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The effect of fibre and fluids on gut health in adults

Submission date
14/09/2011

Recruitment status
No longer recruiting

Registration date
10/02/2012

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many people regularly experience bowel symptoms such as straining or a feeling of incomplete evacuation (not passing all the stool). Research suggests that a healthy stool weight and gut transit time (the time it takes for food to pass through your gut) can reduce the risk of these symptoms and some bowel disorders, such as colorectal cancer. Changes in diet can influence bowel health, for example fibre may help to increase stool weight and maintain a regular bowel habit, therefore the use of dietary intervention has much promise for helping to prevent bowel disorders. Fibre and fluid may help to maintain a regular bowel habit and increase stool weight, but it is not clear which fibre foods or natural fluids are most effective. This study aims to investigate the effect of specific natural foods and fluids on bowel habit, stool weight, gut transit time and other markers of bowel health.

Who can participate?
To take part in this study you need to be aged between 18 and 65 and typically have a low fibre intake and a bowel movement between 3 and 6 times per week. If you have a chronic disease, or take medications, supplements, or food products likely to affect gut motility you will not be able to take part. If you are pregnant or lactating or have undergone procedures involving ionising radiation to the abdomen or pelvic region in the last 12 months you will not be able to take part.

What does the study involve?
In this study we will ask you to add a specific natural food or fluid to your normal diet for 4 weeks. However, your total involvement in the study will be for 10 weeks. This is so we can gather information before and after we ask you to add the food or fluid into your diet. Throughout the study you should continue to eat your normal diet and maintain your usual level of physical activity. We will ask you to attend four appointments at King's College London (KCL). At these appointments we will gather information using questionnaires and face-to-face interviewing. We will also measure your height, weight and percentage body fat. When you visit us at KCL we will ask you to complete questionnaires on your physical activity level, your appetite and the acceptability of the intervention. We will ask you to attend two to four appointments at Queen Mary, University of London for X-rays to be taken so that we can assess your gut transit time. Before each X-ray appointment we will ask you to take two capsules of 'markers' at a specific time of day for 3 days. There is no known risk to health of taking these

capsules, and they are commonly used in research studies to assess gut function. We will ask you to carry out two 7-day stool collections. This would involve collecting all the stools you pass for a period of 7 days. We will give you full instructions and equipment to help with this. We will also ask you to complete various diaries during the study:
A 7-day stool and symptom diary, in which you record how often you open your bowels and the frequency with which you experience any bowel symptoms such as wind, pain, or bloating.
A 7-day food and drink diary, in which you record everything you eat and drink.
A compliance diary, in which you record when you take the food or fluid we have asked you to add to your normal diet.
We will ask if you would like to give an optional blood sample at 2 points during the study. The sample will be approximately 10 ml (1 dessertspoon) of blood. We will use this sample to investigate how your body absorbs the food or fluid we have asked you to add to your diet.

What are the possible benefits and risks of participating?
If you participate in this trial you may experience an improvement in bowel function. Possible side effects include mild gastrointestinal symptoms such as bloating and flatulence, however, the prune dose selected for this trial has been reported to be well tolerated in previous studies. If you choose to provide a blood sample this may be associated with discomfort and may leave a temporary bruise. The risks associated with the X-rays are considered to be small. However, if you are pregnant you should not take part as there is a small risk that X-rays can harm an unborn baby.

Where is the study run from?
The study is led by King's College London. The gastrointestinal transit time measurements will be undertaken at Queen Mary University London.

When is the study starting and how long is it expected to run for?
Participants will be recruited to the trial from approximately January 2012 to October 2012.

Who is funding the study?
California Dried Plum Board, USA

Who is the main contact?
Dr Kevin Whelan
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Study website
http://tinyurl.com/optigut

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial investigating the dose dependent effect of prunes on gastrointestinal health in adults with infrequent bowel movements

Study objectives
Null hypothesis: Consumption of 80 g/day or 120 g/day of prunes in addition to the usual diet will have no effect on stool weight, water and pH, frequency of bowel movement, whole gut transit time, subjective measures of bowel function, faecal bacteria and short chain fatty acids or appetite in healthy adults with infrequent bowel movements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Sub-Committee at King's College London, 22/08/2011, ref: BDM/10/11-92
2. NRES Committee London - West London, 27/10/2011, ref: 11/LO/0860

Study design
Single-centre three-arm parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Patient information sheet can be found at http://www.kcl.ac.uk/medicine/research/divisions/dns/projects/optigut/participant-info-sheet.pdf

Health condition(s) or problem(s) studied
Gastrointestinal health

Interventions
Participants will be randomly assigned to receive a small or a large portion of prunes or control (water) to be consumed every day in addition to the normal diet, for 4 weeks. The small portion of prunes will be 80 g/d (10 prunes) and the large portion will be 120 g/d (15 prunes).

