FULL/LONG TITLE OF THE STUDY

Evidencing the need for routine sensory motor assessment and support for autistic adults and identifying appropriate intervention pathways

SHORT STUDY TITLE / ACRONYM

Evidencing the need for routine sensory motor assessment and support for autistic adults

PROTOCOL VERSION NUMBER AND DATE

Version 1, 4/4/24

RESEARCH REFERENCE NUMBERS

IRAS Number:	330960
SPONSORS Number:	x730
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Funder(s)	NIHR, RfPB

STUDY SUMMARY

Study Title	Evidencing the need for routine sensory motor assessment and support for autistic adults and identifying appropriate intervention pathways
Internal ref. no. (or short title)	X730
Study Design	Mixed methods
Study Participants	Autistic participants
Planned Size of Sample (if applicable)	Phase 1: 110 Phase 2: 100
Follow up duration (if applicable)	N/A
Planned Study Period	24 months; start date: 1/4/24; End of study refers to completion of all objectives
Research Question/Aim(s)	Aim: To provide evidence for the need and acceptability of routine SMD assessments and treatment for autistic adults and to identify and map existing intervention pathways. Objective 1: To summarise need for assessment and intervention Objective 2: To collect evidence to inform the design of future studies to determine effectiveness and costeffectiveness of the SMD intervention pathway Objective 3: Intervention pathway refinement

PROTOCOL CONTRIBUTORS

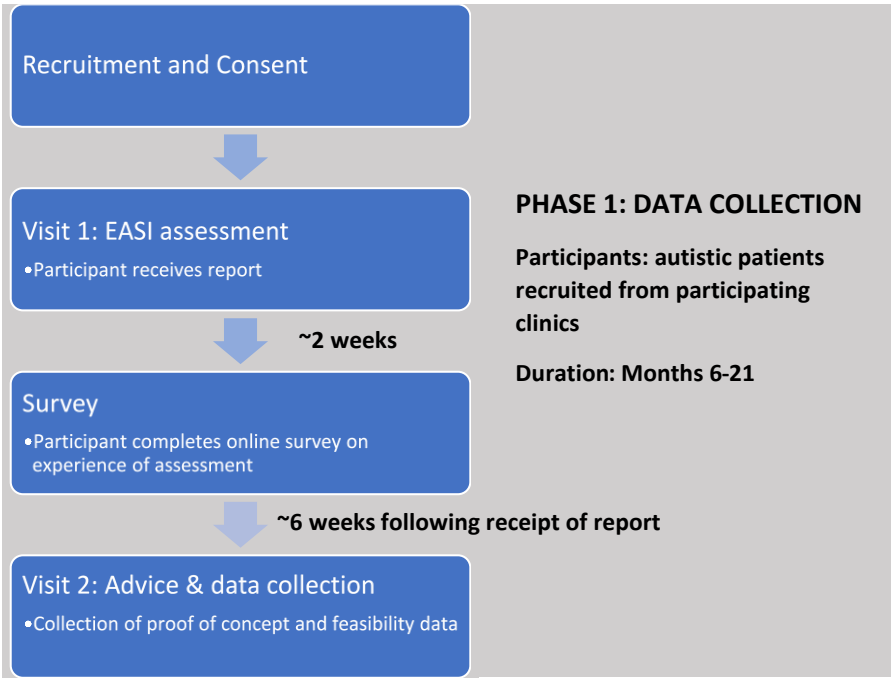
Research team members: Dr Emma Gowen (PI)

