

A research study to establish whether Intensive Interaction can improve communication skills and quality of life for children and young people with Profound and Multiple Learning Disabilities when delivered in educational settings

Submission date 18/04/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/05/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Children and young people with profound and multiple learning disabilities (PMLD) usually have other complex health conditions and need help with many parts of daily life. People with PMLD communicate in different ways, such as facial expressions, vocal sounds and body language. Though familiar people like parents or carers can understand these cues, people with PMLD often find communicating their needs and wishes difficult. Being able to communicate is important for ensuring that children/young people and those who look after them have a good quality of life. Intensive Interaction (II) involves the child's caregiver (in their educational setting or at home) becoming well-tuned to the child or young person in their care so that they can respond to subtle behaviours and forms of communication. II is recommended by speech and language therapists (SLTs) for children with PMLD. However, there is no reliable research to show if II improves children's communication. The aim of this study is to find out whether II improves communication for children and young people (aged 3-25 years) with PMLD.

Who can participate?

Educational settings that provide education to children and young people with PMLD are eligible to take part as long as they have at least 5 children and young people who meet the criteria and have the willingness and capacity to support the trial procedures. Children and young people can take part if their educational setting has signed up to take part and their parent/carer agrees to the trial procedures.

What does the study involve?

Data will be collected from settings and from parents/carers three times: baseline (before the trial starts) and 32 and 52 weeks later. For settings allocated to implement the II, setting staff

will be required to attend training to learn how to deliver II. Parents/carers will be invited to attend this training also. II should be embedded into daily activities with sessions being delivered daily for an 18-week period. For settings allocated to continue as usual, all educational provisions should be continued as normal.

What are the possible benefits and risks of participating?

Benefits may be observed in terms of improvements to communication and quality of life, this is the aim of the work. 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.

Where is the study run from?

The study will take place in educational settings across Great Britain. The research is being conducted by a team of researchers at the University of Kent, University of York, University of Newcastle, University of Sheffield and Bangor University (UK)

When is the study starting and how long is it expected to run for?

March 2023 to June 2027

Who is funding the study?

National Institute for Health and Care Research Health Technology Assessment Programme (NIHR HTA) (UK), ref: 151428

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

326756

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 326756, CPMS 55609

Study information

Scientific Title

A randomised controlled trial to establish the effectiveness and cost-effectiveness of Intensive Interaction delivered in educational settings for improving communication skills and quality of life in children and young people with Profound and Multiple Learning Disabilities compared to usual care: the INTERACT trial

Acronym

INTERACT

Study objectives

This study is a randomised controlled trial (cluster randomised by educational setting) to establish whether Intensive Interaction is clinically and cost-effective in improving communication skills and quality of life in children and young people with Profound and Multiple Learning Disabilities in educational settings.

Hypothesis: The researchers hypothesise that Intensive Interaction delivered in educational settings and at home (18-week programme) compared with standard care will improve communication skills and quality of life in children and young people with Profound and Multiple Learning Disabilities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/04/2023, the University of Kent Tizard Centre Research Ethics Committee (Tizard Centre, Cornwallis North East, University of Kent, Canterbury, CT2 7NF, UK; +44 (0)1227764000; lssjethics@kent.ac.uk), ref: 0817

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Home, School

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a copy of the participant information sheet.

Health condition(s) or problem(s) studied

Profound and multiple learning disabilities

Interventions

The trial design is a cluster-randomised controlled trial with an internal pilot comparing the Intensive Interaction with care as usual. Trial participants are 3-25-year-old children and young people with profound and multiple learning disabilities. The planned sample size is 330 children and young people from 66 educational settings. The primary follow-up will be 32 weeks post-randomisation.

Intervention:

Intensive Interaction (II) is a development-based intervention designed to teach the fundamentals of communication. It requires communication partners to adjust their interaction strategies to engage learners at their own level and in their preferred way. The components of II are referred to as the Fundamentals of Communication and include learning to give brief attention to another person, sharing attention, developing shared attention in activities, taking turns and using and understanding eye contact and facial expressions. Activities are not prescribed but depend on high-quality training on the underpinning principles and regular monitoring to ensure treatment fidelity. As the relationship between interactors is a salient component, II sessions need to take place with a familiar person trained in II principles and mentored by an II-trained Speech and Language Therapist with frequent mentoring sessions. II is a way to support the quality of everyday interactions between communication partners and children and young people with profound and multiple learning disabilities (PMLD). The activity can be pretty much anything that the person is taking part in. We can use II to make changes to how we communicate. We might use a particular tone of voice to make us more interesting to the person. We might use II to respond to the things that people are doing and to follow their lead. For example, we might repeat sounds or body movements that the person uses.

A useful fact sheet on II is available here: <https://www.mencap.org.uk/sites/default/files/2016-11/Intensive%20Interaction%2004.pdf>

Following the training period, settings should deliver II for a minimum of 18 weeks with the duration of each session directed by the person delivering the intervention in a way that is responsive to the child/young person's needs - likely to be around 5-15 min. II should be embedded into daily activities hence we would not want to limit potential opportunities for meaningful interactions to take place by providing practitioners/caregivers with an arbitrary number of sessions to deliver, though we will recommend sessions occur regularly and at least once per day the child/young person attends their educational setting.

