

# Weigh 2 Go: The efficacy of water preloading before main meals as a strategy for weight loss in obese primary care patients

<b>Submission date</b> 01/05/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/04/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There has been a dramatic increase in the number of people who are overweight/obese. Given this high rate of obesity there is a need to investigate the effectiveness of simple and cheap interventions that have the potential to reach the high number of people needing to lose weight. Many popular weight loss programmes advise people to drink water to help control their weight, but no studies have directly tested whether this advice is accurate and actually leads people to lose weight. One particular strategy that might help people lose weight is to drink about a pint of water before their main meals. Studies conducted in the laboratory and a small trial in older people have shown that drinking water before meals leads people to feel more full and satisfied and so this results in them eating less food/calories during their meals. Whilst the results of these previous studies are very encouraging they have many flaws which means we now need to test this question in a bigger study before we can say for sure that drinking water before meals helps people lose weight.

### Who can participate?

We will recruit 88 obese people from GP practices.

### What does the study involve?

Half of the obese people recruited will be asked to drink a pint of water before their main meals and half will not. Participants who are not asked to drink water will instead be asked to imagine their stomach is full before their meals. This is called a comparison group. We will measure the weight of the two groups at the start, middle and end of the study and compare them to see who lost the most weight. We will also ask all participants to provide us with urine samples at the start, middle and end of the study as this will tell us objectively whether the water group drank more water than the comparison group.

### What are the possible benefits and risks of participating?

The results of this study will help us decide whether the instruction to drink water before meals

used in this study is useful in helping people to lose weight. Taking part in the study does not guarantee weight loss, but we hope it may help. We do not anticipate any risks or side-effects from the intervention.

Where is the study run from?  
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?  
May 2013 to November 2013

Who is funding the study?  
European Hydration Institute

Who is the main contact?  
Dr Helen Parretti  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Helen Parretti

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
14351

## Study information

**Scientific Title**  
The efficacy of water preloading before main meals as a strategy for weight loss in obese primary care patients: a randomised controlled trial

## **Acronym**

Weigh 2 Go

## **Study objectives**

There has been a dramatic increase in the number of people who are overweight/obese. Given this high rate of obesity there is a need to investigate the effectiveness of simple and cheap interventions that have the potential to reach the high number of people needing to lose weight. Many popular weight loss programmes advise people to drink water to help control their weight, but no studies have directly tested whether this advice is accurate and actually leads people to lose weight. One particular strategy that might help people lose weight is to drink about a pint of water before their main meals. Studies conducted in the laboratory and a small trial in older people have shown that drinking water before meals leads people to feel more full and satisfied and so this results in them eating less food/calories during their meals. Whilst the results of these previous studies are very encouraging they have many flaws which means we now need to test this question in a bigger study before we can say for sure that drinking water before meals helps people lose weight. We will recruit 88 obese people, half will be asked to drink a pint of water before their main meals and half will not. Participants who are not asked to drink water will instead be asked to imagine their stomach is full before their meals. This is called a comparison group. We will measure the weight of the two groups at the start, middle and end of the study and compare them to see who lost the most weight. We will also ask all participants to provide us with urine samples at the start, middle and end of the study as this will tell us objectively whether the water group drank more water than the comparison group.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee West Midlands - Edgbaston, 08/03/2013, ref: 13/WM/0043

## **Study design**

Randomised interventional trial; Design type: Treatment

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Obesity

## **Interventions**

Intervention group (preloading with water) will be asked to consume 500ml of water (0.8 pints or 2 cups) 30 minutes before main meals each day for 12 weeks and to consume additional water during their meals and throughout the day as desired or dictated by thirst.

Comparator group will be asked to imagine their stomach is full before meals (there will be no mention of preloading to the comparator group).

Weight management consultation - both groups will receive a consultation around weight management strategies (i.e. Eat Well Plate, self-weighing, regular physical activity, etc) at baseline.

Follow-up and contacts - both groups will receive the same follow-up and number of contacts throughout the study. These are comprised of follow-up calls at 2,3 and 9 weeks, home visits at 6 and 12 weeks and a weekly text reminder.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Difference in weight change (objective) between the groups from baseline to 3 months

## **Secondary outcome measures**

1. Dietary intake and beverage consumption measured at baseline and 3 months
2. Measure of fullness and satiety measured at 2, 3 and 9 weeks
3. Total urine volume and specific gravity concentration measured at baseline, 6 weeks and 3 months

## **Overall study start date**

15/05/2013

## **Completion date**

15/11/2013

# **Eligibility**

## **Key inclusion criteria**

1. Patients must be aged  $\geq 18$  years
2. Have a body mass index (BMI) equal to or greater than 30 kg/m<sup>2</sup>
3. Considered suitable to participate by their GP.

Weight and height will be measured objectively by the research team and BMI checked prior to randomisation to ensure eligibility.

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 88

**Key exclusion criteria**

1. Pregnant or breast feeding or intending to fall pregnant within the study time period.
2. Cannot understand or speak English sufficiently to undertake the tasks of the study.
3. Currently attending a weight management programme (including pharmacotherapy or bariatric surgery) or has taken part in a formal weight management programme in the previous three months.
4. Weight loss of >2 kg in previous 3 months.
5. BMI less than 30 kg/m<sup>2</sup>.
6. Dependent on insulin.
7. Use of medication known to affect weight/food intake/energy expenditure.

**Date of first enrolment**

15/05/2013

**Date of final enrolment**

15/11/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Birmingham**

Birmingham

United Kingdom

B15 2TT

## **Sponsor information**

**Organisation**

University of Birmingham (UK)

## Sponsor details

Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2TT

## Sponsor type

University/education

## Website

<http://www.birmingham.ac.uk>

## ROR

<https://ror.org/03angcq70>

# Funder(s)

## Funder type

Government

## Funder Name

European Hydration Institute

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No