Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

ENabling parents of preschool children with Autism spectrum disorders: A study protocol for a multi-centre randomised Controlled Trial of parenting programs (ENACT)

Maj-Britt Posserud

maj-britt.posserud@uib.no

Division of Psychiatry, Haukeland University Hospital

Tore Ivar Malmei Aarsland

Division of Psychiatry, Haukeland University Hospital

Johanne Telnes Instanes

University of Bergen

Synnøva Alsaker

Division of Psychiatry, Haukeland University Hospital

Jon Fauskanger Bjaastad

Stavanger University Hospital

Ragnhild Bjørknes

NORCE

Gunn Karin Brechan-Skjetne

Norwegian University of Science and Technology

Bjørn Brunborg

NORCE

Rhiannon Tudor Edwards

Bangor University

Greg Flynn

Bangor University

Christopher Gillberg

University of Gothenburg

Rolf Gjestad

Haukeland University Hospital

Marianne Berg Halvorsen

UiT The Arctic University of Norway

Silje Marie Heimdahl

Haukeland University Hospital

Anne Lise Høyland
Norwegian University of Science and Technology
Elisabeth Johansen
Autismeforeningen
Charlotte Küpper
Humboldt-Universität zu Berlin
Marianna Ruiz
Norwegian Research Centre
Volkert Siersma
University of Copenhagen
Oddmar Ole Steinsvik
University Hospital of North Norway
Rannei Sæther
Norwegian University of Science and Technology
Anne Karin Ullebø
Sykehuset i Vestfold
Kari Walmsness
Norwegian University of Science and Technology
Philip Wilson
University of Copenhagen
Lucy Thompson
University of Aberdeen
Gro Janne Henningsen Wergeland
Division of Psychiatry, Haukeland University Hospital

Study protocol

Keywords: Autism spectrum disorder, Parents, parent mediated/ based interventions, parenting, parent stress, preschool children, The Incredible Years for Autism Spectrum and Language Delay, randomised controlled trial, effectiveness, cost-effectiveness

Posted Date: August 7th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9171468/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: Competing interest reported. BB and KW are certified instructors for IY group leaders. BB, KW, GBS and RB all work with other parenting programs clinically, in development and/or in research. No other competing interests are reported by any author.

Title {1a}

ENabling parents of preschool children with Autism spectrum disorders: A study protocol for a multi-centre randomised Controlled Trial of parenting programs (ENACT).

Names of protocol contributors {3a}

Maj-Britt Posserud, Department of Child and Adolescent Psychiatry, Division of Psychiatry, Haukeland University Hospital, Bergen, Norway
Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Norway
Tore Ivar Malmei Aarsland, Division of Psychiatry, Haukeland University Hospital, Bergen, Norway
Johanne Telnes Instanes, Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway.
Synnøva Alsaker, Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Norway
Division of Psychiatry, Haukeland University Hospital, Bergen, Norway
Jon Fauskanger Bjaastad, Division of Psychiatry, Stavanger University Hospital, Stavanger, Norway
Ragnhild Bjørknes, Regional Centre for Child and Youth Mental Health and Child Welfare, NORCE, Bergen, Norway; The Norwegian Center for Child Behavioral Development (NUBU), Oslo, Norway
Gunn Karin Brechan-Skjetne, Regional Centre for Child and Youth Mental Health and Child Welfare (RKBU), Department of Mental Health, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway. The Habilitation Service for Children and Young People, St Olavs Hospital, Trondheim, Norway.
Bjørn Brunborg, Regional Centre for Child and Youth Mental Health and Child Welfare, NORCE, Bergen, Norway.
Rhiannon Tudor Edwards, Centre for Health Economics and Medicine Evaluations (CHEME), Bangor, Wales
Greg Flynn, Centre for Health Economics and Medicine Evaluations (CHEME), Bangor, Wales
Christopher Gillberg, Gillberg Neuropsychiatry Centre, Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.
Rolf Gjestad, Division of Psychiatry, Haukeland University Hospital, Bergen, Norway.
Marianne Berg Halvorsen, UiT, The Arctic University of Norway, Department of Psychology, Tromsø, Norway; Department of Child and Adolescent Psychiatry, University Hospital of North Norway, Tromsø, Norway.
Silje Marie Heimdahl, Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Norway
Division of Psychiatry, Haukeland University Hospital, Bergen, Norway
Anne Lise Høyland, Regional Centre for Child and Youth - Mental Health and Child Welfare, Norwegian University of Science and Technology, Trondheim, Norway
Elisabeth Johansen, Autismeforeningen, the Norwegian Autism Organisation.
Charlotte Küpper, Humboldt-Universität zu Berlin, Department of Psychology, Unter den Linden 6, 10099 Berlin, Germany.
Marianna Ruiz, NORCE Research AS, Bergen, Norway.
Volkert Siersma, The Research Unit for General Practice and Section of General Practice, Department of

Public Health, University of Copenhagen, Copenhagen, Denmark.
Oddmar Ole Steinsvik, Pediatric Rehabilitation Unit, University Hospital of North Norway, Tromsø, Norway
Rannei Sæther, Regional Centre for Child and Youth Mental Health and Child Welfare, Department of Mental Health, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway
Department of Rehabilitation Science and Health Technology, Faculty of Health Sciences, OsloMet—Oslo Metropolitan University, Oslo, Norway
Anne Karin Ullebø, Vestfold Hospital Trust, Norway
Kari Walmsness, Regional Centre for Child and Youth Mental Health and Child Welfare, (RKBU) Central Norway, Department of Mental Health, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU), Trondheim, Norway
Philip Wilson, GNC, Centre for Research and Education in General Practice, University of Copenhagen, Denmark
Lucy Thompson, Institute of Applied Health Sciences, University of Aberdeen, Inverness, Scotland
Gro Janne Henningsen Wergeland, Department of Child and Adolescent Psychiatry, Division of Psychiatry, Haukeland University Hospital, Bergen, Norway
Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Norway

Abstract

Background: Autism spectrum disorders (ASD) are diagnosed in 1-2% of children. The parent role in autism is stressful and demanding, and parents often have a prominent supportive role well into adulthood. Parents need evidence-based support, not only to best help their child, but also for their own health. There is, however, a lack of research on parent programs in ASD and little knowledge on how best to help parents. This knowledge gap motivated the current study; Enabling parents of preschool children with Autism spectrum disorder: A randomised controlled trial of parenting programs (ENACT).
Methods: Parents of preschool children (age 2-6 years) with a diagnosis of ASD are invited to participate. The families are recruited from one of four autism clinics within secondary care services across three health regions in Norway. Parents are randomised to receive the Incredible Years – Autism Spectrum and Language Delay module - or a three-day standardised psychoeducational course (care as usual). We aim to include 200-240 families. Data will be collected through parental self-report using digital questionnaires before randomisation, shortly after completing the intervention, 12-months and 24-months after completing the intervention. Qualitative interviews will be conducted before the intervention and after (both short-term and long-term). Intention-to-treat analysis will ascertain the effectiveness and cost-effectiveness in both the primary outcome (Parent Stress Index-Short Form), and secondary outcomes including the Pediatric Quality of Life Inventory, the Parent Sense of Competence Scale, the Vineland Adaptive Behavior Scales, and service and resource use costs.
Discussion: The ENACT study is planned as an effectiveness and cost-effectiveness study of parent

interventions delivered as part of routine care in four autism clinics in secondary care across Norway. The study will contribute to improving the evidence-base of parent follow-up and to improve the availability of such services. Additionally, it seeks to promote more standardised and equitable support for all parents across the participating sites.

Trial registration: Registry: ClinicalTrials.gov. ID number: NCT05750095. Registered 08 January 2022. https://clinicaltrials.gov/study/NCT05750095.

Keywords

Autism spectrum disorder, Parents, parent mediated/ based interventions, parenting, parent stress, preschool children, The Incredible Years for Autism Spectrum and Language Delay, *randomised controlled trial, effectiveness, cost-effectiveness*

Structured summary {1b}

Item	Description
Primary Registry and Trial Identifying Number {4}	Registry: ClinicalTrials.gov. ID number: NCT05750095. https://clinicaltrials.gov/study/NCT05750095 Registered 8 January 2022.
Secondary Identifying Numbers	Ethical approval number: 188940
Source(s) of Monetary or Material Support	Western Regional Health Authority (Helse Vest HF), Norway, funding 2022-2024 (F-12620) and 2025-2027 (F-13405) https://www.helse-vest.no/en/ Kavlifondet, www.kavli.no Stiftelsen DAM, www.dam.no NTNU, www.ntnu.no Northern Norway Regional Health Authority (HNI0068-25)
Primary Sponsor and contact information {3b}	Helse Bergen HF, +47-55970000 Haukeland universitetssjukehus Postboks 1400 5021 Bergen postmottak@helse-bergen.no
Role of sponsor and funder {3c}	Study sponsor and funders have no part in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, or any ultimate authority over any of these activities. Role of study sponsor: Responsible for data protection and personal protection. Role of funders: Controlling that the grant is used according to the intended purpose.
Contact for Public Queries	https://www.enact.no/
Contact for Scientific Queries	Maj-Britt Posserud, maj-britt.posserud@uib.no
Public Title	The ENACT Study

Scientific title	ENabling parents of preschool children with Autism spectrum disorders – a randomised Controlled Trial of parenting programs (ENACT)
Countries of Recruitment	Norway
Health Condition(s) or Problem(s) Studied	Autism spectrum disorder; parental stress
Intervention(s)	The Incredible Years Autism Spectrum and Language Delay Program (IY-ASLD©) (Active condition) First Aid for Parents (Care as usual, CAU; Comparator)
Key Inclusion and Exclusion Criteria	Inclusion criteria: Parents/caregivers of children diagnosed with an autism spectrum disorder, age 2-6 (until turned 7), living in the areas serviced by the four participating clinical centres in Tromsø, Trondheim, Bergen and Haugesund, Norway. Exclusion criteria: Language proficiency insufficient to benefit from the intervention without the assistance of an interpreter. Ongoing major crisis in the family, serious condition in the parent planning to attend. Ongoing participation in another manualised (any) parent program.
Study Type	A multi-centre RCT including four parallel clinical sites in a superiority design comparing IY-ASLD with a standardised parent psychoeducational program (CAU). Parents are randomised by the individual child with a ratio of 1:1 between study arms.
Date of First Enrolment (planned)	1 February 2022
Sample Size	240 (stop criterion)
Primary outcome(s)	The Parenting Stress Index-Short Form IV (PSI-SF)
Key Secondary outcome(s)	The Parenting Sense of Competence Scale (PSOC) The Pediatric Quality of Life Inventory (PedsQL) The Vineland Adaptive Behavior Scales – third edition (VABS-3) Concomitant use of resources (Concom - service and resource use costs) Child quality of life (VAS) Parent quality of life (VAS) Quality-adjusted life years (QALYs) from PedsQL
Ethics Review	Western Norwegian Regional committee for medical and health research ethics (REK Vest); nr. 188940
Individual Trial Participant Data sharing statement	ENACT will apply to the regional ethical committee and data protection officer for individual trial participant-level data to be made available in an anonymised form in a regional data repository, available upon reasonable request.

Protocol version {2}

Current protocol ENACT version 3.1, dated 20th May 2025, approved by the Western Norwegian Regional committee for medical and health research ethics (REK Vest) on the 3rd of July 2025.

Introduction

Background and rationale {9a}

Autism spectrum disorders (ASD) are disabling and impairing conditions diagnosed in 1% of children and 0.5% of adults in Norway (2). ASD is hallmarked by difficulties with social interaction and challenges with independence, causing reliance on parents and supportive systems throughout life for some (3, 4). Furthermore, the social deviance in the child with autism challenges the relational competence of parents (5, 6). Normal parenting skills may be insufficient and ineffective, causing stress as the demands exceed the resources and capability of the parent (7). The high levels of stress in parents are associated with increased risk for mental health problems, divorce, unemployment, and reduced quality of life (8-10). High parent stress may also reduce the effect of interventions in autism (11). Parents of children with ASD thus need effective and evidence-based follow-up, not only for their child, but to support them in their vital role as parents. Improving parental skills and enabling parents to efficiently support their child with ASD has the potential for enormous and life-long improvement for the patient and their families. The overall societal cost of supporting and providing care for an individual with autism in the United States was estimated to be $2.4 million (3). Part of this cost is due to loss of productivity of parents, that are usually the primary caretakers and often have to provide more extensive and long-lasting support well after the children have grown up (12). Even a small improvement will potentially reduce the long-term need for educational services, health services and supportive housing, thus having a strong human and economic impact (13).

The great needs of families with autism led an official Norwegian report to recommend parental programs as an obligatory health service in secondary care (1). Although parental psychoeducation is a mandatory, integral and intuitive part of health care for children with autism, there is a lack of evidence for such interventions in general and for parental programs targeting autism specifically. Studies are few and of poor methodological quality (14). Proper evaluation of parental programs is time- and resource consuming. Nevertheless, parent guidance is provided every day in autism clinics all over the world, at a high cost and with poor scientific underpinning (14). Effective parent programs could have significant downstream benefits, as evidence suggests that developmental social-pragmatic interventions for parents may enhance the child's functioning (15).

We currently know little about what kind of parent programs should be administered to whom, to what extent or in what form. Many different types of parent-mediated interventions exist with different approaches to train parents in supporting their child, finding overall beneficial effects on both child and parent outcomes (16, 17). Parent training seems superior to parent education for reducing disruptive behavior on parent-reported outcomes and also more effective in reducing parent stress (17, 18). This suggests that programs guided by standardised manuals focused on parental strategies may be appropriate for parents of children with ASD.

