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Improving autistic children's social communication with parents in everyday settings

Submission date
09/03/2016

Recruitment status
No longer recruiting

Registration date
10/03/2016

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism is a lifelong condition that affects the way that a person communicates and relates to others. It is a spectrum condition, which means that the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general however, the difficulties sufferers experience tend to fall into social communication (speech and body language), social interaction (recognising and expressing emotions) and social imagination (being able to understand and predict other people's behaviour). Children with autism often find it difficult to transfer skills learned in one setting to another. A previous study (the Preschool Autism Communication Trial, PACT) showed that in a clinical setting it was possible to help improve communication between parents and child however these improvements were less obvious in other settings. The aim of this study is to test ways to transfer the child's communication gains into everyday home and education settings.

Who can participate?
Autistic children aged between 2 and 11 years.

What does the study involve?
This project is split into two phases. In the first phase, all participants receive the PACT-G therapy. This therapy involves coaching the parents in ways of interacting with their child. This takes place over a number of sessions, and is accompanied by sessions in educational settings (preschool or school) with educational staff. This part of the project is to find out whether schools are able take part and how easy it is to recruit participants for the study. In the second phase of the project, participants are randomly allocated to one of two groups. Those in the first group take part in the PACT-G therapy and those in the second group continue as usual, with no additional therapy. Children are assessed, and parents and teachers complete a number of questionnaires at the start, middle (7 months) and end (11 months) of the treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved communication abilities within different settings. There are no notable risks involved with taking part in this study.

Where is the study run from?
The study is run by University of Manchester and takes place in participants' homes and schools across Newcastle, Manchester and London (UK)

When is the study starting and how long is it expected to run for?
February 2016 to July 2019

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

Who is the main contact?
Dr Kathy Leadbitter

Study website
http://www.pact-g.org/

Contact information

Type(s)
Public

Contact name
Dr Kathy Leadbitter

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20208

Study information

Scientific Title
Paediatric Autism Communication Trial – Generalised (PACT-G)

Study objectives

External pilot phase:
The aim of the external pilot phase is to:
1. Demonstrate schools' willingness and ability to engage with the study
2. Demonstrate the ability to recruit and retain participants

Full randomised controlled trial:
The aim of this study is to test an intervention designed systematically to promote generalisation of previously demonstrated clinic-assessed treatment gains into home and school contexts.
Hypotheses:
1. The intervention will show the added efficacy and cost-effectiveness of preschool and school-age autism outcomes in home, school and research settings compared to treatment as usual
2. There will be an increase in the generalisation of acquired communication across contexts and persons, shown by mediation and the mechanistic study

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester Central Research Ethics Committee, 28/01/2016, 15/NW/0912

Study design
External pilot phase: non-randomised feasibility study
Full randomised controlled trial: multi-centre randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Children, Mental Health; Subtopic: Children (all Diagnoses), Mental Health (Autism spectrum disorders); Disease: All Diseases, Autism spectrum disorders

Interventions
External pilot phase:
All participants receive the PACT-G therapy (see below)

Randomised controlled trial:
Participants are randomised to receive the PACT-G therapy (see below) or treatment as usual.

Both groups will have a pre-randomisation baseline assessment, a mid-point (after approx 7 months) and end-point assessment (after approx 11 months).

Detail of the PACT-G intervention
PACT-G therapy is an enhancement of the original clinic-based PACT therapy. This is a 'parent-mediated' therapy in which caregivers are coached, using video-feedback, to interact with their child using evidence-based strategies that facilitate communication development in the child.

Parent sessions: Parents will receive 12 intervention sessions. Prior to starting the intervention, a home visit is conducted to introduce the intervention to the parents, explore the family context and set expectations. Where feasible the first two sessions are delivered in a clinic, allowing the parent to learn early strategies in a controlled environment with a set of toys specially selected to facilitate interaction. Subsequent sessions are a mix of home based sessions and Skype/telephone-delivered consultation. Each parent session begins with a discussion of progress made since the last session. The parent and therapist then watch a 5-minute video, either a video made by the therapist of the parent and child in play or a parent-made video of a home based routine, such as mealtime. The therapist facilitates the parent to identify actions that lead to child communication and to adopt PACT-G strategies in their interaction with the child. Parents are assisted to set goals for themselves, based on the interaction strategies discussed. They are asked to practice these daily, initially in a half hour 'special time', but eventually during naturalistic opportunities throughout the day.

