



# Individual and family-based approaches to increase physical activity in adolescents with intellectual and developmental disabilities: Rationale and design for an 18 month randomized trial

L.T. Ptomey<sup>a,\*</sup>, R.A. Washburn<sup>a</sup>, J. Lee<sup>b</sup>, J.L. Greene<sup>c</sup>, A.N. Szabo-Reed<sup>a</sup>, J.R. Sherman<sup>a</sup>, J.C. Danon<sup>a</sup>, L.N. Osborne<sup>a</sup>, T.D. Little<sup>b</sup>, J.E. Donnelly<sup>a</sup>

<sup>a</sup> Department of Internal Medicine, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160, USA

<sup>b</sup> Department of Educational Psychology and Leadership, Texas Tech University, 2500 Broadway, Lubbock, TX 79409, USA

<sup>c</sup> Department of Health, Sport, and Exercise Sciences, University of Kansas, Lawrence, KS 66045, USA

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## ABSTRACT

Adolescents with intellectual and developmental disabilities (IDD) are less physically active and have lower cardiovascular fitness compared with their typically developing peers. This population faces additional barriers to participation in moderate-to-vigorous physical activity (MVPA) such as reliance on parents, lack of peer-support, and lack of inclusive physical activity opportunities. Previous interventions to increase MVPA in adolescents with IDD have met with limited success, at least in part due to requiring parents to transport their adolescent to an exercise facility. We recently developed a remote system to deliver MVPA to groups of adolescents with IDD in their homes via video conferencing on a tablet computer. This approach eliminates the need for transportation and provides social interaction and support from both a health coach and other participants. We will conduct a 18-mo. trial (6 mos. active, 6 mos. maintenance, 6 mos. no-contact follow-up) to compare changes in objectively assessed MVPA in 114 adolescents with IDD randomized to a single level intervention delivered only to the adolescent (AO) or a multi-level intervention delivered to both the adolescent and a parent (A + P). Our primary aim is to compare increases in MVPA (min/d) between the AO and A + P groups from 0 to 6 mos. Secondly we will compare changes in MVPA, sedentary time, cardiovascular fitness, muscular strength, motor ability, quality of life, and the percentage of adolescents achieving the US recommendation of 60 min. MVPA/d across 18 mos. We will also explore the influence of process variables/participant characteristics on changes in MVPA across 18 mos.

NCT registration: [NCT03684512](https://clinicaltrials.gov/ct2/show/study/NCT03684512)

## 1. Introduction

Approximately 1–3% of the US population is diagnosed with an intellectual or developmental disability (IDD) defined as a disability originating before the age of 10, characterized by significant limitations in both intellectual functioning (IQ < 75) and limitations in 2 or more adaptive behaviors [1]. Both typically developing adolescents and adolescents with IDD have low levels of moderate-to-vigorous physical activity (MVPA) [2,3] However, compared to their typically developing peers, adolescents with IDD have even lower daily MVPA [3]. Phillips

and Holland reported no adolescents with IDD achieved the recommended 60 min of daily MVPA [4]. In a previous trial by our group, MVPA, assessed by accelerometer of adolescents with IDD ( $n = 20$ ), was only 23 min/d [5]. Low MVPA is associated with reduced cardiovascular fitness [6,7], reduced muscular strength and endurance [8,9], and high prevalence of overweight and obesity in adolescents with IDD [10,11].

Several trials have evaluated the impact of exercise training on cardiovascular fitness and chronic disease risk factors in individuals with IDD [12–14]. However, few interventions have been designed

**Abbreviations:** MVPA, moderate to vigorous physical activity; IDD, intellectual and developmental disabilities; AO, adolescent only; A + P, adolescent and a parent  
\* Corresponding author at: University of Kansas Medical Center, Department of Internal Medicine, 3901 Rainbow Blvd, Mail Stop 1073, Kansas City, KS 66160, USA.

**E-mail addresses:** [lpomey@ku.edu](mailto:lpomey@ku.edu) (L.T. Ptomey), [rwashburn@ku.edu](mailto:rwashburn@ku.edu) (R.A. Washburn), [jaehoon.lee@ttu.edu](mailto:jaehoon.lee@ttu.edu) (J. Lee), [jlg@ku.edu](mailto:jlg@ku.edu) (J.L. Greene), [aszabo@kumc.edu](mailto:aszabo@kumc.edu) (A.N. Szabo-Reed), [joesherman@ku.edu](mailto:joesherman@ku.edu) (J.R. Sherman), [jdanon@ku.edu](mailto:jdanon@ku.edu) (J.C. Danon), [lnosborne@ku.edu](mailto:lnosborne@ku.edu) (L.N. Osborne), [todd.d.little@ttu.edu](mailto:todd.d.little@ttu.edu) (T.D. Little), [jdonnelly@ku.edu](mailto:jdonnelly@ku.edu) (J.E. Donnelly).

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specifically to evaluate strategies to improve PA in adolescents with IDD. A 2019 review identified only five PA trials in adolescents with IDD, most of which were unsuccessful [15]. Thus, there is a need to develop and evaluate effective intervention to increase PA in adolescents with IDD.

