Actions to reduce sedentary time in parents and their young children

Submission date 16/09/2011	Recruitment status No longer recruiting	Prospectively registered	
		[X] Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
30/11/2011		[X] Results	
Last Edited 20/12/2016	Condition category Mental and Behavioural Disorders	Individual participant data	

Plain English summary of protocol

Background and study aims

There is enough evidence showing that we should be more active. This study examines how personalised counselling (including a half an hour lecture followed by face-to-face discussions with the researchers) can reduce sedentary time, and what impact this will have on health.

Who can participate?

The study participants are recruited via daycare centres and primary schools in the Jyväskylä region in Finland. Eligible participants are parents of 3-8 year old children having an occupation where they sit more than 50% of their work time. The adults are to be healthy without chronic metabolic or musculoskeletal diseases. The children should be in all-day daycare and should not have developmental or other disorders delaying motor development.

What does the study involve?

The participants are randomly allocated to one of two groups: one receiving personalised counselling at the beginning of the study and the other receiving the counselling at the end of the study. During counselling the parents commit themselves to spending less time in a sitting position and to increasing physical activity during work and leisure time for one year. During leisure time the parents are guided to ensure that children are more active. The participants undergo various tests 5 times a year including physical activity measurements and blood sampling. Physical activity level and motor skills will be measured in children.

What are the possible benefits and risks of participating?

Adult participants will receive information on their health, daily physical activity, body composition, muscle strength and diet. Feedback of childrens physical activity and motor skills will be given. All the subjects will receive tips for increasing physical activity in everyday life. The tests include venous blood samples that sometimes can cause bruising inside of the elbow. Dual energy x-ray absorptiometry is used three times during the study to measure body composition. This procedure results in a radiation dose that corresponds to the amount people typically are exposed to during 2.4 hours in Finland. Heart rate will be measured by placing two electrodes on the chest. Electrodes are also used to measure thigh muscle electrical activity. The

electrodes contain a gel that may cause skin irritation or allergic reaction (this is rare). Physical activity measurements include maximal contractions that are done after a warm-up. These tests may cause muscle or tendon strains but the risk is no greater than in normal exercise at the gym.

Where is the study run from?

The study is conducted at the Department of Biology of Physical Activity, University of Jyväskylä, Finland

When is the study starting and how long is it expected to run for? From April 2011 to December 2014

Who is funding the study? Finnish Ministry of Education and Culture

Who is the main contact? Prof. Taija Juutinen Finni taija.finni@jyu.fi

Study website https://staff.jyu.fi/Members/finni/InPact

Contact information

Type(s) Scientific

Contact name Prof Taija Juutinen Finni

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Tailored Counseling to Increase non-exercise Physical Activity in adults with a sedentary job and in their young children: A year-long randomized controlled trial

Acronym

InPACT

Study objectives

1. Counseling increases physical activity and decreases muscle inactivity time during workday and leisure time in adults

2. Counseling induces behavioral changes that last over 6 months maintenance period 3. There is transfer effect of parental counseling so that also the childrens physical activity increases

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of Central Finland Health Care District approved on 25 March 2011 (Dnro 6U /2011)

Study design Single-center randomized controlled trial

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Physical inactivity and sedentary work

Interventions

Intervention group receives tailored counseling with a half-an-hour common lecture followed by face-to-face discussion with the researcher that results in signing the agreement of the behavioral changes. The intervention is reinforced in the first six months by phone calls and e-mails and the following six months are maintenance period.

Control group undergoes the same assessments but receives no tailored counseling.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. From children, physical activity level is assessed five times a year using triaxial accelerometers that are worn on the waist for one week during waking hours

2. From adults accelerometer data is also assessed 5*1 week during the year

2.1. From adults also heart rate and thigh muscle electrical activity are measured for shorter periods of time

Secondary outcome measures

1. From adults:

1.1. Venous blood samples

- 1.2. Body composition
- 1.3. 12-month physical activity questionnaire
- 1.4. RAND-36

1.5. Work Ability Index and Occupational Stress Questionnaire (Finnish Institute of Occupational Health)

2. Children's fundamental motor skills are evaluated three times during the year

Overall study start date

01/04/2011

Completion date

15/12/2014

Eligibility

Key inclusion criteria

- 1. Healthy men and women with children 3-8 years old
- 2. Having work where they sit more than 50% of their work time
- 3. Children in all-day daycare and at least 10 days per month

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants

200 men and women and their children aged 3-8 years

Key exclusion criteria

1. Self-reported chronic, long-term musculoskeletal disease or progressive neurological disease, diagnosed cardiovascular or metabolic disease with regular medication

2. Families with pregnant mother at baseline and body mass index (BMI) > 35

3. Children with a developmental disorder or other disorders delaying motor development

Date of first enrolment 01/04/2011

Date of final enrolment 15/12/2014

Locations

Countries of recruitment Finland

Study participating centre PO Box 35 Jyväskylä Finland 40014

Sponsor information

Organisation University of Jyväskylä (Finland)

Sponsor details Neuromuscular Reserach Center Department of Biology of Physical Activity PO Box 35 Jyväskylä Finland 40014

Sponsor type University/education

ROR https://ror.org/05n3dz165

Funder(s)

Funder type Government

Funder Name Ministry of Education and Culture (Finland) (42/627/2010)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/12/2011		Yes	No
Results article	results	01/01/2014		Yes	Νο
Results article	results	01/04/2014		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	26/10/2015		Yes	No
Results article	results	01/11/2016		Yes	No