Full/Long Title Of The Study

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

Short Study Title/Acronym

ECHO Intervention Study

Protocol Version Number And Date

Version 1.1 16.05.2024

Amendment History

Amendment No.	Protocol Version and date	Details of Changes Made
	V1.0 28.02.2024	
1	V1.1 16.05.2024	Changes to Sections 4.2 and 5.7 as requested by PRS Sub -Committee of the REC meeting on 1 May 2024 4.2: amended to include protocol for families with limited IT access to Qualitative Study participation 5.7: added End of Study definitions

Research Reference Numbers

IRAS Number	331323
Sponsor Reference	B02065

This protocol has regard for the HRA guidance.

This project will be conducted in accordance with the study protocol and the ethical principles outlined by Good Clinical Practice (GCP) and the Declaration of Helsinki in its most current version.

Signature Page

The sponsor signature on the IRAS form, acts as documented acceptance that the sponsor approves the protocol.

The Chief Investigator should sign below to confirm the following:

The Chief Investigator confirms the protocol has been agreed and accepted and agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: .....

Date: 30/05/2024

Name: (please print):

Sarah Cameron

List of Contents

Key Study Contacts

Chief Investigator	Sarah Cameron Wythenshawe Offices 1 Stancliffe Road Greater Manchester M22 4PJ sarah.cameron@mft.nhs.uk 07976 157683
Co- Investigators	Dr Ceri Ellis B1.18 Ellen Wilkinson The University of Manchester Oxford Road M13 9PL ceri.ellis@manchester.ac.uk 0161 306 6000 Dr Alexandra Sturrock B1.10 Ellen Wilkinson The University of Manchester Oxford Road M13 9PL alexandra.sturrock@manchester.ac.uk 0161 306 6000
Study Contact for Enquiries	Sarah Cameron Wythenshawe Offices 1 Stancliffe Road Greater Manchester M22 4PJ sarah.cameron@mft.nhs.uk 07976 157683
Sponsor	Dr Lynne Webster Manchester University NHS Foundation Trust The Nowgen Centre 29 Grafton Street Manchester M13 9WU research.sponsor@mft.nhs.uk 0161 276 4125
Funder(s)	ECHO Intervention Development and Delivery, and Study of ECHO Intervention Effectiveness funded by: Department of Education Family Hubs and Early Years Interventions Store Street M12WD 0370 000 2288 familyhubs.startforlife@dhsc.gov.uk Manchester Local Authority PO Box 352 Manchester

	M60 2LA 0161 234 1864 07717 802331 nasreen.king1@manchester.gov.uk ECHO Intervention Development and Study of ECHO Intervention Effectiveness funded by: Manchester Local Authority PO Box 352 Manchester M60 2LA 0161 234 1864 07717 802331 nasreen.king1@manchester.gov.uk
Statistician	Dr Catherine Fullwood catherine.fullwood@manchester.ac.uk CityLabs 1.0 Nelson St Manchester M13 9NQ
Key Protocol Contributors	Sarah Cameron Wythenshawe Offices 1 Stancliffe Road Greater Manchester M22 4PJ sarah.cameron@mft.nhs.uk 07976 157683 Dr Ceri Ellis B1.18 Ellen Wilkinson The University of Manchester Oxford Road M13 9PL ceri.ellis@manchester.ac.uk 0161 306 6000 Dr Alexandra Sturrock B1.10 Ellen Wilkinson The University of Manchester Oxford Road M13 9PL alexandra.sturrock@manchester.ac.uk 0161 306 6000 Dr Catherine Fullwood catherine.fullwood@manchester.ac.uk CityLabs 1.0 Nelson St Manchester M13 9NQ

Committees	Trial Management Group (TMG) organized by: Sarah Cameron Wythenshawe Offices 1 Stancliffe Road Wythenshawe Greater Manchester M22 4PJ sarah.cameron@mft.nhs.uk 07976 157683

Study Summary

Study Design	Single-centre, single arm study with mixed methods: Qualitative Study – in-depth qualitative interviews with parents/caregivers who have received the ECHO Intervention as part of their usual pathway of care. ECHO Intervention Study – prospective sample of parents/caregivers receiving the ECHO Intervention to evaluate effectiveness.
Study Participants	Parents/caregivers with children under 24 months scoring Red on WellComm Language Screen (indicating significant language difficulties) and scoring High Likelihood for autism on the Social Attention and Communication Surveillance (SACS-R) (Barbaro et al., 2022) tool in the Manchester Local Authority area recruited through referrals to the Early Years Communication and Language Pathway.
Planned Size of Sample	8-12 parents/caregivers will be recruited for the Qualitative Study. 40 parents/caregivers will be recruited for the ECHO Intervention effectiveness study.
Recruitment Period	12 months
Follow Up Period	12 weeks post-intervention follow-up
Overall Study Duration	16 months
Research Question/Aim(s)	Assess ECHO Intervention effectiveness evidenced through improved communication skills of children at 12-week follow-up.
Study Objectives	Assess the effectiveness of a targeted intervention (ECHO) on the communication skills of children under 24 months with significant language difficulties and social communication difficulties. To evaluate if there is any noticeable effect of the targeted intervention on the parent-child interaction and parent/caregiver wellbeing.

Primary Outcome Measure	**Primary Endpoint**
The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP) (Wetherby, A.; Prizant, B., 2002)	Score at 12-week follow-up
Secondary Outcome Measures	**Secondary Endpoints**
Qualitative interviews	Qualitative Study results collected at interview, at baseline and at 12-week follow-up
WellComm Language Screen Early Years Toolkit – paper version (GL Assessments, 2015)	Score at 12-week follow-up

The Pragmatics Profile of Everyday Communication Skills (Dewart et al., 1995) The Tool to Measure Parenting Self-Efficacy (TOPSE) (Bloomfield et al., 2010) Clinical outcome measure of parent-child interaction	 Score at each session and at 12-week follow-up

Funding and Support in Kind

Funder(s)	**Financial And Non-Financial Support Given** Detail financial and non-financial support given by each organisation listed
Department of Education	Funding for ECHO Intervention Development and Delivery, and Study of ECHO Intervention Effectiveness
Manchester Local Authority	Funding for ECHO Intervention Development, and Study of ECHO Intervention Effectiveness

Role of Study Sponsor and Funder

Manchester University NHS Foundation Trust is acting as sponsor for this study and is assuming overall responsibility for the initiation and management of the study. The Trust will provide permission to conduct the research and monitor the progress of that research. The research team all hold substantive or honorary contracts with the Trust and therefore the sponsor has influence over all aspects of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results which are the responsibility of the research team.

Manchester Local Authority and Department of Education will receive results of the study and may disseminate results.

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study Steering Groups

The Trial Management Group (TMG) will meet monthly throughout the study duration to review the progress of the study, recruitment rate, general research study issues and protocol amendments. The trial management group will include the Chief Investigator, Principal Investigators, and Statistician

Key Words: Autism; parent-child interaction; early intervention; social communication.

Abbreviations

Abbreviation	Definition
APR	Annual Progress Report
CSBS DP	The Communication and Symbolic Behaviour Scales Developmental Profile™
CTIMP	Clinical Trials of Investigational Medicinal Products
ECHO	Early Communication Home-Learning Offer
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice
ID	Identification
IMD	Index of Multiple Deprivation
IQR	Inter-Quartile Range
IRAS	Integrated Research Application System
MFT	Manchester University NHS Foundation Trust
n.d.	No Date
NHS	National Health Service
PPI	Patient and Public Involvement
R&D	Research & Development
R&I	Research & Innovation
REC	Research Ethics Committee
RI SOP	Research & Innovation Standard Operating Procedure
SACS-R	Social Attention and Communication Surveillance – Revised
SAE	Serious Adverse Event
SD	Standard Deviation
SLT	Speech and Language Therapist
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TOPSE	The Tool to Measure Parenting Self-Efficacy

Study Flow Chart

Figure 1. *Flow chart of the participant journey in the ECHO Intervention Study*

Enrolment

Referrals received from health visiting service and/or children centre services. Eligibility and recruitment at initial visit.

Inclusion criteria: Parent/caregiver of child aged under 24 months at the start of intervention; Child Scored Red on WellComm Language Screen within 3 months of the referral; Child Scored High Likelihood of autism on Social Attention and Communication Surveillance (SACS-R) tool; Residing within the Manchester Local Authority for the duration of intervention.

