The Feasibility of Therapeutic Assessment and Neuro-Divergence Assessment (TANDA): Study Protocol

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PROTOCOL SUMMARY

This feasibility study explores the integration of rapid neurodevelopmental Structured Professional Judgement tools (ESSENCE-D and NEURO-Obs assessment) with Therapeutic Assessment (TA) in crisis services for children and young people (CYP). The study will assess the feasibility, acceptability, and implementation of this rapid identification model, aiming to inform a future multicentre Randomised Controlled Trial (RCT).

GLOSSARY OF ABBREVIATIONS

- TA – Therapeutic Assessment
- CYP – Children and Young People
- CAMHS – Child and Adolescent Mental Health Services
- CUAIT- CAMHS Urgent and Acute Intervention Team
- ESSENCE-D – Early Symptomatic Syndromes Eliciting Neurodevelopmental Examination – Diagnostic Aide
- NEURO-Obs – Neurodevelopmental Evaluation through Unscripted Relational Observation Schedule
- NDS – Neurodevelopmental Service
- NHS – National Health Service
- RCT – Randomised Controlled Trial
- SPJ – Structured Professional Judgement

TRIAL PERSONNEL

- Principle Investigator: Dr. Jason Lang
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INTRODUCTION

Children and young people (CYP) who are neurodivergent frequently experience significant additional mental health challenges. Such co-occurrence and overlap often complicate clinical presentations, may decrease quality of life, and increase the demand for mental health services (Byrne et al., 2023). Failure to recognise complexity and underlying neurodivergence, along with other socio-demographic factors in this group, may also compromise clinical care effectiveness (Miller et al., 2023). Many CYP wait for long periods to have their underlying neurodivergence identified (Crane et al., 2015). The integration of early, targeted neurodevelopmental identification into crisis care pathways could offer an effective approach to improving outcomes for this population.

Therapeutic Assessment

Therapeutic Assessment (TA), created by Professor Dennis Ougrin, is a novel model designed for assessing young people who self-harm. It integrates therapeutic intervention with assessment and formulation to improve patient engagement and outcomes. The approach is pragmatic, evidence-based, and aims to enhance the willingness of patients to engage in further therapy by providing immediate therapeutic intervention during distressing times (Ougrin et al., 2009).

Rapid Neurodevelopmental Assessment

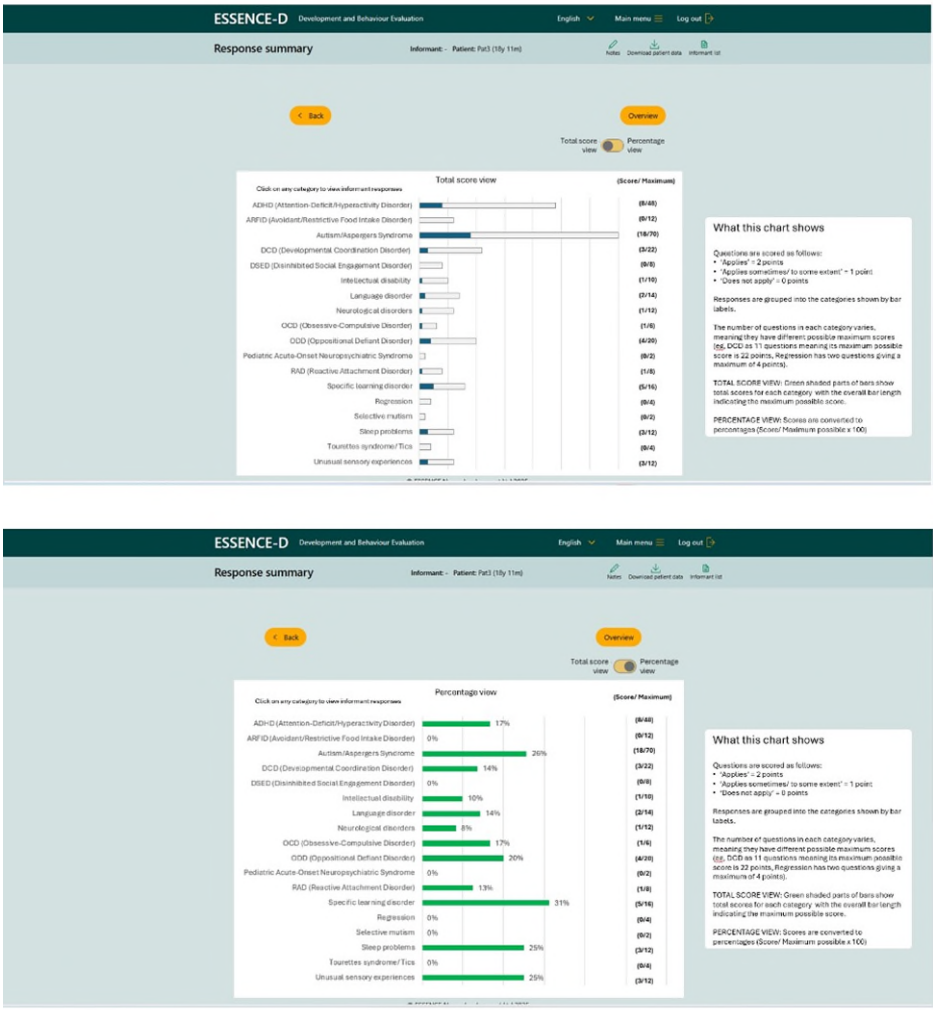
Tools for improving the practicality, reliability and holistic nature of neurodevelopmental assessment are currently being developed. NEURO-Obs (Neurodevelopmental Evaluation through Unscripted Relational Observation Schedule) is a newly developed structured professional judgement (SPJ) tool undertaken by experienced clinicians who interact with the CYP in a relational manner. SPJ tools structure the decision-making process from gathering information and observation and are founded in decision theory.
They do not rely on equaltions, formulas or algorthyms. The augment rather than replace the clinical judgement of the professional (Douglas et al., 2014).

NEUROObs is conversational and play or activity based and involves clinicians skilfully observing traits of neurodivergence in the CYP. These traits may manifest in a number of areas such as motor, language, social and sensory domains. Unlike more established observation tools, NEURO-Obs considers traits across the breadth of neurodivergence, rather than looking at specific traits of individual neurotypes. In turn, this may reduce the time taken to complete assessments, resulting in more rapid outcomes and identification for CYP and their families, along with the potential to reduce waiting lists more generally.

The ESSENCE-D (Early Symptomatic Syndromes Eliciting Neurodevelopmental Clinical Examinations - Diagnostic Aide) is a SPJ digital tool designed to facilitate the early identification and assessment of neurodevelopmental differences in children and young people. It collects comprehensive developmental information from caregivers, using an secure online interface, focusing on key domains such as communication, social interaction, motor skills, attention, and executive functioning. The full version of the tool categorises findings into “Likely” and “Highly Likely” neurodevelopmental profiles, assisting clinicians in formulating a holistic understanding of a young person’s strengths and support needs. The

categorisation is designed to help clinicians think about areas of need. It is not diagnostic and clinicians must continue to use their clinical judgement and multi-informant assessment in line with good clinical practice. However, this functionality results in the ESSENCE-D being classified as a medical device by the MHRA. While the ESSENCE-D is currently undergoing MHRA validation, this process is not yet complete. Therefore, for the purposes of this study, we will use a version of the ESSENCE-D which does not have the algorthim activated. This is referred to as the NA ESSENCE-D (Non Algorthim). Essentially this will mean that the ESSENCE-D acts only as an online questionnaire. The clinician will see only raw questionnaire scores and a histogram of the number of questions answered "never", "sometimes", or "always" by the caregiver (see Figure 1). The clinician will be able to review the answers given by the caregiver to check that the score and histogram are correct.

