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Can taking probiotics ('friendly bacteria') encourage weight loss in people who are overweight?

Submission date
25/11/2019

Recruitment status
No longer recruiting

Registration date
27/11/2019

Overall study status
Completed

Last Edited
13/01/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The human gut (gastrointestinal tract) is home to a host of "friendly bacteria" (probiotics) that support the well-being and health of an individual through a variety of mechanisms. This study aims to assess the potential for daily supplementation with these friendly bacteria to achieve weight loss in overweight individuals going about their daily lives.

Who can participate?
Adults aged between 45 to 65 years with a waist circumference of >89 cm (women) or >100 cm (men) and a body mass index (BMI) between 25 and 29.9.

What does the study involve?
The study is called a double-blind study which means that participants will be randomly assigned to take a capsule containing either the active product (the probiotic) or an identical inactive product (the placebo) every day for 270 days. There will be an equal chance for the participant to be assigned to take active or placebo with neither the participant or researchers aware of who is taking what. During the trial, the participants will also be asked to complete a questionnaire (relating to their general well-being and health), complete a 'Stroop test' (that measures mental sharpness) and provide blood samples at beginning, during and end of trial.
After enrolment to the study, participants are asked to complete a general wellbeing questionnaire and Stroop test, undergo body measurements (e.g. weight, height, waist circumference, hip circumference and blood pressure) and provide a fasting blood sample. Participants will then be randomly assigned to receive capsules containing either the placebo (dummy) or probiotic that are to be taken every day for the following 270 days. During the study, participants will be asked to revisit the trial centre on days 90, 180 and the end of the study (day 270) in order to repeat the wellbeing questionnaire and Stroop test, undergo body measurements and provide blood samples. At the end of the study, scientists will use the information and samples collected to determine if there was any benefit to taking the probiotic supplement.

What are the possible benefits and risks of participating?
It is considered that the daily intake of the probiotics will reduce the bodyweight of participants and improve general wellbeing and mental sharpness. Due to the chance that the participant may receive the placebo, it is perceived that these benefits will be confined to the participants who are randomly assigned the intervention. Participation in the study will bring more information and will improve our understanding of the benefits of daily probiotic supplementation.
There have been no adverse reactions associated with the probiotic product but participants may experience mild side effects such as a change in bowel habit and/ or increased flatulence (intestinal gas) during the first few days of taking the supplement.

Where is the study run from?
The trial is managed and will take place at the Medical Center 'Comac Medical' in Sofia, Bulgaria.

When is the study starting and how long is it expected to run for?
May 2019 to February 2020

Who is funding the study?
Cultech Ltd (UK)

Who is the main contact?
Dr Daryn Michael
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PROBE_FINAL_V.20

Study information

Scientific Title
The Impact of PRObiotics on Body wEight in an overweight population (PROBE)

Acronym
PROBE

Study objectives
Daily probiotic supplementation will support body weight reduction in an free-living overweight population

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/05/2019, Ethics committee at MC "Comac Medical" (South Side Business Centre, 38 Maystor Aleksi Rilets Str (5th floor), Manastirski Livadi, West 1618 Sofia, Bulgaria; +359 2 892 10 00; clients@comac-medical.com), ref: 168/08.05.2019

Study design
Single-centre randomized double-blind placebo-controlled parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact detials to request particpant information sheet

Health condition(s) or problem(s) studied
Healthy overweight individuals aged 45 and over following normal lifestyle

Interventions

Trial subjects are allocated in a 1:1 ratio into two parallel study arms (active arm or placebo arm) according to a randomisation protocol provided by an independent statistician. The intervention comprises a daily dose of active product that contains 50 billion bacteria (Lactobacillus acidophilus, Lactobacillus plantarum, Bifidobacterium bifidum and Bifidobacterium animalis subsp lactis) or a daily dose of placebo that does not contain any bacteria and is identical in appearance to the active product. The intervention period is 270 days.

The active product contains Lactobacillus acidophilus CUL60 (NCIMB 30157), Lactobacillus acidophilus CUL21 (NCIMB 30156), Lactobacillus plantarum CUL66 (NCIMB 30280), Bifidobacterium bifidum CUL20 (NCIMB 30153) and Bifidobacterium animalis subsp lactis CUL34 (NCIMB 30172) at a total of 50 billion cfu per day.

The placebo contains microcrystalline cellulose.

Intervention Type
Supplement

Primary outcome measure
Current primary outcome measure as of 10/06/2020:
Body weight (kg) measured on scales at days 0, 90, 180 and 270

Previous primary outcome measure:
1. Body weight (kg) measured on scales at days 0, 90, 180 and 270
2. Waist circumference (cm) measured by tape at days 0, 90, 180 and 270
3. Hip circumference (cm) measured by tape at days 0, 90, 180 and 270
4. Blood pressure (mmHg) measured by a blood pressure monitor at days 0, 90, 180 and 270

Secondary outcome measures
Current secondary outcome measures as of 10/06/2020:
1. Waist circumference (cm) measured by tape at days 0, 90, 180 and 270
2. Hip circumference (cm) measured by tape at days 0, 90, 180 and 270
3. Blood pressure (mmHg) measured by a blood pressure monitor at days 0, 90, 180 and 270
4. Plasma HDL-cholesterol at baseline days 0,180 and 270
5. Plasma LDL-cholesterol at baseline days 0,180 and 270
6. Plasma triacylglycerol at baseline days 0,180 and 270
7. General well-being assessed using a quality of life questionnaire at days 0, 90, 180 and 270
8. Measurement of cognitive performance using Stroop test at days 0, 90, 180 and 270

Previous secondary outcome measures:
1. Plasma HDL-cholesterol at baseline days 0,180 and 270
2. Plasma LDL-cholesterol at baseline days 0,180 and 270
3. Plasma triacylglycerol at baseline days 0,180 and 270
4. General well-being assessed using a quality of life questionnaire at days 0, 90, 180 and 270
5. Measurement of cognitive performance using Stroop test at days 0, 90, 180 and 270

Overall study start date
11/02/2019

Completion date
17/02/2020

Eligibility

Key inclusion criteria
1. Male or female, aged between 45 to 65 years at start of study
2. Waist circumference >89 cm (women) or >100 cm (men) at start of study
3. Body mass index (BMI) between 25 and 29.9 at start of study
4. Willing to provide fasting blood samples at days 0, 180 and 270

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Immunodeficiency/ immunosuppressive therapy on-going
2. Diagnosed diabetes
3. Pregnant or planning pregnancy
4. Anamnesis of ischemic heart disease, heart failure, prolonged QTc interval, rhythm and conduction disorders – absolute arrhythmia, ventricular extrasystole, atrioventricular block or any other cardiovascular disease deemed by the investigator as a risk for the participation in the study
5. Severe systemic disease (cancer, dementia, advanced organ failure)
6. Weight loss in the last 3 months prior to start of study, which cannot be explained with a dietary regimen or increased physical activity
7. Not on statin therapy nor received any statin therapy in the last 6 months prior to start of study

Date of first enrolment
17/05/2019

Date of final enrolment
22/05/2019

Locations

Countries of recruitment
Bulgaria

Study participating centre
Comac Medical
South Side Business Centre 38
Maystor Aleksi Rilets Str.
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Res. Distr. Manastirski Livadi – West
Sofia
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1618

Sponsor information

Organisation
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Cultech Ltd

Results and Publications

Publication and dissemination plan
Results will be published in a peer-reviewed scientific journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2021	12/01/2021	Yes	No