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Body and future health

Submission date	Recruitment status	[ ] Prospectively registered
28/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/05/2011	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Body and future health: a single centre, single blind, four arm, randomised controlled study

Study objectives
Body fat percentage and metabolic and mental stress can be reduced using a mini-intervention which includes diet and physical activity guidelines and which the participants can carry out using web-based guidelines and with minimal help from specialists. These effects are stronger when the participants use additional web-based exercise coaching program to increase physical activity and improve fitness, or when the participants use additional whey protein drinks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethics Committee of the Central Finland Health Care District on 18th February 2011 (Dnro 3U/2011)

Study design
Single centre single blind four arm randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Obesity

Interventions
The duration of the intervention per participant is 6 months. The participants (goal 160 participants) will be randomised to four groups (40 per group), which are
1. Control group (no lifestyle changes recommended) ,
2. Mini-intervention (internet-based recommendations related to changes in diet and increases in physical activity)
3. Mini-intervention plus web-based coaching program to increase physical activity and improve fitness
4. Mini-intervention plus whey protein product taken 6 dL each day

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Fat percentage measured by Dual Energy X-Ray Absorptiometry (DEXA) at baseline, at 3 and at 6 months follow-up
2. Daily stress level measured by heart rate monitor (based on heart rate variability and determined differently for day and night).

Secondary outcome measures
1. Changes in cardio-metabolic risk factors
2. Changes in diet, physical activity and sleep

Measured from baseline to 6 months follow up.

All questionnaires (including readiness to change, self-efficacy, and acceptance and action questionnaires) and other variables are also analysed to find out which factors predict best adherence and responses to the interventions.

Overall study start date
01/04/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. The participants are healthy volunteers (young adults, 25-40 years) with a body mass index (BMI) of 25-35 kg/m2 and waist circumference over 94 cm (for men) and over 80 cm (for women)
2. Who do not participate regularly in physical activity
3. Who have access to internet at home
4. Who either regularly use milk or are ready to start using milk products (without lactose)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
The goal for the number of participants to be randomised is 160, 40 per each arm.

Key exclusion criteria
1. Chronic disease with regular medication
2. Pregnancy or intention to become pregnant during next 12 months or less than 12 months from latest parturition

3. Milk allergy
4. Eating disorder
5. Regular participation in physical activity (of over 20 min duration more than twice a week) 6. Current smoker or regular smoking during past three months, heavy use of alcohol, use of drugs
7. Over 5 kg weight change during past 6 months
8. Abnormal electrocardiogram

Date of first enrolment
01/04/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Finland

Study participating centre
Department of Health Sciences
Jyväskylä
Finland
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Sponsor information

Organisation
University of Jyvaskyla (Finland)

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Sponsor type
University/education

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Research council

Funder Name
Finnish Funding Agency for Technology and Innovation (TEKES) (Finland)

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