ISRCTN14866272 https://doi.org/10.1186/ISRCTN14866272

Can taking probiotics improve well-being in females suffering from irritable bowel syndrome?

Submission date 20/07/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/07/2022	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/02/2024	**Condition category** Digestive System	[_] 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" that support the well-being and health of an individual through a variety of mechanisms including the promotion of a healthy gut. Compared to males, females suffer from much higher rates of gut issues such as irritable bowel syndrome (IBS) than can have a strong negative effect on their everyday lives. This study aims to assess the potential for daily supplementation with additional "friendly bacteria" (called probiotics) to improve the general well-being (gut symptoms, quality of life and mental health) in female participants with diagnosed IBS.

Who can participate?
Adult females aged 18 to 40 years with diagnosed IBS

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 56 days. There will be an equal chance for the participant to be assigned to take the active or placebo capsule with neither the participant nor the researchers aware of who is taking what. After enrolment at the start of the study, the participants will be asked to complete a series of questionnaires (relating to IBS symptom severity, general well-being and cognitive/mental health) and provide a stool and blood sample. Participants will then be randomly assigned to receive capsules containing either the placebo (dummy) or probiotics that are to be taken every day for the following 56 days. During this time, participants will be asked to complete additional questionnaires related to their IBS severity (every fortnight) and complete a bowel habit diary each time they attempt to pass a stool. At a final visit to the trial center at the end of the study, the participants will asked to yet again complete a series of questionnaires (relating to IBS symptom severity, general well-being and cognitive/mental health) and provide a final stool and blood sample. 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 probiotics will improve general wellbeing and mental health. 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?
Medical Center 'Comac Medical' (Bulgaria)

When is the study starting and how long is it expected to run for?
April 2022 to October 2022

Who is funding the study?
Cultech Ltd (UK)

Who is the main contact?
Dr Daryn Michael
darynm@cultech.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Daryn Michael

ORCID ID
https://orcid.org/0000-0001-8546-1153

Contact details
Cultech Ltd
Unit 2 Christchurch Road
Baglan Industrial Estate
Port Talbot
United Kingdom
SA12 7BZ
+44 (0)1639 825100
darynm@cultech.co.uk

Additional identifiers

Protocol serial number
ProXXIBS_FINAL_V1.2

Study information

Scientific Title
The impact of probiotics on well-being during irritable bowel syndrome: a double-blind, randomised, placebo-controlled, feasibility study in female participants

Acronym
ProXXIBS

Study objectives
Daily probiotic supplementation will improve well-being in a free-living female population with irritable bowel syndrome (IBS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/07/2022, ethics committee at MC "Comac Medical" (South Side Business Centre, 38 Maystor Aleksi Rilets Str (5th floor), Manastirski Livadi, West 1618 Sofia, Bulgaria; +359 (0)2 892 10
00; clients@comac-medical.com), ref: 245/13.07.2022

Primary study design
Interventional

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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Irritable bowel syndrome (IBS)

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 probiotic bacteria or a daily dose of placebo that does not contain any probiotic bacteria and is identical in appearance to the active product. The intervention period is 56 days.

The active product contains Lactobacillus acidophilus CUL60 (NCIMB 30157), Lactobacillus acidophilus CUL21 (NCIMB 30156), Bifidobacterium bifidum CUL20 (NCIMB 30153) and Bifidobacterium animalis subsp lactis CUL34 (NCIMB 30172) at a total of 25 billion cfu per day.

The placebo contains microcrystalline cellulose.

Intervention Type
Supplement

Primary outcome(s)

Irritable bowel syndrome severity measured by the IBS-symptom severity score (IBS-SSS) questionnaire on days 0, 14, 28, 42 and 56

Key secondary outcome(s)
1. Bowel habits measured by bowel habit diaries (BHDs) completed by the participants on a per defecation basis during the intervention period
2. Quality of life measured by quality of life questionnaire [QOLQ], IBS Behavioural-responses questionnaire [IBS-BRQ] and the Hospital Anxiety and Depression Scale [HADS] questionnaires on days 0 and 56
3. Cognitive health measured by the word-colour Stroop test on days 0 and 56
4. The faecal microbiota measured by next-generation 16s sequence analysis and culturomics of stool samples taken on days 0 and 56
5. Circulating biomarkers of IBS measured by ELISA analysis of plasma samples taken on days 0 and 56

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. Females aged 18 to 40 years
2. Diagnosed IBS (according to the Rome IV criteria)
3. Willing to provide faecal/blood samples
4. Not suffering from any other gastrointestinal disorders/conditions or had abdominal surgery
5. Willing to maintain a normal diet and lifestyle throughout the study
6. Normal (or corrected-to-normal) vision without colour blindness in order to complete the cognitive task

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
70

Key exclusion criteria

1. Consumed regular probiotic supplementation within the last 1 month prior to the study
2. Consumed any oral antibiotic within the last 3 months
3. Diagnosed with diabetes
4. Are immunodeficient or undergoing immunosuppressive therapy
5. Diagnosed with arrhythmia, ventricular extrasystole or atrioventricular block
6. Diagnosed with a cardiovascular disease
7. Pregnancy or planning pregnancy
8. Diagnosed with a severe systemic disease e.g. cancer, dementia, advanced organ failure
9. Unexplained loss of weight in recent months

Date of first enrolment
25/07/2022

Date of final enrolment
04/08/2022

Locations

Countries of recruitment
Bulgaria

Study participating centre
Comac Medical
3, Sv. Georgi Sofiyski Str
Triaditsa District
Sofia
Bulgaria
1606

Sponsor information

Organisation
Cultech (United Kingdom)

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?
Results article		29/01/2024	09/02/2024	Yes	No