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Preschool Autism Communication Trial

Submission date	Recruitment status	[ ] Prospectively registered
20/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/10/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
4 Years

Sex

All

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
United Kingdom

England

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

Sponsor information

Organisation
University of Manchester (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, Medical Research Committee and Advisory 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

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
Participant information sheet	Participant information sheet Study website	11/11/2025	11/11/2025	No	Yes

Study website	11/11/2025	11/11/2025	No	Yes