Figure 1: The clinician's view of results from the NA ESSENCE D Questionnaire.



ESSENCE-D may be particularly valuable in streamlining assessments within time-constrained clinical settings, making it a useful addition to crisis care pathways. To date, the tool has been found to be acceptable to parents and carers. Preliminary evidence from a small Test of

Change, in one Scottish health board, also suggested that it helped clinicians to make decisions about the most appropriate next steps and which clinicians need to be involved in these (promoting a holistic joined up approach). ESSENCE-D is currently undergoing a separate international RCT to establish its effectiveness in reducing time to diagnosis.

ESSENCE-D is operated and licenced by Malvern-i. Intellectual property is shared between the Universities of Gothenburg, Glasgow and Malvern-i. NHS Ayrshire and Arran will have a licence which provides freedom to operate the NA ESSENCE-D in relation to this specific trial. The platform meets or exceeds current security requirements. Malvern-i. are the data processor and NHS Ayrshire and Arran, along with the University of Glasgow, are the joint data controllers. Malvern-i will not have access to any patient data.

Prevalence of Mental Health Conditions in Neurodivergent CYP

Approximately 70% of autistic children meet the criteria for at least one psychiatric condition, and 41% have two or more (Mandy, 2022). Another study found that 77.7% of autistic children have at least one mental health condition, with 49.1% experiencing two or more(Kerns et al., 2020). The most prevalent mental health conditions among autistic children include behavioural/conduct difficulties (60.8%), anxiety (39.5%), ADHD (48.4%), and depression (15.7%)(M. Lai et al., 2019).

The risk of mental health challenges in autistic children increases with age. While 44.8% of children aged 3-5 years have at least one mental health condition, this figure rises to 85.9% in those aged 12-17 years (Kerns et al., 2020). Additionally, autistic girls tend to experience higher levels of anxiety and other mental health concerns compared to autistic boys (Malow et al., 2023), (Wright et al., 2023).

Children with ADHD also have a high prevalence of mental health conditions. Anxiety disorders are among the most common, with some studies reporting prevalence rates as high as 37.9% (Mohammadi et al., 2019). Children with ADHD who are also autistic are at even greater risk for anxiety disorders (Casseus et al., 2023), (Hansen et al., 2018).

Behavioural and conduct difficulties, including oppositional defiant disorder (ODD) and conduct disorder, are frequently observed in children with ADHD. ODD is reported in approximately 26.1% of cases, with conduct disorders being more common in boys (Mohammadi et al., 2019) (Larson et al., 2011). Mood disorders, including depression, affect an estimated 14% of children with ADHD (Larson et al., 2011), with older children and adolescents at greater risk (Hansen et al., 2018). Learning disabilities are also highly prevalent, affecting approximately 46% of children with ADHD compared to only 5% of children without ADHD (Yang et al., 2022).

Speech, language and communication needs (SCLN) are also highly prevalent in young people with mental health challenges, yet these often go unrecognised (McCool et al., 2024), which can further contribute to therapy breakdown and disengagement. Although the relationship between SLCN and mental health conditions is complex and intertwined,

there is professional consensus that the co-occurrence impacts individuals' abilities to engage in standardised interventions (Hancock et al., 2022).

Neurodivergent people can also experience language and communication differences and given the above highlighted association between neurodivergence and mental health challenges, communication support needs are a salient factor that must be considered at the outset for this population.

Self-Harm and Suicide in Autistic and ADHD Populations

Self-harm and suicidal behaviours occur at significantly higher rates among autistic children compared to non-autistic peers. Studies indicate that prevalence rates of self-harm and suicidal behaviours in autistic children under 18 range from 7% to 73% (Oliphant et al., 2020) (Oliphant et al., 2021). Perceived social communication differences is a significant risk factor for self-harm with suicidal intent, suicidal thoughts, and plans by age 16 (Culpin et al., 2017).

Psychiatric conditions further increase the risk of self-harm and suicide in autistic individuals (M.-C. Lai et al., 2023). Depression in early adolescence plays a critical role in the relationship between social communication differences and self-harm in autistic children (Culpin et al., 2017). Additionally, genetic predispositions and childhood trauma may contribute to these vulnerabilities (Warrier & Baron-Cohen, 2019), (M.-C. Lai et al., 2023). Autistic girls face an even higher risk of self-harm and suicidal behaviours compared to autistic boys, with specific behaviours like self-cutting being more common (Hull et al., 2024), (Meza et al., 2020).

Children with ADHD also have an elevated risk of self-harm, with an odds ratio of 3.3 compared to neurotypical peers (Curtis, 2022). This risk is particularly pronounced in girls and is often linked to early externalising symptoms and adverse childhood experiences (Meza et al., 2020). There may be an additive risk conveyed by reduced inhibition and increased impulsiveness in this population.

Much of the research explored above relates only to presentations autism and ADHD. It is likely that the wider neurodivergent population, including neurotypes included in the ESSENCE framework (Gillberg, 2010) may also experience these disparities in mental wellness. Previous research has also demonstrated that co-occurrence and overlap between neurodivergent neurotypes in CYP is high (Lang et al., 2024).

Rationale for the Present Study

The increased presence of multiple mental health challenges in neurodivergent childhood populations suggests that CYP presenting to crisis services may benefit from an integrated approach that allows for rapid neurodevelopmental assessment following therapeutic intervention to improve their immediate and long-term outcomes.

It is critical to explore feasible, scalable models of assessment and intervention that can be embedded within existing crisis care pathways. This study seeks to evaluate the feasibility of implementing the TANDA model, which combines Therapeutic Assessment (TA) with rapid

neurodevelopmental SPJ tools (ESSENCE-D and NEURO-Obs assessment) within NHS crisis services. By examining clinician and patient experiences, digital tool integration, and the broader applicability of this model and assessment approaches, the findings will inform future service development and the design of a larger multicentre Randomised Controlled Trial (RCT).

TRIAL OBJECTIVES AND RESEARCH QUESTIONS

Primary Objective:

- Assess the feasibility of integrating rapid neurodevelopmental assessment tools into a TA based crisis clinical care model.

Secondary Objectives:

- Evaluate clinician, caregiver and patient experiences of this approach.
- Assess the feasibility of digitised and/or holistic rapid neurodevelopmental structured professional judgement tools in NHS acute settings.
- Gather preliminary data to inform a future multicentre RCT.

Primary Research Question:

- How feasible is the integration of holistic, rapid neurodevelopmental identification into a TA based crisis care pathway?