Exclusion criteria: The family are currently receiving intervention from another Speech and Language Therapy Service; Parent/caregiver already taking part in the trial with another child; The child or parent has a diagnosis of visual, motor, or hearing impairment; The child has a diagnosis of a developmental disorder other than autism; Current significant and ongoing safeguarding concerns.

n = 40

Baseline

Measures taken at baseline visit

Primary Outcome measure: The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP)

Secondary Outcome measures:

The WellComm Language Screen; The Pragmatics Profile of Everyday Communication Skills; Clinical Outcome Measure Form (child's interaction, non-verbal communication skills, and language skills); The Tool to Measure Parenting Self-Efficacy (TOPSE); A research tool developed from local clinical service recording observations of parent-child interaction

5 ECHO intervention sessions delivered weekly
(Clinical outcome measure of parent-child interaction collected each session)

Endpoint

Measures taken 12 weeks following intervention

Primary Outcome measure: The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP)

Secondary Outcome measures:

The WellComm Language Screen; The Pragmatics Profile of Everyday Communication Skills; Clinical Outcome Measure Form (child's interaction, non-verbal communication skills, and language skills); The Tool to Measure Parenting Self-Efficacy (TOPSE); A research tool developed from local clinical service recording observations of parent-child interaction

1. Background

1.1 Theoretical Background

Early social communication skills, including joint attention, are predictive of later language development (Charman, 2003; Mundy, P., et al. 1990). It is estimated that around 25-30% of autistic children are pre-verbal or minimally verbal in early childhood (Tager-Flusberg & Kasari 2013; Anderson et al. 2007; Rose et al. 2016). These early social and language skills are predictive of outcomes in adolescence and beyond (Gillespie-Lynch et al. 2012; Howlin et al. 2014; Magiati et al. 2014).

Research strongly suggests that interventions should commence as early as possible, even before an official autism diagnosis, particularly during toddlerhood or early childhood (French, & Kennedy 2018). Interventions are increasingly designed for infants not yet diagnosed with autism (Green et al. 2018; (Whitehouse et al. 2019; Whitehouse et al. 2021). This is based on the belief that the infant brain's neuroplasticity provides an ideal window for intervention (Kolb & Gibb 2011; McEachin et al. 1993. Additionally, there is a growing body of evidence supporting the long-term benefits of early intervention (Pickles et al. 2016). Autistic individuals, parents/caregivers, clinicians and professionals have highlighted that effective interventions for the development of language and communication is a top-three priority (Autistica, 2016).

Naturalistic developmental behavioural interventions (NDBIs) and behavioural interventions grounded in behavioural and developmental theory (Schreibman el al., 2015) offer the strongest evidence base for early autism interventions (Sandbank et al., 2020). These interventions align with normative developmental stages and emphasize the child's unique qualities, needs, and interests (Green et al., 2010; Dawson et al., 2010). They have demonstrated positive impacts on social communication skills, although their effects on direct language measures are less clear (Green et al., 2010; Kasari et al., 2015; Shire et al., 2017).

Decades of child development research (Akhtar et al., 1991; Landry et al., 2000; Page et al., 2010; Tomasello, M., & Todd, J., 1983) highlight the importance of early dyadic social interaction for later social communication and adaptation skills. The transactional model of development (Sameroff, 1975; Sameroff, 2009) underscores how a child's interactions with their parent/caregiver, central to their primary environment, shape the development of social communication, self-regulation, and other essential skills. This model does not attribute autism's cause to parent-child interactions but instead suggests that adjusting interaction styles to align with the child's attempts at engagement can support social communication development, potentially benefiting the child's long-term outcomes (Blacher et al., 2013; Doussard–Roosevelt et al 2003).

Current best clinical practices involve clinicians training parents/caregivers in intervention strategies (NICE, 2013). Evidence supports the effectiveness of parent/caregiver-mediated communication interventions on both parent-child interaction and child autism outcomes (Sandbank et al., 2020; Pickles et al. 2016). It is important to note that parent/caregiver-mediated interventions can also positively affect parents/caregivers themselves (Estes et al., 2019). These interventions provide parents/caregivers with training, empowering them with knowledge and skills to enhance communication with their child and better understand their child's behaviour. Research has shown reductions in parent/caregiver stress (Da Paz & Wallander, 2017; Ladarola et al., 2018) and improvements in family wellbeing and quality of life (Leadbitter et al., 2018). However, literature specifically addressing child wellbeing remains limited.

The ECHO targeted communication intervention, designed for children aged under 24 months with significant language difficulties related to social communication issues, is based on naturalistic developmental behavioural evidence. This study aims to assess the impact of a short-term, 5-session targeted intervention on this high-risk population and evaluate its effects on parent-child interaction, child wellbeing, and parent/caregiver wellbeing.

1.2 Local Need Assessment

In Manchester, fewer children achieve a good level of development at the end of their foundation stage compared to the national average (GOV.UK, n.d.). In a cluster of schools in a highly disadvantaged part of Manchester, 50% of the nursery sample had significant language difficulties (Ainscow, M. et al., 2012).

According to the 2019 Index of Multiple Deprivation (IMD), Manchester ranks 6 out of 326 local authorities in England, where 1 is the most deprived (Manchester City Council, n.d.). Any intervention targeting families in Manchester needs to include accommodation for families with limited resources and consider the high levels of demand on local services.

Current waiting times for NHS Speech and Language services are well above the NHS targets, especially for children presenting with social communication difficulties (Clinical data). Current waiting times for initial assessment average 32 weeks with an additional wait of 104 weeks for intervention for children with social communication difficulties. The waiting time has increased due to the pandemic and is identified as a 'key issue that will need addressing' (Manchester Parent Carer Forum, n.d.).

Manchester is also considered 'one of the most linguistically diverse cities in England and Europe' (Manchester City Council, n.d; Manchester City Council, 2024), meaning that any intervention targeting children in Manchester needs to include provision for families with multiple languages and limited English language skills. The ECHO Intervention is designed to be deliverable using interpreters and recommendations can be adapted to be delivered by caregivers in any language. Resources were designed to be accessible to families with limited English and literacy skills such as using visuals and videos.

The First 1001 Days Movement (Parent, n.d.) highlights the importance of the period from conception to age 2 on the developing brain and long-term outcomes. Manchester has an established targeted intervention for children presenting with language difficulties without social communication difficulties focused on parent/caregiver education. This intervention is the basis for the ECHO Intervention with consideration of the research literature concerning universal and targeted level strategies supporting early social communication development.

After consulting relevant research, no intervention was identified for children under 24 months presenting with social communication and language difficulties, which could be delivered in any language at the universal and targeted level, within the constraints of local resources and parent/caregiver engagement needs.

In developing the ECHO Intervention, all children in Manchester presenting with early communication difficulties can receive support within the first 1001 days.

1.3 Evidence from Local Clinical Context

Preliminary clinical data collected from delivery of the ECHO Intervention with 12 children suggests that the ECHO Intervention is effective at improving children's communication skills and parent/caregiver wellbeing. A summary of this data was shared with research funders.

After the final intervention session, parents/caregivers were asked for their perspective on their child's communication skills. All parents/caregivers reported increases in vocalisations and babbles and for some children an increase in using single words in context. All parents/caregivers reported increased use of non-verbal communication such as gestures, using objects, and using noises to communicate needs, as well as increases in eye contact and requests for shared activities. For example, children bringing bottles to ask for a drink and dancing to ask for music videos. Parents/caregivers also reported understanding their child's sensory experiences and reported fewer difficulties managing their child's emotion regulation.

When asked to rate the impact of the intervention, parents/caregivers indicated they experienced improvements in their child's communication, the wellbeing of their child, and their relationship with their child. Parents/caregivers reported the most improvement in their own wellbeing.

Clinical observations noted improvements in children's social and non-verbal communication skills similar to parent/caregiver reports. Clinicians also observed fewer difficulties with transitions and sensory regulation as interventions progressed.

From these clinical data, there are indications that the ECHO Intervention produces positive impacts for children with significant communication difficulties and social communication difficulties. As well as positive impacts on children's communication development, the ECHO Intervention may have a positive impact on child and parent/caregiver wellbeing. These early indications need to be further explored to understand the potential benefits of the ECHO Intervention across a larger group of parents/caregivers.

2. Rationale

Given the evidence for development in the context of social communication differences and autism, early intervention is beneficial for this clinical population. Due to local needs, the intervention is more accessible when delivered in a short course by less specialized practitioners and individualized to family needs. For this reason, the ECHO Intervention may be an effective method of treatment for local families. This study will evaluate the effectiveness of an intervention targeting communication difficulties associated with social communication difficulties, adapted to the context of a community with high levels of deprivation and multilingualism.

3. Research Question/Aim(s)

This study aims to further develop the ECHO Intervention and assess the measurement of effectiveness, perceptions, barriers, and potential harms. It also aims to assess the effectiveness of the ECHO Intervention as evidenced through the improved communication skills of children at 12-week follow-up, and to evaluate if there is any noticeable effect of the targeted intervention on the parent-child interaction and parent/caregiver wellbeing.

3.1 Objectives

Qualitative Study Objectives:

i. Primary Objective: Inform intervention and its measurement development, implementation, and sustainability (Reflexive Analysis (Braun & Clarke, 2006; Braun & Clarke, 2020)).
ii. Secondary Objectives:
   - Identify perceptions of the intervention
   - Identify any benefits and/or harms potentially related to the ECHO Intervention not anticipated by clinicians
   - Identify barriers to implementation and embedding of strategies.

ECHO Intervention Study Objectives:

i. Primary Objective: To assess whether the ECHO Intervention is effective at improving child communication.
ii. Secondary Objectives: To test whether the ECHO Intervention is effective at:
   - Improving parent/caregiver wellbeing and efficacy
   - Increasing parent/caregiver use of parent-child interaction strategies supporting communication development
   - Increasing child's language skills
   - Increasing child's social communication skills.

3.2 Outcome Measures

Qualitative Study Outcomes:

i. In-depth semi-structured interviews with parents/caregivers who received the ECHO Intervention as part of their usual pathway of care.

ECHO Intervention Study Outcomes:

i. Primary Outcome Measure: The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP) (Wetherby, A.; Prizant, B., 2002)
ii. Secondary Outcome Measures, measured at baseline and 12-week follow-up (Parent-Child Interaction Pre/Post also taken at each intervention session)
   - The Tool to Measure Parenting Self-Efficacy (TOPSE) (Bloomfield et al., 2010)
   - Parent-Child Interaction Pre/Post Measure, a clinical tool used in current clinical practice to measure parent-child interaction strategy use
   - WellComm Language Screen Toolkit Early Years – Paper version (GL Assessments, 2015)
   - The Pragmatics Profile of Everyday Communication Skills (Dewart, H., & Summers, S., 1995) to measure changes in child's communication skills

3.2.1 Rationale for Outcome Measures

Outcome measures were selected based upon whether they were suitable for the clinical population. Specific consideration was given to their suitability:

- for the targeted age range,
- for families with languages other than English, and
- for families from similar cultures and ethnicities as the Manchester population.

Consideration was given for the time that outcome measures may take to complete, as children and parents of young children may find it difficult to attend for long periods of time.

Outcome measures were also selected to allow for the views of parents as well as clinical observation, since some children may behave differently during clinical sessions and parents may interpret children's communication differently based on their knowledge of the child and their family's cultural norms.

The Communication and Symbolic Behaviour Scales Developmental Profile™ (CSBS DP) (Wetherby, A.; Prizant, B., 2002) was selected as the primary outcome measure as it is a validated tool standardized for children aged 6-24 months and it was likely to be sensitive to detect small to changes across different early communication skills.

1. Study Design and Methods of Data Collection

4.1 Study Design

A single-centre, one arm design using mixed-methodology including parent/caregiver reports, clinical observations and in-depth semi-structured interviews. Parents/caregivers taking part in the effectiveness study will access the ECHO Intervention as part of their usual pathway of care and will be able to access all other services and interventions on offer in their locality for the duration of their participation in the study. All participants recruited to the study will be offered the ECHO Intervention. At present, the ECHO Intervention is the only intervention available in the standard pathway of care, and thus a no-treatment contro is not deemed ethical given the hypothesised benefits on the parent/caregiver and child outcomes.

4.2 Methods of Data Collection

Qualitative Study

Interviews will be completed using the ECHO Interview Schedule. Interviews will be conducted over Zoom and will be recorded.

When scheduling interviews, participants will be informed that children cannot be present for the duration of the recorded interview. If a child is present during the interview, recordings will be paused until the child is no longer present. Participants will be asked to avoid saying identifiable information during the interview.

If families cannot access the Zoom interview because of IT access, a member of the child's direct care team will attend face-to-face to support the family to access the interview. This could include support with how to access zoom using devices in the family home. It could

also include providing an MFT Laptop to access Zoom. If an MFT laptop is provided, no log in information will be shared, an MFT staff member will be present to ensure the laptop is used correctly and only zoom is accessed, and the laptop will not be connected to any systems that can access confidential information. If internet connection is a concern, families can be invited to a private room at a children's centre to access the Zoom interview.

Only audio recording will be collected from Zoom. Audio recordings will be saved to MFT servers which are password protected to NHS standards. Audio recordings will be labelled using the following format: ECHO Interview Date of interview (DD.MM.YY) Participant number (for example ECHO Interview 05.09.23 P01). Only study staff in the clinical team and authorised personnel will have access to the study folder.

Zoom will be used to create transcripts of audio recordings. Transcripts will be saved to MFT servers in the same folder as audio recordings. Transcripts will be labelled using the same format as audio recordings.

The study staff will ensure that the participants' anonymity is maintained. The study will comply with the Data Protection Act which requires data to be pseudonymised as soon as it is practical to do so with the participant identification number. Audio files and transcripts will be reviewed as soon as possible to correct transcription errors and remove identifiable information in the transcript. Reviews will be completed by the interviewer and checked by another member of the research team. Once the review is complete and the transcript is anonymised, audio files will be stored as source data in secured folders with access restricted to study research members on MFT servers. Only pseudonymised transcript data will be shared for analysis.

ECHO Intervention Study

Data collection will be carried out by clinicians working on the ECHO Intervention study within the Early Years Communication and Language Team in accordance with Good Clinical Practice procedures. Baseline and endpoint measures will be collected by Speech and Language Therapists within the research team. Intervention data will be collected by the Language Development Workers delivering the ECHO Intervention. All staff will attend Good Clinical Practice training and be trained in the study protocol by the Chief Investigator.

All study visits will take place at the parent/caregiver's home, or another suitable location if preferred. A Language Development Worker may be present to support any children while parents/caregivers are answering questionnaires. Paper copies of outcome measures will be stored in a locked cabinet on MFT property and data will be entered by the clinician who collected the data into the research Excel database stored on MFT servers.

Researchers will be present during the completion of research assessments and will support parents/caregivers in understanding and completing assessments. Where appropriate, interpreters will be present to support parents/caregivers to understand and complete assessments.

At each intervention visit, the Language Development Worker providing the intervention will complete observations of parent-child interaction using the Parent-Child Interaction Pre/Post Measure tool. As with baseline and endpoint measures, paper copies of outcome measures will be stored in a locked cabinet on MFT property and data will be entered in the research Excel database stored on MFT servers by the clinician who collected the data.

At the review appointment, a Speech and Language Therapist will collect the endpoint outcome measures through observations and parent/caregiver questionnaires. A Language Development Worker may be present to support any children while parents/caregivers are answering questionnaires. Paper copies of outcome measures will be stored in a locked cabinet on MFT property and data will be entered in the research Excel database stored on MFT servers by the clinician who collected the data.

All study data will be pseudonymised with a study identification (ID). A paper central master file of personal data will be held securely in the Early Years Communication and Language Team office only accessible to trained members of the Early Years Communication and Language Team to be used for operational purposes. This central master file will contain the key linking anonymised participant IDs to personal details. Study data will be entered into the research database by the research staff member who collected the data, with data checking procedures detailed in the database guidance documents adhered to by the delegated research staff member. Appropriate quality control will be carried out during the study and before the database lock at the end of the study. Quantitative data analysis will be undertaken by the study Statistician and Chief Investigator. The Principal Investigators will also have access to the data and will undertake analysis as appropriate and necessary. The Principal Investigators will be responsible for qualitative analysis of the data. The Principal Investigators and study Statistician will store and process pseudonymised data for the purpose of analyses in their personal area of University of Manchester systems in folders only accessible to themselves and stored in compliance with the Data Protection Impact Assessment (DPIA) form approved by MFT Research Department.

