# Study of Early Communication Home-Learning Offer (ECHO), a targeted communication program for parents/caregivers of children under 2 years old with significant language difficulties and social communication difficulties

Submission date 19/06/2024	<b>Recruitment status</b> Recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 08/08/2024	<b>Overall study status</b> Ongoing	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 02/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<ul> <li>Individual participant data</li> <li>[X] Record updated in last year</li> </ul>

### Plain English summary of protocol

Background and study aims

This study will help us understand how the Early Communication Home-Learning Offer (ECHO) affects children with early signs of social communication difficulties. The ECHO is a parent-child interaction program targeted at children under 2 years old to support early communication development. We would like to understand if this intervention makes a difference to children's communication skills. We are also interested in how the ECHO changes how parents/caregivers feel about their parenting.

The ECHO was created to give early support for families of children under 2 years old with language difficulties associated with social communication difficulties. Current clinical data indicates that waiting times for speech and language therapy services are longer than the target 18 weeks in many areas of England and that families might benefit from general advice for supporting their child's communication skills. Currently most community delivered targeted intervention focus on language development while children with social communication difficulties are referred for specialist interventions delivered by speech and language therapists. The ECHO was developed to address this gap and provide a targeted offer that can be delivered by professionals in the community.

Because the ECHO is a new intervention, we need to understand the experiences of the families receiving it. This will provide a better understanding of what families need and how the ECHO can be improved. We will also collect information on how families feel the ECHO is helpful. Our aim is to provide preliminary evidence of the effectiveness and acceptability of this programme, and offer a new intervention, which can support the current population of children and eventually contribute to an evidence based resource for clinicians more widely.

Who can participate?

Families of children under the age of 2 years old who are identified with signs of significant language difficulties and social communication difficulties referred by health visitors and children centres in Manchester Local Authority area.

What does the study involve?

For all children referred to the Early Years Communication and Language Team, we will complete the ECHO intervention. This includes an initial assessment, 5 intervention sessions and a final review.

The 5 intervention sessions will last approximately 45 minutes each and target early communication parent-child interaction strategies.

During the initial assessment visit we will ask parents/caregivers to fill in 2 written questionnaires (TOPSE and CSBS DP), ask questions from another questionnaire (The Pragmatics Profile), and complete 30-45 minutes of assessment (CSBS DP Behaviour Sample, WellComm Language Screen, and Parent-Child Interaction observation) with the parent/caregiver and their child.

The same questionnaires and assessments will be completed at a final review visit 12 weeks following the intervention.

The only difference for families participating in the research study is that we will store data from assessments and questionnaires as well as our clinical observations on a research database. For more information about the ECHO intervention, please use contact details to request.

What are the possible benefits and risks of participating?

Those taking part will not receive any immediate direct benefit but will contribute to our understanding of how to better support families. Data will help us understand how the ECHO is supporting early communication development and parent/caregiver wellbeing. This will help to shape the care that other families receive. Findings will also be shared with local services who are likely to support participants in the future.

Families may be asked questions that cause mild distress, and these will be asked by professionals trained in support families in difficult conversations. Families will be visited at home and NHS risk management procedures will be followed to minimise any risk or distress caused by home visiting.

Where is the study run from?

This study was developed and managed by the Early Years Communication and Language team within the Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is this expected to run for? July 2024 to June 2026

Who is funding this study? Department for Education and Manchester Local Authority (UK)

Who is the main contact? Sarah Cameron, sarah.cameron@mft.nhs.uk

# **Contact information**

Type(s)

Public, Scientific, Principal Investigator

**Contact name** Mrs Sarah Cameron

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# Additional identifiers

**EudraCT/CTIS number** Nil known

IRAS number 331323

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers IRAS 331323

# Study information

### Scientific Title

Early Communication Home-Learning Offer (ECHO): Targeted communication intervention for parents/caregivers of children aged under 24 months identified as having significant language difficulties associated with social communication difficulties: Protocol for a single-centre, single group effectiveness study

**Acronym** ECHO Intervention Study

### **Study objectives**

A targeted intervention (ECHO) on the communication skills of children under 24 months with significant language difficulties and social communication difficulties will produce noticeable improvement in the child's communication skills, on parent-child interactions and parent /caregiver wellbeing.

Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 21/05/2024, London - Bromley Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 2071048118; bromley.rec@hra.nhs.uk), ref: 24/PR/0471

### Study design

Single-centre single-arm study with mixed methods qualitative study and intervention study

# Primary study design

Interventional

#### Secondary study design Non randomised study

**Study setting(s)** Community, Home

#### **Study type(s)** Prevention, Efficacy

### Participant information sheet

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

### Health condition(s) or problem(s) studied

Prevention of long-term language difficulties in children with social communication difficulties

#### Interventions

ECHO program includes parent-child interaction strategies delivered to families in 5 face-to-face sessions targeting shared attention, copying, interpreting behaviour as communication, using visuals, and offering opportunities through pausing and choices.

The ECHO intervention is delivered by Language Development Workers with a level 3 (or above) qualification in Child Development and supervised by Speech and Language Therapists. The ECHO intervention is delivered by the Early Years Communication and Language Team employed by the Manchester University NHS Foundation Trust within the Manchester Local Authority area. It is delivered in family's homes and local children's centres for 5 x 45 minute sessions delivered individually to each family on a weekly basis. Families are followed up 12 weeks after the final session.

### Intervention Type

Behavioural

### Primary outcome measure

The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP) (Wetherby, A.; Prizant, B., 2002) clinical assessment at baseline and 12-week follow up

### Secondary outcome measures

 Qualitative interviews completed via Zoom within 12 months of participation in ECHO
 WellComm Language Screen Early Years Toolkit – paper version (GL Assessments, 2015) measured using clinical observation at baseline and 12-week follow up
 The Pragmatics Profile of Everyday Communication Skills (Dewart et al., 1995) questionnai

3. The Pragmatics Profile of Everyday Communication Skills (Dewart et al., 1995) questionnaire

completed by verbal interview at baseline and 12-week follow up 4. The Tool to Measure Parenting Self-Efficacy (TOPSE) (Bloomfield et al., 2010) questionnaire completed by parent/caregiver at baseline and 12-week follow up 5. Clinical outcome measure of parent-child interaction measured using clinical observation at baseline, each intervention session, and 12-week follow up

#### Overall study start date

01/06/2023

### **Completion date**

30/06/2026

# Eligibility

### Key inclusion criteria

Qualitative Study:

1. Parent/caregiver received at least one ECHO Intervention session within the last 12 months

2. Parent/caregiver residing within the Manchester Local Authority at the time of interview

3. Parent/caregiver having a sufficient level of oral language skills in any language to participate in an in-depth interview as assessed by the researcher's judgement

ECHO Intervention Study:

1. Parent/caregiver and child aged less than 24 months at the start of intervention

2. Parent/caregiver and child who scored Red on the WellComm Language Screen within 3 months of the start of intervention

3. Parent/caregiver and child who scored High Likelihood of autism on Social Attention and Communication Surveillance (SACS-R) tool

4. Residing within the Manchester Local Authority for the duration of intervention

### Participant type(s)

Patient

Age group

Child

Lower age limit

11 Months

### Upper age limit

24 Months

**Sex** Both

**Target number of participants** 40

### Key exclusion criteria

Qualitative Study:

1. Current significant and ongoing safeguarding concerns.

2. Learning disabilities and/or communication difficulties or disorders that significantly impact parent/caregiver's capacity to give informed consent and participate in interview even with interpreter support and use of supportive communication strategies.

ECHO Intervention Study:

- 1. Family currently receiving intervention from another Speech and Language Therapy Service.
- 2. Parent/caregiver already taking part in the study with another child.
- 3. Child or parent/caregiver has a diagnosis of visual, motor, or hearing impairment.
- 4. Child has a diagnosis of a developmental disorder other than autism.
- 5. Current significant and ongoing safeguarding concerns.

Date of first enrolment 01/07/2024

Date of final enrolment 30/01/2026

### Locations

#### **Countries of recruitment** England

United Kingdom

**Study participating centre Manchester university NHS Foundation Trust Early Years Communication and Language Team** 1 Stancliffe Road Manchester United Kingdom M22 4PJ

### Sponsor information

**Organisation** Manchester University NHS Foundation Trust

Sponsor details The Nowgen Centre 29 Grafton Street Manchester England United Kingdom M13 9WU +44 1612764125 research.sponsor@mft.nhs.uk **Sponsor type** Hospital/treatment centre

Website https://mft.nhs.uk/

ROR https://ror.org/00he80998

# Funder(s)

**Funder type** Government

**Funder Name** Department for Education, UK Government

Alternative Name(s) Department for Education, educationgovuk, DfE

Funding Body Type Government organisation

Funding Body Subtype National government

**Location** United Kingdom

Funder Name Manchester City Council

# **Results and Publications**

### Publication and dissemination plan

When the study is completed, results will be analysed and tabulated, and a final study report will be prepared by the Chief Investigator and Principal Investigators. An HRA final study report containing a summary of the results will be completed within 12 months after the study has ended. A more detailed study report will be shared with the Department of Education and the Manchester Local Authority within 2 years of completion of the study. The data will be owned by MFT, and the full study report can be accessed on request to the Early Years Communication and Language Team. Results will also be shared with relevant local services that support families in the target population, in addition to local children's centres and family hubs where local families

in the target population can access them. The results will also be shared with participating families on request via signposting to their local children's centre.

Clinicians will share contact information for the Early Years Communication and Language Team with children centre and family hub staff, so families can get in touch about the results. If families are interested, they can be supported to share their experiences within the local communities.

Information from Qualitative Study interviews will be used to understand the patient story and inform how the ECHO Intervention is experienced by families. This information will help inform how the ECHO Intervention may need to be amended to better meet the needs of the target population.

Wider dissemination in peer-reviewed journals of general and special interest may also be considered with authorship shared between the Chief Investigator and Principal Investigators.

#### Intention to publish date

01/07/2026

#### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

#### IPD sharing plan summary

Stored in non-publicly available repository

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	version 1.1	16/05/2024	24/06/2024	No	No