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# Protocol for the PLAYshop randomised controlled trial: examining efficacy of a virtually delivered parent-focused physical literacy intervention for early childhood on child-specific and family-specific outcomes

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## ABSTRACT

**Introduction** The PLAYshop programme is a novel, brief, theory-based, parent-focused physical literacy intervention in early childhood designed to address the major public health issue of childhood physical inactivity. The primary objective of this study is to examine the efficacy of the virtually delivered PLAYshop programme in increasing preschool-aged children's physical literacy, including fundamental movement skills and motivation and enjoyment.

**Methods and analysis** This study aims to recruit 130 families with preschool-aged children (3–5 years) from Alberta and British Columbia, Canada who will be randomised to an intervention or control group. The PLAYshop programme is informed by the Capability, Opportunity, Motivation, Behavior (COM-B) model and includes four intervention strategies: (1) educational training via a 60 min virtual synchronous workshop, (2) educational resources via handouts, (3) material resources via a goody bag of basic active play equipment and (4) follow-up support via access to a digital app with an online toolkit and four biweekly booster lessons (1-week, 3-week, 5-week and 7-week follow-up). To assess the primary outcome of physical literacy, five fundamental movement skills (overhand throw, underhand throw, horizontal jump, hop, one leg balance) will be measured virtually at baseline and 2-month follow-up using the Test of Gross Motor Development (TGMD) and the Movement Assessment Battery for Children-Second Edition (MABC-2) tools. Additionally, children's motivation and enjoyment will also be assessed at baseline and 2-month follow-up by: (1) parental-report using items from the Preschool Physical Literacy Assessment (PrePLAy) and (2) self-report using an adapted Five Degrees of Happiness Likert scale for children. The control group will receive the PLAYshop programme after the 2-month follow-up.

**Ethics and dissemination** The protocol was approved by the University of Alberta (00093764) and University of Victoria (16-444) Research Ethics Boards. Findings will be disseminated through peer-reviewed publications, conference presentations, social and traditional media and a circulated infographic.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial focuses on child-specific and family-specific outcomes building on previous work that indicates the PLAYshop programme either in-person or virtually delivered, appears efficacious in improving parental outcomes to support children's physical literacy development.
⇒ The PLAYshop programme focuses on the preschool years (3–5 years) a key window of physical literacy development.
⇒ In response to the ongoing COVID-19 pandemic, a virtual protocol for assessing fundamental movement skills was developed and tested. Consequently, a complete battery of fundamental movement skills will not be assessed and a composite fundamental movement skill score will not be calculated.

**Trial registration number** NCT05255250.

## INTRODUCTION

Physical literacy is a holistic and multidimensional construct that involves the interaction of physical (eg, fundamental movement skills) and psychosocial (eg, motivation) components that are related to physical activity.[1–3] Physical literacy is defined by the International Physical Literacy Association as: 'the motivation, confidence, physical competence, knowledge and understanding to value and take responsibility for engagement in physical activities for life'.[4] The importance of physical literacy is gaining international attention. For instance, the WHO has identified physical literacy as an important component in their global action plan to address the worldwide public health issue of physical inactivity.[5]While the development of physical

literacy is considered a lifelong journey, early childhood, in particular the preschool years (3–5 years), is seen as a key period for physical literacy development.[1–3] Specifically, physical literacy development during this period is thought to be a precursor of physical activity throughout childhood and therefore has long-term implications on health and well-being.[1–3]

With the growing understanding of the importance of physical literacy, interventions to target and improve physical literacy have been increasing exponentially since 2015.[6] However, a systematic review on physical literacy interventions conducted in 2020/2021 only found four physical literacy interventions (five articles) that exclusively targeted preschool-aged children (3–5 years).[6] Within the review, these four interventions were all categorised as 'theory-inspired' meaning they lacked significant links between physical literacy components (eg, physical competence, confidence) and intervention content.[6] Additionally all four interventions focused on the childcare setting.[7–11] While educators in the childcare settings are important facilitators of physical literacy in the preschool years, parents also play a critical role in children's physical literacy development.[3] This is especially true considering not all parents need or chose to enrol their preschool-aged child in childcare.[12] Therefore, parent-focused interventions targeting physical literacy development in preschool-aged children are needed.

