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

Information Sheet for Parents/Carers of 16-25 Year-Olds

We would like to invite you and the 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 young person's educational setting is taking part in the INTERACT study and they have identified that your young person is eligible to take part, as he/she is aged 16-25 years old and has PMLD.

This information sheet explains what taking part in this study will involve for you and your young person, as well as your role as a designated consultee (to advise whether, in your opinion, your young person would want to be involved in the study) under Section 32 of the Mental Capacity Act 2005. Please read this information and, if you decide you would like your young person and yourself to take part, please complete a Consent & Consultee Declaration form (your young person's educational setting will provide you with either a link to an online consent & consultee form or a paper consent & consultee form). You and your young person 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 a 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 copying 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 young person 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 during January–May 2025 and the other half will be offered the training at the end of the study (i.e. after 31st December 2025). This is decided randomly using a computer. If your young person's setting is chosen at random to use Intensive Interaction and, if you agree to take part, your young person will receive the Intensive Interaction intervention during January–May 2025 (more information below). Your young person will continue to receive all other treatment or support as usual regardless of the group their setting is allocated to.

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What are the possible benefits of taking part?

Intensive Interaction may help your young person 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.

What will taking part involve for my young person?

- We will ask your young person's educational setting to provide us with some information about your young person.
    - This includes: the names of staff who currently support them in their learning and confirmation of their PMLD diagnosis.
- Your young person's setting will provide us with a 10 minute video recording of your young person and their main teacher taking part in a communication activity during September–October 2024, June–July 2025, and November–December 2025. The interaction will be naturalistic showing the teacher and young person interacting as they typically would.
- We will ask your young person's main teacher to complete a questionnaire about your young person during September–October 2024, June–July 2025, and November–December 2025.
    - This is to provide ratings of your young person's cognitive development, communication and social interaction, environmental interaction, quality of life, and behaviour, and to report whether changes have been made to your young person's education, health and care plan. We will also ask about how your young person receives nutrition, support and intervention your young person receives, any sight or hearing impairments, and other conditions they may have, such as epilepsy and autism.
- If your young person'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 young person for a minimum of 18 weeks during January–May 2025.
    - Intensive Interaction will be embedded into daily activities and each session will likely to be around 5-15 minutes, depending on your young person's needs.
    - We will ask settings to complete a diary/session record log to record the number and duration of sessions delivered, the techniques used and how your young person responded.

Being your young person's consultee

The Mental Capacity Act 2005 protects the rights of people who are not able to make decisions for themselves. The Act requires that before a person who is unable to consent for themselves is entered into a study, another suitable person must be identified who can act on their behalf as a consultee. This consultee can then advise the research team on whether, in their opinion, the person who lacks capacity would want to be involved in the project. The consultee must not have a conflict of interest such as being part of the research or gaining financial benefit. You are being approached to be a consultee because your young person is aged 16 or over and does not have the capacity to consent for him/herself.

What are the duties of a consultee?

The main responsibility of a consultee is to advise the research team whether they think the person without capacity to consent for themselves would be happy to take part in the study. If you agree to act as consultee, the research team would ask you to consider what you know of your young person's wishes and feelings, consider their interests, and to let us know of any advance decisions they may have made about participating in research. These should take precedence. If you decide your young person would have no objection to taking part, we will ask you to read and sign the Consent & Consultee Declaration Form, provided by your young person's educational setting as a link to an online form or as a paper form. We will also give you a copy to keep.

If you have any questions or concerns throughout the study or you think your young person should be withdrawn, please feel free to contact us. You can request that your young person is withdrawn from the study at any time, without giving a reason and without their care or education being affected.

In order to help you make the decision about acting as a consultee and advise the research team about the young person's wishes, this information sheet describes what is involved in the study.

What will happen if I don't want to take on the role of a consultee?

If you are unsure about taking on the role of a consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility, and this will not affect the care or education your young person currently receives. One of the requirements for participants aged 16 or over in our study is for a parent/carer to act as the young person's consultee and give consent for them to take part, so if you do not wish to take on the role of a consultee your young person will not be able to be included in the study. This will in no way affect the care or education your young person currently receives.

What will taking part involve for me in addition to my consultee duties?

- We will ask you to complete questionnaires during September–October 2024, June–July 2025, and November–December 2025.
- 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 young person's date of birth, gender, ethnicity, living arrangements.
    - Your gender, ethnicity, relationship status.
    - Ratings of your young person's quality of life, mood, interest and pleasure.
    - Your well-being and care-related quality of life.
    - Resource-use for your young person (e.g. healthcare, social care, educational services, medication use, and days missed from employment/education/training to care for your young person).
- If your young person's educational setting is chosen at random to use Intensive Interaction, you will be invited to complete online training to learn how to use Intensive Interaction at home.
    - You will be given access to a training website and asked to complete 4 units about Intensive Interaction, which will take approximately 4 hours.
    - If you struggle to access the training website, where possible a Speech and Language Therapist will go through the training units with you either via a video call or in person, depending on the geographical location and the capacity of the Speech and Language Therapist.
    - A Speech and Language Therapist (who is also supporting your young person's setting) will provide support weekly for the first 4 weeks and then monthly. This ongoing support will be via video call, phone or email 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 young person's needs.
    - We will provide you with a session record log to complete to log your Intensive Interaction sessions.
- 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 young person'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 young person 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 young person's care or education in any way.

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

If you fully withdraw your young person from the study, we will not collect any further information about your young person and any intervention delivery to your young person 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 young person's setting. If you decide to withdraw at any stage, we will use the information collected so far about you and your young person, 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 young person's PMLD distressing. Some young people may not want to engage with the intervention. If at any time a young person appears distressed, the session would be stopped. If a young person 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.

The University of York will securely share your contact details with the research team at University of Sheffield (and potentially with an external Speech and Language Therapist allocated to your young person's education setting for the study) to enable them to support you to complete Intensive Interaction training and use this with your young person.

We will use REDCap and Qualtrics survey software to collect information for the study. Data will be securely stored by the University of York, University of Kent and University of Sheffield. Video recordings, provided by settings, will be stored securely by the University of Kent. The University of Kent, University of York and University of Sheffield 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. For further information about how we will use the information collected for the study, see: york.ac.uk/healthsciences/research/trials/trials-gdpr/ and media.www.kent.ac.uk/se/40432/ResearchParticipantUniversityLevelPrivacyNotice.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 young person 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 end 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 young person 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 London - Camden & Kings Cross Research Ethics Committee (Ref: 24/LO/0415) and has been logged with the Health Sciences Research Governance Committee at University of York.

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. If you would like to speak to an independent contact, who is not directly involved in the research, you can contact Professor Jenny Thomson, Speech and Language Therapist, University of Sheffield (j.m.thomson@sheffield.ac.uk).

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 or the research study? Please contact:
INTERACT study team, 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 young person to take part in the INTERACT study, please complete a Parent/Carer Consent & Consultee Declaration Form as soon as possible. Your young person's educational setting will provide you with either a link to complete this online or a paper form.

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