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Evaluating a strengths and needs assessment for autistic adults

Submission date
04/02/2025

Recruitment status
No longer recruiting

Registration date
05/02/2025

Overall study status
Completed

Last Edited
10/03/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
A diagnosis of Autism in itself does not provide enough information to plan appropriate post-diagnostic support. Autistic adults want to know what their diagnosis means for them and to have an easy way to communicate their strengths and needs to others, such as employers or educators. This study will test whether a Strengths and Needs Assessment for autistic adults, based on the World Health Organisation's International Classification of Functioning Disability and Health (ICF) could be used in diagnostic settings to help manage post-diagnostic support. The ICF assessment asks about personal abilities, day-to-day activities and things in the environment that may help or hinder everyday life. At the end of the assessment, a personalised report is produced. The study will collect data about how usable and acceptable the assessment and report are. The study team will also talk to clinicians and autistic service users to see whether it would be feasible and acceptable to use this assessment in NHS clinical settings.

Who can participate?
1. Autistic adults (aged 18 years and older) who have received their autism diagnosis from one of the participating diagnostic settings within the previous four weeks.
2. Clinicians involved in the study at each clinical site.

What does the study involve?
Diagnostic clinicians will pass on information about the study to service users when they receive their autism diagnosis. Participants will then have four weeks to read this information and decide whether to take part in the study. Once registered for the study, participants will complete a short questionnaire asking for demographic information (e.g., gender, age, ethnicity) and will be randomly allotted into either the intervention group or the treatment-as-usual group. This will be done using a method which will ensure that groups are balanced in terms of demographic characteristics (i.e., age, gender, ethnicity). The study aims to recruit 72 autistic adults who have been recently diagnosed (within the previous four weeks) across three NHS diagnostic services (Sheffield Adult Autism and Neurodevelopmental Service, Leeds Autism Diagnostic Service, Cambridgeshire Lifespan Autism Spectrum Service). Of these people, 36 will be allocated to the intervention group and will be asked to complete the Strengths and Needs Assessment, standardised questionnaires (mental health and quality of life) and continue with their standard post-diagnostic care. Another 36 will be allocated into the treatment-as-usual

group and will be asked to complete standardised questionnaires (mental health and quality of life) and continue with their standard post-diagnostic care. Questionnaires will be completed at baseline (timepoint 1) and three months later (timepoint 2).

A subsample of participants will be invited to an interview after timepoint 2 where they will ask about what participants thought about the trial procedure (intervention and treatment as usual groups), their experiences of post-diagnostic support, and what they did and did not find helpful about the Strengths and Needs Assessment (intervention group only). Clinicians will also be asked what they thought about the trial procedure in a focus group held at the end of the data collection period. If the trial procedure and assessment are considered acceptable to autistic adults and clinicians in this small-scale trial, this may be used to plan a large-scale trial of the Strengths and Needs Assessment.

What are the possible benefits and risks of participating?
Benefits:
The Strengths and Needs Assessment has the potential to significantly improve post-diagnostic support for autistic adults, through enabling self-management and tailored service provision via the administration of a standardised assessment. By taking part in the study, participants and clinicians will be able to provide feedback on the assessment and the feasibility of using it as part of post-diagnostic support. Participants who complete the assessment (intervention group only) will receive a summary report which highlights areas of strengths and needs in their day-to-day lives which they may find useful for planning support. All participants in the study will be compensated for their time in completing study measures.

Risks:
The post-diagnostic period may be an overwhelming time for autistic adults. Therefore, participants are given 4 weeks to consider the information provided about the study before deciding whether they would like to take part. Some participants could also find answering questions about their strengths and needs, or mental health and quality of life, stressful. To mitigate this, they will be provided information about the content of these assessments so that participants are prepared for the types of questions asked. They will also be signposted to appropriate resources and support after completing the assessments. Completing the questionnaires may take some time (especially for the intervention group) which may lead to inconvenience and feel burdensome. However, participants will be able to complete the assessments at a time which is convenient for them and can complete them in as many chunks as they would like. Participants will be given up to 2 weeks to complete the assessments and they will be able to take breaks and pick up where they left off.

Participants who are allocated to the treatment-as-usual group may feel disappointed at not receiving the Strengths and Needs Assessment. The study team will ensure that the information provided to participants explains the importance of having this non-intervention group to prepare participants for this possibility.

A subsample of participants will be invited to take part in an interview. There will be no obligation to take part in the interview and consent to participate in this part of the study will be taken separately from participation in the main study. To mitigate any stress associated with being interviewed, participants will be provided with the questions before the interview so they can prepare their answers if they would like to. They will also be offered the choice of whether they would prefer to have their interview online or in-person and these will be done at a time which is convenient to participants. Participants will also be able to bring a friend, supporter or relative to the interview if they would like to.

Where is the study run from?
The University of Sheffield, in collaboration with 3 study sites (NHS Autism Diagnostic Centres in Leeds, Sheffield and Cambridge). The research team includes other researchers from the University of Sheffield, an Autistic advisor, and a steering group of Autistic adults. The study is sponsored by Sheffield Health and Social Care NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
April 2025 to December 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme

Who are the main contacts?
1. Professor Megan Freeth (The University of Sheffield; Principal Investigator), m.freeth@sheffield.ac.uk
2. Dr Marianne Day (The University of Sheffield, Research Associate), marianne.r.day@sheffield.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
350522

Central Portfolio Management System (CPMS)
66984

National Institute for Health and Care Research (NIHR)
206579

Study information

Scientific Title
Evaluating a standardised post-diagnostic strengths and needs assessment for autistic adults: an acceptability and feasibility study

Study objectives
The study objectives are to assess the acceptability and feasibility of the Strengths and Needs Assessment as a clinical tool for use in the immediate post-diagnostic period by autistic adults and clinicians within NHS adult Autism diagnostic services. This is in preparation for a pragmatic RCT, and this study will pilot the study design and methods to be used in the larger-scale RCT.
The research questions are:
Are the proposed recruitment, randomisation, and data collection methods acceptable and feasible for use within NHS adult Autism diagnostic services?
Is the Strengths and Needs Assessment acceptable for use by autistic adults after receiving an autism diagnosis?
What are the potential benefits or harms of completing the Strengths and Needs Assessment?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/03/2025, East Midlands - Nottingham 2 Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8009; nottingham2.rec@hra.nhs.uk), ref: 25/EM/0041

Primary study design
Interventional

Study design
Multicentre interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-diagnostic support for autistic adults

Interventions
Autistic participants will be recruited via information sheets provided to them at their diagnostic appointments in three clinical settings. Autistic participants will follow these steps:
1. After reading the study information and having the opportunity to ask questions, participants will complete an online form to register their interest in the study and provide contact details.
2. Participants will then be asked to complete a short demographic questionnaire which will also ask participants to confirm when and where they received their diagnosis.
3. Participants will then be randomised into the intervention group or the treatment as usual group and will be informed about which group they have been assigned to.
4. The intervention and treatment as usual groups will be asked to complete baseline measures of mental health and quality of life. These questionnaires will be hosted online and will take around 10-15 minutes to complete.
5. The intervention group will then be asked to complete the Strengths and Needs assessment. This will be via an online link which will be emailed to participants. The Strengths and Needs Assessment has 253 items which ask participants to rate their functioning in body functions, activity and participation and also about environmental factors which may help or hinder functioning. In previous studies, completion of the Strengths and Needs Assessment has taken between 20-60 minutes and largely depends on how long participants spend leaving additional comments. The assessment can be completed over 2 weeks. If a participant wishes to take a break the assessment auto-saves and the participant can pick up where they left off at a later time. Participants will also be asked about the acceptability and usability of the assessment. Following completion, participants will be sent a summary report by the research team which will highlight some areas of strength and some areas where people may benefit from support (needs).
6. The intervention and treatment as usual groups will be asked to complete follow-up measures of mental health and quality of life at 3 months following baseline. These are identical to their baseline measures and are hosted online.
7. A subgroup of participants from the intervention and treatment as usual groups will be invited to take part in an interview with a researcher. These interviews may be online or in-person at a time and place convenient to participants. Interviews will take around half an hour and will be recorded and transcribed. Interviews will cover the acceptability of the study procedures and the Strengths and Needs assessment (intervention group only), any benefits or adverse events arising from taking part in the study, and experiences of post-diagnostic support.

