

REACH-ASD Trial: A randomised controlled trial of a new workshop programme offering information, empowerment and emotional support to parents of children recently diagnosed with Autism Spectrum Disorder

Submission date 10/09/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/09/2019	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Between 20-50% of parents will experience difficulties with their mental health in the period following their child's ASD diagnosis; feelings of shock, grief, disorientation and disempowerment are common. Some parents experience stress about a lack of appropriate support for their child. Many are desperate to understand more about the condition and ways in which they can help their child. Best practice guidelines recommend post-diagnosis family support. However, current provision is patchy across the UK, a source of increasing dissatisfaction for both parents and professionals, and crucially it lacks any evidence base for effectiveness. The aim of this study is to assess the EMPOWER-ASD programme. EMPOWER-ASD is an evidence-based group programme which aims to support parents following their child's ASD diagnosis by combining: information about ASD; strategies to support their child's communication, wellbeing and behaviour; psychological strategies focused on parental adjustment and wellbeing to boost parental mental health, adaptation, and understanding of ASD. The programme consists of five weekly group sessions which last for three hours.

Who can participate?

Parents/primary caregivers of children aged 2-15 years who have received a diagnosis of ASD in the last 12 months in the Greater Manchester area

What does the study involve?

An independent researcher will ask the parent questions (verbally and in written questionnaires) about their mental health and other aspects of family life and about the wellbeing and functioning of their child with ASD. The researcher will also ask the child's teacher to fill in a questionnaire about the child. Parents will be randomly allocated to two groups. Two-thirds of parents, chosen at random, will be invited to attend the EMPOWER-ASD intervention in addition to their usual services; a third will continue to receive their usual services without additional

intervention from the trial. Parents will complete further written questionnaires after 3 and 6 months. After 12 months, the independent researcher will visit the parents' home and repeat the interviews and questionnaires that they did at the beginning. The researcher will also ask the child's teacher to fill in a questionnaire about the child again.

What are the possible benefits and risks of participating?

Parents in both groups will have the opportunity to talk to and share their story and viewpoint with a researcher. This is something that many parents value.

Parents randomly allocated to the trial intervention group will receive the comprehensive group-based intervention delivered by trained professionals. There is preliminary evidence that parents like these groups and find them helpful, but it is not known if they are beneficial (that is what the research aims to find out). Many parents of children with ASD have an altruistic motive to taking part in research and value the opportunity to take part in a trial that may help improve care of families of a child with ASD in the future. It is anticipated that there will be no serious potential risks to parents taking part in the trial. However, there is a time commitment involved in taking part in the research assessments. In order to minimise disruption and inconvenience to parents the researchers will offer a range of options for the timing of research assessment visits. The intervention will also require time commitment from the parent. Parents will be fully informed of the time commitment required for the intervention before consent, and it is entirely their decision as to whether or not to participate. Some of the parent interviews and questionnaires potentially cover topics that some parents may find difficult. These tools are used very widely in research and clinical practice. Some parents have found completing assessments like these an 'intense' experience but have also commented that it has been very useful to identify and communicate their feelings in this way. During interviews, researchers will present questions in a sensitive way and offer the parent the chance to take a break or halt the interview if the parent becomes upset.

Where is the study run from?

A total of six NHS partner centres are involved in REACH-ASD. These will be community paediatric teams/child development teams and child and adolescent mental health teams that are involved with ASD assessment and intervention.

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

September 2019 to A2023

Who is funding the study?

National Institute for Health Research Health Technology Assessment Board (UK)

Who is the main contact?

1. Dr Kathy Leadbitter

reach-asd@manchester.ac.uk

kathy.leadbitter@manchester.ac.uk

2. Dr Richard Smallman

Richard.smallman@manchester.ac.uk

Study website

<https://sites.manchester.ac.uk/reach-asd/>

Contact information

Type(s)

Public

Contact name

Dr Kathy Leadbitter

ORCID ID

<http://orcid.org/0000-0002-0744-2800>

Contact details

Faculty of Biology, Medicine and Health
Division of Neuroscience and Experimental Psychology
3.312 Jean McFarlane Building
The University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 275 5969
kathy.leadbitter@manchester.ac.uk

Type(s)

Public

Contact name

Dr Richard Smallman

ORCID ID

<http://orcid.org/0000-0002-8957-4005>

Contact details

Faculty of Biology
Medicine and Health
Division of Neuroscience and Experimental Psychology
3.312 Jean McFarlane Building
The University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7943
Richard.smallman@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

268914

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HTA 17/80/09, IRAS 268914

Study information

Scientific Title

REACH-ASD trial: a randomised controlled trial of psycho-education and acceptance & commitment therapy for parents of children recently diagnosed with ASD

Acronym

REACH-ASD

Study objectives

The principal objective is to evaluate the clinical effectiveness of the EMPOWER-ASD intervention on parental mental health as measured by the General Health Questionnaire-30 (GHQ-30) at 12 months follow-up.

