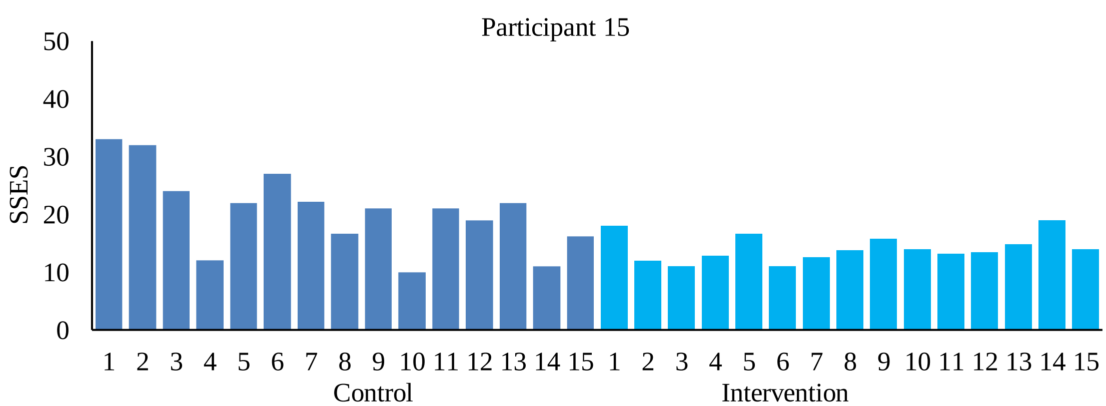

Participant 7
SSES
0
10
20
30
40
50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention


Participant 9
SSES
0
10
20
30
40
50
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Control
Intervention









Note. Orange = days where participants met the recommended 60 minutes of MVPA per day.

VITA

Kristina Irene Suorsa

Candidate for the Degree of

Doctor of Philosophy

Thesis: THE IMPACT OF A LOW-INTENSITY PHYSICAL ACTIVITY INTERVENTION ON HEALTH BEHAVIOR CHANGE IN PEDIATRIC CANCER SURVIVORS

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Psychological Services Center Student Associate August 2011-May 2017
Supervisors: Lana Beasley, Ph.D., Tony Wells, Ph.D., R. Matt Alderson, Ph.D., Stephanie Sweatt, Ph.D., & Maureen Sullivan, Ph.D.
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Professional Memberships:

Society of Pediatric Psychology