

A health tool kit: primary prevention of obesity of preschoolers - the fit von klein auf randomised study in Lower Saxony, Germany

Submission date

29/05/2009

Recruitment status

No longer recruiting

Registration date

15/07/2009

Overall study status

Completed

Last Edited

15/07/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.fitvonkleinauf.de>

Contact information

Type(s)

Scientific

Contact name

Prof Thomas Danne

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

4148

Study information

Scientific Title

Primary prevention of obesity of preschoolers in Lower Saxony, Germany: the Fit von klein auf single-centre, randomised, cross-over, longitudinal, prospective intervention study

Acronym

KICK

Study objectives

To study if primary prevention of obesity in preschoolers is feasible already in four year olds with a health tool kit focussing on physical activity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission der Medizinischen Hochschule Hannover approved on the 7th June 2006 (ref: 4148)

Study design

Single centre randomised cross-over longitudinal prospective intervention study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Paediatric obesity

Interventions

Intervention duration: 12 months

Intervention measures:

1. Health tool kit "Fit von klein auf" (physical activity, nutrition, stress management)
2. Record card of physical exercises for care givers in the kindergarden
3. "Physical Activity Protocol"
4. Parental information sessions (psychology and nutrition)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in body mass index (BMI) standardised for gender and age, measured annually.

Secondary outcome measures

1. Body measures: height, weight, waist, hip and abdomen circumferences
2. Health related quality of life: KINDL-Kiddy (4 - 7 years) (interview and questionnaire for parents)
3. Motor performance: MOT 4 - 6
4. "Physical Activity Protocol" of kindergardens

Measured annually.

Overall study start date

01/07/2006

Completion date

30/06/2010

Eligibility**Key inclusion criteria**

1. Kindergartens selected on the basis of representativity for Lower Saxony
2. Boys and girls with birth date from 1st July 2001 until 31st December 2002
3. Informed consent of parents

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

900 children

Key exclusion criteria

1. Lack of consent
2. Physically and mentally handicapped children
3. Planned relocation during the study period

Date of first enrolment

01/07/2006

Date of final enrolment

30/06/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Kinderkrankenhaus auf der Bult

Hannover

Germany

30173

Sponsor information**Organisation**

BKK Landesverband Niedersachsen/Bremen (Germany)

Sponsor details

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Sponsor type

Government

Website

<http://www.bkk-ni-hb.de/>

Funder(s)

Funder type

Government

Funder Name

BKK Landesverband Niedersachsen/Bremen (Germany) - health insurance company (<http://www.bkk-ni-hb.de/>)

Funder Name

National Action Forum for Diabetes Mellitus (Nationales Aktionsforum Diabetes Mellitus [NAFDM]) (Germany) (<http://www.nafdm.de/>)

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