Intensive Interaction for Children and Young People with Profound and Multiple Learning Disabilities: The INTERACT Study

Parent/Carer Information Sheet

We would like to invite you and the child/young person you are responsible for to take part in the INTERACT study. The study is looking at an intervention to support communication skills in children and young people with profound and multiple learning disabilities (PMLD).

You have been given this information because your child's educational setting is taking part in the INTERACT study and they have identified that your child is eligible to take part, as your child is aged 3-15 years old and has PMLD.

This information sheet explains what taking part in this study will involve for you and your child. Please read this information and, if you decide you would like to take part, please complete a consent form (your child's educational setting will provide you with either a link to an online consent form or a paper consent form). You and your child do not have to take part if you do not want to. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study and why is it important?

We know that children and young people with PMLD often struggle to communicate with those that care for them such as their parents, carers and teachers. These difficulties mean that they are sometimes unable to communicate their needs, what they like and don't like, and are unable to take part in social activities such as turn taking.

Intensive Interaction is development-based intervention designed to teach the fundamentals of communication. During an Intensive Interaction session, the practitioner works with the child/young person, responding to what they do by imitating and joining in. More information about Intensive Interaction can be found here: https://www.youtube.com/watch?v=EppQXyI5FX0&t=34s . Although there is some research to suggest that Intensive Interaction can be beneficial to individuals with PMLD, further research is needed to understand how educational settings can use Intensive Interaction to support children and young people with PMLD.

Will my child receive the Intensive Interaction intervention?

To find out how well Intensive Interaction works, half of the educational settings taking part in this study will receive training and ongoing support to use Intensive Interaction and the other half will not. This is decided randomly using a computer. If your child's setting is chosen at random to use Intensive Interaction and, if you agree to take part, your child will receive the Intensive Interaction intervention during January - May 2024 (more information below). Your child will continue to receive all other treatment or support as usual regardless of whether their setting is chosen to use Intensive Interaction.

What are the possible benefits of taking part?

Intensive Interaction may help your child with their communication skills. This study will provide important information about the effectiveness of Intensive Interaction for children and young people with PMLD. As a thank you for taking part, you will receive a £15 voucher after completing the final questionnaire for the study.

This study is funded by the NIHR Health Technology Assessment programme (HTA Project: NIHR151428). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

What will taking part involve for my child?

- We will ask your child's educational setting to provide us with some information about your child.
    - This includes: the names of staff who currently support them in their learning and any interventional support they receive in their educational setting
- You child's setting will capture a short video recording of your child completing an assessment of communication opportunities (which involves completing scripted activities) with their main teacher during September/October 2023, June/July 2024, and November/December 2024 and will share this with us.
- We will ask your child's main teacher to complete a questionnaire about your child during September/October 2023, June/July 2024, and November/December 2024.
    - This is to provide ratings of your child's cognitive development, communication and social interaction, environmental interaction, and behaviour, and to report whether changes have been made to your child's education plan.
- If your child's educational setting is chosen at random to use Intensive Interaction, a trained member of staff (e.g. teacher, TA, SENCO) will deliver the intervention to your child for a minimum of 18 weeks during January - May 2024.
    - Intensive Interaction will be embedded into daily activities and each session will likely to be around 5-15 minutes, depending on your child's needs.
    - We will ask settings to complete a diary to record the number and duration of sessions delivered.

What will taking part involve for me?

- We will ask you to complete questionnaires during September/October 2023, June/July 2024, and November/December 2024. You will be able to choose whether you complete these online (on your computer or smart phone) or via a phone or video call with a research assistant
- The questionnaires collect information about:
    - Your child's age, gender, ethnicity, home life, health
    - Your age, gender, relationship status, education, employment and history of receiving parental support related to your child's diagnosis
    - Ratings of your child's quality of life, mood, interest and pleasure
    - Your well-being, sense of competence, care-related quality of life
    - Resource-use for your child (e.g. healthcare, social care organisations, educational services, and medication use).
- If your child's educational setting is chosen at random to use Intensive Interaction, you will be invited to attend 2 half-day training sessions to learn how to use Intensive Interaction at home.
    - The training will cover the basics of Intensive Interaction and will be delivered by a Speech and Language Therapist who is supporting your child's educational setting.
    - The training will be delivered flexibly and may be online, face to face, or hybrid.
    - The Speech and Language Therapist will provide support weekly for the first 4 weeks and then monthly thereafter. This ongoing support will be delivered flexibly, online, face to face, or hybrid, according to need and is designed to build confidence and skill in using Intensive Interaction.
    - You will be asked to embed Intensive Interaction into your daily activities at home (for 18 weeks) with each session lasting around 5-15 minutes, depending on your child's needs.
    - We will provide you with a diary to complete to log how often you use Intensive Interaction at home with your child.
- You may be asked to take part in an interview about your experiences of taking part in the study and using Intensive Interaction. You don't have to agree to be contacted about participating in an interview if you do not want to. This will not affect your or your child's participation in the study. If you are interested in taking part in an interview, you will receive a separate information sheet and consent form for this.
- We will also ask whether the research team can contact you in the future to follow-up this research or to let you know about any other new research studies. Agreeing to this is completely optional. If you agree to this, your contact information will be kept on a secure database when the study has finished.

Do we have to take part and what happens if I change my mind?