Secondary research questions

Objective 1: To complete intervention co-design with practitioners and two groups of parents: testing of acceptability and feasibility through satisfaction ratings and qualitative evaluation, and modification and finalisation of intervention manual (feasibility phase)

Objective 2: To identify perceptions of the intervention and barriers to implementation within routine service provision (process evaluation in main trial)

Objective 3: To test the effectiveness of the EMPOWER-ASD intervention over usual care on parental knowledge, wellbeing, health status, and adjustment, and parenting stress and self-efficacy, at 12, 26- and 52-week follow-up

Objective 4: To test the effect of the intervention on: (i) family wellbeing; and (ii) child wellbeing, behaviour and adaptive functioning at 52-week endpoint

Objective 5: To assess the: (i) net costs and quality adjusted life years (QALYs) of the intervention compared to TAU and whether, when compared to TAU, the intervention is cost-effective (primary analysis); (ii) cost-effectiveness of the intervention using measures of parental mental health and child wellbeing (sensitivity analysis)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval 22/11/2019, North West-Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8009; nrescommittee.northwest-gmeast@nhs.net), REC ref: 19/NW/0596

Study design

Multi-centre two parallel-group single (researcher)-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Mental health and well-being of parents/caregivers of children recently diagnosed with Autism Spectrum Disorder (ASD)

Interventions

Randomisation to the intervention will be conducted through the online randomisation service of the King's College London Clinical Trials Unit web-based randomisation service.

Randomisation will be on an individual child basis, with one "index" parent per child, using a 2:1 ratio (10 to intervention, 5 to TAU), and stratification by recruitment centre. Supervising clinicians will contact families to feedback allocation and invite to intervention groups where applicable.

Treatment as Usual (TAU)

Standard care pathways are specified within the NICE guidelines, but vary considerably across services and NHS Trusts. Provision ranges from no follow-up care to one or more of: single session review; NHS or charity-led group interventions of varying intensities; individual needs-led interventions; or onward referral. Feedback from clinicians gives similar patterns of variation within the Greater Manchester region. These centre differences will be captured via detailed service-use data collection and factored into the design and analyses by stratifying the randomisation by centre.

Trial Intervention:

The EMPOWER-ASD programme, a closed-group manualised intervention composed of 5 x 3-hour sessions. The programme contains 3 components:

1. ASD Psycho-education and Empowerment

A workshop model developed and delivered over 10 years within the Manchester University NHS Foundation Trust Child and Adolescent Mental Health Service (MFT CAMHS). The model uses collaborative problem-solving to skill up parents to become ASD experts. Themes include: (i) understanding ASD; (ii) understanding and working with the education system; (iii) enabling your child's communication and understanding; and (iv) understanding and managing emotions, behaviour and sensory needs. Parents are informed about evidence-based practice and directed to local, national and online sources of information and support.

2. Acceptance and Commitment Therapy (ACT)

A brief manualised ACT programme developed specifically for parents of children with ASD. The sessions aim to develop psychological flexibility and promote stress reduction and adjustment through two main principles: (i) acceptance of those things beyond your control: reflection on any current struggles/stress surrounding the child's diagnosis/condition and existing strategies for dealing with this; the option of accepting these struggles/difficult thoughts and feelings

rather than fighting against them; simple mindfulness techniques to deal with stressful situations; (ii) commitment to making changes that are important to you and your family: reflection on core parenting values and the barriers in putting those values into action, particularly in light of the child's needs and recent diagnosis, and any possible solutions to overcome those barriers; making a commitment to moving towards one's core values. These two principles are introduced and reinforced through explanations, metaphors, videos, individual reflection and tasks, and group discussion, role play and experiential exercises.

3. Access to a secure web portal to support programme-related content.

The ACT component is a manualised 5-hour programme developed specifically for parents of children with disabilities, used with the developers' consent. The sessions aim to develop psychological flexibility and promote stress reduction and adjustment through two main principles: (i) Acceptance of those things beyond your control, and (ii) Commitment to making changes that are important to you and your family.

The control group will receive treatment as usual.

