

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

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| <b>Submission date</b><br>11/12/2012   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>21/12/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>03/07/2017       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data   |

## 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?

Kasey Parker

kparker@cheo.on.ca

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Kristi Adamo

**Contact details**

Childrens Hospital of Eastern Ontario Research Institute

Healthy Active Living and Obesity Research

401 Smyth Rd, Rm 215

Ottawa

Canada

K1H 8L1

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kadamo@cheo.on.ca

## 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/m<sup>2</sup>) 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

Ottawa

Canada

K1H 8L1

## **Sponsor information**

**Organisation**

Canadian Institute of Health Research (Canada)

**Sponsor details**

160 Elgin Street

9th Floor, Address Locator 4809A

Ottawa

Canada

K1A 0W9

+1 (0)613 941 2672

RC-Grants@cihr-irsc.gc.ca

**Sponsor type**

Government

**Website**

<http://www.cihr-irsc.gc.ca>

**ROR**

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

## **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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 29/07/2014   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/09/2017   |            | Yes            | No              |