

Parent-delivered early language intervention for children with Down syndrome (PACT-DS)

Participant Information Sheet (PIS)

This PIS should be read in conjunction with [The University Privacy Notice](#)

You are being invited to take part in a research project which will explore the feasibility of a parent-delivered early language intervention for children with Down syndrome (which is called Parents and Children Together or PACT-DS). Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

Who will conduct the research?

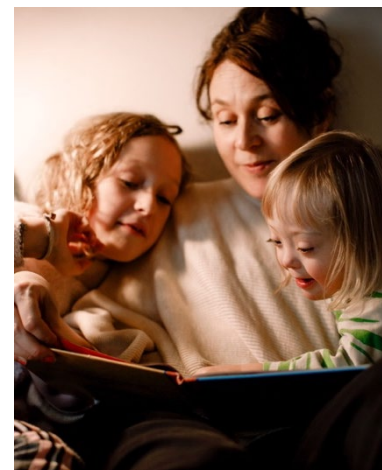
This research is being conducted by researchers at The University of Manchester (Dr Kelly Burgoyne and Dr Kirstie Hartwell; Manchester Institute of Education) and the University of Reading (Professor Vesna Stojanovik and Dr Emma Pagnamenta).

What is the purpose of the research?

Parents and Children Together (PACT-DS) is a language teaching programme that parents work on with their child at home to help their child:

- Learn lots of new words and how they work in sentences.
- Listen to and talk about stories.
- Understand and describe stories.
- Enjoy books and reading.

Parents/caregivers and children work on PACT-DS every day (5 days a week) for about 20-minutes. In the programme, parents/caregivers and children share storybooks, talk about words and their meanings, and tell stories together.



What is PACT-DS?

The PACT-DS programme is an adaptation of the PACT programme which was originally developed for typically developing children at risk of early language delays. A recent study showed that PACT is effective in supporting children's early language development. We have worked closely with a small group of (6) families to adapt PACT for parents/caregivers and young children with Down syndrome. In this project, we would like to see if the adapted programme, PACT-DS, is feasible and acceptable for parents and children who have Down syndrome, as they also often have difficulties learning language. PACT-DS may offer parents/caregivers ways to support their child's speech and language development, that is in addition to any other speech and language therapy services children are receiving.

This project will evaluate the feasibility and acceptability of PACT-DS with parents/caregivers and young children with Down syndrome. The results of this project will help us determine whether it is

feasible to conduct a further, larger study to evaluate the programme. To achieve this, this project will look at whether the programme is appropriate and acceptable for parents/caregivers to deliver at home, and its potential usefulness in support children's language and communication skills.

Who can take part?

We are looking for 30 children with Down syndrome (aged 3-6 years) and their parents/caregivers (up to 60 parents/caregivers in total) to take part. To be able to take part children and parents/caregivers should meet the following criteria:

- 1) Children need to have a diagnosis of Down syndrome.
- 2) Children need to be aged 3-6 years at the start of the study.
- 3) Family home postcode must be within 40 miles of The University of Manchester or University of Reading.
- 4) Parents/caregivers must be able to read and speak English.
- 5) Children need to have a minimum expressive vocabulary of 10 (English) words/signs (measured by parent-completed checklists).
- 6) Children need to have a cognitive level of at least 18 months (which will be measured by the research team using the Mullen Scales of Early Learning). As a broad indication, the types of skills this would reflect would be interest in books, being able to attend to a picture and be able to use two hands together e.g. to grasp an object.

Please note that twins are not able to take part. Families will be enrolled into the project on a first come, first served basis. Recruitment will close when we have signed up max 30 children and their parents/caregivers as participants.

Will the outcomes of the research be published?

We will prepare at least one journal article reporting findings from the study. In addition, a summary of the findings will be distributed via contact lists, websites and social media sites. We may also give a presentation of the project at a Down syndrome/early language research conference/event.

Disclosure and Barring Service (DBS) check

All members of the research team who come into contact with children will have undergone an appropriate level of DBS check.

Who has reviewed the research project?

The project has been reviewed by The University of Manchester Research Ethics Committee 1 and the University of Reading Research Committee.

Who is funding the research project?

This project is funded by the Economic and Social Research Council (ESRC).

What would my involvement be?

What would I be asked to do if I took part?

Families who meet the inclusion criteria will be offered a place on the trial. Once you accept your place in the trial, we will complete baseline assessments with you and your child. Following baseline assessments, you will be randomly allocated to either the PACT-DS group or the Comparison group.

Comparison group

Families in the comparison group will be offered general training on supporting language development for children with Down syndrome. This will involve 3 online sessions, delivered as a

group, over the 30-week delivery phase. In addition, on completion of the project, families will have the option of receiving PACT-DS or an evidence-based reading intervention for children with DS (Burgoyne et al., 2012).

PACT-DS group

Families allocated to the PACT-DS group will be trained by the research team to deliver PACT-DS. The programme is organised into 6 x 5-week Blocks. You will be asked to work through the programme with your child at home, delivering daily (5 x week) sessions of about 20-25 minutes, over 30-weeks. All materials and resources needed to deliver the programme will be provided. Parents/caregivers will receive materials for Block 1 of the programme at training; subsequent Blocks will be sent as you progress through the programme.

PACT-DS should complement any other speech and language therapy services your child is receiving; you would not be asked to stop any other therapy you are currently taking part in but would be asked to deliver PACT-DS in addition to any other therapy.

If you are in the PACT-DS group, you will be asked to come to a half-day group training session at The University of Manchester/University of Reading (travel expenses will be reimbursed) to learn how to use the programme at home with your child. We will ask you to work through the PACT-DS programme with your child at home every day (5 days a week) for 20-25 minutes over 30-weeks. Any adult main caregiver can attend the training and deliver the programme at home (e.g., grandparent, older adult sibling). Telephone and email support will be provided by the research team throughout. The research team will also conduct a minimum of 2 home-visits with each family during the delivery phase to observe intervention delivery and provide individualised feedback and support.

You will also be invited to take part in a Facebook support group alongside other parents/caregivers in the PACT-DS group. The research team and 'parent experts' who took part in Stage 1 of the programme will be part of the group to answer any queries you may have about delivering the programme. **Please note** if you choose to participate in this group, your name/Facebook profile would be identifiable to other members. Involvement in the group is entirely optional and you can leave at any time without explanation.

How will we evaluate the programme?

During the project, we need to objectively assess potential benefits of the PACT-DS programme for children and their families. To evaluate this, we will ask all children and their parents/caregivers (e.g., in both the PACT-DS and comparison group) to take part in a range of assessments detailed below at 3 time-points during the project:

1. September 2023 ("pre-test").
2. July 2024 ("immediate post-test").
3. December 2024 (6 months after the project ends, "delayed post-test").

Child assessments: Trained researchers will work with your child to complete a range of assessments at each time point, to measure children's early language and communication skills. We will also take a 10-minute video-recording of you and your child during a) shared reading and b) free play. At delayed post-test, researchers will also complete measures of early literacy skills with your child.

Child assessments will take place either at the University of Manchester/University of Reading campus, or at your child's school/nursery, according to parent preference. All tests will be

administered by trained members of the research team. All child assessments will be video recorded for quality assurance purposes.

Parent completed measures: Parents/caregivers in the project will also be asked to complete a range of measures at each time point. These measures will ask for information about the child's development, their language and communication skills, and family background. Parents/caregivers will also be asked to complete questionnaires about their own emotional well-being.

Parent interviews: Between immediate and delayed post-test (July – December 2024) we will invite a sample of parents/caregivers from the project to participate in a short 1:1 interview (via face-to-face or by telephone/video-call) to talk about key themes that arise from the online parent evaluation surveys. **Interviews will be audio recorded.**

In addition to these assessments, families in the PACT-DS group will also be asked to provide us with some information about their use of the programme during the 30-week delivery period using a daily record form.

Will I be compensated for taking part?

Travel costs to visit the University for training and assessment will be reimbursed for reasonable travel expenses (within a 40-mile radius of the University of Manchester/Reading, second-class return travel tickets if travelling by public transport; travel by personal vehicle payable at 0.45p per mile). We will also offer families a written report of their child's assessment at each time point.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Information Sheet to keep, and you will need to complete the Participation Agreement form. You have the right to withdraw at any time without giving a reason and without detriment to yourself by not continuing on the project. You can withdraw by contacting the research team using the details below. However it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. If you decide not to take part in the study you do not need to do anything further.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect some information about you and your child:

- Child's first name, child's surname, child's date of birth, child's sex
- Parent/carer's first name, parent/carer's surname, parent/carer's phone number, parent/carer's email address
- Residential address of parent/carer and child
- Record of consent

Only the research team will have access to this information. Full details of how we will collect, manage and store the information we collect from/about you can be found in the [University Privacy Notice](#).

Disclosure/Safeguarding

As we will be asking you to share video recordings of intervention sessions completed in your homes, and researchers will be visiting families at home to observe intervention sessions, there is some risk of disclosure and/or safeguarding issues. The research team will manage any disclosures/safeguarding issues in the field (i.e. in children's homes) or on the video recordings by completing a disclosure of information form and contacting the Local Safeguarding Lead as soon as possible.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including video and audio recordings. (NB. All audio recordings will be destroyed once they have been fully transcribed). If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult the [University of Manchester Privacy Notice for Research Participants](#).

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester and The University of Reading are joint Data Controllers for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following ways:

- Participants will be provided with an assigned ID number (Study ID) known only to the research team (known as pseudonymised) – your name and any other identifying information will be removed and replaced with this ID. Only the research team will have access to the key that links this ID number to your personal information.
- Data will be pseudonymised immediately following consent.
- All hard copies of data will be stored in a locked cabinet in the project office at the Manchester Institute of Education at The University of Manchester or The University of Reading. This information will also be stored electronically on encrypted servers and electronic devices authorised by The University of Manchester/University of Reading.
- Data (including audio recordings) will be transferred within the research team and with University-approved 3rd party transcription services using Dropbox for Business, a University-approved data transfer service
- Audio recordings will be used to create transcripts by a third party who is a UoM approved supplier. All personal identifiable information will be removed from the final transcript and audio recordings will be destroyed upon completion of the transcription.
- The personal information we hold about you and your child will be destroyed within 5 years of the end of the project by December 2029.
- The anonymized final data set will be stored indefinitely in a repository.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

DR KELLY BURGOYNE – KELLY.BURGOYNE@MANCHESTER.AC.UK 0161 275 7208

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact: **The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL**, by emailing:

research.complaints@manchester.ac.uk or by telephoning **0161 306 8089**

If you wish to contact us about your data protection rights, please email:

dataprotection@manchester.ac.uk or write to: **The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL** at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#): **0303 123 1113**.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

DR KELLY BURGOYNE – KELLY.BURGOYNE@MANCHESTER.AC.UK / 0161 275 7208;

DR KIRSTIE HARTWELL – KIRSTIE.HARTWELL@MANCHESTER.AC.UK