Usual Care:

Children and young people in the comparator or 'control' arm will receive the usual care. Given that there are no particular recommendations for what this should comprise, children and young people in the control arm will likely receive a range of interventions. The standard practice currently includes a range of communication and interaction approaches, for example Talking Mats, Objects of Reference, Makaton Signing, Picture Exchange Communication System, Communication Passports/Profiles, II, visual support, music-based approaches, drama/story-telling approaches, Sensory Stories, Social Stories and switch-based approaches. Educational settings implement their approaches through a combination of individual sessions and the embedding of the approach into daily interactions. Delivery of these approaches is mostly by teachers and teaching assistants with SLTs providing advice and support. Training received by staff is mixed with training providers including SLT and Educational Psychology Services, organisations such as Mencap, other educational settings and in-house training, though for many of the approaches, no training is received.

The researchers will further seek to establish what care as usual looks like for the educational settings included in the trial by surveying all educational settings prior to randomisation to enquire about their usual practices, and at the end of their involvement in the trial to confirm what the participating children and young people actually received.

Randomisation will occur after consent has been obtained and baseline data collected from parents/carers and educational professionals. A statistician at York Trials Unit (YTU) who has no involvement with settings or in setting recruitment will randomise educational settings to either the control or intervention arm using a 1:1 allocation ratio. YTU will randomise educational settings using a minimisation algorithm to ensure the best possible balance across educational setting characteristics within each group. A dedicated computer program, MinimPY, will be used for randomisation via minimisation using the factors:

1. Primary only/all-age educational settings;
2. Residential/non-residential educational settings;
3. Specialist setting or mainstream with a specialist unit;
4. Number of children and young people with PMLD (latest available data; dichotomised at the median for recruited educational settings in the first batch to be randomised);
5. Local authority region.

Intervention Type

Behavioural

Primary outcome measure

Communication skills measured using the Communication Complexity Scale (CCS) at baseline, 32 and 52 weeks

Secondary outcome measures

All secondary outcome measures will be collected at baseline, 32 and 52 weeks post-randomisation:

1. Cognitive development, communication, social and environmental interaction measured using Routes for Learning
2. Changes to educational care assessed through reviews of Education Plans
3. Behaviour problems measured using the Behaviour Problems Inventory (BPI-S)
4. Quality of life measured using the Quality of Life-Profound Multiple Disabilities, Mood Interest and Pleasure Questionnaire, Child Health Utility 9D, EQ-5D-Y
5. Parental well-being measured using the Parenting sense of competence scale, Warwick-Edinburgh Mental Well-being Scale, The Carer Experience Scale
6. Health care, social care and educational support service use measured using a bespoke instrument

Overall study start date

01/03/2023

Completion date

30/06/2027

Eligibility

Key inclusion criteria

Educational settings:

1. Special Educational Needs and Disabilities (SEND) educational settings or mainstream educational settings with SEND units around Great Britain
2. At least five children and young people meeting the eligibility criteria
3. Capacity and willingness to agree to the requirements of participation outlined in a memorandum of understanding, which will ask them to confirm that they have the capacity and willingness to release staff to receive training; to deliver the intervention as intended with those children and young people participating in the trial; and to complete the outcome measures.

Children and young people:

1. Attends an educational setting taking part in the trial
2. Have PMLD
3. Parent/guardian willing to give consent/act as a consultee for the child or young person
4. Parent/guardian willing to attend II training
5. Parent/guardian willing to continue with the intervention at home
6. Parent/guardian willing to complete outcome measures
7. Child or young person is expected to remain at the setting for the duration of the trial

Note: there are no specific inclusion/exclusion related to age.

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

330

Key exclusion criteria

Educational settings:

1. Setting unable to fulfil the requirements of the MOU
2. Currently deliver weekly or more frequent II
3. Staff have recently been formally trained in II
4. Insufficient eligible children and young people

Children and young people:

1. Currently receiving weekly or more frequent II from II-trained staff within their educational setting
2. Have a degenerative condition or dementia

Date of first enrolment

05/05/2023

Date of final enrolment

30/11/2025

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Wales

Study participating centre

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University of York

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Funder(s)**Funder type**

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

The dissemination plans involve working closely with the full range of stakeholders for whom the study will be of relevance and interest. This will include clinical and educational professionals working with children and young people with PMLD as well as parents/guardians and voluntary

sector organisations. Activities will include engagement throughout the study, ultimately informing a range of outputs to ensure the learning from this study effects the appropriate change for the benefit of those with, and those caring for children and young people with PMLD.

In addition to producing the HTA report, the researchers will publish open-access articles in relevant academic journals covering the disciplines of Speech and Language Therapy and Psychology. They will also prepare articles for practitioner journals and magazines and present them to conferences such as the National Association for Special Educational Needs (NASEN) which supports all education practitioners, the International Association for the Scientific Study of Intellectual and Developmental Disabilities, and the European Academy of Childhood Disability.

A plain English summary bulletin will be sent to all participating educational settings and the parents/guardians of the children and young people taking part. This will be translated into other languages as required. The bulletin will also be shared with other non-participating special education educational settings, mainstream educational settings that cater for PMLD pupils and other stakeholders, including the applicants' extensive contacts with professional organisations such as the RCSLT, their Clinical Excellence Networks and other policy-making bodies. Awareness-raising work with educational settings and local authorities will aim to underpin and support the subsequent implementation of any revised guidance.

Intention to publish date

31/12/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository and will be included in the subsequent results publication.

IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication