

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

Submission date 06/08/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Autism is a naturally occurring, largely genetic condition that affects how that person understands their environment and interacts with other people, with around 1-1.5% of people diagnosed in the UK. Sensory and motor difficulties (SMD), such as hypersensitivity to sound and light, and difficulties with carrying out physical movements, occur in ~80% of autistic people. SMD can cause significant problems with day-to-day tasks, such as getting dressed, eating and maintaining employment – often leading to anxiety, depression, fatigue, a restricted lifestyle and reduced quality of life. Despite the serious impact of SMD, autistic adults do not receive routine assessment and support for their SMD unless they also have a diagnosed Learning Disability (LD), which is usually picked up in early childhood and supported accordingly. This study aims to show the need for routine SMD assessments and treatment for autistic people without LD and what kinds of support would help, leading towards an innovative new SMD pathway. The study will start by showing what proportion of autistic adults that do not have a LD need SMD support and how many are likely to take this up.

Who can participate?

Autistic adults aged 18 years old and over

What does the study involve?

Participants will be recruited via autism diagnostic clinics to receive an SMD assessment (involving tasks such as positioning one's own body) and a follow-up appointment with a specialist clinician. These will show how many patients offered the assessment wanted to be assessed, the range of their SMD and what types of support were useful. Second, information will be collected on what the volunteers thought about the assessment and how they benefitted, this will help plan how to test the new pathway. Third, workshops with the research team and a survey of clinicians will identify which of the assessments and support options should be included in the pathway.

Patient and Public Involvement and sharing our findings

Previous work with autistic people confirmed the importance of but lack of SMD assessment and support and guided our decisions around recruitment and assessment to maximise benefit for volunteers. This project will be co-produced with two autistic team members who will attend

team meetings and workshops. Advice will also be sought from ~15 members of the Autism@Manchester Expert by Experience advisory group and implemented where practicable. Participants will benefit immediately by acquiring greater personal awareness and understanding, together with recommendations to help manage their SMD. The longer-term goal of introducing an SMD pathway is to improve the quality of life for autistic people. Blogs and presentations about the findings will be shared with autistic people and clinicians through Autism@Manchester, support groups, charities, NHS trusts and related social media. The study team will reach professionals via conferences and publications.

What are the possible benefits and risks of participating?

Where is the study run from?

Autism clinics at Greater Manchester Mental Health (GMMH) and MerseyCare NHS trusts

When is the study starting and how long is it expected to run for?

April 2024 to March 2026

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme

Who is the main contact?

Dr Emma Gowen, emma.gowen@manchester.ac.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

330960

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

X730, IRAS 330960, NIHR206138, CPMS 57232

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/08/2024, North West - Greater Manchester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; gmcentral.rec@hra.nhs.uk), ref: 24/NW/0157

Study design

Non-randomized cross-sectional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Diagnostic, Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Sensory motor conditions in autistic people

Interventions

For phase 1, consented autistic participants will be offered the Evaluation in Ayres Sensory Integration (EASI) assessment. Study OTs will collect demographics, perform the EASI, the Occupational Circumstances Interview and complete assessment reports detailing any need for sensory motor support (Objective 1) and specific support recommendations. Participants will receive a report detailing any sensory-motor difficulties and any support recommendations.

Within 2 weeks of this first visit, participants will be sent an online survey asking about their experience of the assessment, using an acceptability survey and bespoke questions. This has the benefit of (a) participants being more likely to remember the assessment and (b) maintaining engagement in the study.

Participants will have a 1-hour follow-up appointment ~6 weeks after receiving the report for the clinician to 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 of 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 for evaluation in future studies.

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. A second workshop with the research team will involve a 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. 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 allow everyone to raise issues. The scoring stage will only be conducted after workshop 2 using an online private Likert scale form for each individual.

Intervention Type

Behavioural

Primary outcome measure

Evidence on the level of need for sensory and motor difficulties (SMD) assessment in autistic adults without LD will be measured using the % of autistic adults without LD who are willing to take up an SMD assessment and the % of these that are identified as needing support following assessment recorded in study data at one time point

Secondary outcome measures

1. Proof of concept and feasibility measured using open-ended qualitative survey items and Quality of life (European Quality of Life 5 Dimensions 5 Level Version) to facilitate future development and evaluation of the toolkit and pathway at one time point
2. 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 enabled and measured using study data at one time point

Overall study start date

01/04/2024

Completion date

31/03/2026

Eligibility

Key inclusion criteria

Phase 1:

1. Diagnosis of an Autism Spectrum condition without a Learning Disability (LD)
2. >18 years without LD
3. Presenting at participating adult autism diagnostic clinics (GMMH and Merseycare)

Phase 2:

1. Clinicians who assess and support autistic adults with sensory motor needs
2. Able to understand written English and access the internet
3. >18 years of age

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Phase 1: 110; Phase 2: 100

Key exclusion criteria

Phase 1:

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

Phase 2:

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

Date of first enrolment

01/10/2024

Date of final enrolment

30/11/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Greater Manchester Mental Health NHS Foundation Trust

Prestwich Hospital

Bury New Road

Prestwich

Manchester

United Kingdom

M25 3BL

Study participating centre

Merseycare NHS Trust

V7 Building

Kings Business Park

Prescot

United Kingdom

L34 1PJ

Sponsor information**Organisation**

Greater Manchester Mental Health NHS Foundation Trust

Sponsor details

Harrop House Bury New Road

Prestwich,

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England

United Kingdom

M25 3BL

+44 (0)161 271 0722

researchoffice@gmmh.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.gmmh.nhs.uk//>

ROR

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. 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.
2. 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.
3. 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.
4. 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).
5. 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.
6. 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.
7. 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.
8. 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.

Intention to publish date

01/04/2027

Individual participant data (IPD) sharing plan

The study report, anonymised participant-level data set and any statistical code will be made openly available using Open Science Framework (<https://osf.io/>) once the results have been published.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	04/04/2024	08/08/2024	No	No