HRA PROTOCOL COMPLIANCE DECLARATION

This protocol has regard for the HRA guidance and order of content

TITLE PAGE

FULL TITLE OF THE STUDY

The SEEM Study: Safe Efficient and Enjoyable Mealtimes: Creating a toolkit for families of children who need assistance with eating and drinking – an observational study

SHORT STUDY TITLE / ACRONYM

Mealtime Observation & Reflection Study: SEEM

PROTOCOL VERSION NUMBER AND DATE

Version 4 11/03/2024

RESEARCH REFERENCE NUMBERS

IRAS Number: 325687

SPONSORS Number: ETH2324-1785 (extension to approved project ETH223-2185)

FUNDERS Number: MGU0540

REC Number: 23/EM/0208

SIGNATURE PAGE

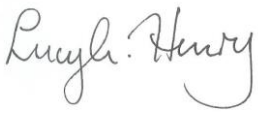
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 publically 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.

For and on behalf of the Study Sponsor:

Signature:



Date:

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Name (please print):

Lucy Henry.....

Position: Professor/Research Centre Lead for the Centre for Language & Communication Science Research, City, University of London

Chief Investigator:

Signature:

Date: .

21/04/24

.....

Name: (please print):

Sally Morgan.....

IRAS no. 325687 REC study no.

Barts Charity no. MGU0540

City, University of London no. ETH2324-1067

Mealtime Observation & Reflection Study: SEEM
Version: 4

Contents

KEY STUDY CONTACTS

Chief Investigator & Principal Investigator (Experienced PhD student researcher fulfilling both roles)	Sally Morgan Senior Lecturer in Speech & Language Therapy/ Clinical Doctoral Fellow, City, University of London, Department of Language & Communication Science, Northampton Square, London EC1V 0HB 020 7040 0194 Clinical Doctoral Research Fellow role: sally.morgan.2@city.ac.uk Senior Lecturer role: sally.morgan@city.ac.uk
Study Supervisors	**Primary:** Professor Katerina Hilari (Primary Supervisor) City, University of London, Department of Language & Communication Science, Northampton Square, London EC1V 0HB k.hilari@city.ac.uk 020 7040 4660 **Secondary:** Dr Kathleen Mulligan (Second Supervisor) City, University of London, Department of Health Services Research Management, Northampton Square, London EC1V 0HB kathleen.mulligan.1@city.ac.uk 020 7040 0889

	Clinical: Dr Kelly Weir (Clinical Supervisor) Honorary Senior Research Fellow, Department of Language & Communication Science, City, University of London/ Associate Professor, Melbourne School of Health Sciences, University of Melbourne Director of Allied Health Research, The Royal Children's Hospital The University of Melbourne Grattan Street, Parkville, Victoria, 3010, Australia kelly.weir@rch.org.au kelly.weir@unimelb.edu.au +61 481 467 739
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Sponsor's primary contact	Alison Welton Secretary to School of Health & Psychological Sciences Research Ethics Committee, City, University of London, Deanery, School of Health & Psychological Sciences, Northampton Square, London EC1V 0HB 020 7040 5704 a.welton@city.ac.uk

Funder	Barts Charity, Ground Floor, 12 Cock Lane, London EC1A 9BU 0207 7618 1717 hello@bartscharity.org.uk
PPI Group	Run by the Principal Investigator throughout the PhD project. A group of 3 diverse mothers of children and young adults who have neurodisability and eating, drinking and swallowing difficulties (dysphagia).
SLT Stakeholder Group	Run by the Principal Investigator for the whole PhD project. A group of 12 Speech & Language Therapists who all work clinically within this area of specialism, children with neurodisability who have dysphagia and need mealtime assistance.
Clinical Advisor	Sonja Jacobs (Clinical Lead for Barts Childrens Community Therapies Team). This expert SLT and pre-doctoral researcher gave feedback on the protocol's development.
Methodological Advisor	Professor Melanie Nind (University of Southampton/National Centre for Research Methods) provided advice and guidance regarding a particular methodology used within the study: Video stimulated recall, reflection and dialogue (VSRRD)(1)

STUDY SUMMARY

Study Title	The SEEM Study: Safe Efficient and Enjoyable Mealtimes: Creating a toolkit for families of children who need assistance with eating and drinking – an observational study
Internal ref. no. (or short title)	Mealtime Observation & Reflection Study: SEEM (ETH2223-2185)
Study Design	This is a cross-sectional observational study using mixed methods. Qualitative methods: Video observation Video stimulated recall, reflection and dialogue Quantitative methods Demographic data Swallow-sound recording
Study Participants	Family-carers of school-aged children (5;0-15;11 years) who need physical mealtime assistance due to neurodisability and eating, drinking and swallowing difficulties (oropharyngeal dysphagia)
Planned Size of Sample (if applicable)	N=20 Family-carer and child dyads (10 dyads)
Planned Study Period	September – December 2023
Research Question/Aim(s)	To explore the family-carers' and children's experiences of, and decision making, during mealtime assistance, including barriers and facilitators to following mealtime recommendations

	To explore whether family-carers who provide mealtime assistance to school-aged children with neurodevelopmental dysphagia can identify signs of oral and pharyngeal dysphagia and how they respond.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Barts Charity, Ground Floor, 12 Cock Lane, London EC1A 9BU 0207 7618 hello@bartscharity.org.uk	Nurse/Allied Health Professional (N/AHP) 0.6te for 5 years Clinical Doctoral fellowship £292,344.65
City, University of London Northampton Square, London EC1V 0HB	PhD project financial management support. Some top up funding for PhD fees and training costs.

ROLE OF STUDY SPONSOR AND FUNDER

Sponsor

City, University of London will sponsor this study as the PhD project is being undertaken through the University, and specifically through Sally Morgan under the supervision of Professor Katerina Hilari, Department of Language & Communication Science, City, University of London.

Funder

The Barts Charity Nursing/Allied Health Professional (N/AHP) Clinical Doctoral Fellowship panel requested 3 anonymous peer reviews and themselves peer reviewed and awarded complete funding for this project (MGU0540). There is ongoing accountability to Barts Charity surrounding the progression of this study and the overall project through annual and completion reporting. However, Barts Charity will not have direct input into the project's design, conduct and analysis. For the purposes of dissemination Barts Charity will be acknowledged as the project's funder.

Funding and supply of equipment

The study budget has been reviewed by the SHPS research office and approved by the University's finance office and deemed sufficient to cover the requirements of this study.

Equipment costs for the study are covered in the grant including; video camera, neck mic, noise-cancelling headphones, audio-recorder, infection-control wipes, laptop, University mobile number and stationary. Funding will also cover salary costs of the PhD student, PhD fees, other courses and conferences or dissemination and costs for transcription including a small amount of translation of videos if required.

No funding arrangements are being provided to local collaborating sites. The Organisation Information Document will be used as a contract agreement for each site.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

PhD Supervisory Group:

This study is a part of a multi-method project being completed in partial fulfilment of a PhD within the Department of Language & Communication Science, City University of London. There are 3 supervisors:

Primary Supervisor: Professor Katerina Hilari

Second Supervisor; Dr Kathleen Mulligan

Clinical Supervisor: Dr Kelly Weir

All three supervisors have contracts with City, University of London; Kelly Weir an honorary one. The supervisory group provide a level of accountability to ensure the project's targets are met, to ensure completion as well as providing oversight upon the conduct of the study.

Speech & Language Therapy Stakeholder Group:

A group of Speech & Language Therapist (SLTs) (n=12) have been consulted throughout the PhD project and in relation to this study (n=9), convened by the PI. They are all independent from the funder, Sponsor and investigators and all work clinically within this area of specialism, children with neurodisability who have dysphagia and need mealtime assistance. They are diverse when compared to the general SLT profession and are from across the country working in different settings e.g., acute, community and with different employers e.g., NHS, independent. The group has guided and given feedback on aspects of the whole project (previous survey of SLT practice) and this study, specifically:

- Eligibility criteria (ability for SLTs to screen caseload)
- Approach to recruitment
- Data collection methods: Video and swallow sound recordings and video stimulated recall reflection and dialogue (VSRRD)
- Training materials for local SLTs at Participant Identification Centre sites
- Family-carer and child Information Sheet/Video presentation
- Family-carer demographics form
- Child participant demographics form

They will continue to be involved during the project contributing to:

- Interpretation of findings (sense checking)

And will be acknowledged in dissemination and outputs.

Patient & Public Involvement (PPI) Group – Parent Expert Group (PEG):

This group is independent from the Sponsor and investigators, though convened by the PI with members receiving payment for costs and if they accept it a fee for their time and expertise paid from the PI funded budget. Prior to funding the whole project, including this study, was guided through PPI with 2 mothers and one young person with Cerebral Palsy, all with experience of eating, drinking and swallowing difficulties (dysphagia). Since the start of the PhD project one group member has remained

with two members added. This study has been developed in consultation with the Parent Expert Group (PEG) consisting of some diverse mothers (n=3) of children and young adults who have neurodisability and dysphagia. They have experience of receiving Speech & Language Therapy services, including mealtime guidelines and many other services in a variety of settings.

This group has guided and given feedback on aspects of the project and this study, specifically:

- Approach to recruitment
- Consent
- Data collection methods: Video and swallow sound recordings via neck mic, VSRRD
- Participant information and consent form development

They will continue to be involved during the project contributing to:

- Interpretation of findings (sense checking)
- Dissemination and outputs

Methodological and Clinical Advisors:

In addition to the clinical supervisor and feedback from the SLT Stakeholder group, discussions have taken place with one SLT advisor who has expertise in working clinically with this population and in SLT research; Sonja Jacobs (Clinical Lead for Barts Childrens Community Therapies Team). She provided initial feedback on the protocol. Finally, advice and liaison has been sought from Professor Melanie Nind (University of Southampton/National Centre for Research Methods) regarding a particular methodology used within the study: Video stimulated recall, reflection and dialogue(1). Both advisors are independent from the funder. Sonja Jacobs is a guest lecturer for the sponsor.

Protocol Contributors:

The protocol has had contribution within its development from several sources. The original proposal received 3 anonymous peer reviews and review by the Barts Charity panel and was awarded full funding. There is ongoing annual and completion accountability to Barts Charity but they do not have a direct input into the project's design, conduct and analysis.

