

Preschool Autism Communication Trial

Submission date 20/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

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

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0401546

Study information

Scientific Title

Preschool Autism Communication Trial

Acronym

PACT

Study objectives

The main hypothesis is that the addition of a systematic, theory-based preschool family intervention, targeted on known core social communication impairments in autism, will result in significant improvement in autism-specific symptoms compared to Treatment As Usual (TAU).

Secondary hypotheses are that:

1. This improvement will be mediated by changes in specific aspects of parent-child communication targeted by the treatment
2. General language development will be accelerated
3. Teacher-observed child adaptation will be improved

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Manchester Research Ethics Committee, 09/03/2006, ref: 05/Q1407/311

Study design

Three-site two-arm single (rater) blinded randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Study information for participants in <http://www.medicine.manchester.ac.uk/pact/participants/>

Health condition(s) or problem(s) studied

Autism

Interventions

Treatment versus treatment as usual, evaluated on standard autism and behavioural instruments and including health economic analysis.

Trial treatment: the PACT intervention targets core social interactive and language /communication impairments in autism, which have been identified in developmental research. The treatment is manualised and staged to reflect the developmental progression of pre-linguistic skills and video feedback is used throughout the treatment. Following the 6-month primary intervention, there is a second 6-month period in which there are monthly booster sessions. These focus on the consolidation and generalisation of treatment gains into everyday routines.

TAU: families in both arms of the trial will continue with TAU provided by their services. All aspects of TAU will be measured as part of the economic data collection, which will allow us to evaluate its nature and intensity.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcome measures amended as of 01/08/2007:

Endpoint is 13 months after start of treatment. The primary outcome will be the total score on the ADOS-G, a structured play-based assessment between researcher and child, videotaped for independent coding within domains of reciprocal social interaction, language, communication and autism specific behaviours. It will be rated blind to case status. The ADOS-G is the gold standard observational measure of autism specific symptoms. There will also be economic analysis including cost effectiveness.

Primary outcome measures provided at time of registration:

Endpoint is 12 months after start of treatment. The primary outcome will be the total score on the ADOS-G, a structured play-based assessment between researcher and child, videotaped for independent coding within domains of reciprocal social interaction, language, communication and autism specific behaviours. It will be rated blind to case status. The ADOS-G is the gold standard observational measure of autism specific symptoms. There will also be economic analysis including cost effectiveness.

Secondary outcome measures

Added as of 31/07/2007:

Parent-Child Interaction measure (PCI): MacArthur Communication Development Inventory (MCDI), Preschool Language Scales (PLS) and the Teacher Vineland Adaptive Behaviour Schedule (TVABS)

Overall study start date

13/02/2006

Completion date

12/10/2009

Eligibility

Key inclusion criteria

Children between the ages of 2 and 4 years 11 months, fulfilling diagnostic criteria for core autistic disorder on both social and communication domains of the Autism Diagnostic Observation Schedule-Generic (ADOS-G) - the primary outcome measure, and on two out of the three functional domains of the Autism Diagnostic Interview-Revised (ADI-R).

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

4 Years

Sex

Both

Target number of participants

144; 72 in each treatment arm

Key exclusion criteria

1. Cases where primary language at home is not English
2. Significant hearing or visual impairment in child or adult
3. Clinically severe psychiatric illness in parents

We judge that the above features could make a treatment based on dyadic communication unreliable to administer.

4. Children below a threshold of 11-month non-verbal developmental age assessed on the Mullen scales of early learning will also be excluded

Additional exclusion criteria added as of 01/08/2007:

5. Twins
6. Epilepsy requiring regular medication

Date of first enrolment

13/02/2006

Date of final enrolment

12/10/2009

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Booth Hall Children's Hospital
Manchester
United Kingdom
M9 7AA

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
University of Manchester
Manchester
England
United Kingdom
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Sponsor type
University/education

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

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

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Funder Name

Department for Education and Skills (DFES) (UK)

Funder Name

Department of Health (DoH) (UK)

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	19/06/2010		Yes	No
Results article	results	21/12/2015		Yes	No
Results article	long-term follow-up results	19/11/2016		Yes	No