

The supporting physical activity in childcare environments (SPACE) study

Submission date 29/09/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/08/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Research suggests that pre-schoolers engage in low levels of physical activity. In fact, as little as 36% of Canadian 2-3 year olds and 44% of 4-5 year olds regularly engage in physical activity and based on previous research, only 54% of pre-schoolers engaged in at least 60 minutes per day. This is alarming, as Canadas Physical Activity Guidelines for the Early Years recommend pre-schoolers engage in 180 minutes of daily activity. When measuring physical activity during childcare hours only, it was found that children were well below the guidelines at a daily average of 133 minutes. These low levels of physical activity are distressing as this behaviour plays an important role in childrens health and is associated with loads of positive health benefits, including healthy bodyweight promotion, slowing the development of cardiovascular (heart) disease, improving motor skill development, and improving quality of life. Most pre-schoolers attend some form of childcare and spend most of their time there. Therefore, this is the best place to promote physical activity among pre-schoolers. Recent Canadian research revealed that children who attended centre-based childcare were 1.65 times more likely to be obese in childhood compared with those who received parental care. The need for efficient interventions to improve physical activity levels is important given the current prevalence of obesity in children. The main aim of this study is to implement and evaluate an evidence-based health promotion intervention aimed at increasing the physical activity levels for pre-schoolers attending centre-based childcare.

Who can participate?

Childcare centres will be invited to participate if they have one or more full-day preschool-aged classrooms at their facility. Pre-schoolers (aged 2.5-4 years) will be invited from these centre-based childcare facilities in London Ontario, Canada.

What does the study involve?

The childcare centres will be randomly allocated to either the experimental or control group. The intervention period will last 8 weeks (weekdays only; Monday-Friday), during the spring and summer months. Centres allocated to the experimental group will receive the intervention designed to increase physical activity. This will include environmental changes, physical activity-related staff training and curriculum changes. Those allocated to the control group will continue their daily curriculum as usual. Childcare providers and pre-schoolers will complete the same

study assessments as those in the experiment group. All assessments will be completed by participants (pre-schoolers and childcare providers) and conducted by trained research staff at the start of the study, at 8 weeks, and 6 and 12 months after the end of the program. Physical activity assessments will last one week for each classroom during childcare hours; Monday-Friday only, for each of the four assessment points (i.e., at the start, 8 weeks, 6- and 12-month follow-up). The 6- and 12-month follow-up time points will allow us to find out the long-term impact of the intervention and to identify if changes in physical activity levels can be maintained.

What are the possible benefits and risks of participating?

Preschool participants in this study may benefit from a potential increase in their physical activity levels and associated health benefits. All families of preschool participants, childcare staff and centre directors will receive a small token of appreciation for each data collection point (e.g., 4 x \$10 gift card to a local grocery store, \$5 gift card to Chapters bookstore, and a \$50 gift card for Scholars Choice, respectively) and a letter of thanks to acknowledge their assistance and contribution to the study. There are no known physical, social, or economic risks due to participation in this study. With physical activity participation, there is always a risk of injury (e.g., falling, tripping, etc.); however, these risks are no higher than any other typical day at childcare.

Where is the study run from?

The study is run from The University of Western Ontario; however, all aspects of participation in the study will take place at the participating childcare centres.

When is the study starting and how long is it run for?

September 2014 to August 2017

Who is funding the study?

The Canadian Institutes of Health Research (CIHR), Canada

Who is the main contact?

Dr Trish Tucker

ttucker2@uwo.ca

Contact information

Type(s)

Scientific

Contact name

Dr Patricia Tucker

Contact details

1201 Western Rd

Elborn College, Rm 2547

University of Western Ontario

London

Canada

N6G 1H1

-

ttucker2@uwo.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Grant Award # R4368A10; ROLA # 0000033871

Study information

Scientific Title

The Supporting Physical Activity in Childcare Environments (SPACE) study: a randomized controlled trial

Acronym

SPACE

Study objectives

The primary objective of this research program is to develop and implement an effective and appropriate physical activity program in centre-based childcare facilities. Given that our primary outcome variable is physical activity levels, we will know if our research program has been effective if we see an increase in minutes of moderate-to-vigorous physical activity (MVPA) and total physical activity (TPA) in preschoolers who participate in the experimental condition. We hypothesize that participants who receive the SPACE study intervention will demonstrate increased MVPA and TPA engagement from baseline to follow-up compared to participants in the control condition.

