iPLAY for Inclusion: Intervention RCT Protocol Registration

Table of Contents

Methods

Trial design

This study is a cluster-randomised controlled trial. Schools will be recruited in waves. When two matching schools are recruited (criteria below), we will schedule baseline data collection at both schools within three weeks of each other. We will then randomise these schools using the method described below (1:1 allocation, intervention:wait-list control). Post-test data collection will occur approximately 1-year later (± 4 school weeks). After post-test data collection, the control schools will receive the intervention.

Participants

Settings and locations where the data were collected

Government primary schools will be invited to participate on the basis of the following criteria:

- School is within 3 hours of our university
- School has not previously completed our iPLAY
- School has 10 or more children with intellectual disabilities in Years 2–5

To publicise the study, staff from both our university and the Department of Education will send emails to principals and head teachers.

Participants

All teachers in participating schools will be eligible to participate in professional learning, with student-level data only collected from children with intellectual disabilities in Years 2–5. Children with intellectual disabilities will be excluded under two circumstances. Children will be excluded if they have a physical disability that precludes them from running. Children with mild physical disabilities will still be eligible, because these disabilities are often comorbid with intellectual disabilities. For example, children in wheelchairs would be excluded, but children with mild cerebral palsy would be included. Similarly, children will still be eligible if they have mild, comorbid developmental disorders (e.g., level 1 Autism Spectrum Disorder, mild Childhood-Onset Fluency Disorder); however, children will be excluded if their developmental disorder precludes them from responding to verbal questions (e.g., level 2 and 3 Autism Spectrum Disorder would be excluded based on this criteria).

Interventions

This intervention aimed to build upon two studies conducted with students in mainstream classes (Cohen et al., 2015; Lonsdale et al., 2016). These previous implementations included six components to promote physical activity participation and fundamental movement skill competency. These components included:

1. Quality PE and School Sport
2. Classroom Energisers
3. Physically Active Homework
4. Active Playgrounds
5. Links to Community Physical Activity

6. Parent Engagement

iPLAY for Inclusion will include similar components, but will include additional content on positive behaviour support (MacDonald & McGill, 2013) and universal design for learning (Ok et al., 2017). As per previous studies (Lonsdale et al., 2016), an iPLAY mentor (employed by the project team) will deliver a professional learning workshop and follow-up individualized mentoring to primary teachers. These activities will be supported by an online learning and resource platform (following Lonsdale et al., 2016). Teachers within the schools will then deliver intervention components. All classroom teachers will deliver curricular components of the intervention (e.g., quality PE and school sport). The curricular components are largely built around making classes SAAFE (Lubans et al., 2017): Supportive, Active, Autonomous, Fair and Enjoyable. Within each school the principal will identify up to three classroom teachers as 'Leaders'. Leaders will deliver non-curricular components of the intervention (e.g., active playgrounds) and support other teachers with implementation of curricular components.

Mentors

Mentors will be current and recently retired teachers with NSW Education Standards Authority (NESA) specialist accreditation in Health and PE. These specialist teachers are ideally placed to deliver the intervention as primary school teachers will regard them as credible. In addition to holding NESA accreditation in Health and PE, inclusion criteria for mentors will include: (i) smartphone ownership, (ii) basic computer skills, (iii) a valid driver's license and (iv) access to a vehicle to travel to schools. Mentors will be recruited via professional associations (Australian Council for Health Physical Education and Recreation), NSW Department of Education social media advertising and the project team's existing professional networks.

Mentor training

During 2.5 days of face-to-face workshops, the project team will train mentors to deliver the intervention. Workshops will include: (i) familiarization with the intervention components and procedures and their rationale, (ii) review of answers to predetermined 'frequently asked questions', (iii) discussion regarding methods to establish mentors' credibility, 'relatability' and likeability, (iv) problem solving exercises regarding likely challenging scenarios, and (v) role-playing exercises.

Mentor delivery

Mentors will complete the following tasks in each school:

1. Deliver a 2-hour workshop at the school to all teachers. The workshop will focus on the curricular components of the intervention. It will include a 1-hour classroom session in which the mentors will present information videos with content and then facilitate discussion and activities using presentation slides provided by the project team. The workshop will also include a 1-hour practical session in which the mentor will demonstrate quality teaching using a lesson plan provided by the project team.
2. Observe one PE or school sport lesson for each teacher and provide feedback to the teacher during a 30-minute meeting. This observation and feedback process will require mentors to visit each school, with the number of visits determined by the number of teachers in the school. On average, we expect mentors to visit once per term.

3. Meet with leaders to facilitate implementation of non-curricular intervention components (4 × 1 hour meetings – 1 per term). In most cases, these meetings will be conducted face-to-face on the same day as mentors visit schools to observe teachers' delivery of PE and school sport lessons. However, in some circumstances (e.g., very small schools in which mentors only need to visit once or twice to observe all classroom teachers' PE/school sport lessons), a teleconference or internet-mediated video conference may be chosen to complete this meeting.

Methods to ensure high quality and consistent delivery of the workshop and the observation feedback meetings include:

1. At the end of the training workshops and before delivering the intervention in schools, mentors will complete an examination regarding project procedures and workshop content (e.g., answers to frequently asked questions).
2. During the face-to-face workshops, mentors will deliver all content to teachers using videos produced by the project team.
3. Discussion of video content and learning activities for teachers during the workshop will be based on slides and a lesson plan provided by the project team.
4. Mentors will access videos and presentation slides through the project website. Thus, the project team will be able to verify if and when each component was accessed.
5. The project team will provide mentors with answers to frequently asked questions for each workshop, and update this list as the project progresses.
6. Mentors will upload their lesson observations using a structured template within the project website or smartphone app (iOS and Android versions will be available).
7. Mentors will participate in annual meetings that will provide them with ongoing professional learning and support. The project team will lead these face-to-face meetings.

Curricular components – classroom teachers

Classroom teachers will participate in professional learning designed to help them implement the curricular intervention components. This training will involve a 2-h workshop (face-to-face), 6 h of online learning (8 × 45 minute modules), a mentoring meeting and a peer observation. Completion of these activities will provide each classroom teacher with 14 h of professional learning that is registered with NESA. To maintain their accreditation, NSW teachers are required to accumulate 50 h of NESA registered professional learning every five years. The project team will provide this professional learning free of charge. The project team will not offer any other compensation to teachers.

Professional learning for classroom teachers

Professional learning will assist teachers to implement three components: (i) quality PE and school sport, (ii) classroom movement breaks (known as 'energizers'), (iii) physically active homework.

To ensure intervention components are relevant for teachers working with children with intellectual disability, each component embraces two principles that focus on inclusive education: universal design for learning and positive behaviour support.

To begin, a mentor will facilitate one 2-h face-to-face workshop at each school. After the initial workshop, teachers will complete eight online modules designed to reinforce and extend

knowledge and skills gained in the initial workshop. During the workshop, mentors will encourage teachers to complete the online modules in small groups approximately once per month (e.g., at stage meetings). This collaborative approach is intended to foster the development of a community of practice within each school. However, modules can also be completed independently.

At the end of the face-to-face workshop, each teacher will create a learning plan to complete the rest of the program. The learning plan will describe when each teacher intends to complete each of eight modules. Upon completion of each module, the website/app will prompt teachers to reflect on their learning plan and adjust target dates, as required. Teachers will also have the ability to modify this learning plan at any time – i.e., without prompting. During the intervention, teachers will be prompted via a notification on their smartphone and/or an email when a new module is due for completion (according to each teacher's self-selected, individualized learning plan).

Online learning activities will include brief instructional videos and engaging tasks that allow teachers to understand the rationale behind each teaching strategy. Each module will be designed to take 45 min to complete, but teachers will be able to stop and start mid-module. Each module will include an action plan task in which teachers will set implementation goals for their PE and sport lessons. At the beginning of each online module, teachers will reflect on their progress towards goals set in the action plan from the previous module. In addition to the website, professional learning will also be available via a smartphone app on both iOS and Android platforms.

A mentor will be assigned to each school and will observe one 30-min PE or sport lesson delivered by each consenting classroom teacher. Mentors will then meet individually with each teacher for 30 min to promote and guide self-reflection and provide feedback concerning the observed lesson. Feedback from mentors will be guided by an online observation checklist that prompts mentors to discuss the SAAFE (Supportive, Active Autonomous, Fair and Enjoyable) teaching principles, which are based on self-determination theory tenets. During this conversation, the classroom teacher will answer reflective questions on the website/app.

Recently introduced regulations in NSW mandate that teachers engage in peer lesson observation. In our program, teachers will be observed by one of their peers while they teach a 30-min PE or sport lesson. Afterwards, the pair will use a SAAFE checklist hosted on the project website/app as the basis for a 30-min peer discussion activity. As in the mentoring session, classroom teachers will answer reflective questions on the website/app during the peer discussion activity.

Teachers who join a school after the intervention has started and/or miss the face-to-face workshop will be able to complete an online version of that component. They will complete all other aspects of the program as usual unless they join the school after the intervention has finished and a mentor is not available for the lesson observation component. In this instance, leaders will be asked to facilitate this component.

Classroom teacher delivery

Support for classroom teachers' implementation of the curricular components will include smartphone prompts, teaching resources, and the mentoring described previously. The smartphone app will provide reminders for teachers to implement strategies from their action plan. Teachers will be able to choose the interval for these reminders. The website and smartphone app will allow teachers to download resources (e.g., lesson plans, activity descriptions, and classroom movement break videos) that support intervention implementation. Also, when teachers set their action plan in each module, the web-based platform will identify resources that are specifically relevant to the skills/activities that the teacher has planned for the coming weeks. Links to these resources plus the action plan will be emailed to the teacher.

Leader training

We will work with school principals to recruit up to three leaders per school. These teachers will assume responsibility for the delivery of the non-curricular components of the intervention (e.g., active playgrounds) and support other teachers with their implementation of the curricular components.

Each leader will complete a series of four online learning modules (45 mins × 4 modules = 3 hours) designed to teach them how to implement the non-curricular components of the intervention.

Leader delivery

Once all leaders in a school have completed the online training, the leaders will meet as a group with their school's mentor. The purpose of this 1-h meeting will be to set implementation goals for each non-curricular component and to determine the specifics of how leaders will support classroom teachers' delivery of the curricular components (i.e., who will do what and when). The leaders' implementation plan for each school will be recorded on the website. As leaders make implementation progress in their schools, they will log this information, including reflections on facilitators and barriers.

In addition to recording their implementation of the non-curricular components on the website/app, leaders will be asked to meet with their school's mentor for one hour once per term to discuss progress and set new implementation goals. This meeting will also provide an opportunity for leaders and mentors to discuss classroom teachers' implementation of the curricular components. Checklists to guide these meetings will be available on the website and mentors will be responsible for ensuring these are logged at the end of the meeting.

Procedure

Principals and teachers will provide written informed consent to participate in the cluster RCT. Students will provide assent and parents will provide written informed consent for their child to participate. Trained research assistants will collect all student level outcomes in the cluster RCT. These data collectors will not be informed of schools' allocation to the intervention or control condition; however, due to the use of social marketing within intervention schools (e.g., posters), our ability to meaningfully blind these researchers is diminished. However, research assistants responsible for coding videos of fundamental movement skills will be blinded to allocations. The

potential risk of bias for many measures in this study is low (e.g., objective measures of physical activity) and statisticians will also be blinded to each school's allocation.

Primary outcome measure

A series of studies (Capio et al., 2016; Eguia et al., 2015; Simons et al., 2008; Simons & Eyitayo, 2016) have shown that fundamental movement skills can be reliably assessed in children with intellectual disabilities (Maïano et al., 2019). These assessments also predict physical activity, cardiorespiratory fitness, and weight status in typically developing children and adolescents (Holfelder & Schott, 2014; Lubans et al., 2010). They also predict many health and developmental outcomes in children with intellectual disabilities (Maïano et al., 2019). Importantly, fundamental movement skills are an important predictor for children's long-term physical activity (Eguia et al., 2015; Maïano et al., 2019; Westendorp et al., 2011). These skills are also a core learning objective of primary school physical activity, and are amenable to change from interventions (Morgan et al., 2013).

As a result, our primary outcome will be fundamental movement skill competence via the Test of Gross Motor Development-3 (Webster & Ulrich, 2017). This updated version has been validated for children with developmental disorders, including intellectual disabilities (Allen et al., 2017; Magistro et al., 2018; Simons & Eyitayo, 2016). Because time did not allow us to assess all 13 skills in the full TGMD-3, we chose the three skills for each subscale that explained the most variance in children with intellectual disabilities (see Magistro et al., 2018; Simons et al., 2008). For the locomotor skills subscale, the most information was provided by the run, gallop and hop (Magistro et al., 2018). For object control skills, the most information was provided by the one-hand strike, dribble, and kick (Magistro et al., 2018). These subsets largely overlap with the most important items from other validation studies (Simons et al., 2008; Simons & Eyitayo, 2016).

Students will be provided with a physical demonstration by a research assistant, a practice attempt, and a set of visual prompts (which led to better psychometric properties in children with autism; Allen et al., 2017). They will be asked to complete each skill two times, and the outcome will be coded by a research assistant who is blind to the treatment allocation. 10% of the data will be coded in duplicate to assess inter-rater reliability. Using a process-oriented approach, the primary outcome will be the raw score, totalled across both trials of all six skills. We will measure fundamental movement competency for all physically able children (i.e., those who can run and do not use a wheelchair) with intellectual disabilities whose parents provide consent.

Secondary outcome measures

Cardiorespiratory fitness

Both cardiorespiratory fitness and fundamental movement skills are important outcomes of a physical activity intervention. Children's cardiorespiratory fitness has declined over the past three decades (Tomkinson et al., 2019; Tomkinson & Olds, 2007). In addition, children with intellectual disabilities demonstrate lower fitness than their typically developing peers (Faison-Hodge & Porretta, 2004; Frey et al., 2008; Lorenzi et al., 2000; Rimmer et al., 2010). However, measuring cardiorespiratory fitness in young people with intellectual disabilities is

challenging. Most assessments fail to meet established reliability and validity standards (Oppewal et al., 2013). Few were validated on children, and reliable field tests have lacked evidence of their validity (Oppewal et al., 2013).

We chose the 300-yard run after pilot testing because: we wanted a short, simple measure, given our young sample; and the 300-yard run has been shown to be reliable in young people with intellectual disabilities (Aufsesser, 1979; Baumgartner & Horvat, 1991; Oppewal et al., 2013). Children will be asked to run or walk as fast as they can over 300 yards, timed by a research assistant. This time will be our indicator of cardiorespiratory fitness.

Student physical activity (objective measure)

We will measure students' physical activity behavior over a period of seven days using GENEActiv accelerometers (Activinsights, Cambridge, United Kingdom) worn on the non-dominant wrist. GENEActiv accelerometers are valid measures of physical activity for children with intellectual disabilities (Leung et al., 2017). Wrist-based accelerometry may be more acceptable for children compared with hip-worn monitors, resulting in greater compliance and less missing data (compliance between 86.7% and 98.9%; Leung et al., 2017). Data will be reduced using evidence-based, best-practice procedures at the time of analysis. At present, this involves using the Euclidean norm minus one (ENMO) method to apply cut-points to the data, providing estimates of time in different intensities of activity (e.g., moderate vs. vigorous). Accelerometry data will be used to examine: (i) within school activity, (ii) recess and lunch activity, (iii) after-school activity, (iv) weekend activity and (v) total activity.

Questionnaire Items

Students will also be asked questions about their physical self-concept via individual administration of the self-description questionnaire, individual administration (SDQ-IA physical subscale; Marsh et al., 2005; Tracey & Marsh, 2000). We selected the six items of the physical self-concept subscale that did not overlap with the enjoyment measure, described below. In the individual administration version, students are guided by a researcher to first ask whether they agree with the statement, then asked to what extent. We chose this response mechanism for all other assessments for consistency and because it has been validated in children with intellectual disability (Tracey & Marsh, 2000). Students will use this response scale to report on their enjoyment for physical activity and their life satisfaction. For enjoyment, three items were chosen from the Physical Activity Enjoyment Scale (e.g., "I enjoy sport and PE"; Motl et al., 2001). For life-satisfaction, students will rate their wellbeing on the personal wellbeing index for intellectual disability (Cummins & Lau, 2005), using the single-item measure of life satisfaction because it has been shown to demonstrate comparable validity to longer measures (Cheung & Lucas, 2014).

Students will report their sex, the country in which they were born and the language they speak at home. We will use this information to categorize students into one of seven ethnic backgrounds (English, European, Middle Eastern, Asian, African, South Pacific or 'other'),

based on the Australian Bureau of Statistics' Standard Classification of Languages. We will ask parents to note their child's birthday.

Sample size

There have been few school-based physical activity interventions in children with intellectual disabilities, particularly assessing the influence on fundamental movement skills. In typically developing children, a meta-analysis of interventions found a large pooled effect size on overall gross-motor competency (SMD = 1.42, 95% CI = 0.68–2.16; Morgan et al., 2013). To estimate our effect size, we used the smallest pooled effect size reported in that meta-analysis (object control = .63; 95% CI = 0.28, 0.98). We used these data and those from the Department of Education to get other parameters for sample size estimation: ~20 students per school in Years 2-5 with an intellectual disability, and a conservative 30% consent rate. While we plan to assess the interaction between treatment (between groups IV) and time (within groups IV) using a mixed factorial design, we conservatively estimated the sample size using post-test means. We used G*Power 3 to estimate the required sample size (Faul et al., 2007). We then calculated a design effect using the ICC from previous research (0.08; Cohen et al., 2015) and the method provided by Bland (2004). Given the above parameters, we needed 20 schools (10 intervention, 10 control) with 115 students total (5-6 students per school) to reach >80% power.

Randomisation

Schools will be randomised in waves as they are recruited. When schools are recruited, they will be matched on school type (mainstream vs. schools for special purposes), Index of Community Socio-Educational Advantage (ICSEA), and location (urban vs. remote). Then, an experienced statistician who is not part of the research team will use a computer-generated algorithm (Moore & Schnakenberg, 2016) to randomised matched schools.

Blinding

We will be unable to blind staff because they will be aware of the training during recruitment for the trial. We will not tell students whether or not their school will be receiving training. We cannot, however, prevent staff from discussing the training with students. Also, due to social marketing material (e.g., posters) in the school, students may be aware that their teachers have completed iPLAY training. The likelihood of students' awareness influencing results would be low.

Statistical methods

To assess pre-post differences on all student-reported variables, we will use linear mixed models. Student scores will be nested within teachers and we will account for this via a random intercept. We will assess the interaction between treatment and time on gross fundamental movement skill competency. We hypothesise that the influence of time on competency will be greater for those in the intervention group. This process will also be used to assess intervention effects for all secondary outcomes (i.e., cardio-respiratory fitness, self-concept, motivation, wellbeing, physical activity). We will conduct sensitivity analyses to assess whether findings are robust when controlling for demographic variables. We'll also conduct an as-per-protocol analysis by assessing whether completion of the professional learning moderates the effect of

the intervention. Rather than using an arbitrary cut-off, we will use learning analytics to identify the percentage of the course that teachers completed at post-test. We will then assess whether this percentage explains variance in the effect of the program on their students. Using full information maximum likelihood to account for attrition, our data will follow intention-to-treat procedures.

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