The PLAYshop programme, a novel, brief, theory-based, parent-focused physical literacy intervention for early childhood, was developed to tackle current evidence gaps. The theoretical frame of this trial is the Capability, Opportunity, Motivation, Behaviour model (COM-B).[13] Capability (C) refers to the physical and psychological ability to enact the behaviour. Opportunity (O) refers to the social and physical environment that enables the behaviour. Finally, Motivation (M) refers to the reflective or automatic mechanisms that activate or inhibit the behaviour.[13] These three factors are considered the critical determinants of behavioural performance that mediate all behaviour change techniques.[13]

Previous feasibility and pilot PLAYshop programme work has indicated that most parents found the programme very/extremely useful (82%) and were satisfied/extremely satisfied with its content (95%) and delivery (96%).[14] Additionally, preliminary efficacy for increases in parental knowledge (ie, capability), perceived availability of resources (ie, opportunity) and confidence (ie, motivation) to support children's physical literacy development was observed.[14 15] In the previously mentioned systematic review,[6] the first iteration of the PLAYshop program[14] was classified as 'theory driven' highlighting the substantial links between physical literacy components and the PLAYshop intervention content.[6] In response to the ongoing COVID-19 pandemic, the in-person workshop, the core component of the PLAYshop programme, was converted to a virtual format and a virtual protocol for measuring fundamental movement skills was created. Preliminary findings support the feasibility and potential positive outcomes of the virtual PLAYshop programme, with similar findings for perceived usefulness and satisfaction, as the in-person PLAYshop programme.[16] An important next step is examining the efficacy of the virtually delivered PLAYshop programme on child-specific and family-specific outcomes.

## Study objectives and hypotheses

The primary objective of this study is to examine if the virtually delivered PLAYshop programme increases preschool-aged children's physical literacy, including fundamental movement skills and motivation and enjoyment, compared with controls. The secondary objective is to examine if the virtually delivered PLAYshop programme increases preschool-aged children's physical activity,coparticipation in physical activity with parents, and parental physical activity modelling, compared with controls. The tertiary objectives are to examine: (1) if the virtually delivered PLAYshop programme increases parents' capability, opportunity and motivation to support preschool-aged children's physical literacy development, compared with controls and 92) the level of, and factors that influence, implementation at the family and programme delivery level.

It is hypothesised that increases in preschool-aged children's physical literacy, physical activity, parent–child coparticipation, and parental physical activity modelling in physical activity will be greater in the intervention group, compared with the control group. Additionally, it is hypothesised that increases in parents' capability, opportunity and motivation to support preschool-aged children's physical literacy development will be greater in the intervention group, compared with the control group.

## Trial design

Study objectives will be addressed using a single-blind, parallel group, two-arm, superiority randomised controlled trial design. Research coordinators will randomly assign parent-child dyads using a computer-generated 1:1 sequence to intervention group (group 1) or control group (group 2) after baseline measures are completed. The control group will receive the PLAYshop programme after the completion of study measures. Research coordinators will be aware of the group allocations to coordinate random assignment and the scheduling of workshops and measures. Participants will not be told if they have been assigned to the intervention or control group, rather they will be told they have been assigned to group 1 or group 2. However, participants may be able to determine whether they are in the intervention or control group based on the timing of when they receive the PLAYshop programme. Additionally, research assistants who are scoring the fundamental movement skills will not be told if a participant is part of the intervention or control group. However, as described in detail below, only the intervention group participates in an interview. Research assistants may recall from an earlier

data collection session if an interview was conducted with the parent of the child performing the fundamental movement skills.

## METHODS AND ANALYSIS

This trial protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement.[17] The trial was registered with the Clinical Trials Registry maintained at the National Library of Medicine at the National Institutes of Health ( ClinicalTrials.gov: NCT05255250).

