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Feasibility and Safety of a Group Physical Activity Program for Youth with Type 1 Diabetes

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**Abstract:**

**Background/Objective:** Many adolescents with type 1 diabetes do not achieve 60 minutes of daily moderate to vigorous physical activity (MVPA). Recognizing the importance of peer influence during adolescence, we evaluated the feasibility and safety of a group MVPA intervention for this population.

**Subjects:** Eighteen adolescents with type 1 diabetes (age 14.1±2.3yr, female 67%, Black or Latino 67%, median body mass index 92%'ile, A1c 79.9±25.1 mmol/mol, 9.5±2.3%).

**Methods:** Intervention sessions (35min MVPA and 45min discussion) occurred 1x/week for 12 weeks. Feasibility and safety metrics were enrollment, completion of intervention and assessments, cost, and hypoglycemia rates. Participants completed MVPA (accelerometry), and exploratory nutritional, psychosocial, clinical, and fitness variable assessments at baseline, 3mo, and 7mo. Hedges' effect sizes were calculated.

**Results:** Enrollment was 16% and intervention completion 56%. Assessment completion at 7mo was 67% for MVPA, nutrition, and fitness, 83% for psychosocial assessments, and 94% for clinical assessments. Cost was $1,241 per completing participant. One episode of mild hypoglycemia occurred during the sessions (0.6%). Self-reported daily fruit/vegetable servings ($d$= -0.72) and diabetes self-management behaviors decreased over time ($d$= -0.40). In the 10 completers, endurance run score improved ($d$= 0.49) from low baseline levels, while systolic blood pressure decreased ($d$= -0.75) and low-density lipoprotein increased ($d$= 0.49) but stayed within normal ranges.

**Conclusions:** The protocol for the group MVPA intervention was safe and had some feasibility metrics meriting further investigation. MVPA levels and glycemic control remained sub-optimal, suggesting the need for more intensive interventions for this population.

**MeSH Key Words:** Diabetes Mellitus, Type 1; Behavior, Adolescent; Exercise; Glycated Hemoglobin A

**Abstract Word count:** 225

**Abbreviations:**

ADA; American Diabetes Association

BMI %'ile; Body Mass Index Percentile

CVD; cardiovascular disease

DSME; diabetes self-management education

MPACER; Modified Progressive Aerobic Cardiovascular Endurance Run

MVPA; Moderate-to-vigorous intensity physical activity

PACER; Progressive Aerobic Cardiovascular Endurance Run

## Introduction

It is critically important for adolescents living with type 1 diabetes to achieve and maintain regular engagement in moderate-to-vigorous intensity physical activity (MVPA). For adolescents in general, engaging regularly in MVPA along with other healthy lifestyle behaviors (healthy eating, controlling body weight) is vitally important for well-being and physical (1), cognitive (2), and psychosocial development (3). Patterns of engagement in MVPA and other healthy lifestyle behaviors established during adolescence are likely to persist into adulthood (4). Failure to engage in MVPA and other healthy lifestyle behaviors during adolescence is associated with poorer lifelong health outcomes, including coronary heart disease, atherosclerosis, and all-cause mortality (5). Just 8% of adolescents engage in MVPA at the recommended level of 60 minutes per day (6), and adolescents with type 1 diabetes report inadequate patterns of MVPA similar to those without chronic conditions (7). For adolescents with type 1 diabetes, maintaining the recommended level of regular MVPA is even more important because of the effects regular MVPA can have on keeping glycemic levels as close to normal as possible and preventing and/or delaying microvascular complications and cardiovascular disease (CVD) (8,9).

Among the challenges of engaging in regular MVPA for adolescents with type 1 diabetes are the need for monitoring blood glucose levels and adjusting diet and insulin before, during, and after MVPA. Adolescents, parents, and healthcare providers have reported that these responsibilities are carried out without adequate support resources (10-12). Adolescence is a period of transition in type 1 diabetes management, in which responsibility for diabetes management shifts from being family-centered to being more autonomous (13). Adolescents and healthcare providers have concerns that teachers and coaches supervising organized sports have limited knowledge and understanding of safe diabetes management to support them with engagement in MVPA (10). Lack of support for self-management of type 1 diabetes for MVPA may account for the fact that fewer than half of adolescents with type 1 diabetes make appropriate adjustments to diet and insulin to accommodate MVPA (14). Preparing adolescents with type 1 diabetes for the challenges of decision-making about engagement in MVPA is therefore a health and safety priority.

As shown in 25 studies, adolescents with type 1 diabetes can safely perform regular MVPA with instructors and/or clinicians carefully supervising blood glucose levels, diet, and insulin adjustments, as well as the frequency, intensity, and duration of MVPA sessions (for review see (15)). Regular MVPA led also to health benefits including better glycemic control, body composition, lipid profiles, and cardiopulmonary fitness (15). The 2018 ISPAD Clinical Practice Consensus Guideline for Exercise in Children and Adolescents with Diabetes presents evidence-based guidelines but emphasizes the lack of data on how to successfully and safely promote them among those who are sedentary (9).

To our knowledge, only three prior trials have been focused on increasing unsupervised MVPA behavior by fostering autonomy regarding MVPA goals and related self-management and decision-making skills. Marrero et al. (16) provided three educational sessions that included 45 minutes of supervised MVPA and related self-management instruction to sedentary adolescents with type 1 diabetes, followed by 12 weeks when they were instructed to perform the same routine independently 3 times per week guided by a collection of videos from which they could select MVPA routines according to personal preference and abilities. Participants reported high adherence to the program (87%) and had increased cardiopulmonary fitness. Wong et al. (17) also provided home exercise videos to children and adolescents with type 1 diabetes, along with written self-management guidelines, exercise logs, and weekly telephone interviews about their logs, but adherence was lower (~50%) and fitness unchanged. More recently, sedentary adolescents with type 1 diabetes together with exercise physiologists developed personalized exercise prescriptions (18,19). Prescriptions included goals devised from personal preferences and barriers, individualized self-management counseling and feedback, and family support networks devised using principles from social cognitive and family systems theories. Participants in the study increased their MVPA from 10 to 40 minutes per day. Together, these results indicate the potential for these youth to increase habitual, unsupervised, safe MVPA with individualized guidance and family support.

Recognizing the importance of peer influence during adolescence, we sought to build on these studies by seeing if promotion of regular MVPA could be implemented in adolescents with type 1 diabetes in a group format. The body of evidence supporting group interventions in youth with type 1 diabetes is growing. Group interventions that allow for interactions among youth with type 1 diabetes have helped to improve type 1 diabetes self-management (20). Adolescents with type 1 diabetes have expressed interest in participating in interventions with their diabetes peers (21). Therefore, an MVPA intervention that incorporates not only family support but also peers with type 1 diabetes who may share unique concerns related to their activity may help meet the psychosocial needs of adolescents with type 1 diabetes (13).

Thus, the purpose of this study was to evaluate the feasibility and safety of a group MVPA intervention for adolescents with type 1 diabetes that included their parents and peers and to estimate the probable magnitude of the pre-post effect on MVPA and other exploratory outcomes (nutritional, psychosocial, clinical, and fitness) pertinent to self-management of type 1 diabetes.

## Methods

Participants. Adolescents with type 1 diabetes (11-19 years) receiving care at the Yale Children's Diabetes Program were approached at quarterly clinic visits and invited to participate. Inclusion criteria included: sedentary lifestyle and not on medications (e.g., corticosteroids) or other medical conditions requiring special approaches to diabetes management around engaging in MVPA (e.g., current pregnancy). The study was approved by the Yale University Institutional Review Board and in accordance with the Declaration of Helsinki. For completing the assessments, participants received $25 at baseline, $35 at 3 months, and $50 at 7 months.

Intervention. The intervention was initially offered twice per week at a single site on weeknights, to match the frequency of the Yale *Bright Bodies* comprehensive child weight management program that has demonstrated large effects and maintenance (22). However, the first 6 eligible candidates all stated that weekday schedule conflicts and/or travel distance precluded their attendance. Therefore, the schedule was changed to one session per week on Saturdays from January to June 2017 at two sites, one in New Haven, CT in the gymnasium of an elementary/middle magnet school (n=12) from 10:00-11:30am, and the other in Fairfield, CT (n=6), in the fitness center of a local private university from 3:15-4:45pm. Participants were initially told 12 sessions were required to earn a completion certificate, but only 4 achieved this so it was relaxed to 10 to make a more attainable goal. To accommodate participants with later enrollment and/or absences, 9 weeks of additional sessions were offered at both sites.

Each session consisted of 35 minutes of MVPA followed by 45 minutes of discussion of relevant topics. The intervention targeted two identified barriers to MVPA for adolescents with type 1 diabetes (10,11,23). First, it augmented supervised MVPA exercises and games with diabetes self-management education (DSME) and glucose self-monitoring activities so that adolescents could develop skill controlling their own glucose around enjoyable MVPA activities.

Second, it created an environment to practice MVPA exclusive to peers with type 1 diabetes and to alleviate social concerns regarding disclosure of diabetes around MVPA (e.g., testing glucose before school sports) (10,11,23). Our intention was that decision-making and self-monitoring skills learned and practiced in this safe environment would transfer to sustaining active living outside the sessions as well.

The MVPA activities were led by graduate and undergraduate exercise physiology students and derived from *Bright Bodies*, though with a shorter duration to allow time for diabetes safety procedures. Sessions targeted 60% to 80% of age-predicted maximum heart rate and included a warm-up, basic sports drills (plyometrics, agility drills), and non-competitive active games (e.g. balloon relay, tag, sprinting games, team juggling). Polar H7 heart rate monitors and Team Software (Polar Electro Inc., Bethpage, NY) allowed participants to track their heart rates projected on a screen in real-time. To encourage MVPA outside the sessions, participants were provided handouts with technical descriptions of the activities taught as well as information on community fitness centers.

The weekly discussions were led by a graduate nursing student and an advanced practice nurse. One session was an orientation with personal introductions and an overview of safety guidelines. Three sessions focused on DSME for exercise (benefits of exercise, exercise basics and safety, and exercise and diabetes problem-solving) and nutrition (Dietary Guidelines for Americans (24) plus diabetes-specific advice on carbohydrate counting and limiting sugars (25)). Eight sessions focused on discussions around coping skills. These sessions included discussions of strategies for coping with stress (stress management, relaxation techniques) and discussions of personal diabetes stories, communication skills, and conflict resolution (20) followed by practice of coping skills through developing role-playing scenarios in groups of 2-4 participants. At each makeup session, one of the above discussion topics was chosen based upon what had already been completed by the fewest number of the participants attending that day.

To ensure safety, all participants received clearance to participate in the exercise by their diabetes care provider. In addition, the American Diabetes Association (ADA) guidelines (8) for self-monitoring blood glucose and urine ketones, if indicated, and appropriate adjustments of diet and insulin before, during, and after engaging in MVPA, were followed. Participants self-monitored blood glucose using their own glucometers. If participants did not have access to their own glucometer or ketone strips, they were provided. Carbohydrate containing foods and drinks (e.g. orange juice, glucose tablets) were available when indicated by glucose testing or symptoms. Participants with trace or small amounts of urine ketones were allowed to participate in the MVPA session, but those with higher amounts were assisted in contacting an on-call provider for instructions regarding insulin adjustments. In these cases, the on-site and on-call team overseeing intervention safety determined that participating in the MVPA session would not be safe until their glucose was in safer levels. Participants were encouraged to be vigilant for symptoms of hypoglycemia during sessions as well as for the remainder of the day since MVPA increases the risk for nocturnal hypoglycemia (8). If participants experienced fatigue, dizziness, or other hypoglycemia symptoms, they refrained from participating in the MVPA while checking blood glucose and ingested carbohydrates until their glucose was at a safer level. After the MVPA component of the session was completed, participants again checked their blood glucose and self-corrected their levels through eating or drinking fast-acting carbohydrate containing foods and/or drinks and/or reducing their insulin doses as indicated. Additional carbohydrate containing foods and drinks were provided in case they needed to consume additional carbohydrates during their ride home. The principal investigator (GA) and study physician (SW) reviewed each participants' weekly blood glucose logs for safety issues each week during the intervention phase.

Parents were invited to take part in optional activities. These were offered concurrently with the adolescent intervention and included physical activity (walking, yoga, or cardio boxing) and group discussion of topics pertinent to parenting an adolescent with type 1 diabetes.

Assessments. Upon enrollment, sociodemographic data were collected using a brief survey administered to parents, and development status was assessed by the pubertal development scale (26). All other assessments were performed at baseline, 3-months, and 7-months. Participants wore a GT9X accelerometer (Actigraph™, Pensacola, FL) on the hip for seven days at each timepoint (1min epochs, 2,296 counts/min MVPA cutoff (27)). Calculated wear time (27) for all timepoints was ≥10hr on ≥4 days including ≥1 weekend day. Participants self-reported daily screen time (28). Participants also kept a food diary for three days and answered follow-up queries regarding brands, portion sizes, and types of food. Outcomes calculated by Nutracheck software (with intraclass correlation coefficient among the 10 subjects completing diaries at all 3 timepoints) were daily fruit and vegetable consumption (0.79), total intake (0.38) and percentage intake from fat (-0.13).

Participants also completed psychosocial surveys. The Pediatric Quality of Life Inventory Diabetes Module contains 23 Likert-type items with higher scores reflecting better diabetes-related quality of life (29) (Cronbach's α in our sample = 0.73). The Fear of Hypoglycemia Worry subscale (HFS-W) includes 18 Likert-type items with higher scores reflecting greater worry about experiencing hypoglycemia (30) (Cronbach's α in our sample = 0.94). The Diabetes Self Care Inventory contains 14 Likert-type items with higher scores reflecting better adherence to prescribed diabetes self-management regimen (31) (Cronbach's α in our sample = 0.60). The Self-Perception Profile for Adolescents social acceptance subscale includes 5 statements scored on a 4-point scale with higher scores reflecting greater perceived social confidence (32) (Cronbach's $\alpha$ in our sample = 0.66).

HbA1c levels were measured by the DCA Vantage Analyzer (Bayer, Tarrytown, NY). Height (Seca Stadiometer, Hamburg, Germany) and weight (Scale Tronix, Welch Allyn Inc, Skaneateles Falls, NY) were measured without shoes and body mass index (BMI) categorized for age and gender percentile (%'ile) (33). Fat percentage was measured by leg-to-leg bioelectrical impedance analysis (Tanita Body Fat Analyzer 300, Tanita Corp of America, Inc, Arlington Heights, IL), and waist circumference by Gulick tape measure at the narrowest point of the torso. Resting blood pressure was taken by averaging two measurements on the left brachial artery from the seated position after at least 5 minutes of quiet rest (Omron BP760N, Omron Healthcare, Lake Forest, IL). If the measurements differed by >5 mmHg, then a third was taken and the closest two averaged. Plasma lipids and serum C-reactive protein were measured in blood samples collected at baseline and 3 months (ACE Alera automated chemistry analyzer, Alfa Wasserman Diagnostic Technologies, West Caldwell, NJ).

Participants completed fitness evaluation by the 15-meter Progressive Aerobic Cardiovascular Endurance Run (PACER) modified to the slower starting speed of 6.4 km/hr and pace increases of 0.4 km/hr per minute (MPACER) (34,35). The MPACER intraclass correlation coefficient among the 10 subjects completing at all three timepoints was 0.80 indicating good reliability.

Interested participants (n=16) and their parents/guardians participated in a semi-structured exit interview by a graduate nursing student not involved with the intervention. Each family was interviewed individually by telephone. Participants were asked what they did and did not like about the intervention and its specific activities. Interviews were audio recorded, de-identified, and transcribed for analysis.

Data Analysis. Feasibility metrics (with *a priori* standards) were recruitment (25%-40% of approached candidates enrolling) and completion of intervention (50%-65%) and assessments (65%-80%). *Post hoc*, we calculated cost per completing participant (staff + space rental + participant transportation, divided by attendance per session and multiplied by number of required sessions). Safety was assessed by paired t-tests of blood glucose before and after the exercise sessions, as well as frequency of hypoglycemia during MVPA and amount of carbohydrate correction given at the sessions. Differences in variables over the 3 timepoints were assessed by Hedges' effect size (0.20 considered small, 0.50 medium, 0.80 large) and a 1x3 repeated measures analysis of variance followed by post hoc Bonferroni-adjusted two-sided t-tests.

In all analyses, variables were summarized by descriptive statistics and tested for normality by the Shapiro-Wilks test. Non-normally distributed variables were log-transformed to satisfy the underlying assumption of normality, or square root transformed in the case of variables containing values <1, then back-transformed for reporting outcomes. Analyses followed intent-to-treat procedures with forward imputation for missing follow-up data. Cases with missing baseline data were excluded for that variable. Analyses were performed in SPSS 24.0 for Windows (Armonk, NY).

A full cohort analysis was performed including all participants who completed baseline testing (n=18). In addition, we examined outcomes in the 10 intervention completers to explore the probable magnitude of the pre-post effect of our group MVPA activities (i.e., non-competitive games) on clinical and fitness variables. Baseline differences were assessed between completers and non-completers by unpaired t-tests for continuous variables and Chi-squared tests for categorical variables.

Interviews were analyzed using qualitative description (37) using Atlas.ti$^{TM}$ 7 software (Berlin, Germany). All transcripts were read in their entirety and then a subset of transcripts was reviewed for inductive coding by two independent reviewers who agreed on initial codes (GA and KJ). Remaining transcripts were coded independently, consensus obtained (KJ and Nishat Islam), and grouped into themes. All emergent themes will be presented in a forthcoming manuscript. Here, we present common themes about what the participants liked about the program.

**Results**

<u>Recruitment.</u> From 116 eligible candidates approached during recruitment efforts, 18 adolescents enrolled (16%) (Figure 1). The majority of the sample was female, Black or Latino (67%), and reported annual household income of less than $40,000 (Table 1).

<u>Intervention and Assessment Completion.</u> Participants attended a median 8 of the first 12 sessions (range 3-12), and a median of 10 sessions (range 3-21) after including makeup classes, meaning 10 out of 18 met the required 10 sessions to achieve completion (56%). A greater proportion of the participants from the New Haven site (n=9 out of 12) versus the Fairfield site (n=1 out of 6) completed the intervention (p=0.02). Parents (n=14) attended a median of 6 of the first 12 sessions (range 1-10) and a median of 8 sessions (range 1-13) after including makeup classes. Proportion of parents attending was not different between completers (7 out of 10) and non-completers (7 out of 8, p=0.38). The most common reason for both non-enrollment and non-completion was that the time/location of sessions conflicted with prior commitments or was

too much travel distance to justify relative to benefits they expected from the intervention (Table 2). Assessment completion rates are given in Table 3.

Cost per completing participant was calculated for the New Haven site, the location of nearly all completers. Each session cost space rental ($220), personnel ($294), and participant transportation ($10 each plus $15-$45 for each of n=5 who needed taxi fares or drove more than 60 miles) and was attended by a median of 6 participants (range 4 to 9), meaning the average cost for one participant to complete 10 sessions was $1,241.

Regarding safety, mean blood glucose levels at the start of the physical activity portion of the sessions were on average above ADA target range but dropped to within target range at the end of this portion (Figure 2). A median of 5 (interquartile range 2 – 11) grams of fast acting carbohydrates were ingested by the participants before, during, and/or after MVPA. Of the 18 participants, 15 took supplemental carbohydrates in at least one session. There were four instances of recognized self-reported hypoglycemia symptoms during MVPA, but only one episode involved blood glucose below the commonly used clinical threshold of 3.9 mmol/L (3.4 mmol/L, 61 mg/dL) that resolved within 15 minutes of recognizing and initiating fast acting carbohydrate ingestion treatment.

Estimates of effect of the treatment on MVPA are shown in Table 3. For both the full cohort and completers, MVPA was low and screen time high at baseline and they did not change over time. Changes over the course of the study in factors pertinent to self-management of type 1 diabetes are also shown in Table 3. In the full cohort, at baseline, participants reported that they had low fruit and vegetable consumption, average diabetes-related quality of life, followed their prescribed regimen for diabetes care more than 50% of the time with occasional lapses, rarely worried about hypoglycemia, and had good perceived social confidence. They had overweight BMI %'ile, poor glycemic control, and endurance run score below median for age and gender (Table 3). Body fat, waist circumference, blood pressure, and lipid profile were within normal ranges.

Over time, diabetes-related quality of life increased although only the pairwise comparison between 3-months and 7-months was significant. Fruit and vegetable consumption decreased as did self-management behaviors. No other variables changed.

At baseline, completers (n=10) did not differ significantly from non-completers for any variables measured ($p>0.05$), although tended to have higher baseline diabetes-related quality of life (68.2±9.7 vs 56.0±16.4, $p=0.07$) and higher Diabetes Self Care Inventory scores (3.9±0.5 vs 3.4±0.4, $p=0.09$).

Over time, completers increased their MPACER scores (baseline median 23, interquartile range (18,51); 3mo median 31, interquartile range (20,62); 7mo median 31, interquartile range (22,65); $d_{baseline, 7mo} = 0.49$, $P_{time}<0.01$, $P_{baseline, 7mo}=0.01$). They also decreased their systolic blood pressure (baseline 112.8±11.6 mmHg, 3mo 107.1±9.3 mmHg, 7mo 105.8±4.9 mmHg, $d_{baseline,7mo}=-0.75$, $P_{time}=0.04$, pairwise comparisons not significant,) and increased their low-density lipoprotein ($d_{baseline,3mo}=0.49$, baseline 2.23±0.54, 3mo 2.52±0.59 mmol/L, $P_{time}=0.02$,) but both remained within normal ranges. No other variables changed ($p>0.05$).

Three of the 10 intervention completers could not attend the 7-month assessment for personal reasons, so those data points were analyzed by intent-to-treat with forward imputation, except for HbA1c, height, weight, and blood pressure which were measured at the diabetes clinic within 2 months of the 7-month timepoint, using the same devices and procedures.

Interviews lasted 27±8 min. Two themes emerged: (1) they like sharing personal experiences with peers; and (2) they reported that non-competitive MVPA games helped their sense of collaboration. These are illustrated by the following quote: "I thought it was good how we all came together, and we just talked about the situations we all went through. All of our own things that we go through in our lives. So, we could see that something that we had in common and that we weren't going through it alone."

**Discussion**

Adolescence is a crucial period for establishing patterns of regular engagement in MVPA and safe diabetes management behaviors around MVPA for people living with type 1 diabetes. In this study, we assessed the feasibility and safety of a program that used a novel group intervention to promote MVPA and positive self-management behaviors around MVPA for these adolescents. This intervention addressed common barriers to MVPA for adolescents with type 1 diabetes by combining group MVPA sessions with DSME, coping skills discussions, and parent classes. Besides feasibility and safety, we also calculated the pre-post effect size on MVPA and explored changes in factors pertinent to self-management of type 1 diabetes.

