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New parent group intervention to Manage Repetitive Behaviours in young children with autism spectrum disorder (ASD)

Submission date
11/06/2012

Recruitment status
No longer recruiting

Registration date
11/06/2012

Overall study status
Completed

Last Edited
26/08/2016

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
Repetitive behaviours (RBs) are a core feature of autism spectrum disorder (ASD). These RBs can cause significant social impairment and distress for the individual and their family, interfere with learning and decrease the likelihood of positive interaction and acquisition of new skills. There is no parent group based intervention targeting RBs for young children with ASD. Most early ASD parent groups focus on social communication skills. We have developed with parents and professionals a new parent-based group intervention that focuses on identification, understanding and management of RBs in young children.

The short-term aim is to conduct a study of our new parent group intervention to help parents understand and manage their childs RBs. This study will inform the design of a larger study and help us identify what level of treatment is required to maximise benefits to individual children with ASD. The long-term objective is to enable parents to have a better understanding of why children with ASD may show several RBs, and manage those behaviours which cause difficulty for the family.

Who can participate?
We will recruit 36 parents of young children with autism, ASD or Asperger syndrome, aged 3 to 8 years, who show several RBs.

What does the study involve?
Participating families will be randomly allocated to either the intervention group or the control group. Families in the intervention group will be contacted by the study team to arrange attending the parent group sessions. They will remain under the overall clinical responsibility of local teams and should continue to receive their existing routine care while the group intervention is taking place. Families in the control group will remain under overall clinical care of local teams and should continue to receive their existing routine care. Families in both arms of the trial will receive research assessments at baseline, and after 10, 18 and 24 weeks. If possible we would ask that any medication taken by the child is kept at the same level (i.e., until after the final study assessments have been completed).

What are the possible benefits and risks of participating?
This group course has been shown to be helpful in our preliminary development study. This new study will indicate how feasible and acceptable the Managing Repetitive Behaviour groups are, as well as suggesting how much change occurs in parents confidence and childrens behaviour. We do not think there are any disadvantages or risks if you participate in this study. The questionnaires ask about everyday behaviours of your child, so we do not anticipate that this will cause any problem for you. All travel expenses for attending assessments and group sessions will be reimbursed.

Where is the study run from?
Parent groups will be based in the North East of England (UK)

When is study starting and how long is it expected to run for?
February 2012 to February 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Vicki Grahame
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Contact information

Type(s)
Scientific

Contact name
Dr Victoria Grahame

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11829

Study information

Scientific Title
Pilot randomised trial of a new parent group intervention to Manage Repetitive Behaviours in young children with autism spectrum disorder (ASD)

Acronym
MRB

Study objectives
This study is a feasibility and acceptability randomised controlled trial (RCT) of a parent group intervention to manage repetitive behaviours in young children with ASD. Parents are randomly allocated to intervention or to a waiting list control. It is hoped that by increasing parents' confidence and knowledge of strategies the impact of RBs on the child and family willl be reduced.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Reserach Authority: NRES Committee North East - Newcastle & North Tyneside 1, First MREC approval date 09/12/2011, ref: 11/NE/0379

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Mental Health Research Network; Subtopic: Autism spectrum disorders; Disease: Autism spectrum disorders

Interventions
Parents are randomly allocated to intervention or to a waiting list control.

MRB, Acceptability and feasibility pilot RCT to help parents understand and manage repetitive behaviours in young children with ASD. 8 week manualised parent group intervention. Each session lasting 2 hours per session run by experienced specialist early years teacher and a co-therapist.

Follow Up Length: 6 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Target Repetitive Behaviour Vignette; Timepoint(s): Baseline, end of intervention, 18 weeks and 24 weeks

Secondary outcome measures
1. 10min Parent-Child Interaction in Play; Timepoint(s): Baseline, end of intervention, 18 and 24 weeks follow-up
2. Clinical Global Index of Improvement (CGI-I); Timepoint(s): 18 weeks and 24 weeks
3. Repetitive Behaviours Questionnaire (RBQ2); Timepoint(s): RBQ 2 completed by the parent and teacher. Baseline, end of intervention, 18 and 24 weeks follow-up
4. The Parental Self-Efficacy scale; Timepoint(s): Baseline, end of intervention, 18 and 24 weeks follow-up

Overall study start date
10/02/2012

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Child aged 3 to 8 years old with a diagnosis of ASD
2. Parent sufficient spoken English to take part in assessments and groups
3. Agree not to try other new interventions while involved in study
4. Target Gender: Male & Female; Upper Age Limit 8 years ; Lower Age Limit 3 years

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit

8 Years

Sex
Both

Target number of participants
Planned Sample Size: 36; UK Sample Size: 36; Description: 36 young children with ASD aged 3-8 years

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/02/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Complex Neurodevelopmental Disorders Service
Newcastle
United Kingdom
NE6 4QD

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust (UK)

Sponsor details
Complex Neurodevelopmental Disorders Service
Walkergate Park Centre Benfield Road
Newcastle
United Kingdom
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Sponsor type
Charity

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Grant Codes: PB-PG-1010-23305

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	01/10/2015		Yes	No