### Patient and public involvement

The PLAYshop programme and data collection procedures used in this trial, as outlined in this protocol, take into account feedback from parents and workshop leaders from previous PLAYshop feasibility and pilot studies.[14 15]

### Intervention condition

The PLAYshop programme includes four intervention strategies, which are described in detail elsewhere.[15] Briefly, the first and main strategy is conducting educational training via a 60 min virtual synchronous workshop with interactive activities and educational messages embedded with physical literacy concepts. Activities focus on developing children's fundamental movement skills while supporting their movement knowledge, confidence and motivation. The second strategy is the distribution of educational resources via hard copy handouts, including the Canadian 24-Hour Movement Guidelines[18 19] and activity ideas. The third strategy is providing material resources via a goody bag of inexpensive active play equipment that is used in the workshop to engage in different activities. Finally, the fourth strategy is providing follow-up support post-workshop via access to a digital app with an online toolkit as well as four biweekly booster lessons. The digital app was built using the Pathverse platform—a no-code app builder.[20] The COM-B was employed to identify specific strategies to support parents to adopt target behaviours. A description of the implementation strategies used in the PLAYshop programme and how they align with the relevant COM-B factors and behaviour change techniques has been previously published.[15]

### Control condition

After follow-up measures are complete, the control group will get access to the PLAYshop programme, with the exception of the four biweekly boosters as the dose assessment within the boosters is only needed for the intervention group.

### Participants

#### Inclusion and exclusion criteria

Children aged 3–5 years and their parents who live in a non-rural area, defined as a population centre of at least 1000 people according to Statistics Canada,[21] in the provinces of Alberta and British Columbia are eligible for this trial. Targeting families in these locations will ensure manageable time zone differences for virtual data collection sessions and workshops as well as affordable shipping of accelerometers and equipment goody-bags. Non-rural areas will help ensure adequate internet bandwidth for virtual sessions and workshops. If a family has more than one child in the 3–5 years age range, both children will be invited to participate. However, data from only one child will be randomly selected to be included in analysis.

There are four exclusion criteria for this trial: (1) families that have participated in a prior PLAYshop pilot or feasibility study; (2) families with children who have been diagnosed with a developmental delay or disorder/condition that may affect gross motor development or limit their ability to be physically active; (3) families with parents who do not comfortably speak or read English and (4) families that do not have access to a smartphone/tablet with camera and microphone. Of note, almost all Canadian adults that are of an average child-rearing age own a smartphone.[22] A screening interview will be conducted to ensure participants meet eligibility criteria.

#### Recruitment

Recruitment will occur primarily through targeted online advertising (eg, paid Facebook advertising). Recruitment may also occur via participant databases and through community, childcare, and preschool organisations. Recruitment began in February, 2022 and it is anticipated that recruitment will be complete in January, 2023 and data collection will be complete in March, 2023.

### Measures

#### Procedures

After determining a family is eligible and interested, they will complete baseline measures. At baseline, parents will complete an online consent form and questionnaire via REDCap, an electronic data capture tool.[23] Children's fundamental movement skills and their self-reported enjoyment will be assessed at a recorded virtual Zoom session. The designated parent and preschool-aged child will wear an accelerometer for seven consecutive days while awake. The designated parent is the person that spends the most time with the child during play activities. If play time is equal across two parents, and both are willing to participate, we will randomly select one parent. After the baseline data collection, parent-child dyads will be randomly assigned to intervention (group 1) or control (group 2). Those randomised to the intervention group will be scheduled for a workshop within the next 2 weeks and will complete a second online questionnaire immediately after the workshop. As part of the biweekly (ie, 1, 3, 5, 7 weeks postworkshop) booster lessons parents will complete brief check-in questions via the app. Approximately 2 months after the workshop, they will complete the 2-month follow-up measures. Specifically, parents will complete a third online questionnaire, children's fundamental movement skills and their self-reported enjoyment will be assessed at a recorded virtual Zoom session, and the designated parent and preschool-aged child will

again wear an accelerometer for seven consecutive days. Additionally, at the end of the virtual Zoom sessions, brief semi-structured interviews will be conducted with parents. Parent–child dyads randomised to the control group, will complete a second online questionnaire 1 week after the baseline virtual session. Approximately 2 months later, they will complete the 2-month follow-up measures. Follow-up measures mirror those of the intervention group with the exception of the semi-structured interviews, which will not be conducted with control group parents. To help encourage children to wear the accelerometer for seven consecutive days at baseline and 2-month follow-up, parents will be given seven stickers at each time point that children can place on a sticker chart to mark they have worn their accelerometer for the day. Parents will also be given one small toy at each time point that they can give to their child at the end of the week for wearing the accelerometer. Once these components are completed, parent–child dyads in the control group will be scheduled for a workshop in the near future and will receive access to the app post-workshop. Booster lessons, including check-in questions, will not be sent to control group parents. Please see figure 1 for a summary of these research study components and timelines.

