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Managing repetitive behaviours parent group study

Submission date
06/08/2018

Recruitment status
No longer recruiting

Registration date
07/08/2018

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Managing Repetitive Behaviours (MRB) is an eight-session parent-mediated group intervention for parents of young children (aged 3-9 years & 11 months) with a diagnosis of Autism Spectrum Disorder. MRB aims to support parent to develop an understanding of the form and potential function of their child's challenging Restrictive Repetitive Behaviour (RRB). It also aims to support parents to develop effective strategies to improve the management of their child's challenging RRB in order to reduce the negative impact of these behaviours on child, parent and family functioning. Functional analysis principles will help parents to understand where and how to intervene and to develop alternative strategies and techniques to manage their child's negative experiences across a range of everyday contexts. The programme is delivered in eight two-hour sessions using a manualised programme which builds systematically on prior learning. This study aims to evaluate the clinical and cost effectiveness of MRB compared with Learning About Autism (a psychoeducation parent group, equivalent to current best practice), for the management of challenging RRB in children with ASD.

Who can participate?
Parents/carers aged 18 and over who have a child aged between 3 years and 9 years and 11 months with Autism or Autism Spectrum Disorder

What does the study involve?
Participants are randomly allocated to receive either the MRB intervention or a psychoeducation group (Learning About Autism). Parents are invited to attend eight group sessions with about seven other parents. Each group session lasts two hours and they take place about a week apart. There are breaks during the school holidays. Both the MRB group and the Learning About Autism group give parents the opportunity to meet other parents. Parents are contacted immediately after they complete all eight of the group sessions and then again 24 weeks and 52 weeks later to arrange home visits. During these home visits a member of the research team talks with the parent about their child's RRB in particular situations and they complete some questionnaires.

What are the possible benefits and risks of participating?
Families who take part in this study will be given an opportunity to contribute to research which

will help to improve our understanding of ASD and RRB. Finding out whether the MRB or Learning About Autism groups are effective will help find out which is the most helpful intervention to other families with young children with ASD within early intervention services. The disadvantages or risks of participating in this study are minimal. Parents may find it upsetting to discuss their child's feelings and reactions. This will be minimised by ensuring that the group is run by experienced professionals who are able to create a safe and supportive environment.

Where is the study run from?
1. Northumberland, Tyne and Wear NHS Foundation Trust (UK)
2. Tees, Esk and Wear Valleys NHS Foundation Trust (UK)
3. NHS Lothian (UK)

When is the study starting and how long is it expected to run for?
April 2018 to March 2022

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

Who is the main contact?
Ayesha Mathias
Ayesha.Mathias@newcastle.ac.uk

Study website
https://research.ncl.ac.uk/mrbstudy/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39269; HTA 16/111/95

Study information

Scientific Title
Managing repetitive behaviours: a clinical and cost effectiveness trial of a parent group intervention to manage restricted and repetitive behaviours in young children with autism spectrum disorder

Study objectives
The primary objective of this trial is to evaluate the clinical and cost effectiveness of the Managing Repetitive Behaviours (MRB) parent group intervention compared with Learning About Autism (a psychoeducation parent group, equivalent to current best practice), for the management of challenging RRB in children with ASD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2018, South West – Cornwall and Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead,
Bristol, BS1 2NT; Tel: +44 (0)207 104 8033, +44 (0)207 104 8004; Email: nrescommittee.southwest-cornwall-plymouth@nhs.net), REC ref: 18/SW/0173

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Repetitive behaviours in children with autism spectrum disorder

Interventions
This is a multicentre, 2 arm randomised control trial with 3 sites across England and Scotland. Patients will be randomised 1:1 to receive either the MRB intervention or psychoeducation group (Learning About Autism)

First, potentially eligible parents will be identified and approached by a health professional. If parents are interested in taking part after reading the information sheet, they will be asked to complete the Expression of Interest form (included with the sheet) and hand it to their child's health professional or post it directly to us via the envelope provided. The parents can contact the research team anytime to have their questions answered.

After the trialists have received the expression of Interest form, the parent will be called to discuss the study and answer any further questions they might have. If they are happy to take part, a member of the research team will arrange to meet with them and their child at home (or another place that is easy for them) to answer any questions they have. If the parent decides to take part, they are asked to sign a consent form and to complete some questionnaires. This will take around 1 hour.

The trialists will also arrange another visit to see both the parent and child at the university base. At this visit, they will ask the parent to complete some questionnaires and we will do an assessment of communication and social interaction with the child. The visit will take about 1.5 – 2 hours.

We will ask if we could approach the child's teacher so he/she can complete a questionnaire about the child's repetitive behaviours in the classroom.

After the university visit, the parent will be allocated to either the eight week MRB parent group OR the eight week Learning About Autism group run by the National Autistic Society. Which group they are allocated to will be decided randomly by a computer programme, not a member of the research team.

Whichever group they are in, the trialists will invite the parent to attend eight group sessions with approximately seven other parents. They would like the same parent to attend each session, but a second, adult family member is welcome to join the group too. Each group session will last two hours and they will take place about a week apart. There will be breaks during the

school holidays. Both the MRB group and the Learning About Autism group give parents the opportunity to meet other parents.

Regardless of which group the parent is in (either MRB or Learning About Autism), they are contacted immediately after they complete all eight of the group sessions, and then again 24 weeks and 52 weeks later to arrange home visits. During these home visits a member of the research team will talk with the parent about their child's RRB in particular situations and will ask to complete some questionnaires.

Intervention Type
Behavioural

Primary outcome measure
Improvement or no improvement at 24 weeks, based on the clinical global impression of improvement (CGI-I)

Secondary outcome measures
Primary Economic Outcome Measure
Cost per additional child achieving at least the target improvement in CGI-I scale will be calculated in each pathway

Secondary Child Outcome Measures
1. Restrictive Repetitive Behaviours (RRB), measured using Target Behaviour Vignette at baseline, Week 10, Week 24 and Week 52
2. RRB, measured using Repetitive Behaviour Questionnaire - 2 (RBQ-2) at baseline, Week 10, Week 24 and Week 52
3. RRB, measured using Teacher Repetitive Behaviour Questionnaire 2 (Teacher RBQ-2) at baseline, Week 10, Week 24 and Week 52
4. Adaptive functioning, measured using Vineland Adaptive Behaviour Scales III (VABS III) at baseline and Week 24

Parent Outcome Measures
1. Behaviours typically exhibited by children with ASD, measured using parent self-efficacy questionnaire at baseline, Week 10, Week 24 and Week 52
2. Parenting stress specific to core and co-morbid symptoms of ASD, measured using Autism Parenting Stress Index (APSI) at baseline, Week 10, Week 24 and Week 52
3. Wellbeing, measured using Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, Week 24 and Week 52

Secondary Family Outcome Measures
Autism Family Experience Questionnaire (AFEQ) at baseline, Week 24 and Week 52

Secondary Economic Outcome Measures
1. Healthcare resources which are used by the children, measured using resource use questionnaire at baseline, Week 24 and Week 52. This will be calculated to result in an average cost of services per pathway
2. Costs and time lost to travel, measured using time and travel questionnaire at baseline
3. Health-related quality of life of caregivers reported per child, measured using EQ-5D-5L questionnaire at baseline, Week 24 and Week 52
4. Health-related quality of life of the child with RRB, measured using CHU9D proxy version at baseline, Week 24 and Week 52

Updated 04/04/2019: VABS II changed to VABS III.

Overall study start date
01/04/2018

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/08/2019:
Parents/carers aged 18 years and over who:
1. Have a child aged between 3 years and 9 years and 11 months at the time of consent with a clinical diagnosis of Autism or Autism Spectrum Disorder
2. Have sufficient spoken and written English to:
2.1. Provide written informed consent
2.2. Complete the assessments including being able to identify one or more challenging RRB
2.3. Participate in the group-based intervention
3. Are willing to be randomised and attend all the group sessions for the allocated arm of the study
4. Agree to maintain their child's current medication regime up to 24 weeks (unless change is advised by child's clinician)
5. Agree not to participate in any other trials while involved in the trial up to 24 weeks

Previous inclusion criteria:
Parents/carers aged 18 years and over who:
1. Have a child aged between 3 years and 7 years and 11 months at the time of consent with a clinical diagnosis of Autism or Autism Spectrum Disorder
2. Have sufficient spoken and written English to:
2.1. Provide written informed consent
2.2. Complete the assessments including being able to identify one or more challenging RRB
2.3. Participate in the group-based intervention
3. Are willing to be randomised and attend all the group sessions for the allocated arm of the study
4. Agree to maintain their child's current medication regime
5. Agree not to participate in any other trials while involved in the trial up to 24 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Parent and child currently taking part in another parent group-based intervention
2. Parent with a current severe learning disability or a severe disabling mental illness that interferes with ability to take part in group-based intervention trial
3. Sibling is taking part in this study

Date of first enrolment
01/09/2018

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Complex Neurodevelopmental Disorder Service (CNDS)
Northumberland, Tyne and Wear NHS Foundation Trust
Walkergate Park
Benfield Road
Newcastle upon Tyne
United Kingdom
NE6 4QD

Study participating centre
Derwentside CAMHS
Tees, Esk and Wear Valleys NHS Foundation Trust
Derwentside Child and Family Centre
192 Medomsley Road
Consett
United Kingdom
DH8 5HT

Study participating centre
Royal Hospital for Sick Children
NHS Lothian
9 Sciennes Rd

Edinburgh
United Kingdom
EH9 1LF

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust

Sponsor details
St. Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3XT
+44 (0)191 246 7221
Lyndsey.Dixon@ntw.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Newsletters summarising the progress and findings of the study will be sent to families and local professionals who have taken part in recruitment and supported the study, both during the trial to support retention, and at the end of the study to share findings. The study protocol will be published, and findings will be written up for academic peer reviewed journals (including open access) and presented at relevant national and international conferences.

Intention to publish date

31/07/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/04/2021	03/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		09/06/2025	01/09/2025	Yes	No