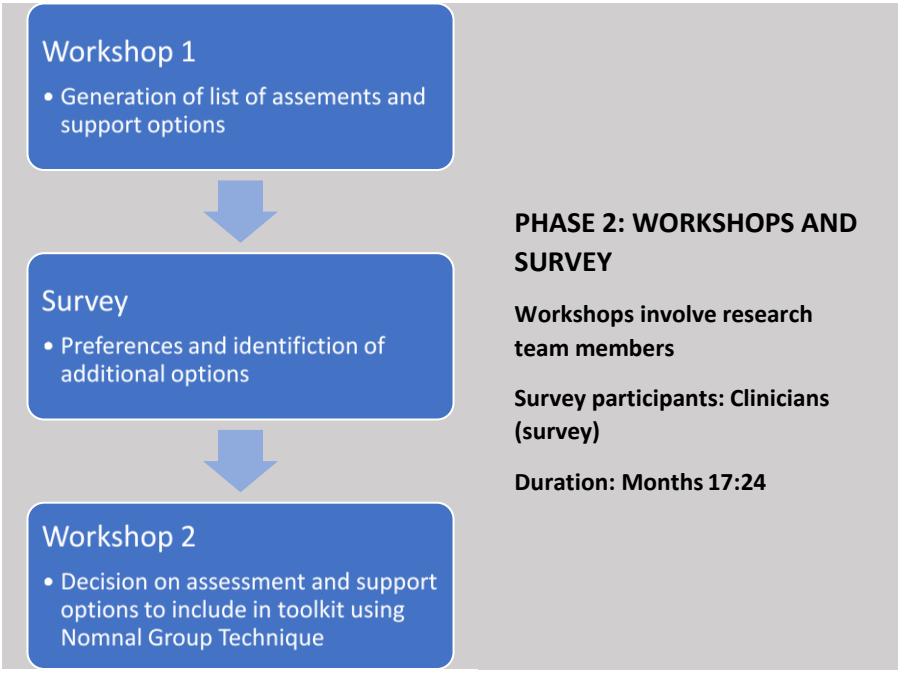
Co-Is: Georgia Fair, Dr Ellen Poliakoff, Dr Helen Hawley-Hague, Dr Martin Eden, Peter Baimbridge, Helen Bucke.

Sponsors and funder have no role in study design, conduct, data analysis, interpretation, writing and dissemination of project and have no control on the final decision regarding any of these aspects of the study.

KEY WORDS: Autistic adults, sensory, motor, sensory motor assessment

STUDY FLOW CHART





Flow chart of study. Phase 1 consists of collection of participant data using theEvaluation in Ayres Sensory Integration (EASI) assessment. Phase 2 involves two workshops with the team members and a survey with clinicians to develop the toolkit

1 BACKGROUND AND RATIONALE

The project addresses two gaps. First, the absence of a referral pathway for Sensory and Motor difficulties (SMD) for autistic adults without Learning Disabilities (LD). As there are already existing SMD pathways for autistic patients with LD, there is a need to focus on those without LD who make up two thirds of autistic adults.[1] Second, the absence of clinical guidance around assessment and support options for SMD in this population, once autistic patients are referred.

Autism is a life-long developmental condition that affects how a person communicates and interacts with people. SMD, such as hypersensitivity, poor manual and eye-hand coordination and unstable balance occur in at least 80% of autistic individuals and are present from infancy through to adulthood.[1-4] The importance of SMD is recognised through their recent inclusion in the diagnostic criteria for autism.[5] As the ability to appropriately sense, move around and interact with our environments is involved in all aspects of life, SMD impact negatively on daily living skills, quality of life (QoL), education, employment and mental health of autistic people.[6-10] For example, in recent focus groups led by the PI,[6,7] autistic adults without LD revealed how SMD impacted upon daily activities such as getting dressed, handwriting, hobbies, cooking and personal hygiene and reported trips and falls. These difficulties led to stress and anxiety, physical and mental fatigue and a restrictive lifestyle due to avoiding certain environments. SMD also had a profound effect on social and emotional wellbeing, causing strained relationships, exclusion and bullying leading to feelings of embarrassment, frustration, fear, isolation and poor self-esteem:

"You can start to hate yourself. I actually shut myself away from the world for ten years because of this [motor coordination difficulties].[6]

Clinical team members describe how SMD affect their patients' ability to function in the community and engage with others and with education. They have observed that SMD can have a negative impact on dietary choices, personal hygiene, house cleanliness, and overall QoL.

Despite this impact, our stakeholder engagement involving autistic people and clinicians across different UK networks (Autism@Manchester, Merseycare autism services, Royal College of Occupational Therapists (OTs)) revealed that SMD in autistic individuals without LD are not routinely assessed and supported either during or following diagnosis, with availability being dependent on location and limited by a lack of trained practitioners. Furthermore, there is no standardised guidance or evidence directing clinicians to appropriate interventions for SMD. Lack of assessment and support for autistic individuals without LD is likely due to the importance of SMD in this group only recently being recognised. [6-10] Indeed, recent discussion on twitter by autistic individuals in response to our publication on SMD [6] highlights agreement that SMD are a concern and there is lack of support. A clearly defined, specific pathway for autistic individuals without LD is required as the delivery and range of assessments and support options will differ to those with LD. The aim of this project is to provide evidence for the level of need for routine SMD assessments and treatment for autistic adults without LD and to identify and map existing assessment and intervention options. Following the MRC Framework for development and evaluation of complex interventions,[11] this project represents the start of a journey to make a step change in the way SMD are assessed and treated. **Our vision is that autistic patients without LD from any service can be referred to this novel SMD intervention pathway, and that those newly diagnosed will be routinely referred, leading to better QoL for the individual and less reliance on health and social care services.**