4.3 Schedule of Procedures

Qualitative Study

Procedures	**ECHO Intervention sessions 1-5 (Received as part of standard clinical practice*)**	**Review (Standard clinical practice 12 weeks after session 5)**	**Telephone call (At least 24 hours after review)**	**Interview (Within 12 months of session 5)****
Recruitment for Qualitative Study		X		
Telephone call to discuss participation queries			X	
Interview				X

* Participants for the Qualitative Study do not need to participate in the ECHO Intervention Study

** Interviews will be conducted a minimum of 24 hours after Review session

Procedures	ECHO Intervention Study visits (7)			
	Screening	**Baseline (Minimum 24 hrs after screening)**	**ECHO Intervention sessions 1-5*** **	**Review**** **(12 weeks after session 5)**
Recruitment for ECHO Intervention Study	X			
Informed consent		X		
Demographics		X		
All ECHO Intervention Study outcome measures collected		X		X
Parent-Child Interaction Pre/Post Measure completed		X	X	X

***May be conducted between 3 and 21 days after previous visit (including baseline visit)

****May be conducted up to 4 weeks before or after the 12-week window

4.3.1 Rationale for Schedule of Procedures

The structure of the ECHO Intervention schedule is based on the successful Early Years Communication and Language Pathway that has been embedded in Manchester since 2015 (Lee & Ashworth, 2020). Attendance from local families was more consistent when intervention was limited to 5-6 sessions offered weekly and delivered flexibility around family schedules.

Review at 3 months following the final intervention session is based on recommendations in the CSBS DP and WellComm Language Screen Toolkit manuals (Wetherby & Prizant, 2002; GL Assessments, 2015).

Interviews will be conducted within 12 months of the final intervention session to allow for recruitment during standard clinical visits to minimize disruption to families while allowing for the inclusion of families at different time periods following intervention. This will give a broader range of perspectives that may develop over the year post-intervention. This schedule also allows flexibility in the scheduling of interviews, which may support the inclusion of a wider range of families.

2. Study Sample and Recruitment

5.1 Eligibility Criteria

All individuals will be considered for inclusion in this study regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation except where the study inclusion and exclusion criteria EXPLICITLY state otherwise.

5.1.1 Inclusion Criteria

Qualitative Study:

- Parent/caregiver received at least one ECHO Intervention session within the last 12 months.
- Parent/caregiver residing within the Manchester Local Authority at the time of interview.
- 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:

- Parent/caregiver of a child aged less than 24 months at the start of intervention.
- Parent/caregiver of a child who scored Red on the WellComm Language Screen within 3 months of the start of intervention.
- Parent/caregiver of child who scored High Likelihood of autism on Social Attention and Communication Surveillance (SACS-R) tool.
- Residing within the Manchester Local Authority for the duration of intervention.

5.1.2 Exclusion Criteria

Qualitative Study:

- Current significant and ongoing safeguarding concerns.
- 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:

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

5.2 Study Setting and Sample Identification

Parents/caregivers of children aged between 12 and 24 months with significant language and communication difficulties and significant social communication difficulties residing in the Manchester Local Authority area.

Due to the large multi-ethnic and multilingual population in Manchester, it is anticipated that the study population will include families from multi-ethnic backgrounds with English as an Additional Language. The intervention has been designed with cultural diversity in mind and interpreters will be provided for families as needed.

More families of low socio-economic status are likely to be eligible for the study based on prevalence data that children from more deprived backgrounds are at risk for significant communication difficulties.

This is a single-centre study only and recruitment will take place at the parent/caregiver's home, or another suitable location if preferred . Participants will be identified by Speech and Language Therapists in the Early Years Communication and Language Team who will identify suitable recruits at initial appointments. Suitable recruits will then be approached with a Participant Information Sheet.

5.3 Sampling

5.3.1 Size of Sample

Qualitative Study

Data collection in the form of semi-structured in-depth interviews will be conducted until saturation of themes in the data collected is reached. It is expected that between 8-12 families will need to be interviewed to achieve saturation, based on similar literature (Neely et al., 2015; Thompson et al., 2017). This is consistent with the approach outlined in Braun and Clarke (2019).

ECHO Intervention Study

It is expected that 40 families will be recruited. This is a pragmatic sample size for an early exploratory study designed to generate hypotheses. The decision to target 40 families is based on prior experience with the intervention and considerations of time constraints, deeming it a realistic goal for recruitment. Allowing for 10% dropout, a medium effect size of 0.48 can be detected with alpha of 0.05 and 80% power. Assuming a clinical difference of 7, this equates to a standard deviation of 14.6.

5.3.2 Sampling Technique

Participants will be selected using a convenience sampling technique from all eligible patients accessing the Early Years Communication and Language Pathway. This sampling technique is used as there is only a small population of participants who can be identified using available resources for this study. Convenience sampling is a more cost-effective method of sampling for a study of this scope (Jager et al., 2017). A convenience sampling technique will limit generalizability (Jager et al., 2017) and further research will be necessary if the study demonstrates effectiveness in this limited sample.

This study is not blinded as there is no comparison group. The intervention will be delivered by different staff to those collecting baseline and endpoint measures to reduce potential bias.

5.4 Recruitment

Qualitative Study

All eligible families who have previously completed the ECHO Intervention will be offered the opportunity to participate in this Qualitative Study. A Speech and Language Therapist in the research team will inform these families of their eligibility to take part in interviews about their experiences in the ECHO programme during routine appointments in clinical practice, and a Participant Information Sheet will be shared with the potential participant. Families will be contacted by telephone by an administrative assistant from the research team at least 24 hours after receiving the Participant Information Sheet to ask if they are interested in participating, unless they have previously indicated they are not interested in participating.

ECHO Intervention Study

All eligible families referred for ECHO Intervention as part of the local Early Years Communication and Language Pathway will be offered the opportunity to participate in the effectiveness study. Families will be informed of the study and given a Participant Information Sheet by a Speech and Language Therapist in the research team after the child has scored High Likelihood on SACS-R during standard clinical practice. Families will be booked for an initial session as part of standard clinical practice and will be asked by a Speech and Language Therapist in the research team if they would like to participate in the ECHO Intervention Study during this visit. If a family consents, they will be asked to sign a consent form and baseline measures will be taken. If a family does not consent, they will receive the ECHO Intervention as part of standard clinical practice, but data will not be included in the study.

Children will be referred to the Early Years Communication and Language Team by the Health Visiting Team following their 9-month Child Health Check offered to all families. Children may also be referred by Outreach Workers in the local children's centres following a WellComm Language Screen offered during Outreach support or whilst parents/caregivers attended the centre. Children referred to the Early Years Communication and Language Team will be screened for eligibility for the ECHO Intervention Study. These two referral pathways should increase the likelihood of low income and isolated families being referred as well as families reluctant to engage with medical services. Interpreters are available to referrers so that families with limited English skills may also receive support.

As part of standard practice, all children referred to the Early Years Communication and Language team who score Red on WellComm are offered screening with the Social Attention and Communication Surveillance Tool (SACS-R) unless:

- they have an identified visual or hearing difference,
- they have identified motor differences other than delayed development,
- they have an identified developmental or medical condition that impacts social communication development, or
- there is concern that offering the SACS-R at this time may cause distress or harm.

As part of standard practice, children who score High Likelihood for autism on the SACS-R are referred for early communication intervention within the Early Years Communication and Language Service. Parents/caregivers of these children will be assessed by Speech and Language Therapists within the research team for their eligibility to participate in the ECHO effectiveness study. Speech and Language Therapists in the research team have access to patient details as part of standard clinical practice. A parent/caregiver's decision whether to participate in the study will not impact on the treatment options they will be offered or the treatment they will receive.

Parents/caregivers will be invited to participate in the study after their treatment options have been discussed at the initial appointment with the Early Years Communication and Language Team. A Speech and Language Therapist will give eligible parents/caregivers a Participant Information Sheet and will inform parents/caregivers that they will be asked about their willingness to participate at the next appointment. A home visit will be booked for 1-2 weeks' time.

5.5 Consent

Qualitative Study

Participants will be contacted by a member of the research team via telephone at least 24 hours after receiving a Participant Information Sheet to discuss their interest in participation. Information in the Participant Information Sheet will be reviewed verbally during this discussion to ensure it has been read and understood. Telephone interpreting services will be used if requested by families with English as an additional language.

