Effects of breakfast and nitrate intake on working memory, mood, blood vessel stiffness and brain blood flow in adolescents

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/02/2022		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/02/2022	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
16/09/2024	Other			

Plain English summary of protocol

Background and study aims

Nitrate can be primarily found in green leafy vegetables and beetroot and has important implications for brain and vascular health. Inorganic nitrate has been shown to have short-term effects on improving cognitive performance i.e. mental functionality, lowering blood vessel stiffness and modulating cerebral blood flow (CBF): which is the blood flow supplying oxygen and nutrients to the brain. Studies exploring these investigations have focused on adults and thus studies are lacking in the adolescent population. Therefore, this study aims to investigate the immediate effects of nitrate consumption on mental ability, measures of blood vessel stiffness and changes in hemoglobin levels in a sample of Swedish adolescents. Furthermore, breakfast is considered to be important for overall health and well-being in this population, and the effects of breakfast consumption on mental ability, feelings of mood (how positive or negative one feels), alertness and sleepiness will also be explored.

The primary research question is: What effect does nitrate have on working memory mental ability and are there significant differences in these results and feelings of mood/alertness /sleepiness between those consuming a high nitrate breakfast, standardised low nitrate breakfast and consuming no breakfast. Secondary questions include:

- 1. Are blood vessel stiffness and overall brain blood flow significantly different in the high nitrate breakfast group compared to the other groups?
- 2. Are changes in mental ability associated with changes in hemoglobin levels, and how are changes in brain blood flow influenced by nitrate intake?

This study will provide an insight into what immediate effects nitrate has on the ability to perform tasks requiring memory and how well this is performed in adolescents and if this can be partly explained through changes in brain blood flow. Whether nitrate has an effect on blood vessel stiffness will also be explored and results can be compared to adult populations. Results will also provide an insight into the significance that consuming breakfast has on feelings of mood, alertness and sleepiness and if breakfast consumption has an effect on mental ability. The possible implications of this research are that nitrate intake from beetroot could be a feasible way to help improve brain health and reduce the risk of cardiovascular disease. Furthermore,

breakfast consumption can help adolescents to feel alert and focused as well as help to improve overall well-being; in turn potentially influencing academic performance and achievement at school.

Who can participate?

Adolescents aged 13-15 (grade 7-8) in the participating schools.

What does the study involve?

This study will investigate the short-term effects of nitrate from beetroot juice and breakfast on cognitive function, psychological factors (e.g. mood), blood vessel stiffness and cerebral blood flow.

Researchers will carry out a familiarisation visit at school and some data collection will take place in the familiarisation visit and all experimental data collection will occur at the laboratory at The Swedish School of Sport and Health Sciences. Participants will come to the laboratory in pairs and half a day will be required for all data collection to be completed. Participants will either consume breakfast with nitrate, breakfast without nitrate or have no breakfast. The primary outcome is mental ability and secondary outcomes are: psychological factors, blood vessel stiffness and brain blood flow. Physical activity and diet will be regulated and monitored on pretest days via a diary log and accelerometers to objectively measure physical activity.

This study is novel as the effects of nitrate on these outcomes in this population group has not been investigated before. Thus results from the study will provide an insight into the effect that nitrate has on brain and vascular health and the impact that breakfast has on mental ability and psychological well-being.

What are the possible benefits and risks of participating?

Participants may feel uncomfortable drinking the beetroot juice and may feel uncomfortable when having the fNIRS cap on their head (to measure brain blood flow during working memory tasks). The benefits of participating are to be part of a novel and unique scientific study and to receive a gift voucher for participation.

Where is the study run from?

The Swedish School of Sport and Health Sciences (Gymnastik- och idrottshögskolan) (Sweden)

When is the study starting and how long is it expected to run for? January 2022 to February 2023

Who is funding the study?
The knowledge foundation (Sweden)
Coop AB (Sweden)
Skanska (Sweden)
IKEA (Sweden)
Kronprinsesseparets stiftelse (Generation Pep, Sweden)
Konsumentföreningen Stockholm (Sweden)

Who is the main contact? Björg Helgadóttir bjorg.helgadottir@gih.se

Study website

http://www.gih.se/hjarnhalsaiskolan

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Acute effects of nitrate on cognition, arterial stiffness and cerebral blood flow and the effects of breakfast on mood in a sample of Swedish adolescents: a cross-over randomised trial

Acronym

ABBaH Beet

Study objectives

- 1. Cognitive performance will be significantly higher in the high-nitrate breakfast group compared to the low nitrate breakfast group.
- 1.1 Cognitive performance will be significantly higher in the high-nitrate breakfast group compared to the breakfast omission group.
- 1.2 Cognitive performance will be significantly higher in the low-nitrate breakfast group compared to the breakfast omission group.
- 2. Scores for positive mood will be significantly higher in the high nitrate breakfast group

compared to the breakfast omission group.