The first stage is to estimate the uptake of assessment and need for SMD support, its acceptability to patients and to establish a toolkit of appropriate existing assessment and intervention options that clinicians can use to aid decision-making. This will be achieved through SMD assessments with participants to demonstrate the need and provide data on proof of concept, feasibility and support requirements that will feed into workshops to develop the toolkit that will be comprehensively evaluated in future studies. This study will focus on participants from diagnostic clinics to enable us to evidence the basic level of need for SMD support in autistic individuals without LD, but later studies will include wider clinics.

The project is aligned with the NHS Long Term Plan and Department of Health and Social Care national strategy for autistic individuals[12] which aim to improve understanding of the needs of autistic people and facilitate better access to health and social care, including improving post diagnostic support. Autistic patients will benefit through receiving support for their SMD and clinicians will benefit through being able to provide assessments and intervention for an integral aspect of their patients' health.

2. RESEARCH QUESTION/AIM(S)

To provide evidence for the need and acceptability of routine SMD assessments and treatment for autistic adults and to identify and map existing intervention pathways.

2.1 Objectives

Objective 1: To summarise need for assessment and intervention Determine the % of autistic adults without LD who are willing to take up a SMD assessment and the % of these that are identified as needing support following assessment.

Objective 2: To collect evidence to inform the design of future studies to determine effectiveness and costeffectiveness of the SMD intervention pathway Collect proof of concept, acceptability and feasibility data

Objective 3: Intervention pathway refinement Conduct workshops and a survey to develop a toolkit outlining existing SMD assessments and intervention options.

2.2 Outcome

The long-term outcome of the SMD assessment and support pathway is to improve physical and mental health, independence and employment opportunities for autistic individuals by recognizing and supporting their SMD. This will be accomplished directly through support provision made available through the SMD pathway, and also indirectly by facilitating access and delivery of other healthcare required by autistic people. Taking the first steps to reach this outcome, this project will produce:

- Output 1: Evidence on the level of need for SMD assessment in autistic adults without LD.
- Output 2: Proof of concept and feasibility data to facilitate future development and evaluation of the toolkit and pathway.
- Output 3: A prototype SMD toolkit providing an itemised list of resources, detailing when they could be used (based on patient presentation), what they measure or support, available

evidence base and what training might be required. For the first time, it will bring together materials in one place.

3. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

See Fig.1 flow chart for overview of the study and Appendix 1 for Gantt chart.

Phase 1: Data collection phase

For phase 1, consented autistic participants will be offered the Evaluation in Ayres Sensory Integration (EASI) assessment. [13] The EASI has been chosen as although it is designed and validated for children, clinical team members use it for adults and recommend its use as a decision tool for identifying SMD and further assessment/support. Furthermore, as recommended by reviews,[14-15] it is a multidimensional assessment using both observation and self-report and measures both sensory and motor elements. The study OTs will collect demographics, perform the (EASI), the Occupational Circumstances Interview and complete assessment reports detailing any need for SMD support (Objective 1) and specific support recommendations. Data about the visit will be collected using study forms (See Visit 1 Participant Data Form). We will also ask clinicians to collect information that will help determine feasibility of future studies (Number assessed for eligibility, Number approached, Number given verbal consent (or not and reasons), numbers of non English speaking patients attending during the study). Participants will receive a report detailing their SMD and any support recommendations.

The next day after visit 1,participants will be sent an online survey asking about their experience of the assessment, using an acceptability survey[16] and bespoke questions (see InterimQuestions). They have up to 2 weeks to complete the survey. This has the benefit of (a) participants being more likely to remember the assessment and (b) maintaining engagement in the study. The RA can provide support (telephone, email, zoom call) and email for the survey and provide the option of paper. If participants do not or are unable to complete the forms, the OTs will administer this questions during visit 2.

Participants will have a 1 hour follow up appointment ~6 weeks after receiving the report so the clinician can provide further advice and collect proof of concept and feasibility data (Objective 2). This will consist of data to determine participant views around the acceptability of the report and perceived impacts using open-ended qualitative survey items. Feasibility data will be collected to test whether it is possible to collect reliable outcome measures for future economic evaluation (validated QoL questionnaires recommended for use in economic evaluation: European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L)), and to identify additional outcome measures from the participants' comments to be used in future work. Bespoke data collection forms will be used to collect resource use associated with each session (e.g. time taken, staff involved) and identify facilitators and barriers. See Visit 1 Participant Data Form for all data collected during visit 2.

The RA will use descriptive statistics to analyse data collection forms and survey responses and framework analysis (The Consolidated Framework for Implementation Research (CFIR)) on the open-ended comments, as in our previous research.[17] The nature and extent of any missing data from the QoL questionnaires will be explored using descriptive statistics. Unit costs from published sources (e.g. www.pssru.ac.uk) will be attached to resource use data. Costs associated with delivering assessments will be collated and summarised to demonstrate feasibility of costing this element of the pathway. Data will be analysed using Stata, R and MS Excel software.

Phase 2: Workshops and survey

During phase 2, the assessment and support recommendations extracted from the EASI reports in phase 1, will be presented at a stakeholder workshop involving the multidisciplinary research team to generate a list of additional assessments and existing support options. These lists will be circulated via a survey to a wider group of clinicians (~100 OTs and physiotherapists, recruited via our networks) to identify their preferred options and any additional assessments and interventions (see Phase 2 Survey). A second workshop with the research team will involve discussion of the survey findings and agreement on recommendations for assessment and support pathways, based on clinical and scientific evidence. Workshops will employ a Nominal Group Technique to refine the content of the toolkit and assess the level of consensus around assessment and support (see details below). This technique follows set stages of silent idea generation, 'round robin', clarifications and scoring enabling workshop participants time to think in silence and all to contribute. This is important as we wish to obtain information as well as develop guidance and the group is comprised of a mix of autistic people, clinicians and researchers so will give everyone the opportunity to raise issues. The scoring stage will only be conducted after workshop 2 using an online private Likert scale form for each individual. Those assessment/support options that achieve 75% agreement for importance will be included in the toolbox. Attendees will be emailed these options together with those that were equivocal to allow final discussions.

Workshop details

The workshops will likely be conducted remotely (Zoom/Teams) due to the different geographical locations of the team. Emma (PI) along with support from the RA will chair each workshop and provide information to the attendees on the questions and process prior to the workshop so they can prepare. The workshops will follow The Nominal group Technique process. [18,19]

Workshop 1

1. Introduction on process and context. Aim is to identify assessment and support options.
2. Silent idea generation: Workshop attendees are shown an initial list of assessment/support options. They are presented with the following two questions and are given 15 mins per question to generate ideas. The two questions will be presented separately.
    i. Q1 When an autistic patient is being assessed for SMD what do you think are important aspects or assessments to consider in this evaluation (these could be tasks, assessments or abilities)
    ii. Q2: When an autistic patient is receiving support for SMD what do you think are important aspects or support options to consider (these could be interventions, treatments or abilities)

   The RA and PI will be available for questions.
3. Round robin: Each person offers a single idea in turn until all ideas are exhausted. Attendees can either present their thoughts verbally or through text that is read out/displayed on screen. All ideas displayed on a screen
4. Clarification stage: Each attendee in turn raises any points of clarification

Workshop 3

1. Introduction on process and context. Aim is to agree on recommendations

2. Silent idea generation: Updated assessment and support options (along with indications/barriers etc) presented in turn. Workshop attendees are given 15 mins per question (questions are asked separately). The two questions will be around what assessment and support options should be included in the SMD pathway and indications/barriers etc. The RA and PI will be available for questions.
    a. Q1: Are there any further assessment/support options you wish to add
    b. Q2: What are the indications or barriers to the different assessments/support options?
3. Round robin: Each person offers a single idea in turn until all ideas are exhausted. Attendees can either present their thoughts verbally or through text that is read out/displayed on screen. All ideas displayed on a screen. Need to remind participants that there is no debate or interruptions until everyone has contributed.
4. Clarification stage: Each attendee in turn raises any points of clarification
5. Individual scoring. Assessment and support ideas are entered into a document and emailed to attendees as an online questionnaire within 72 hours of the workshop. As with previous research in a similar area[18,19], a 9 point likert scale [not important/do not agree (1) to important/strongly agree] will be used. The level of agreement will be 75% across 3 different ranges, 1-3 (not important), 4-6 (important but not critical), 7-9 (important). Importance measured through Likert is considered more appropriate then ranking methods for this study as we are aiming to include all assessments/support options that are relevant rather than remove options that might be more lowly ranked but still considered important. Those assessment/support options that achieve 75% agreement for important will be included in the toolbox. Attendees will be emailed these options together with those that were equivocal to allow final discussions. It is possible that through discussions some of the equivocal options may be included as additional options to be considered in particular circumstances.

