

## CASE STUDY

### **Effect of and intervention designed to increase physical activity, reduce sedentary behaviour, and increase children's consumption of fruit and vegetables: Active for Life School Year-based cluster randomised controlled trial.**

#### **CATEGORISING**

**Kind**

Research project involving living people

**Type**

Clinical trial

**Subtype**

Clinical trials with interventions that are neither a therapeutic product nor a transplant product, nor a transplant ("other clinical trial")

#### **BACKGROUND**

This study investigated the effectiveness of a school-based intervention to increase physical activity, reduce sedentary behaviour, and increase children's consumption of fruit and vegetables.

#### **METHODS**

Participants were children in school year 4 (age 8-9 years) at recruitment and baseline assessment, and in year 5 during the intervention and follow-up assessments. Schools were randomly allocated to receive either the Active for Life intervention or standard teaching. The Active for Life intervention provided teacher training, lessons, and child-parent interactive homework plans, the materials required for lessons and homework, and written materials for school newsletters and parents. Schools in the control group received standard teaching. Pre-specified primary outcomes were accelerometer assessed minutes of moderate to vigorous physical activity per day, accelerometer assessed minutes of sedentary behaviour per day, and reported daily consumption of servings of fruit and vegetables.

#### **QUESTIONS OF THE CATEGORISER**

**Does the research project come under the scope of application of the Human Research Act?**

Yes

**BECAUSE**

This project was based on a study protocol that defined the exact procedures that were used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). It investigated the effectiveness of a school-based intervention to increase physical activity, reduce sedentary behaviour, and increase children's ("persons") consumption of fruit and vegetables ("research concerning function of the human body").

**Is the research project a project involving living persons?**

Yes

**BECAUSE**

Primary school children ("persons") participated in this study.

**Is the research project a clinical trial?**

Yes

**BECAUSE**

The investigator randomly assigned ("prospectively assigned") primary schools to receive either standard teaching or the Active for Life intervention to increase physical activity, reduce sedentary behaviour, and increase children's consumption of fruit and vegetables. The study assessed the between-group difference in minutes of moderate to vigorous physical activity per day, minutes of sedentary behaviour per day, and reported daily consumption of servings of fruit and vegetables ("to investigate its effect on health").

**Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?**

No

**BECAUSE**

**Does the trial involve investigating a medical device (in vitro diagnostics excluded) or any other device as defined in Article 1 of the Medical Devices Ordinance of July 1, 2020?**

No

**BECAUSE**

**Does the trial investigate an intervention that is neither a therapeutic product nor a transplant product, nor a product according to Art. 2a para. 2 Therapeutic Products Act (TPA) (Status from May 26, 2021), nor a transplant?**

Yes

**BECAUSE**

The study asked if the Active for Life intervention increased physical activity, reduced sedentary behaviour, and increased children's fruit and vegetable more than standard teaching did. A teaching intervention is not a medicinal product or device, a transplant or transplant product, a gene therapy, or a pathogenic organism.

**Does the trial investigate a transplant product?**

No

**BECAUSE**

**Does the trial investigate gene therapy or a pathogenic organism?**

No

**BECAUSE**

**Does the intervention involve minimal risks and stress for the participating persons?**

Yes

**BECAUSE**

The study asked if the Active for Life intervention increased physical activity, reduced sedentary behaviour, and increased children's fruit and vegetable more than standard teaching did. Teaching interventions do not create more than minimal risk or stress to participants.