- 2.1 Scores for positive mood will be significantly higher in the low-nitrate breakfast group compared to the breakfast omission group.
- 2.2 There will be no significant differences in positive mood between the high-nitrate breakfast group and low-nitrate breakfast group.
- 3. Scores for alertness will be significantly higher in the high-nitrate breakfast group compared to the low-nitrate breakfast group.
- 3.1 Scores for alertness will be significantly higher in the low-nitrate breakfast group compared to the breakfast omission group
- 3.2 There will be no significant difference in alertness between the high nitrate-breakfast group and the low-nitrate breakfast group
- 4. Scores for negative mood will be significantly higher in the breakfast omission group compared to the high-nitrate breakfast group
- 4.1 Scores for negative mood will be significantly higher in the breakfast omission group compared to the low-nitrate breakfast group
- 4.2 There will be no significant difference between negative mood between the high-nitrate breakfast group and low-nitrate breakfast group
- 5. Scores for sleepiness will be significantly higher in the breakfast omission group compared to the high-nitrate breakfast group
- 5.1 Scores for sleepiness will be significantly higher in the breakfast omission group compared to the low-nitrate breakfast group
- 5.2 There will be no significant difference between sleepiness between the high-nitrate breakfast group and low-nitrate breakfast group
- 6. The high nitrate-breakfast group will have significantly lower arterial stiffness than the lownitrate breakfast group.
- 6.1 The high nitrate-breakfast group will have significantly lower arterial stiffness than the breakfast omission group.
- 6.2 There will be no significant differences in arterial stiffness between the low-nitrate breakfast group and breakfast omission group.
- 7. There will be a significant correlation between cognitive performance and changes in CBF.
- 8. The high-nitrate breakfast group will have significantly different levels of oxygenated and deoxygenated hemoglobin during cognitve task periods compared to the low-nitrate breakfast group.
- 8.1 The high-nitrate breakfast group will have significantly different levels of oxygenated and deoxygenated hemoglobin during cognitve task workloads compared to the breakfast omission group.
- 8.2 There will be no significant differences in total hemoglobin levels between the low-nitrate breakfast group and the breakfast omission group during cognitive task workloads.
- 9. Salivary nitrate levels will be significantly higher across all time points in the high-nitrate breakfast group compared to the low nitrate breakfast group.
- 9.1 Salivary nitrate levels will be significantly higher across all time points in the high-nitrate breakfast group compared to the breakfast omission group.
- 9.2 There will be no significant differences in nitrate levels between the low-nitrate breakfast group and the breakfast omission group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/01/2022, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: Dnr 2021-07053-01

Study design

Interventional single-blinded cross-over randomized controlled 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

Improving cognitive function, positive feelings of emotion, levels of alertness and vascular health.

Interventions

Participants will be randomised by the researchers via a computer-generated random order of experimental conditions, that is equally assigned to every participant.

There will be three conditions:

- 1. No breakfast provided
- 2. A standard breakfast provided e.g. bread, cheese, orange juice
- 3. A standard breakfast provided with a nitrate-rich beetroot juice.

The duration of these intervention arms will be 20 minutes and no follow-up will occur. Each participant will be involved in every intervention arm one time.

Intervention Type

Supplement

Primary outcome measure

Cognitive function (measured with n-back tests) measured 5 minutes pre-intervention, 30 minutes and approximately 180 minutes post-intervention.

Secondary outcome measures

1. Mood (VANAS, PAS and KSS) measured 10 minutes pre-intervention, just after post-intervention and around 90 minutes post-intervention

- 2. Arterial stiffness (PWA and PWV measured 25 minutes and 210 post-intervetintion
- 3. Cerebral blood flow (fnirs) measured at 30 minutes and approximately 180 minutes post-intervention

Overall study start date

26/01/2022

Completion date

03/02/2023

Eligibility

Key inclusion criteria

- 1. Adolescents between the ages of 13-15 years
- 2. Attending schools in the Stockholm area
- 3. Vaccinated for covid 19

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

13 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

43

Total final enrolment

60

Key exclusion criteria

- 1. Not understanding Swedish
- 2. Diagnosed with diabetes, epilepsy, vascular health conditions/circulatory abnormalities, visual /auditory impairments or those receiving treatment from depression, sleep disorders, psychosis or other psychiatric condition

Date of first enrolment

25/02/2022

Date of final enrolment

08/11/2022

Locations

Countries of recruitment

Sweden

Study participating centre

The Swedish School of Sport and Health Sciences (Gymnastik- och idrottshögskolan)

Lidingövägen 1 Stockholm Sweden 11433

Sponsor information

Organisation

Swedish School of Sport and Health Sciences

Sponsor details

Lidingövägen 1 Stockholm Sweden 114 33 +46 812053701 hjarnhalsabarn@gih.se

Sponsor type

University/education

Website

http://gih.se

ROR

https://ror.org/046hach49

Funder(s)

Funder type

Research organisation

Funder Name

The knowledge foundation (Sweden)

Funder Name

Coop AB (Sweden)

Funder Name

Skanska (Sweden)

Funder Name

IKEA (Sweden)

Funder Name

Kronprinsesseparets stiftelse (Generation Pep, Sweden)

Funder Name

Konsumentföreningen Stockholm (Sweden)

Results and Publications

Publication and dissemination plan

A study protocol that is published in a peer-reviewed journal

One paper investigating the effects of nitrate on cognitive function, cerebral blood flow and arterial stiffness and the effects of breakfast on cognitive function and psychological factors. Published in a peer reviewed journal.

OR two papers: one investigating the effects of nitrate on cognitive function, cerebral blood flow and arterial stiffness and one investigating the effects of breakfast on cognitive function and psychological factors. Published in a peer reviewed journal.

Intention to publish date

30/06/2023

Individual participant data (IPD) sharing plan

Data available upon reasonable request but the data cannot leave Sweden (bjorg. helgadottir@gih.se)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/05/2023	22/05/2023	Yes	No

<u>Results article</u> 13/09/2024 Yes No