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Effectiveness of rehydration with green tea on recovery from dehydration

Submission date
30/03/2023

Recruitment status
No longer recruiting

Registration date
12/04/2023

Overall study status
Completed

Last Edited
21/08/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Maintaining hydration by drinking fluid is one way to prevent heat-related illness in a hot environment. Caffeine-containing beverages, including green tea (GT), have been avoided as rehydration beverages because caffeine has been assumed to exert a diuretic/natriuretic action (increase urination). However, the influence of caffeine intake on urine output is not well documented in dehydrated individuals. The aim of this study is to examine the effect of fluid replacement with GT on body fluid balance and kidney water and electrolyte handling in dehydrated individuals.

Who can participate?
Healthy men and women aged over 20 years in the Nara or Kansai area

What does the study involve?
Participants attend the laboratory for three trials. No alcohol or salty food should be consumed for at least 24 hours. Before reporting to the laboratory participants are asked to eat a light breakfast (a box of Carolie Mate, Otsuka) and drink a bottle of water (560 ml). After voiding and keeping a seated position for 30 min, participants will provide a urine sample and a fingertip blood sample and their body weight is measured. Then, participants are dehydrated by performing four bouts of stepping exercise for 20 minutes separated by 10 minutes of rest. After the exercise, participants keep a seated position for 30 minutes after the end of exercise at a room temperature of 25 °C. At the end of the equilibrium period, measurements of hemoglobin concentration, blood sampling for plasma sodium concentration, urine sampling and measurement of body weight are performed. After these measurements, participants are asked to drink water, green tea, or caffeinated water equal to the volume of fluid lost during the dehydration protocol. Urine sampling and body weight measurement are performed 0.5, 1 and 2 hours later, and hemoglobin concentration and plasma sodium concentration are also measured after 2 hours.

What are the possible benefits and risks of participating?
Participants will benefit from receiving their own personal rehydration profile. Dehydration induced by exercise in heat may be uncomfortable, and participants may feel tired and thirsty, but the dehydration level induced by this protocol is relatively small and the exercise intensity is

low. Participants are allowed to quit the experiment whenever they do not want to continue. Participants may also experience a little discomfort during blood sampling from the finger. An experienced person will do this to minimise any discomfort.

Where is the study run from?
Nara Women's University (Japan)

When is the study starting and how long is it expected to run for?
November 2019 to September 2022

Who is funding the study?
ITO EN, Ltd, and Nara Women's University (Japan)

Who is the main contact?
Dr Akira Takamata, takamata@cc.nara-wu.ac.jp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19-32

Study information

Scientific Title
Effect of fluid replacement with green tea on body fluid balance and renal responses under mild thermal hypohydration

Study objectives
Rehydration with green tea does not cause excessive diuresis/natriuresis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2019, extension approved 14/12/2020, Review Board on Human Experiments of Nara Women's University (Kitauoya Nishimachi, Nara, 630-8506, Japan; +81 (0)742 20 3338; kenkyou@cc.nara-wu.ac.jp), ref: #20-37

Study design
Interventional randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Laboratory, Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Hydration status monitoring

Interventions
After baseline measurement, subjects were dehydrated by performing four bouts of stepping exercise for 20 min separated by 10 min of rest. They were asked to ingest an amount of water (H2O), GT, or caffeinated H2O (20 mg/100 ml; Caf-H2O) that was equal to the volume of fluid loss during the dehydration protocol; fluid balance was measured for 2 h after fluid ingestion. Randomization was performed using randomization.com.

Intervention Type
Other

Primary outcome measure
1. Fluid balance is calculated from the change in body weight measured with an electric balance for 2 hours of the dehydration period and 2 hours after the ingestion of fluids. Body weight

measurements are performed at baseline, immediately after the dehydration period, 0.5, 1 and 2 hours after fluid ingestion.
2. Fluid retention ratio at 2 hours after fluid ingestion calculated from the ingested fluid weight and retained fluid calculated body weight change

Secondary outcome measures
1. Urinary flow rate calculated from the weight of sampled urine, in which subjects were asked to empty the urinary bladder, and the time between sampling. Urine collections are made at baseline, immediately after the dehydration protocol, and 0.5, 1, and 2 hours after fluid ingestion.
2. Urinary excretion rate of osmotically active substances, sodium, potassium, and chloride, calculated from the urine flow rate and urine osmolality (osmometer), sodium, potassium, and chloride (ion-selective electrodes). Urine collections are made at baseline, immediately after the dehydration protocol, and 0.5, 1, and 2 hours after fluid ingestion.

Overall study start date
22/11/2019

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Healthy young male and female volunteers
2. Age >20 years
3. BMI 18-25 kg/m²
4. No known cardiovascular, renal or metabolic disease

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
20 Years

Sex
Both

Target number of participants
12

Total final enrolment
13

Key exclusion criteria

1. Overweight or obese (BMI >25 kg/m²)
2. Current or former cardiovascular, renal or metabolic disease
3. Currently taking prescribed medication

Date of first enrolment
01/02/2020

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Japan

Study participating centre
Depatment of Environmental Health, Nara Women's University
Kitauoya Nishimachi
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Sponsor information

Organisation
Nara Women's University

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Sponsor type
University/education

Website
http://www.nara-wu.ac.jp/index-e.html

ROR
https://ror.org/05kzadn81

Funder(s)

Funder type
Industry

Funder Name
ITO-EN, Ltd

Funder Name
Nara Women's University

Results and Publications

Publication and dissemination plan
We intend to present the results at the Japan Society of Nutrition and Food Sciences Annual Meeting in Sapporo in May 2023. We also hope to publish the data in a relevant journal in 2023.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon request from Akira Takamata (takamata@cc.nara-wu.ac.jp)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/08/2023	21/08/2023	Yes	No