

Probiotics and health in non-pregnant women: GetGutsy Study

Submission date 26/04/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Current plain English summary as of 14/05/2019:

Background and study aims

The study is looking specifically at women of reproductive age (18-65 years) who are not currently pregnant and have a body mass index (BMI) ≥ 28 Kg/m². An elevated BMI is associated with developing type 2 diabetes, high blood pressure, high cholesterol and heart disease in later life. The aim of this study is to find out whether daily consumption of a probiotic in a food supplement form could reduce inflammation and improve blood markers of health in this population. A probiotic is a food supplement containing beneficial bacteria that has been shown to be good for human health.

Who can participate?

Women aged between 18 and 65, who are not currently pregnant, have a body mass index (BMI) ≥ 28 Kg/m² and who are otherwise healthy.

What does the study involve?

On contacting the research team a screening appointment is arranged. Participants are asked to complete a 3-day food diary, undergo body measurements (e.g. weight, height, waist circumference, hip circumference, mid-upper arm circumference and body fat assessment), and provide a fasting blood sample and a stool sample (which may be done at home and brought to the hospital using the equipment provided). Blood results and body measurements will be reviewed and those who meet the eligibility criteria are then invited to participate in the study. Any abnormal results are reported to the participant's General Practitioner (GP). At this point participants are randomly allocated to receive either the placebo (dummy) or probiotic supplement to take daily for 12 weeks. Neither the participant nor the researcher know which they are taking until the study is complete. The research team check in with participants via phone and/or email to ensure they have enough capsules and that they are having no difficulties. After 12 weeks a final appointment is arranged again taking all the above information and samples. At this point, participants are offered optional personalized health and nutrition advice/feedback based on information from their initial screening visit.

What are the possible benefits and risks of participating?

There are no known or anticipated risks associated with this study. It has been shown that there

are no health risks or adverse side effects associated with taking probiotics. Many women consume probiotics as part of their daily diet. Participants may find that remembering to take the probiotic each day is a minor inconvenience and may find it inconvenient providing the required samples.

Where is the study run from?

University College Dublin, National Maternity Hospital, Dublin (Ireland)

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

April 2018 to April 2020

Who is funding the study?

Science Foundation Ireland

Who is the main contact?

Prof. Fionnuala McAuliffe

Previous plain English summary:

Background and study aims

The study is looking specifically at women of reproductive age (18-45 years) who are not currently pregnant and have a body mass index (BMI) $\geq 30\text{kg/m}^2$. An elevated BMI is associated with developing type 2 diabetes, high blood pressure, high cholesterol and heart disease in later life. The aim of this study is to find out whether daily consumption of a probiotic in a food supplement form could reduce inflammation and improve blood markers of health in this population. A probiotic is a food supplement containing beneficial bacteria that has been shown to be good for human health.

Who can participate?

Women aged between 18 and 45, who are not currently pregnant, have a body mass index (BMI) $\geq 30\text{kg/m}^2$ and who are otherwise healthy

What does the study involve?

On contacting the research team a screening appointment is arranged. Participants are asked to complete a 3-day food diary, undergo body measurements (e.g. weight, height, waist circumference, hip circumference, mid-upper arm circumference and body fat assessment), and provide a fasting blood sample and a stool sample (which may be done at home and brought to the hospital using the equipment provided). Blood results and body measurements will be reviewed and those who meet the eligibility criteria are then invited to participate in the study. Any abnormal results are reported to the participant's General Practitioner (GP). At this point participants are randomly allocated to receive either the placebo (dummy) or probiotic supplement to take daily for 12 weeks. Neither the participant nor the researcher know which they are taking until the study is complete. The research team check in with participants via phone and/or email to ensure they have enough capsules and that they are having no difficulties. After 12 weeks a final appointment is arranged again taking all the above information and samples. At this point, participants are offered optional personalized health and nutrition advice/feedback based on information from their initial screening visit.

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Contact information

Type(s)

Scientific

Contact name

Prof Fionnuala McAuliffe

Contact details

UCD Perinatal Research Centre

University College Dublin

National Maternity Hospital

Dublin

Ireland

D2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EC 28.2017

Study information

Scientific Title

Probiotics and health in non-pregnant women: GetGutsy randomised controlled trial

Acronym

GetGutsy

Study objectives

Consuming a probiotic capsule everyday for 12 weeks will positively impact markers of metabolic health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Committee at The National Maternity Hospital, Dublin 2, Ireland, 13/03/2018, ref: EC 28.2017

Study design

Single-centre double-blinded interventional randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Current interventions as of 14/05/2019:

Women will be recruited from the Greater Dublin area. They will self identify to the research team in response to flyers, recruitment stalls, social media alerts, and emails. They will be provided with written information about the study. Once the subject has provided informed consent they will undergo a screening visit and eligibility assessment. Subjects will be randomised in a random way to one of two study groups: the intervention group who will consume a probiotic capsule daily for 12 weeks; or the control group who will consume a placebo capsule daily for 12 weeks. The study statistician, who will not be involved in data collection, will produce computer-generated sets of random allocations before the study starts. At the screening visit, eligible subjects will be given an envelope to open, and will be in that study group for the duration of the study. Neither investigators nor subjects will know which study group is placebo or probiotic during the duration of the study.

All study products will be manufactured under Good Manufacturing Practice conditions. The trial products, both probiotic and placebo, will be provided as identical white capsules, prepacked in tubes, and consecutively numbered for each woman according to the randomisation schedule, concealing allocation from the research team and subjects.

Eligible subjects will be provided with a 12-week supply of capsules at baseline. Compliance will be monitored at 2-week regular intervals by email, phone and text communications with participants. At 12-weeks, a further study visit will be arranged.

Baseline sampling will include: demographic details, BMI calculation, lipids screening, anthropometry, blood sampling, stool sample, and dietary assessment with a 3 day food diary.

Sampling at 12-weeks will include: anthropometry, blood sampling, stool sample, and dietary assessment with a 3 day food diary.

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Sampling at 12-weeks will include: anthropometry, blood sampling, stool sample, and dietary assessment with a 3 day food diary.

Intervention Type

Supplement

Primary outcome measure

Level of C-reactive protein, measured by laboratory analysis at baseline and at 12 weeks

Secondary outcome measures

Collected at baseline and at 12 weeks:

1. Body weight and body fat change, determined by changes in BMI, waist circumference, waist:

hip ratio.

2. Inflammation, investigated by measuring changes in inflammatory markers including TNF-alpha
3. Insulin resistance, determined using HOMA index and HbA1c
4. Lipids, assessed by analysis of circulating lipids

Overall study start date

26/04/2018

Completion date

30/04/2020

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 14/05/2019:

1. Non-pregnant women aged between 18 to 65 years capable of giving informed consent
2. BMI $\geq 30\text{Kg/m}^2$
3. Waist circumference $> 80\text{cm}$ OR waist:hip ratio ≥ 0.85
4. Raised fasting triglyceride levels

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Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

A sample size of 80 is required for a 0.6 change score of log CRP, at 80% power and a type I error rate of 0.05, 40 per group.

Total final enrolment

64

Key exclusion criteria

Current participant exclusion criteria as of 14/05/2019:

1. Pregnant or planning to become pregnant in the following 6 months
2. Age < 18 years or > 65 years

3. Inadequate level of English to provide informed consent or communicate with the researchers
4. Having a condition or taking a medication, dietary supplement or food product that the investigator believes would interfere with the objectives of the study
5. Actively involved in a weight-loss programme

Previous participant exclusion criteria:

1. Pregnant or planning to become pregnant in the following 6 months
2. Age < 18 years or > 45 years
3. Inadequate level of English to provide informed consent or communicate with the researchers
4. Having a condition or taking a medication, dietary supplement or food product that the investigator believes would interfere with the objectives of the study
5. Actively involved in a weight-loss programme

Date of first enrolment

21/05/2018

Date of final enrolment

31/12/2019

Locations

Countries of recruitment

Ireland

Study participating centre

National Maternity Hospital & University College Dublin

Dublin

Ireland

2

Sponsor information

Organisation

University College Dublin

Sponsor details

UCD Clinical Research Centre

St. Vincent's Hospital

Elm Park

Dublin

Ireland

D7

Sponsor type

University/education

ROR

<https://ror.org/05m7pjf47>

Funder(s)

Funder type

Research organisation

Funder Name

Science Foundation Ireland

Alternative Name(s)

SFI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Ireland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/04/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Fionnuala McAuliffe. The data will be anonymised participant data, if requested for appropriate scientific scrutiny of results, for 7 years after last publication. Consent from participants will have been obtained. Additional documents (such as study protocol, statistical analysis plan, other) are not available.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/03/2022	24/05/2022	Yes	No
Other publications	Study within A Trial	24/10/2022	14/11/2022	Yes	No

