

Open label probiotics trial and effects on anxiety/depression in irritable bowel syndrome (IBS) patients

Submission date 15/08/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 12/09/2008	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/06/2018	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2014-001854-40

Protocol serial number

R16767

Study information

Scientific Title

A pilot study, open label, placebo controlled, non-randomised trial of the influence of Lactobacillus Shirota on anxiety and depression in patients with irritable bowel syndrome (IBS)

Study objectives

Can regular daily consumption of 2 x 65 ml bottles of a probiotic drink (Yakult containing Lactobacillus Shirota) by patients diagnosed with irritable bowel syndrome (IBS) and moderate to severe anxiety and/or depression, have a therapeutic effect on both symptoms of IBS and anxiety/depression in conjunction with routine General Practitioner (GP) care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

REC Yorkshire and The Humber - Sheffield, 16/06/2014, ref: 14/YH/0176

Study design

A pilot study, open label, placebo controlled, non-randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable bowel syndrome, associated anxiety and/or depression

Interventions

Eligible patients will be seen by a therapist trained in the study protocol. Over a 3-month patient recruitment period, 40 patients with a primary diagnosis of IBS will be assessed for IBS symptoms using the ROME II Criteria, anxiety (using the Beck Anxiety Inventory) and depression (using the Beck Depression Inventory II), at baseline and again at the end of a 3-month trial.

During the trial, patients in the trial arm will be provided with routine GP care plus a fortnightly supply of 65 ml bottles of Yakult probiotic drink containing Lactobacillus Shirota sufficient for two bottles per day over the 3-month period. This will be sent direct to either the GP Practice or the Clinical Research and Trials Unit at UEA, dependent upon the patient's preference, by Yakult for collection by the patient. The control arm will be provided with routine GP care plus a fortnightly supply of a Longlife Milk Shake. If they were taking medication at the beginning of the trial, this would have been at a stable dose for at least 4 weeks before entry into the trial.

Trial and control arm patients will be selected from different GP Practices participating in the trial to minimise cross-over and contamination of information between patients. At the end of the 3-month trial, each patient in both study arms will be asked to complete the outcome measures again and will be asked if they have been given information from any source outside the trial about probiotic supplementation.

Intervention Type

Supplement

Primary outcome(s)

1. Beck Anxiety Inventory (16+ at baseline to determine moderate to severe anxiety)
2. Beck Depression Inventory (20+ at baseline to determine moderate to severe depression)

The outcomes will be taken at baseline and again at 12 weeks. As a pilot study, no interim measures were felt necessary over this relatively short timescale.

Key secondary outcome(s)

1. Irritable bowel syndrome measures using ROME-II Criteria
2. Acceptability of intervention (qualitative)

The outcomes will be taken at baseline and again at 12 weeks. As a pilot study, no interim measures were felt necessary over this relatively short timescale.

Completion date

03/10/2014

Eligibility**Key inclusion criteria**

1. Aged between 20 and 50 years, either sex
2. Diagnosis of IBS using Rome II Criteria and either moderate/severe anxiety and/or depression
3. Medication on stable dosage for at least 4 weeks before entry into the study
4. Demonstrates a full understanding of the study protocol and its requirements
5. Demonstrates willingness to take either trial probiotic or control placebo as required in the study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Already taking regular probiotic supplement
2. No IBS
3. Has IBS but not moderate/severe anxiety or depression
4. Unstable medication
5. Lactose intolerance
6. Demonstrates difficulty in understanding study protocol requirements
7. Does not agree to take either trial probiotic or control placebo as required in the study protocol

Date of first enrolment

06/10/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of East Anglia

Norwich

United Kingdom

NR4 7TJ

Sponsor information

Organisation

Yakult UK Ltd (UK)

ROR

<https://ror.org/03wmnrc91>

Funder(s)

Funder type

Industry

Funder Name

Yakult UK Ltd (UK) (ref: R16767)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type

[HRA research summary](#)

Details

Date created

Date added

28/06/2023

Peer reviewed?

No

Patient-facing?

No