Participating clinicians will be informed about procedures for providing information and recording information distribution by the research team at a site meeting before data collection. Following this they will be asked to:
1. Give a short description of the study at each diagnostic appointment and pass on an information leaflet to potential participants. They will explain to service users that they will have 4 weeks to decide whether they would like to participate and record serial numbers of leaflets which have been distributed at these appointments.
2. Following the data collection period, clinicians will be invited to a focus group which will explore the acceptability and feasibility of the study procedures, the perceived benefit of using the Strengths and Needs in diagnostic settings, any adverse events experienced during the study and barriers to implementation. The focus group will last for around one hour and will be recorded and transcribed.

Intervention Type

Other

Primary outcome(s)
The primary outcome measures will be the acceptability and feasibility of the Strengths and Needs Assessment. These will be measured immediately following completion of the Strengths and Needs Assessment at baseline and will be completed by the Intervention group only.
1. Acceptability of the Strengths and Needs Assessment will be measured using one item from the Theoretical Framework of Acceptability.
2. Usability of the assessment will be measured using the System Usability Scale total score.
Feasibility of study procedures will be measured for both groups (Intervention and Treatment as Usual) using participant eligibility rates; recruitment rates; attrition; and reporting of any potential benefits and harms. This will be supplemented with qualitative feedback from semi-structured interviews with a sub-sample of autistic participants and focus groups of clinicians.

Key secondary outcome(s)
The following secondary outcome measures are mental health and quality of life measures that are assessed at baseline and 3-month follow-up:
1. The EuroQol 5-level EQ-5D (EQ-5D-5L) is a widely used tool to measure health-related quality of life (HRQoL). It assesses individuals' perceptions of their health status across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.
2. The PHQ-9 (Patient Health Questionnaire-9) is a widely used self-report questionnaire designed to assess the severity of depression symptoms. It is a brief, nine-item tool that asks individuals to rate the frequency of various depressive symptoms they have experienced in the past two weeks.
3. The GAD-7 (Generalized Anxiety Disorder 7-item scale) is a widely used self-report questionnaire designed to screen for and assess the severity of generalized anxiety disorder (GAD).
4. The ReQoL-10 (Recovering Quality of Life-10) is a self-report questionnaire designed to measure individuals' perceptions of their mental health recovery. It focuses on key aspects of recovery, such as hope, connectedness, and personal growth.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Adults (18 years and older).
2. Diagnosed with autism at one of the 3 study sites during the duration of the study data collection period.
3. No diagnosis of a co-occurring learning disability.
4. English speaker with adequate language proficiency to complete the Strengths and Needs assessment.
5. Clinicians at the 3 study sites who are involved in the study (i.e., clinicians who provide information about the study to potential participants, and study site leads).

Participant type(s)
Health professional, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Aged 17 years or younger.
2. Participants with no formal diagnosis of autism.
3. Participants who received their diagnosis before the period of the study or from another diagnostic service.
4. Unable to consent or to complete the Strengths and Needs assessment.
5. Participants who have a diagnosis of a co-occurring learning disability.

Date of first enrolment
01/04/2025

Date of final enrolment
30/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridgeshire Lifespan Autism Spectrum Service (CLASS)
Chitra Sethia Centre,
Fulbourn
Cambridge
England
CB21 5EF

Study participating centre

Leeds Autism Diagnostic Service (LADS)
Aire Court,
Lingwell Grove
Leeds
England
LS10 4BS

Study participating centre
Sheffield Adult Autism Neurodevelopmental Service (SAANS)
77 Osborne Road
Sheffield
England
S11 9BJ

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The anonymised datasets created and analysed in this study will be stored in the University of Sheffield's online data repository (ORDA) and will be available for other researchers to use. No personal data will be stored in these datasets. Demographic, interview and focus group data will not be stored to ensure participant confidentiality. Data from the Strengths and Needs assessment will not be stored as it is still under development and cannot be publicly shared.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/03/2026	10/03/2026	Yes	No
Participant information sheet			04/02/2025	No	Yes
Protocol (preprint)		07/04/2025	17/04/2025	No	No