The original proposal has had guidance from 3 PPI members, two parents and one young person. In addition the NIHR North East Thames Research Design Service provided feedback from a specialist in ethics and their lay review panel. The proposal was co-developed by the PI PhD student and the project supervisors; Professor Katerina Hilari (Primary Supervisor – City, University of London), Dr Kathleen Mulligan (secondary supervisor – City, University of London), Dr Kelly Weir (clinical supervisor – University of Melbourne) and has had input from two clinical advsors; Honorary Professor Celia Harding (City, University of London) and Sonja Jacobs (Barts Health NHS Trust).

Since the successful Barts Charity N/AHP Clinical Doctoral Fellowship award this protocol has been developed to provide more detail. This has been through consultation with the clinical advisor (Sonja Joacobs, Barts Health), one methodological advisor (Melanie Nind, University of Southampton/National Centre for Research Methods), the SLT stakeholder group and Parents Expert Group. The specifics have been oulined above (roles and responsibilities of the PPI group, SLT Stakeholder group and advisors).

The study has had and will have regular input from the supervisory team, which will similarly guide decision making about conduct, design, analysis and dissemination.

KEY WORDS:

Dysphagia, Mealtime assistance, Parent Child Interaction, Swallowing Disorders, Neurodisability, Paediatric Feeding Disorder

STUDY FLOW CHART

Study flow for each (potential) participant (Identification, recruitment, consent & participation):

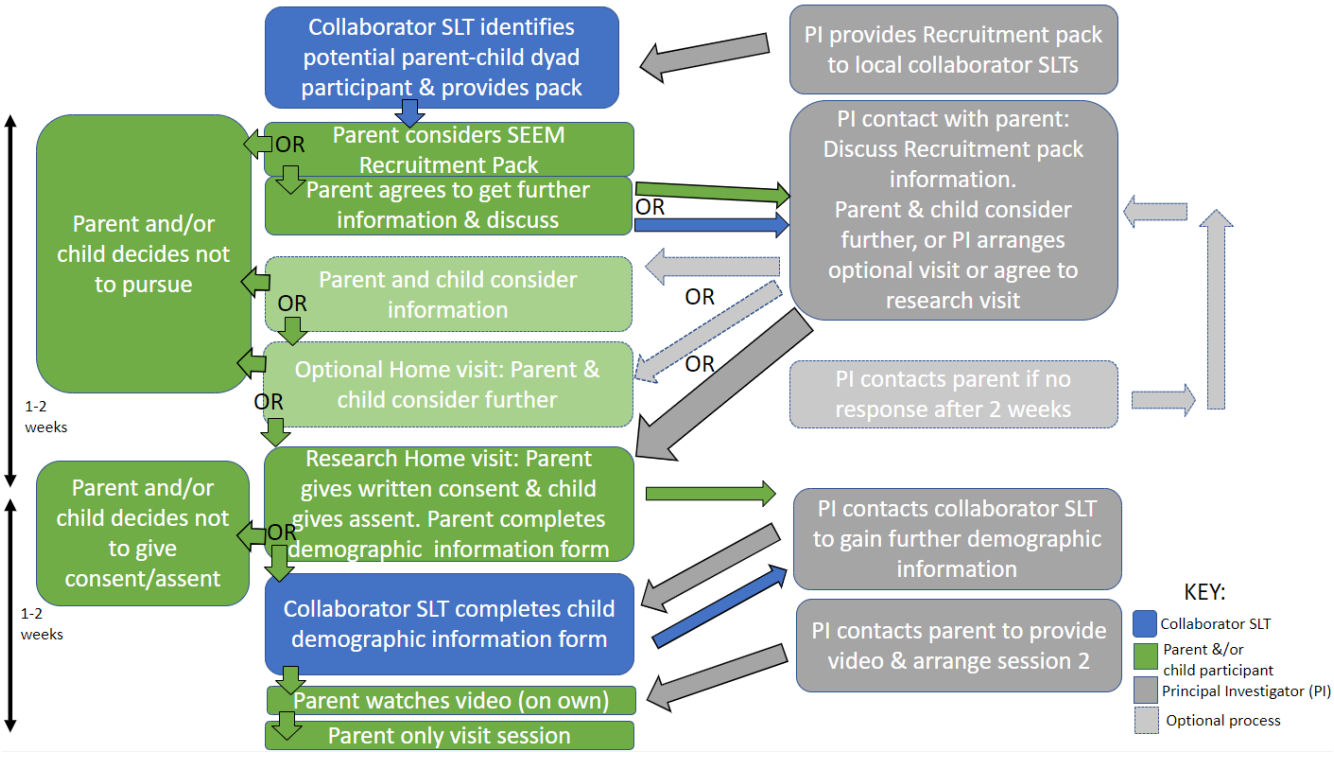

FIGURE 1: WHOLE STUDY FLOW DIAGRAM

GANNT chart of project 2023-24	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug
Background: **Study Set Up**													
Ethics & HRA													
R&D approvals													
Site training													
Study													
Participant identification													
Recruitment													
Session 1 data collection													
Session 2 data collection													
End of study: Session 2 with family-carer participant (10).													
Analysis													
Write up & dissemination													
Write up													
Prepare peer-reviewed journal submission													
Write & provide lay summary													

The study will close in end of June 2024 with the final session 2 with the final family-carer participant (10). This study's analysis will be completed by August 2024. The findings will be used for the final part of the PhD project, co-creation of a strategy toolkit. This may mean some additional exploration of the data with write up of the full PhD due for submission September 2025.

IRAS no. 325687 REC study no.

Barts Charity no. MGU0540

City, University of London no. ETH2324-1067

Mealtime Observation & Reflection Study: SEEM
Version: 4

STUDY PROTOCOL

The SEEM Study: Safe Efficient and Enjoyable Mealtimes: Creating a toolkit for families of children who need assistance with eating and drinking – an observational study

1 BACKGROUND

SUMMARY

Children with neurodevelopmental disabilities frequently have eating and drinking difficulties (neurodevelopmental dysphagia)(2), and are at an increased risk of premature death from choking and respiratory disease(3, 4). Recent guidance has recommended these children require an eating and drinking plan(5) and a focus on nutrition and enjoyment of meals in addition to safety(5, 6). Improving mealtime safety, efficiency and enjoyment is essential to reduce risks and improve nutrition. The Speech & Language Therapist (SLT) is the key health professional who assesses and then provides mealtime recommendations to carers(5). This research project aims to develop an intervention to enhance SLTs' support for family-carers to enhance mealtime safety, efficiency and enjoyment. The intervention will take the form of a best practice toolkit.

RELATED LITERATURE

People, including children, with neurodevelopmental disabilities (Cerebral Palsy, profound and multiple Learning disabilities) die prematurely(3). Recent investigations have identified a high risk of choking and respiratory disease (4.9 times higher). There is a need to target eating and drinking difficulties (dysphagia) in rehabilitation(2, 4). Improved dysphagia management may reduce avoidable hospital admissions(7) and other serious consequences, such as malnutrition and reduced quality of life. Neurodevelopmental dysphagia is under-identified by carers(8, 9) with carer interventions considered a key priority(9), particularly family-carers (84% of a school-aged child's annual meals are at home).

Providing mealtime assistance is a complex task as frequently a child with neurodevelopmental dysphagia will have co-occurring cognitive and/or speech impairments as part of their neurodevelopmental disability. Therefore, the family-carer cannot rely on the child to self-report difficulties. Instead, they need to observe for subtle visual signs e.g., reduced chewing (oral dysphagia) and/or auditory signs e.g., cough, wet breathing sounds (pharyngeal dysphagia). They then need to make appropriate behaviour changes e.g., slow down pace of eating and drinking, food texture modification, often with specific changes targeted to specific signs. This needs to occur to support safety while also maximising mealtime efficiency and enjoyment(5).

Speech & Language Therapists (SLTs) are the key professional providing mealtime recommendations to carers of people with dysphagia. There are some consensus guidelines of potential good practice for adults with learning disability(10) and some broad guidance for children with Cerebral Palsy(5) e.g., behaviour areas to target (texture modification, positioning), but not how to target them. Many children with neurodevelopmental disabilities do not fit within these guideline groups. There is some research into clinical practice for pre-school children(11), and a small number of studies in adults(12, 13), but only one small school-aged study has been identified, which explored only one technique, mealtime mat use, and found inconsistent SLT practice(14). This is a serious gap in the research base considering this age group's specific needs e.g., change in service delivery to school-based from home-visiting pre-school services, increased risk with increasing age(5).

What is the family-carers' and children's experiences of, and decision making, during mealtime assistance, including barriers and facilitators to following mealtime recommendations?
We need to explore the family-carers' and children's experiences of mealtime assistance, including decision making, as well as the barriers and facilitators to following SLT mealtime recommendations. If family-carers do not follow the SLT recommendations there is a risk to the safety, efficiency and enjoyment of the meal with impacts on the child's health and child and family-carer wellbeing(15).

A few studies have indicated that carers inconsistently follow SLT mealtime recommendations in adults(13) and pre-school children(16), with no studies in school-aged children. Carers often do not follow mealtime recommendations, with different carers following different recommendations e.g., positioning, texture, and no clear pattern or trend identified(13, 16). These researchers have suggested techniques to increase carers' likelihood to follow recommendations, focusing on information and skills training e.g., demonstration of how to modify textures (12, 17) rather than other aspects e.g., beliefs about consequences of not following recommendations, limited physical resources.

To support family-carers to follow recommendations we need to know more about mealtimes in general e.g., the conflicting feelings family-carers express that mealtime assistance is both a struggle and a time for social bonding(18) or that healthcare professionals rate the safety of mealtimes higher than quality of life, compared to family-carers(19, 20). A small research base indicates that family-carer to child communication differs (more directive) when the child has, or had, feeding difficulties(15, 21). It is not clear whether this directive approach is beneficial or reduces interaction quality and mealtime enjoyment. There is limited research that has explored the complex tacit decision-making that family-carers complete during each mealtime.

