PACT-G
Paediatric Autism
Communication Trial –
Generalised

LOCAL CONTACT
DETAILS

PACT G Parent Participant Information Sheet

PACT-G

The Paediatric Autism Communication Trial – Generalised (PACT-G) is a research study looking at whether PACT-G therapy, a social communication therapy for children with autism, helps improve autism symptoms. We'd like to invite you to take part in our research. This leaflet gives you information about the research and what it would involve for you if you decide to take part. A researcher from the team will be happy to go through this leaflet with you and answer any questions you may have.

What is this purpose of this 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 to communicate better with adults outside the family, that is, any 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 interacting better 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 older primary school aged children with autism.

Why are we asking you?

You have a child between 2 and 11 years of age who has been diagnosed with autism. For our study we are aiming to include around 250 families like yours, who speak sufficient English to be able to complete our assessments and take part in the therapy.

Do I have to take part?

Taking part in this study is entirely voluntary. You are free to choose whether or not to take part. If you do decide to take part you can keep this information leaflet for reference and once you have had a chance to ask any questions and consider the answers, you will be asked to sign a form giving your consent to taking part. If you do decide to take part, you are still free to withdraw from the study at any time and without giving a reason. If you decide not to take part or withdraw at any point, this will not affect any services for you and your child. For school-age children who are able to do so, we will also ask the child if they agree to take part in the assessments and therapy – they can tell us this or communicate it to us in whatever way suits them best.

What will happen if I take part?

The research will take place between 2016 and 2018 and you will be involved with the study for a period of one year.

First, one of our research team will meet with you and your child to explain the study in detail, answer your questions and to carry out a range of initial assessments.

Some of these assessments will be to confirm that your child is eligible to take part in the study. If your child is not eligible our researchers will discuss the reasons for this with you. You will still receive a written summary of the assessments.

These assessments also act as a start or 'baseline' against which we can measure any change in your child's skills over the time you are involved in the study. The assessments will take place over two sessions (or three if needed), each lasting about 2 ½ hours including breaks. One of these sessions will need to be in our assessment clinic but the other session(s) could be at home or the clinic depending on which is more convenient for you. We will pay back your expenses for these visits. During these sessions, the researcher will make a detailed assessment of your child's social and communication abilities, their level of language, and their general level of learning ability. Through questionnaires and interviews with you, we will gather detailed information about your child's development and current skills at home, your experiences as parents and as a family, your understanding of your child's skills and difficulties and what effect these may have had on your lives. We will make a short video of you and your child playing together to look at the way that you and your child communicate and interact together. Finally, we will want to find out about any help or services that you may have received over the previous six months and any additional expenses that you may have had because of your child's difficulties. In this study we will not be doing any physical or medical investigations on your child, such as blood or urine tests or X-rays.

Once this 'baseline' assessment is complete, we will prepare a written summary for you and, with your permission, send it to the health professionals looking after your child, your child's school and to your child's GP. Some of the activities will be videoed to allow us to study them afterwards as part of the research. These videos will be kept safe and secure in our research centre along with all the other paper work and will be destroyed after an agreed period at the end of the study.

We will also, once we have the agreement from your child's school's or nursery, visit your child in their school or nursery to carry out some assessments there. This will include making a video recording of your child interacting with a key person in school, such as a learning support assistant (LSA) who works with your child.

Following these assessments, all the families in the PACT-G study will continue to receive the same services provided by their local health and educational services as they usually would. Then half the families will, in addition, receive the new PACT–G therapy described below, and half will not. For the families who receive the therapy it will be provided to the parent and also a key person (such as the LSA) in nursery/school. Because we do not know whether this new therapy will help or not, the fairest and best way of testing this out is to have two groups, one receiving, and one not receiving, the therapy. A computer programme will be used to "randomly allocate" each family to one of the groups. This means that the group you are put into is decided completely by chance and does not depend on anything about you or your child. There will therefore be two groups, one with usual services, and one with usual services plus the new therapy.

After seven months there will be another shorter assessment session in clinic for all families which will involve a video recording of you and your child playing, and an interview. This will take about 45 minutes. At this point another video recording will be made in your child's nursery/school of your child playing or carrying out an activity with their key school helper there.

After one year we will repeat the assessments that we did at the beginning of the study to find out how your child and family have progressed during this time. These assessments will also be videoed. Your expenses in relation to all these research assessments will be paid back to you and we will be able to offer you a £40 voucher to thank you for your efforts in taking part.

During this study period of one year there are no restrictions on what you or your family do or the services and treatments that you access.

What is the additional therapy being tested?

The PACT-G therapy is an extension of the Pre-school Autism Communication Therapy developed by the PACT consortium and tested in the original PACT study.

The therapy is an approach to help parents understand and communicate with their child with autism. If you are in the PACT-G therapy group you 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 and some will be 30-45 minute discussions by telephone or using skype. You may be offered the opportunity to attend the first two face to face sessions in clinic but the rest of these sessions will take place at your home. During these sessions the speech and language therapist (SLT) will talk with you about how your child communicates and watch how you play and communicate with your child. She will make and show you videos of you and your child playing together and discuss with you what else you might do to help your child communicate more. A video record of this discussion between you and your therapist will be made. After each session you will be given a written home programme and we will be asking you to spend about half an hour every day at home practising the techniques discussed. In the telephone or skype sessions you will have the opportunity to discuss your progress at home with the speech and language therapist and work together to solve any problems or issues. Once you have completed all 12 sessions we will ask you to carry on with the home practice until the end of the year.

At about the same time your SLT will be working in the same way with a key person in your child's nursery/ school, who will be asked to practise similar techniques for 20 minutes a day, at least 3 times a week, between the therapy sessions. The exact timing of the work in the nursery/school may vary depending on term times, but there will always be some overlap in time with your sessions.

In addition to your sessions with the SLT you will be invited to monthly conversation meetings, arranged between yourself and the key person working with your child in the nursery/ school. These will give you both the opportunity to share together the techniques and strategies you are using and your child's progress with them. We will provide you with a written summary of these conversations. These meetings will continue after the home and school/nursery sessions have been completed, up till the end of the one year study period.

What are the possible benefits of taking part?

All children in this study (i.e. both those in the usual services and the usual services plus new therapy groups), will have detailed assessments from skilled professionals at regular intervals and you will receive a written report about these assessments. Most families find this useful.

We do not at this stage know whether the new therapy will be helpful for children with autism, their parents/families or the child's teachers. However, the regular meetings with the child's key school/nursery staff, which forms part of the therapy, may be useful in making sure you and school are helping develop your child's communication in a similar way.

More generally, by making a fair test of any benefits of the therapy, the results of this study should help in the development of therapy and education for children with autism throughout the UK; participation in the PACT-G study is an opportunity to be part of this wider aim.

What are the possible disadvantages and risks of taking part?

We do not anticipate that this study will result in any disadvantages or risks to families and have not found any unwanted effects from this therapy in our previous study. For all families there is of course a time commitment required for the assessment visits. For families allocated to usual services plus the new therapy, additional time is needed for therapy sessions, home practice and home-school meetings. This may have effects on family life. We will try to schedule sessions at times to suit you. By mutual agreement it may be possible for some of these sessions to take place outside normal working hours. In our previous preliminary studies, families found the assessment process and intervention generally acceptable.

Will the information be kept confidential and how will it be stored?

All your information is kept completely confidential and will not be shared with anyone outside of the research team and those responsible for monitoring the study, without your further express written consent. The only exception to this rule of confidentiality is in cases where we are concerned that your child's well-being or safety is at risk and this would be discussed with you; in some rare cases, we may also have an obligation to disclose information to statutory authorities directly, for example if we learn that somebody close to your child poses a risk.

