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

Submission date
22/07/2011

Recruitment status
No longer recruiting

Registration date
10/11/2011

Overall study status
Completed

Last Edited
02/10/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Study website
http://www.medicine.manchester.ac.uk/IBASIS

Contact information

Type(s)
Scientific

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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 famiy'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. Neurophyisological 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
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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?
Results article	results	01/02/2015		Yes	No