Interventions targeting interpersonal factors, e.g., parental or caregiver education/support, can shape the PA behavior of adolescents through direct modeling, providing support and positive reinforcement, enforcing household rules that encourage or discourage PA, and creating a home environment supportive of PA [16,17]. In typically developing children/adolescents, interventions to increase PA by targeting parenting practices have been minimally effective [18,19]. However, adolescents with IDD are more dependent on their parents than typically developing adolescents. Thus, interventions that include a parent component may be effective for increasing PA in this group. Several cross-sectional studies have shown an association between greater parental support and higher parent/caregiver proxy reported PA in adolescents with IDD [20–22]. Curtin et al. [23] randomized overweight adolescents with Down syndrome (DS) to a 6-mo. intervention designed to improve nutrition and MVPA with ( $n = 11$ ) or without parental training/support ( $n = 10$ ). On average MVPA (accelerometer) increased 18 min/d ( $p = .01$ ) with parental training/support and decreased 7 min/d ( $p = .30$ ) without parental training/support. However, Hinckson et al. [24] reported no change in PA assessed by parent self-report in a 10-wk. school-based, single-arm trial in 22 adolescents with IDD that included a family educational component.

The limited information available and the potential health benefits of increased MVPA highlight the need to evaluate the effectiveness of multi-component interventions targeting both intra (adolescent) and interpersonal levels (parents and peers) to promote increased MVPA in adolescents with IDD. This need led to the development of the current randomized trial designed to compare two remotely delivered intervention strategies to increase MVPA in adolescents with IDD; a single level intervention delivered to the adolescent only and a multi-level intervention delivered to both the adolescent and a parent.

## 2. Methods and materials

### 2.1. Overview of study design (Table 1)

One hundred fourteen adolescents with mild to moderate IDD and one of their parents will be randomized to an 18-mo. trial with 6 mos. active intervention period, a 6 mos. maintenance period, and a 6 mos. no-contact follow-up to compare changes in objectively assessed MVPA (ActiGraph LLC, Pensacola, FL) in adolescents with IDD randomized to a single level intervention delivered to the adolescent only (AO), or a multi-level intervention delivered to both the adolescent and a parent (A + P). Adolescents in both intervention groups will be asked to attend three 40-min., home-based, group MVPA sessions/wk. (5–7 adolescents, 0–6 mos.) and one 40-min. education/support session/wk. during mos. 7–12. Group sessions will be conducted by a trained health coach using video conferencing software (Zoom™ Video Conferencing Inc., San Jose, CA). Adolescents will be asked to complete a weekly activity homework assignment that in conjunction with the remote sessions will help them achieve a target of 300 min of MVPA/wk. Parents of adolescents in the AO group will receive a reminder phone call if the adolescent misses > 3 consecutive scheduled sessions. Parents of adolescents in the A + P group will be asked to participate in the group video MVPA sessions and homework activity, and to attend education/support sessions with their adolescent and health coach. These sessions will inform parents regarding the role of MVPA in health and function and provide strategies for increasing MVPA in both their adolescent and themselves. The primary aim is to compare changes in MVPA (min/d) between the AO and A + P groups across 6 mos. Our secondary aims are to compare changes between the AO and A + P groups on the following variables across 18 mos.:1) MVPA (min/d) and sedentary time

**Table 1**

Design overview for the active 18-month weight management intervention.

	Interventions Groups	
	Adolescent Only (AO)	Adolescent + Parent (A + P)
MVPA recommendation	60 min/d	60 min/d
MVPA group sessions via video conferencing	Yes	Yes
Session Participants	Adolescent Only	Adolescent + Parent
Session frequency		
–6 mos.	3 d/wk.	3 d/wk.
7–12 mos.	1 d/wk.	1 d/wk.
13–18 mos.	0 d/wk.	0 d/wk.
Session intensity	≥ 4 METs	≥ 4 METs
Session duration	40 min	40 min
Session content	Stretch/aerobic activity/RE	Stretch/aerobic activity/RE
Provide access to PA resources	Yes	Yes
MVPA Self-monitoring	Fitbit	Fitbit
Parent contacts		
Participants	NA	Parent + Adolescent
Purpose	NA	Education/support/feedback
Format	NA	FaceTime™
Parent Session Frequency		
–6 mos.	NA	1 d/mo.
7–12 mos.	NA	1 d/mo.
13–18 mos.	NA	0 d/mo.
Duration	NA	30 min
Parent Facebook group	NA	Yes

Note: MVPA = Moderate-to-Vigorous Physical Activity, RE = resistance exercise.

(adolescents and parents), 2) cardiovascular fitness, 3) muscular strength, 4) motor ability, 5) quality of life. We will also compare the percentage of adolescents achieving an average of 60 min/d of MVPA (US recommendation) across 18 mos. Lastly, we will examine the influence of the following process variables/participant characteristics to identify salient factors impacting change in MVPA across 18 mos.: attendance at group video (AO-adolescent; A + P-adolescent/parent) and education/support sessions (A + P only), self-monitoring of PA (AO-adolescent; A + P-adolescent/parent), parental use of Facebook page (A + P only), peer interactions/support during group PA sessions, adolescent self-efficacy, social support and barriers for PA, parental MVPA, parental beliefs and attitudes toward PA, parental time constraints, adolescent age, sex, and IDD diagnosis.

### 2.2. Methodological justification

**Theoretical Model.** The proposed intervention is based on Social Cognitive Theory [25]. Specifically, we will employ participant and parent goal setting (weekly MVPA goals), self-monitoring of MVPA (Fitbit), stimulus control (strategies to decrease cues for sedentary behavior, and increase cues for more desirable PA behaviors), prompts (iPad calendar reminders), scheduling time for MVPA, environmental cues, modeling (by parents and other adolescents), positive reinforcement (Fitbit feedback, positive reinforcement from group session leader, incentive system) social support (group session leader, parents, other adolescents), and other self-regulatory techniques in both intervention arms. Social support [26,27], parent support [21,22], self-efficacy for exercise [26], and motor fitness [20] have all been associated with higher levels of PA in individuals with IDD. Additionally, our intervention will address both the intrapersonal and interpersonal components of the Social Ecological model for behavioral change [28,29].

**Use of Technology Delivered Sessions.** Adolescents with IDD face several barriers which increase the complexity of developing interventions to increase PA for this group. The limited information on barriers to PA suggests adolescents with IDD perceive that physical activities are too difficult to learn, lack a partner for PA, have to rely on

a parent for transportation to facilities for PA, and are unaware of the potential health benefits of PA [30]. This suggests that alternative strategies for delivery of PA interventions, such as remote delivery, which eliminates the transportation barrier, should be implemented. Interventions using real-time video conferencing have been used to improve health and modify behaviors in typically developing children and adolescents who are overweight or obese, or have health conditions such as asthma or diabetes [31,32]. Interventions to increase MVPA, delivered via video conferencing to groups of adolescents with IDD in their homes, represent a potentially effective approach for increasing MVPA in this group. This approach requires no travel commitment for parents, since the need for transportation to a YMCA, community center, etc. is eliminated, and offers the potential for peer support and socialization, which may be important for initiation and maintenance of MVPA. Technology, including computers and tablets, has been used to teach academic subjects and improve social and daily life skills in individuals with IDD across the age spectrum [33,34]. Results from a single arm, short-term (12 wks.) pilot trial ( $n = 31$ ) conducted by our group showed the feasibility of delivering an intervention to increase MVPA in adolescents with IDD via video conferencing [35]. Real-time exercise sessions were delivered 3 times/wk. by a health coach, trained by a specialist in adapted physical education, to groups of 5–7 adolescents in their homes via video conferencing (Zoom™ software) on an iPad mini. Twenty-nine participants completed the trial (94%). Participants attended 77% of scheduled video sessions. Daily steps increased significantly from week 1 (6853 steps/d) to week 12 (8554 steps/d, 25%,  $p = .046$ ). Self-efficacy for exercise ( $p = .07$ ) and enjoyment for exercise ( $p = .046$ ) increased from baseline to 12 wks. This approach promoted interactions between both the health coach and participants (24/session), and between individual participants (12/session). This is in contrast to low levels of social interaction reported in groups of adolescents with IDD while engaging in leisure time activities [36]. Parents indicated that the video conferencing approach was attractive because it provided an opportunity for their adolescent to participate in PA, and for social interaction with their peers in a non-threatening home environment.

### 2.3. Participant eligibility

Primary care physician (PCP) clearance will be required for both adolescents and the participating parent. To enhance generalizability, adolescents with congenital heart disease, or other chronic diseases, will be allowed to participate with PCP clearance. Inclusion/Exclusion criteria are presented in Table 2.

Recruitment Procedures/Randomization. Organizations and community agencies serving individuals with IDD will be mailed/emailed an information brochure that describes the project. Additionally, we will use email list serves and media advertising (print, radio, internet) to target families living in the recruitment area. Potential participants

will be asked to contact a member of the study team to obtain details about the program and complete the initial eligibility screening. Home visits will be scheduled with parents/adolescents deemed to be initially eligible to describe the project, answer questions, verify eligibility, and obtain parental consent for participation by the adolescent, as well as a separate parental consent. Adolescents age 18 and over, who are their own legal guardian, will sign their own consent. Project staff will fax/email a form to the potential participant's PCP, which describes the eligibility criteria, study requirements, and request for clearance for participation. Parents of adolescents found to be ineligible will be provided with written materials describing available resources for assisting their adolescent with increasing PA. Cohorts of ~10–20 adolescent/parent dyads will be recruited and computer randomized. Adolescents will be stratified by sex and the presence or absence of DS, and sequentially randomized by the study statistician with equal allocation to the AO or A + P arms.

### 2.4. Intervention components

The intervention components for the AO and A + P arms are identical with the exception of the parental involvement component.

### 2.5. MVPA recommendations

Current US guidelines recommend a minimum of 60 min of MVPA each day for children/adolescents with or without disabilities [37]. However, as described the limited available data suggest that few adolescents with IDD currently meet this recommendation [4,38]. Therefore, the recommended daily MVPA, which will be identical for both groups, will progress from ~15 min/d during wk. 1, and gradually increase 10 min/d every 2 wks. During the active intervention to ~60 min/d at wk. 11, and remain at 60 min/d through mo. 18.

### 2.6. PA self-monitoring

Participants in both arms will be asked to wear a Fitbit Charge 3™ (35.5 mm × 28 mm) activity tracker on their non-dominant wrist over the duration of the 18-mo. trial. Real-time data from the Fitbit is automatically transferred, via the web, to cloud storage maintained by Small Steps Labs LLC (Fitabase, San Diego, CA). Immediate participant feedback via a graphic display of daily steps, minutes of sedentary time, time spent in light, moderate and vigorous PA, and heart rate relative to pre-set goals will be available on the iPad. This data, accessible to health coaches, will be used *only* to provide motivation and feedback during intervention sessions. Outcome data for MVPA and sedentary time will be assessed by accelerometer. Participants will be reminded to wear and charge the Fitbit during group exercise sessions, and will receive automatic reminder messages via the iPad using the iCal app.

