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Diet and exercise interventions improve health markers in individuals with an increased risk of disease

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
18/04/2018

Overall study status
Completed

Last Edited
18/04/2018

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

Background and study aims
The purpose of this study was to examine whether lifestyle patterns mimicking those of our ancestors, such as food and movement patterns, would influence health markers for those individuals at an increased risk for disease.

Who can participate?
Individuals between the ages of 18-65 years, with an increased risk of cardiovascular and metabolic disease (i.e. Metabolic Syndrome) were recruited for this study.

What does the study involve?
Subjects consumed a Paleolithic diet for 4 weeks with sedentary activity, returned to their habitual dietary patterns and sedentary activity for 4 weeks, and then consumed the Paleolithic diet with high intensity exercise for 4 weeks.

What are the possible benefits and risks of participating?
There were no known benefits or high risks to the trial.

Where is the study run from? (what are the approximate number and names of centres taking part in this trial, if there is a lead centre, which one is it?)
This study took place at Grand Valley State University Exercise Physiology Testing Laboratory.

When is study starting and how long is it expected to run for?
Recruitment for the trial began April 20, 2016.

Who is funding the study?
No outside funding supported this trial.

Who is the main contact?
Amy Gyorkos, gyorkosa@gvsu.edu

Contact information

Type(s)
Scientific

Contact name
Dr Amy Gyorkos

Contact details
4423 Kindschi Hall of Science
Allendale
United States of America
49401

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13

Study information

Scientific Title
Carbohydrate-restricted diet and HIIT exercise improves cardio-metabolic, inflammatory profiles, and cognition in metabolic syndrome: a randomized crossover trial

Study objectives
Diet and exercise patterns that more closely resemble those of our evolutionary past will favorably affect inflammatory, cardio-metabolic, and cognitive profiles in individuals characterized as having metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at Grand Valley State University, 20/04/2016, ref: 16-105-H

Study design
Randomized two-phase crossover trial

Primary study design
Interventional

Secondary study design

Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Metabolic syndrome, according to the National Cholesterol Education Program-Adult Treatment Panel III

Interventions
The two phases of the crossover design included a carbohydrate-restricted Paleolithic-based diet with sedentary behavior (CRPD-Sed) and a carbohydrate-restricted Paleolithic-based diet with high intensity interval training (CRPD-Ex). Both phases were 4 weeks in duration and separated by a 4-week washout period during which subjects returned to baseline behaviors.

Intervention Type
Behavioural

Primary outcome measure
Cardiovascular and metabolic health were assessed following 4 weeks of diet or diet and exercise intervention. Blood was collected at 0, 4, 8, and 12 weeks. Assessments included lipoprotein markers (Cholestech LDX® system), adiposity (hydrostatic weighing), metabolic markers (enzyme-linked immunosorbent assay) and VO2max (peak exercise test).

Secondary outcome measures
Cognition functioning was assessed using Brain-Derived Neurotrophic Factor protein content (enzyme-linked immunosorbent assay), performance on the Stroop Test, as well as a self-reported measure of cognitive symptoms and function (Medical Outcomes Study Cognitive Functional Scale).

Overall study start date
01/08/2015

Completion date
20/08/2017

Eligibility

Key inclusion criteria
1. Aged 18-60 years
2. Metabolic syndrome (MetS), according to the National Cholesterol Education Program-Adult

Treatment Panel III.
3. Stable weight for at least 3 months
4. Relatively sedentary (defined as engaged in exercise <30 min/day or VO2 peak <45 ml/kg/min)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Special diets
2. Medications for chronic disease
3. Cardiovascular, metabolic, pulmonary, or osteoarticular disease

Date of first enrolment
20/04/2016

Date of final enrolment
20/08/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Grand Valley State University
United States of America
49401

Sponsor information

Organisation
Grand Valley State University

Sponsor details
1 Campus Drive
Allendale
United States of America
49401

Sponsor type
University/education

ROR
https://ror.org/001m1hv61

Funder(s)

Funder type
University/education

Funder Name
Grand Valley State University

Alternative Name(s)
Grand Valley State College, Grand Valley, Grand Valley State Colleges, GVSU, GV

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
20/08/2018

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other