### Primary outcome measures

The primary outcome of this trial is preschool-aged children's physical literacy, including fundamental movement skills and motivation and enjoyment. Children's fundamental movement skills will be measured virtually via a recorded Zoom session with parents using a smartphone/tablet to film the skills. A research assistant will later score the skills by watching the videos. We will measure five skills, including two manipulative skills (ie, overhand throw, underhand throw), two locomotor skills (ie, horizontal jump, hop) and one balance/stability skill (ie, one leg balance) from the Test of Gross Motor Development (TGMD)[24] and the Movement Assessment Battery for Children-Second Edition (MABC-2) tools.[25] These skills were selected because they align with the PLAYshop workshop, require minimal space and equipment (eg, adult balled-up socks) and significant correlations with large effect sizes (r=0.5–0.7)[26] were observed between the selected manipulative and locomotor skills and total motor skills in a previous study in this age group.[27] Research staff have already been trained to establish inter-rater reliability on a set of pilot videos. Inter-rater reliability for these pilot videos was an ICC≥0.90, with the exception of the horizontal jump (ICC=0.79).[16] Additional training will be completed for the horizontal jump prior to scoring the study videos.

Existing measures of motivation and enjoyment suitable for preschool-aged children are extremely limited.[3] Children's motivation and enjoyment will be assessed at baseline and 2-month follow-up via: (1) parental-report using items from the Preschool Physical Literacy Assessment (PrePLAy)[28] and (2) self-report using an adapted Five Degrees of Happiness Likert scale for children.[29] The PrePLAY tool includes four items with five response options (strongly disagree to strongly agree).[28] The scores of the four items will be summed. The PrePLAY tool will also be included in the second online questionnaire (1–2 weeks after baseline), which will enable the assessment of test–retest reliability in this sample. Previous research indicates this scale has good internal consistency reliability (α=0.841) in a sample of early childhood educators.[28] In this same sample, 2-week test–retest reliability ranged from 0.47 to 0.74 across motivation and enjoyment items and male and female children.[28] Finally, in terms of convergent validity, the motivation and enjoyment scale was not significantly associated with the Peabody Developmental Motor Scale-2 but it was significantly associated with accelerometer-measured total physical activity and moderate-physical to vigorous-physical activity in girls.[28]

The adapted Five Degrees of Happiness Likert scale includes one item with five smiley face response options (slightly happy face; active play is okay but I rather be doing something else to very happy face; really love being active and it is my favourite thing to do).[29] At the virtual Zoom session, the scale will be explained to children and they will be asked to point to which face looks most like them when doing active play like running, jumping, throwing, chasing or dancing. Previous research on a sample of 9–11 years old has shown that these response options produce within and between children variance, and unlike other smiley face response options, all scale response options were used in this sample of children.[29] The scale, including the explanation to children, was adapted by the research team to make it relevant for active play and preschool-aged children. Face scales have been used in other fields (eg, paediatric pain) with children as young as 3 years old.[30 31]

### Secondary outcome measures

The secondary outcomes of this trial are children's physical activity and parent–child coparticipation in physical activity, and parental physical activity modelling. Children's physical activity and parent–child coparticipation in physical activity outcomes will be measured at baseline and 2-month follow-up with Actigrah wGT3X-BT accelerometers. Children and designated parents will wear the devices during waking hours on a belt around the waist for seven consecutive days. Validated cut-points for preschoolers and adults will be used to classify counts into sedentary time or physical activity.[32 33] This accelerometer model has a Bluetooth proximity detection feature that can determine the presence (eg, same room in a house, at the park together) or absence of close proximity between two accelerometers. Previous research has shown 82% sensitivity and 81% specificity for determining the presence of close proximity between parents and preschoolers using this feature.[34]

Parent–child coparticipation in physical activity in the past month and parental physical activity modelling will also be measured at baseline and 2-month follow-up in the online questionnaires. The parent–child coparticipation