**Table 2**

Participant eligibility criteria for an 18-month physical activity intervention in adolescents with intellectual and developmental disabilities.

Inclusion	
Residential Status	Living at home with a parent or guardian who is willing to participate in the intervention, with no plans to change this living situation and/or to leave the study area in the next 18 mos.
Age	10–21 years
Diagnosis	Mild to moderate IDD as verified by their PCP
Ambulatory	Must be able to participate in physical activity.
Health status	Must provide physician clearance to participate.
Communication	Sufficient functional ability to understand directions, communicate preferences, wants, and needs through spoken language
Internet	Internet access in the home
Exclusion	
Parent health concerns	If the parent who will participate in the intervention with the participant has a serious medical risk, such as cancer, recent cardiac event, i.e., heart attack, stroke, angioplasty, or cannot participate in physical activity.
Pregnancy	Pregnancy during the previous 6 mos., currently lactating or planned pregnancy in the following 24 mos. Participants who become pregnant will be removed from the study and referred to appropriate agencies for consultation.

## 2.7. Introduction to materials

After each participant's baseline testing appointment (described in detail below), a member of the study team will outline study requirements and distribute all equipment, iPads, Fitbits, resistance bands, etc. The health coach will describe and demonstrate the Zoom™ software and the Fitbit, and will allow time for practice and questions.

## 2.8. Zoom orientation

Each cohort of adolescents and parents in both intervention arms will be asked to attend an orientation session (~30 min) led by their health coach. These sessions will be conducted on a Zoom conference call one week before the start of the intervention. This meeting is designed to establish rapport between the health coach and participants, and between participants themselves, prior to initiating the group video conference exercise sessions. Additionally, basic stretching exercises, the use of the resistance bands, and simple dance movements will be demonstrated and practiced.

## 2.9. Remote group physical activity sessions

**Schedule.** Group exercise sessions will be scheduled between 4 and 8 p.m., on 3 days/wk. from baseline to 6 mos. and 1 day/wk. during mos. 7–12. Participants in each cohort will be offered the choice between 2 session times each day. This meeting frequency and time were selected based on the preferences of parents of adolescents with IDD that participated in our pilot trial [35]. Prompts reminding participants in both intervention groups of upcoming sessions will be sent via the iPad.

**Delivery.** Group exercise sessions will be delivered using an iPad tablet computer provided to all participants. The iPad will be pre-loaded with video-conferencing software (Zoom™) which allows participation by multiple users. Participants will be provided with an iPad/HDMI adaptor, which allows video conference sessions to be displayed on a larger TV screen, if desired. Tutorials describing trouble shooting for common technical problems, e.g., internet connectivity etc., will be loaded on the iPad. Participants with technical issues during the intervention can also contact research staff by phone or email. Access to non-study related materials, e.g., web browsing, app store etc., will be blocked on all iPads until completion of the maintenance intervention (12 mos.). The iPads for both groups will also be pre-loaded with the Fitbit, Zoom, Dropbox, and Rooster Money applications.

**Content.** Each session will include a warm-up (~5 min), moderate-to-vigorous intensity aerobic and resistance exercise (~30 min), and cool-down/stretching (~5 min). The resistance exercise component may be especially relevant for adolescents with DS who have reduced muscle strength compared with adolescents with other forms of IDD, as well as their typically developing peers [9]. All exercise sessions will be conducted by a health coach experienced in working with adolescents with IDD. The aerobic/resistance exercises, accompanied by music, will include walking/jogging in place, dancing, imitating animal movements, vertical/horizontal jumps, squats, and Thera-Band exercises for major muscle groups. Activities will be modified for participants having difficulty with specific movements. The intensity of the initial sessions will be light-to-moderate, with intensity increasing to moderate-to-vigorous at ~ 6 weeks. During each session, health coaches will encourage interactions between participants in support of their peer's efforts to increase MVPA, and provide participant feedback relative to their level of weekly MVPA as assessed by the Fitbit. As the intervention progresses, adolescent participants will be asked to volunteer to create and lead the group in a brief (3–5 min) exercise bout. Adolescents will also be encouraged to interact with each other by performing activities such as tossing an imaginary ball to other participants, or challenging other participants to complete a skill such as 10 hops on one leg etc. All group sessions will be video recorded, and will be available on a

Dropbox folder on the iPad for use by participants and/or parents across the 18-mo. trial.

## 2.10. Homework assignments

Adolescents who participate in all 3 weekly exercise sessions will have the potential to accumulate ~90 min of MVPA/wk. (~13 min/d). Thus, MVPA outside these sessions will be required to meet weekly recommendations. Health coaches will provide weekly challenges in the form of meeting a goal for increased steps, trying a new activity, or creating and performing their own exercise routine etc. Scheduled group sessions will be reduced to 1/wk. during mos. 7–12, thus the volume of MVPA to be completed outside the group session, i.e., “homework” will increase to meet the recommended daily MVPA. Participants will be provided Dropbox access to previous exercise sessions they can complete on their own to meet weekly MVPA goals, if desired. Information regarding increasing PA, available from the National Center on Health, Physical Activity and Disability (NCHPAD) and the Special Olympic athletes home training guide, and similar material appropriate for parents, will also be loaded on the iPads of both intervention arms.