Feasibility results were mixed. Intervention (56%) and assessment completion (67%-78%) met standards, although intervention MVPA requirements were substantially relaxed from initial targets and previous programs (16,17,19). Also, recruitment was low (16%). The group format precluded enrollment and attendance for a number of participants with location and scheduling concerns. Our attempt to mitigate these barriers by adding the second location/time in Fairfield was mostly ineffective, as only one participant from this smaller group completed. Besides these *a priori* targets, the *post hoc* calculated cost was higher than a previous personalized MVPA intervention ($1,241 vs $175 per participant) (19). The group format increased cost since staffing needs were independent of attendance on a given day, transportation was required, and space rental fees kept facilities open on weekends when most participants were able to attend. Although group interventions have potential to meet the psychosocial needs of adolescents with type 1 diabetes (13,20,21), these barriers must be considered.

The intervention was safe, in that it met the needs of participants in self-correcting their glucose levels before, during, and after each of the 12 sessions. It yielded only one incidence of mild clinical hypoglycemia that was recognized and treated quickly.

In addition to the barriers to feasibility, the data do not support the possibility of our intervention improving MVPA or screen time in these sedentary youth. The modest change in median MVPA had a negligible effect size and was within range expected from seasonal variation (38) given the study timetable. This result raises the question of what barriers were most responsible for the low MVPA and high screen time we observed, and how they could be better addressed in future interventions.

Among previously reported barriers to MVPA in type 1 diabetes (10,11,23), our sample appeared to be more affected by sub-optimal self-management than social functioning or worry about experiencing hypoglycemia. Diabetes self-management behaviors typically decline during the transitional adolescence period (13), and such a trend was evident in our sample based upon declining self-care inventory scores, dietary quality, and sub-optimal glycemic control (Table 3). Moreover, lapses in diabetes self-management behaviors tended to occur more often among non-completers than completers. By contrast, even though adolescence is characterized by social concerns about disclosure of diabetes diagnosis (10,13) and worry about experiencing hypoglycemia (39), all participants reported that they had high perceived social confidence and rarely worried about hypoglycemia, indicating that these potential barriers to MVPA were less pertinent to them. Moreover, they had lower blood glucose levels from above ADA target range into ADA target range after the MVPA sessions with extremely low incidence of hypoglycemia.

These data indicating sub-optimal self-management as a prominent barrier to MVPA in our sample support our rationale for emphasizing DSME and glucose self-monitoring activities in our intervention. However, the group format may not be ideal. Previously, adolescents with type 1 diabetes who completed individualized self-management counseling and personalized goal-setting strategies increased their MVPA from sedentary to as much as 40 minutes per day (16,19). Data from other age groups may also be informative. Group interventions including weekly MVPA and DSME sessions for adults (40) and young children (9-11 years) (36) with type 1 diabetes did not increase MVPA outside the group sessions. Taken together, these data and ours indicate a personalized goal-setting approach may be more effective at promoting habitual MVPA for type 1 diabetes (19).

Nonetheless, participants in the previous group intervention for adults with type 1 diabetes improved peak oxygen uptake and systolic blood pressure compared to non-participating controls (40). It is possible that even group interventions unable to promote MVPA more than once per week could still gain from this modest MVPA dose some positive impact on clinically important outcomes for type 1 diabetes. We lacked the power to test whether our intervention could achieve this in adolescents, since compared to the previous study (40) we had a smaller sample size, lower session attendance, indirect rather than direct assessment of cardiopulmonary fitness, and no control group. Nonetheless, we observed favorable pre-post effects on endurance run score and systolic blood pressure among those who completed the sessions. If these were observed in a more rigorous study with higher completion rate, it would support our group MVPA activities (i.e., non-competitive games) as an alternative to individual exercises that foster social collaboration not attainable from the latter, while still providing some of the same clinical benefits. On the other hand, no group MVPA intervention for type 1 diabetes to our knowledge has yielded any effect on poor glycemic control or overweight BMI, reinforcing previous findings that these outcomes require a more intensive intervention (15,22).

This study had several limitations. First, it was a small pre-post feasibility study lacking power to confirm any of the effect sizes observed. Secondly, the feasibility barriers encountered may affect translatability of the protocol. Third, two of the measures (Diabetes Self-Care Inventory, Self-Perception Profile) had low reliability in this sample. Fourth, food diaries bear potential for underreporting. We mitigated this concern by only analyzing fruit and vegetable servings, since they had moderate reliability in our sample and past reports indicate socially desirable foods are less prone to selective underreporting (41), but had to omit other dietary outcomes (total and fat intake) that were not supported by these indicators. Finally, our findings for this population with type 1 diabetes, poorer glycemic control, and low level of worry regarding hypoglycemia may not be generalizable to a population of youth with type 1 diabetes in better glycemic control. In particular, the latter group may need an intervention placing greater emphasis on worry about hypoglycemia.

Despite these limitations, this study was one of the few studies of MVPA in adolescents with type 1 diabetes guided by behavioral considerations and measuring changes in behavioral processes, and the only one to utilize a group approach including not only parents but also peers. Also, in previous studies, diverse samples of adolescents including sociodemographic groups at elevated risk of physical inactivity and overweight (low income, female gender, ethnic/racial minority) within the type 1 diabetes and general adolescent population (42,43) have not been as well represented in the study samples as they were in the current study. Adolescents in homes facing economic challenges often live in disadvantaged neighborhoods (higher concentration of poverty, greater number of abandoned homes) leading to more limited opportunities for engagement in MVPA (e.g. family activities, free play, and organized sports).