Intervention Type

Behavioural

Primary outcome measure

Parental mental health assessed using General Health Questionnaire- 30 at 1-year follow-up

Secondary outcome measures

Current secondary outcome measures as of 12/07/2022:

Parent outcomes, measured at baseline and 12-, 26- and 52-week follow-up:

1. Parental ASD knowledge assessed using the Knowledge of Autism Questionnaire – UK
2. Parental wellbeing assessed using Warwick & Edinburgh Mental Wellbeing Scale
3. Parent health status assessed using EQ-5D-5L
4. Parental adjustment to diagnosis assessed using Reaction to Diagnosis Questionnaire
5. Parenting stress assessed using Autism Parenting Stress Index
6. Parenting self-efficacy assessed using Tool to measure Parenting Self Efficacy

Family wellbeing and child functioning outcomes , measured at baseline and 52-week follow-up:

1. A parent-nominated self-report measure of family experience and wellbeing developed through parent consultation within previous trials (Autism Family Experience Questionnaire)
2. Expressed emotion as a blind-rated measure of family emotional climate (Autism Five Minute Speech Sample)
3. Child wellbeing assessed using Child Health Utility 9D Index
4. Child emotional and behaviour difficulties assessed using parent- and teacher (blind)-rated Strengths and Difficulties Questionnaire
5. Adaptive functioning assessed using parent(blind)-rated Vineland Adaptive Behaviour Scales

Previous secondary outcome measures:

Parent outcomes, measured at baseline and 12-, 26- and 52-week follow-up:

1. Parental ASD knowledge assessed using Revised Autism Knowledge Survey
2. Parental wellbeing assessed using Warwick & Edinburgh Mental Wellbeing Scale
3. Parent health status assessed using EQ-5D-5L
4. Parental adjustment to diagnosis assessed using Reaction to Diagnosis Interview
5. Parenting stress assessed using Autism Parenting Stress Index
6. Parenting self-efficacy assessed using Tool to measure Parenting Self Efficacy

Family wellbeing and child functioning outcomes , measured at baseline and 52-week follow-up:

1. A parent-nominated self-report measure of family experience and wellbeing developed through parent consultation within previous trials (Autism Family Experience Questionnaire)
2. Expressed emotion as a blind-rated measure of family emotional climate (Autism Five Minute Speech Sample)
3. Child wellbeing assessed using Child Health Utility 9D Index
4. Child emotional and behaviour difficulties assessed using parent- and teacher (blind)-rated Strengths and Difficulties Questionnaire
5. Adaptive functioning assessed using parent- and teacher (blind)-rated Vineland Adaptive Behaviour Scales

Overall study start date

01/09/2019

Completion date

30/04/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 13/10/2020:

1. At consent, child aged between 2 years 0 months and 15 years 11 months. This is the age-range typically seen by ASD diagnostic teams.
2. At referral, child with a diagnosis of ASD from an NHS professional within the last 12 months.
3. One "index" adult (child's parent/primary caregiver; must be aged 18 years or over) per child, nominated by family on "intention to participate" basis
4. Child with ASD is a patient of one of the trial collaborating centres

Previous inclusion criteria:

1. At consent, child aged between 2 years 0 months and 15 years 11 months with a diagnosis of ASD from an NHS professional within the last 12 months.
2. One "index" adult (child's parent/primary caregiver; must be aged 18 years or over) per child, nominated by family on "intention to participate" basis
3. Child with ASD is a patient of one of the trial collaborating centres

Participant type(s)

Carer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

380 parents/primary caregivers of children aged 2-15 years with a recent ASD diagnosis recruited from 6 Greater Manchester NHS centres

Total final enrolment

379

Key exclusion criteria

1. Adult with insufficient English language to preclude participation
2. Adult with significant learning disability or significant hearing/visual impairment to preclude participation
3. Adult with current severe psychiatric condition to preclude participation
4. Significant current safeguarding concerns within family, identified by referring clinician

Date of first enrolment

01/12/2019

Date of final enrolment

30/04/2022

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**University of Manchester**

Faculty of Biology, Medicine and Health
Division of Neuroscience and Experimental Psychology
3.312 Jean McFarlane Building
The University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information**Organisation**

Manchester University NHS Foundation Trust

Sponsor details

Central Research Office
Nowgen Building
Grafton Street
Manchester
England

United Kingdom
M13 9WL
+44 (0)1612764125
lynne.webster@mft.nhs.uk

Sponsor type

Hospital/treatment centre

Website

mft.nhs.uk

ROR

<https://ror.org/00he80998>

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

Data will be reported and disseminated by:

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

A written summary of the study results will be sent to all participants in the form of a newsletter at the end of the study. Parents will be invited to attend a dissemination event in Manchester. We will publish our findings on the study website.

Intention to publish date

14/04/2024

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		22/07/2022	25/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	12/06/2023	10/11/2023	No	No
Statistical Analysis Plan	Health Economic Analysis Plan version 3	31/10/2023	18/12/2023	No	No
Other publications		18/09/2024	08/10/2024	Yes	No
Results article		05/03/2025	18/03/2025	Yes	No