If a family gives verbal consent to participate during the telephone conversation, a consent form will be sent to the participant by post with a pre-paid, self-addressed envelope for participants to return consent forms by post. Participants will be contacted to book an interview once the written consent form has been received by the Early Years Communication and Language Team.

All research team members obtaining consent will have completed training in obtaining informed consent. Participants will be given an opportunity to ask questions during this discussion.

ECHO Intervention Study

Eligibility and discussion of the purpose of the ECHO Intervention Study will occur at the initial contact visit with a Speech and Language Therapist from the research team. A Participant Information Sheet will be given to families and a baseline visit will be booked for at least 24 hours later. A baseline visit is part of standard clinical care for the ECHO Intervention and can be completed on the same day as the first intervention session. At the baseline visit, the Speech and Language Therapist will discuss participation in the study with parents/caregivers. If parents/caregivers consent, the consent form will be completed with the Speech and Language Therapist. Consent forms will be held securely on MFT property in the Early Years Communication and Language Team Office. Where appropriate, interpreters will be present to support parents/caregivers to understand information relevant to the intervention study and informed consent.

All parents/caregivers will be asked if they continue to consent to participation at each intervention session carried out in the home, or another suitable location if preferred, with a

Language Development Worker meeting ECHO training requirements detailed in the ECHO Manual.

Withdrawals can either be made by the participant or the research team. Participants may withdraw from the study at any time, without giving a reason. The research team may withdraw a participant from the study for welfare or safeguarding reasons, if participation is no longer in their interest, or if contact for follow-up is lost for a prolonged period of time. The research team will complete a withdrawal form stating the date and reason for withdrawal. Data collected up until the point of withdrawal will be used unless participants request their data to be removed from the study. If participants request all data to be removed, this information will be deleted. Participants will not be replaced.

5.6 Participant Compensation

Participants will not receive compensation as the study does not require any additional expense beyond standard clinical care.

5.7 End of Study

The end of study is the completion of all final monitoring and data collection.

3. Statistics and Analysis

6.1 Data Analysis

Qualitative Study

Interview data will be analysed using Reflexive Analysis as outlined by (Braun & Clarke, 2006; Braun & Clarke, 2019; Braun & Clarke, 2020). Reflexive Analysis begins with the recognition that any clinical researcher will have biases that cannot be controlled for, but which should be understood and built into the generation of data when interpreting interview data. This data will help us explore the complex and contributing factors making up parental viewpoints around the success of ECHO. It will allow us to understand which themes need to be captured in outcome measures for later iterations of this programme development, ar it will support participant partnership in intervention development.

The Speech and Language Therapist (SLT) that conducted the interview will ensure that the participant's identity is protected within any stored data. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so. Transcripts will be checked by another member of the research team. Once the transcript is finalised and pseudonymised, audio files will be stored as source data in secured folders with access restricted to study research members on MFT servers. Only pseudonymised transcript data will be shared for analysis.

Reflexive Analysis will be led by the SLT researcher with contributions in multiple key ways from the wider research team. This will ensure reflexive practice and careful consideration of theme generation. In the first instance, the team will independently undertake a deep reading of a first chosen transcript. Then, they will perform a line-by-line analysis, assigning preliminary codes and highlighting potential themes in the data, again independently. They will come together in a first meeting to discuss their finding and contribute to a shared understanding of the first transcript. A preliminary manual coding frame will result from this meeting, which can then be applied to a second transcript, again independently reviewed by

the research team. A second meeting will be held to discuss changes to the coding frame resulting from the second transcript. In a third round of coding the team will attempt to fit the new coding frame to a third paper. A third meeting will bring together the team's thoughts on the existing coding frame, and how those codes might best be hierarchically organised. At this point, the lead SLT researcher will continue the analysis, by applying the coding frame to the remaining transcripts. It is possible that further iterations of the codes or thematic structure may occur after this point, taking into account findings from the different interviews. Changes will be made in email correspondence with the team until it is agreed that the frame is a good fit for all the data.

Prototypical quotes will be collected to exemplify the meaning of the code. These quotes will represent an array of participants. A member of the team will perform a final validity check of the table of themes, codes, and associated quotes. Findings will be reported in line with APA standards (Levitt, 2019).

ECHO Intervention Study

All variables will be presented with appropriate descriptive statistics and graphics to examine for completeness and form. No imputation will be made for missing data, but in the event of larger numbers, sensitivity analyses may be utilised. The study will present the mean (SD), median (IQR), and counts (%) of baseline demographics.

The primary outcome will be reported at baseline and endpoint timepoints, alongside the change from baseline using appropriate descriptive statistics such as mean, median and SD/IQR. A paired t-test or Wilcoxon signed rank test as appropriate will be used to assess the difference between baseline and endpoint.

The quantitative secondary measures, the TOPSE, and parent-child interaction clinical measures will be presented as an overall score,with appropriate descriptive statistics at baseline and the endpoint. The TOPSE will be scored according to validated methods described in the TOPSE Manual (Bloomfield et al., 2010) and the parent-child interaction clinical measure will be scored according to current clinical practice. Differences between the two timepoints will be examined using paired t-tests or Wilcoxon signed-rank tests. Exploratory analyses will also examine these measures at an item level to identify any responses where the difference in scores between baseline and review is distinctive compared to other items in that measure. Boxplots will be used to illustrate the spread of the differences for each item.

WellComm Screen results will be presented as the number and percentage (with 95% binomial confidence intervals) of children who score Red, Amber, and Green at review. All children will score Red at baseline as this is part of the eligibility criteria. Children scoring Amber or Green at review indicates that they have made clinically significant progress as Red indicates significant language difficulties, Amber indicates mild to moderate language difficulties, and Green indicates no language difficulties.

The Pragmatics Profile provides qualitative data consisting of parents' descriptions of their child's communication which will be analysed using the descriptive method as recommended by the Pragmatics Profile manual (Pragmatics Profile of Everyday Communication Skills).

Confounding variables such as maturation effects cannot be controlled for in this study and any significant effects identified will need to be further studied in a randomised control trial to

control for confounding variables. This analysis is therefore to be considered as hypothesis generating.

2. Ethical and Regulatory Considerations

7.1 Risks and Burdens to Participants and Researchers (if applicable depending on the study intervention)

Families participating in the study will receive the same intervention and number of visits as families not participating in the study as the study aims to assess the effectiveness of standard clinical care. Participants should not be at any increased risk compared to families accessing standard clinical care outside of the study.

The ECHO Distress Protocol in the ECHO Intervention Manual details procedures to follow in the event of any distress caused by the ECHO Intervention.

Families will be offered home visits, but alternative sites may be available if the family prefer or if there are concerns with visiting the home. Alternative sites include another home suggested by the family, or a children's centre. Virtual sessions may be offered if no suitable site can be found. Visits will be offered to accommodate families' working hours and children's schedules where possible.

Some families participating in this study may speak languages other than English. Outcome measures have all been reviewed to ensure that they can be used with families speaking languages other than English, and that they are culturally appropriate for families in Manchester. Outcomes measures will be evaluated for cultural and linguistic appropriateness at the point of data collection and any adaptations will be made in line with the published guidance for that outcome measure and recorded in the Case Report Form and deviation log. The ECHO Intervention was designed to be deliverable with interpreters and cultural sensitivity was considered in the design of the intervention.

The research team are equipped with lone worker devices and will follow MFT lone worker and home visiting safety protocols. The research team will maintain training on safeguardir procedures in line with MFT mandatory training policies.

The study population will include families from a range of social-economic backgrounds. The research team are aware of local services available if families report financial or related barriers to participating in the study. Home visits are offered based on clinical knowledge that home visits are more accessible to many families in the target population.

7.2 Research Ethics Committee (REC) and Other Regulatory Reviews & Reports

Ethical approval for the ECHO study has been sought from an NHS Research Ethics Committee/Health Research Authority through the Integrated Research Application System (IRAS Number 331323).

Any further changes or amendments to this study protocol will be reviewed and detailed at the beginning of the protocol.

7.2.1 NHS REC Reviewed Research

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee (REC) for the study and all supporting documents including the protocol, information sheets, informed consent forms and other relevant documents. The study team will be responsible for the maintenance of a study site file or TMF, in which all current and superseded study documents will be retained. Also contained in the site file/TMF will be the approval documentation including correspondence with relevant authorities such as the HRA and REC.