Although our program was safe, some feasibility metrics were encouraging, and results indicated the potential for improving cardiopulmonary fitness score among those completing it, the major shortcoming we found was the inability to detect an increase in MVPA outside of intervention sessions. Given the success of personalized programs to promote MVPA outside of intervention sessions (19) relative to less frequent group interventions such as this one and others (40), future MVPA interventions should consider personalized delivery. However, investigators should examine positive social interactions like our participants reported by hybridizing it with in-person group sessions and other communication modes that are developmentally appropriate for adolescents with type 1 diabetes (e.g., phone, email, text messaging, and social media) (36). Promotion of more MVPA outside of sessions may help achieve improvements to glycemic control and overweight that were not achieved in the present study, as has been demonstrated in previous studies that used higher volume of MVPA (15). It is noteworthy that our participants had minimal need for supplemental fast-acting carbohydrates at the sessions (~20 kcal per 35min MVPA) suggesting they could lose body weight if practicing them more frequently.

In conclusion, we found a group MVPA intervention for sedentary adolescents with type 1 diabetes designed to enhance self-management, decision making, and coping around MVPA to be safe and have some feasibility metrics that merit further investigation. Indicators of low MVPA, poor nutrition, poor glycemic control, and BMI above healthy levels suggest the need for more intensive interventions in this at-risk population.

**Conflict of interests**

The authors declare no potential conflict of interests.

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**Table 1.** Demographic data of enrolled participants. Presented as mean±SD for normally distributed variables and median (25th %'ile, 75th %'ile) for non-normally distributed variables.

| **Characteristic** | **Entire Group (N=18)** | **Completers† (N=10)** |
|---|---|---|
| Age, years | 14.1±2.3 | 14.2±2.7 |
| HbA1c (mmol/mol) | 80±25 | 72±19 |
| HbA1c (%) | 9.2±2.3 | 8.7±1.8 |
| Diabetes duration (years) | 2.3 (0.7, 5.9) | 1.4 (0.7, 4.7) |
| Insulin Delivery Method, CSII (%) | 8 (44%) | 5 (50%) |
| Child gender, Female (%) | 12 (67%) | 6 (60%) |
| Child race/ethnicity, N (%) | | |
| Latino | 7 (39%) | 4 (40%) |
| African American | 5 (28%) | 2 (20%) |
| White | 5 (28%) | 3 (30%) |
| Asian | 1 (6%) | 1 (10%) |
| Household income | | |
| <$20,000 | 6 (33%) | 3 (30%) |
| $20,000-$39,999 | 4 (22%) | 3 (30%) |
| ≥$40,000 | 6 (34%) | 3 (30%) |
| Missing | 2 (11%) | 1 (10%) |
| Body Mass Index %'ile | 91.7 (82.9, 95.0) | 91.4 (78.3, 95.5) |
| Obese (≥$95^{th}$ %'ile) | 6 (33%) | 4 (40%) |
| Overweight (≥$85^{th}$, <$95^{th}$ %'ile) | 7 (39%) | 2 (20%) |
| Normal weight (<$85^{th}$ %'ile) | 5 (28%) | 4 (40%) |

Completers did not differ significantly from non- completers for any variables measured (p>0.05). CSII, Continuous subcutaneous insulin infusion. †Attended >10 sessions.

**Table 2.** Barriers to recruitment and completion

| Reasons for Non-Enrollment† | # of Participants | |
|---|---|---|
| Time/location conflicted with previous commitments, or was too much travel distance to justify relative to benefits they expected from the intervention | 4 | 31% |
| No reason given | 3 | 23% |
| Decided it would not be worthwhile | 2 | 15% |
| Study assessments too much burden | 2 | 15% |
| Medical clearance | 1 | 8% |
| Switched medical provider | 1 | 8% |
| Total | 13 | |
| **Reasons for Non-Completion‡** | **# of Participants** | |
| Time/location conflicted with previous commitments, or was too far to justify | 5 | 63% |
| Found other way to be active | 2 | 25% |
| Travel out of state | 1 | 13% |
| Total | 8 | |

†among those signing the consent form but not completing baseline assessments;
‡among those enrolled.

**Table 3.** Outcomes at baseline, 3 months, and 7 months. Presented as mean±SD for normally distributed variables and median (25th %'ile, 75th %'ile) for non-normally distributed variables.

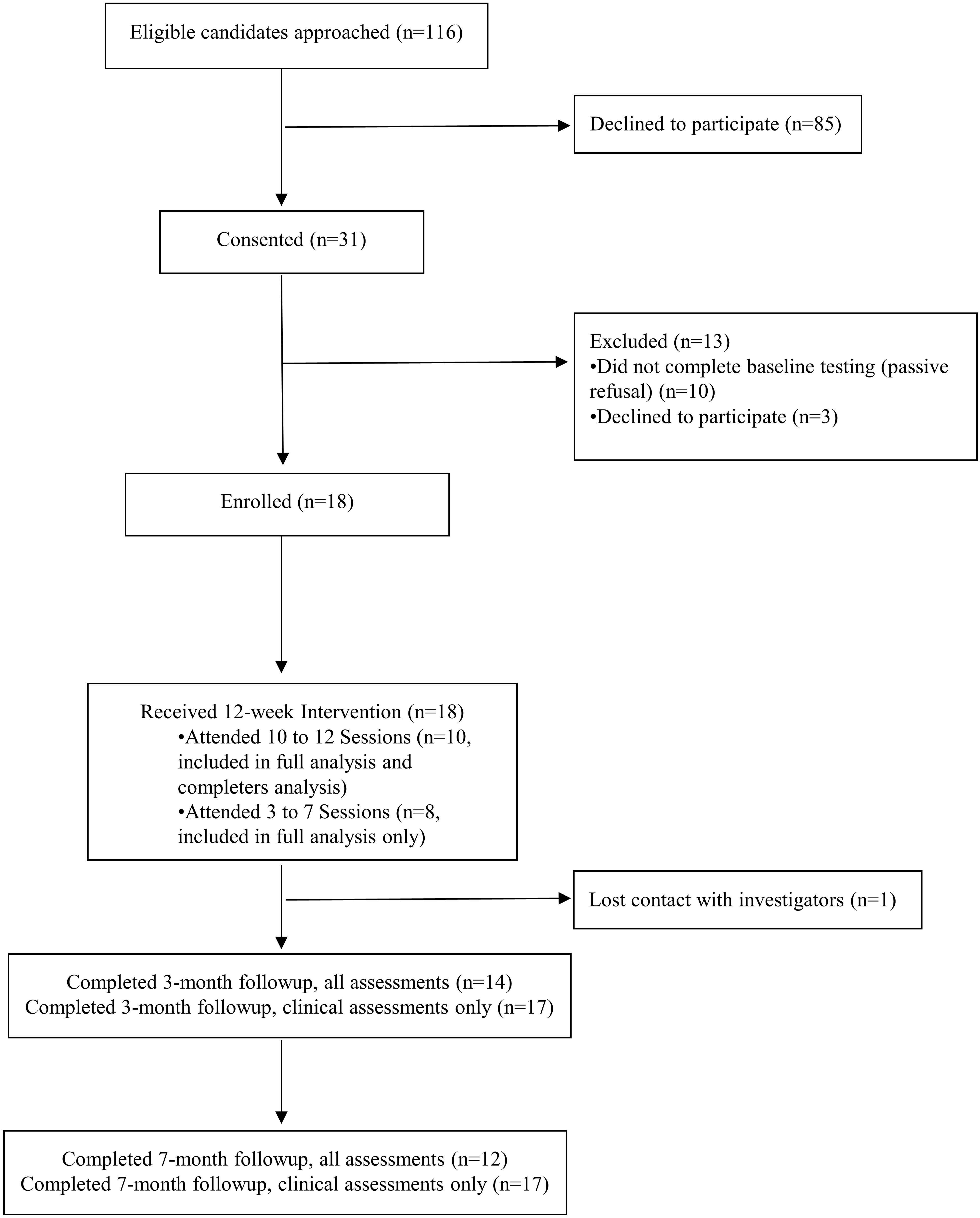
| | Baseline | 3 months | 7 months | *P* | Effect Size (*d*) | |
|---|---|---|---|---|---|---|
| Physical Activity & Nutrition | N=16 | N=15† | N=12 | | 3mo-Baseline | 7mo-Baseline |
| MVPA (min/day) | 21 (10, 36) | 19 (8, 30) | 25 (10, 39) | 0.92 | 0.00 | 0.03 |
| Screen Time (hr/day) | 3.5 (1.0, 5.6) | 3.8 (2.0, 6.6) | 2.3 (0.8, 4.4) | 0.50 | 0.14 | -0.12 |
| Fruit & Vegetable Servings per day* | 1.3 (0.4, 2.3) | 0.6 (0.0, 2.3) | 0.5 (0.0, 1.5) | 0.01 | -0.55 | -0.72 |
| Psychosocial | N=18 | N=17 | N=15 | | | |
| Peds Quality of Life, Diabetes Module (0-100)** | 63±14 | 60±16 | 69±17 | 0.01 | -0.17 | 0.37 |
| Hypoglycemia Fear Survey, Worry Subscale (0-4) | 0.8 (0.3, 1.7) | 0.8 (0.4, 1.4) | 0.8 (0.4, 1.3) | 0.36 | -0.01 | -0.25 |
| Self-Care Inventory (1-5)*** | 3.6 (3.2, 4.0) | 3.5 (3.2, 4.2) | 3.1 (3.0, 3.9) | 0.04 | -0.22 | -0.40 |
| Self-Perception Profile, Social Acceptance Subscale (1-4) | 3.1 (2.4, 3.6) | 3.2 (2.8, 3.4) | 3.2 (2.8, 3.7) | 0.18 | 0.21 | 0.33 |
| Clinical & Physical Fitness | N=18‡ | N=17§ | N=17¶ | | | |
| HbA1c (%) | 9.5±2.3 | 9.4±2.1 | 9.2±1.9 | 0.69 | -0.03 | -0.10 |
| HbA1c (mmol/mol) | 80±25 | 79±23 | 77±21 | 0.69 | -0.03 | -0.10 |
| Body mass index percentile | 91.7 (82.9, 95.0) | 93.0 (82.8, 96.1) | 92.3 (84.4, 96.1) | 0.96 | 0.05 | 0.06 |
| Waist Circumference (cm) | 76.0 (72.5, 79.8) | 76.5 (72.5, 79.5) | 77.8 (72.0, 83.4) | 0.14 | -0.02 | 0.21 |
| Body Fat (%) | 29.8±4.8 | 29.8±4.9 | 29.7±6.3 | 0.92 | 0.00 | -0.03 |
| Systolic Blood Pressure (mmHg) | 112±10 | 109±9 | 110±10 | 0.43 | -0.30 | -0.17 |
| Diastolic Blood Pressure (mmHg) | 75 (65, 78) | 69 (63, 78) | 69 (66, 73) | 0.51 | -0.20 | -0.18 |
| Total Cholesterol (mmol/L) | 4.05±0.72 | 4.23±0.74 | | 0.38 | 0.23 | |
| High Density Lipoprotein (mmol/L) | 1.36±0.19 | 1.34±0.28 | | 0.72 | -0.12 | |
| Low Density Lipoprotein (mmol/L) | 2.22±0.56 | 2.39±0.57 | | 0.36 | 0.31 | |
| Triglycerides (mmol/L) | 1.02±0.68 | 1.12±0.71 | | 0.65 | 0.16 | |
| C-Reactive Protein (mg/L) | 1.1 (0.3, 2.2) | 1.0 (0.4, 2.1) | | 0.16 | 0.33 | |
| MPACER Scores (last lap completed) | 26 (19, 45) | 26 (18, 50) | 25 (19, 49) | 0.60 | 0.16 | 0.17 |

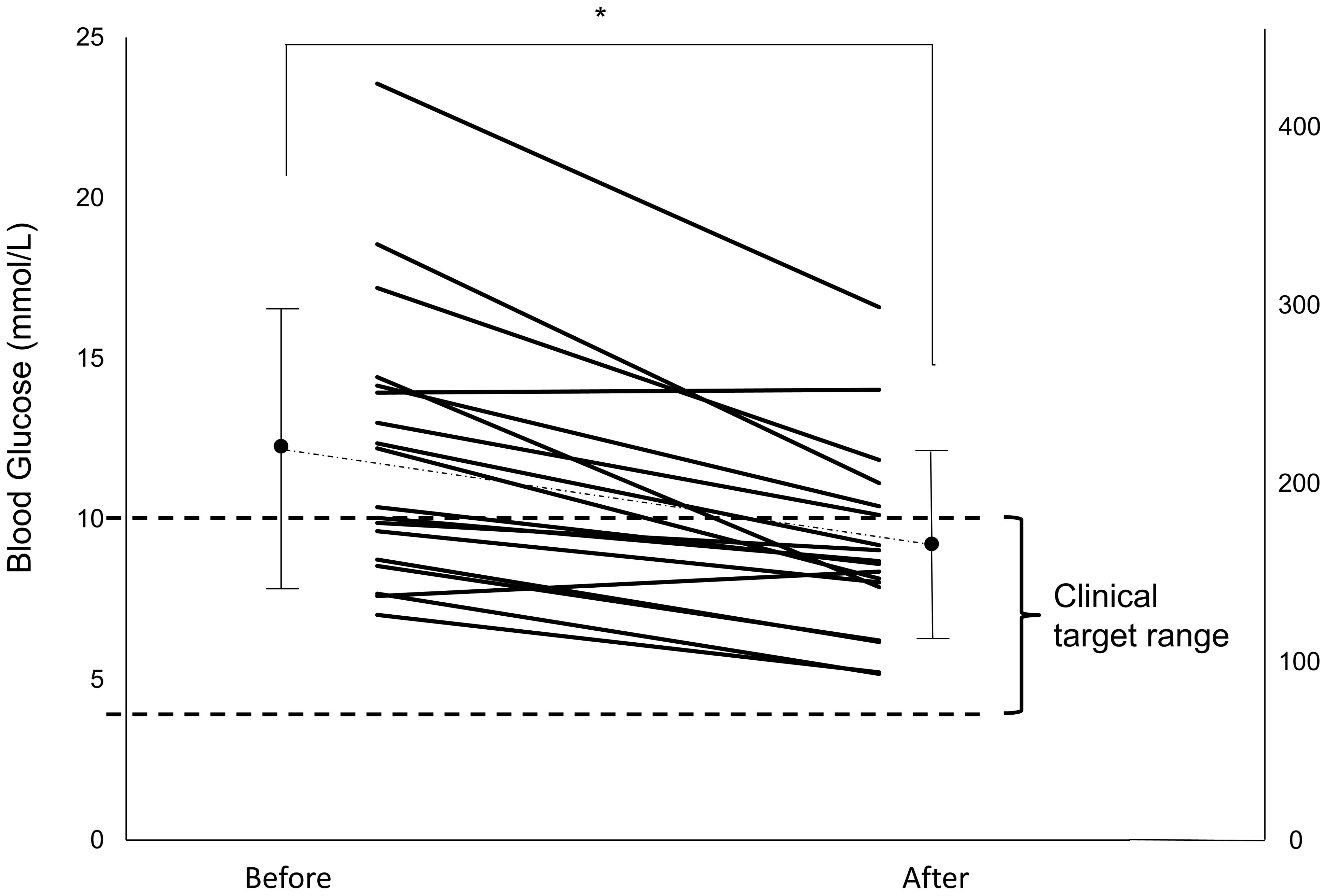
*p=0.01 3mo vs baseline, p=0.04 7mo vs baseline; **p=0.002, 7mo vs 3mo. ***p=0.03, 7mo vs baseline. †Fruits & Vegetables N=14; ‡Lipids N=17, C-reactive protein N=15; §MPACER N=14; ¶Waist circumference, body fat % N=15; MPACER N=12. Cases with missing baseline data excluded for that variable, cases with missing follow-up data replaced by forward imputation. MVPA-Moderate to Vigorous Physical Activity; MPACER-Modified progressive aerobic cardiovascular endurance run.

## Figure Legends

**Figure 1.** Flowchart for enrollment and follow-up of study participants.

**Figure 2.** Mean blood glucose of each participant before and after the physical activity portion of the intervention sessions. Circles represent sample mean, error bars sample standard deviation, dotted line change of sample mean value after versus before physical activity, and solid lines change of each individual participant after versus before physical activity. *$p<0.01$ after vs before physical activity ($d$ = -0.81). Clinical target range refers to American Diabetes Association guidelines (25).


Eligible candidates approached (n=116)
Declined to participate (n=85)
Consented (n=31)
Excluded (n=13)
•Did not complete baseline testing (passive refusal) (n=10)
•Declined to participate (n=3)
Enrolled (n=18)
Received 12-week Intervention (n=18)
•Attended 10 to 12 Sessions (n=10, included in full analysis and completers analysis)
•Attended 3 to 7 Sessions (n=8, included in full analysis only)
Lost contact with investigators (n=1)
Completed 3-month followup, all assessments (n=14)
Completed 3-month followup, clinical assessments only (n=17)
Completed 7-month followup, all assessments (n=12)
Completed 7-month followup, clinical assessments only (n=17)



*
25
20
15
10
5
0
Blood Glucose (mmol/L)
400
300
200
100
0
mg/dL
Clinical
target range
Before
After