## 2.11. Parental involvement

**AO Arm.** One parent/guardian will be asked to attend the orientation session, monitor MVPA across the intervention, and complete survey instruments at baseline, 6, 12, and 18 mos. (See assessments). By design, parental involvement in the AO group will be limited to reminder contacts (phone/text/email) from the health coach if their adolescent misses 2 consecutive exercise sessions. Contact attempts will be limited to 3 for each occurrence.

**A ± P Arm.** One parent/guardian will be asked to attend the orientation session, monitor MVPA across the intervention, and complete survey instruments at baseline, 6, 12, and 18 mos. In addition that parent will be asked to participate in the group video exercise sessions, and attend 30-min. education/support sessions with their adolescent (1 session/mo., 0–12 mos.) delivered remotely on the iPad using FaceTime™. These sessions, led by the health coach, will be designed to educate and support parents in assisting their adolescent with meeting their 300 min/wk. goal for MVPA, and to assist parents with meeting their own weekly MVPA goal (150 min/wk.) [37]. Each session will include a review of PA self-monitoring data, goal setting, strategies to increase and support MVPA, and discussion of a topic relevant to MVPA. Topics will include the importance of MVPA for health and function, how to include MVPA in the daily schedule, how to reduce barriers to PA, appropriate types of activity, creating a safe environment for PA, alternative activities for inclement weather, importance of hydration, etc. Session outlines and materials will be preloaded on the iPad where they can be accessed by adolescents/parents at any time. We will also create a private Facebook page for parents of adolescents in the A + P arm. Health coaches will post weekly helpful tips for adolescents/parents relative to increasing their MVPA, and provide information on community events and resources relative to PA (e.g., walk/running events, recreation center activities, etc.). Parents will also be encouraged to exchange information regarding opportunities for PA in their area, form support or activity groups, and post questions for the health coach to be answered during education/support sessions, etc.

## 2.12. Health coach training

We currently have 3 health coaches with experience in delivering group exercise using video conferencing to groups of adolescents with IDD. If needed, new health coaches will be trained, and will shadow an experienced health coach for a minimum of 3 mos. Prior to delivering the intervention on their own. We will conduct weekly meetings with all health coaches to discuss issues relative to intervention delivery. The

same health coach will deliver both the AO and A + P interventions in each cohort to reduce the potential for health coach effects.

### 2.13. Participant incentives

Positive behavioral support programs have been successful in promoting behavioral change in individuals with IDD. Reinforcement systems are common practice in working with adolescents with IDD and widely used by schools, community organizations, and parents in the home setting. These strategies provide modest incentives to motivate participants to meet their goals. For this study participants will be able to earn stars which can later be exchanged for money. Participants will be able to earn up to 2 stars each week, one for completing self-monitoring of PA on 5 of 7 days of that week, and one for attending 2 of the 3 scheduled exercise sessions during mos. 0–6 or the one session scheduled during mos. 7–12. The allowance iPad app, Rooster Money (Rooster Money LLC, London, England), will be used to distribute stars to participants. Participants will get a notification on their iPad every time they receive a star as well as a note for what goal they achieved to get the star, and how many stars they currently have. Participants will receive \$10 each time they obtain 10 stars. Additionally, adolescents and parents will both receive \$50 for completion of each of the 4 outcome assessments. As an additional incentive, participants will be allowed to keep the iPad and the Fitbit on completion of the active intervention (12 mos.).

## 3. Outcome assessments

With the exception of our primary outcome, MVPA, all outcomes will be assessed at either our Lawrence, or Kansas City, KS laboratories, based on participant preference at 0, 6, 12 and 18 mos. These assessments will be completed by trained staff blinded to intervention conditions. Staff will receive refresher training and complete reliability assessments for all physical measures 2–3 times/yr.

### 3.1. MVPA

MVPA and sedentary time (secondary outcome) in both adolescents and parents will be assessed at baseline (mo. 0), 3, 6, 9, 12, 15, and 18 mos. using an ActiGraph model wGT3x-BT tri-axial accelerometer. The ActiGraph provides valid and reliable assessments of PA in typically developing adolescents [39,40] and in adolescents with IDD [41,42]. Participants will be asked to wear the ActiGraph on a belt over the non-dominant hip at the anterior axillary line during waking hours for 7 consecutive days, with the exception of bathing, swimming, and contact sports. Research staff will distribute and demonstrate proper placement of the ActiGraphs at laboratory visits scheduled at baseline 6, 12, and 18 mos. ActiGraphs will be distributed by mail for the 3, 9, and 15 mo. assessments. Daily reminders to comply with the ActiGraph protocol will be sent to participants' iPads each morning during the 7-day monitoring period. ActiGraphs will be initialized and downloaded using ActiLife Software version 6.13.3 or higher (ActiGraph Corp, Pensacola, FL) and set to collect in the raw data mode from all 3 axes at 60 Hz. For the participants younger than 18 years of age, we will use the age-specific cut-points for children/adolescents proposed by Freedson et al. [39,43]. Data will be aggregated over 60-sec epochs to mirror the collection interval on which the Freedson age-specific cut-points were developed [39,43]. For parents and adolescents over 18 years old, accelerometer data will be processed using the protocol for adults used in the 2003–2004 and 2005–2006 cycles of NHANES [2,44].