- Workshop 3 will also include a separate discussion on feasibility. These aspects will be discussed within the framework of Implementation Theory, considering wider, organisational issues, not just individual issues.
    - Discussion on most relevant outcome measures
    - How to make assessments/support accessible to harder to reach patients. Those where their social issues are extreme and they are scared to leave home/try anything new
    - Training/time required
    - Any adaptations
    - Evaluability assessment: expected outcomes of the pathway and the data that could be collected to assess processes and outcomes,
    - Potential study sites and No. of available trained clinicians
    - Barriers/changes in practice required
        - cost
    - Types of clinics that would refer and types that would benefit

4 STUDY SETTING

For phase 1, autistic participants will be approached at two adult autism diagnostic clinics at GMMH and Merseycare. Consent to contact will be taken at these sites to allow the RA or CSO to discuss the study further and obtain consent.

Consented participants will be offered the assessment by the OT at a choice of 5 sites to accommodate travel requirements. These include the University of Manchester (M13 9PL), Maghull Health Park site (L31 1HW)), Hollins Park Hospital (WA5 1QG), Community Hub Norris Green (L11 5BS) or Willis House (L35 2YZ). A quiet room is needed only.

For phase 2, the workshops will be conducted remotely (e.g Microsoft Teams)

5 SAMPLE AND RECRUITMENT

5.1 Eligibility Criteria

5.1.1. Inclusion criteria

Phase 1

- Diagnosis of an Autism Spectrum condition without a Learning Disability (LD)
- >18 years without LD
- Presenting at participating adult autism diagnostic clinics (GMMH and Merseycare)

Phase 2

- Clinicians who assess and support autistic adults with sensory motor needs
- Able to understand written English and access the internet
- >18 years of age

5.1.2 Exclusion criteria

Phase 1

- Outside of stated age range.
- Diagnosis of a Learning Disability
- Unable to understand verbal and written English as they will need to respond to both verbal and written questions
- Outside stated diagnostic clinics.

Phase 2

Clinicians who do not assess and support autistic adults for sensory motor needs

5.2 Sampling

5.2.1 Size of sample

Phase 1: A conservative prevalence of 80% SMD, aiming for a precision of 7.5% and a 95% confidence level would require approximately 110 participants to estimate the % of patients requiring support for SMD.[20] This number will also allow us to estimate parameters relating to feasibility such as recruitment, with a reasonable degree of precision. The clinics see ~360 diagnosed patients without LD per year and with a conservative estimate of 33% uptake the recruitment target is achievable.

Phase 2: ~100 participants. Participants would be clinicians (OTs, physiotherapists, Speech and Language Therapists) who work with autistic adults without LD recruited from various national networks and organisations (Autism@Manchester, Merseycare autism services, Royal College of Occupational Therapists, Royal College Mental Health Section, NW Neurodiversity Network, Chartered Society for Physiotherapists, NHS consulting path for LD and autism). This number is based on practical time constraints and discussion with the research team. We consider this to be an adequate sample for gaining input on the assessment and support options available. Across the networks and organisations, there are >40,000 members, but not all of these will work with autistic people. The survey will be open for up to 3 months and if we do not reach our target sample number, we will close the survey and analyse the collected data.

5.2.2 Sampling technique

Phase 1: Convenience (opportunity sampling) will be used. All eligible autistic participants at the two clinics will be asked if they would like to participate. The reason for this is to understand the take up rate of a SMD assessment so we can summarise the need for this assessment. Recruitment will take place over a 15 month interval.

Phase 2: Convenience (opportunity sampling) will be used through relevant mailing lists (see 5.2.1) as well as snowball sampling. This is to target the relevant sample group.

