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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2008	**Overall study status** Completed	
Last Edited 06/06/2018	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2014-001854-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
06/10/2008

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

Age group
Adult

Sex

Both

Target number of participants
80 referrals, 40 to final analysis (30 trial arm, 10 control arm)

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
England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
Yakult UK Ltd (UK)

Sponsor details
c/o Dr Linda Thomas, UK Science Manager
Artemus
Odyssey Business Park
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Sponsor type
Industry

ROR
https://ror.org/03wmnrc91

Funder(s)

Funder type
Industry

Funder Name
Yakult UK Ltd (UK) (ref: R16767)

Results and Publications

Publication and dissemination plan
Planned publication in Pharmaceutical Science Journal.

Intention to publish date
03/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No