The secondary outcome measures for preschoolers include sedentary behaviour and BMI. We hypothesize that preschool participants who receive the intervention will demonstrate lower levels of sedentary behaviour and lower BMI scores at follow-up compared to control participants. Secondary outcome measures also include childcare providers physical activity levels, knowledge, and self-efficacy. It is hypothesized that the childcare providers who participate in the experimental condition will demonstrate greater activity levels, knowledge, and higher self-efficacy than those who are in the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Western Ontarios Health Sciences Research Ethics Board (full board review), 30/10/2014, ref: 105779

Study design

Parallel clustered randomized controlled trial with a single-blinded design (single-centre)

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available.

Health condition(s) or problem(s) studied

An evidence-based health promotion intervention aimed at improving the physical activity levels of preschoolers in centre-based childcare

Interventions

The following is a description of our planned trial interventions (of which will take place over an 8-week period during the spring and summer months):

1. Experimental condition:

Randomly selected childcare centres (i.e., clusters) will be assigned to the experimental condition. Centres will participate in the SPACE study, which entails environmental modifications, staff training, and curriculum changes to their preschooler classrooms; all of which are designed to encourage physical activity participation among preschoolers. The intervention period will last 8 weeks (weekdays only; Monday-Friday), after which the intervention will cease.

The specific components of the intervention will be guided by the steering committee and are discussed below:

(a) Environmental modifications will involve the addition of portable play equipment (for use indoors and outdoors) shown to predict physical activity levels among preschoolers (Bower et al., 2008; Vanderloo et al., 2012). The equipment provided will be available for the full 8-week duration of the intervention, and will be rotated on a daily basis (e.g., on Mondays, tricycles will be added to their typical equipment offerings, on Tuesdays, hula hoops will be provided, etc., in addition to pavement markings that will be added to the outdoor play area). Each participating childcare centre will keep the equipment provided to them.

(b) Physical activity-related staff training will involve lunch time or evening sessions with childcare providers and directors assigned to this condition. Staff training will be led by members of the research team. These sessions, four in total, will provide childcare staff with information regarding:

1. Physical activity recommendations for preschoolers
2. Resources available to improve activity participation in the childcare centre (e.g., Hop, Skip, Munch)
3. The need for shorter bouts of activity
4. The need to incorporate physical activity into their indoor curriculum.

(c) Curriculum modifications will target the outdoor playtime provided to children specifically. Because researchers suggest that preschoolers are the most active during the first 10 minutes of outdoor playtime, rather than affording children two 1-hour outdoor playtime sessions, preschoolers will receive four 30-minute outdoor play periods. This outdoor time will comprise

unstructured free play, including engagement with portable play equipment to facilitate an increase in time dedicated to gross motor activity. Other less fundamental components of the intervention include the use of guest physical activity teachers.

2. Control condition (no treatment)

Childcare centres randomly assigned to the control group will continue their typical daily curriculum and outdoor playtime for the duration of the intervention and follow-up period. Childcare providers and preschoolers will complete the same study instruments as those in the experiment group (with the exception of the section of the Childcare Provider Physical Activity Questionnaire and the focus groups which examine the feasibility of implementing the SPACE intervention). Upon completion of the SPACE program, all centres allocated to this group may opt to receive the intervention training and resources.

All assessments will be administered by trained research staff and completed by participants (preschoolers and childcare providers in each condition) at baseline, post-intervention (i.e., 8 weeks), and 6 and 12 months following the conclusion of the program.