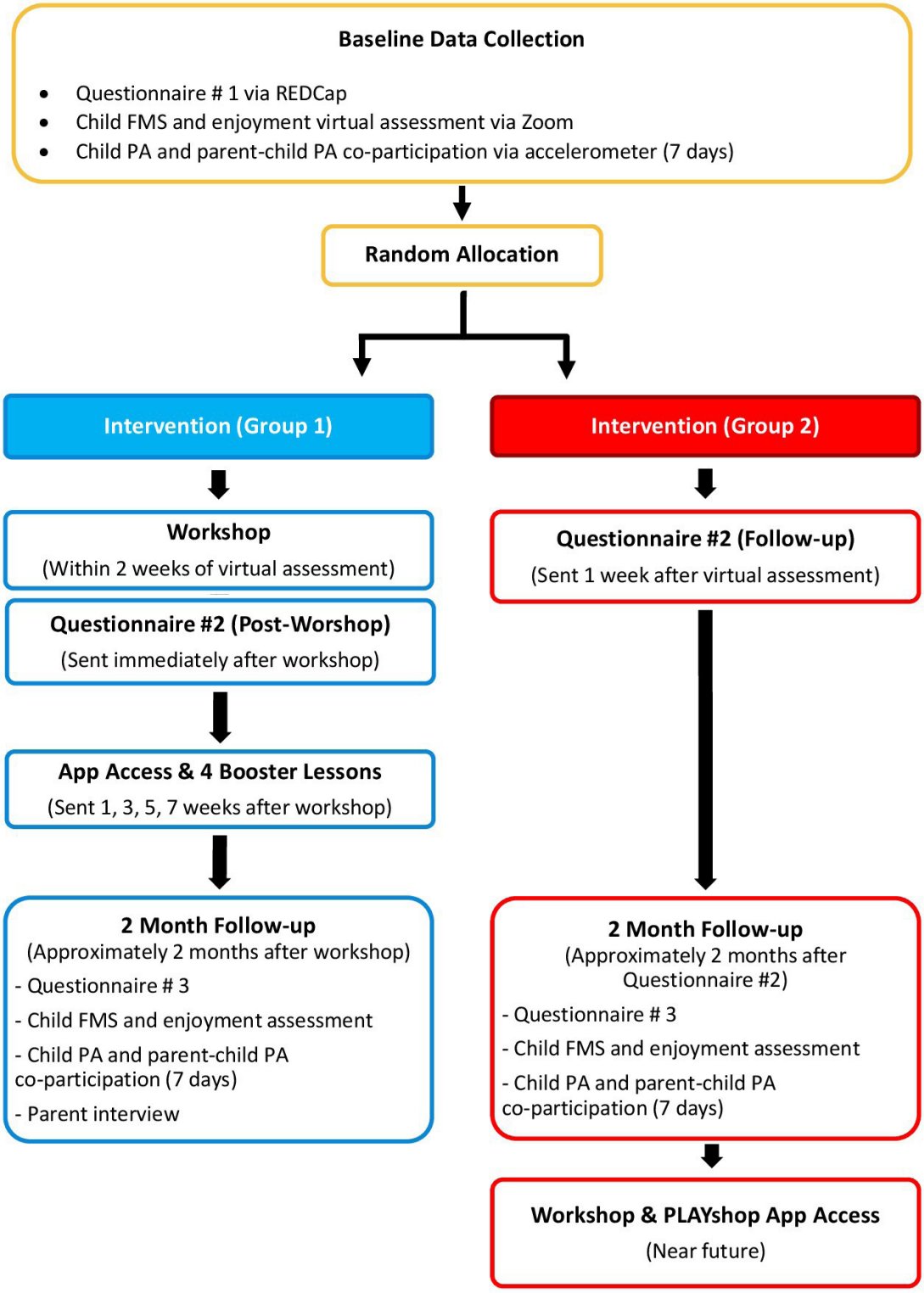


**Figure 1** Summary of study components and timelines. FMS, fundamental movement skills; PA, physical activity.

in physical activity scale includes four items with response options ranging from 1 (never) to 5 (4 or more times per week).[35] The scores of the four items will be summed. These items were adapted from an expert informed concept mapping analysis of parenting practices for 5–12 years old.[35] The parental physical activity modelling scale includes three items with response options ranging from 1 (strongly disagree) to 4 (strongly agree). The scores of the three items will be summed. These items are from the Activity Support Scale for Multiple Groups.[36] These scales will also be included in the second online questionnaire (1–2 weeks after baseline) to enable the assessment of test–retest reliability in this sample. Preliminary findings from our previous work found the internal

consistency reliability ranged from α=0.88 at baseline to 0.69 at 2-month follow-up for parent–child coparticipation in physical activity and α=0.88 at baseline to 0.87 at 2-month follow-up for parental physical activity modelling.[16]