### 3.2. Cardiovascular fitness

Cardiovascular fitness will be assessed using a modified Balke treadmill test [45]. The treadmill will initially be set at 2.6 m.p.h., 0% grade. The speed will remain constant and grade will increase 1% each

min until the participant reaches 75% age predicted maximal heart rate ( $HR_{max}$ ).  $HR_{max}$  for participants without DS will be predicted using the equation for typically developing children and adolescents ( $208 - 0.7 * (\text{age in years})$ ) [46].  $HR_{max}$  for participants with DS will be predicted as  $210 - 0.56 * (\text{age in years}) - 15.5 * (\text{DS})$ , where  $DS = 2$ , as suggested by Fernhall et al. [47] to account for the lower  $HR_{max}$  associated with DS [6,48]. Submaximal treadmill protocols have been previously validated in individuals with IDD [49,50].

### 3.3. Muscular strength

Lower body muscle strength will be assessed using a standard 5-repetition maximum protocol [51] on a Cybex plate-loaded leg press calculated with the Brzycki, et al. 1-repetition maximum prediction equation [52]. Participants will begin with a brief warm-up (~5 min) on the treadmill followed by instruction on proper leg press form. After one light warm-up set (~10 repetitions) to ensure proper form, weight will be selected with the goal of achieving 5-repetition maximum. Weight will continue to be increased until the goal is reached, with 60 s. rest between each attempt. Predicted 1-repetition maximum assessments have been used successfully in adolescents with IDD [53]. We will use grip strength as an indicator of upper body strength. Grip strength will be measured using a hand dynamometer (Model: Jamar Plus Electronic, Patterson Medical, Warrenville, IL). Participants will be asked to stand straight with their elbows flexed at 90° and instructed to clench the handle as strong as possible. We will collect 3 measures from both their dominant and non-dominant hand, and scores from each hand will be averaged. Grip strength has been successfully used in individuals with IDD [54,55].

## 4. Motor ability

Motor ability will be assessed by the Gross Motor Quotient and Percentile obtained from Test of Gross Motor Development-second edition (TGM-2) [56]. The TGM-2 requires ~20 min to administer and has been used in the NHANES National Youth Fitness Survey [57], and in individuals with IDD [58,59].

### 4.1. Quality of life

Quality of life will be assessed with the Personal Well-Being Index-Intellectual Disability [60,61]. Cronbach alpha of 0.76, and 1- to 2-wk. test-retest reliability of 0.58 have been reported in individuals with IDD [60].

### 4.2. Self-Efficacy and Social Support

Self-efficacy and social support will be assessed using the Self-Efficacy for Activity for Persons with Intellectual Disabilities Scale, and the Social Support for Activity for Persons with Intellectual Disabilities Family Scale [62]. Chronbach's alpha in individuals with IDD was 0.73 for both scales. Barriers for PA will be assessed using the 12-item Barriers to and Support for PA questionnaire [63].

### 4.3. Parent's beliefs/attitudes toward PA

Parent's beliefs/attitudes toward PA will be assessed with an adapted version of the Healthy Buddies Parent Nutrition and Physical Activity Survey, which has been previously used with parents of adolescents with IDD [64].

### 4.4. Parent time constraints

Parent time constraints will be assessed with the Leisure Time Satisfaction Scale [65]. This scale was developed to assess the impact of caregiving on caregivers' leisure time satisfaction, which will be used as

a proxy for parental time constraints.

#### 4.5. Descriptive outcomes

To characterize our study sample, we will measure weight, height, and waist circumference in adolescents and parents at baseline, 6, 12, and 18 mos. Weight will be measured in light clothing on a calibrated scale (Model #PS6600, Belfour, Saukville, WI) to the nearest 0.1 kg. Standing height will be measured with a portable stadiometer (Model: #IP0955, Invicta Plastics Limited, Leicester, UK). BMI will be calculated as weight (kg)/height (m<sup>2</sup>). BMI percentile for adolescents will be obtained using the CDC calculator (<http://apps.nccd.cdc.gov>). Waist circumference will be assessed using the procedures described by Lohman et al. [66].

#### 4.6. Process variables

**Intervention fidelity.** Study staff will review recordings from all scheduled exercise sessions and parent/participant meetings (A + P group). The content delivered will be compared with a checklist of scheduled activities/topics. Feedback will be provided to all health coaches, and those covering < 80% of scheduled activities/topics will receive additional training and will be dismissed if the problem recurs.

**Session attendance** for both group exercise and adolescent/parent education/support sessions will be obtained from records maintained by the health coach, and expressed as the percent of possible sessions from 0 to 6 mos. and 7–12 mos.

**Self-monitoring of PA** will be assessed as the percentage (total days worn/ total days enrolled in the intervention) of days with Fitbit data over a minimum of 8 h. between 6 am and midnight (0–6, 7–12, 13–18 mos.).

**Parental use of the Facebook page** (A + P group) will be tracked as the frequency of posting, i.e., posts/d (initial and replies) averaged over 3 time periods: (0–6, 7–12, 13–18 mos.).

**Peer interactions/support.** Staff will review video recordings of a random sample (33%) of group exercise sessions to identify and classify both peer-to-peer and health coach to adolescent interactions. Interactions will be quantified and coded as verbal/non-verbal (waving, pointing, shaking head in agreement/disagreement), and as positive, neutral or negative, and relative to support, using a checklist.