Do family-carers who provide mealtime assistance to school-aged children with neurodevelopmental dysphagia identify signs of oral and pharyngeal dysphagia and how do they respond.
It is unclear whether family-carers who provide mealtime assistance can identify signs of oral and pharyngeal dysphagia, and how they respond. Research suggests that family-carers either do not identify signs of dysphagia, or deny/underestimate them(19, 22). In a recent study of young children with Cerebral Palsy(23) SLTs identified visual signs of dysphagia (e.g., eye tearing) in 68% of the cases through video observation, yet family-carers only reported signs in 46% of children, with 60% agreement with SLTs ($k=0.2$, $p<.01$)(23). This has highlighted the need to ensure that family-carers

can identify the signs of dysphagia more consistently, as non-identification is a considerable barrier to following mealtime recommendations.

THE PLANNED STUDY

This planned study is a mixed-methods cross-sectional observational study of a family-carer and child mealtime. The target population is children (aged 5 to 15 years) who require physical mealtime assistance due to their neurodisability and oropharyngeal dysphagia. Every family-carer and child dyad will have two direct sessions with the Principal Investigator: one observation of a typical mealtime with both the family-carer and child (Session 1), followed by a session with the family-carer only (Session 2). Session 1 will include video recording of the family-carer and child mealtime with two views (Video 1: view of the family-carer to observe general mealtime interactions and behaviour) (Video 2: view of the child's face and neck to observe signs of oropharyngeal dysphagia e.g., cough). In addition, a swallow-sound recording will be taken using a neck microphone (Audio recording 1) and brief conversation with child about their mealtime (Video 3). During session 2 the family-carer will view the video of the mealtime (Video recording 1) and using the methodology of video stimulated recall reflection and dialogue (VSRRD)(1) to discuss the mealtime, their general thoughts, emotions and experiences of mealtime assistance and mealtime guidelines and to reflect on their decision-making. This will be audio-recorded (Audio recording 2).

This study's findings will be used together with findings from two other studies completed as part of the PI's PhD - a systematic review of the literature and a survey of SLT clinical practice - to co-create a toolkit to support discussions between SLTs and families of children who need assistance with eating and drinking.

2 RATIONALE

In summary the current evidence is as follows:

1. Providing mealtime assistance is a complex task with multiple potential behaviours to adapt and change alongside the wider importance of a mealtime within a family unit. Carers of adults and pre-school children with neurodevelopmental dysphagia follow mealtime recommendations inconsistently with potential risks to the safety, efficiency and enjoyment of the meal, but the experience of school-aged children's family-carers is unknown.

2. It is unclear whether family-carers who provide mealtime assistance to school-aged children with neurodevelopmental dysphagia can identify signs of oral and pharyngeal dysphagia, and if so, how they respond.

3. The small number of studies that have explored barriers to following mealtime recommendations in carers of people with neurodevelopmental dysphagia have not used a theoretically based model of behaviour change. They have recommended and targeted a limited number of behaviour change techniques to support carers to follow mealtime recommendations.

This study aims to address these evident needs within the research evidence base. It addresses two of the top twenty priorities for dysphagia research (general and paediatric) identified by the RCSLT & NIHR(24):

> "Do people with dysphagia and/or their families/carers carry out recommendations to improve the safety/effectiveness of swallowing at meal times?"
>
> "Are caregivers aware of how to identify eating/drinking difficulties?"

In addition, our PPI engagement prior to the proposal for research funding and since the award highlighted these two priorities as key, together with the need to support family carers to assist their child at each mealtime. Moreover, discussion with the SLT stakeholder group and research completed so far as part of this PhD project (a survey of current clinical practice) indicated that SLTs are aware of the difficulties in supporting families in this area however had limited strategies to use, and these were not necessarily targeted at the barrier to adherence a family-carer faced.

The consequences of incorrect mealtime assistance can be severe for a child's health (choking, hospital admission), physical wellbeing (faltering growth) and quality of life (fear of mealtimes, not 'eating out'). A toolkit that supports SLTs and family-carers to discuss potential and agree suitable mealtime guidelines that can be adhered to has potential to improve all these outcomes.

3 THEORETICAL FRAMEWORK

According to the Medical Research Council (MRC) complex intervention guidance (Skivington et al., 2019), complexity can be due to various factors including "the range of behaviours targeted; expertise and skills required of those delivering and receiving the intervention; the number of…settings..; or the permitted level of flexibility of the intervention". Using this description, mealtime recommendation

provision to carers of children with neurodevelopmental dysphagia can be described as a complex intervention. The MRC provided guidance in 2006(25) on the stages to develop and evaluate a complex intervention. Recently the guidance has been updated(26) with four main stages of intervention development outlined: development or identification of an intervention, feasibility, evaluation and implementation. This project falls within the first stage, development of a complex intervention, due to the limited research base and policy guidance outlined above. This stage of intervention development has additional specific guidance,(27) 'actions to consider' when developing an intervention. These are not necessarily linear with some overarching actions that are constantly reviewed and adapted. Many are being considered throughout the PhD as well as this study e.g., Bring together a team (Supervisory group), Involve stakeholders (SLT stakeholder and PEG). These actions also include the need to 'draw on existing theory' and 'undertake primary data collection' as outlined below.

Draw on existing theory: As recommended, the project is informed by established behavioural theory (28-30) to select appropriate behaviour change techniques to help overcome specific barriers and thus help enhance family-carers' mealtime assistance (chapters 8&9). The frameworks chosen, the Behaviour Change Wheel(31) and the more detailed underlying aspects of the Theoretical Domains Framework(28) and Behaviour Change Techniques Taxonomy(29), are defined as 'Theory and evidence based' approaches for intervention development by O'Cathain et al. (2019)(27).

Undertake primary data collection: In a context of limited evidence for current intervention methods(32) it is important to explore the views of all stakeholders for any intervention to succeed. By exploring barriers and enablers to family-carers' following mealtime recommendations, including tacit often hidden knowledge the proposed research will identify the domains that need to be addressed systematically.

The research will use established theory(30) to select appropriate behaviour change techniques to overcome specific barriers and thus help enhance family-carers' mealtime assistance.

4 RESEARCH QUESTION/AIM(S)

This study is part of a multi-method PhD project that will develop a best practice toolkit for Speech & Language Therapists (SLT) to use with family-carers to ensure meals are safe, efficient and enjoyable for school-aged children with neurodevelopmental dysphagia who need mealtime assistance.

4.1 Objectives

1. To explore the family-carers' and children's experiences of, and decision making, during mealtime assistance, including barriers and facilitators to following mealtime recommendations

2. To explore whether family-carers who provide mealtime assistance to school-aged children with neurodevelopmental dysphagia can identify signs of oral and pharyngeal dysphagia and how they respond.

4.2 Outcome

The findings of this study with be synthesised alongside findings from two other studies within the broader PhD project: a systematic literature review and a survey of clinical practice. This all will then be used to complete study 4, development of a toolkit for Speech & Language Therapists (SLT) to use with family-carers to ensure meals are safe, efficient and enjoyable for school-aged children with neurodevelopmental dysphagia who need mealtime assistance.

This toolkit will include:

- recommended behaviours family-carers need to develop and adapt to assist their child to have safe, efficient and enjoyable mealtimes and

- techniques SLTs can use to support family-carers to perform the recommended behaviours.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This study uses a mixed-methods approach, predominately qualitative methodologies. Little is known about the mealtimes of family-carers and school-aged children who require mealtime assistance and so a qualitative methodology is appropriate.

5.1 Data collection

The research data will be collected in two sessions, one with the family-carer and child (Mealtime visit, Session 1) and one with the family-carer only (Session 2). In addition, demographic and clinical data will be collected, with participant consent, from the child's SLT. The flow of data collection is outlined in figure 2.

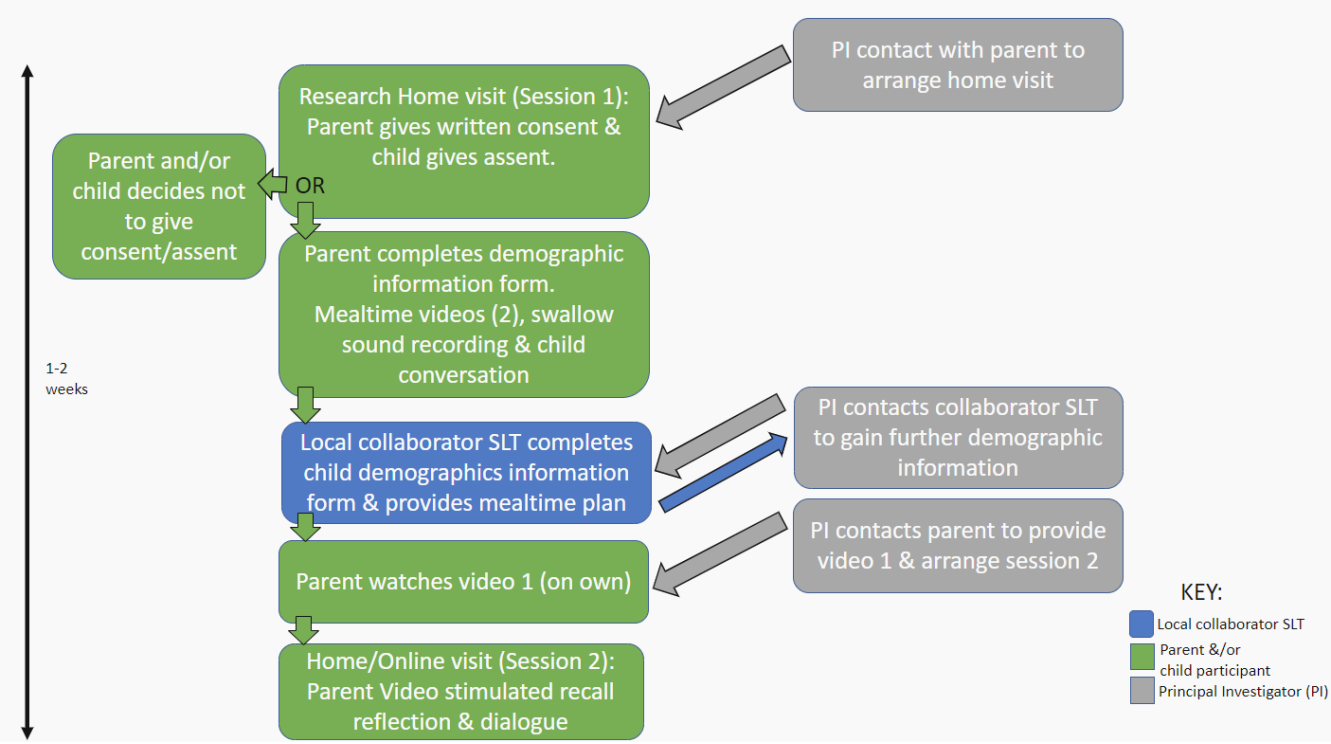

FIGURE 2: DATA COLLECTION FLOW DIAGRAM

Mealtime visit (Session 1):

The Principal Investigator will visit the family-carer and child at a date and time convenient to them to observe a mealtime (lunch or evening meal) while the child is being assisted by the family-carer. Written consent will be provided by the family-carer (Appendix 1: Consent form).

Family-carers will be asked to provide minimal relevant information about their characteristics by completing a one-page form (Appendix 2). This information will support sampling as the study aims to collect data representative of a diverse range of experiences and backgrounds, alongside providing demographic data for context when disseminating results. It will be completed either during session 1 or 2, either via an online Qualtrics link or on paper, dependent on their preference with PPI guidance suggesting the family-carer may prefer to be asked the questions by the researcher to avoid disclosing literacy difficulties.

Child assent via suitable means for their age and ability e.g., videos head nod, acceptance of the Principal Investigator's presence will be confirmed before data collection begins.

The Principal Investigator will record the mealtime using three recorders:

- Video 1: Wide view of the family-carer and child. Allows observation of experience of mealtime e.g., family-carer and child communication/interaction, mealtime assistance provided, and some of the child's eating, drinking and swallowing skills and difficulties e.g., tries to self-feed, deep chest breath
- Video 2: Close up view of the child's face and neck. Allows close observation of the child's eating, drinking and swallowing skills and difficulties e.g., skin colour changes, eye watering
- Audio 1: Swallow sound recording via a neck microphone taped to the child's throat (Child Information Sheet B&C videos within Appendix 3, Participant Information Sheet for photo of equipment). Allows record of swallow sounds that cannot be picked up by the videos. Will allow an association analysis to determine whether signs of difficulty in the videos (e.g., child's swallow appears late) are matched to the audio sign of an aspirating swallow (wet sounds heard if food/drink enters the larynx)

The Principal Investigator will take field notes prior to the start of the recordings and during to support analysing the data collected e.g., foods being eaten, texture of foods eaten, equipment being used etc.

The recordings will be synchronised by playing a brief tone just before the meal. The Principal Investigator will remain in the room to monitor the equipment e.g., via noise cancelling headphones for the swallow-sounds to ensure the mic does not move. The Principal Investigator will aim to be as unobtrusive as possible following the lead of the family-carer as to where to be within the room.

The recordings will ideally be for the whole mealtime. Following the mealtime, the Principal Investigator will briefly ask the child their views about their meal and mealtime assistance. The approach will be adapted for the child's age, developmental level, language and speech ability and will be video recorded (Video 3).

Following the Session 1 visit, the recordings will all be transferred to a secure OneDrive. In situations when the family-carer has used their home language in conversation during the mealtime video a suitable translation will be sourced

Local SLT provided data:

Following informed written consent, the Principal Investigator will contact the local collaborator and/or relevant local SLT to provide the relevant demographic case information e.g., age, diagnosis, EDACS levels, by completing a form (see Appendix 4 for all data requested) and will upload the child's current

SLT mealtime recommendations. This will be extracted from the child's healthcare notes accessible to them as part of clinical care. Data will be sent to the Principal Investigator by completion of a secure online individual-link survey software, Qualtrics.

VSSRD visit (Session 2):

The approach to data collection will use video stimulated recall reflection and dialogue(1). Prior to session 2 the family-carer will be provided with a copy of video 1 via a secure individual link to the OneDrive stored video or via the secure egress email system. They will be asked to have watched the video to become familiar with it and to choose two key points that they feel are important in some way when reflecting on this mealtime and mealtime assistance. Allowing this time also supports the family-carer to get over initial feelings when viewing themselves on video in private, before viewing it together. The Principal Investigator will also watch video 1 and choose two key places they would like to explore e.g., a point when the family-carer changed their approach, a time when they perceive clear signs of dysphagia.

Soon after the mealtime visit (1-5 days typically, 2 weeks maximum ideally) the Principal Investigator will meet again with the family-carer. This will either be at the family-carer's home again or if preferred via an online video call meeting using Zoom or MS Teams. The Principal Investigator will go through the signed consent form again to ensure the family-carer remembers what will happen during the session and with the data following the session and confirm verbal consent again.

The Principal Investigator and family-carer will meet (session 2) to view the mealtime video (video 1), starting with their pre-chosen parts, depending on the mealtime video length. During the session the Principal Investigator and/or the family-carer can decide to view other parts as the discussion develops as suitable for the discussions flow. This methodology allows the family-carer to reflect on what was happening in the meal, like a delayed 'think aloud' approach. The Principal Investigator will encourage the family-carer to discuss their thoughts, feelings and decision-making during the meal and for this to lead into a discussion of other mealtimes and their experiences of providing mealtime assistance and receiving mealtime recommendations to follow. This approach allows for deep reflection on the family-carer's experience and aims to expose their tacit skills and decision-making when providing mealtime assistance. The 'dialogue' aspect of this approach aims to have a full forward and back discussion rather than purely video stimulated recall, with the Principal Investigator expecting to learn new and potentially unanticipated insights into the family-carers thinking and experiences, with the family-carer also potentially gaining new insight through reflection. This session will be guided by a topic guide (Appendix 5). The session will be audio recorded on to an encrypted SD card within an audio recording device or via PC if completing the session via a video call, recorded to the device not the cloud and transferred straight after to the secure OneDrive space. The PI will provide the family-carer with a debrief information sheet at the end of the session.

5.2 Data analysis

To answer the research questions and to support transferability of this qualitative study a range of analyses are planned. Some data sources will be analyzed using multiple approaches and are used together to answer the research questions. These are outlined in the following figure:

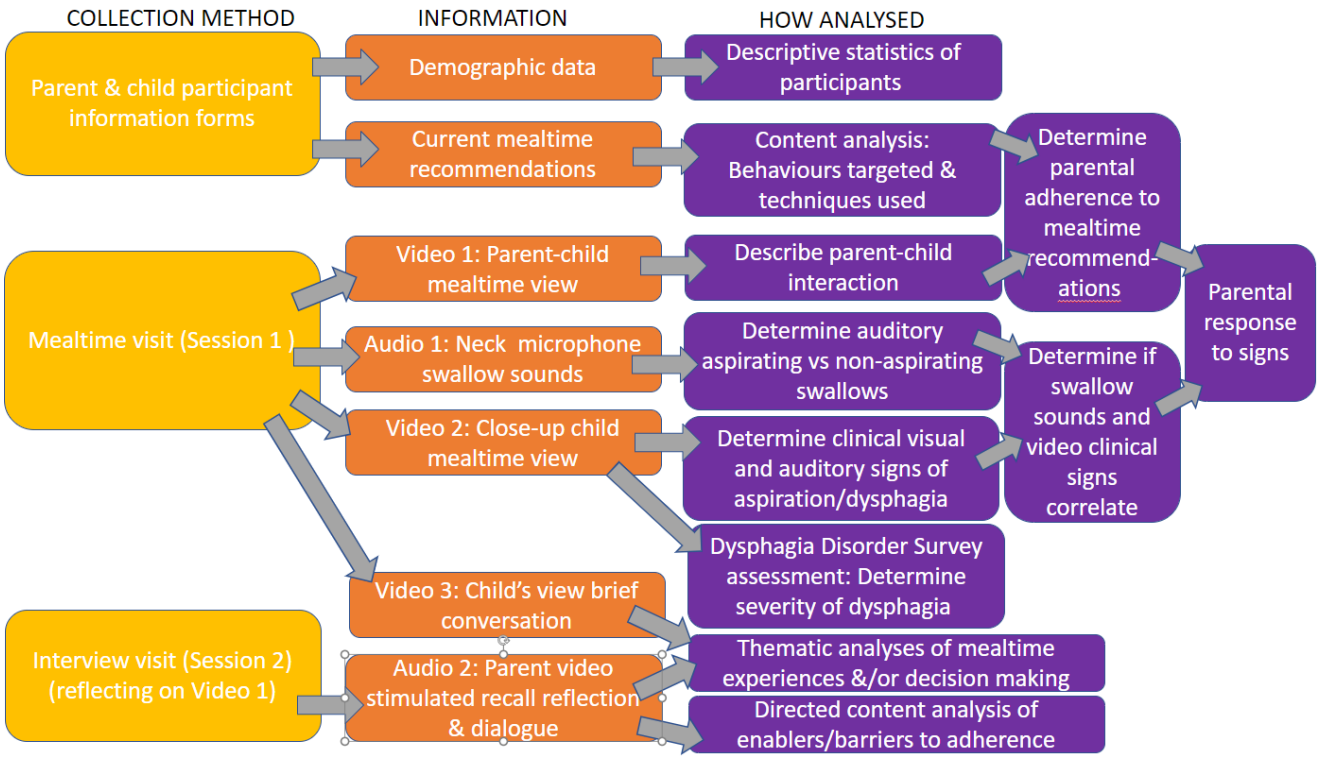

FIGURE 3: DATA ANALYSIS FLOW

Any required translation of home language use during the mealtime video (1) will be completed by a City, University of London approved translator with appropriate data sharing/confidentiality agreements in place. Transcription of the child conversations will be completed by the PI with the

family-carer VSRRD audio recordings transcribed by a university approved transcription company with appropriate data sharing/confidentiality agreements in place.

The analyses will use various standard software packages (video player, word, excel) with shared analysis completed by shared access to the secure password protected OneDrive space. In addition, NVivo software may be used for analysis for some of the qualitative data collected as more user-friendly and adaptable than combining video player and excel with coding possible onto individual video clips; child conversation videos and transcripts (Analysis 4), mealtime video interaction analysis (5), family-carer VSRRD transcripts.

Firstly, to describe the participants, the following analyses will be completed:

TABLE 1

	Data	Analysis method
1	Demographic data on child (from local collaborator SLT) & family-carer (session 1 or 2)	Descriptive statistics. The anonymised information forms will be analysed using descriptive statistics e.g., percentages of child participants by age, diagnosis, EDACS level and family-carer by role (parent, grandparent), ethnicity etc.
2	Personalised SLT mealtime recommendations	To determine the target behaviours recommended e.g., texture changes, meal pacing and the techniques used to support adherence for each child's SLT recommendations directed-content analysis(34) will be completed. This will identify the target behaviours recommended and map the techniques used to the BCTT(29). Two people will analyse a sample of the mealtime recommendations for discussion and consensus decisions until agreement is reached on accurate mapping to the taxonomy.
3	Mealtime videos (1 & 2)	To determine the severity rating of the child's eating drinking and swallowing skills using the Dysphagia Disorders Survey (35). This is peer-reviewed published clinical observational assessment with good validity and inter-rater reliability. The PI & Clinical Supervisor (KW) have completed certification in this assessment. They will separately view the mealtime videos and rate the child on the assessment and compute the Dysphagia Severity Staging Scale score.

To explore the children's and family-carer's experiences of, and decision making, during mealtime assistance, including barriers and facilitators to following mealtime recommendations

TABLE 2

	Data	Analysis method
4	Child conversation (video 1, transcript 1)	To determine the child's experiences of this supported mealtime the child conversations will be transcribed verbatim by the PI. They may vary from non-verbal responses to the PI's presence and end of the meal, a structured discussion using TalkingMats™ to a verbal discussion via a high-tech speech output device. Depending on the data a simple qualitative analysis will be competed or a more in-depth reflexive thematic analysis (36). Reference will be made to both the video and the transcripts to analyse any subtle nuances of communication. A member of the supervisory team will analyse a sample of the data to allow for discussion on analysis approach and themes formulated to support trustworthiness and ecological validity.
5	Mealtime video 1	To determine the interaction patterns and communication within each mealtime as part of the mealtime experience the family-carer-child mealtime video (1) will be analysed using NVivo software following a method outlined in previous research. This in-depth interaction analysis (25) will explore the communication between the family-carer and child during the meal e.g., whether conversation focus on the mealtime or on other topics. A member of the supervisory team will analyse a sample of the data initially to allow for discussion on analysis with consensus established through discussion.
6	Family-carer VSRRD session (audio 2, transcription 2)	To determine the family-carers experiences and decision-making during mealtimes reflexive thematic analysis(36) will be completed. The audio recordings will be transcribed by a company and checked by the PI and then analysed using the 6 stages of reflexive thematic analysis. A sample of the transcripts will be analysed by another member of the research team to allow for discussion on analysis approach and themes formulated to support trustworthiness and ecological validity.
7	Family-carer VSRRD session (audio 2, transcription 2)	Directed-content analysis(33) determining any barriers to adherence discussed matched to TDF(37) and any strategies that have assisted/hindered matched to the BTTT(29). KM will analyse a sample of the mealtime recommendations for

		discussion and consensus decisions until agreement is reached on accurate mapping to the taxonomy.

To explore whether family-carers who provide mealtime assistance to school-aged children with neurodevelopmental dysphagia can identify signs of oral and pharyngeal dysphagia and how they respond.

TABLE 3

	Data	Analysis method
9	Mealtime videos (1 & 2)	To determine any oral dysphagia (visual signs) e.g., drooling, and pharyngeal dysphagia (visual and auditory signs) e.g., eye tearing, coughing for each child's mealtime. The PI and clinical supervisor will separately view all mealtime videos and will note each time a sign of difficulty is identified, what type of sign and which timed video clip noting them on a checklist. They will meet regularly initially for the 1-2 videos with an aim to discuss and reach consensus. They will then separately view all other videos and will examine inter-rater agreement. This approach uses a similar methodology to Benfer and colleagues (33).
10	Swallow Sound recordings	To determine swallow sound signs of dysphagia (32) from neck mic recordings for each child's mealtime. Following ear training the PI and KW by independently rating all swallows. They will identify some main elements of the swallow sound recording; wet sounds in the larynx before the swallow, the quality of the swallow sounds and wet sounds following the swallow using a checklist. They will meet regularly initially for the 1-2 audio recordings with an aim to discuss and reach consensus. They will then separately view all other videos and will examine inter-rater agreement.
11	Mealtime videos (1 & 2) & swallow sound recordings (analyses 9 & 10)	To look for any associations between mealtime visual and auditory signs of difficulty from the mealtime videos 1&2 (analysis 9) and the swallow sounds identified as dysphagia (analysis 10).
12	Mealtime videos & data from analyses 2, 9, & 11.	To establish family-carer's responses to each visual and auditory dysphagia sign for their child, e.g., when child coughs do they pause (as recommended) or continue, to determine their responsiveness following similar

		methodology to Charpentier et al.'s study (16). The PI will analyse the videos cross-referencing the recommendations in the mealtime guidelines (analysis 2) e.g., is the recommended utensil, pacing etc. used. The PI will also analyse the family-carer's response to any signs of dysphagia identified from the previous video analysis (analysis 9, 11) cross referencing their response and any behaviours recommended in the mealtime recommendations.

6 STUDY SETTING

This study is multi-site, using three Participant Identification Centres (PIC) which are NHS community (or integrated) Trust sites. Data collection will take place only after all ethical and research and development approvals. The children will be receiving Speech & Language Therapy services from the clinical team in these sites who may be based within their local school or via a clinic base. The sites have been selected to support recruitment of a diverse range of family-carers and children and also reflect the demographic of the funder's locality. Although children will be identified through the NHS trust, the setting for the study will be the family-carer and child's home.

All sites will follow the same process. Potential local lead SLT collaborators have been identified at each site who have discussed the project with their clinical team of SLTs. PPI guidance suggested that parents would prefer contact from their treating familiar SLT rather than a lead SLT collaborator and so there will be a local lead SLT collaborator with a small number of local SLT collaborators within each site who specifically have these potential participant children on their caseload. Once local approvals are in place (Confirmation of Capacity and Capability, local SLT team manager) the PI will liaise with the lead local SLT collaborator. Following a training session, the lead local SLT collaborator and local SLT collaborators within the team (working with school-aged children with neurodisability and oropharyngeal dysphagia) will identify potential participants from their clinical database (Appendix 6). The local SLT collaborators will initiate the approach by providing the recruitment pack to the family-carer (Participant Information Sheet, link to child-friendly participant information and consent form). The family-carer will contact the PI if interested in participating or can request their local SLT collaborator provide their contact details to the PI. This will initiate the informed consent process carried out by the PI.

SITE ORGANISATION INFORMATION DOCUMENT

Organisation Information Documents and Schedule of Events forms for each site and have been created. Each site will undertake the same activities; including identification of potential participants using the inclusion and exclusion criteria and approaching parents to provide information about the project.

TABLE 4

Site Requirements	Activity
Local lead SLT collaborator and local SLT collaborators identify potential participants	The SLT collaborator will use the clinical database/caseload to identify potential participants using the study inclusion and exclusion criteria. This will be a collaborative process with the PI to support the sampling framework but ensuring that no personal information is provided to the PI prior to the consent process.
Local SLT collaborator to approach family-carers	The SLT collaborator of the school-aged child's will approach the family-carer regarding the study and provide the recruitment pack which includes the Participant Information Sheet, the family-carer consent form and the PI's contact details. If the family-carer request it, the local SLT will contact the PI and provide the family-carer's contact details. The consent process will not be undertaken by the local SLT but by the PI.
Local collaborator to provide child demographic and case information and a copy of the child's current mealtime recommendations	Following written consent the PI will provide the local collaborator SLT with a unique link to complete a short child case information form and upload the current mealtime recommendations document
GP letter	The child's GP will receive a letter from the PI to inform them of their participation in the study with a copy sent to the local SLT for the child's SLT healthcare records (Appendix 7).

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The eligibility criteria have been determined by the PI and supervisory team. They have been developed in consultation with the PPI group members and SLT stakeholder group who reported they would be able to screen and identify for these aspects.

7.1.1 Inclusion criteria

Children who:

- Have neurodisability (using Morris et al's (34)definition)
- Are aged 5;0-15;11 years
- Are in school year 1 and above
- Have oral-pharyngeal dysphagia type eating and drinking difficulties with severity level rated as Eating and drinking ability classification system (EDACS) levels: II-V(35))
- Have current SLT mealtime recommendations
- Have oral meals (>10 mouthfuls) (If tube fed is at Childrens eating and drinking activity scale (CEDAS) level: 3, 'tube use with consistent intake of food and/or drink. Oral intake partially meets nutrition and/or hydration needs', not 2(36))
- Are dependent on carer to feed meals (EDACS: Requires Assistance or Totally dependent(35))
- Are living with family-carer

Family-carers of participant children who:

- Are a family-carer (Parent, grandparent or other relative or foster-carer)
- Are aged ≥18 years old
- Provide regular mealtime assistance (>3/week)
- Have conversational English sufficient for video stimulated recall reflection and dialogue session e.g., able to complete a healthcare case history interview without an interpreter present, as reported by the recruiting local SLT.

7.1.2 Exclusion criteria

Child has characteristics outside of the inclusion criteria. For example:

- Under 5 years old or 16 and over
- Not school year 1 and above e.g., in reception
- Child with eating and drinking difficulties that are not due to oropharyngeal dysphagia e.g., child with Avoidant and Restrictive Food Intake Disorder.
- None or mild eating and drinking difficulties that are rated lower on the EDACS: I-II(35)
- Do not have SLT mealtime recommendations e.g., new to service and not yet provided
- Predominately tube fed (not orally fed) (CEDAS 1 & 2(36).

- Not dependent on carer to feed meals (EDACS: Independent(35))
- Not living with a family-carer e.g., in residential setting with paid carers

In addition, children will be excluded if they:

- have a tracheostomy in situ or are on oxygen therapy (will interfere with swallow sound recording)
- are unwell at the time of recruitment, e.g., immediately post-seizure or has a chest infection (not typical)
- are under safeguarding proceedings

Family carer has characteristics outside of the inclusion criteria. For example:

- Are aged under 18 e.g., a sibling
- Do not provide regular mealtime assistance (<3 times/week)
- Are unable to complete the family-carer VSRRD session in English without an interpreter

In addition, family-carers will be excluded if they:

- Have mental health difficulties that would impair their ability to participate effectively or create an unmanageable risk e.g., psychosis
- If a risk assessment suggests that a lone home visit is inappropriate e.g., domestic violence situation in the home.

7.2 Sampling

Purposive sampling will be used with the aim of providing a wide range of diverse experiences and backgrounds to support the transferability of the data.

7.2.1 Size of sample

This is a qualitative study, and a small number 10 family-carer dyads (20 participants) will provide a large corpus of data to analyse. **I**t is envisaged that purposive sampling will provide a diverse range of profiles and experiences and that this participant dyad number for recruitment and data analysis is feasible within the constraints of this part of the PhD project.

7.2.2 Sampling technique

Purposive sampling will be used within this study. A sampling frame (Appendix 7) will be used to consider the differing participant characteristics of family-carers and the child e.g., age, gender ethnicity, monolingual/multilingual, child's diagnosis, dysphagia severity, family-carer (mother, father, other). Close liaison with the local collaborators will aim to identify a diverse range of family-carer and child dyads.

7.3 Recruitment

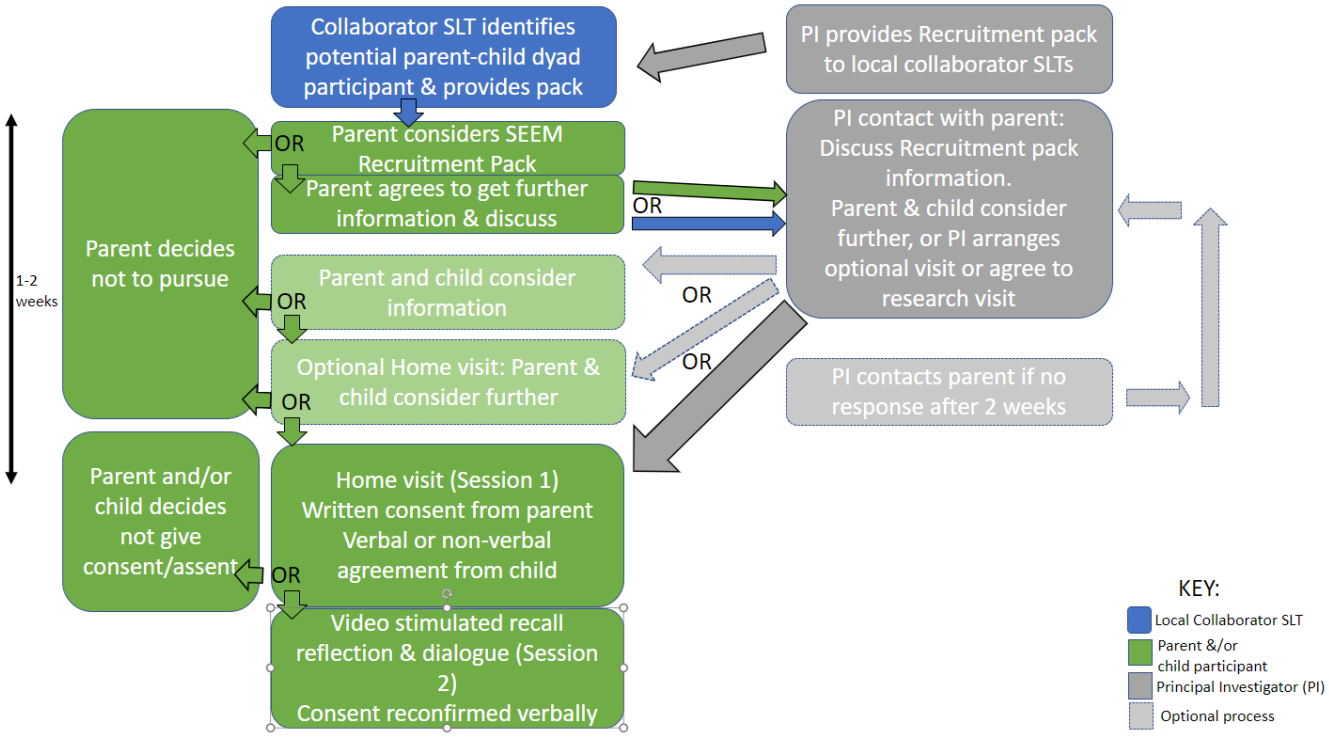

FIGURE 4: RECRUITMENT & CONSENT FLOW

The sites for this study have been identified and selected with the rationale as discussed above (Section 6: Study setting). Local sites each have a lead local collaborator who will be briefed in detail about the project. The PI will also provide training to the local SLT team regarding the study, the recruitment process and the inclusion and exclusion criteria and will have the local collaborator information pack (Appendix 6). The local SLT will approach family-carers and provide them with the recruitment pack and the contact details of the PI in the most suitable method for each individual e.g., at the end of a face to face, video call or telephone appointment, via email or another messaging service (Appendix 9). The PPI group indicated that an approach by a familiar health professional would be preferable. The family-carer will be able to request that the local SLT provides their contact details to the PI if interested or can choose to contact the PI directly when they have considered the information. The recruitment pack will contain the Participant Information Sheet alongside a highlighted suggested link to a child information video (access level recommended by the local SLT) and the family-carer consent form. Both PPI and SLT stakeholder groups reported that a video was the most appropriate format for this group of children who are likely to have limited physical skills and potentially limited literacy and language comprehension skills.

Both groups also suggested that video C would also be suitable for family-carers to access as an initial introduction to the project alongside the information sheet, particularly if they had reduced literacy skills.

After contact from the family-carer either directly or via the local SLT the PI will contact the family-carer. This first contact will be open to offer the family-carer the chance to ask any questions they may have about taking part in the study before deciding whether to take part. The PI will check whether the family-carer has shared the child-friendly information with their child yet, and if not encourage them to do so. The Principal Investigator will provide this material via email or in paper format by post if requested and will adapt resources if required e.g., provide materials using a specific symbol system for the child. If the family-carer is happy to proceed the Principal Investigator will arrange the first visit (session 1). This will be a minimum of one week later to allow them to consider their decision further. If the family-carer wishes to consider their decision some more, and or discuss the decision with their child first they can decide to do so. The Principal Investigator will suggest that they provide the family-carer and child a week to allow sufficient time to decide whether to take part and contact the Principal Investigator to arrange the first visit (Session 1). The PPI feedback suggested a week was more than sufficient to ensure busy family-carers did not forget. If there is no contact within 2 weeks the Principal Investigator will contact the family-carer to check if they want to take part, as suggested in PPI feedback to remind the family-carer of the option of taking part, with no further follow-up if there is no response.

All family-carers will be offered an optional pre-visit for the child to meet the Principal Investigator and examine the equipment used during session 1. Initially this visit was a planned part of the study but PPI feedback indicated it should be made optional to reduce time burden and as these families and children are very familiar with similar type visits by health professionals.

7.3.1 Sample identification

As discussed above three sites have been identified and selected. Each local site has a lead local collaborator who has discussed the study in agreeing to be a collaborator and will be briefed fully. The local team will also receive training.

The lead local collaborator and/or local collaborator SLT will identify suitable child participants and their family carers from their clinical database, in liaison with the researcher to support purposive sampling.

This method ensures that neither the Principal Investigator nor any of the research team will have access to the personal identifiable information in the clinical records without prior parental consent.

Participants will not receive any incentives for taking part in the research e.g., payment for their time. However, following their participation their child will receive a thank you card with a £20 Amazon voucher, as an acknowledgement for volunteering their time and contribution to the study.

7.3.2 Consent

The Principal Investigator who will request consent is an experienced SLT with 20 years plus experience of communicating with diverse families and with children with complex physical, learning and/or communication needs.

At the start of session 1 the Principal Investigator will explain the family-carer consent form and receive written consent. This will include going through each relevant section with the family-carer initialing each section they agree to. It will specifically include the discussion that some elements are core e.g., completing session 1 and 2, providing demographic information on the child while some are optional e.g., permission to use quotes and/or use video recordings in dissemination and/or future research and training. It will also be made explicitly clear that the family-carer can refuse to provide consent and take part in the study or can withdraw during the study, for any reason. Withdrawal from the study will have no impact on any SLT services received by the family.

The child will be approached in an appropriate way for their age and developmental level, to provide assent/agreement. This will be via non-verbal means typically and will be recorded at the start of the videos if it can be clearly indicated.

The Principal Investigator will aim to set up the video camera views to solely record the family-carer and child however if there are other adults or children present, they may be recorded, particularly their voice if they speak or their face if they move into shot. Additional adults will be provided with an information sheet (Appendix 18) to explain the purpose of the study, the data collection process, storage and analysis. This will also be given to the family-carer for any additional children that they have present during the session. Verbal consent will be taken from all present before recording the family-carer and child mealtime while they are present with their name recorded and kept securely with the family-carer consent form.

At session 2 the PI will go through the signed consent form again with the family-carer to ensure they remember what will happen in the video stimulated recall reflection and dialogue session and what will happen with the data following the session to re-confirm consent verbally.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Ethical considerations

This project should not create major risks as it is observing a typical activity, a mealtime. However, it is acknowledged that the study has ethical considerations that require active management. The study design has been developed in consultation with PPI and SLT stakeholders to ensure acceptability to SLT local collaborators at the Participant Identification Centres and to family-carer participants and their children. An application for ethical approval is being sought through NHS REC and centrally through the Health Research Authority (HRA), via the Integrated Research Application system (IRAS, no: 325687).

The key areas where ethical, legal and management issues apply in this project are:

Assessment & management of risk

Burden and benefits

Data protection and patient confidentiality (see 8.6)

Conflict of interest

8.1.1 Assessment and management of risk

IDENTIFICATION OF CHILD CLINICAL NEED DURING NON-CLINICAL CONTACT:

The Principal Investigator is a highly specialist SLT and so may identify a clinical need for a review of their mealtime recommendations due to changes e.g., new seating equipment, child shows many signs of potentially unsafe eating/aspiration. The family-carer and/or child will be signposted to routes for support verbally as relevant for each trust using local information gathered in prior discussion with the lead collaborator for each site e.g., method to request SLT review/re-referral and local support groups. In discussion with the family-carer the PI will discuss how the family-carer can access SLT services for their child and the local SLT and GP will be alerted via the use of an optional section of the GP letter (Appendix 7). If this raised awareness or discussion of the process causes any family-carer distress the PI will offer support e.g., offer a pause/break and signpost to general family-carer support. PPI group feedback felt that this would be seen as supportive and positive benefit of the study rather than an intrusion. All participants will also receive a debrief form with general support advice e.g., GP, government and national charity websites (Appendix 10).

CHILD & ADULT SAFEGUARDING:

The Principal Investigator has a current DBS check and has completed e-learning for health mandatory safeguarding training. There is potential that the family-carer may share information during sessions e.g., indicate they are considering suicide, or the Principal Investigator may witness something e.g., domestic violence that indicates that the family-carer and/or child is at risk of harm. This risk is reduced as if these factors are already known then the family-carer would have been excluded. Nevertheless, it is still possible to occur. If there is a disclosure or the PI witnesses an incident that would require action the Principal Investigator will follow the university safeguarding policy (Appendix 11) including reporting the concerns to the University's Governance & Integrity Manager who is the Designated Safeguarding Officer (DSO) for research activity. The DSO will then liaise with the Designated Safeguarding Lead who will report to all external agencies e.g., Social Services and the local Trust as appropriate following the policy. The PPI and stakeholder groups

acknowledged this potential issue and so clear explanation of the process if it should arise are outlined in the Participant Information Sheet.

HEALTH & SAFETY:

The PI has completed all University and all learning for health mandatory training e.g., manual handling, fire, infection control.

When considering infection control the UK Covid19 restrictions have ended, however the children in this study are considered clinically vulnerable. The Principal Investigator has had their full schedule of vaccines, will wear a mask if requested by the family when visiting and will follow other suggested guidance e.g., encourage ventilation.

The neck mic will be attached to the child's throat by microfoam tape which is hypoallergenic, The Principal Investigator will check regarding allergies to this substance or other adhesives before the session. The neck mic will be cleaned between use from one participant to another using an alcohol sterilizing wipe.

Otherwise, there are no anticipated risks outside of typical practice for a clinical Speech & Language Therapist. If there are any incidents, then the university's incident reporting policy will be followed (Appendix 12).

RISK TO PRINCIPAL INVESTIGATOR – LONE WORKING

The data collection approach will involve home visits. The PI has completed Suzy Lamplugh training and will follow the university's lone working policy (Appendix 13). The local collaborator SLT will have screened out high risk visits as part of the exclusion criteria e.g., child with active safeguarding investigation, known domestic violence situation. The PI will complete a visit risk assessment e.g., check route and location, have the use of a university mobile phone number and share her location and check in before and after the visit with a relevant member of staff e.g., the primary supervisor.

8.1.2 Burden

TIME BURDEN OF STUDY:

This study is with children who have a high level of health needs and input, with family-carers likely to be busy with managing this. The PPI guidance from parents with similar experiences did not think the project would be too burdensome as most of the activity is done during a typical mealtime, with potential benefits of a home visit from a SLT Principal Investigator. They did suggest some changes in relation to time burden. Therefore, a pre-visit to meet the child and get them familiar with the equipment was made optional. The study protocol is that the child will only have one visit and the family-carer two, one with the option of an online format if less burdensome.

COERCION:

The PPI group members felt that the recruitment approach allowed family-carers the chance to not take part without any feeling of coercion. Although they will be approached by their local collaborator SLT the Recruitment pack is clear that there is no expectation that they should take part and they will be able to ignore the Recruitment information with no contact with the PI. Once they initiate contact with the PI the family-carer will continue to be able to decide not to take part or have additional time to decide or gain additional information. The PPI group, however, felt one gentle follow-up reminder would be useful, and non-threatening as parents have busy lives and may just have forgotten (See Figure 2). During data collection participants will be reminded that taking part is optional and will not impact on their clinical care.

INTRUSIVENESS:

The PPI parents suggested that family-carers and children are familiar with being observed, including use of video-recording as part of typical clinical care. The family-carer can choose the home visit mealtime that they prefer e.g., best date/time. If family-carers are concerned that the child may not settle with a new person, they can accept the optional pre-visit. If a family-carer and/or child are distressed during the video, or the family-carers' VSRRD session then the session will be paused, and they will be offered a chance to end. If need be, a follow-up second visit will be arranged if the family-carer and/or child agrees with no further visits if distress is experienced again. The family-carer and/or child will be signposted to routes for support within the debrief sheet relevant to the need e.g., GP, Local SLT service, national charity or local parent support group.

The video reflection may also feel intrusive. PPI parents suggested that this aspect of the study however may be the most beneficial aspect for them personally. The family-carer will receive the video to view before the visit. This will allow the family-carer to get over initial feelings of embarrassment when viewing themselves on video in private, before viewing it together. The family-carer will select some clips to view that will encourage a more balanced power dynamic in the session, making it a 'dialogue'. At the end of the video stimulated recall reflection and dialogue session the PI will provide the family-carer with a debrief information sheet providing information and support.

CHILD CAPACITY TO GIVE ASSENT/AGREEMENT:

The children in this study are likely to have communication difficulties alongside dysphagia and so ascertaining assent needs careful thought to ensure the dignity and rights of the child are upheld. The Principal Investigator is a highly specialist SLT with expertise with children with such needs and this is evident in the different child participant information sheets. The local SLT will provide information on the best approach to support a child's understanding and communication level by indicating the link for the family to use on the recruitment pack and the Principal Investigator will discuss with the family-carer prior to the visit if any specific resources are required e.g., specific symbol system. The optional pre-visit can also be provided to allow time for the child to meet the Principal Investigator and discuss the study in whatever way is suitable, including e.g., mostly non-verbally by using a high-tech communication device.

SWALLOW-SOUND RECORDING/USE OF NECK MIC:

Use of a neck mic is not typical however it has been successfully used in previous work with children with neurodisability. In PPI and SLT stakeholder discussion it was noted that these children often have neck contact e.g., bib/scarf, stethoscope. The Principal Investigator can offer the optional visit to try on the neck mic and leave equipment to practice with. If either the family-carer or PI feels it is impacting on the child's mealtime and/or causing irritation or distress it can be removed during data collection with the other data gathered or a decision made to provide the neck mic for a period for familiarity before a new appointment is offered for data collection.

8.1.3 Benefits:

The PPI group reported that they thought that the opportunity for a family-carer to reflect in-depth on a mealtime would be potentially beneficial for their insight and personal development. They also felt that an additional observational visit from a SLT in the role of PI could be beneficial and stated that if any clinical issues were identified that warranted a review by the local collaborator SLT then this would be beneficial and well received, rather than perceived as a risk or intrusion.

CONFLICT OF INTEREST

There is no identified conflict of interest. Within this study the research team, including the PI visiting the families are independent of the clinical team. The research team have no connection with suppliers of equipment or analysis software.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Prior to the commencement of this study a favourable ethical opinion will be sought via the HRA for the study protocol, informed consent form and other relevant documents (as previously outlined). In addition, University research ethics approval and local approvals will be required at each site to ensure infrastructure and capacity is adequate for the requirements of the study. All correspondence with the REC, HRA and local R&D departments will be retained within the site files (electronic PDFs).

The Principal Investigator will prepare annual reports for the regulatory bodies as required and including the funder Barts Charity. The annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Principal Investigator will notify the REC at the end of the study. If the study is ended prematurely, the Principal Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Principal Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.2.1 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Principal Investigator will ensure that appropriate approvals from participating organisations are in place (see above). For any amendment to the study, the Principal Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Principal Investigator will work with sites (R&D departments at NHS sites and local collaborators) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.2.2 Amendments

After approvals are granted, should any amendments to the research project be made, the Principal Investigator will discuss with the supervisory team whether they are substantial or non-substantial (according to HRA guidelines). The Principal investigator will then consult with the Sponsor for approval and notify the relevant reviewing bodies i.e. the REC, HRA and local R&D as required. This will be completed on the amendments section of the IRAS form, which will be used for communication with the aforementioned regulatory bodies. An amendment history will be documented (Appendix 17) and a new version of the protocol (with appropriate version numbering control) will be saved and brought to the attention of the research team and regulatory bodies, the old protocol version will be archived for audit purposes.

8.3 Peer review

This study has undergone a high quality rigorous independent, expert and proportionate peer review to meet the requirements of the sponsor, and for the purposes of the funder, Barts Charity, through the N/AHP Clinical Doctoral fellowship application. This included three independent anonymous peer reviews completed (with expertise in speech and language therapy, dysphagia and children with neurodisability) alongside an interview panel of 5 people from Barts Charity. The experts and panel were independent of the Principal Investigator and Supervisors' host institution.

8.4 Patient & Public Involvement (PPI)

PPI, alongside SLT stakeholder engagement has been a key driving force within the development of this PhD project and this specific study The PEG members have lived experience matching the participants but with their children being just older than the inclusion criteria. They have shared a range of experiences related to Speech & Language Therapy services, including mealtime guidelines and support the aims and objectives of this study.

This group has guided and given feedback on many aspects of the project and this study, with response to the views noted throughout the protocol. The main areas of input relate to:

- Recruitment process

- Accessibility guidance to ensure informed consent and accurate determination of child assent/agreement

- Data collection methods acceptability: Video and swallow sound recordings via neck mic, VSRRD approach, visit numbers and location

They will continue to be involved during the project contributing to:

- Interpretation of anonymised findings (sense checking)

- Dissemination and outputs

8.5 Protocol compliance

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. As the PI is collecting all the data we do not anticipate any deviations from the protocol and expect high compliance. However, the PI will monitor for any protocol deviations and discuss them as necessary with the Primary Supervisor.

A protocol violation is a breach which is likely to have an effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study;

(b) the scientific value of the study.