Secondary Research Questions:

- How effectively can rapid holistic neurodevelopmental SPJ tools (NA ESSENCE-D and NEURO-Obs) be integrated into NHS acute settings?
- What acceptability to children, young people, and their families of receiving assessments and interventions within the TANDA model?
- What acceptability to clinicians of providing assessments and interventions within the TANDA model?
- What methodological insights can be gathered to inform the design of a future multicentre Randomised Controlled Trial (RCT)?

STUDY DESIGN

This study is designed as a single-site, mixed-methods feasibility study, incorporating both quantitative and qualitative data collection approaches. The study will be comprised of three distinct work packages, allowing for a structured and iterative evaluation of the feasibility, acceptability, and implementation of the TANDA model. The mixed-methods design ensures that both statistical feasibility indicators and experiential insights from participants and clinicians are captured, thereby providing a comprehensive understanding of the intervention's potential for broader implementation.

Justification for Study Design

A feasibility study is an appropriate approach for an early-stage investigation of a novel assessment and intervention model, such as TANDA, within crisis services. Given that this model integrates Therapeutic Assessment (TA) with rapid neurodevelopmental assessment tools, it is essential to determine its practicality, clinician engagement, and patient/caregiver acceptability before considering a larger-scale trial.

A single-site design was chosen to allow for close monitoring and iterative refinements to the study processes while minimising variability across different service settings. This controlled setting enables researchers to systematically address any operational challenges before scaling up to a multicentre trial.

A mixed-methods approach provides a robust framework for understanding feasibility from multiple perspectives. Quantitative data, such as recruitment rates, retention rates, and intervention adherence, will offer objective indicators of feasibility. Qualitative data, including participant and clinician interviews, will provide deeper insights into user experiences, potential barriers, and facilitators of implementation.

Work Package Overview

WP1: Ethics Approval, Governance Setup, and Training of Clinicians (Months 1-2)

- Obtain necessary ethics approvals from the NHS Research Ethics Committee and Research and Development (R&D) approvals from NHS Ayrshire and Arran, the host NHS board.
- Establish study governance structures, including data management protocols and compliance with GDPR regulations.
- Recruit and train clinicians in the implementation of the TA model, NA ESSENCE-D, and NEURO-Obs assessment tools to ensure fidelity to the intervention framework.

WP2: Participant Recruitment, Assessment, and Intervention Implementation (Months 3-10)

- Recruit CYP presenting to crisis services who meet inclusion criteria.
- Obtain informed consent to participate from participants and their families.
- Once the initial presenting crisis has been managed using TA techniques, and when clinically ready, implement the rapid neurodevelopmental assessment.
- Monitor clinician adherence to intervention protocols and provide ongoing supervision.
- Collect real-time data on feasibility indicators, such as recruitment rates, intervention completion rates, rates of representation to crisis services, and participant retention.
- Conduct qualitative interviews and focus groups with clinicians, CYP, and families to assess acceptability and explore perceived benefits or challenges.

WP3: Data Analysis and Feasibility Assessment (Months 11-12)

- Analyse quantitative feasibility indicators, including recruitment and retention rates, assessment completion rates, and clinician adherence.
- Perform thematic analysis of qualitative data to identify key themes related to intervention feasibility and potential improvements.
- Integrate quantitative and qualitative findings to generate recommendations for refining the TANDA model.

This structured design ensures that the study comprehensively evaluates feasibility, laying the groundwork for a future multicentre Randomised Controlled Trial (RCT).

TRIAL RECRUITMENT

Inclusion Criteria:

- CYP aged 12-17 years and 12 months presenting to crisis services following self-harm or suicidal ideation.
- CYP identified as potentially neurodivergent. (Either through clinical judgement or from having been previously referred to the NDS)
- CYP and their families who have provided informed consent to participate.

Exclusion Criteria:

- CYP requiring immediate inpatient care.
- CYP for whom TA is deemed clinically inappropriate (E.g., those with English skills which require an interpreter, pre-existing Intellectual Disability, or where assessment for possible Intellectual Disability or FASD would be clinically required, gross reality distortion due to psychosis or inebriation, an immediate risk of violence or suicide and being admitted to psychiatric units.) (Extracted from the TA Manual).
- CYP who already have an established neurodivergent diagnosis.
- CYP who do not have the capacity to provide informed consent.

CYP eligible for the TANDA study will be identified through their routine presentation to the local CUAIT team. The study will be embedded within clinical pathways and delivered alongside standard clinical care.

Step 1: Identification of Eligible Participants (Normal Clinical Visit)
When a CYP presents to CUAIT in crisis, they will receive the usual assessment and intervention processes, including contact with a clinician and a Therapeutic Assessment (TA) as part of Treatment as Usual (TAU).

Step 2: Clinical Identification of Possible Neurodivergence (Normal Clinical Visit / Recruitment Activity)
During the course of the initial contact or Therapeutic Assessment, if a CUAIT clinician forms the opinion—through clinical judgement or prior referral—that the CYP may be neurodivergent, they will consider the family for participation in the study.

Step 3: Initial Approach and Verbal Consent to Contact (Normal Clinical Visit / Recruitment Activity)
The clinician will introduce the study to the family, provide the Participant Information Sheet (PIS), and offer an opportunity to ask initial questions. If the family expresses interest, the clinician will seek verbal consent to pass their contact details to a member of the research

team. This verbal consent and information sharing will be documented in the medical record.

Step 4: Appointment with Study Clinician (Study Visit 1)
Interested participants will be offered an appointment with a study clinician, scheduled at least one month following their initial crisis presentation.

Step 5: Assessment of Suitability and Capacity (Study Visit 1)
At this appointment, the study clinician will conduct an updated assessment of risk and mental health status, and will assess the CYP's capacity to provide informed consent for participation in the research study.

Step 6: Informed Consent for Study Participation (Study Visit 1)
If the clinician deems it appropriate, the family will be given a further opportunity to review the Participant Information Sheet and ask any remaining questions. Written informed consent to participate in the study will then be obtained. Competency to provide consent will be assessed at this point and either written informed consent will be provided from the participant or the caregiver as appropriate. Which ever party does not provide the consent will be asked to provide assent instead to ensure that both young person and caregiver assent to the study.

Step 7: Completion of NA ESSENCE-D and NEURO-Obs Assessment (Study Activity)
Following consent, the family will be sent a link to complete the NA ESSENCE-D questionnaire. Upon completion, the research assistant (RA) will inform the study clinician, and the family will be scheduled for their NEURO-Obs assessment appointment.

Step 8: NEURO-Obs Assessment Appointment (Study Visit 2)
The CYP and family will attend the NEURO-Obs assessment. Results from this, the modified NA ESSENCE-D and clinical judgement will form the basis of the clinical formulation. In most cases, the clinician will provide a verbal summary of findings and recommendations at this appointment. A written formulation and recommendation letter will be issued to the family as soon as possible after the appointment.

As part of routine practice and in-line with current diagnostic guidelines, a collateral history may be obtained from someone else who knows the young person well, such as a teacher or another suitable informant if the young person is not at school.

This letter will also be shared with the CYP's General Practitioner, the referring CUAIT clinician, and any other professionals involved in the CYP's care, as per usual practice. It will be uploaded to the clinical portal and will form part of the medical record.

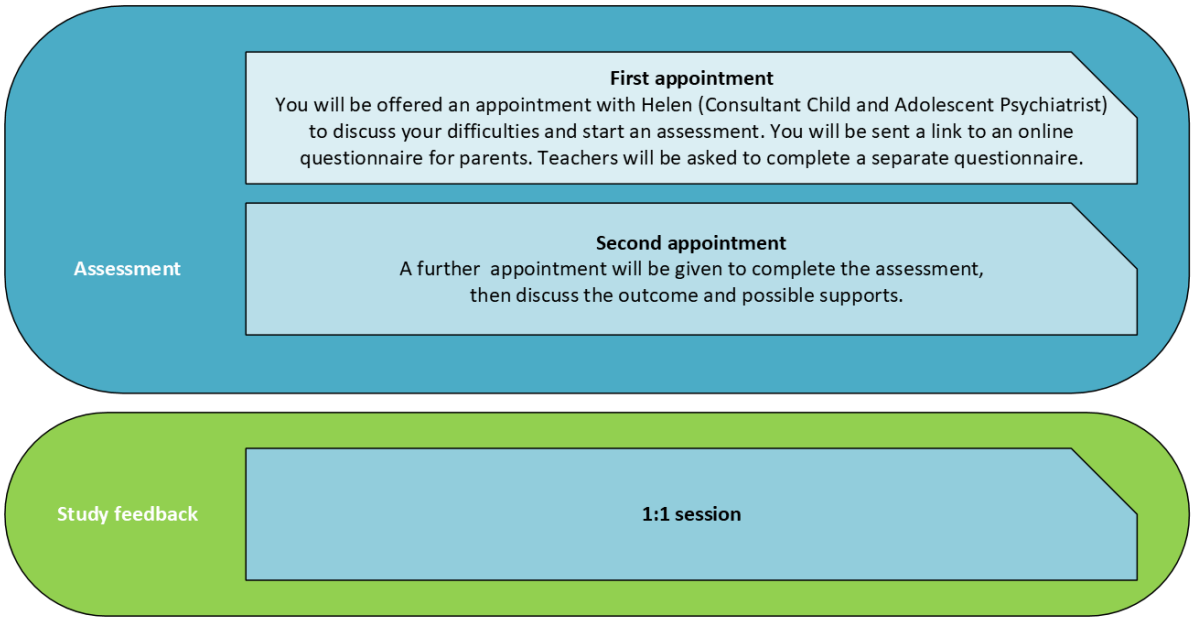


Figure 2: Study appointment sequence

Step 9: Post-Diagnostic Support and Signposting (Study Visit 2)
Where clinically indicated, post-diagnostic support or signposting will be offered in discussion with the CYP and their family, tailored to individual needs and preferences.

Step 10: Transition to Research Follow-Up (Research Follow-up)
Once the clinical journey has been completed, the study RA will be informed. The family will then be contacted to complete a follow-up survey and invited to participate in a qualitative interview to explore their experience of the assessment process. Qualitative interviews will be conducted by a RA.

Step 11: Completion of Participation (Research Follow-up)
Following survey completion and/or qualitative interview, the family's direct involvement in the study will conclude. Participants who take part in the qualitative interview will be offered a £25 gift voucher as a thank you for their time.

Step 12: Feedback and Dissemination (Research Follow-up)
At the end of the study, a plain language summary of the findings will be provided to all participants who expressed interest in receiving study outcomes.

For CYP and families who do not provide consent, they will continue with treatment as usual, and they will not be disadvantaged in any way by not participating in the study.

CYP and families will be able to withdraw at any stage. Data hitherto collected prior to withdrawal will be included in the study.

Participation and data will be pseudononymised so that no individual CYP or family can be identified.

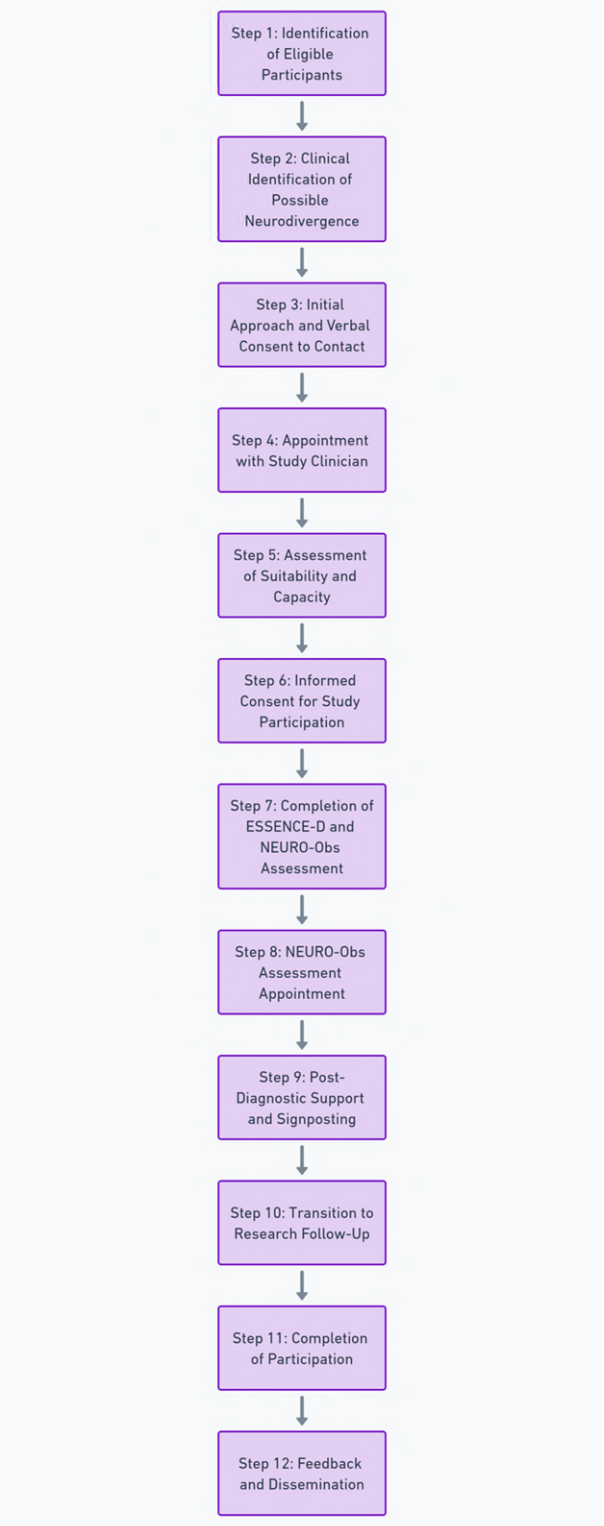


Figure 3: Participant Flow Diagram

OUTCOME MEASURES

This study will assess multiple feasibility indicators and preliminary effectiveness measures to determine the viability of integrating Therapeutic Assessment (TA) and neurodevelopmental SPJ tools (NA ESSENCE-D and NEURO-Obs) into crisis services. These outcome measures have been selected to capture key aspects of feasibility, acceptability, implementation fidelity, and preliminary indications of clinical utility.