#### 4.7. Exit interview

We will conduct structured interviews by phone with a 20% random sample of participants and parents from both intervention arms to gather information that might be useful for improving the intervention and/or implementing the intervention in settings serving adolescents with IDD. Topics will include preference for the AO or A + P interventions, reasons for missing scheduled sessions for both the parent and participant, intervention length, difficulties with compliance, suggestions for improvements and overall satisfaction with the intervention, parent's enjoyment of the exercise and educational sessions, health coaches, PA recommendations etc.

#### 4.8. Analysis plan and statistical power

**Power.** This trial is powered to detect a between arm difference (AO vs. A + P) in the change of MVPA (0–6 mos.) of 10 min/d. This represents an additional 70 min of MVPA/wk. An increase in MVPA of this magnitude is associated with improved adiposity and cardiovascular fitness in typically developing adolescents [67,68], and potentially in adolescents with IDD, a group with low baseline levels of MVPA [69,70]. Statistical power to detect a significant effect on MVPA across 6 mos., the primary aim in the proposed 2-arm randomized design, depends on the following parameters: the number of participants in each arm ( $J$ ), the number of measurements ( $n = 21$ ; 7 days at 0, 3,

and 6 mos.), correlations among repeated measures ( $r$ ), and effect size ( $f$ ). Assuming a conservatively large standard deviation for change in MVPA in both arms (35 min/d), corresponds to a small to moderate effect size ( $f = 0.14$ ). The correlation between repeated measures of MVPA (3 mo. interval) in our pilot trial was  $r = 0.22$ . To be conservative, we assumed a higher correlation ( $r = 0.25$ ) for this sample size calculation. Based on these assumptions, power analysis using G\*Power 3.1.9.2 shows a sample of 114 adolescents ( $J = 57$ /arm) would provide 81% power to test overall between arm differences across time, i.e., group effect. This sample size would also provide  $\geq 80\%$  power to detect a group difference in change, i.e., time-by-group interaction, as small as  $f = 0.09$ . Missing data will be fully recovered via multiple imputation as discussed subsequently, which will remove or minimize (if present) confounding effects of missingness on our statistical power. The secondary aims were not powered to detect between group differences.

**Baseline equivalence.** We will compare baseline characteristics, e.g., age, sex, race/ethnicity, BMI, IDD diagnosis, etc., between the AO and A + P arms using independent-samples  $t$ -test for continuous variables and chi-square/Fisher test for categorical variables, to assess the degree to which randomization resulted in equivalent groups. Variables that demonstrate a significant nonequivalence will be controlled for in our analytic models to improve the accuracy in estimates of the intervention effect. Prior to modeling, missing data for each outcome will be imputed as described subsequently.

**Primary aim analysis.** Our primary aim, to compare changes in MVPA (min/d) between the AO and A + P arms from 0 to 6 mos., will be evaluated using general mixed modeling for repeated measures. Specifically, the model will examine linear/nonlinear change over time (21 measurements = 7 days at each of 0, 3, and 6 mos.); i.e., time effect, overall group difference across time, i.e., group effect, and group difference in change, i.e., time-by-group interaction, controlling for day of the week (weekday/weekend) and baseline characteristics imbalanced between the groups. For example, a significant interaction will indicate that adolescents in the A + P arm achieve more minutes of MVPA compared to adolescent in the AO arm, and this difference becomes greater across time. A proper error covariance structure will be determined based on relative model fit, e.g., Akaike information criteria, adjusted Bayesian information criteria.

**Secondary Aim analysis.** Our secondary aim, to compare changes between the AO and A + P arms on the following variables across 18 mos.: 1) MVPA (min/d) and sedentary time (adolescents and parents), 2) cardiovascular fitness, 3) muscular strength, 4) motor ability, and 5) quality of life, will be evaluated using a similar general mixed modeling approach. The models will examine linear/nonlinear change over time (7 days at each of 0, 3, 6, 9, 12, 15, and 18 mos. for MVPA and sedentary time; 0, 6, 12, and 18 mos. for all other outcomes), overall group difference across time, and group difference in change. We will also longitudinally compare the percentage of adolescents achieving the 60 min/d MVPA (US recommendation) using generalized mixed modeling for repeated binary measures (yes/no in each observed day). In a secondary analysis, we will fit a general mixed model that includes cardiovascular fitness, muscular strength, motor ability, and quality of life as time-varying covariates, and assess their association with MVPA aggregated across months controlling for group.

**Exploratory aims.** If there are no between arm differences in the longitudinal change in MVPA across 18 mos., general mixed models will be fitted for the two arms combined to examine the association for the process variables/participant characteristics with MVPA. These variables include: attendance at group video (AO-adolescent; A + P-adolescent/parent) and education/support sessions (A + P only), self-monitoring of PA (AO-adolescent; A + P-adolescent/parent), parental use of Facebook page (A + P only), peer interactions/support during group PA sessions, adolescent self-efficacy, social support and barriers for PA, parental MVPA, beliefs and attitudes toward PA and parental time constraints, age, sex, and IDD diagnosis. However, if there is a

significant group difference in MVPA, we will determine whether the previously listed process variables/participant characteristics explain/attenuate the intervention effect, i.e., moderation, by testing a 2-way interaction with the group effect and/or a 3-way interaction with the group-by-time interaction term. Some covariates will be measured only at baseline (age, sex, IDD diagnosis), some will be summarized across the trial (attendance at group video and education/support sessions, self-monitoring of PA, parental use of Facebook page, peer interactions/support during group PA sessions), while others will be assessed at specific time points (BMI, adolescent self-efficacy, social support and barriers for PA, parental MVPA, beliefs and attitudes toward PA and parental time constraints). Thus, we will carefully design our models to assure the appropriateness of the analysis. All analyses will be conducted using R and SAS 9.4 or higher.

