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Drinking water and weight loss in overweight adolescents

Submission date
10/01/2013

Recruitment status
No longer recruiting

Registration date
18/01/2013

Overall study status
Completed

Last Edited
18/01/2013

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Studies suggest that drinking water can help dieting adults lose weight faster. Drinking water seems to help when adults consume a large amount of drinking water, at least one litre per day, or enough to have dilute (light-colored) urine. Drinking water also seems to help adults most when the weight loss diet is low in carbohydrate.
In addition to not knowing if the effects of drinking water are due to its zero calories and/or its effects on hydration, researchers are not sure if drinking water can help everyone who wants to lose weight.
Weight loss is notoriously difficult for overweight children. Studies are needed to find out (1) if drinking water is an effective way to help overweight children lose weight, and if yes, (2) how much drinking water is necessary, given that children may need a different amount of water than adults.
This study was designed to find out if overweight adolescents can lose weight faster if they drink enough water to have clear urine each day while eating a lower carbohydrate diet.

Who can participate?
Overweight children, who attended information sessions about weight management and/or previously participated in other research studies at
Childrens Hospital Oakland, CA were given information about the study. Children were included in the study if they were overweight, between 9 to 13 years old, regularly drinking beverages like milk, juice, sodas or sports drinks, not already drinking 2L per day water, and willing to have the study foods for 8 weeks.
Potential participants were not included in the study if they had any health condition that could make study participation harmful, such as acute illness, any condition or medication that stimulates anti-diuretic hormone release or promotes weight gain.
Out of 36 boys and girls, who wanted to participate, 28 started the study.

What does the study involve?
Participation in the 8 week feeding study involved weekly clinic visits over 9 consecutive weeks. For 5 days each week, the children wrote down what types of foods they ate at each meal. Each week, study staff measured the childrens body weight, collected a urine and saliva sample, and reviewed what they were eating. For 8 weeks after the first clinic visit, all children were given

two bags of commercially available, ready-to-eat salads, soups, fruit, and nuts, with instructions not to eat bread, noodles, rice, potatoes, or other foods that contain flour or sugar. We explained to all of the children that foods that turn into sugar in the blood (like bread, noodles, rice, potatoes, and pastries) make it hard to burn fat, because the bodys rule is to always burn up sugar in the blood first. If you keep the sugar in your blood relatively low, there is more chance to burn fat.
The study participants were randomly assigned to one of two drinking water groups. One group was told to drink only water, no other beverages, because many other beverages contain sugar and result in excess calories. The second group was also told to drink only water, but more specifically, to drink enough water each day to have clear urine by the afternoon. We explained to the second group that yellow pee is a sign that cells are shrinking from not enough water, and when cells shrink they prefer to burn sugar instead of fat.
After the free-food portion of the study ended, the children were invited to come back after 6 months for follow-up assessments.

What are the possible benefits and risks of participating?
This study included assessments that are not generally available through standard care. Participants received multiple weeks of diet, insulin, and hydration assessments, free meals for 8 weeks, and free delivery of bottled drinking water. Study participants benefited by losing weight and learning weight management strategies.
Risks included possible dislike of the study foods, time required for attending the clinic visits and keeping daily study records, and discomfort or embarrassment related to the study foods or drinking water. The children were eating salads that no one else was eating at school. They reported many trips to the bathroom. All study related procedures were non-invasive and did not hurt.

Where is the study run from?
The study took place at outpatient research clinics at the Childrens Hospital & Research Center Oakland, in Oakland CA, USA.

When is the study starting and how long is it expected to run for?
The study happened in two 8 week sessions between September 2010 and June 2011.

Who is funding the study?
The study was funded by Nestle Waters and NIH grants.

Who is the main contact?
Dr. Jodi Stookey
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Drinking water to dilute urine osmolality is associated with greater weight loss than drinking water following thirst in overweight pre-adolescents eating lower glycemic foods: A completers analysis of a controlled trial

Study objectives
Drinking water to dilute urine osmolality is associated with greater weight loss than drinking water following thirst in overweight pre-adolescents eating lower glycemic foods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Childrens Hospital & Research Center Oakland Institutional Review, Sept 24, 2010, ref: Board#: 2007-031

Study design
Completer's analysis of a randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Overweight / Weight loss

Interventions
Drinking water treatments
All participants were instructed to drink water to minimize blood carbohydrate and insulin levels and maximize fat oxidation. They were told that drinking water was expected to help them lose weight, because drinking water has a glycemic index of zero, and is known to increase fat oxidation by 30% or more compared to other beverages via its normalizing effects on insulin. They were told that the goal of this 8 week study was to describe the cumulative effect of greater fat oxidation over time on weight loss. Participants assigned to both the control and test treatments were instructed to drink water instead of other beverages.