Primary Feasibility Outcomes

Recruitment and Retention Rates

- **Justification**: Assessing recruitment and retention rates will help determine whether the study is feasible within NHS crisis services. If recruitment targets are not met, this will provide valuable insights into potential barriers, such as clinician engagement, participant acceptability, or systemic constraints. Retention rates will indicate whether the intervention is engaging and acceptable to participants and families.
- **Measurement**: Number of eligible participants approached, proportion consenting to participate, and proportion completing all study components.

Acceptability of Assessments and Intervention (Qualitative Feedback)

- **Justification**: Understanding the acceptability of the TANDA model from both clinician and participant perspectives is essential for refining the intervention before a larger-scale trial. Acceptability will also impact long-term implementation and scalability within NHS settings.
- **Measurement**: Semi-structured interviews and focus groups with CYP, families, and clinicians; participant satisfaction surveys.

Fidelity of TA and NEURO-Obs Assessments

- **Justification**: Ensuring that clinicians adhere to the intended intervention model is critical for determining feasibility. High fidelity suggests that the intervention can be delivered consistently, while lower fidelity may indicate the need for additional training or modifications to the protocol.
- **Measurement**: Clinician self-reports, independent fidelity checks via case review, and supervision records.

Secondary Feasibility and Preliminary Effectiveness Outcomes

Completion Rates of NA ESSENCE-D and NEURO-Obs Assessments

- **Justification**: The extent to which the SPJ tools can be integrated into crisis care will determine their feasibility for future larger-scale trials. If completion rates are low,

barriers such as clinician workload, technical issues, or participant burden will need to be addressed.
- **Measurement**: Number of assessments completed relative to the number initiated; feedback from clinicians on usability.

Participant Engagement and Satisfaction

- **Justification**: Measuring engagement and satisfaction will provide insights into whether CYP and families find the assessments and intervention meaningful and useful.
- **Measurement**: Self-reported engagement levels and satisfaction ratings from CYP and families.

Clinician Confidence and Perceived Utility of the Model

- **Justification**: Since successful implementation depends on clinician engagement, assessing their confidence and perceived value of the TANDA model will help identify potential barriers and facilitators for future adoption.
- **Measurement**: Pre- and post-intervention surveys assessing clinician confidence in using TA, NA ESSENCE-D, and NEURO-Obs.

Preliminary Mental Health and Crisis Outcomes

- **Justification**: While this is a feasibility study, gathering preliminary data on clinical outcomes will help identify whether the intervention has the potential to improve crisis care and mental health outcomes in CYP.
- **Measurement**: Changes in self-reported distress levels (where appropriate), clinician-rated improvements in crisis resolution, and reduction in crisis service use (where data is available).

DATA COLLECTION

A combination of quantitative and qualitative data collection methods will be used to assess feasibility, acceptability, and preliminary effectiveness of the TANDA model. Data will be gathered from clinical assessments, structured surveys, and qualitative interviews to ensure a comprehensive evaluation of the intervention's implementation and impact.

Demographic and Clinical Data Collection

To contextualise findings and assess representativeness, demographic and clinical data will be collected from participants upon recruitment:

- **Age**
- **Sex**
- **Deprivation index** (using SIMD data)
- **Presenting complaint** (reason for referral to crisis services)
- **Family history of identified neurodivergence (diagnosed or self reported)**

- **Interventions received prior to and during crisis care other than the TA**

This data will allow for subgroup comparisons and inform future scalability of the intervention.

NA ESSENCE-D and NEURO-Obs Assessment Outcomes

To evaluate the feasibility of neurodevelopmental assessments within crisis care, the following data will be collected:

- **Parent Report Outcomes:**
  - Was the collected developmental information helpful in reacing the final diagnosis?
  - How did the time taken to complete the modified history compare to service as usual?
- **NEURO-Obs assessment outcomes:**
  - Observational conclusions regarding neurodivergence
  - Time to reach an overall diagnostic conclusion
  - Final diagnosis (if applicable) and referral outcomes

The collection of these data points will help determine the efficiency and clinical utility of these tools in crisis settings. All outcomes will be freely accessible in the public domain via open access journal publications, thus Malvern-i, the developers of ESSENCE-D will not be given any preferential feedback on the performance of the tool.

Recruitment and Retention Metrics

To assess feasibility, recruitment and retention data will be gathered:

- **Number of eligible participants identified**
- **Number of participants who consent to participate**
- **Retention rates at different study time points**
- **Dropout rates and reasons for attrition**

These measures will help identify barriers to recruitment and retention that may inform future studies.

Acceptability and Experience of TANDA (Qualitative Interviews & Surveys)

Structured surveys and qualitative interviews will be conducted with CYP, families, and clinicians to explore their experiences and perceptions of the intervention:

- **Children and Young People (CYP) & Families:**
  - Experience of undergoing the TANDA assessment process
  - Perceived impact of the intervention on crisis resolution and understanding of neurodivergence
  - Satisfaction with assessment tools and engagement with clinicians

- Suggestions for improving service delivery
- **Clinicians:**
  - Perceived feasibility of integrating TANDA into existing crisis pathways
  - Confidence in using the new approach to neurodevelopmental assessment
  - Barriers and facilitators to implementation
  - Perceived usefulness of assessment outcomes in informing care plans

Qualitative data will be thematically analysed to identify key themes regarding acceptability and implementation.

Intervention Fidelity Measures

To evaluate adherence to the intervention protocol and ensure consistency in delivery:

- **Clinician adherence to TA model and assessment protocols** (assessed via structured fidelity checklists)
- **Supervisory session logs documenting adherence and deviations**
- **Case reviews to assess consistency across different clinicians**

Fidelity data will help refine training procedures and enhance protocol adherence in future trials.

Preliminary Clinical and Service Outcomes

While this feasibility study is not designed to assess effectiveness, preliminary outcome measures will be collected to inform future trial designs:

- **Changes in distress levels** (self-reported by CYP where appropriate)
- **Change in score of KIDSCREEN (a quality of life measure in routine use within NHS Ayrshire and Arran)**
- **Clinician-rated crisis resolution and stability post-intervention**
- **Service use indicators (e.g., re-presentation to crisis services within 3 months)**

Data Collection Procedures and Timings

To ensure transparency and rigour, all data collection activities will follow a structured schedule, using validated tools and secure systems. The table below summarises what data will be collected, how, and at what time point:

Data Type	Time Point	Method of Collection	Source
Demographic & Clinical Data	Baseline (initial consent/recruitment)	Electronic case report form completed by clinician	Medical records / clinical interview

Data Type	Time Point	Method of Collection	Source
NA ESSENCE-D history & NEURO-Obs outcomes	During neurodevelopmental assessment	NA ESSENCE-D app (parent-reported); clinician observation	NA ESSENCE-D app / NEURO-Obs proforma
Parent feedback on assessment process	Post-assessment	Online structured survey	Qualtrics
Recruitment and retention metrics	Ongoing throughout study	Recorded by research team in study logs	Recruitment logs
CYP and family experience of TANDA	Within 2–4 weeks post-assessment	Semi-structured interview via MS Teams	Interview (recorded and transcribed)
Clinician feedback on feasibility	Within 2–4 weeks post-participant discharge	Online survey and/or semi-structured interview	Qualtrics and/or MS Teams
Fidelity checklists	Post-assessment or during supervision	Completed by supervisor based on session review	Structured checklist
Supervision session logs	Throughout study	Maintained by supervisor	Internal documentation
Preliminary clinical and service outcomes	4–6 weeks post-intervention	Qualtrics survey (CYP self-report), clinician review, records	KIDSCREEN tool, case notes, Qualtrics

Surveys will be administered using Qualtrics, a secure online platform accessible via email invitation. CYP surveys will be adapted to their developmental level and available in paper format if digital access is a barrier.

Qualitative interviews with CYP, families, and clinicians will be conducted via Microsoft Teams, in line with the Participant Information Sheet (PIS). Participants will choose a time that suits them and will be supported to ensure accessibility needs are met. With informed consent, interviews will be **audio-recorded using encrypted NHS-approved devices** and transcribed **verbatim** by a GDPR-compliant transcription service. Audio files and transcripts will be securely stored on **NHS Ayrshire & Arran's encrypted servers**, accessible only to authorised members of the research team.

A detailed Data Management Plan will be provided outlining data storage, access, and destruction procedures in accordance with sponsor and NHS governance requirements.

DATA MANAGEMENT AND PROCESSING

Potential participants will be approached to participate in the study as outlined in the section above. Participants will be children, young people, and their families, and only necessary demographic and contact details will be forwarded to the study investigator.

Study Research Assistants will complete a Research Passport to enable access to relevant NHS Ayrshire and Arran systems to allow them to facilitate the study. Contact details for potential participants will be saved in a secure, password-protected database stored on secure NHS Ayrshire & Arran's encrypted servers . No data will be stored on mobile devices. Potential participant details will include name, contact details, and relevant clinical identifiers.

Information entered into the NA ESSENCE-D tool will be processed by Malvern-I as the vendors of the tool. Data transfer will be done through secure channels and Malvern-i will have no access to the personal data of any participant.

If a potential participant indicates they do not wish to participate in the study, their data will be deleted from the recruitment database at that point. Contact details for participants who choose to participate will be retained securely until the end of the study, after which they will be deleted.

Audio recordings of interviews will be collected to capture qualitative data. These recordings will be saved to secure NHS Ayrshire & Arran servers and stored until the end of the study, at which point they will be deleted.

Recordings will be transcribed verbatim by the study research assistants. Transcriptions will be pseudonymised, transferred using the University's secure FTP process, and stored in University Secure OneDrive servers for analysis. Transcriptions will be retained for 10 years in line with University policy on the University's data archiving system Enlighten. Recordings will be deleted at the end of the study.

Participants will not be identifiable after transcription. A unique code key will be assigned to each participant, stored separately from the main dataset on NHS secure systems. This code key will only be accessible by the chief investigator to facilitate withdrawal requests. In all subsequent analysis and reporting, only pseudononymised data will be used.

Should a participant disclose information that could inadvertently identify them, this information will be redacted in any written reports or publications.

Qualitative data will be thematically analysed using NVivo software (or similar licenced software) and stored on University of Glasgow secure OneDrive servers until the end of the study, and then archived for upto 10 years after the study ends on the En;lighten archiving system, in line with University policy.

Anonymised data may be shared with other researchers who have ethical approval and legitimate grounds for requesting the data in accordance with open science principles. No identifiable information will be disclosed.

The study will fully comply with all University of Glasgow Information Governance Policies which meet or exceed current GDPR legislation. These policies can be found here and here.

SAFETY, RISKS AND MITIGATIONS

Clinical Care and Risk Management

Participants will be CYP and families engaged with crisis services and will receive care from experienced clinicians within NHS Ayrshire and Arran's CUAIT Team. These staff members are highly trained in crisis management and have significant experience working with CYP presenting with self-harm and suicidal ideation. All clinical interventions, including TA, will be delivered by qualified CUAIT clinicians, ensuring that participants receive appropriate, evidence-based care throughout their involvement in the study. The CUIAT clinicians will have access to clinical supervision locally and supervision from the team who developed TA on a monthly basis for the duration of the trial.

TA has previously been demonstrated to have good acceptability and positive outcomes for CYP who have self-harmed or who experience suicidal ideation. It is a collaborative and structured intervention designed to improve understanding of distress and enhance coping strategies. As such, it is well-suited to integration within crisis services, and this study seeks to assess its feasibility as part of routine care.

Supervision and Clinical Oversight

Medical supervision and oversight of the CUAIT team will be provided by the team's consultant psychiatrist Dr Liana Romaniuk. In the case of her absence, clinical supervision will be provided by Dr. Helen Smith (Consultant Forensic Child and Adolescent Psychiatrist). In her absence, clinical supervision will be undertaken by the deputising medical staff member within NHS Ayrshire and Arran, in accordance with board procedures. This ensures that any clinical concerns arising during the study can be addressed promptly and in line with standard NHS governance structures.

Participant Safety and Support

While some discussions triggered by the qualitative interviews may be emotionally challenging for participants, all CYP will have access to their usual care providers for support. If distress occurs, participants will be encouraged to seek assistance from their clinicians or other appropriate services. This information will be clearly outlined in the Participant Information Sheet.

There is a low risk of a participant making a disclosure that affects the health, safety, or welfare of an individual. If such a disclosure occurs, child protection legislation will apply, and the investigator will take appropriate action in line with NHS Ayrshire and Arran safeguarding policies.

Any adverse incidents will be reviewed by the trial monitoring group and reported through NHS Ayrshire and Arran's existing governance and reporting mechanisms.

Minimising Participant Burden

The time burden on participants will be kept to a minimum, with study interviews lasting approximately 45 minutes to one hour. Participants may opt out of the study at any time, and flexible scheduling will be offered to accommodate their needs. In order to reduce travel expenses, research interviews will be conducted on-line using Microsoft Teams or Zoom at the preference of the participant.

Recruitment and Mitigation Strategies

Given the pressures on crisis services, recruitment challenges are anticipated. However, discussions with NHS partners indicate strong interest in the study. Engagement with clinical teams, health boards, and key stakeholders will help mitigate recruitment difficulties by ensuring clear communication about the study's purpose, benefits, and operational feasibility**.**

Risk Management Procedures

- All clinicians delivering the intervention are **trained in crisis management** and will follow standard protocols to ensure participant safety.
- **Clinical responsibility for all CYP involved in the trial remains with NHS Ayrshire and Arran,** and all staff will follow clear clinical escalation processes which are already in place within the Health Board.
- Any **adverse incidents** will be monitored by the **trial oversight group** and reported through NHS Ayrshire and Arran's governance frameworks.
- Ongoing **supervision and fidelity monitoring** will be provided to ensure protocol adherence and mitigate clinical risks.