No, participation is entirely voluntary and it is up to you whether you would like you and your child to participate. If you do agree to participate, you are free to withdraw from the study at any time, without explanation. If you decide not to take part or to withdraw from the study, this will not impact your child's care or education in any way.

If you withdraw your child from receiving the intervention, we would still like to know how your child is progressing. We will still ask you and your child's setting to complete questionnaires about your child if you are happy with this. If you withdraw from completing questionnaires, your child's setting will continue to complete questionnaires about your child, and continue to deliver the intervention to them (if allocated to do so), if you are happy with this.

If you fully withdraw your child from the study, we will not collect any further information about your child and any intervention delivery to your child as part of the study will stop.

If you would like to withdraw from any part of this study, please contact the research team (using the details at the end of this information sheet) or your child's setting. If you decide to withdraw at any stage, we will use the information collected so far about you and your child, unless you ask us to remove your data.

What are the possible disadvantages and risks of taking part?

Some parents/carers may find talking about their child's PMLD distressing. Some children may not want to engage with the intervention. If at any time a child appears distressed, the session would be stopped. If a child shows continued signs of distress, they would be withdrawn from the study. You can discuss any issues or concerns with the research team at any time.

What will happen to the information collected?

All information collected during the study will be treated with the strictest confidence and will be processed and stored in compliance with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018.

We will not share anything you have told us with anyone else, without your permission. However, there may be very rare circumstances where confidentiality may need to be breached. Such a breach would only occur in the most extreme cases, if, for example, information disclosed related to criminal activity or implied that an individual has been, or is, at risk of harm.

For the purposes of this study, the University of Kent and the University of York are joint data controllers, as defined in the UK GDPR. This means that they are jointly responsible for looking after the information collected for the study, using it properly and ensuring this research study is compliant with GDPR.

Personal data will be processed under Article 6 (1) (e) (Processing necessary for the performance of a task carried out in the public interest) and Special Category data under Article 9 (2) (j) (Processing necessary for ... scientific ... research purposes) of the UK GDPR (2018). This is our legal basis for processing the data collected for the study.

We will use REDCap and Qualtrics survey software to collect information for the study. Data will be securely stored by the University of York and University of Kent.

The University of Kent and the University of York take information security seriously and have used appropriate technical and organisational measures to protect data. Access to information is restricted on a need-to-know basis and security arrangements are regularly reviewed to ensure their continued suitability. Further information about how we will use the information collected for the study can be found at: york.ac.uk/healthsciences/research/trials/trials-gdpr/ and https://research.kent.ac.uk/ris-research-policy-support/wp-content/uploads/sites/2326/2021/06/GDPR-Privacy-Notice-Research.pdf

Information collected may be looked at by other people involved in the running and supervision of the study to check that it is being carried out correctly. People who do not need to know who you and your child are will not be able to access names or contact details. Your data will have a code number instead.

You have rights in relation to your data (see: https://www.york.ac.uk/records-management/dp/individualsrights/).

We will analyse the data collected in order to answer the research questions in this study. All individually identifiable data will be destroyed 10 years after the end of the study (expected to be June 2027). Anonymous data may be kept indefinitely by the research team and potentially shared with other researchers or archiving organisations (such as the UK Data Archive) for research purposes only.

What will happen to the results of the research study?

When the study has finished, we will present our findings at conferences and we will put the results in research papers and on websites so that it can inform future support for children and young people with PMLD. You and your child and their setting will not be identifiable in any published report or output arising from the research.

We will also contact all participants involved in the study to let them know the results of the research. Newsletters will also be sent out to all participants throughout the study.

Who is organising and funding the research?

The research is being carried out by researchers at University of Kent, University of York, University of Sheffield, Newcastle University, and Bangor University, as well as by collaborators from PAMIS and the Council for Disabled Children. It is being funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (HTA Project: NIHR151428). The University of Kent is the sponsor for this study.

Who has reviewed the study?

This study has been reviewed and given a favourable ethical opinion by Tizard Ethics Committee, University of Kent (Ref: 0817) (contact: lssjethics@kent.ac.uk). The study has been logged by Health Sciences Research Governance Committee (University of York) (contact: stephen.holland@york.ac.uk).

What if there is a problem?

If you have a concern or question about any aspect of this study, you can speak to the research team who will do their best to answer your questions. Contact details are listed at the bottom of this sheet.

You can also contact the University of York's Data Protection Officer at dataprotection@york.ac.uk or the University of Kent's Data Protection Officer at dataprotection@kent.ac.uk

If you are unhappy with how we have handled your personal data, please contact the Data Protection Officers using the details above, so that we can try to put things right. If you are unhappy with our response, you have a right to complain to the Information Commissioner's Office (https://ico.org.uk/make-a-complaint/ or phone 0303 123 1113).

Who do I contact for more information or if I have further questions?

Questions about **Intensive Interaction**? Please contact:	Questions about the **research study**? Please contact:
Dr Jill Bradshaw, Co-Chief Investigator for the INTERACT Study. University of Kent. Email: j.bradshaw@kent.ac.uk Tel: 07710088477	INTERACT study team at York Trials Unit, University Of York. Email: ytu-interact@york.ac.uk Tel: 01904 325157

The INTERACT study also has a website with further information: www.interacttrial.com

Interested in taking part? Next steps:

If you are happy for your child to take part in the INTERACT study, please complete a parent/carer consent form as soon as possible. Your child's educational setting will provide you with either a link to an online consent form or a paper consent form.

Thank you for taking the time to read this information sheet.