### Tertiary outcome measures

The tertiary outcomes of this trial are parental capability, opportunity and motivation to support preschool-aged children's physical literacy development and implementation, including parental satisfaction and perceived usefulness, facilitators and barriers and dose. Parental capability (knowledge (nine items) with five response options), opportunity (perceived availability of resources (one item) and perceived barriers (five items), both with five response options), and motivation (confidence (11 items), beliefs (four items), outcome expectations (three items), intentions (two items), perceived behavioural control (four items), all with five response options) will be measured in all three questionnaires. Scores for each scale with multiple items will be summed. We have previously used these questions[15] that are adopted from previous research[37] or developed specifically for the PLAYshop programme. Internal consistency reliability for these outcomes has ranged from α=0.50–0.89.[15]

Parental satisfaction and perceived usefulness will be measured in the parental questionnaire immediately after the workshop in the intervention group only. Three questions (ie, rate your overall level of satisfaction with the workshop content, rate your overall level of satisfaction with the workshop delivery, how useful do you feel this training will be to you?) with five response options (not satisfied to extremely satisfied or not useful to extremely useful) will be used, consistent with our previous work.[14 15] Satisfaction and perceived usefulness of the intervention will also be explored via brief semistructured interviews with parents from the intervention group at 2-month follow-up.

Barriers and facilitators will be explored via brief semistructured interviews with: (1) parents from the intervention group at 2-month follow-up and (2) workshop leaders at the end of the study, approximately 1 year after the first workshop.

Dose will be explored via brief semistructured interviews with parents from the intervention group at 2-month follow-up. Additionally, dose will be assessed via check-in questions as part of the bi-weekly (ie, 1, 3, 5, 7 weeks postworkshop) booster lessons in the intervention group and through tracking app usage in the intervention group. The main check-in question at each booster lesson ask parents how many active play sessions they have done with their child in the past 2 weeks.

### Participant characteristics

Participant characteristics of the child (eg, age, sex, ethnicity, childcare, number of siblings) and parent (eg, age, sex and gender, marital status, country of birth, education, previous training) will be collected in the baseline questionnaire. We have previously used these questions[15] that are adopted from Statistics Canada or previous research.[36 38 39]

## Data management

Participants will be informed in an information letter that all data will be kept confidential (see online supplemental material). Specifically, the data that are collected will correspond to a participant number and not identifying personal information (apart from age at data collection). The procedures for storing data on password protected computers and/or secure servers in Canada will also be described in the information letter. Additionally, it will be outlined in the letter that participants may withdraw from the study at any time and that any data collected can be withdrawn if the request is made within 1 month of data collection. To ensure data management procedures are being followed correctly, research staff and volunteers will complete a confidentiality agreement outlining their responsibilities when handling/collecting data prior to beginning work followed by training on the data management procedures. One procedure will be notifying the principal investigator or research coordinator immediately if there is a breach in confidentiality. This intervention does not have a data management committee, though the research coordinator will provide regular updates on recruitment and trial progress to the principal investigator.

## Data monitoring

This intervention does not have an auditing process and an interim analysis is not planned. This is a minimal risk intervention. Parents will be instructed prior and reminded at the beginning of the workshop/fundamental movement skill assessments that proper footwear is required (non-slip) and the space they are using should be clear of most furniture and small items or tripping hazards (eg, toys) so that there is open space to play. Research staff will document and report any adverse events to the research coordinator and/or principal investigator and appropriate action will be taken.