The study team are responsible for producing progress reports throughout the study, including annual reporting (APR) to REC as required. The Chief Investigator will notify the REC of the end of the study and will submit a final report with the results, including any publications/abstracts, to the REC within 12 months of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

No participants will be enrolled into this research study prior to the study being reviewed by the relevant regulatory authorities and receiving HRA and REC approvals, as well as approval from the R&D Office at Manchester University NHS Foundation Trust.

7.3 Amendments

7.3.1 Studies Involving the NHS

Any amendments to the study shall be reviewed by the Sponsorship Team prior to submission. Any non-substantial amendments shall be notified to the HRA. Any substantial amendments, along with amended documentation, shall be approved by the REC and HRA prior to implementation as per nationally agreed guidelines. The Chief Investigator or designee will work with the R&I department to put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

7.4 Peer Review

The ECHO Intervention Study is being conducted under the request from the Department of Education who determined the need for more evidence of the effectiveness of this intervention. This decision was reviewed and agreed by the Manchester Local Authority and the Head of Service for Speech and Language Therapy at MFT.

An independent peer review was completed by a lecturer in Speech and Language Therapy from the division of Psychology, Communication and Human Neuroscience at the University of Manchester.

7.5 Patient & Public Involvement

The ECHO Intervention was developed by Sarah Cameron in consultation with families of infants with social communication difficulties. These discussions occurred during regular clinical visits with families, as part of an informal audit of service provision and client needs.

Prior to the development of ECHO, home visits consisted of semi-structured conversations with parents about their concerns and questions regarding their child's communication

development, and clinical observations of the adult and child's interactions designed to identify baseline abilities, set targets, and identify intervention outcomes.

Feedback and direct consultation with parents highlighted a number of concerns which needed to be addressed in a programme aimed at parents.

- An understanding that sensory needs and behavioural difficulties are often interlinked but that support for these concerns was required at the same time.
- A general lack of knowledge about the effects of screen-time on child communication and behaviour and how to manage this.
- An awareness that children need to play but difficulties in managing this during a clinical consultation.
- Varied parental understanding of autism and social communication which needs to be addressed through training.

It also highlighted areas of good practice which could support better child engagement with the process, in particular, singing was thought to be helpful and enjoyable for the children.

The ECHO programme responded to parental concerns and preferences in intervention, by offering parents opportunities to discuss their child with clinicians trained and able to impart information and resources about these key points of concern (e.g., sensory needs and screen-time). In addition, ECHO responds to the varied learner needs of the parents regarding social communication, offers play partners for children during parent focused discussions and incorporates singing activities to engage children in the session.

Parents also contributed to the identification of outcome measures suitable for understanding the potential benefits of this programme to both parents and children. In particular, they highlighted potential benefits to parent and child well-being, parental feelings of efficacy, and child communicative ability. Outcome measures were selected with consideration for how well they would capture these changes.

In a second wave of patient involvement, Sarah Cameron trialled the ECHO Intervention with 12 different families, and participating parents were invited to give further feedback through discussions and an anonymous feedback form. This stage helped refine the intervention further, ensuring it reflected parental concerns. It also generated a consistent model of practice which was recorded in the ECHO Manual. During this process, clinical outcome measures were completed to understand the potential impacts of the intervention, as well as to investigate which outcome measures were suitable to this population.

Clinical experts were included in this process at multiple stages of review. This included discussion and reflection about the observations and parent feedback as interpreted primarily by Sarah Cameron, in order to avoid potential bias. In addition, clinicians trained to deliver the ECHO Intervention were included in consultations and the development of the ECHO Manual.

During the programme development, parents with communication difficulties and neurodivergence were also consulted on their ability to access the programme and understand its content. Sarah Cameron had conversations with two neurodivergent parents of children with possible neurodivergence to understand their experience of the service. These discussions informed resource development and adaptions within the ECHO Intervention and the study, including the option for Qualitative Study participants to receive

interview questions in advance and all ECHO Intervention participants to receive Outcome measure forms in advance, where possible.

Going forward with this project, the parental interviews will offer a systematic means of reviewing the ECHO programme and its future development.

Due to the nature of the funding for this intervention, there is a requirement to evaluate the effectiveness of the intervention.

Research materials were shared with families currently receiving ECHO Intervention for feedback. Parents were given the opportunity to complete questionnaires and feedback about their experience. Their comments were taken into consideration but did not require any change to the research protocol. Parents were also shown the Participant Information Sheets and consent forms and their comments were acted upon.

Dr Alexandra Sturrock, Principal Investigator, is a steering group member for autism@manchester which is a community funded by the National Institute for Health Research, the Wellcome Trust, and the University of Manchester, to support the collaboration between academics, clinicians, practitioners, autistic individuals and their family and carers, as well as to share knowledge and understanding around autism research.

The research team will engage with autism@manchester at key times across the research life cycle to elicit feedback on materials, protocols, findings, and for dissemination purposes. This will comprise one round of email questions relating to material development and one talk to members of the autism@manchester group at a live event to elicit ideas for interpreting findings and developing the programme for future clinical use.

As funding is not available to pay autism@manchester contributors at this time, the research team will provide a lay summary of findings at the end of the project to autism@manchester as a thank you. Should this project go to a next round of funding the research team will build in costs for consultations with autistic communities at this stage.

7.6 Protocol Compliance

- The research team will be vigilant in protocol deviations and will record them on a study specific deviation log which will be regularly assessed by the PPI.
- Deviations that may affect the safety, physical or mental integrity of participants or scientific value of the study will be reported by the research team to the study sponsor via research.sponsor@mft.nhs.uk.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. These should also be reported to the sponsor without delay.
- The Trial Management Group (TMG) meetings will be held with the Chief Investigator and research team every month to discuss the intervention protocol, resolve issues, and share any amendments. Meetings can also be scheduled as needed if an urgent amendment or issue arises.
- Parent/caregivers' use of recommendations will be measured using the Parent-Child Interaction Pre/Post Measure. Audit visits will be completed by qualified Speech and

Language Therapists to ensure treatment is being delivered in adherence to the ECHO Intervention Manual and that the study protocol is being followed.

7.7 Data Protection and Participant Confidentiality

7.7.1 Data Management

Data protection and confidentiality procedures will be specified and followed, in keeping with Good Clinical Practice and the General Data Protection Regulation 2018. All audio recordings will be made only after written consent has been obtained from parents/caregivers. All audio recordings will be held on password protected NHS secure servers in folders with access restricted to the study team. Physical copies of assessments will be held in a locked cabinet and on encrypted hard drives, in accordance with pre-specified highly secure procedures on NHS premises. All data will be kept confidential, accessed only by the study team. Personal information may be shared only with parent/caregiver consent, for example with clinicians involved with the family. The only time that personal information will be shared without parent/caregiver consent is if there are serious concerns about the safety or wellbeing of a child or vulnerable adult. In this event, local procedures for safeguarding children and vulnerable adults will be followed. Paper-based data collection forms from validated tools and used in standard care will be used as source data. Collection of specific personal information may be recorded in certain validated questionnaire and assessment forms that the ECHO study team do not have permission to alter. This information includes child's name, birthdate, NHS number, age, gender, ethnicity, birth history (prematurity) and parent's name and relationship to child. This information will be collected and entered into the database by the same clinician and the clinician already has access to this information as part of standard clinical duties. Names will not be entered into the research database. Personal and sensitive data will be stored separately and securely on a password-protected section of the NHS servers and/or hard drive in a secure office located at NHS facilities. If personal information needs to be emailed, this will be in an encrypted form.

The data will be stored on NHS premises. Paper copies will be stored centrally in secured cabinets in the Early Years Communication and Language Team office. Electronic data will be stored on NHS servers. The custodian will be Sarah Cameron, Chief Investigator of the study.

At the end of the study, the data will be stored for a period of 5 years before being destroyed.

Qualitative Study

Only audio recording will be collected from Zoom. Audio recordings will be saved to MFT servers in a study specific area only accessible to study members with delegated responsibilities related to audio recordings which are password protected to NHS standards. Audio recordings will be labelled using the following format: ECHO Interview Date of interview (DD.MM.YY) Participant number (for example ECHO Interview 05.09.23 P01). Only study staff and authorised personnel will have access to the study folder.

Zoom will be used to create a transcript of audio recordings. Transcripts will be saved to MFT servers in the same folder as audio recordings. Transcripts will be labelled using the same format as audio recordings.

