# BOOSTH: promoting physical activity in primary schools in combination with serious gaming

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The primary aim of this study is to examine prospectively the effects of BOOSTH on moderate to vigorous PA (MVPA) in primary school children (5th to 7th grade).

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeOther conditionStudy typeInterventional

# **Summary**

#### ID

NL-OMON46520

Source

ToetsingOnline

**Brief title** 

We BOOSTH Limburg

## **Condition**

Other condition

## **Synonym**

N.A.

#### **Health condition**

reguliere populatie kinderen

## **Research involving**

Human

# **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Maastricht

Source(s) of monetary or material Support: Provincie Limburg

## Intervention

Keyword: Physical activity, Primary school, Serious gaming

#### **Outcome measures**

## **Primary outcome**

The primary endpoint is moderate to vigorous physical activity (min/day) as measured with the Actigraph G3X+ accelerometer.

# **Secondary outcome**

- · Objectively measured step count via the BOOSTH activity tracker
- · Subjectively measured PA behaviour via the BAECKE questionnaire
- · Motivation towards PA as measured with the BREQ questionnaire
- · Anthropometry as measured via BMI-Z score (length and weight measurements) and weight circumference
- · Screen time by asking questions about amount of hours watching T.V or playing console games/ computer
- · Quality of life as measured with the Kidscreen questionnaire and the PedsQL questionnaire
- Cardiovascular alterations (i.e. blood pressure, pulse wave felocity and retinal image)

Aerobic finess as measured with the 20m shuttle run test

- Process evaluation about the methods and implementation
- · Parenting style as measured with the parenting practices questionnaire and
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the CGPQ questionnaire

- The evolution of BMI z-score during childhood on PA behavior and cardiovascular health parameters-
- Policy regarding PA promotion and lessons

# **Study description**

# **Background summary**

Physical inactivity is considered to be one of the ten principal risk factors for death worldwide. Children need to perform one hour of daily moderate-to-vigorous intensity physical activity whereof at least twice a week these activities are of vigorous intensity. In 2010, the percentage of 4-11 year-old normoactive Dutch children was approximately 20%. Previous interventions that aimed to increase childhood physical activity produced small to negligible effects. One possible explanation is that individuals were not intrinsically motivated towards physical activity during the intervention period. Children spend a substantial amount of their time behind a game consule. There are a number of applications that motivate increase in physical activity in a fun way through engaging individuals in games that mix real and computing worlds. These games became known as serious games. In this study we want to investigate if BOOSTH can stimulate physical activity behaviour in primary school children (grades 5th to 7th).

## Study objective

The primary aim of this study is to examine prospectively the effects of BOOSTH on moderate to vigorous PA (MVPA) in primary school children (5th to 7th grade).

## Study design

The study design will be a randomized controlled trial regarding a physical activity intervention. A 1:1 randomization will be applied with intervention schools and matched control schools. The intervention school will recieve the BOOSTH intervention. The intervention duration is 6 months. Measurements will be performed at baseline and 3, 6 and 12 months after the start.

#### Intervention

The investigational treatment is the BOOSTH physical activity intervention.

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Children in the intervention school will start with the BOOSTH intervention on top of the regular PE lessons. The child will receive the BOOSTH activity tracker. The child (under supervision of the teacher) needs to download the BOOSTH sync app and the BOOSTH game app. Therefore it is important that the child or their parents has a device with Bluetooth. We will create a login account for each child. After installing the apps, the activity tracker measures step counts, which are translated into activity points. These activity points will be used to unlock levels in the BOOSTH game app. The child synchronizes their activity points, with Bluetooth connection, in the BOOSTH sync app and immediately the child can open the BOOSTH game app to play a level in the game. The child needs seven green lights (corresponding to 30 minutes of performed physical activity) to unlock a level in the game. The first four levels are for free, to gain the interests of the child, but thereafter the child needs to be physically active to unlock the rest of the levels in the game.

The intervention school receives the BOOSTH intervention that involves strategies to promote physical activity throughout the day.

# Study burden and risks

There are no associated risks in this study and the intervention is non-invasive. We expect that the intervention can have beneficial effects for the intervention population such as meeting the norm of physical activity, an intrinsic motivation towards physical activity and an improved health status. Measurements will be done four times (at baseline and 3,6 and 12months after the start). Measurements will be performed during regular school time. Children in the intervention school are allowed to keep BOOSTH after the intervention period. Children in the control school will receive BOOSTH as a compensation for their participation at the end the study.

# **Contacts**

#### **Public**

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#### Scientific

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# **Trial sites**

## **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years) Children (2-11 years)

## Inclusion criteria

Inclusion criteria for the school:

- · The school needs to be located in the Limburg- region of the Netherlands.
- · At least 25 students enrolled in grades 5, 6 and 7; Inclusion criteria for the subject:
- · Boys and girls, in 5th-7th grade (age range 7-13 years) (at time of inclusion)
- · Informed consent signed by both parents and children aged 12 years and older.
- · The child or their parent has a technological device (i.e. tablet, iPad) with Bluetooth option (to synchronize activity points (and playing the BOOSTH game));Inclusion criteria for the parents:
- Informed consent signed by both parents

## **Exclusion criteria**

Exclusion criteria for the school:

The school has plans to merge with another school or plans to relocate in the upcoming year.; Exclusion criteria for the subject:

Children who are wheelchair dependent.; Exclusion criteria for the parents: N.A

# Study design

# **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Other

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-09-2018

Enrollment: 1230

Type: Actual

# **Ethics review**

Approved WMO

Date: 07-03-2018

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 03-10-2018
Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

Register ID

CCMO NL64324.068.17