

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

<b>Submission date</b> 25/11/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/01/2021	<b>Condition category</b> Other	<input type="checkbox"/> 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

Dr Daryn Michael

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**Protocol serial number**

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 a 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 Aleksii 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

**Study type(s)**

Prevention

**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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

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5th fl.

Res. Distr. Manastirski Livadi – West

Sofia

Bulgaria

1618

**Sponsor information**

## Organisation

Cultech Ltd

## ROR

<https://ror.org/00555bk04>

## Funder(s)

### Funder type

Industry

### Funder Name

Cultech Ltd

## Results and Publications

### 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?
<a href="#">Results article</a>	results	06/01/2021	12/01/2021	Yes	No