Education setting sessions: Therapy in the educational setting begins 1 - 2 months after the parent has commenced therapy, with a start time integrating into the school term schedule. In the education setting PACT-G sessions will be delivered to trained learning support assistants (LSA), who are additional staff with a specific remit to attend to the child's special needs and thus with dedicated individual time in the classroom or nursery. LSAs and other education staff receive an initial training session to introduce them to PACT-G therapy. The education-based intervention then consists of therapist-LSA sessions that mirror the therapist-parent sessions in the home. Videos are made of the LSA and the child and are used to coach the LSA in the use of appropriate PACT-G strategies. The LSA then implements these with the child daily in class time. There are 12 therapist-LSA sessions over 6 months, alternating in-school visits and skype /telephone consultation. PACT-G strategies will also be integrated in a complementary way with other communication strategies that may already be in use in the school.

Collaboration between parent and educational staff: Importantly, the separate therapeutic work with parents and LSAs described above will be supplemented with a schedule of joint parent-LSA meetings to support the work and ensure consistent use of strategies across home and education settings. The meetings will use the manualised technique of 'Structured Conversation with Parents' (SCP). Meetings are structured around 'explore', 'focus', 'plan' and 'review' stages, which allow the LSA and parent to share experiences and maximize intervention consistency.

Intervention Type
Other

Primary outcome measure
External pilot phase:
1. School engagement rate is determined by the total number of schools which have signed up to participate at the end of pilot phase, i.e. 6 months
2. Family recruitment rate is determined by the total number of families which have consented up to participate at the end of pilot phase, i.e. 6 months

Main randomised controlled trial:
Efficacy of the PACT-G therapy, which is assessed at mid-point (approx 6 - 8 months) and end-point (approx 11 months), with exact assessment tools to be determined during the external pilot phase.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2016

Completion date
30/07/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/10/2017:
1. Child over 2 years 0 months and under 11 years 0 months
2. Child has confirmed diagnosis of autism spectrum disorder
3. Child meets criteria for core autism on the Autism Diagnostic Observation Schedule (ADOS-2) and the Social Communication Questionnaire
4. Children who are aged 5 years and over are between P3 and P8 for the English curriculum
5. Parent has spoken English which is adequate to participate in this communication based intervention and speaks English to their child at least some of the time

Previous inclusion criteria:
1. Child between 2 and 11 years (in primary school) with a diagnosis of autism
2. Family will have spoken English at home which is adequate to allow them potentially to participate in this communication based intervention

-Pre-school cohort:
1. Aged 2 years to 4 years 11 months
2. Meeting criteria for core autism on 2 from 3 modules of Autism Diagnostic Observation Schedule (ADOS-2) the Autism Diagnostic Interview -Revised (ADI-R)
3. Parents using spoken English at home
4. Above 12 months equivalent level in general (non language) development.

-School age cohort:
1. Aged 5 to 11 years
2. In primary school for length of participation in study
3. Meeting criteria for ASD on the Autism Diagnostic Observation Schedule (ADOS-2) and Social Communication Questionnaire (SCQ)
4. Developmentally from the beginning of intentional language to the beginning of fluent speech

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
Planned Sample Size: 24 in External pilot phase and 244 in main RCT; UK Sample Size: 24 and 244

Total final enrolment
249

Key exclusion criteria
Current exclusion criteria as of 18/10/2017:
1. Having a sibling with ASD already in the trial
2. Participation in PACT pilot phase
3. Child has <= 12 months nonverbal age equivalent
4. Long-term severe hearing or visual impairment in child or parent
5. Epilepsy that is uncontrolled by medication
6. Severe learning disability in the parent or current clinically severe psychiatric illness in parent
7. Current safeguarding concerns or other family situation that would affect child / family participation in the trial
8. No agreement to participate from child's education setting

Previous exclusion criteria:
1. Having a sibling with autism already in the trial
2. Only one child with autism per family can be included
3. Seizures uncontrolled by medication
4. Neither child or parent will have long term severe hearing or visual impairment that would limit participation in the intervention
5. Current clinically severe psychiatric illness in parents

Date of first enrolment
01/07/2016

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Manchester
Room 3.316, Jean McFarlane Building
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Sponsor information

Organisation
Central Manchester & Manchester Children's University Hospitals NHS Trust & University of Manchester

Sponsor details
5th Floor (Research)
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol is currently available at http://www.pact-g.org. The trialists are planning to submit the protocol and analysis plan for publication within the next few months. Planned publication of the study results in a high-impact peer reviewed journal in 2020.

Intention to publish date
30/07/2020

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	protocol	21/09/2018		Yes	No
Statistical Analysis Plan	version v1.2	18/10/2019	02/03/2020	No	No
Statistical Analysis Plan	version v1.2	07/10/2019	02/03/2020	No	No
Statistical Analysis Plan	version v1.2	18/10/2019	03/03/2020	No	No
Results article		01/04/2022	21/03/2022	Yes	No
Results article		01/05/2022	25/04/2023	Yes	No
HRA research summary			28/06/2023	No	No