During the orientation, family beliefs and rules about beverages, and barriers to beverage change were discussed with each participant. The importance of complying with the protocol, as a participant in research, was emphasized. Each participant was given a refrigerator magnet with an image of drinking water and a blue water faucet light, as reminders about the drinking water goal. Bi-weekly delivery of bottled water was initiated after the Week 2 orientation. Each participant had a choice of plain, non-carbonated or carbonated water in large or small bottles. To support the beverage change, extra water was provided to allow other household members to drink water with the participant.

Control:
Participants assigned to the control treatment were instructed to drink water instead of other beverages following thirst. Those assigned to the test treatment were instructed to drink water instead of other beverages and drink enough water each day to have dilute, urine daily. Participants assigned to the test treatment received additional information about the role of drinking water in limiting osmotic stress on cells and maintaining cell hydration. The adverse effects of osmotic stress on metabolism, including decreased body fat breakdown and fat oxidation, insulin resistance, and decreased physical performance and energy expenditure, were described. Participants assigned to the test treatment were also told that concentrated, yellow urine is an easy-to-watch indicator of cell shrinkage in the body, and that drinking water swells cells and causes urine dilution. Participants assigned to the test treatment were not given an absolute volume of water to consume, but rather instructed to gauge how much water they should drink by watching their urine color.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Body weight was measured in duplicate, using a calibrated clinical scale, at baseline, and then weekly for 8 consecutive weeks.

Secondary outcome measures

Saliva insulin - Unstimulated saliva was passively collected for determination of saliva insulin at baseline, and then weekly for 8 weeks. Saliva insulin was determined by Enzyme-linked immunosorbent assay (ELISA) using a commercially available kit and microplate spectrophotometer.

Overall study start date
09/01/2010

Completion date
06/01/2011

Eligibility

Key inclusion criteria
1. All participants were screened for a body mass index (BMI) above the 85th percentile for age and sex
2. Motivation to lose weight
3. Daily intake of caloric beverages, including juice, soda, milks, and/or sports drinks, less than 2L per day drinking water
4. Willingness to adopt food and beverage changes
5. Boys and girls, at any stage of puberty
6. Who spoke English or Spanish

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Any health condition that could make study participation harmful
2. Acute illness
3. A fluid balance disorder
4. Any chronic condition or medication that stimulates vasopressin release, or any condition for which venipuncture is counter indicated.
5. Potential participants were also excluded if they had any condition or medication known to promote weight gain.
6. Specific exclusion criteria included:
6.1. Renal disease (previous diagnosis, +3 proteinuria dipstick test, frequent urination)
6.2. Congestive heart failure
6.3. Adrenal insufficiency
6.4. Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)
6.5. Chronic pain
6.6. Psychogenic polydipsia

6.7. Bleeding disorders
6.8. Hemophila
6.9. Recent cancer chemotherapy
6.10. Syndromic conditions (e.g. Prader-Willi, Bardet-Biedl)
6.11. Weight loss pharmacotherapy
6.12. Anti-depressent, anti-psychotic or lipid-lowering medications, adrenergic or cholinergic drugs, clofibrate, chlorpropamide, carbamazepine, phenothiazines, vincristine, cyclophosphamide, morphine barbiturates, opiates, and glucocorticoid therapy in excess of physiologic dosing (i.e. > 15 mg/m2/d).
7. Persons who had lost weight in the previous 2 months were excluded
8. Persons who expressed aversion to drinking water or the prescribed study foods, or who had plans to move to a new address during the study period were also excluded from the study

Date of first enrolment
09/01/2010

Date of final enrolment
06/01/2011

Locations

Countries of recruitment
United States of America

Study participating centre
Children's Hospital Oakland Research Institute
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Sponsor information

Organisation
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Sponsor type

Hospital/treatment centre

Website
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Funder(s)

Funder type
Industry

Funder Name
Nestle Waters (USA)

Funder Name
National Institutes of Health (NIH) (USA) grant number 1R25HL096365-01

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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