



Information Sheet for Health Professionals

Thank you for considering making a referral to the Paediatric Autism Communication Trial – Generalised (PACT-G). PACT-G is a three site Randomised Controlled Trial of an enhanced parent-mediated, communication-focused intervention for children with autism and their families.

Nature of the study

Background: A previous study by our group with an earlier, clinic-based version of PACT-G therapy (PACT therapy) showed that, on average, the therapy helped children communicate more with their parent. However the therapy did not help children so much communicate socially with adults outside the family, that is, the social communication improvements gained did not seem to generalize. You can read more about the original PACT study on the PACT website (<http://www.bbmh.manchester.ac.uk/pact>).

The current study: In the PACT-G study we want to see if we can help children to generalise what they were able to learn with their parent in the clinic so that they are also communicating more with other adults and in other situations. We think that delivering the therapy to both the parent and to a key person, such as a learning support assistant, in the child's nursery/ school will help. We also think that working with the parent and the school staff in their own settings, i.e. at home and in nursery/school rather than in the clinic, will help the children to use any new skills more widely. Our earlier study included young children between 2 and 5 years of age. In the new study we will again be inviting parents of young children with autism to join the study and we also want to see if the therapy is useful for primary school aged children with autism.

The study is funded by the National Institute of Health Research and the Medical Research Council and will run between 2016 and 2020. The study is led from the University of Manchester in collaboration with the University of Newcastle and the Institute of Psychiatry and St Thomas' Hospital in London. Clinical sites in which the treatment will be delivered are CMFT; GSTT or NTW.

The study is designed to recruit 244 children and their families into the trial and to randomise them into two parallel groups:

1. Continuing their treatment as usual (TAU).
2. Continuing treatment as usual with the addition of the PACT-G therapy.

PACT-G Trial Office, University of Manchester, Room 3.316 Jean McFarlane Building, Oxford Rd, Manchester, M13 9PL Tel: 0161 275 5969 Email: PACT-G@manchester.ac.uk

The PACT-G therapy

The PACT-G therapy will be delivered by Speech and Language Therapists employed/ seconded by the local Health Trusts under the direction of the senior therapists within the research team. The PACT-G therapy is an enhanced and extended version of the PACT intervention, aimed at generalising the communication gains found with the original intervention across people and contexts.

Families in the therapy group will have 12 PACT-G therapy sessions with a speech and language therapist (SLT) from our team. Some of these sessions will be 1½ hour face to face sessions delivered at home and some will be 30-45 minute discussions by telephone or using skype. Face to face sessions use video feedback methods to facilitate parental observation of their child's communication and to encourage parents to adapt their interaction with their child in order to increase child communication. After each session parents are given a written programme and asked to carry out half an hour of home practice with their child each day. Between face-to-face sessions they will also have a telephone/skype session with the speech and language therapist to discuss progress and problem-solve any issues arising. Once the parent has completed all 12 sessions we will ask them to carry on with the home practice until the end of the year.

At about the same time the speech and language therapist will also deliver a similar therapy to a key person in the child's educational setting; exact timing will depend on school term times but there will always be overlap with the parent's sessions. Monthly meetings between parents and the key education person will also be organised.

Inclusion criteria for referral to PACT-G

- Child between 2;0 years and 11;0 years (in primary school) with a diagnosis of autism.
- ***Pre-school children*** will have above 12 months equivalent level in general (non language) development.
- ***Primary school children*** will range in development from the beginning of intentional communication to social communication at a 5 year level, with communication difficulties associated with autism including limited communication initiation and conversation turn-taking.
- ***All children*** The family will have spoken English at home which is adequate to allow them potentially to participate in this communication based intervention. Neither child or parent will have long term severe hearing or visual impairment that would limit participation in the intervention. There will be no current clinically severe psychiatric illness in parents.

Referral procedure

You are welcome to ring one of the research team to discuss a referral or seek further information.

If you think the child and family meet these criteria, please

- Introduce the study in outline to the family as per this leaflet. Please use your discretion as to whether it is appropriate to introduce the study to the parents at the same time as a diagnosis of autism is given, or whether it should be introduced at a later time.
- Ask for their permission that one of the research team contact them to arrange a phone call or home visit to discuss the study in more detail
- Complete the enclosed study referral form and fax to the research team

Following referral

1. The research team will contact the family and arrange a visit to introduce themselves, explain the study procedure and show the family the patient information leaflet.
2. After a 24 hour period for consideration the family will be invited to consent to the study.
3. If they consent then the research team will arrange the baseline assessment which will take place both at home and in a clinic setting.
4. If the child meets inclusion criteria for the study, we will register the family and put the family forward for randomisation.
5. You will be informed along with the family by the research team of the results of randomisation.
6. Families randomised to the PACT-G therapy will be contacted by the Trial therapists to initiate the therapy. They will remain under the overall clinical responsibility of local teams and can continue to receive their existing routine care while the PACT-G therapy is added.
7. Families randomised to TAU will remain under overall clinical care of local teams and can continue to receive their existing routine care.
8. Families in both arms of the study will receive research assessments at baseline, 6 months and 11 month endpoint. These assessments are made blind to treatment allocation.
9. With parental consent, the family and referring professional will receive a written feedback as a result of the baseline assessment and of the end point assessment.