The study staff will ensure that the participants' anonymity is maintained. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so. Audio files and transcripts will be reviewed as soon as possible to correct transcription errors and remove identifiable information in the transcript. Reviews will be completed by the interviewer and checked by another member of the research team. Once the review is complete and the transcript is pseudonymised, audio files will be stored as source data in secured folders with access restricted to study research members on MFT servers. Only pseudonymised transcript data will be shared for analysis.

ECHO Intervention Study

All study data will be pseudonymised with a study identification (ID). A central master file of personal data will be held securely in the Early Years Communication and Language Team office to be used for operational purposes, and this will contain the key linking anonymised participant IDs to personal details. Study data will be entered into the research database by the research staff member who collected the data, with data checking procedures detailed in the study database guidance documents adhered to by delegated members of the research team. Appropriate quality control will be carried out during the study and before the database lock at the end of the study.

7.8 Indemnity

The NHS indemnity scheme will apply to this study to ensure it meets the potential legal liability of the sponsor, equipment, employer, and investigators/collaborators for harm to participants arising from the management, design and conduct of the research. No arrangements will be made for the payment of compensation in the unlikely event of harm.

7.9 Monitoring

The study will be subject to the audit and monitoring regime of Manchester University NHS Foundation Trust in line with applicable MFT SOPs and policies. The study will have, as a minimum, an annual survey sent out for completion by a member of the research team.

7.10 Access to the Final Study Data Set

The study final data set will be stored using study codes on a single data Excel spreadsheet at MFT. A record of patients' names and their unique subject identifier will be stored for the study on a database on MFT password protected computers behind the MFT firewall to allow for the study investigators, if needed, to query original records.

The final pseudonymised data will be shared with the study Statistician and Principal Investigators for analysis. The study Statistician and University of Manchester investigators will not have access to patient identification records or any identifiable patient data.

A copy of the pseudonymised analysis dataset will be held in password protected files on University of Manchester servers accessible on password protected computers for the purpose of analysis.

8. Safety Reporting

This study will follow MFT policy RI SOP 08C Safety Reporting for Non-CTIMPs (studies other than CTIMPs and MHRA-Regulated Device Trials).

Reports of Serious Adverse Events (SAEs) that are:

- related to the study (i.e., they resulted from administration of any of the research procedures) and
- unexpected (i.e., not listed in the protocol as an expected occurrence)

will be emailed to the REC using the Non-CTIMP safety report to REC form. Such reports will be sent within 15 days of the Chief Investigator becoming aware of the event.

For all participants we will collect information about adverse events at each visit and record adverse events in a standard format. We will capture adverse events that pertain to both the parent/caregiver participating in the study and their child. In addition to recording medical advers events in the standard way, we will also include events particularly relevant to the ECHO Intervention, such as those relating to wellbeing, mental health, and difficult family circumstances. Some of these circumstances may preclude the parent/caregiver's continued participation in the study.

Information about the adverse event will be collected, including but not exclusive to: categorisation, description of event, length of time, start/stop date, ongoing status, relationship to intervention, and whether it is deemed a Serious Adverse Event.

Adverse events will be collected and monitored by the research team routinely. SAEs will be reported to the project management group and sponsor. If any of the SAEs are a suspected or unexpected reaction to the intervention (it is acknowledged that this is highly unlikely in this study), these will be reported immediately to the sponsor and Research Ethics Committee.

9. Dissemination

9.1 Dissemination Policy

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.

9.2 Authorship Eligibility Guidelines and Any Intended Use of Professional Writers

Authorship will be granted to the Chief Investigator, Principal Investigators, and Statisticians by individual name as well as group authorship by the Early Years Communication and Language Team.

10. Archiving

The study data will remain the property of MFT. At the end of the study all documents and data relating to this project will be stored offsite for 5 years following completion of the project, in line with MFT policies and in accordance with ICH GCP.

11. References

Ainscow, M. et al. (2012). Making schools effective for all: rethinking the task. In *School leadership & management 32.3* (pp. 197-213).

Akhtar, N., Dunham, F., & Dunham, P. (1991). Directive interactions and early vocabulary development: The role of joint attentional focus. *Journal of Child Language, 18*(1), 41-49. doi:10.1017/S0305000900013283

Anderson, D. K., Lord, C., Risi, S., DiLavore, P. S., Shulman, C., Thurm, A., ... & Pickles, A. (2007). Patterns of growth in verbal abilities among children with autism spectrum disorder. *Journal of consulting and clinical psychology, 75*(4), 594.

Autistica. (2016). *Your Top Questions: Shaping the Future of Autism Research with Community Priorities.* Retrieved 2023, from Autistica: https://www.autistica.org.uk/downloads/files/Autism-Top-10-Your-Priorities-for-Autism-Research.pdf

Barbaro, J., Sadka, N., Gilbert, M., Beattie, E., Li, X., Ridgway, L. Lawson, L. P., & Dissanayake, C. (2022). Diagnostic Accuracy of the Social Attention and Communication Surveillance-Revised With Preschool Tool for Early Autism Detection in Very Young Children. *JAMA network open, 5*(3). doi:e2146415

Blacher, J., Baker, B. L., & Kaladjian, A. (2013). Syndrome specificity and mother–child interactions: Examining positive and negative parenting across contexts and time. *Journal of autism and developmental disorders, 43*, 761-774.

Bloomfield, L., Kendall, S. and Fortuna, S. (2010). Supporting parents: development of a tool to measure self-efficacy of parents with learning disabilities. *British Journal of Learning Disabilities, 38*, 303-309. doi:https://doi.org/10.1111/j.1468-3156.2009.00607.x

Braun, V. & Clarke, V. (2020). Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. *Counselling and Psychotherapy Research, 21*(1), 37-47.

Braun, V. &. (2019). Reflecting on reflexive thematic analysis. *Qualitative research in sport, exercise and health, 11*(4), 589-597.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology, 3*(2), 77-101.

Charman, T. B.-C. (2003). Predicting language outcome in infants with autism and pervasive developmental disorder. *International Journal of Language & Communication Disorders, 38*(3), 265-285. doi:10.1080/136820310000104830

Clinical data. (n.d.).

Da Paz, N. S. (2017). Interventions that target improvements in mental health for parents of children with autism spectrum disorders: A narrative review. *Clinical psychology review, 51*, 1-14.

Dawson, G., Rogers, S., Munson, J., Smith, M., Winter, J., Greenson, J., ... & Varley, J. (2010). Randomized, controlled trial of an intervention for toddlers with autism: the Early Start Denver Model. *Pediatrics, 125*(1), e17-e23.

Dewart, H., & Summers, S. (1995). *Pragmatics profile of everyday communication skills in children*. Retrieved June 15, 2023, from Windsor: NFERNelson: https://communicationmatrix.org/Community/Posts/Content/8154

Doussard–Roosevelt, J. A., Joe, C. M., Bazhenova, O. V., & Porges, S. W. (2003). Mother–child interaction in autistic and nonautistic children: Characteristics of maternal approach behaviors and child social responses. *Development and psychopathology, 15*(2), 277-295.

Estes, A., Swain, D. M., & MacDuffie, K. E. (2019). The effects of early autism intervention on parents and family adaptive functioning. *Pediatric Medicine (Hong Kong, China), 2*.

French, L., & Kennedy, E. M. (2018). Annual Research Review: Early intervention for infants and young children with, or at-risk of, autism spectrum disorder: a systematic review. *Journal of Child Psychology and psychiatry, 59*(4), 444-456.

Gillespie-Lynch, K., Sepeta, L., Wang, Y., Marshall, S., Gomez, L., Sigman, M., & Hutman, T. (2012). Early childhood predictors of the social competence of adults with autism. *Journal of autism and developmental disorders, 42*, 161-174.

GL Assessments. (2015).

GOV.UK. (n.d.). *Early Years foundation stage profile results, academic year 2021/22.* Retrieved June 12, 2023, from https://explore-education-statistics.service.gov.uk/find-statistics/early-years-foundation-stage-profile-results/2021-22

Green, J., Aldred, C., Charman, T., Le Couteur, A., Emsley, R. A., Grahame, V., ... & Taylor, C. (2018). Paediatric Autism Communication Therapy-Generalised (PACT-G) against treatment as usual for reducing symptom severity in young children with autism spectrum disorder: study protocol for a randomised controlled trial. *Trials*, 1-13.

