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

Recruitment status No longer recruiting	[X] Prospectively registered		
	Protocol		
Overall study status	Statistical analysis plan		
Completed  Condition category	☐ Results		
	Individual participant data		
Digestive System	Record updated in last year		
	No longer recruiting  Overall study status  Completed  Condition category		

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

Dr Rod Lambert

#### Contact details

School of Allied Health Professions University of East Anglia Earlham Road Norwich United Kingdom NR4 7TJ

## 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

Αll

## 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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes