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Activity Begins in Childhood - a study to inspire healthy active behaviour in preschoolers

Submission date	**Recruitment status**	[X] Prospectively registered
11/12/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2017	Other	

Plain English summary of protocol

Background and study aims
Physical activity (PA) is an important part of healthy childhood development. Typical Canadian preschoolers spend a great deal of time in daycare, environments which can have a very strong influence on their levels of daily movement. PA levels are low in these settings, with kids spending lots of time sitting. This study will test the ability of daycare providers to incorporate PA into the daily routine when they are provided with appropriate training and tools to do so. This study will also look at whether engaging the parents and asking them to encourage PA at home provides additional benefit. This will be the first study in Canada attempting to modify PA behaviour in licensed daycare centres and looking at parental involvement. This is important because inactivity can lead to the development of chronic diseases like obesity and heart disease and prevention must start early.

Who can participate?
Preschool children between the ages of 3-5 years who are enrolled full-time in a registered daycare in Canada's National Capital Region. Daycare centers must have at least 10 children enrolled and they must be enrolled for at least 6 months.

What does the study involve?
Participating daycare providers are randomly allocated to one of three groups. One group of daycare providers is trained to increase all types of PA and reduce time spent sitting around. Another group of providers has the same training but parents of kids in their care also receive training on how to incorporate PA into their child's daily routine. The last group of daycares offers their typical curriculum. Study staff visit daycare centers and take measurements from each consenting child. PA is measured using a device called an accelerometer (like a pedometer). Each child wears this device for 1 week at a time. Height, weight and body composition are also measured. Skills such as running, hopping, jumping and ball control are also assessed. All measurements are done at the beginning of the study and 3 and 6 months later. Consenting parents/guardians are asked to fill out questionnaires.

What are the possible benefits and risks of participating?
This study could help children be more physically active, assist them in maintaining a healthy body weight and subsequently reduce the risk of getting heart disease. There are no major

health risks in this study. It is possible that some children may feel a bit of stiffness or muscle soreness when they increase their physical activity.

Where is the study run from?
Daycare centers in Canada's National Capital Region

When is the study starting and how long is it expected to run for?
January 2013 to March 2014

Who is funding the study?
Canadian Institute of Health Research

Who are the main contacts?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOP 123326

Study information

Scientific Title
Activity Begins in Childhood - a randomized controlled trial to inspire healthy active behaviour in preschoolers

Acronym
ABC

Study objectives
The primary hypothesis is to evaluate the efficacy of the ABC intervention protocol delivered in licensed daycare settings alone (intervention- DC) versus standard daycare curriculum (control-CON) to increase preschoolers overall physical activity (PA) levels and specifically time spent in moderate to vigorous PA (MVPA).

The secondary hypotheses are to:
1. To evaluate the potential additive contribution of a parent/guardian-driven home PA - promotion in addition to the daycare-provider facilitated intervention on its own (i.e. intervention- DC + HOME)
2. To evaluate the efficacy of the ABC intervention arms to decrease the amount of time spent in sedentary behaviour
3. To evaluate the effects of the ABC intervention arms on fundamental and gross motor skills in preschoolers attending daycare
4. To evaluate the effects of the ABC intervention arms on preschool childrens anthropometrics, such as height, weight, body mass index, lean body mass, fat mass, and percent body fat
5. To assess the effects of the ABC intervention on daycare providers attitudes, control beliefs, perceived competency and intentions toward incorporating PA into the daycare curriculum, and examine whether these social-cognitive variables impact PA in children

Ethics approval required
Old ethics approval format

Ethics approval(s)
CHEO Research Ethics Board, 24/11/2012, ref: 12/158X

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Promoting healthy active behaviour in preschoolers for prevention of downstream chronic disease

Interventions

Intervention 1: ABC intervention protocol delivered in licensed daycare settings alone (intervention- DC).
Intervention 2: ABC intervention protocol delivered in licensed daycare settings + parent /guardian home component (intervention- DC + HOME).
Comparator: Standard daycare curriculum (control- CON). This group will receive all ABC programming and related resources after completion of the study.

