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Understanding the hydration potential of commonly consumed drinks

Submission date 20/03/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/03/2015	**Overall study status** Completed	
Last Edited 02/03/2016	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The volume and composition of any drink makes a difference to how much of the volume is retained by the body and how much is excreted as urine. The pattern of urine output in the hours after drinking a fixed volume of a drink provides information about the impact of that drink on the body's ability to retain fluid (i.e., how well it can act as a hydration drink). While there is some knowledge about the impact of different drinks on urine output, no study has set out to investigate the hydrating potential of a wide range of drinks that are commonly drank in daily life. This study therefore aims to determine the hydrating potential of a range of drinks. The knowledge gained from this project should allow the researchers to develop a hydration index for different drinks (much in the same way as a glycaemic index has been developed for different foods). This hydration index information could be developed further for use with athletes, older adults, or other clinical populations where fluid replacement may be an important aspect of daily life.

Who can participate?
Healthy moderately active men, aged 18-35, in Stirling, Bangor or Loughborough.

What does the study involve?
You are required to attend the laboratory on four occasions. You should avoid participating in any intense physical activity on the day before or morning of the laboratory visits. No alcohol should be consumed for at least 24 hours and no food for at least 10 hours before entering the laboratory. One hour before entering the laboratory you will drink 500 ml of water. You will provide a urine sample and a blood sample will be taken from a vein in your arm. After this you will be weighed and then asked to drink 1L (4 x 250 ml) of a test drink (a different drink on each of the four lab visits). The test drinks include still water and others from the following: sparkling mineral water, Coca-Cola, diet cola (Coca-Cola Zero), sports drink (Powerade), oral rehydration solution (Dioralyte blackcurrant flavour), fruit juice (orange juice), beer, coffee, tea, cold tea, full fat milk, skimmed milk. Urine samples will then be collected each hour over a period of 4 hours.

What are the possible benefits and risks of participating?
You shall benefit from participating in the study by receiving your own, personal hydration index profile. Results of the study shall be used in order to inform practice by developing a hydration

index. You shall be required to drink 1L of fluid over a 30-minute period on each lab visit. This may be uncomfortable for some people due to stomach fullness and/or frequent need to urinate, but it is an important part of this study and you will be allowed to empty your bladder when you wish. You will also experience a little discomfort when a needle is inserted into your arm to enable blood sampling. An experienced person will do this to minimise any discomfort.

Where is the study run from?
The University of Stirling, Bangor University, and Loughborough University (UK)

When is the study starting and how long is it expected to run for?
February to August 2014

Who is funding the study?
The European Hydration Institute

Who are the main contacts?
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Contact information

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Development of an hydration index: a randomized trial to assess the potential of different beverages to affect hydration status in adult males

Study objectives
We hypothesized that the macronutrient content and electrolyte content of different drinks would impact upon fluid delivery and retention following the ingestion of a fixed volume of fluid. We hypothesized that differences in the capacity to maintain hydration status could be used to develop an hydration index for a range of different beverages.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the ethics committees of:
1. University of Stirling (School of Sport Research Ethics Committee), 07/02/2014, ref: SSREC #670
2. Bangor University (School of Sport, Health and Exercise Sciences Ethics Committee), 14/02/2014, ref: S/PhD13-13/14
3. Loughborough University (Ethical Approvals [Human Participants] Sub-Committee of the Loughborough University Ethics Committee), 07/01/2014, ref: R13-P221

Study design
Randomised cross-over study

Primary study design
Interventional

Study type(s)
Other

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

Interventions
After baseline samples were collected, each participant consumed 1L of fluid over a 30-minute period (4 x 250 ml delivered at 7.5-min intervals) and hydration status was monitored at hourly intervals over the subsequent 4 hours. Participants ingested water as a control trial (Highland Spring™, Perthshire, UK) and consumed three of the following drinks in a randomised, counter-balanced order: sparkling water (Highland Spring™, Perthshire, UK), Coca-Cola® (Uxbridge, UK), Diet Coke® (Uxbridge, UK), Powerade® (Coca-Cola®, Uxbridge, UK), Dioralyte™ (Sanofi. One, Surrey, UK), orange juice (Tesco Everyday Value, Hertfordshire, UK), lager beer (Carling®, Staffordshire, UK), instant black coffee (Nescafe® Original, York, UK), hot black tea (PG tips®, Unilever, London, UK), cold black tea (PG tips®, Unilever, London, UK), whole milk (4% fat; Tesco, Hertfordshire, UK) or skimmed milk (0.1% fat; Tesco, Hertfordshire, UK). We obtained n=72 observations for water, and n=17 observations for each of the other test drinks.

Intervention Type
Other

Primary outcome(s)
1. Net fluid balance over each hour for 4 hours (fluid ingested minus cumulative urine output)
2. Hydration Index at each hour over 4 hours (net fluid balance comparison to water as a control)

Key secondary outcome(s))
1. Urine and serum osmolality at baseline and at each hour following fluid ingestion for 4 hours (freezing point depression method within 48 hours of sample collection)
2. Sodium and potassium net balance assessed immediately post-drinking and each hour following fluid ingestion for 4 hours (flame photometry method within 5 days of sample collection)

Completion date
21/08/2014

Eligibility

Key inclusion criteria
1. Healthy male volunteers
2. Aged 18-35
3. BMI 18-27 kg/m2

4. No known cardiovascular, renal or metabolic disease
5. Moderately active
6. Moderate alcohol use

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Male

Key exclusion criteria
1. Overweight or obese (BMI >27 kg/m2)
2. Competitive athletes during competition season
3. Current or former cardiovascular, renal or metabolic disease
4. Habitual consumption of alcohol (>21 units/week) or regular (>1/week) high (10 units) intake
5. History of psychiatric illness
6. Actively seeking to gain or lose weight
7. Currently taking prescribed medication

Date of first enrolment
21/02/2014

Date of final enrolment
07/07/2014

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre

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Sponsor information

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Organisation
Loughborough University (UK)

Organisation
University of Stirling

ROR

https://ror.org/045wgfr59

Funder(s)

Funder type
Research organisation

Funder Name
European Hydration Institute

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No