One of the few *manualised* parent programs for ASD that are available in Norwegian services is the Incredible Years Autism Spectrum and Language Delay Program (IY-ASLD©)(16, 19, 20). The IY-ASLD program emphasises promoting positive relationships and teaches parents, through child-directed narrative play, how to strengthen children's communication, language, social, and self-regulation skills. It also guides

parents in positive limit setting and effective behavior management (20). It was implemented in Norway in 2017, first at Haukeland University Hospital (HUS) and St. Olavs Hospital (SOH) in Trondheim, then also at Stavanger University Hospital (SUS) and University Hospital of North Norway (UNN) from 2026. Smaller studies have investigated the feasibility and effect of the IY-ASLD (9, 21, 22), and there has also been two smaller RCTs (23, 24). The studies find that the IY-ASLD is well received and there seems to be beneficial effects, but the studies have been limited in power and scope, and longer follow-up was suggested (21, 23, 24). The need for parent programs and lack of clear evidence base for such programs motivated the current study of the IY-ASLD.

Explanation for the choice of comparator {9b}

Parental follow-up in ASD is mandatory in Norway but may in practice vary considerably both in quantity and content, particularly across different time periods and clinics (25). To address this challenge, we developed a standardised version of care as usual (CAU) as comparator, called “First Aid for Parents”. This program consists of a three-day in-person psychoeducational course based on CAU for parents from the lead study site (Bergen).

Objectives {10}

The current study aims to evaluate the effectiveness and cost-effectiveness of IY-ASLD compared with CAU for parents of children aged 2-6 years with ASD on parental stress (primary outcome), parental sense of competence, parent and child quality of life, child functioning, and service use and resource costs (secondary outcomes). Additionally, the study seeks to explore predictors of effect, including child characteristics and parental factors.

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}

The study has involved parents from the national autism stakeholder organisation «Autismeforeningen», and parents will be involved in the design, conduct and reporting of the study, notably in design and content of informed consent, information from participants and in development of the active control condition, as well as in development of interview guides, and analysis of qualitative data. The study has a close collaboration with stakeholder organisations and will present the study and findings at local, regional, national and international conferences and meetings targeting both the public, stakeholders, services and the scientific community.

Trial design {12}

A multi-centre RCT including four clinical sites in a superiority design comparing IY-ASLD with a standardised parent psychoeducational program (CAU).

Methods: Participants, interventions and outcomes

Trial setting {13}

Recruitment and interventions are carried out at the four participating community clinics in Bergen, Haugesund, Trondheim and Tromsø, representing the western, northern and middle parts of Norway. All participating clinics have specialised teams for autism assessment and/or intervention, and form part of the regular secondary health care system, where families of children in Norway are referred to for diagnostic evaluation and/or follow-up of ASD. The four clinics represent three of the four health regions in Norway. Three of the clinics form part of paediatric neurodevelopmental services, while the Bergen clinic is organised under the child and adolescent mental health services (CAMHS). In Norway, the follow-up of children with autism before school age is a public responsibility and is provided by the education system, secondary health care, or a combination of both, depending on geography, organisation, and context. Parental follow-up by secondary health services after the ASD diagnosis is also a legal right, but its delivery, content and scope vary significantly.

Characteristics of the people who are needed for the trial

Characteristic	The people we would expect to see included
Age	Parents aged 18 or older. Their child must be aged 2-6 years (inclusive).
Sex	Any (sex is obtained through the personal identity number)
Gender	Any (gender identity is not reported/asked for)
Race, ethnicity and ancestry	Predominantly white Norwegian. Approximately 20-30% of other ethnicities/race.
Socioeconomic status	Participants are expected to be roughly representative of the Norwegian population SES, albeit with a higher immigrant representation due to the higher immigrant background in families with autism.
Geographic location	Norway. A mix of urban and rural communities from the Western, Middle and Northern parts of Norway.
Other characteristics relevant to the trial	By “parent” in this study we refer to adults who function as a caretaker of the child in their daily life. However, to participate in the study, one adult with legal right to do so must consent to the study on behalf of the child as information on the child is collected (see also {32a}). As autism is a highly heritable condition, many parents participating may have neurodiverse traits.

Eligibility criteria for participants {14a}

Inclusion criteria: Parents/caregivers of children diagnosed with an autism spectrum disorder, age 2-6 (until turned 7), living in the areas serviced by the four participating clinical centres. One or both parents may participate. The parent first completing baseline questionnaires is defined as the primary respondent. If a family has more than one child fulfilling inclusion criteria, they may participate reporting on one of the

children and are encouraged to report on the child with the largest needs.

Exclusion criteria: Language proficiency insufficient to benefit from parental program without the assistance of an interpreter. Families with ongoing major crisis (e.g. disruptive divorce), and parents who suffer from serious disorders/conditions interfering with the program are not eligible to participate (e.g. ongoing psychosis, advanced cancer). Simultaneous participation in another manualised parent program.

Eligibility criteria for sites and those delivering interventions {14b}

Sites must be clinics specialised in assessment and/or follow-up of preschool children with ASD. Individuals providing the intervention must be experienced clinicians working at the autism clinics and having received training for the intervention.

Who will take informed consent? {32a}

Informed consent is collected digitally from participating parents/guardians using electronic signatures approved by Norwegian authorities (BankID) via the study trial digital platform (EasyTrial). Parents are defined as adults that function as daily caretaker of the child, meaning also stepparents and foster parents may participate. Parents consent on their own behalf, and minimum one legal guardian must also consent on behalf of the child as data on the child is collected in the study.

Additional consent provisions for collection and use of participant data and biological specimens {32b}

N/A, biological specimens are not collected in the study.

Intervention and comparator

Intervention and comparator description {15a}

Experimental condition:

The Incredible Years for Autism Spectrum and Language Delays program (IY-ASLD):

The IY-ASLD consists of 13 x 2.5-hour weekly sessions with small groups of parents of 5-8 index children. The program is delivered to parents through a collaborative, group-based format that includes discussions, video vignettes, modelling, and guided practice. It teaches effective strategies for promoting positive interactions and managing behavior. Group leaders support parents in adapting the content and strategies to match their child's developmental level.

Active control condition:

Care as usual (CAU) - "First Aid for Parents":

A three-day introduction program on communication skills, psychoeducation and approaches to daily challenges of nutrition, sleep, hygiene and daily living skills. The workshops will be held once a month in the same semester as the experimental condition to ensure similar treatment periods and time from randomisation and follow-up.

Both interventions are delivered in-person at the respective clinics participating in the study.

Criteria for discontinuing or modifying allocated intervention/comparator {15b}

N/A. Both interventions are established behavioral interventions that are unlikely to be associated with substantial adverse effects.

Strategies to improve adherence to intervention/comparator {15c}

Within the active intervention, according to the manual, there are individual follow-up phone calls between sessions, and opportunity for individual catch-up before each next session. In the control condition, parents are offered a replacement class if they miss out on course days (in the next regular course). All group IY-ASLD leaders are supervised on fidelity by a certified IY instructor on recorded sessions. Both IY-ASLD and CAU clinicians are asked to fill out a brief content fidelity checklist after each session.

Concomitant care permitted or prohibited during the trial {15d}

Participation in another manualised parent program simultaneously with participation in the ENACT trial is not allowed, all other concomitant care is permitted (information on concomitant care is collected in the Concom questionnaire, see {16}).

Ancillary and post-trial care {34}

No specific post-trial care is planned apart from the trial's 12 and 24-months follow-up (digital questionnaires). About 10% of families will also be invited to qualitative interviews. At the end of the trial, families are transferred to/continue their regular CAU in the primary/secondary services.

Outcomes {16}

Primary outcome measure

Parenting Stress Index-Short Form IV (PSI-SF).

The PSI-SF is a 36-item parental self-report questionnaire that assesses a variety of challenges producing an overall composite measure of parental stress, including stress related to interaction with the child, in relationship to the parents' personal situation and their well-being. It has good psychometric properties (26) and is one of the most used questionnaires globally and in corresponding parental program research specifically (23, 24). The PSI-SF will be completed individually by parents before randomisation (T0), after conclusion of intervention (T1), as well as 12- and 24-months after completing the intervention (T2 and T3).

As ASD is a life-long disability with need for long-term follow-up, we have chosen as primary outcome the difference in mean change in PSI from baseline (T0) to final follow-up at 24 months in the primary respondent (T3).

Secondary outcome measures

***Parenting Sense of Competence Scale (PSOC*)**

The PSOC is a parent self-report questionnaire consisting of 17 items and two subscales (27). It has good reliability and validity (28) and has been shown to strongly correlate with perceived parental stress in children with ASD and other developmental disorders (29). To be completed individually by all participating parents

(T0, T1, T2, T3).

Parent Quality of Life (ParQoL)

Parents are asked to fill out their overall perception of their own QoL as a VAS (0-5 with 0.25 intervals) (T0, T1, T2, T3).

The Pediatric Quality of Life Inventory (PedsQL)

The PedsQL is a validated questionnaire (30, 31). The parent proxy for children 2-4 years consists of 21 items in four domains: physical, emotional, social and preschool function. To be completed individually by all participating adults (T0, T1, T2, T3).

Child Quality of Life (ChQoL)

As the social domain may artificially deflate the QoL in autism, parents are also asked to fill out their own overall perception of their child's QoL as a visual analogue scale (VAS, 0-5 with 0.25 intervals) (T0, T1, T2, T3).

The Vineland Adaptive Behavior Scales – third edition (VABS-3)

The VABS is a measure of daily function in various domains, including social and communicative function (32-34). The VABS-3 questionnaire is sent in an individual link to the primary respondent and filled out by one parent or jointly using a digital platform (Q-global). To reduce the load on parents and due to the extent of the VABS-3, it will only be collected at T0 and T3.

Concomitant Treatment and Resources (Concom)

Concom is a self-report questionnaire for parents of children with ASD, including resource and all service use costs, including alternative therapy and diet costs. To be completed individually by all participating parents (T0, T1, T2, T3).

Child medical journal

Additional information on the child's autism, general level of ability and adaptive functioning will be collected from the medical journal, including e.g. Autism Diagnostic Interview-Revised (ADI-R) (35-37), the Autism Diagnostic Observation Schedule, second edition (ADOS-2) (38) and the Wechsler Preschool and Primary Scale of Intelligence (WPPSI) (39). These measures are the gold standard both in autism diagnostic work and research and have been validated for use in Norway (33, 40, 41).

Process evaluation

Data will be gathered to facilitate an evaluation of the process of the trial (in parallel to evaluation of the outcomes). Quantitative data will include dates of intervention groups, which groups have been attended by which practitioners, where the interventions take place, the uptake of supervision sessions per practitioner, practitioner notes, practitioner fidelity checklists, and group attendance by participants. Qualitative data will be gathered primarily via interviews with parents and in focus groups with practitioners.

Qualitative interviews

Interviews on parent stress and related factors will be performed with a combination of convenience and purposive sampling of parents before randomisation.

Post intervention, about 10% of parents will be invited from all participating sites (combination of convenience and purposive sampling) to do an interview on their experiences of the interventions and its effects. We will include parents from both interventions and perform interviews with parents in the short-term after intervention (<12 months) and in the long-term (>12 months).

Harms {17}

The behavioral interventions are established parent interventions with no anticipated harms or serious consequences. Any unforeseen adverse events will be handled on site by the clinicians delivering the interventions and communicated to the PI/study coordinator who will report to the study sponsor.

Participant timeline {18}

Recruitment is performed continuously through the year with batches starting in spring or autumn and running through spring/autumn. Randomisation is performed after informed consent and completion of baseline data collection (T0), aiming for a time window of less than three months from baseline to start of intervention. The interventions lasts 3-4 months and post intervention (T1) questionnaires will be sent out within a month after completing the intervention. At 12- and 24-months after completing the intervention, questionnaires will be sent out to collect follow-up data (T2 and T3 respectively) (Figure 1). Recruitment started January 10th 2022 and final recruitment is planned for March 31st 2026.

Sample size {19}

Based on power calculations with statistical power of 0.8, a medium effect size (d = 0.5) and α=0.05, a sample size of minimum 64 families per group, in total 128 families are required to detect a statistically significant difference between groups. Based on experience from autism follow-up in the clinic we allow for a drop-out rate of 30%. To allow for similar drop-out of 30% longitudinally and maintain power at the 24-month follow-up, we aim to include up to 240 families (stop criterion).

Recruitment {20}

The study clinics are all specialised clinics responsible for the assessment of ASD in their respective regions, thus covering the entire eligible population. During assessment of the child to determine the presence of autism, parents are interviewed at length using structured interviews. During the later feedback of the assessment to parents, the clinician at the participating sites will inform eligible parents about the study orally and in print. Information about the study is also available on the study website, and is presented at parent organisation sites, flyers and in the participating clinics. The information catalogue will also mention the study and there will be information about the study in the course catalogue at the basic parent diagnostic course that is offered to all parents as part of CAU.

Interested parents are asked to register their contact details in a webtool (SurveyXact) or their interest will be recorded by interview physically/by phone. They will be handed detailed information about the study, in paper and/or link to the study website (depending on their preference). The information and informed consent will be signed electronically using a national personal electronic identification method designed for secure online authentication and digital signing (BankID), to read and sign the informed consent at their leisure. Data will be collected by Easytrial and Q-Global set-up.

The four participating clinics diagnose and/or treat up to 220-270 children with ASD every year, ensuring a large pool of families eligible for inclusion. Immigrant families are frequent in this patient group, and some of these families will not be eligible due to language barriers (and will receive standard follow-up with interpreter). When 12-16 families have been recruited at a particular site, randomisation to IY-ASLD or standardised CAU will be performed. Each clinic will run one or two IY-ASLD groups each year with the CAU condition in parallel, depending on recruitment.

Assignment of interventions: randomisation

Sequence generation: who will generate the sequence {21a}

The randomisation and allocation is computer-generated in blocks of two, in the order that parents complete the baseline questionnaires, i.e. whenever two families at one site have completed the baseline questionnaires, they are randomised. Groups start when the group minimum number of five families has been allocated to the active intervention.

Sequence generation: type of randomisation {21b}

Allocation is performed by intervention site, in blocks of two families. The randomisation protocol has an asymmetrical allocation procedure to ensure individual blinding of allocation while maintaining equal numbers over time, meaning within each block both families may be allocated to the same intervention.

Allocation concealment mechanism {22}

Randomisation, and allocation is performed in the same operation computer generated by the trial software. The allocation is then communicated directly to the clinical teams performing the intervention by the study coordinator who is not involved in data analyses.

Implementation {23}

Participants are enrolled by signing up digitally. After digital consent and fulfilment of questionnaires, the participants are randomly assigned to interventions as described in . The study coordinator then informs the clinicians at the corresponding site who informs the participants and schedules the intervention.

Assignment of interventions: blinding

Who will be blinded {24a}

Data analysts will be blinded to the allocation variable for the primary outcome analyses.

How will be blinding be achieved {24b}

The study coordinator who is not involved in the intervention nor in the data analyses will provide the data analysts with an anonymised dataset excluding any intervention details other than intervention batch and site and an uninformative allocation variable (e.g. “green” and “blue”).

Procedure for unblinding if needed {24c}

N/A. As the intervention is behavioral and psychoeducational, neither clinicians nor participants can be blinded to intervention allocation and only data analysts will be blinded.

Data collection and management

Plans for assessment and collection of outcomes {25a}

Assessment of the autism diagnoses is done by certified clinicians as part of the diagnostic work-up before participation in the study. All outcome data is collected digitally (quantitative) using self-report digital questionnaires. Questionnaires will be completed by all participants before randomization (T0), after conclusion of intervention (T1), as well as 12- and 24-months after completing the intervention (T2 and T3). Interviews will be administered by researchers/PhD students to collect qualitative data before and after intervention as described in {16}.

Plans to promote participant retention and complete follow-up {25b}

Digital reminders and several opportunities for completion will be provided to participants, as well as assistance with questionnaire completion if requested, e.g. by phone calls and offer to fill out in person at the clinic. Parents will also receive gift-cards upon completion of questionnaires/interviews in the follow-up, as compensation for their time and effort. Parents who discontinue but agree to stay in study may still contribute to follow-up data.

Data management {26}

Data entry, coding, security, and storage is handled by the study coordinator using Easytrial software, including initial data quality checks (e.g. double data entry; range checks for data values). Further data management documentation will be provided in the statistical analysis plan and will be submitted as an update to *Trials* before data lock. All data is handled pseudonymised with linkage key stored separate to data. Personal identifiers will by law requirements be stored for five years after the end of the study, at which point the data set will be anonymised (projected date December 2035).

Confidentiality {33}

Data collected during the course of the research is kept strictly confidential and accessed only by members of the trial team and may be looked at by individuals from the Sponsor organisation or study sites where it is relevant to the participant taking part in this trial.

Participants are allocated an individual trial number. Participants' details are stored on a secure database under the guidelines of the European Union General Data Protection Regulations (EU GDPR) 2018. The FHU study coordinator (in collaboration with the PI) manages access rights to the data set. We anticipate that anonymised trial data may be shared with other researchers to enable international prospective meta-analyses.

The PI and study staff involved with this study will comply with the requirements of the EU GDPR and the Norwegian Personal Data Act 2018 that incorporates the EU GDPR.

All data is collected digitally directly onto a secure server where it is stored pseudonymised. Information of allocation of participants will be shared using phone call or the digital health journal or using the secure Norwegian Patient Registry number. Qualitative interviews are recorded digitally and downloaded to the sponsors secure server where it will also be transcribed.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}

The primary outcome for the study will be difference in the PSI-SF total score, measured at 24-months post-intervention (T3). This will be analysed using a linear regression model, with variance estimates adjusted for clustering and repeated measurements through generalised estimating equations (GEE). As the secondary outcomes are also continuous variables, they will be analysed using the same models. Cost-effectiveness analyses will calculate the cost per unit change in the primary outcome measure over the trial time horizon (24 months post-intervention). The primary analysis will take a public sector multi-agency perspective, and secondary analyses will take a societal perspective (42, 43). A statistical analysis plan (SAP) and a health economics analysis plan (HEAP) will be published as an update to the protocol publication. See also the logic model and the accompanying walk-through of logic model.

Who will be included in each analysis {27b}

The principal analyses will be intent-to-treat (ITT) where all included (and not excluded) parents are in the analysis in the groups they are allocated to conform the randomisation (regardless of compliance).
The per-protocol (PP) analysis will include all families that attended a minimum of one session.

How missing data will be handled in the analysis {27c}

We will adjust for potential differential attrition by inverse probability weighting (IPW). Here, a multivariable logistic regression model gives estimates for the probability of an observation being non-missing; weights are the inverse of these probabilities and are implemented for the observations that are non-missing. GEE adjust the variance for such weighting (44).

Methods for additional analyses (e.g. subgroup analyses) {27d}

We plan to stratify the above analyses [for the primary outcome], through the inclusion of an appropriate interaction term in the linear regression models, by the subgroups of 1.) parent resources as measured by a composite score of SES and social support, and 2.) child functional level as reported by parents in the VABS-3.

Interim analyses {28b}

N/A, due to the duration of the study, the nature of the intervention, absence of possible adverse events and expected possible outcomes.

Protocol and statistical analysis plan {5}

The protocol will be accessible through this publication, with the main statistical analysis plan (SAP) and the health economy analysis plan (HEAP) submitted as Updates to the current publication before data lock.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}

The PI and the study coordinator will work closely together running the study, data collection and study management. The trial master file and the study coordinator will be located within a trial research centre run by the university and the university hospital in collaboration, providing all the logistical support for the study. All the sites have their local site manager and trial site files, delegated from the main study site (Bergen). The intervention fidelity for the active condition is overseen by an IY-ASLD licensed psychologist independent from the PI, from the second study site (Trondheim), by guidance, fidelity checks and follow-up of every IY group.

The PI and study coordinator will meet with the study team regularly (approx. monthly) to manage the operation of the trial. They will periodically take advice from a Scientific Advisory Board (SAB) comprised of experts in the field who do not have a stake in the outcome of the trial. The SAB and the extended study group (operational team plus co-investigators) will aim to meet in person a minimum yearly, with the study group and SAB biannually or more often as required.

Composition of the data monitoring committee, its role and reporting structure {28a}

There is no external Data Monitoring Committee (DMC) in this trial. Best practice sources indicate that a DMC is usually required for trials with higher risk, longer duration, multiple sites, or safety endpoints (45). Behavioral trials with minimal risk often rely on internal monitoring and oversight instead of an external DMC. In this behavioral program trial, the absence of a DMC is consistent with these recommendations, since the study involves low-risk interventions, weekly monitoring, supervision, and treatment fidelity checks. The study sponsor has internal reporting routines with yearly reporting of the trial for internal supervision of all clinical studies and will provide monitoring of the study during the trial accordingly. The SAB will also provide oversight as outlined above.

Frequency and plans for auditing trial conduct {29}

The study sponsor will provide monitoring of the trial, in addition to yearly obligatory reporting of trial progress.

Protocol amendments {31}

Major protocol amendments/new protocol versions will be submitted to the regional ethical committee for approval and is then updated in the trial site files and on the study website (www.enact.no).

Dissemination policy {8}

Study results will be communicated through scientific journal articles, conferences, Ph.D. dissertations and study and affiliated webpages. As part of the agreement for grant funding, all scientific journal publications will be open access. Results of scientific work will also be communicated to participants through our website

and newsletters and to the wider public in popular form through media, podcasts, and other digital channels.

Discussion

The ENACT study is a multi-centre RCT conducted across four parallel clinical sites in a superiority design comparing IY-ASLD with a standardised parent psychoeducational program (CAU). ENACT has the potential to make a significant contribution to the understanding of how parent training programs for parents of children with ASD performs in Norwegian health services. The knowledge gained regarding the effectiveness and cost-effectiveness of the IY-ASLD program will provide policymakers with critical evidence and could inform the enhancement of support programs for families of children with autism.

The present study highlights the little empirical foundation currently available to guide clinical decision-making. As emphasised in previous reviews, the field is characterised by small sample sizes, methodological limitations, and considerable variability in intervention content and delivery (14). By applying a rigorous evaluation strategy within routine services, the ENACT study provides important real-world data that can contribute to narrowing this evidence gap.

An important implication of this study lies in its relevance for public health planning. In Norway, as in many countries, national policy documents emphasise the importance of providing early and systematic support for parents (1). Evidence from ENACT can contribute to informing these policies by clarifying whether established parent programs, such as the Incredible Years, are effective and cost-effective, feasible and suitable for families with children with ASD. Furthermore, by embedding research within routine practice, the study delivers valuable insight into how parent interventions can be scaled and implemented without compromising quality.

Strengths of the study include the randomisation, structured outcome measures, a large sample size across multiple sites, collaboration with stakeholders, long-term follow-up, and the aim to examine cost-effectiveness. Given that many previous studies on parent programs have been limited by small sample sizes and a lack of long-term outcomes, prioritising a larger sample and long-term outcomes were key objectives of the ENACT study. Overall, the ENACT study represents an important step forward in addressing the critical gap in the empirical foundation for parent programs within the field of autism.

Trial status

Recruitment started 10th January 2022 and is ongoing. Recruitment will stop by March 31st 2026.

Abbreviations

ADI-R: Autism Diagnostic Interview-Revised

ADOS: Autism Diagnostic Observation Schedule

ASD: Autism Spectrum Disorder

BankID: Electronic identification

CAMHS: Child and adolescent mental health services

CAU: Care as usual

CHEME: Centre for Health Economics and Medicine Evaluations

ChQoL: Child Quality of Life

Concom: Concomitant use of resources questionnaire

DMC: Data Monitoring Committee

ENACT: Enabling parents of children with autism spectrum disorders, a randomised controlled trial

EU GDPR: European Union General Data Protection Regulations

FHU: Research Unit for Health Surveys

GEE: Generalised estimation equations

HEAP: Health economy analysis plan

HUS: Haukeland University Hospital

IPW: Inverse probability weighting

ITT: Intent to treat

IY-ASLD: Incredible Years Autism Spectrum and Language Delays program

NTNU: Norwegian University of Science and Technology

ParQoL: Parent Quality of Life

PedsQL: The Pediatric Quality of Life Inventory

PhD: Philosophie Doctor

PI: Principal Investigator

PSI-SF: Parent Stress Index, short form

PSOC: Parenting Sense of Competence Scale

RCT: Randomised Controlled Trial

REK Vest: Western Regional Ethics Committee

SAB: Scientific Advisory Board

SAP: Statistical analysis plan

SES: Socioeconomic status

SOH: St. Olavs Hospital

SUS: Stavanger University Hospital

UNN: University Hospital of North Norway

VABS-3: The Vineland Adaptive Behavior Scales – third edition

VAS: Visual analogue scale

WPPSI: Wechsler Pre-school and Primary Scale of Intelligence

Declarations

Acknowledgements

The authors gratefully acknowledge all parents and the Norwegian Autism Association for valuable input during the development of this study and its protocol. We also extend our thanks to all collaborating institutions and professionals whose contributions were essential to this work.

We recognize the key efforts of the clinical units responsible for participant recruitment and delivery of the two interventions: the Child and Adolescent Habilitation Services at Helse Fonna, Haugesund; St. Olavs Hospital, Trondheim; the University Hospital of North Norway, Tromsø; and the Department of Child and Adolescent Psychiatry at Haukeland University Hospital, Bergen. We especially thank the whole team at the special autism clinic and the leader Veslemøy Sandvik for contributing to and supporting the study.

We further thank the Regional Centers for Child and Youth Mental Health and Child Welfare (RKBU) in Western Norway (NORCE), Central Norway (NTNU), and North Norway (UiT) for their sustained support and commitment to improving services for children and families.

We would like to thank Professors Edmund Sonuga-Barke, Kimberley Goldsmith and Sarah Byford at King's College London for their kind, timely and helpful advice and guidance to the challenging world of parental programs research.

Finally, we acknowledge our study coordinator Trine Leikanger and the entire team at the Research Unit for Health Surveys (FHU) at the University of Bergen for their invaluable contributions to the study logistics and data collection.

Authors' contributions {3a}

MP is the Principal Investigator; she conceived the study, led the grant proposal, acquired funding and led the protocol development.
JI contributed to study design and to development of the proposal and study protocol.
JFB contributed to the study design and contributed to the protocol manuscript.
EJ contributed to the conception and study design.
TA, RG and VS are the lead trial methodologists and contributed to the protocol manuscript.
RB contributed to the design and conception of the study, as well as the grant proposal and protocol manuscript.

AU contributed to the design and conception of the study, as well as the protocol manuscript.
CG contributed to the study design and the grant proposal.
SH, SA, GBS, RS, and KW contributed to the study design and the protocol manuscript.
OS and MH contributed to the study design and the protocol manuscript.
MR contributed to the study design.
CK contributed to revision and editing of the protocol manuscript.
ALH contributed to the design of the study and the protocol manuscript.
RTE and GF contributed to the study design and protocol manuscript in relation to health economics.
LT and PW contributed to the design and conception of the study, as well as the grant proposal and protocol manuscript.
GJW contributed to the conception and study design and to revision and editing of the protocol manuscript.
All authors read and approved the final manuscript
Authorship on future trial publications will be determined applying standard ICMJE guidelines.

Sources of funding and other support {7a}

Western Regional Health Authority (Helse Vest HF), Norway, is the main funder with two funding periods: Grant number F-12620 in 2022-2024 and grant number F-13405 running from 2025-2027 (https://www.helse-vest.no/en/).

Other funders have supported with PhD and post-doc/researcher grants, notably the Kavli foundation, www.kavli.no (https://kavlifondet.no/2025/09/gir-foreldre-verktoyene-de-trenger-for-barnas-og-samfunnets-beste/), the DAM foundation www.dam.no, the Norwegian University of Science and Technology (NTNU), www.ntnu.no and the Northern Norway Regional Health Authority (Grant HNI0068-25).

None of the funders have had any role in the design of the study and collection, analysis, and interpretation of data and in writing of the manuscript.

Availability of data and materials {6}

Anonymised individual participant data (IPD) related to the primary and secondary outcomes of the trial will be made available after publication of the main trial results provided permission from the regional ethical committee and the data protection officer. The data may be shared with qualified researchers for purposes such as meta-analyses, secondary analyses, or other ethically approved research.
Data will be provided upon reasonable request to the corresponding author. Requests must include a scientifically sound research proposal and will be evaluated by the trial's data access committee. A data use agreement will be required prior to granting access.

Ethics approval and consent to participate {30}

The study has been approved by the Western Norwegian Regional committee for medical and health research ethics (REK Vest); number:188940.
Consent will be collected from all participating adults, and from minimum one guardian on behalf of their

child.

Consent for publication

N/A, no data is published herein.

Competing interests {7b}

BB and KW are certified instructors for IY group leaders. BB, KW, GBS and RB all work with other parenting programs clinically, in development and/or in research. No other competing interests are reported by any author.

Authors' information (optional)

643 Figure 1. ENACT trial timeline

		TRIAL PERIOD						
		Enrolment			Intervention	Follow-up		
			T0			T1	T2	T3
Enrolment	Eligibility screen	+						
	Informed consent	+						
	Randomisation			+				
Intervention	The Incredible Years				13 sessions			
	First-Aid for Parents				3 sessions			
Parent reported data	Personal data		+			(+)	+	+
	Parent stress index, short form		+			+	+	+
	Parent quality of life (VAS)		+			+	+	+
	Parent sense of competence		+			+	+	+
	Paediatric quality of life, proxy		+			+	+	+
	Child quality of life, proxy (VAS)		+			+	+	+
	Concomitant use of resources		+			+	+	+
	Vineland adaptive behaviour scales		+					+
Qualitative data	Participant interviews		+			+		
	Group leader interviews					+		
Other data	Child hospital records	+						

(+) Some but not all items are included.

644

645

646

References

1. NOU 2020:1. Tjenester til personer med autismespekterforstyrrelser og til personer med Tourettes syndrom. Chapter 2 (p.19), Chapter 6 (pp. 112-113), Chapter 7 (p. 138). Oslo: Departementenes sikkerhets- og serviceorganisasjon, Teknisk redaksjon; 2020.
2. Posserud MB, Solberg BS, Engeland A, Haavik J, Klungsoyr K. Male-female ratios in autism spectrum disorders by age, intellectual disability and attention deficit/hyperactivity disorder. Acta Psychiatr Scand. 2021.
3. Buescher AV, Cidav Z, Knapp M, Mandell DS. Costs of autism spectrum disorders in the United Kingdom and the United States. JAMA pediatrics. 2014;168(8):721-8.
4. Magiati I, Tay XW, Howlin P. Cognitive, language, social and behavioural outcomes in adults with autism spectrum disorders: a systematic review of longitudinal follow-up studies in adulthood. Clinical psychology review. 2014;34(1):73-86.
5. Neff KD, Faso DJ. Self-Compassion and Well-Being in Parents of Children with Autism. Mindfulness. 2015;6(4):938-47.
6. Cappe E, Wolff M, Bobet R, Adrien JL. Quality of life: a key variable to consider in the evaluation of adjustment in parents of children with autism spectrum disorders and in the development of relevant support and assistance programmes. Qual Life Res. 2011;20(8):1279-94.
7. Karst JS, Van Hecke AV. Parent and family impact of autism spectrum disorders: a review and proposed model for intervention evaluation. Clin Child Fam Psychol Rev. 2012;15(3):247-77.
8. Bonis S. Stress and Parents of Children with Autism: A Review of Literature. Issues Ment Health Nurs. 2016;37(3):153-63.
9. Evans S, Crumpton J. Incredible Years® Autism Spectrum Parent Programme: Pilot Study, Powys, 2015-2017. Powys Teaching Health Board, Wales, United Kingdom, 2017.
10. Özgür BG, Aksu H, Eser E. Factors affecting quality of life of caregivers of children diagnosed with autism spectrum disorder. Indian journal of psychiatry. 2018;60(3):278.
11. Osborne LA, McHugh L, Saunders J, Reed P. Parenting Stress Reduces the Effectiveness of Early Teaching Interventions for Autistic Spectrum Disorders. Journal of Autism and Developmental Disorders. 2007;38(6):1092.
12. Howlin P, Goode S, Hutton J, Rutter M. Adult outcome for children with autism. J Child Psychol Psychiatry. 2004;45(2):212-29.
13. Heckman JJ. Skill formation and the economics of investing in disadvantaged children. Science. 2006;312(5782):1900-2.
14. O'Donovan KL, Armitage S, Featherstone J, McQuillin L, Longley S, Pollard N. Group-based parent training interventions for parents of children with autism spectrum disorders: A literature review. Review Journal of Autism and Developmental Disorders. 2019;6(1):85-95.
15. Smith T, Iadarola S. Evidence Base Update for Autism Spectrum Disorder. J Clin Child Adolesc Psychol. 2015;44(6):897-922.
16. Cheng WM, Smith TB, Butler M, Taylor TM, Clayton D. Effects of Parent-Implemented Interventions on Outcomes of Children with Autism: A Meta-Analysis. Journal of Autism and Developmental Disorders. 2023;53(11):4147-63.
17. Iadarola S, Levato L, Harrison B, Smith T, Lecavalier L, Johnson C, et al. Teaching Parents Behavioral Strategies for Autism Spectrum Disorder (ASD): Effects on Stress, Strain, and Competence. Journal of Autism and Developmental Disorders. 2018;48(4):1031-40.
18. Bearss K, Johnson C, Smith T, Lecavalier L, Swiezy N, Aman M, et al. Effect of parent training vs parent education on behavioral problems in children with autism spectrum disorder: a randomized clinical trial. JAMA. 2015;313(15):1524-33.
19. Webster-Stratton. Manual for the Incredible Years Autism Spectrum and Language Delays programme for parents with preschool children. Seattle, US: : Incredible Years Inc.; 2015.

20. Webster-Stratton C, Dababnah S, Olson E. The Incredible Years® Group-Based Parenting Program for Young Children with Autism Spectrum Disorder. In: Siller M, Morgan L, editors. Handbook of Parent-Implemented Interventions for Very Young Children with Autism. Cham: Springer International Publishing; 2018. p. 261-82.
21. Dababnah S, Olson EM, Nichols HM. Feasibility of The Incredible Years Parent Program for Preschool Children on The Autism Spectrum in two U.S. sites. Research in Autism Spectrum Disorders. 2019;57:120-31.
22. Wahdan MM, Malak MZ, Al-Amer R, Ayed A, Russo S, Berte DZ. Effect of incredible years autism spectrum and language delays (IY-ASD) program on stress and behavioral management skills among parents of children with autism spectrum disorder in Palestine. Journal of Pediatric Nursing. 2023;72:45-52.
23. Williams ME, Hastings RP, Hutchings J. The Incredible Years Autism Spectrum and Language Delays Parent Program: A Pragmatic, Feasibility Randomized Controlled Trial. Autism Res. 2020;13(6):1011-22.
24. Villalta L, Elias M, Llorens M, Vall-Roqué H, Romero-González M, Valencia-Agudo F. Implementation of the incredible years-ASLD® program in autism and preterm children with communication and/or socialization difficulties in Spain (FIRST STEPS): a feasibility study. Children and Youth Services Review. 2025;177:108422.
25. Öst L-G. Att utvärdera psykoterapi och kritiskt granska psykoterapistudier: Natur och kultur; 2016.
26. Kornør H, Martinussen M. Måleegenskaper ved den norske versjonen av Parenting Stress index, 3. versjon (PSI). *PsykTestBarn* 2011; 1:2 Available from: https://psyktestbarn.r-bup.no/no/artikler/psi-parenting-stress-index#.
27. Johnston C, Mash EJ. A Measure of Parenting Satisfaction and Efficacy. J Clin Child Psychol. 1989;18(2):167-75.
28. Ohan JL, Leung DW, Johnston C. The parenting sense of competence scale: Evidence of a stable factor structure and validity. Can J Behav Sci. 2000;32(4):251-61.
29. Daulay N, Ramdhani N, Hadjam NR. Sense of Competence as Mediator on Parenting Stress. The Open Psychology Journal. 2018;11(1).
30. Reinfjell T, Diseth TH, Veenstra M, Vikan A. Measuring health-related quality of life in young adolescents: reliability and validity in the Norwegian version of the Pediatric Quality of Life Inventory 4.0 (PedsQL) generic core scales. Health Qual Life Outcomes. 2006;4:61.
31. Varni JW, Burwinkle TM, Seid M. The PedsQL as a pediatric patient-reported outcome: reliability and validity of the PedsQL Measurement Model in 25,000 children. Expert Rev Pharmacoecon Outcomes Res. 2005;5(6):705-19.
32. Cicchetti D, Carter A, Gray S. Vineland-II, VABS-II. In: Volkmar FR, editor. Encyclopedia of Autism Spectrum Disorders. New York, NY: Springer New York; 2013. p. 3284-. doi.org/10.1007/978-1-4419-1698-3.
33. Heyerdahl S, Eikeseth S. Måleegenskaper ved den norske versjonen av Vineland Adaptive Behavior Scales - Second Edition (Vineland-II). *PsykTestBarn* 2014; 1:2. Available from: https://psyktestbarn.r-bup.no/no/artikler/vineland-adaptive-behavior-scales.
34. Sparrow S, Cicchetti D, Balla D. Vineland-II Norsk versjon. Vineland Adaptive Behavior Scales (2. utg.). . Stockholm: NCS Pearson Inc. 2011.
35. Surén P, Havdahl A, Øyen A-S, Schjølberg S, Reichborn-Kjennerud T, Magnus P, et al. Diagnosing autism spectrum disorder among children in Norway. Tidsskrift for den Norske laegeforening : tidsskrift for praktisk medicin, ny raekke. 2019.
36. Rutter M, Lecouteur A, Lord C. The Autism Diagnostic Interview-Revised (ADI-R). Los Angeles, CA, Western psychological Services. 2003.

37. So Hyun K, Hus V, Lord C. ADI-R. 2013. In: Encyclopedia of Autism Spectrum Disorders [Internet]. New York, NY: Springer New York; [59-. doi.org/10.1007/978-1-4419-1698-3]. Available from: https://doi.org/10.1007/978-1-4419-1698-3_100066 https://link.springer.com/content/pdf/10.1007%2F978-1-4419-1698-3_100066.pdf.
38. Lord C, Rutter M, DiLavore P, Risi S, Gotham K, Bishop S. Autism diagnostic observation schedule–2nd edition (ADOS-2). Los Angeles, CA: Western Psychological Corporation. 2012;284.
39. Wechsler D. Wechsler preschool and primary scale of intelligence—fourth edition. The Psychological Corporation San Antonio, TX. 2012.
40. Halvorsen M, Helverschou S. Måleegenskaper ved den norske versjonen av autism diagnostic interview-revised (ADI-R). PsykTestBarn. 2017;1:5.
41. Brøndbo PH, Høyland AL. Måleegenskaper ved den norske versjonen av Autism Diagnostic Observation Schedule, Second Edition (ADOS-2). *PsykTestBarn*2018; 1:4.
42. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes: Oxford university press; 2015.
43. Edwards RT, McIntosh E. Applied health economics for public health practice and research: Oxford University Press; 2019.
44. Dufouil C, Brayne C, Clayton D. Analysis of longitudinal studies with death and drop-out: a case study. Statistics in medicine. 2004;23(14):2215-26.
45. Bierer BE, Li R, Seltzer J, Sleeper LA, Frank E, Knirsch C, et al. Responsibilities of data monitoring committees: consensus recommendations. Therapeutic Innovation & Regulatory Science. 2016;50(5):648-59.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- ENACTLogicmodelwithtext.docx