Green, J., Charman, T., McConachie, H., Aldred, C., Slonims, V., Howlin, P., ... & Pickles, A. (2010). Parent-mediated communication-focused treatment in children with autism (PACT): a randomised controlled trial. *The Lancet, 375*(9732), 2152-2160.

Hennink, M. & Kaiser, B. (2022). Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Social Science & Medicine, 292*, 114523. doi:https://doi.org/10.1016/j.socscimed.2021.114523.

Howlin, P., Savage, S., Moss, P., Tempier, A., & Rutter, M. (2014). Cognitive and language skills in adults with autism: a 40-year follow-up. *Journal of Child Psychology and Psychiatry, 55*(1), 49-58.

Jager, J., Putnick, D. L., & Bornstein, M. H. (2017). II. More than just convenient: The scientific merits of homogeneous convenience samples. *Monographs of the Society for Research in Child Development, 82*(2), 13-30.

Kasari, C., Gulsrud, A., Paparella, T., Hellemann, G., & Berry, K. (2015). Randomized comparative efficacy study of parent-mediated interventions for toddlers with autism. *Journal of consulting and clinical psychology, 83*(3), 554.

Kolb, B., & Gibb, R. (2011). Brain plasticity and behaviour in the developing brain. *Journal of the Canadian Academy of Child and Adolescent Psychiatry, 20*(4), 265.

Ladarola, S., Levato, L., Harrison, B., Smith, T., Lecavalier, L., Johnson, C., ... & Scahill, L. (2018). Teaching parents behavioral strategies for autism spectrum disorder (ASD): Effects on stress, strain, and competence. *Journal of Autism and Developmental Disorders, 48*, 1031-1040.

Landry, S. H., Smith, K. E., Swank, P. R., & Miller-Loncar, C. L. (2000). Early maternal and child influences on children's later independent cognitive and social functioning. *Child development, 71*(2), 358-375.

Leadbitter, K., Aldred, C., McConachie, H., Le Couteur, A., Kapadia, D., Charman, T., ... & Green, J. (2018). The Autism Family Experience Questionnaire (AFEQ): An ecologically-valid, parent-nominated measure of family experience, quality of life and prioritised outcomes of early intervention. *Journal of Autism and Developmental Disorders, 48*, 1052-1062.

Leadbitter, K., Macdonald, W., Taylor, C., Buckle, K. L., & PACT Consortium*. (2020). Parent perceptions of participation in a parent-mediated communication-focussed intervention with their young child with autism spectrum disorder. *Autism, 24*(8), 2129-2141.

Lee, L. & Ashworth J. (2020). *Impact Report for the Early Years Communication and Language Pathway for year 1/4/2029 to 31/3/3020.* Manchester.

Levitt, H. M. (2019). Reporting qualitative research in psychology: How to meet APA style journal article reporting standards. *American Psychological Association*. doi:10.1037/0000121-000

Magiati, I., Tay, X. W., & Howlin, P. (2014). Cognitive, language, social and behavioural outcomes in adults with autism spectrum disorders: A systematic review of longitudinal follow-up studies in adulthood. *Clinical psychology review*, 73-86.

Manchester City Council. (2024, February 28). *Census 2021 - Overview*. Retrieved from Manchester City Council: https://www.manchester.gov.uk/info/500388/census_2021/8622/census_2021_-_overview

Manchester City Council. (n.d.). *Manchester City Council Report for Information*. Retrieved June 12, 2023, from https://democracy.manchester.gov.uk/documents/s9767/Manchesters%20Language%20Diversity.pdf

Manchester City Council. (n.d.). *The Council and Democracy Deprivation, Deprivation: data and intelligence*. Retrieved June 12, 2023, from https://www.manchester.gov.uk/info/200088/statistics_and_intelligence/2168/deprivation#:~:text=Key%20deprivation%20statistics%3A&text=Each%20small%20area%20in%20England,1%20is%20the%20most%20deprived

Manchester Parent Carer Forum. (n.d.). *Social Communication Pathway faqs*. Retrieved June 12, 2023, from http://manchesterparentcarerforum.org.uk/social-communication-pathway-faqs/

McEachin, J. J., Smith, T., & Lovaas, O. I. (1993). Long-term outcome for children with autism who received early intensive behavioral treatment. *American journal of mental retardation: AJMR, 97*(4), 359-72.

Mundy, P., Sigman, M., & Kasari, C. (1990). A longitudinal study of joint attention and language development in autistic children. *Journal of Autism and developmental Disorders, 20*(1), 115-128.

Neely, J. C. (2015). Building voices: Teens connect to their communities through youth journalism websites. *International Journal of Communication, 9*, 20.

NICE. (2013). *Recommendations | Autism spectrum disorder in under 19s: support and management | Guidance | NICE.* Retrieved from www.nice.org.uk: https://www.nice.org.uk/guidance/cg170/chapter/Recommendations

Page, M., Wilhelm, M. S., Gamble, W. C., & Card, N. A. (2010). A comparison of maternal sensitivity and verbal stimulation as unique predictors of infant social–emotional and cognitive development. *Infant Behavior and Development, 33*(1), 101-110.

Parent. (n.d.). *1001 days - parent-infant foundation.* Retrieved June 12, 2023, from https://parentinfantfoundation.org.uk/1001-days/

Pickles, A., Le Couteur, A., Leadbitter, K., Salomone, E., Cole-Fletcher, R., Tobin, H., ... & Green, J. (2016). Parent-mediated social communication therapy for young children with autism (PACT): long-term follow-up of a randomised controlled trial. *The Lancet, 388*(10059), 2501-2509.

Rose, V., Trembath, D., Keen, D., & Paynter, J. (2016). The proportion of minimally verbal children with autism spectrum disorder in a community-based early intervention programme. *Journal of Intellectual Disability Research, 60*(5), 464-477.

Sameroff, A. (1975). Transactional models in early social relations. *Human development, 18*(1-2), 65-79.

Sameroff, A. (2009). The transactional model. *American Psychological Association.*

Sandbank, M., Bottema-Beutel, K., Crowley, S., Cassidy, M., Dunham, K., Feldman, J. I., ... & Woynaroski, T. G. (2020). Project AIM: Autism intervention meta-analysis for studies of young children. *Psychological bulletin, 146*(1), 1.

Schreibman L, Dawson G, Stahmer AC, Landa R, Rogers SJ, McGee GG, Kasari C, Ingersoll B, Kaiser AP, Bruinsma Y, McNerney E, Wetherby A, Halladay A. (2015). Naturalistic Developmental Behavioral Interventions: Empirically Validated Treatments for Autism Spectrum Disorder. *J Autism Dev Disord, 45*(8), 2411-28. doi:10.1007/s10803-015-2407-8

Shire, S. Y., Chang, Y. C., Shih, W., Bracaglia, S., Kodjoe, M., & Kasari, C. (2017). Hybrid implementation model of community-partnered early intervention for toddlers with autism: A randomized trial. *Journal of Child Psychology and Psychiatry, 58*(5), 612-622.

Tager-Flusberg, H., & Kasari, C. (2013). Minimally verbal school-aged children with autism spectrum disorder: The neglected end of the spectrum. *Autism research, 6*(6), 468-478.

Thompson, J. L., Sebire, S. J., Kesten, J. M., Zahra, J., Edwards, M., Solomon-Moore, E., & Jago, R. (2017). How parents perceive screen viewing in their 5–6 year old child within the context of their own screen viewing time: a mixed-methods study. *BMC public health, 17*(1), 1-9.

Tomasello, M., & Todd, J. (1983). Joint attention and lexical acquisition style. *First language, 4*(12), 197-211.

Wetherby, A. & Prizant, B. (2002). *CSBS DP manual : communication and symbolic behavior scales : developmental profile*. Brookes Publisher.

Whitehouse, A. J., Varcin, K. J., Alvares, G. A., Barbaro, J., Bent, C., Boutrus, M., ... & Hudry, K. (2019). Pre-emptive intervention versus treatment as usual for infants showing early behavioural risk signs of autism spectrum disorder: a single-blind, randomised controlled trial. *The Lancet Child & Adolescent Health, 3*(9), 605-615.

Whitehouse, A. J., Varcin, K. J., Pillar, S., Billingham, W., Alvares, G. A., Barbaro, J., ... & Hudry, K. (2021). Effect of preemptive intervention on developmental outcomes among infants showing early signs of autism: A randomized clinical trial of outcomes to diagnosis. *JAMA Pediatrics, 175*(11), e213298-e213298.