

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

| | | |
|--|--|---|
| Submission date 01/05/2013 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 01/05/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 06/04/2016 | Condition category 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
hmp719@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Helen Parretti

Contact details
School of Health Sciences
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
hmp719@bham.ac.uk

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 ≥ 18 years
2. Have a body mass index (BMI) equal to or greater than 30 kg/m²
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/m².
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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/09/2015 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |