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Cycling for weight loss in an 'altitude simulation chamber'

Submission date	Recruitment status	[_] Prospectively registered
05/03/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2022	Other	

Plain English summary of protocol

Background and aims
Women willing to lose overweight may do so by reducing their food intake or by enhancing their physical activity but the results of both approaches rely on the nutrients involved. It is hypothesized that cycling under mildly reduced environmental oxygen consumes more body fat than cycling under normal environmental oxygen conditions. Results will be used to optimize oxidation of body fat for weight loss by low-intensity cycling.

Who can participate?
Healthy women aged 20 - 40 years, willing to lose overweight by low-intensity cycling.

What does the study involve?
Women with overweight perform a 50-min cycling protocol, that encloses phases of rest, cycling at a personalized low intensity and of recovery, in an 'altitude simulation chamber' at two occasions within a period of 2 weeks, in randomized order once under normal (N-Ox: 20.9 %) and once under mildly reduced (R-OX: 17.0 %) normobaric oxygen. O2 consumption and CO2 production of subjects are measured continuously by use of a 'ventilated hood system'. Results inform about the metabolic costs of cycling and the ratio in which these costs are covered by carbohydrates and fat. Moreover, 4 fingertip blood samples are taken to determine glucose and lactate concentrations (mM) to get secondary evidence about the use of carbohydrates and fat during low-intensity cycling in women with overweight.

What are the possible benefits and risk of participating?
Results may help to raise the oxidation of body fat for weight loss by low-intensity cycling.
The risk of mildly reduced oxygen (R-Ox: 17 %), comparable with the oxygen level during a long-distance air flight, is commonly well tolerated by healthy subjects.

Where is the study run from?
HAN University of Applied Sciences, Nijmegen, The Netherlands.

When is the study starting and how long is it expected to run for?
June 2009 to June 2011

Who is funding the study?
HAN University of Applied Sciences, Nijmegen, The Netherlands
WUR University, Wageningen, The Netherlands
Dutch Ministry of Economic Affairs (PIDON fund) - The Netherlands

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CMO nr: 2009/341; ABR nr: 29211.091.09

Study information

Scientific Title
Comparison of metabolic responses to low intensity cycling under normal and mildly reduced normabaric oxygen in women with overweight

Study objectives
Cycling under mildly reduced normobaric oxygen in an 'altitude simulation chamber' might be a feasible way to raise oxidation of body fat for weight loss as far as reduced oxygen conditions enhance metabolic costs of exercise e.g. by an urge to increase the recycling of lactate to glucose (Cori cycle).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2010, Regional Ethics Committee Arnhem (Radboud UMC, P.O. Box 9101 [internal post 628], NL - 6500 HB Nijmegen - The Netherlands; +31. (0)243613154; commissiemensgebondenonderzoek@radboudumc.nl), ref: CMO nr: 2009/341; ABR nr: 29211.091.09.

Study design
Single centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
To raise oxidation of body fat during low intensity cycling in women willing to lose overweight

Interventions
Participants perform a 50-min protocol, enclosing phases of rest, cycling at a personalized low intensity and recovery, in an 'altitude simulation chamber', at two occasions within a period of 2 weeks, in randomized order once under normal (N-Ox: 20.9%) and once under mildly reduced (R-Ox: 17.0%) normobaric oxygen.

Within the chamber (2.4 x 3.8 x 2.7m; 25m³) an upright bike ergometer combines with a "ventilated hood system" for open-circuit respiratory gas exchange of cyclists.

The 20 participants were listed in alphabetical order of initials and randomised by their odd (N-Ox ~ R-Ox) or even (R-Ox ~ N-Ox) position.

Intervention Type
Other

Primary outcome(s)
Measured during periods of rest, cycling and recovery:
1. O2 consumption (VO2: mL O2/min)
2. CO2 production (VCO2: mL CO2/min)
derived from differences in content of O2 and CO2 measured between air samples drawn from the inlet (ambient air in the chamber) and outlet (ambient air modified by respiration) of a 'ventilated hood'. Both sample lines are analyzed simultaneously by a dual channel Servomex 4100 gas analyzer (Servomex, Zoetermeer, The Netherlands). Each channel accommodates a paramagnetic O2 transducer serially connected to an infrared CO2 transducer. Differences in content of O2 and CO2 between sample lines caused by respiration, down to 0.01 %, are measured accurately during ventilation of the hood with 250 L of ambient air per min. To this purpose the entire analogue output range of the transducers (20 mA, being converted to 10 mV) is calibrated for a linear measuring range of only 1.00 %. VO2 and VCO2 measured at the same timeoptimize accuracy of 'real-time' changes in metabolism regarding metabolic costs (~VO2) and substrate use (~ VCO2/ VO2) before, during and after cycling. Mean values of data collected at 20 sec intervals during 5 min are calculated for 4 phases within the cycling protocol: Rest (5-10 min), Initial cycling (22-27 min), Final cycling (35-40 min) and Recovery (40-45 min))

Key secondary outcome(s))
1. Blood oxygen saturation (SaO2: %) measured using pulse oximeter
2. Heart rate (HR: min-1) monitored by reflectance finger pulse-oxymetry using the PulseOx 7500 (SPO Medical, Simi Valley CA, USA)
3. Glucose (mM) measured using a single sample of 10 µL fingertip capillary blood using a Biosen C-line analyzer (EKF Diagnostics, Sopachem, Ochten, The Netherlands)
4. Lactate (mM) measured using a single sample of 10 µL fingertip capillary blood using a Biosen C-line analyzer (EKF Diagnostics, Sopachem, Ochten, The Netherlands)
5. Rate of perceived exertion (RPE value: Borg scale: 6 – 20)
All secondary outcome measures are collected at min 6, 26, 39 and 46 and assumed to represent the 4 phases of the cycling protocol mentioned under primary outcome measures

Completion date
01/06/2011

Eligibility

Key inclusion criteria
1. Women willing to lose overweight by low intensity exercise
2. Low active
3. 20 - 40 years of age

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex

Female

Total final enrolment
20

Key exclusion criteria
1. Anemia
2. Type 1 or type 2 diabetes
3. Hypertension
4. Heart disease

Date of first enrolment
01/04/2010

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
HAN University of Applied Sciences
Kapittelweg 33
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Sponsor information

Organisation
HAN University of Applied Sciences

ROR
https://ror.org/0500gea42

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Wageningen University and Research Centre

Alternative Name(s)
Wageningen UR, WUR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
PIDON Fund (Dutch Ministry of Economic Affairs)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Raw data prepared for publication are stored at Wageningen University and will be made available after publication for a period of 2 years upon reasonable requests for inspection or research purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2022	05/05/2022	Yes	No