kofam

Koordinationsstelle Forschung am Menschen

BEISPIELSTUDIE

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.

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art

Unterart
Klinischer Versuch mit Interventionen, die weder ein Heilmittel oder ein Transplantatprodukt noch eine Transplantation sind ("übriger klinischer Versuch")

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.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

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").

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

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

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Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Ja

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").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?
Nein

BECAUSE

Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?
Nein

BECAUSE

Wird in der Studie eine Intervention untersucht, die weder ein Heilmittel oder ein Transplantatprodukt, noch ein Produkt nach Art. 2a Abs. 2 Heilmittelgesetz (HMG) (Stand ab 26. Mai 2021) oder eine Transplantation ist?
Ja

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.

Wird in der Studie eine Gentherapie oder ein pathogener Organismus untersucht?
Nein

BECAUSE

Ist die Intervention mit höchstens minimalen Risiken und Belastungen für die Teilnehmenden verbunden?
Ja

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.

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