5.3 Recruitment

5.3.1 Sample identification

Phase 1

GMMH: Clinicians in NHS diagnostic autism clinics will make eligible patients aware of the project and gain verbal consent for a clinical studies officer (CSO, a member of the R&D team) to speak to the patient about the study, in person or by email (a preference will be noted). The CSO will approach the patient at their next appointment in the clinic, or by email, whichever is preferred. They will give details about the study (supported with the advert, participant information sheet and what to expect document). Interested individuals could then chose to contact the research team themselves or give written consent to contact. Personal details and medical information will not be shared between the clinicians and the clinical studies officer prior to consent being given by the potential participant to be contacted.

Project adverts will also be distributed and displayed at drop-in autism clinics and post diagnostic support groups. Members of the research team will present talks at post-diagnostic group sessions and hand out the advert. Potential participants will contact the research team to notify them of their interest or those patients who have given consent to contact will be contacted by the research team. Interested participants will be sent the Participant Information Sheet (PIS). If a potential participant does not respond to an email from the research team, a follow up email will be sent after 2 weeks. If there is still no response, no further emails will be sent.

Merseycare: Clinicians will make eligible patients aware of the project at a follow up/feedback session, held on a separate day to their diagnostic assessment appointment. They will give details about the study (supported with the advert, participant information sheet and what to expect document). Interested individuals could then chose to contact the research team themselves or give written consent to contact.

Based on PPI and research team input it was considered important that gaining study consent for contact occurred after the initial diagnostic appointments, to prevent patients feeling overwhelmed. People offered the assessment but who did not take it up will be recorded by the CSO/clinician in the consent to contact form. Those opting out will be given the opportunity to provide reasons for not taking part using sensitively worded questions, although it will be clear that they do not need to tell us. All details will be collected anonymously and it will be made clear that their ongoing care is not affected.

Phase 2
An advert will be posted to relevant clinical mailing lists (see 5.2.1) known by the research team. Participants will be able to click on the link to the survey and read the PIS. If they are happy to take part, they can then fill in the consent form and complete the survey.

5.3.2 Consent

Phase 1
Consent to contact will initially be collected by the clinicians/CSO or the participants can choose to contact the RA on the research team. The RA will contact those willing to take part in the study using their preferred contact preference (email, phone, video call) and confirm inclusion criteria and take consent. For consent, the RA will send the PIS, “what to expect document” and videos and give participants the chance to ask any questions. The "what to expect” document will contain photos of the rooms, and tests as well as hyperlinks to online videos. The videos will be created by the research team and demonstrate the different types of tests and activities that participants will be asked to do at each visit. The RA will ask whether participants would like the opportunity to discuss the study via video call/phone. Either via email or during the video call, the RA will briefly describe what will happen during the 2 visits, their right to withdraw at any stage without affecting their treatment, confidentiality and potential risks/benefits of participating. Participants will be directed to an electronic consent form in Qualtrics.

Once the participant has given consent, their contact details will then be passed to the Occupational Therapists on the team who will arrange visit 1. Participants will be sent a reminder email 2 days prior to their scheduled visit 1 and visit 2. Assessment of capacity will be performed by the Occupational Therapists at visit 1 by asking the patient to summarise the study purpose, their involvement and benefits/risks. Willingness to continue participation will be checked by the Occupational Therapists at visit 1 and 2.

Phase 2

Once they have clicked on the link to the survey, participants will read the PIS, then if they are happy to take part, complete the consent form. They will have the opportunity to contact the RA if they have any questions, prior to taking part.

6 ETHICAL AND REGULATORY CONSIDERATIONS

6.1 Assessment and management of risk

Risks to participants

Phase 1

- Participant findings requiring further investigation: During the assessment the OT may notice signs that require investigations (e.g signs associated with neurological or musculoskeletal conditions). In such a case, the OT will refer the participant to their GP which will be detailed in the PIS.

- Potential for participants to reveal current or future illegal activities or for researcher to we have concerns about participant's safety or the safety of others. There is a low risk of this occurring. In such a case the OT/researcher would need to inform the relevant authorities. Participants are informed about this in the PIS and there is an item on the consent form.

- Participant inconvenience: Participants will need to attend two visits - an initial assessment visit ~2-3 hours and a follow up visit of 1 hour. These will be clearly stated in the PIS. A choice of locations for the assessment and follow-up visit will be provided to facilitate participation and clear guidance on how to get to the location provided. To minimise inconvenience and stress they will have the option to book the visits on days which are most suitable for them. There will also be different time options from which participants can choose to attend for their visits. These will be within the normal opening hours of NHS clinics.

- Participants may become fatigued during visit 1 or 2. The clinician will be mindful of these with regular breaks planned at particular points during the visit. They will also remind the participant that the can ask for a break at any time. The EASI assessment is a validated non invasive assessment tool that is frequently used by OTs.

- Potential for participants to become distressed or frustrated during the examination if upsetting topics arise or they cannot do some of the tasks: Participants will be given the option of a break if they feel overwhelmed. Prior and during each test participants will be instructed to try their best but not to worry if they are unable to do some tasks. If any participants continue to be distressed, a distress policy will be actioned (attached).

Phase 2

- Inconvenience: For the survey participants, there will be inconvenience of time. It will be clearly stated in the PIS how long the survey is likely to take so that they can decide whether they have the time to complete it.

- Coercion: Information about the study will be advertised via clinical mailing lists. If individuals know study team members they may feel obliged to take part. However, this is mitigated through the survey being anonymous.

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

- Before the start of the study, a favourable opinion will be sought from the NHS REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.
- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An 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.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

- Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place and that the site has issued confirmation of capacity and capability to support study.
- For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

In the case of an amendment, the PI will submit a valid notice of amendment of the REC and will decide (in conjunction with relevant team members) whether it constitutes a minor or major amendment. The PI will communicate with the relevant stakeholders (clinicians, team members, R & D) about the amendment. The most recent protocol version will be tracked through version and date numbers.

Safety reporting

A Standard Operating Procedure (SOP) for monitoring and reporting Adverse Events will be followed. The SOP will ensure that Adverse Events are monitored and reported throughout the study in line with sponsor (GMMH) policies and local site reporting systems for Severe Adverse Events (SAEs). Any unlikely events occurring in research context will be reported to both Trust site and GMMH research offices. Trust site reporting will be carried out through a local incident reporting system. GMMH reporting will be carried out by emailing the GMMH R&I office. SAEs will be reported to GMMH and Trust site. Trust site Medical Electronic records will be used to record research related information, including consent, in line with their SOPs.

6.3 Peer review

The study team and sponsor have reviewed this protocol.

6.4 Patient & Public Involvement

Development of the project

Autistic members of the research team, PB (PPIE Co-I) and GH (PPIE collaborator) have commented on the funding application, advising on recruitment and inclusion strategies, assessment processes and suggesting changes to aid clarity. The Autism@Manchester expert by experience advisory group (consisting of ~15 autistic people and family members) have confirmed the importance of topic, the need for personalised support and the importance of identifying SMD as a cause of mental health or social issues, as well as highlighting the current lack of assessment and support.

Current and Future involvement

We will work closely with two autistic individuals – PB and GH throughout the project as well as obtain advice from the Autism@Manchester expert by experience group, enabling in-depth co-production as well as seeking involvement from a broader range of autistic people.

PPI activities include:

- PB and GH to attend team meetings and workshops to discuss research protocol, data analysis, provide context to findings, co-produce the toolkit and advise on dissemination. They will also test out study material, assessment and follow up visit procedures to advise on modifications.
- Consulting the virtual and face to face Expert by Experience group at the start and end of the project to obtain advice on recruitment and retention, outcome measures, participant facing material, dissemination.
- Participants in current study will have the option to become involved in PPI at the next step.

PPI co-leads EG and EP will link the PPI members with the rest of the team, providing summary updates every 3 months. Evaluation will be conducted by the co-leads. They will compile a shared co-production log to record comments from meetings/emails, suggested changes on documents and actions (or reasons for no-action). These notes will be used to feedback to the PPI contributors, as is done for the Expert by Experience groups and to complete the GRIPP2 reporting checklist.

7.0 DATA STORAGE AND PATIENT CONFIDENTIALITY

Phase 1

Paper copies of the EASI assessment forms, data collection forms and surveys will be scanned onto the OTs Mersey Care OneDrive, then shredded. If paper copies need to be stored prior to scanning, they will be stored in locked filing cabinets within Merseycare premises. These documents, together with the OTs report would then be emailed by the OTs to the study RA using NHS email encryption. Documents that are purely research related will be deleted off OneDrive while the assessment reports will be either be added to the participants patient records on the Rio electronic patient record system (for Merseycare participants) or sent to the participants GP (GMMH participants) and deleted off OneDrive. The report will only be added to the patient record system/send to the GP with written consent from the participant.

The transferred data would be stored on a NHS secure drive and deleted from email accounts. Participants data will be pseudo-anonymised so that each participant is given a number. The linkage file will be encrypted and stored in a separate folder to the other study files and only the study team (RA, PI and Georgia Fair) will have access to this file. Consent to contact forms will be stored in locked filing cabinets at GMMH and Merseycare premises and routinely collected by the RA or scanned and emailed to the RA by NHS email encryption. Paper copies will be scanned, uploaded to the NHS secure drive, then shredded. Study consent forms downloaded from Qualtrics will be stored on the NHS secure drive and deleted from Qualtrics.

Phase 2

In phase 2, anonymous survey data will be collected by Qualtrics which is a University approved platform. It will be downloaded onto the NHS secure drive and deleted from Qualtrics within 2 weeks.

Across phases

Only members of the study team will have access to the data files on the NHS secure drive. The RA and team members will work directly on this drive. Data will be stored for 10 years following the end of the study. Consent forms will be retained for 5 years. The PI is the data custodian.

Other non-sensitive documents (e.g. protocols, blank ethics documents) will also be stored on a study onedrive and the University of Manchester Research Data Storage area.

8 DISSEMINIATION POLICY

8.1 Dissemination policy

- The data is owned by the study sponsor – GMMH (on a non-restrictive licence). On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared. NIHR RfPB will be acknowledged in publications/presentations. Relevant summaries and publications will be added to the study website.
- The project is relevant for autistic individuals and their family members and clinicians and researchers involved in diagnosing and supporting autistic people. This includes OTs, Clinical Psychologists, Psychiatrists, Nurses, Physiotherapists and Speech and Language Therapists.
- Findings will be disseminated via mailing lists and social media channels (e.g. Autism@Manchester, Salfordautism support group, UK charity Autistica) reaching clinicians, researchers and autistic individuals. The results will be discussed with the Autism@Manchester Expert by Experience group who will advise on the impact to the autistic community, dissemination strategies and implementation of the next stage. For phase 2, a lay summary will be sent round the clinical mailing lists.
- The project will be presented to the involved Trusts and the Northwest Neurodiversity network consisting of clinicians working with autistic adults and disseminated to the Chartered Society of Physiotherapy and clinical mailing lists within the research team. Findings will also be presented at autism and clinical conferences (e.g. National Autistic Society, Autism Today, Royal College of OTs/Psychiatrists annual conference, Translation@Manchester) as well as submitted for publication (e.g. Autism in Adulthood, Autism or British Journal of OT).
- We envisage that some OTs may use the toolkit and can begin providing us with informal feedback via a survey on the toolkit website so we can continue to refine the toolkit.
- NHS England are investing in developing consultants in LD and/or autism and we will present at the NHS England Centre for Advancing Practice conference to access all the consultants. We will also promote our results through our NIHR Applied Research Collaborations Greater Manchester to reach a broader range of academics, patient groups and health professionals.
- During recruitment in phase 1, participants can optionally consent to receiving a lay summary of the research findings at the end of the study which will also contain links to any publications. In addition, they will be provided with a debrief document containing details about Autism@Manchester and how to join the mailing list and social media channels. If they choose to join these, they will receive the biannual Autism@Manchester newsletter which will also contain a summary of the study and will be kept informed of wider autism research, events and further involvement opportunities at The University of Manchester and affiliated Universities.
- The study report, anonymised participant level data set and any statistical code will be made openly available using Open Science Framework once the results have been published.

8.2 Authorship eligibility guidelines and any intended use of professional writers

All research team members will contribute and be authors on the final study report and associated publications. Order of authorship will be discussed during preparation of each paper.

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	Study management
	Milestone
	Phase 1 activities
	Phase 2 activities
	PPI activities
	Dissemination

APPENDICIES

9.1 Gantt chart

Activity/Month	1 to 4	5 to 8	9 to 12	13 to 16	17 to 20	21 to 24
Ethics submission and approval						
Assessment protocol, data collection forms finalised						
Recruitment setup						
Team meetings	1 &2		3			4
PPI activities	Expert group		Discussion of emerging findings			Expert group
Milestone 1: Data collection start						
Phase 1: Data collection						
Milestone 2: Data collection end						
Objective 1 & 2 analysis						
Milestone 3: Objective 1 & 2 analysis complete						
Phase 2: Workshops and survey						
Milestone 4: Completion of workshops and survey						
Objective 3 analysis and collation of materials						
Milestone 5: Objective 3 Toolkit compete						
Milestone 6: PPI evaluation complete						
Dissemination						