ISRCTN11295995 https://doi.org/10.1186/ISRCTN11295995

Probiotics and health in non-pregnant women: GetGutsy Study

Submission date	Recruitment status
26/04/2018	No longer recruiting
Registration date	**Overall study status**
15/05/2018	Completed
Last Edited	**Condition category**
14/11/2022	Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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) ≥ 30kg/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 45, who are not currently pregnant, have a body mass index (BMI) ≥30kg/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.

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Prof. Fionnuala McAuliffe

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

Protocol serial number
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

Study type(s)
Treatment

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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Intervention Type
Supplement

Primary outcome(s)
Level of C-reactive protein, measured by laboratory analysis at baseline and at 12 weeks

Key secondary outcome(s))
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

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 ≥ 30Kg/m^2
3. Waist circumference > 80cm OR waist:hip ratio ≥ 0.85
4. Raised fasting triglyceride levels

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4. Raised fasting triglyceride levels

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
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Sponsor information

Organisation
University College Dublin

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

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