During the first week, subjects will consume half portions (e.g. 40 g/d, 60 g/d), following which they will consume the full portions for the remaining 3 weeks. Subjects will be asked to consume the prunes throughout the day, once in the morning (before 12:00) and once in the afternoon / evening (after 15:00). After the intervention participants will consume their normal diet before being assessed 4 weeks later at follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Difference in stool weight and frequency of bowel movement between the three study arms at the end of the intervention, as determined by a 7 day total stool collection at baseline and at the end of the intervention
2. Stool and symptom diary completed at baseline, two weeks, end of intervention and four week follow-up, respectively

Secondary outcome measures
1. Difference in gastrointestinal transit time between the three groups at the end of the intervention, as determined by radio-opaque markers and abdominal X-ray fluoroscopy taken at baseline and end of intervention.
2. Difference in stool consistency and gastrointestinal symptoms between the three groups at the end of the intervention as determined by a 7 day stool and symptom diary completed at baseline, two weeks, end of intervention and four week follow-up. Measurements will include abdominal pain and discomfort, bloating or distension, increased flatulence, belching or burping, stomach or abdominal gurgling, urgency, incomplete evacuation, nausea, heartburn, acid regurgitation, tiredness and lethargy and number of complete spontaneous bowel movements (CSBM). Participants will classify all bowel movements throughout the study according to the Bristol Stool Chart.
3. Difference in stool water and pH between the three groups at the end of the intervention as determined by analysis of stool samples collected at baseline and at the end of the intervention.
4. Difference in stool microbiota and volatile compounds (e.g. short chain fatty acids) between the three groups at the end of the intervention, determined by qPCR and GLC analysis of stool samples collected at baseline and at the end of the intervention.
5. Difference in plasma levels of phenolic compounds between the three groups at the end of

the intervention, determined by analysis of blood samples taken at baseline and at the end of the intervention.
6. Difference in appetite between the three groups at the end of the intervention as determined by questionnaire completed at baseline, end of intervention and four week follow-up.

Overall study start date
01/01/2012

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Adult men and women between the ages of 18 to 65 years
2. Adults with stool frequency of 3-6 times per week
3. Adults able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 participants

Key exclusion criteria
1. Regular consumption of dried fruit (based on specific screening questions)
2. Consumption of more than one portion of whole grain cereals per day (>1 x 80g) and more than three portions of fruit and vegetables per day (>3 x 80g) or more than five portions of fruit and vegetables per day (>5 x 80g)
3. Dislike of prunes
4. Consumption of any pre or probiotic (in food products or as supplements) in the last 4 weeks prior to, or during the study
5. Adults taking medications known to effect gut motility, for example prokinetic agents (such as metoclopramide, domperidone, erythromycin, azithromycin), anti-emetics agents, narcotic analgesic agents (such as methadone, fentanyl), anticholinergic agents for irritable bowel syndrome [BS], medications for constipation (including enemas, cathartics, polyethylene glycol solutions, lactulose), 5HT3 antagonists, anti-diarrheal agents (such as loperamide), opiate agents used to treat diarrhoea, non-steroidal anti-inflammatory drugs [NSAIDs] (more than once daily).
6. Subjects who have taken a course of antibiotics in the last 4 weeks prior to, or during the study
7. Subjects with any gastro-intestinal disease including IBD and coeliac disease, history of diverticulitis

8. Subjects with co-morbid illnesses such as cardiovascular, endocrine, renal or other chronic disease likely to affect motility
9. Previous GI surgery, except cholecystectomy and appendectomy
10. Patients with neurological diseases such as multiple sclerosis, strokes, spinal cord injuries, and those who have problems with cognizance, i.e. a mini-mental score of <15 and/or are legally blind will be excluded
11. Patients with Hirschsprung's disease, or active local anorectal problems such as anal fissures, bleeding haemorrhoids, etc
12. Subjects with eating disorders
13. Use (more than six times in last 3 months) of laxatives, fibre supplements etc
14. Patients defined as having constipation or IBS based upon Rome III criteria for both
15. Females of childbearing age who are not practicing birth control and/or who are pregnant or lactating. (A urine pregnancy test will be performed on female participants prior to X-ray fluoroscopy)

Date of first enrolment
01/01/2012

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
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SE1 9NH

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Other

Funder Name
California Dried Plum Board (USA)

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	01/02/2019		Yes	No