The Supervisory team and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase. Should any deviations, non-compliances or breaches to the approved protocol occur, then appropriate documentation of these events will be undertaken using the relevant forms and made available for audit should this need arise.

8.6 Data protection and patient confidentiality

This project's design has been carefully developed to ensure best practice in Data Protection and patient confidentiality by strictly adhering to the DPA (2018) and General Data Protection Regulation (GDPR; 2016). A Data Protection Impact Assessment was completed for the project in conjunction with the City, University of London Information Governance department including completion of a Data Management Plan (Appendix 14). All data management will follow the University's Data Protection Policy (Appendix 15).

The project will be assigned an Information Asset Owner (IAO), Sally Morgan who will provide governance of the study data protection procedures and responsibilities in accordance with the City, University of London Data Protection policy. The IAO has completed information governance training (mandatory City, University GDPR training and e Learning for Health training.

Adherence to GDPR (2016) will be achieved by following guidelines for researchers from HRA (https://www.hra.nhs.uk/planning-and-improving-research/policies-standardslegislation/data-protection-and-information-governance/gdpr-guidance/). During the consenting process with participants, full transparency statements will be provided in the PIS regarding the purposes of storing their personal data, how long it will be stored for, their rights for erasure, who will have access to it (supervisory research team, sponsor/regulatory bodies in case of audit and potential for secondary data analysis with opt out option) and the procedures in place to keep it secure. Only the minimum amount of personal data will be requested for the purposes of the research and all personal data will be kept updated, if/when the participants notify the team of any changes. Electronic personal data and research data will be stored within the PI's personal secure OneDrive space which has AES 256-bit encryption and is accessed via a password protected account with a 2-step verification process. This

facility has adequate storage capacity for the video and audio data for this study, as advised by the departmental tech support team.

The recruitment process is planned to not provide the PI with any personal information until the family-carer has indicated an interest in the study (name and contact details only) and then no further information until the formal written consent process is complete.

Whenever possible data will be pseudoanonymised material as soon as possible in the research process. Throughout and after completion of the project, there will be limited access to participants' personal data. The research team will only have access to data as required and only via a specific link to the OneDrive folder, not via email attachment. The process for collection, use and storage of different types of personal data is outlined below.

CONSENT FORM AND EMAIL AND TELEPHONE COMMUNICATION DATA:

Potential participants will be in contact with the Principal Investigator during the recruitment process. This contact will be via to/from The Principal Investigator's University email or Zoom account, telephone and/or mobile number. All messages will be deleted as soon as possible with personal contact details to enable visits and communication stored securely within a specific folder within OneDrive.

The participant will complete a paper consent form which will be brought to the University site as soon as possible and if not on the same day will be stored in a locked cabinet in the PI's home until it can be taken to the University. If an additional adult is present their name will be recorded and kept with the family-carer consent form. The paper consent forms will be stored separately in a locked filing cabinet at SM's office which requires a photo ID swipe card for access. Personal identifiable data and consent forms will be stored separately to the research data.

DEMOGRAPHIC DATA:

The child demographic and clinical information will be collected via Qualtrics City University's approved online platform for surveys and other suitable data collection. Qualtrics is a secure encrypted transfer system and is GDPR compliant: https://www.qualtrics.com/platform/security/.

The local SLT collaborator will receive a unique link to complete an individual child participant's form with an upload function to provide the child participant's personalised mealtime recommendations

document. The family-carer will complete their demographic data form online via another Qualtrics survey link or on paper, using a pseudonym. Paper forms will be scanned to be saved onto OneDrive. The PI will then download both forms' information into Excel and download the mealtime recommendations document, providing a pseudonym and redacting any organisational names and logos. All data will then be securely stored in the OneDrive folder using pseudonyms with the original forms in Qualtrics deleted. The pseudonym – personal name code list will be stored separately from the research data. Demographic information will be aggregated as needed to reduce the risk of identification when results are published.

AUDIO RECORDINGS:

Audio recording 1 (swallow sound recording) is personal but is not identifiable. It will however be stored securely as for all recordings.

Zoom © will be used to enable the video call for session 2 if preferred to a home visit. This software is fully GDPR compliant and is regularly used in qualitative research. Audio recordings collected via online Zoom meetings will be saved to a university encrypted device, not the cloud and then immediately uploaded to the Principal Investigator's secure OneDrive folder. The VSRRD audio recordings will be transcribed using a City University approved service which is GPDR compliant, transcription company or NVivo software.

Audio recording 2 (family-carer VSRRD session) will be transcribed verbatim with pseudonyms used or redaction for any identifying names of people or organisations. The anonymised transcript will be used for analysis with NVivo, with the recording kept securely until completion in case of the need for reference. Quotations will only be used in dissemination with explicit optional consent and be selected for use as non-identifiable.

VIDEO RECORDINGS:

Video data creates special data management, consent and confidentiality governance considerations. Section 8.4 and throughout this protocol a carefully considered study design is outlined, including PPI consultation, with the aim of addressing consent and confidentiality matters. Video will be captured onto encrypted memory cards in the video camera and audio onto the audio recorder. Wherever possible raw video and audio data for initial analysis will be immediately uploaded, for secure storage onto OneDrive and the original data will be deleted from the recording devices (PC or memory card). If immediate upload to OneDrive is not possible then the encrypted cards will removed from the devices and will be stored on transit in a padlocked bag. The recordings will be uploaded to Onedrive and

deleted from the memory cards within a maximum of 24 hours of being recorded, usually by the end of visit day when the PI returns to their University office or home.

The visit will occur during a typical mealtime therefore this may be a family mealtime with other family members, parents, grandparents, siblings etc. present. The video cameras will be set up to record solely the family-carer and child as much as is possible. Verbal consent and agreement will be sought from all present to record after providing the 'Additional Person Present Information Sheet' (Appendix 18). If another family-member is recorded, when possible the face of the other family-member will be blurred using suitable technology or their voice muted before analysis occurs if it does not prevent analysis of the family-carer or child. Video clips will not be used for dissemination in any form if they have additional people within the video even if the family-carer has given consent for their sharing.

If a family-carer uses their home language during the mealtime video, then a translation will be sourced. This will be provided by an agreed University provider and whenever possible the audio only will be provided. Translation will only be procured by a university approved supplier that meets GPDR standards, listed in City, University of London's marketplace or via the procurement team including potential employment of a specific language translator via UniTemps.

Video 1 will be shared with the family-carer to individually view and consider before session 2. This will be provided by a specific individual link to the individual video within OneDrive. If a family-carer had difficulty accessing it can also be provided using the university approved email system for transferring personal data, Egress: https://www.egress.com/ The family-carer will sign the consent form agreeing not to share the video further and will be asked to view the video on their own. Session 2 will include the Principal Investigator and family-carer viewing parts of the video together. This will be within a mutually agreed private confidential space, either the family-carer's home or via an online Zoom meeting. The video will be played using the Principal Investigator's approved encrypted device.

All analysis will be completed in a confidential space where no one else will view/hear the data while it is being viewed/listened to and analysed. Some data will be viewed in Australia, where one of the research team is based. The same process will apply for accessing and viewing the data with it remaining stored in the UK-based OneDrive account and not downloaded to another device. Sharing of video clips as part of dissemination will only occur if explicit consent is granted.

ARCHIVING

Handling of all data within this study will strictly comply with General Data Protection Regulations (2018) and the Data Protection Act (DPA; 2018). Archiving of study data will follow the Sponsor's standard procedure. Therefore, after completion of the study the Principal Investigator confirms that she will archive the study master file (containing anonymised research data) for 10 years. This will be

subsequently destroyed in a confidential and secure manner. Electronic data will be stored within the OneDrive folder as explained above). Any hard paper copies of relevant anonymised study data will be scanned and stored. Personal data used for administrative purposes for the project will be stored for a minimum period of 12 months following the end of the study and will subsequently be destroyed in a secure manner, in order to adhere to GDPR guidance.

The Principal Investigator confirms that he/she will archive the study master file within OneDrive for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The local collaborator at each participating site agrees to archive his/her respective site's study documents for ten years and in line with all relevant legal and statutory requirements.

8.7 Indemnity

City, University of London holds insurance against claims from participants for harm caused by their participation in this study. Participants may be able to claim compensation if they can prove that City, University of London has been negligent (Appendix 16)

8.8 Access to the final study dataset

Access to participants' personal data will be restricted to a minimum number of persons i.e. only those that need to have access for the purpose of the study. Therefore, only the individuals involved in carrying out the study will have access to the full dataset, will include the Principal Investigator, Primary supervisor and two secondary supervisors.

If the regulatory bodies such as the City, University of London ethics committee or Health Research Authority provide a formal request to access the full dataset this will be facilitated in accordance with the data protection protocol laid out in this protocol.

Future access to the dataset for secondary analysis will only be undertaken with the consent of all participants and this option to consent/decline is outlined in the Participant Information Sheet and consent form.

9 DISSEMINATION POLICY

9.1 Dissemination

This protocol, following ethical approval will be published open access on the Open Science Framework website: https://osf.io/.

The data arising from this study will be owned by the project Sponsor – City, University of London. On completion of the study the data will be analysed and prepared for a Final Study Report in the form of a PhD Thesis. This will be stored in the City, University of London library and on City Research Online for general access. The Principal Investigator will prepare work for publication, in collaboration with the research team, during the study. Successful publications will be advertised through academic networks on Twitter and ResearchGate and uploaded to City Research Online. Any publications will acknowledge the Barts Charity as funders and City, University of London as sponsor. Study participants, the PPI group and the SLT Stakeholder group will be notified regarding publications and the overall outcome of the study, through a written report. In addition, there will be a final presentation of the whole PhD project at a celebration event. Presentations may also be delivered at conferences and other relevant for a. Parent participants will be informed of the purposes for any use of the video footage in subsequent dissemination, as outlined in section 7.2.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Final Study Report will be in the form of a PhD Thesis written by the Principal Investigator.

Authorship eligibility for any publications will follow guidelines as defined by The International Committee of Medical Journal Editors. This recommends that authorship be based on the following four criteria:

• Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

• Drafting the work or revising it critically for important intellectual content; AND • Final approval of the version to be published;

AND • Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

APPENDICES

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