### Statistical analyses and sample size calculation

Using established procedures, missing outcome data will be evaluated for pattern of missingness (eg, missing at random, missing completely at random) and the corresponding strategy will be used to address it.[40 41] Intention-to-treat analyses will be performed in addition to sensitivity analyses. Cronbach's alphas (α) will be calculated for outcome variables with multiple items. Descriptive statistics will be used to describe the study sample. Additional analyses will be conducted to compare: (1) adherers to the study versus drop-outs and (2) baseline variables between intervention and control groups. For the primary outcomes, which have two time points (ie, baseline and 2-month follow-up), the efficacy of the intervention will be tested with a doubly multivariate analysis of covariance (MANCOVA) repeated measures

test, covarying for baseline values or covariates if needed. If the omnibus test is significant, a series of analysis of covariance (ANCOVA) repeated measures tests will be conducted for each primary outcome, covarying for baseline values or covariates if needed. For the secondary outcomes, which have two time points (ie, baseline and 2-month follow-up), specifically children's physical activity and parent–child coparticipation in physical activity, the efficacy of the intervention will be tested using a series of ANCOVA repeated measures tests, covarying for baseline values or covariates if needed. Separate testes will be conducted for each outcome variable. For tertiary outcomes that have three time points (ie, baseline, 1–2 weeks follow-up, 2 week follow-up), specifically parental capability, opportunity and motivation to support preschool-aged children's physical literacy development, the efficacy of the intervention will be tested using a series of ANCOVA repeated measures tests, covarying for baseline values or covariates if needed. Separate testes will be conducted for each outcome variable. Tests will be accompanied by effect size estimations for use in future proposals. Additionally, descriptive analyses will be conducted for parental satisfaction and perceived usefulness as well as app data on dose.

With a sample size of 130 participants (65 intervention, 65 control), we will have 80% power to detect a medium effect size f=0.31 (approximately d=0.60) at a probability of 0.05, for an MANCOVA interaction.[42 43]This effect size is estimated from a previous childcare physical activity intervention in preschoolers that included fundamental movement skills as a secondary outcome.[44] Sample size calculations account for 30% lost to follow-up/missing data based on our previous work, including a parent–child accelerometer study.[15 45]

Each semistructured interview will be digitally recorded and verified by the family within 1 week of the interview, then it will be uploaded into NVivo for analysis. Data will be inductively analysed following the process recommended for multidisciplinary health research.[46 47] First, the research coordinator will work through the complete data set and generate preliminary codes and categories via independent, open coding of each interview.[47] Second, a team member will review a partial data set to assist in finalising the working analytical framework.[46] Each interview will be coded twice and categories and text units will be reviewed to explore subcategories. The research team will discuss and reach negotiated consensus regarding any controversial categorisations. Where possible, data will be charted into a matrix in NVivo to support interpretation of causes, consequences and relationships.[47] Lastly, final themes and interpretive concepts will be generated to describe or explain the data.

## ETHICS AND DISSEMINATION

The study protocol was approved by the University of Alberta (00093764) and University of Victoria (16-444) Research Ethics Boards. Any protocol amendments will be reviewed and approved by these ethics boards and the Clinical Trials Registry, where applicable. At baseline, parents will provide written informed consent for themselves and their child via REDCap (see online supplemental material).[23] The signature feature on REDCap allows for participants to electronically give their signature.[23] Parents will be asked for their verbal consent to video record each virtual session and again for audio recording the interview. Formal written or oral assent from the children will not be collected due to their young age. However, if at any point the child does not want to perform any or all of the fundamental movement skills, answer the enjoyment question, or partake in the workshop they do not have to. This is outlined in the letter of information. Information on confidentially has been provided in the Data management section in the Methods section.

Trial findings will be disseminated to academic audiences through peer-reviewed papers and conference presentations. Trial findings will be disseminated to non-academic audiences through traditional and social media as well as through our network of knowledge users. Findings will also be disseminated to participating families who expressed interest in receiving information regarding the study findings. Authorship for peer-review papers will follow the International Committee of Medical Journal Editors has defined authorship criteria.[48] The participant-level data will not be publicly available due to limitations of ethical approval involving the participant data and anonymity.

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**Contributors** VC and P-JN conceived the idea for the study. VC, RR, SL, P-JN are grant holders. VC, MPr, RR, SL, P-JN contributed to the design of the protocol. VC led the writing of the protocol. MPo and MPr are responsible for the project oversight. All authors contributed to refinement of the study protocol and approved the final manuscript.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

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