There are, however, many benefits to research teams sharing data (such as levels of child skill, and questionnaire answers) with each other. It allows different assessments and therapies to be compared with each other. It also allows us to answer important research questions more effectively by combining the information from different projects so that patterns emerge more clearly. We would only ever share data with other research teams with your additional written permission. Data would be in an anonymised form; this means that scores on PACT-G assessments may be shared but there would be no information at all that could trace those scores back to your child or family.

We follow strict guidelines concerning the use and storage of research information. All the information will be kept securely. Paper copies are locked in filing cabinets in secure offices. Computer files are stored on devices that are encrypted (protected) and kept separately in secure storage. The research data is stored in an anonymised way, that is, the assessment information is kept with an ID number, not with any of your personal information such as name or address.

No identifying information will appear on any reports or presentations we produce. We occasionally like to include video clips as examples in training or presentations. We would talk to you about this specifically and require your additional written consent to go ahead with this.

As part of the study, we will need to share videos of your child with other researchers and therapists in the PACT-G team. This is done using a secure online computer system, which can only be accessed by the PACT-G team with a password. A further password is then needed to open each video. The folders being used are based within the computer system of Central Manchester Hospitals NHS Trust and are subject to high levels of security and monitoring.

Who is organising and funding the research?

This research is being funded the National Institute of Health Research and the Medical Research Council. We are working in close collaboration with the National Autistic Society and other patient groups. The PACT-G Team is based in the Universities of Manchester and Newcastle, and the Institute of Psychiatry and St Thomas' Hospital in London. The Study is overseen as Sponsor by Central Manchester University Hospitals NHS Foundation Trust and managed by the University of Manchester but if you are in the North-East or London your local PACT-G Team will contact you and be responsible for their part of the research work with you.

All Research and Therapy staff hold a valid enhanced Disclosure and Barring Service (DBS) check – (formerly known as a CRB check).

Who has reviewed the study?

The study has been reviewed by scientific referees from National Institute for Health research (NIHR) and the Medical Research Council (MRC), and by the North West – Greater Manchester Central Research Ethics Committee. It is subject to Research Governance Procedures in the Universities and NHS sites where it is taking place.

What will happen to the results of this study?

We will send you regular newsletters to keep you updated on the progress of our research and our findings. Once the study has finished we will publish the main results in scientific publications that are read by professionals and researchers. We will present our findings at conferences including those attended by parents of children with autism. There will also be reports which will be shared with our colleagues in the National Autistic Society and other support groups. Our website is another way we keep people informed of the progress of the study and its results.

(http://www.bbmh.manchester.ac.uk/pact).

What happens after this study?

After the research period you will continue with your regular treatment and care from health and education and other services. This study is currently only funded until the one year follow-up. However the PACT team hope in the future to get additional funding to re-contact all families included in the study, to find out how your child and the family are progressing. We would like to inform you of this possibility now. However agreeing to this current study does not commit you to taking part in such a future follow up; separate consent would be asked for that.

What if new information becomes available during the study?

If any new and relevant information becomes available during the study relating to the therapy that you are receiving, then we will let you know about this. If the new information was such as to need a change of therapy we would discuss this with you.

What if something goes wrong or if I have a question or complaint?

In the first instance speak to your researcher, who will do their best to answer your question or address your concern. Alternatively you can speak to your local PALS (Patient Advice and Liaison Service) by:

Manchester:

Tel: 0161 276 8686 E-mail: pals@cmft.nhs.uk

North East:

North of Tyne: Tel: 0800 0320202 E-mail: northoftynepals@nhct.nhs.uk

South of Tyne: Tel: 0800 3284397 E-mail: pals@ntw.nhs.uk

London:

Tel: 0207 188 8801 E-mail: pals@gstt.nhs.uk

If you wish to make a formal complaint about the study, please contact the University of Manchester Research Practice and Governance Coordinator by:

Telephone: 0161 275 8093 Email: research-governance@manchester.ac.uk

Contact for Further Information

[Add contact details for each site]