

# Run2gether for health!

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To evaluate if the program \*Run2gether\* can change physical behavior in children with obesity and/or diabetes, and thereby increase physical fitness level and insulin sensitivity en reduce body weight. An additional goal for children with diabetes,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33192

### Source

ToetsingOnline

### Brief title

Run2gether

### Condition

- Other condition
- Diabetic complications
- Diabetic complications

### Synonym

Children with diabetes and/or obesitas

### Health condition

secundaire preventie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** ZonMw, sport keten die de sportschoenen gedeeltelijk sponsort

## Intervention

**Keyword:** Children, Diabetes, endurance training, obesitas

## Outcome measures

### Primary outcome

- \* Percentage of finishers and active participation in the programm ;
- \* Physical fitness, tested with the Bruce protocol on a treadmill;
- \* Anthropometry: BMI and waist circumference;
- \* Insulin sensitivity: HbA1C and insulin/carbohydrate ratio.

### Secondary outcome

- \* Level of activity measured with \*activity diary and activitymonitor\*. BMI and waist circumference of the elder;
- \* Diabetes management: Fluctuations in blood glucose levels;
- \* Blood vessel characteristics and endothelial function

### Evaluation of the process

A questionnaire with questions about the contentment of both child and elder about the program, will be conducted at the end of the program. Specific feedback towards possible improvements about the program will be request. On a website available for all parents, communication about possible incidents and problems will be possible. With all information gathered, analysis about strong and weak points of the program will be made, with which it is possible to

redesign the program for future events. These analysis will be conducted by all participants and professionals who participated in this project.

Main topics of this evaluation will be:

- A report of the amount of contacts with the diabetes nurse . In addition more specific questions will be asked about the quality and contentment of the participants with the advice and care provided by this nurse;
- The amount of occasions that participants visited the website;
- The amount of bilateral contact between the participants;
- How much time needed to coach all participants, to make cost-effectiveness analyses possible;
- Evaluation about analogue events in future, supported by government funding, insurance companies, employees and sport clubs, to make sure that appropriate future funding is not an issue anymore.

## Study description

### Background summary

The prevalence of diabetes in children in the Netherlands is approximately 5000 individuals, with an increase of 250 patients every year. In addition, the prevalence of childhood obesity is increasing enormously in the Netherlands. Also these individuals are already early in lifetime prone to be at risk for developing diabetes. Children in the western world are becoming less physical active, while it is especially important for these two groups to be physical active on a regular base. An active lifestyle has got important benefits for good health. Main goals for these two groups are to increase sensitivity of insulin and to reduce the risks for cardiovascular diseases on the mid-long term. Because parental influence are of great importance during early lifespan, this project aims on a intervention with a child supported by the active participation by one of the parents. Because parents contribute to a large extend to the education and development of a child and because physical inactivity is often based on a family culture, parental support is very

important for a growing child. By providing a program that aims at both child and elder, parents retain their roles as important determinants of risk and protective behavior, but this time in a good healthy manner.

## **Study objective**

To evaluate if the program \*Run2gether\* can change physical behavior in children with obesity and/or diabetes, and thereby increase physical fitness level and insulin sensitivity and reduce body weight. An additional goal for children with diabetes, is to improve their diabetes management. Besides a risk profile for possible future cardiovascular problems is made, by assessing characteristics of the blood vessels and the endothelial function.

Because this is a pilot-oriented study, main goals are to test how many participants are able to finish the 6 months of training and to measure the effectiveness of the intervention. In addition, the program is evaluated afterwards and adjusted if necessary. We consider the program as a success, if at least 70% of the participants are able to accomplish the 6 months of training. We assume that long-term lifestyle changes are possible, if the participants are able to conduct our 6 months of training. To be successful, our intervention must be also proven effective on body characteristics and physical fitness.

## **Study design**

What is the effect of the exercise program on children with diabetes and/or obesity with active parental support on:

- \* Percentage finishers after the 6 months of training;
- \* Physical fitness, activity level, BMI, waist circumference and insulin sensitivity.

This pilot study will be conducted as a pre-post design with a convenient cohort, with one baseline measurement at start and one measurement after finishing the 6 months program.

## **Intervention**

The intervention consists of a workshop, a 6 months training period, online feedback and a final event as a reward.

The program will kick off with a workshop in which the importance of good nutrition will be explained, along with the role of insulin and the effect on the blood sugar levels. Next, exercise capacity for the participating children is tested. Based on these results, children will be divided in different training groups. The training program will be conducted both under supervision in groups and on an individual base (child and parent). Group lessons are performed once a week, with a decreasing frequency in time and an increasing occurrence of individual training sessions following a prescribed training schedule. Children will report their results in a personal online web-dossier,

which is accessible for child, parents, investigator and the diabetes nurse. The diabetes nurse will be available for children to ask questions about their diabetes management in relationship to sport.

## **Study burden and risks**

This program is aimed at healthy changes in behavior towards physical activity, to provide participants with opportunities to create a better medical condition and to provide important tools and information about secondary prevention of different kind of diseases. The minimal risks regarding this program are less significant than possible improvements of healthiness of the participants. With this program, promising long-term changes of the physical condition are possible.

## **Contacts**

### **Public**

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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

Both groups

- \* Aged 8-12 years
- \* Signed informed consent
- \* participation of 1 parent guaranteed

Obesity/overweight

- \* Proposed BMI-values in relationship to age as stated by Cole et al. (Ref = attachment C1)
- diabetes mellitus type 1
- \* Diagnosed with diabetes mellitus type 1

## Exclusion criteria

- \* Mental retardation
- \* Contraindication for physical activity
- \* Contraindication for running

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-12-2009
Enrollment:	60
Type:	Actual

## Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 25-11-2009

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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

CCMO

### ID

NL29164.091.09