The ABC intervention will last approximately 6 months, with baseline assessment prior to ABC implementation and follow-up assessments at 3 and 6 months.

After assessing if daycare and parent/guardian environments (DC + HOME group only) are suitable to administer ABC program, daycare providers will learn ABC program by attending two 3-hour workshops provided by a Master Trainer and parents/guardians will learn ABC intervention by viewing two 45-minute webinars. To ensure ABC understanding and compliance, 1-hour bi-weekly pep sessions will take place at the daycares by a Master Trainer and bi-weekly post cards will be mailed to the parents/guardians. Workshop/webinar related questionnaires will also be administered.

All consenting parents/guardians from each group will be asked to complete socio-demographic and quality of life questionnaires. As well, mothers of participating children will be asked to fill out a pregnancy and lifestyle questionnaire.

All consenting children from each group:
1. Will be expected to wear an accelerometer for 1 week at a time to measure physical activity levels
2. Will have their fundamental gross motor development skills tested; and
3. Will have their anthropometric and body composition taken

Intervention Type

Behavioural

Primary outcome measure

Physical activity will be measured using an Actical accelerometer which is an omni-directional sensor that measures the occurrence and intensity of motion. Accelerometers will be worn on three separate time points: baseline, 3 and 6 months post workshop intervention. Activity data will be summarized and reported as activity minutes per hour, computed from tallied counts for each activity level average across wear time.

Secondary outcome measures

1. Fundamental/gross motor skills: The test of Gross Motor Development -2 (TGMD-2) will be used to evaluate the effects of the intervention on children's movement skills. The TGMD-2 is a validated standardized norm-referenced measure of 12 common gross motor skills of children ages 3 to 11 years. This test will be conducted at baseline, 3 and 6 months post intervention.
2. Anthropometry and body composition: Height, weight, body mass index, lean body mass, fat mass, and percent body fat will be measured. Height will be measured using a wall-mounted stadiometer (Seca GmBH & Co Kg, Hamburg Germany). Body weight will be assessed using a

standard weight scale. Body Mass Index (kg/m2) and body composition (lean body mass, fat mass, percent body fat) will be assessed using a RJL Quantum IV bioelectrical impedance analyzer system (RJL Quantum IV, RJL Systems, Michigan, 48035). These assessment will be conducted at baseline, 3 and 6 months post intervention.
3. Questionnaire data: Daycare providers/parents/guardians personal beliefs and self-efficacy towards incorporating a physical activity program into the regular daycare programming or home environment will be assessed using a short questionnaire before and after workshops /webinars. Daycare/home environments will be assessed at baseline, 3 and 6 months post intervention. Quality of life will be assessed using the pediatric quality of life (PedsQL) questionnaire at baseline, 3 and 6 months post intervention. Socio-demographic and pregnancy and lifestyle information will be collected from parents/guardian at baseline.

Overall study start date
28/01/2013

Completion date
29/03/2014

Eligibility

Key inclusion criteria
1. Male or female
2. English or French
3. Preschool children between age 3-5 years
4. Preschool children enrolled full-time in licensed daycares in Canada's National Capital Region
5. Preschool children enrolled in daycares for the duration of this 6-month study
6. At least 10 or more children enrolled in the preschool program

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
18 daycares (9 daycares in Winter cohort and 9 daycares in Summer/Fall cohort) and 306 children (153 per cohort)

Key exclusion criteria
1. Parents/guardians of children that do not sign informed consent
2. Inability of children/parents/guardians to communicate in English or French

Date of first enrolment
28/01/2013

Date of final enrolment
29/03/2014

Locations

Countries of recruitment
Canada

Study participating centre
Children's Hospital of Eastern Ontario Research Institute
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Sponsor information

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Sponsor type
Government

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ROR
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Funder(s)

Funder type

Government

Funder Name
Canadian Institutes of Health Research

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/07/2014		Yes	No
Results article	results	01/09/2017		Yes	No