

# Investigation of WCFS1 on the gut microbiota of autistic spectrum disorder (ASD) children

<b>Submission date</b> 16/11/2011	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2011	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/04/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and aims?

Autism spectrum disorders (ASD) are a group of disorders which predominantly manifest behaviourally. However ASD children also commonly suffer gut symptoms, such as diarrhoea, constipation and abdominal pain. The bacteria that live within the gut may play a role in the gut symptoms. Children with ASD have higher levels of certain gut bacteria (such as Clostridium) and have different types of bacteria, compared to non-ASD children. Probiotics (functional foods) are good or beneficial bacteria used to modify the composition and activity of the gut bacteria and can reduce certain gut symptoms. The main aim of the research is to examine whether feeding a probiotic called Lactobacillus plantarum WCFS1 can change the gut bacteria in ASD children (to be more like that on non-ASD children) and/or reduce gut symptoms.

### Who can participate?

Children/adolescents with a clinical diagnosis of ASD, aged between 4-16, who have gut problems (minimum of 3 episodes in the last 6 months) and live within 75 miles of Reading study

### What does the study involve?

The study will take place over 7-weeks, week 1 (baseline) will enable control data to be collected, and the following 6-weeks will be the feeding period. All parts of this study will take place in the participants home, with visits made by the investigators at times convenient for you and your child.

Your child will be randomly assigned to one of two groups (A or B) and will receive either the probiotic or placebo. Participants will consume a single portion of the treatment (probiotic or placebo) once a day. The study will be double blinded which means that neither the participants (you and your child) nor the investigators will know which treatment each child receives.

**Microbiology:** During the study period your child will provide 4 faecal samples, 2 at baseline and 2 in after feeding (week 6). The faecal samples will be analysed using a number of techniques to examine the gut bacteria and different biomarkers of gut function.

**Gut symptoms:** During the 7-weeks a daily diary will be filled in to assess bowel movement(s) /gut symptoms using a severity scale (requiring a tick answers). In addition, any medication your child is taking or has during the study will also have to be recorded, including the type, dosage, start and end date of the medication.

**Behavioural assessment:** A single diagnostic assessment of the child's ASD will be done using the

Autism Diagnosis Observation Schedule (ADOS). The ADOS is often used in research as a standardised measure of a child's ASD. A trained researcher from the Department of Psychology (University of Reading) will carry out this assessment. Further to this, you as the parent/guardian will be asked to complete the Social Communication Questionnaire (SCQ), to provide the developmental history of your child.

Your child will be asked to do a computerised test (Connors Continuous Performance Test; CPT) twice during the study (once each in weeks 0 and 6). This test measures selective and sustained attention. Whilst the child carries out the CPT, an infrared camera (Qbtest) will track your child's head movement which will provide feedback measures for hyperactivity, inattention and impulsivity.

Two parent/guardian questionnaires (Developmental Behaviour Checklist; DBC-P) about your child's behaviour will need to be completed (one in week 0 and the other in week 6). In addition, we would like your child's main teacher/teaching assistant to fill in the equivalent DBC-T in week 0 and week 6.

What are the possible benefits and risks of participating?

Possible benefits include overall improvements in your child's gut health. Lactobacillus plantarum WCSF1 is safe for human consumption and thus does not pose any risk during this study. Changes in diet can sometimes lead to gut symptoms in certain individuals. However, there is no known report of adverse effects following Lactobacillus plantarum WCSF1 feeding. In addition, each participant completing the study will be able to trial the probiotic by receiving 6-weeks supply (open-label follow on).

Where is the study run from?

The study will be run and funded by the University of Reading.

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

The study will be open to participants from approximately January 2012 to June 2012.

Who is the main contact?

Holly Ambrose (trial co-ordinator)

[h.n.ambrose@pgr.reading.ac.uk](mailto:h.n.ambrose@pgr.reading.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Anne McCartney

### Contact details

Food and Nutritional Sciences

Whiteknights

PO BOX 217

Reading, Berkshire

United Kingdom

RG6 6AH

+44 (0)1183 788 593

[a.l.mccartney@reading.ac.uk](mailto:a.l.mccartney@reading.ac.uk)

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

n/a

## Study information

### Scientific Title

Investigation of the effects of Lactobacillus plantarum WCFS1 supplementation on the gut microbiota and gut symptoms of children with autistic spectrum disorder (ASD)

### Study objectives

Supplementation of the probiotic, Lactobacillus plantarum WCFS1 can modulate the gut microbiota associated with ASD, alleviate the gastrointestinal symptoms commonly suffered by ASD children, and affect the child's behaviour.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. NRES Committee South Central - Southampton, 19/08/2011 ref: 11/SC/0261
2. University of Reading Research Ethics Committee, 15/11/2011 ref: 11/56

### Study design

Single-centre randomised double-blind placebo controlled parallel study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Screening

### Participant information sheet

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

### Health condition(s) or problem(s) studied

Autistic spectrum disorder

## **Interventions**

A randomised placebo-controlled, double blind parallel feeding study testing a probiotic (Lactobacillus plantarum WCFS1) and a placebo. A single dose ( $4.5 \times 10^{10}$  CFU/g) will be consumed daily for period of 6 weeks.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. To use multiple molecular techniques to investigate whether probiotic (Lactobacillus plantarum WCFS1) supplementation can modulate the gut microbiota associated with ASD
2. Particular interest will focus on quantification, and changes in the diversity and dynamics of lactic acid bacteria and clostridia

## **Secondary outcome measures**

1. Can probiotic (Lactobacillus plantarum WCFS1) supplementation alleviate the gastrointestinal symptoms commonly suffered by ASD children?
2. Does probiotic (Lactobacillus plantarum WCFS1) supplementation affect the behaviour of ASD child?

Investigation of non-invasive inflammatory markers and faecal Clostridium toxicity genes and the effects of probiotic supplementation on these.

## **Overall study start date**

01/01/2012

## **Completion date**

31/01/2012

# **Eligibility**

## **Key inclusion criteria**

1. Children / adolescents with clinical diagnosis of ASD
2. Children with gut problems (minimum of 3 episodes in the last 6 months)
3. Aged between 4-16 years
4. Consent given by parent/guardian

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

4 Years

## **Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

Seventy children aged 4-16 with a diagnosis of ASD, who have gut symptoms.

**Key exclusion criteria**

1. Prebiotic / probiotic administration within the last 6 weeks
2. Involvement in another study involving drug/medication affecting gastrointestinal (GI) motility during the month prior to and throughout the study
3. Living more than 75 miles from Reading, UK

**Date of first enrolment**

01/01/2012

**Date of final enrolment**

31/01/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Food and Nutritional Sciences**

Reading, Berkshire

United Kingdom

RG6 6AH

## **Sponsor information**

**Organisation**

University of Reading (UK)

**Sponsor details**

c/o Dr Mike Proven

Whiteknights

Reading

England

United Kingdom

RG6 6AH

**Sponsor type**

University/education

**Website**

<http://www.reading.ac.uk/>

**ROR**

<https://ror.org/05v62cm79>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

University of Reading (UK)

**Alternative Name(s)**

UoR

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration