ISRCTN81099965 https://doi.org/10.1186/ISRCTN81099965

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
No longer recruiting

Registration date
03/05/2023

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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?
1. Dr Kerry Bell, kerry.bell@york.ac.uk
2. Prof. Jill Bradshaw, j.bradshaw.2@bham.ac.uk
3. Prof. Catherine Hewitt, catherine.hewitt@york.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Kerry Bell

ORCID ID
https://orcid.org/0000-0002-7610-5429

Contact details
York Trials Unit
Department of Health Sciences
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904321325
kerry.bell@york.ac.uk

Type(s)

Principal investigator

Contact name
Prof Jill Bradshaw

ORCID ID
https://orcid.org/0000-0002-0379-8877

Contact details
Professor of Communication, Health and Social Care
Intellectual Disabilities Research Institute (IDRIS)
University of Birmingham
School of Social Policy and Society
Edgbaston
United Kingdom
B15 2TT
-
j.bradshaw.2@bham.ac.uk

Type(s)
Public

Contact name
Mrs Katie Carlisle

Contact details
York Trials Unit
Ground Floor ARRC Building
Department of Health Sciences
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 1904 324227
katie.carlisle@york.ac.uk

Type(s)
Scientific

Contact name
Dr Jane Blackwell

ORCID ID
https://orcid.org/0000-0002-5878-8959

Contact details
Trial Coordinator
York Trials Unit
Ground Floor ARRC Building
Department of Health Sciences

University of York
Heslington
York
United Kingdom
YO10 5DD
+44 1904 323868
jane.blackwell@york.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
326756

Central Portfolio Management System (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

Study type(s)
Treatment

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%20Interraction%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(s)
Communication skills measured using the Communication Complexity Scale (CCS) at baseline, 32 and 52 weeks

Key secondary outcome(s))
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

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/12/2025:
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 complete outcome measures
5. 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.

Previous 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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
0

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
19/12/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
York Trials Unit (University of York)
University of York
Heslington
York
England
YO10 5DD

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository and will be included in the subsequent results publication.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/04/2026	10/04/2026	Yes	No