Definition and Reporting of Adverse Events

For the purposes of this study, an *adverse event (AE)* is defined as any untoward medical or psychological occurrence in a participant that arises during the study period, regardless of whether it is considered related to the intervention. This includes, but is not limited to:

- Worsening of mental health symptoms
- Self-harm or suicidal behaviour
- Serious safeguarding concerns
- Any incident requiring urgent or unplanned clinical intervention

Serious Adverse Events (SAEs) are those that result in death, are life-threatening, require hospitalisation or prolongation of existing hospitalisation, result in persistent or significant disability/incapacity, or are otherwise considered medically significant.

All adverse events will be documented by the clinician involved using standard NHS Ayrshire and Arran incident reporting procedures (e.g. DATIX). In addition:

- SAEs will be reported to the Chief Investigator and the Trial Management Group (TMG) within 24 hours of identification.
- The TMG will review all AEs and SAEs at their scheduled meetings (or sooner if needed) to determine whether further action or protocol amendment is required.
- The Sponsor and NHS Research & Development Office will be notified of any SAE related to the research procedures in accordance with their reporting timelines.

SAMPLE SIZE AND PROPOSED RECRUITMENT RATE

The sample size for this feasibility study has been determined to balance practicality and the need to generate meaningful feasibility data to inform a future multicentre Randomised Controlled Trial (RCT).

Target Recruitment

- 30-50 children and young people (CYP) over 8 months.
- This range allows for flexibility in recruitment while ensuring enough data is collected to assess feasibility indicators.

Justification for Sample Size

A feasibility study does not require a formal power calculation, as the primary aim is not to test efficacy but to evaluate practical considerations**,** such as recruitment rates, retention, acceptability, and intervention fidelity**.** The target sample size is based on:

- Expected caseload within crisis services over the recruitment period.
- Previous feasibility studies in similar settings.
- Consideration of potential dropouts due to the nature of crisis care.
- Ensuring adequate data collection to refine study processes ahead of a larger trial.

STATISTICAL ANALYSIS

Quantitative data collected in the study will be analysed using descriptive statistics to assess feasibility indicators such as recruitment rates, retention rates, data completeness, and intervention adherence. Means, medians, standard deviations, and confidence intervals will be calculated where appropriate to summarise participant characteristics and outcome measures.

Qualitative data from surveys, interviews and focus groups with clinicians, CYP, and families will be analysed using thematic analysis. This process will involve coding transcripts to

identify key themes, patterns, and perspectives related to the acceptability, feasibility, and implementation challenges of the TANDA model. NVivo software will be used to manage and organise the data. Themes will be iteratively refined to ensure the findings accurately represent participant experiences and can inform the design of a future multicentre RCT.

ORGANISATIONAL TRIAL MANAGEMENT AND OVERSIGHT ARRANGEMENTS

Study Oversight and Governance

The study is sponsored by the University of Glasgow, with close collaboration between the study investigators and NHS partners. The governance structure will ensure that the trial is conducted according to protocol, ethical guidelines, and safety standards.

Trial Oversight Group (TOG)

A Trial Oversight Group (TOG) will be established to oversee the conduct of the trial, ensuring adherence to protocol and reviewing any adverse incidents. The TOG will have the authority to stop the trial should safety concerns be identified that cannot be managed through standard risk mitigation strategies.

- Membership will include study investigators, independent clinical experts, and NHS representatives.
- The University of Glasgow Sponsor will have a role in overseeing the trial and may attend TOG meetings as required.
- The TOG will meet quarterly or more frequently if required due to safety concerns.

Adverse Event Monitoring and Safety Reporting

- All adverse incidents will be reported through NHS Ayrshire and Arran's standard clinical governance framework.
- The TOG will review all reported adverse incidents and determine appropriate action.

Regular Trial Monitoring and Quality Assurance

- Monthly investigator meetings will be held to discuss trial progress, recruitment challenges, and emerging findings.
- Data monitoring and audits will be conducted regularly to ensure data integrity and adherence to ethical and research governance standards.
- Supervision and protocol fidelity monitoring will be implemented to ensure clinical assessments and interventions are delivered consistently across study sites.

Communication and Reporting

- Regular progress reports will be submitted to the University Sponsor and NHS Ayrshire and Arran which will be reviewed at the CAMHS clinical governance meeting and fed into the NHS Ayrshire and Arran governance system.
- Monthly review meetings will be conducted to assess overall study progress and any necessary adjustments.
- A final trial report will be prepared, summarising key findings, safety outcomes, and recommendations for future research.

ETHICS AND REGULATORY APPROVALS

Prior to the commencement of participant recruitment, full ethical approval will be sought from the NHS Research Ethics Committee (REC) to ensure that the study adheres to established ethical standards for research involving children and young people in crisis care. This approval process will include a detailed review of the study protocol, participant information sheets, consent procedures, and risk mitigation strategies to safeguard participant welfare.

In addition to ethical approval, NHS Research and Development (R&D) approval will be obtained from the relevant NHS Board before recruitment begins. This approval is necessary to ensure alignment with local NHS governance policies, data protection regulations, and clinical service integration. Only after securing both REC and NHS R&D approvals will recruitment and study activities commence.

The preliminary proposal has already been discussed and approved at the NHS Ayrshire and Arran Clinical governance meeting in November 2024.

FINANCE AND INSURANCE

This study is supported through a Mental Health Translational Research Collaboration (MH-TRC) pump-priming grant in the amount of £39,034**.** This funding has been allocated to support key aspects of the study, including research personnel, training for clinicians, and the integration of the NA ESSENCE-D and NEURO-Obs assessment tools within crisis care pathways. The funding also covers essential administrative and logistical costs required to ensure the smooth implementation of the feasibility study.

All study activities will be covered by institutional insurance provided by the University of Glasgow and the NHS**.** This insurance ensures that both researchers and participants are protected in accordance with University policies on research governance. Any liabilities or risks associated with the study will be managed under these insurance provisions, providing a safeguard for all parties involved.

END OF TRIAL

The study will formally conclude following the completion of final data collection, analysis, and reporting, which is expected to be around the autumn of 2026. At this point, all qualitative and quantitative data will have been collected, processed, and analysed to assess the feasibility and acceptability of the TANDA model within crisis care settings.

Upon completion of data analysis, a final study report will be prepared summarising key findings, feasibility indicators, and recommendations for refining the intervention. This report will be shared with key stakeholders, including NHS partners, the University of Glasgow, and funding bodies.

Additionally, a public-facing summary will be made available to ensure accessibility for families and clinicians involved in the study.

AUTHORSHIP AND PUBLICATION

This study will be written up for publication in a suitable professional academic journal. Results of this study will also be disseminated to other interested stakeholders, including involved health boards, health boards with whom the investigator has professional links, and may also be reported in poster or oral presentation format for presentation at scientific or professional meetings or conferences.

Links to the published article or conference abstracts may also be circulated on the investigator's social media channels or channels associated with the involved health boards, stakeholders, or the University of Glasgow.

Authorship will be conferred in accordance with the rules of the accepting journal. The funding recioeved will be acknowledged in all publications.

In addition, for those participants who have indicated that they would like to receive the results of the study, they will receive a lay-person summary of the results and outcomes of the research. This will be administered and sent through NHS A&A's systems, who will continue to have contact details for the family. Participants will give written informed consent for this contact to be made.

REFERENCES

Casseus, M., Kim, W., & Horton, D. (2023). Prevalence and treatment of mental, behavioral, and developmental disorders in children with co-occurring autism spectrum disorder and attention-deficit/hyperactivity disorder: A population-based study. *Autism Research*, *16*, 855–867. https://doi.org/10.1002/aur.2894

Culpin, I., Mars, B., Pearson, R., Golding, J., Heron, J., Bubak, I., Carpenter, P., Magnusson, C., Gunnell, D., & Rai, D. (2017). Autistic Traits and Suicidal Thoughts, Plans, and Self-Harm in Late Adolescence: Population-Based Cohort Study. *Journal of the American Academy of Child and Adolescent Psychiatry*, *57*, 313–320. https://doi.org/10.1101/165860

Curtis, L. (2022). Commentary: Suicide risk is high, but often overlooked, in autistic spectrum disorder populations. *Journal of Child Psychology and Psychiatry, and Allied Disciplines*. https://doi.org/10.1111/jcpp.13627

Douglas, K. S., Hart, S. D., Webster, C. D., Belfrage, H., Guy, L. S., & Wilson, C. M. (2014). Historical-Clinical-Risk Management-20, Version 3 (HCR-20 ^{V3}): Development and Overview. *International Journal of Forensic Mental Health*, *13*(2), 93–108. https://doi.org/10.1080/14999013.2014.906519

Gillberg, C. (2010). The ESSENCE in child psychiatry: Early Symptomatic Syndromes Eliciting Neurodevelopmental Clinical Examinations. *Research in Developmental Disabilities*, *31*(6). https://doi.org/10.1016/j.ridd.2010.06.002

Hansen, B., Oerbeck, B., Skirbekk, B., Petrovski, B., & Kristensen, H. (2018). Neurodevelopmental disorders: prevalence and comorbidity in children referred to mental health services. *Nordic Journal of Psychiatry*, *72*, 285–291. https://doi.org/10.1080/08039488.2018.1444087

Hull, L., Stark, I., Lundberg, M., Ahlqvist, V., Nordström, S. I., Ohlis, A., Hadlaczky, G., Rai, D., & Magnusson, C. (2024). Sex differences in self-harm and suicide in young autistic adults. *Acta Psychiatrica Scandinavica*. https://doi.org/10.1111/acps.13736

Kerns, C., Rast, J., & Shattuck, P. (2020). Prevalence and Correlates of Caregiver-Reported Mental Health Conditions in Youth With Autism Spectrum Disorder in the United States. *The Journal of Clinical Psychiatry*, *82 1*. https://doi.org/10.4088/jcp.20m13242

Lai, M., Kassee, C., Besney, R., Bonato, S., Hull, L., Mandy, W., Szatmari, P., & Ameis, S. (2019). Prevalence of co-occurring mental health diagnoses in the autism population: a systematic review and meta-analysis. *The Lancet. Psychiatry*. https://doi.org/10.1016/S2215-0366(19)30289-5

Lai, M.-C., Saunders, N., Huang, A., Artani, A., Wilton, A., Zaheer, J., Ameis, S., Brown, H., & Lunsky, Y. (2023). Self-Harm Events and Suicide Deaths Among Autistic Individuals in Ontario, Canada. *JAMA Network Open*, *6*. https://doi.org/10.1001/jamanetworkopen.2023.27415

Lang, J., Wylie, G., Haig, C., Gillberg, C., & Minnis, H. (2024). Towards system redesign: An exploratory analysis of neurodivergent traits in a childhood population referred for autism assessment. *PLOS ONE*, *19*(1), e0296077. https://doi.org/10.1371/journal.pone.0296077

Larson, K., Russ, S. A., Kahn, R., & Halfon, N. (2011). Patterns of Comorbidity, Functioning, and Service Use for US Children With ADHD, 2007. *Pediatrics*, *127*, 462–470. https://doi.org/10.1542/peds.2010-0165

Malow, B., Qian, Y., Ames, J., Alexeeff, S., & Croen, L. (2023). Health conditions in autism: Defining the trajectory from adolescence to early adulthood. *Autism Research*, *16*, 1437–1449. https://doi.org/10.1002/aur.2960

Mandy, W. (2022). Six ideas about how to address the autism mental health crisis. *Autism*, *26*, 289–292. https://doi.org/10.1177/13623613211067928

Meza, J., Owens, E., & Hinshaw, S. (2020). Childhood predictors and moderators of lifetime risk of self-harm in girls with and without attention-deficit/hyperactivity disorder. *Development and Psychopathology*, *33*, 1351–1367. https://doi.org/10.1017/S0954579420000553

Mohammadi, M., Zarafshan, H., Khaleghi, A., Ahmadi, N., Hooshyari, Z., Mostafavi, S., Ahmadi, A., Alavi, S., Shakiba, A., & Salmanian, M. (2019). Prevalence of ADHD and Its Comorbidities in a Population-Based Sample. *Journal of Attention Disorders*, *25*, 1058–1067. https://doi.org/10.1177/1087054719886372

Oliphant, R., Smith, E., & Grahame, V. (2020). What is the Prevalence of Self-harming and Suicidal Behaviour in Under 18s with ASD, With or Without an Intellectual Disability? *Journal of Autism and Developmental Disorders*, *50*, 3510–3524. https://doi.org/10.1007/s10803-020-04422-6

Oliphant, R., Smith, E., & Grahame, V. (2021). What is the prevalence of self-harming and suicidal behaviour in under 18s with autism spectrum disorder, with or without an intellectual disability? *BJPsych Open*, *7*. https://doi.org/10.1192/bjo.2021.743

Ougrin, D., Zundel, T., & Ng, A. V. (2009). *Self-Harm in Young People: A Therapeutic Assessment Manual*. CRC Press. https://doi.org/10.1201/b13320

Warrier, V., & Baron-Cohen, S. (2019). Childhood trauma, life-time self-harm, and suicidal behaviour and ideation are associated with polygenic scores for autism. *Molecular Psychiatry*, *26*, 1670–1684. https://doi.org/10.1038/s41380-019-0550-x

Wright, N., Courchesne, V., Pickles, A., Bedford, R., Duku, E., Kerns, C., Bennett, T., Georgiades, S., Hill, J., Richard, A., Sharp, H., Smith, I., Vaillancourt, T., Zaidman-Zait, A., Zwaigenbaum, L., Szatmari, P., Elsabbagh, M., & Team, P. (2023). A longitudinal comparison of emotional, behavioral and attention problems in autistic and typically developing children. *Psychological Medicine*, *53*, 7707–7719. https://doi.org/10.1017/S0033291723001599

Yang, Y., Zhao, S., Zhang, M., Xiang, M., Zhao, J., Chen, S., Wang, H., Han, L., & Ran, J. (2022). Prevalence of neurodevelopmental disorders among US children and adolescents in 2019 and 2020. *Frontiers in Psychology*, *13*. https://doi.org/10.3389/fpsyg.2022.997648