# Understanding the hydration potential of commonly consumed drinks

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

## 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? Dr Stuart Galloway (Stirling); s.d.r.galloway@stir.ac.uk Prof Neil Walsh (Bangor); n.walsh@bangor.ac.uk Dr Phil Watson (Loughborough); P.Watson2@lboro.ac.uk

# **Contact information**

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#### Type(s)

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

#### Secondary study design

Randomised cross over trial

#### **Study setting(s)** Other

Study type(s) Other

#### Participant information sheet

#### 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<sup>™</sup>, Perthshire, UK) and consumed three of the following drinks in a randomised, counterbalanced order: sparkling water (Highland Spring<sup>™</sup>, Perthshire, UK), Coca-Cola® (Uxbridge, UK), Diet Coke® (Uxbridge, UK), Powerade® (Coca-Cola®, Uxbridge, UK), Dioralyte<sup>™</sup> (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 measure

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

#### Secondary outcome measures

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)

Overall study start date

21/02/2014

## **Completion date**

21/08/2014

# Eligibility

#### Key inclusion criteria

Healthy male volunteers
 Aged 18-35
 BMI 18-27 kg/m2
 No known cardiovascular, renal or metabolic disease
 Moderately active
 Moderate alcohol use

#### Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit 18 Years

## Upper age limit

35 Years

Sex

Male

#### Target number of participants

72 (n=24 at each site)

#### 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** England

Scotland

United Kingdom

Wales

**Study participating centre University of Stirling** Health and Exercise Sciences Research Group Stirling United Kingdom FK9 4LA

**Study participating centre Bangor University** School of Sport, Health and Exercise Sciences Gwynedd Bangor United Kingdom LL57 2DG

**Study participating centre Loughborough University** School of Sport, Exercise and Health Sciences Epinal Way Loughborough United Kingdom LE11 3TU

## Sponsor information

**Organisation** University of Stirling (UK)

#### Sponsor details

Airthrey Road Stirling Scotland United Kingdom FK9 4LA

**Sponsor type** University/education

Website www.stir.ac.uk

**Organisation** Bangor University (UK)

#### Sponsor details

Gwynedd Bangor Wales United Kingdom LL57 2DG

**Sponsor type** University/education

Website www.bangor.ac.uk

**Organisation** Loughborough University (UK)

#### Sponsor details

Epinal Way Loughborough England United Kingdom LE11 3TU

**Sponsor type** University/education

Website www.lboro.ac.uk **Organisation** University of Stirling

Sponsor details

**Sponsor type** Not defined

Website http://www.stir.ac.uk/

ROR https://ror.org/045wgfr59

# Funder(s)

**Funder type** Research organisation

**Funder Name** European Hydration Institute

# **Results and Publications**

#### Publication and dissemination plan

We intend to present the results at a meeting organised by the funders of the research (European Hydration Institute) in London in June 2015. We also hope to publish the data in a relevant clinical journal in 2015.

Intention to publish date

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