**Missing data.** Missing due to either attrition, e.g., participant dropout or nonresponse, will be handled by multiple imputation, in which an expectation-maximization (EM) algorithm supplies prior estimates of missing values for a subsequent Monte Carlo Markov Chain (MCMC) procedure [71]. A sufficient number of imputed datasets will be created to ensure accurate recovery of missing data; and analysis results from each imputed dataset will be combined to make valid statistical inferences. All measured variables will be incorporated into the imputation process as auxiliary variables, thereby satisfying the missing at random (MAR) assumption [72].

## 5. Discussion

Adolescents with IDD represent a sizeable and underserved segment of the population with low levels of MVPA. Low MVPA is associated with reduced cardiovascular fitness [6,7], reduced muscular strength and endurance [8,9], and high prevalence of overweight and obesity in adolescents with IDD [10,11]. Low cardiovascular fitness in adolescence is associated with increased risk of chronic disease and premature mortality in adulthood [73,74], while obesity in adolescence increases the probability of becoming an obese adult [75]. Increased rates of chronic disease in individuals with IDD reduce quality of life, and increase the burden on families, care providers, and disability services [76]. Similar to typically developing adolescents, increased MVPA in adolescents with IDD increases cardiovascular fitness [20] and muscular strength and endurance [77], and reduces chronic disease risk [13]. Thus, an accessible, effective intervention to increase PA in adolescents with IDD has the potential for significant public health impact.

Adolescents with IDD face several barriers which increase the complexity of developing interventions to increase PA for this group. Barriers, which make the initiation and maintenance of PA difficult for typically developing adolescents, are amplified in adolescents with IDD as a result of cognitive impairment, which may result in difficulty with planning, delaying rewards, taking initiative, and understanding abstract information [78]. Additionally, adolescents with IDD face several unique challenges to engaging in MVPA. These include not enjoying being active on their own, being self-conscious about participating in PA with their typically developing peers, and dependence on parents for transportation to a gym or community center to participate in PA. Remote group delivery, as we have proposed, eliminates these barriers and allows interaction between participants, which has the potential to increase accountability, social support, and rapport in a group with a high potential for social isolation. Results from our pilot trial in adolescents with IDD, using the group exercise approach, showed a 25% increase in daily PA over 12 wks. In contrast, previous trials in adolescents and adults with IDD by our group [5] and others [79], which included recommendations for self-directed PA with minimal support, have shown small, clinically irrelevant increases in MVPA. Thus, we chose to use remote group MVPA in both intervention groups, and evaluate the role of parental support on changes in MVPA.

We designed this as an 18-mo. trial, including a 6-mo. active intervention, a 6-mo. maintenance intervention, and a 6-mo. no contact

follow-up to allow comparison of the impact of our interventions on adoption and maintenance of MVPA in adolescents with IDD, as well as the sustainability of any increases in MVPA following completion of the interventions. The assessment of MVPA following completion of active intervention (6 mos.) will allow a between group comparison of short-term sustainability of any intervention effects. Improvements in motor ability, cardiovascular fitness, muscular strength, self-efficacy and social support in adolescents in both intervention arms, and increased parental MVPA, parental education on strategies to support MVPA, continued access to videos from group exercise sessions, and parental support from social media (Facebook™) in the A + P group may contribute to continued short and long-term sustainability of increased MVPA.

Design and methodologic strengths of this trial include: 1) Randomized design with equal allocation to groups with concealed allocation of group assignments. 2) Adequate statistical power to address the primary aim. 3) Strategies to ensure the recruitment of sufficient participants to achieve our desired sample size. 4) Retention/incentive strategies to reduce loss to follow-up. 5) Secondary and exploratory aims to maximize the use of data; e.g. analysis to examine the impact of process variables/participant characteristics on change in MVPA. 6) The use of a theory-based intervention delivered by trained health coaches. 7) Delivery of both intervention arms by the same health coach to cohorts of participants to minimize health educator effects. 8) Review of recordings of all scheduled exercise and parent/participant meetings to ensure intervention fidelity. 9) Assessments completed by trained staff blind to intervention arm. 10) Evaluation of staff inter-rater reliability for all physical assessments (2–3 times/yr.). 11) Exit interviews with participants to obtain information for improving and/or implementing the intervention.

Adolescents with IDD represent a sizeable and underserved segment of the population with low levels of MVPA, which results in significant negative health, social, and financial consequences. Options for increased MVPA in this group are limited. Information on the impact of parental support and education on adoption and maintenance of MVPA in adolescents with IDD is limited to short-term trials, in small samples, that have produced conflicting and unimpressive results. This trial will determine the effectiveness of a single level intervention delivered to the adolescent only and a multi-level intervention delivered to both the adolescent and a parent to increase MVPA in adolescents with IDD. Both intervention arms have the potential to increase MVPA using a scalable and sustainable format, which could be used by community agencies or others to efficiently deliver PA to adolescents with IDD in their homes.

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