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Dietary study to investigate the nutritional effectiveness and tolerability of a ready-to-drink meal replacement

Submission date
20/04/2016

Recruitment status
No longer recruiting

Registration date
27/04/2016

Overall study status
Completed

Last Edited
31/05/2018

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
Poor nutrition is a major source of health problems globally, both in developed and developing countries. Diets consisting of a single, nutritionally complete food have the potential to make high quality nutrition significantly more accessible, overcoming the barriers of convenience and cost. Soylent is a meal replacement drink which is designed to include all of the nutrients an average adult needs in a meal. The aim of this study is to find out whether Soylent alone can replace food as a healthy source of nutrition for a period of one month. Few studies have investigated how consuming such a food as the only source of nutrition affects healthy adults, when done for long periods of time. Most of the work done in the field of nutrition has focussed on controlled diets in populations with specific conditions, such as obesity (being very overweight). This study investigates Soylent's effectiveness as a nutritionally complete meal replacement.

Who can participate?
Healthy adults aged between 18 and 40 who have a normal UK diet, including 'junk food' at least once per week.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group consume Soylent as their only food source for one month. Those in the second group continue with their usual dietary habits for the duration of the study. Aside from these dietary instructions, participants continue their usual lifestyle during the study period. Participants in both groups have their physiological health monitored every two weeks at the study center and are asked to give blood and urine samples for this purpose. Participants are also asked to complete daily questionnaires to monitor how their digestive system reacts to the diet and effects on their appetite and weekly questionnaires to assess their wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Leatherhead Food Research (UK)

When is the study starting and how long is it expected to run for?
September 2015 to March 2016

Who is funding the study?
Soylent (USA)

Who is the main contact?
Dr Joe Levine

Contact information

Type(s)
Scientific

Contact name
Dr Joe Levine

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11629830

Study information

Scientific Title
Soylent as a nutrition source: a randomized, controlled one-month pilot human dietary study

Study objectives
Soylent, a nutritionally complete ready-to-drink meal replacement, can serve as a healthy sole source of nutrition for extended periods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reading Independent Ethics Committee, 18/09/2015, ref: 080915-3

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Nutritional completeness of a ready-to-drink meal replacement in healthy adults

Interventions
Soylent study arm participants were instructed to consume only Soylent as their nutritional source. Soylent was distributed in ready-to-drink bottles of 414 ml (400 kcals) each. Participants were provided with sufficient Soylent to consume up to 5 bottles per day, with additional provided as requested; participants self-determined the amount they consumed each day. They were allowed to consume black tea or coffee (no milk or sugar) to prevent caffeine withdrawal effects. Participants were also allowed to consume their habitual alcoholic beverages. Compliance was assessed with a self-reported daily diary.

Control study arm participants were instructed to continue their usual dietary habits.

Biomarkers were assessed on study day 1, day 15, and day 30. Participants were instructed to minimize changes in their usual lifestyle and to avoid high intensity physical activity and alcohol 24 hrs prior to each test day. Participants were also asked to consume their evening meal before 8pm the night before, and to fast until the test morning. Drinking during this period was not allowed, except for water.

Total treatment duration was 29 days. The trial was concluded upon completion of the practical intervention.

Intervention Type

Primary outcome measure

1. Comprehensive metabolic profile is measured using a blood test at study day 1, day 15, day 30
2. Complete blood count is measured using a blood test at study day 1, day 15, day 30

Secondary outcome measures
1. Weight is measured using a scale at day 1, day 15, day 30
2. Lipid profile is measured using a blood test at day 1, day 15, day 30
3. Vitamin and mineral status is measured using a blood test at day 1, day 15, day 30
4. Fatty acid levels are measured using a blood test at day 1, day 15, day 30
5. Urinalysis is measured using a urine sample at day 1, day 15, day 30
6. Satiety/appetite/cravings are measured using self reported questionnaires (numerical scale of 1 "not at all" to 10 "very high") each day
7. Bowel movements are measured using self-reported ratings from the Bristol Stool Chart each day.
8. Self-reported subjective energy levels and wellness are measured using SF-12 each week

Overall study start date
26/09/2015

Completion date
30/03/2016

Eligibility

Key inclusion criteria
1. Age between 18 and 40 years
2. BMI between 22 and 30 kg/m^2
3. Apparently healthy, measured by questionnaire: no reported current or previous metabolic diseases or chronic gastrointestinal disorders
4. Weight stable (no significant weight loss or gain in the past 6 months)
5. Reported alcohol consumption <= 10 units/week
6. Consumption of a normal UK diet, with the inclusion of 'junk food' at least once per week ('junk food' defined by the contracting group as take away meals, fast food, crisps, chocolate, ice cream)
7. Informed consent signed

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Subject has any health conditions that would prevent them from fulfilling the study requirements, put the subject at risk, or would confound the interpretation of the study results as judged by the Principal Investigator or Study Physician
2. Subjects with a significant current or previous medical history, as assessed by questionnaire
3. Subjects with a history of eating disorders
4. Subject has gastrointestinal malabsorption (from celiac disease, colitis, surgery, etc)
5. Medication: any medication that might affect the study measurements
6. Currently taking any vitamin or mineral supplements, or having taken these within the past 3 months
7. Subject has a known allergy or sensitivity to soy containing nutritional products
8. Complete Blood Count or Comprehensive Metabolic Profile values outside normal ranges, as assessed by the study physician
9. Participating in another clinical trial
10. Pregnant or breast feeding women
11. Not willing to use appropriate contraceptive methods to avoid pregnancy during the study

Date of first enrolment
05/10/2015

Date of final enrolment
22/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leatherhead Food Research
Randalls Road
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Sponsor information

Organisation
Soylent

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Soylent

Results and Publications

Publication and dissemination plan
Results will be submitted for peer-reviewed journal publication.

Intention to publish date
30/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date