

Body and future health

Submission date 28/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/05/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
FI-40014

Sponsor information

Organisation
University of Jyväskylä (Finland)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration