

# Intervention within the British Autism Study of Infant Siblings (iBASIS)

<b>Submission date</b> 22/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Recent research has opened up the possibility of very early intervention for infants at high risk of developing autism (i.e., who are siblings of children already diagnosed). Theory suggests that some aspects of brain and genetic functioning may be responsive to environment effects, especially during the estimated 1000 hours of one-to-one social interaction in the first year with parents/caregivers. Treatment could therefore be targeted to modify this aspect of the infant's environment. There are new methods to identify behavioural and biological markers in infancy that may be associated with later emergence of autistic spectrum disorder (ASD). Furthermore, there is indirect evidence that treatment at this age may be appropriate and effective: there are established treatments for diagnosed autism later in the pre-school years which do show effectiveness, and evidence that similar treatment approaches can show positive effects on parent-infant interaction and functioning in non-autistic infants. The aim of this study is to test a targeted treatment at the end of the 1st year in high-risk infant siblings. The aim is to work with parents to help them understand their infant's particular communication style and adapt to it in order to promote their infant's social and communicative development.

### Who can participate?

8-10 -month-old infants at high genetic risk of autism (i.e., with an older sibling diagnosed with an autism spectrum disorder).

### What does the study involve?

Participants are randomly allocated to one of two groups. One group receives no treatment and the other group participates in the iBASIS programme. The iBASIS programme takes place in families' homes and involves 10 1-hour visits from a trained therapist over 5 months. Each session involves the therapist making a video recording of the parent and infant interacting and playing at home for about 6 minutes. The therapist and parent will watch the video recordings together and parents will receive detailed feedback from the therapist about their interaction. We look at how opportunities for communication could be enhanced. During each session the therapist will explain clearly what the parent will be doing and parents will be able to ask questions at any time.

What are the possible benefits and risks of participating?

The study will give information on the feasibility, acceptability and impact of this treatment. Numerous previous studies indicate that there is no evidence of any harmful effect, although we will be evaluating this carefully as part of our work.

Where is the study run from?

The University of Manchester (UK)

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

May 2011 to April 2013

Who is funding the study?

Autistica and the Waterloo Foundation (UK)

Who is the main contact?

Clare Holt

clare.holt@manchester.ac.uk

### **Study website**

<http://www.medicine.manchester.ac.uk/IBASIS>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Jonathan Green

### **Contact details**

The University of Manchester

Room 4.307

Jean McFarlane Building

Oxford Road

Manchester

United Kingdom

M13 9PL

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jonathan.green@manchester.ac.uk

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7267

# Study information

## Scientific Title

Intervention within the British Autism Study of Infant Siblings (iBASIS): a pilot single-blinded randomised controlled trial

## Acronym

iBASIS

## Study objectives

Does the iBASIS intervention show evidence of improving infant functioning in the short and medium term? Is the intervention feasible in the UK and acceptable to parents? Does the intervention improve parent-child communication? Is there any evidence of adverse effects?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. London Research Ethics Committee, 23/04/2009 ref: 09/H0718/14
2. Central Manchester University Hospitals, ref: R00720
3. Central and North West London, ref: KUKCC1101

## Study design

Pilot single-blinded randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Home

## 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

Autism Spectrum Conditions

## Interventions

Two parallel groups: intervention and non-intervention. Research assessments will be made independently and blind to treatment status.

The iBASIS intervention would take place in families' homes and would involve visits from a trained therapist. The iBASIS programme lasts 5 months: there are 10 sessions in total - 1hr each.

The first six sessions will be weekly at the family's home. The following four will be separated by three weeks.

Each session will involve the therapist making a video recording of the parent and infant interacting and playing in a natural setting at home for a period of about 6 minutes. The therapist and parent will watch the video recordings together and parents will receive detailed feedback from the therapist about features of the interaction.

We look at how opportunities for communication could be enhanced. We also agree how parents might be able to explore more and practice the things we discuss in between these sessions; and the programme aims that parents will be able to do about 30 minutes of such 'practice' daily.

During each session the therapist will explain clearly what the parent will be doing and parents will be able to ask questions at any time.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Autism Observation Scale for Infancy (AOSI): a validated instrument designed to measure developmental atypicality. It has shown predictive validity to later diagnosis of autism.

### **Secondary outcome measures**

1. Coding of parent-child interaction: Global and micro measures of the parent-infant interaction coded from a free-play session. The coding aims to assess the impact of the i-BASIS intervention on parental sensitive responsiveness and dyadic mutuality.
2. Neurophysiological and brain biomarkers: The infant will complete a range of assessments including their response to social stimuli and gaze patterns
3. Qualitative analysis of parent intervention to address subjective impact of intervention

### **Overall study start date**

01/05/2011

### **Completion date**

01/04/2013

## **Eligibility**

### **Key inclusion criteria**

1. Families live within therapist travel distance
2. Aged between 0 and 9 months at the time of referral
3. Have older sibling diagnosed with an autism spectrum disorder (ASD)
4. English spoken at home

### **Participant type(s)**

Patient

### **Age group**

Neonate

**Sex**

Both

**Target number of participants**

50

**Key exclusion criteria**

1. Child does not meet BASIS and iBASIS criteria
2. Known genetic or cognitive impairment
3. More than one infant

**Date of first enrolment**

01/05/2011

**Date of final enrolment**

01/04/2013

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

The University of Manchester

Manchester

United Kingdom

M13 9PL

**Sponsor information****Organisation**

University of Manchester (UK)

**Sponsor details**

Faculty of Medical and Human Sciences

The University of Manchester

Simon Building

Brunswick Street

Manchester

England

United Kingdom

M13 9PT

**Sponsor type**

University/education

**Website**

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

**ROR**

<https://ror.org/027m9bs27>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Autistica (UK) protocol ref: 7267

**Funder Name**

The Waterloo Foundation (UK) ref: 770-1025

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2015		Yes	No