PHASE 1 of the study (September 2014–April 2015) will entail participant recruitment (members of steering committee, preschoolers, and childcare centres), the formation of the steering committee, and the creation of the steering committees terms of reference. During this time, the steering committee will discuss the logistical challenges to implementing the intervention, so that these barriers can be dealt with prior to Phase 2. PHASE 2 (May 2015–September 2016) will focus primarily on delivering the intervention, follow-up periods, and the analysis of pre- and post-intervention data. PHASE 3 will entail the remaining analyses as well as knowledge translation activities and dissemination of study findings.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Physical activity levels, to know if our research program has been effective if we see an increase in minutes of moderate-to-vigorous physical activity and total physical activity (MVPA and TPA, respectively). This outcome will be measured using accelerometers, which have been acknowledged in research as the most favourable tool for assessing young childrens (i.e., 0-5 years) habitual activity patterns (Cliff et al., 2009; Oliver et al., 2007; Pate et al., 2010). Specific to this study, preschoolers physical activity and sedentary behaviours will be measured using Actical accelerometers (MiniMitter, Bend, Oregon). These lightweight omnidirectional motion sensors (which do not record the childrens location) will provide detailed data on the duration (summed into minutes of physical activity), intensity, and frequency of the childrens movements (Van Cauwenberghe et al., 2011) as well as step counts. A 15-second epoch length will be applied to capture the sporadic activity and intermittent periods of rest of the young participants (Cliff et al., 2009; Colley et al., 2010; Pate et al., 2010; Pfeiffer et al., 2006). The Acticals will be secured to the participants right hip using an adjustable neoprene belt and will be programmed to begin collecting activity data on the morning of the first day of data collection. Wear-time of the accelerometers will be recorded in a daily log.

Physical activity assessments using accelerometers will last one week for each classroom during childcare hours; Monday-Friday only, for each of the four assessment points (i.e., baseline, post-intervention, 6- and 12-month follow-up). The 6- and 12-month follow-up time points will allow us to determine the long-term impact of the intervention and to identify if changes in physical activity levels can be maintained.

Secondary outcome measures

The secondary outcome measures for preschoolers include sedentary behaviour (decreased time) and BMI (decreased score). Secondary outcome measures also include childcare providers physical activity levels, knowledge, and self-efficacy.

1. Demographics: Parents of preschoolers will be asked to complete a demographic questionnaire at baseline to gather information regarding potential correlates of preschoolers physical activity (e.g., their preschoolers age, sex, ethnic origin, family income, parent education levels, parent activity levels, as well as the child's physical activity participation outside of childcare [e.g., swimming lessons, soccer]). This tool will also capture parent/guardian physical activity levels along with their height and weight (for BMI calculations). Such data will be entered as predictors of physical activity in our analyses.

2. Anthropometric measures: A number of anthropometric measures will be taken from the children at pre-, post-intervention, and at 6- and 12-month follow-up. These measures are: height (using a Seca 214 'Road Rod' Portable Stadiometer; nearest 0.1 cm); weight (using a Tanita 700-TBF300GS Body Fat Analyzer w/Goal Setter scale; nearest 0.1 kg); and waist circumference (using a measuring tape; nearest 0.1 cm). The data collected will be used to calculate the child's standardized body mass index score (BMI-z). All of these data will be recorded in a separate tracking sheet for each participant.

3. Childcare Provider Physical Activity Questionnaire: This questionnaire, comprising the validated Adapted Godin Leisure Time Physical Activity Questionnaire (Irwin, 2007) along with questions devoted to activity knowledge and practice, will be administered to childcare providers prior to the onset of the intervention to examine their current physical activity levels, knowledge, and practice within their childcare centres. Childcare providers have acknowledged their influence on preschoolers activity levels, as such, it is important to examine their own knowledge and practice (Copeland et al., 2012). This questionnaire will be re-administered post-intervention and at 6- and 12-month follow-up to determine if any changes in their physical activity-related knowledge and behaviours occurred and were sustained after the intervention.

4. Childcare Provider Physical Activity Self-Efficacy Questionnaire: Self-efficacy, an individual's confidence in his/her ability to perform a particular behaviour, represents a major component of social cognitive theory and is arguably one of the most important determinants of behaviour (Bandura, 1989). Childcare providers have noted lack of self-efficacy as a barrier to facilitating physical activity engagement in early learning environments (Copeland et al., 2012; Froelich Chow et al., 2011). A physical activity self-efficacy questionnaire, developed for the purpose of the present study (based on Bandura's Guide for Constructing Self-Efficacy Scales; Bandura, 2006), will be administered both pre- and post-intervention, 6- and 12-month follow-up to assess whether a significant change occurred in providers confidence to engage preschoolers in physical activity while in childcare (as well as whether this change was maintained after the intervention).

5. Quality of Life Questionnaire: The Pediatric Quality of Life Inventory (PedsQL) 4.0 (Varni et al., 1993), a reliable and valid inventory for the preschool population (aged 2-4 years), will be used (Varni et al., 2007). Specifically, the parent report for children of PedsQL 4.0 Generic Core Scales questionnaire will be administered.

6. Child Temperament Questionnaire: Previous research has acknowledged preschoolers temperament as influencing their engagement in physical activity within childcare (Tucker et al., 2011). As such, the Children's Behaviour Questionnaire (CBQ; very short form; Putnam et al., 2006; Rothbart et al., 2001) will be administered. Used with children aged 3 to 7 years old, this tool will be employed to determine temperament across the dimensions of effortful control, surgency/extraversion, and affectivity (all via parent-report).

7. Program Evaluation Survey: Questions regarding the interventions feasibility and acceptability will be asked post-intervention as part of the process evaluation (to ensure we receive feedback from all childcare providers assigned to the experimental condition). This tool will be developed

with the steering committee and pilot-tested with a sample of childcare staff to ensure the appropriateness of questions.

8. Focus Groups with Childcare Providers: Focus groups with childcare providers from the experimental condition will be undertaken to gather their perspectives regarding the appropriateness of the SPACE study, the feasibility of implementation, and suggestions for improvement. These qualitative discussions will allow us to gather rich data regarding the logistical challenges and the strengths and weaknesses of the SPACE study that cannot be captured on a questionnaire. A semi-structured interview guide will be used to conduct four focus groups (anticipating between 20-30 participants in total). All focus groups will be completed at participating childcare centres and will be led by an experienced moderator and co-moderator. If after four focus groups saturation has not been reached, additional focus groups will be completed.

Overall study start date

01/01/2015

Completion date

31/08/2017

Eligibility

Key inclusion criteria

Childcare centres will be invited to participate if they have one or more full-day preschool-aged classrooms at their facility. A sample of male and female preschoolers (aged 2.5-4 years) will be drawn from these centre-based childcare facilities in London Ontario.

Inclusion criteria for childcare centres include:

1. Must provide childcare in London, Ontario from a centre-based facility
2. Must have at least one preschool classroom
3. Must have childcare providers in the preschool classroom who are willing to participate
4. Must speak/read English

Inclusion criteria for pre-schooler participants include:

1. Must be enrolled in the preschool classroom of a participating centre
2. Must be between the ages of 2.5 and 4 years of age at baseline
3. Must be expected to remain in childcare for the next 12 months
4. Must have a parent/guardian that can read and write English
5. Must speak and understand English
6. Must receive parental consent

Participant type(s)

Patient

Age group

Child

Lower age limit

2.5 Years

Upper age limit

4 Years

Sex

Both

Target number of participants

(80 over the age of 18 years, 348 under the age of 18 years)

Key exclusion criteria

Exclusion criteria for childcare centres include:

1. Not located in London, Ontario
2. Do not have a preschool classroom
3. Do not have childcare providers in the classroom who are willing to participate
4. Not an English-speaking facility.

Inclusion criteria for pre-schooler participants include:

1. Not between the ages of 2.5 and 4 years at baseline
2. Not expected to remain in childcare for the next 12 months
3. Not enrolled in a preschool classroom of a participating centre
4. Do not speak English
5. Parent/guardian does not read/write in English

Date of first enrolment

01/01/2015

Date of final enrolment

31/08/2017

Locations**Countries of recruitment**

Canada

Study participating centre

University of Western Ontario

London

Canada

N6G 1H1

Sponsor information**Organisation**

Canadian Institutes of Health Research (Canada)

Sponsor details

160 Elgin Street, 9th Floor
Address Locator 4809A
Ottawa
Canada
K1A 0W9

Sponsor type

Government

ROR

<https://ror.org/01gavpb45>

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research - Grant Award # R4368A10; ROLA # 0000033871

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Publication and dissemination plan

1. Planned publication of a paper based on the primary outcome measure, with other papers focusing on the secondary outcome measures to follow
2. Plans to engage in various knowledge translation activities with study participants and community stakeholders

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/02/2016		Yes	No
Results article	results	07/09/2017		Yes	No
Results article	results	01/05/2018		Yes	No
Results article	results	01/12/2018		Yes	No