Individual and Family-Based Approaches to Increase Physical Activity in Adolescents with Intellectual and Developmental Disabilities

NCT Title: Promotion of Physical Activity in Adolescents with Intellectual and Developmental Disabilities

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Protocol and Analysis Plan

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Specific Aims

Adolescents with intellectual and developmental disabilities (IDD) are less physically active and have lower cardiovascular fitness compared with their typically developing peers. Similar to their typically developing peers, low moderate-to-vigorous physical activity (MVPA) and low cardiovascular fitness are associated with increased chronic disease risk and decreased quality of life in this group. Adolescents with IDD also face additional barriers to participation in MVPA including dependence on parents for transportation to exercise facilities, lack of appropriate exercise facilities, lack of professionals with expertise regarding their specific needs, and lack of peer support. The limited number of trials that have evaluated strategies to increase MVPA in adolescents with IDD were generally short-term (8-24 wks.), non-randomized, and were conducted in small samples (n=≤ 30), at a gym, community center or other type of facility, and were generally unsuccessful in increasing MVPA. Data from our group, and others, suggest that the time and expense required for parents to transport their adolescents to a facility represents a major barrier to participation in PA. This suggests that alternative strategies for delivery of PA interventions for adolescents with IDD, which eliminate the transportation barrier, need to be developed and evaluated. Results from our single arm, short-term (12 wks.) pilot trial (n= 29) suggest the feasibility of delivering an intervention to increase MVPA in adolescents with IDD via video conferencing. In our pilot, health coaches delivered three 30-min. real-time MVPA sessions/wk. via video conferencing on an iPad (Zoom software), to groups of 5-6 adolescents with IDD in their homes. Participants were asked to complete additional MVPA between scheduled group sessions. Participants attended 77% of possible sessions, with an average heart rate of ~124 beats/min. This approach promoted interactions between both the group leader and participants (24/session), and between individual participants (12/session), and a 25% increase from baseline in objectively assessed daily PA (Garmin Vivofit). However, the effectiveness of the group video approach, or the effect of including parental education/support to increase and maintain MVPA over a longer time-frame (12-18 mos.) in adolescents with IDD is unknown. Parental involvement may be important in increasing MVPA in adolescents with IDD, who by the nature of their condition are more dependent on parents that typically developing adolescents. Thus, as requested by PAR-14-315, we propose to compare the effect of two 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. We propose an 18 mo. trial (6 mos. active, 6 mos. maintenance, 6 mos. no-contact follow-up) using intent-to-treat principles to compare changes in objectively assessed MVPA in 114 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 arms will be asked to attend three 40-min., home-based, group MVPA sessions/wk. (0-6 mos.) and one 40-min. sessions/wk. during mos. 7-12. A trained health coach will conduct group exercise sessions using video conferencing software (Zoom™ Video Conferencing Inc., San Jose, CA). Adolescents will be asked to complete a weekly activity homework assignment to reach 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 more than two consecutive scheduled MVPA sessions. Parents of adolescents in the A+P group will be asked to participate in the group video MVPA sessions, attend educational/support sessions with their adolescent and the health coach regarding the role of MVPA in health and function and support their adolescent in completing their activity homework assignments. Education/support sessions will include strategies for increasing MVPA in both the adolescent and parent (0-6 mos. 2 session/mo.; 7-12 mos. 1 session/mo.).

Primary aim: *To compare changes in MVPA (min./d) between the AO and A+P groups across 6 mos.* We expect a significantly greater increases in MVPA in adolescents in the A+P vs. the AO group.

Secondary aims: *To compare changes between the AO and A+P groups on the following variables across 18 mos.:*1) MVPA (min/d) and sedentary time (adolescents and parents). Adolescents only: 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. We expect more favorable changes for all secondary outcomes in adolescents in the A+P vs. the AO group.

Exploratory aims. *To 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, and parental time constraints, adolescent age, sex and IDD diagnosis.

Rationale

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 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=0.01) with parental training/support and decreased 7 min./d (p=0.30) 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.

Research Plan and Design

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 more than 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.

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		
0-6 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™*
Session Frequency		
0-6 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

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.

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.

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. Remote video chat sessions (Zoom) will be scheduled with interested participants and their parent to describe the project in detail, answer questions, verify eligibility, and to obtain parent consent and adolescent assent. Study staff will set up a virtual Zoom meeting that allows for remote video chat. Prior to the consent meeting families will be emailed a link for a KUMC REDCap survey they will contain the consent and assent documents. Additionally, Study staff will "share screen" the consent document and walk through each section, noting questions that arise, and answer these questions fully. Participants and adolescents will sign the consent/assent documents on the REDCap survey. Study staff will then print and provide the participant with a full-signed consent form for their records at the baseline testing meeting.

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.

Intervention Components

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

MVPA recommendations

Current US guidelines recommend a minimum of 60 min. of MVPA each day for children/adolescents with or without disabilities [25]. However, as described the limited available data suggest that few adolescents with IDD currently meet this recommendation [4, 26]. 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.

PA Self-Monitoring.

Participants in both arms will be asked to wear a Fitbit Charge 3™ (35.5 mm x 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.

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.

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.

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[27]. 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.

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.

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 additional 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.) [25]. 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.

Participant Incentives

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 session 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.).

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.

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 [28, 29] and in adolescents with IDD [30, 31]. 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. [28, 32]. Data will be

aggregated over 60-sec epochs to mirror the collection interval on which the Freedson age-specific cut-points were developed [28, 32]. 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, 33].

Cardiovascular Fitness

Cardiovascular fitness will be assessed using a modified Balke treadmill test [34]. 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*(age in years)) [35]. HR_{max} for participants with DS will be predicted as 210–0.56*(age in years)–15.5*(DS), where DS=2, as suggested by Fernhall et al. [36] to account for the lower HR_{max} associated with DS [6, 37]. Submaximal treadmill protocols have been previously validated in individuals with IDD [38, 39].

Muscular Strength

Lower body muscle strength will be assessed using a standard 5-repetition maximum protocol [40] on a Cybex plate-loaded leg press calculated with the Brzycki, et al. 1-repetition maximum prediction equation [41]. 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-repetiton maximum. Weight will continue to be increased until the goal is reached, with 60 sec. rest between each attempt. Predicted 1-repetition maximum assessments have been used successfully in adolescents with IDD [42]. 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 [43, 44].

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) [45]. The TGM-2 requires ~20 min. to administer and has been used in the NHANES National Youth Fitness Survey [46], and in individuals with IDD [47, 48]. During the COVID 19 lockdown motor ability will be assessed remotely.

Quality of life

Quality of life will be assessed with the Personal Well-Being Index-Intellectual Disability [49, 50]. Cronbach alpha of 0.76, and 1- to 2-wk. test-retest reliability of 0.58 have been reported in individuals with IDD [49].

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 [51]. 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 [52].

Parent's Beliefs/Attitudes Towards 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 [53].

Parent Time Constraints

Parent time constraints will be assessed with the Leisure Time Satisfaction Scale [54] and parent stress scales.

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^2). 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.[55]. During the COVID-19 lockdown height, weight, and waist circumference will not be collected.

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 0-6 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 hrs. 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.

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.

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 [56, 57], and potentially in adolescents with IDD, a group with low baseline levels of MVPA [58, 59]. 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 ≥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 [60]. 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 [61].

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