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A randomized controlled trial of modular psychotherapy for autistic youth

Submission date	Recruitment status	[X] Prospectively registered
09/10/2025	Recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
21/10/2025	Ongoing	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
22/10/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This project aims to improve mental health care for autistic children and adolescents (ages 6–18). Many autistic youth experience anxiety, depression, and other emotional or behavioral difficulties, but few personalized, evidence-based programs are available in routine clinical care. This study will test whether a structured and individualized modular psychotherapy program, called SEBASTIEN (Schema-, Emotion-, and BehAvior-focuSed Therapy), is more effective than standard care in improving well-being and daily functioning.

Who can participate?
Children and adolescents aged 6–18 years who have a confirmed autism diagnosis and are receiving services from Child and Adolescent Mental Health Services (CAMHS) at Innlandet Hospital Trust or Lovisenberg Diaconal Hospital in Norway.

What does the study involve?
Participants and their parents will first complete a personalized assessment to identify the child's top challenges and treatment goals. Families will then be randomly assigned to one of two groups:
1. SEBASTIEN program: 16 weekly 60-minute therapy sessions focusing on the child's personalized goals. The therapist will work both with the child and the parents using structured methods to address difficulties such as anxiety, depressed mood, inflexibility, social skills, and self-care.
2. Treatment as Usual (TAU): regular follow-up in CAMHS. Clinicians will receive results from the personalized assessment and supervision from a researcher / experienced clinician in how to use them to guide care.
Sessions may be audio- or video-recorded for quality and safety monitoring.
Families will complete short weekly questionnaires and follow-up assessments at 3, 6, 12, and 24 months after treatment. Teachers and siblings (if applicable) will also complete some questionnaires.

What are the possible benefits and risks of participating?
Benefits:
1. Personalized assessment for all participants, making care more relevant to each family's needs.

2. Possible improvements in mental health, coping skills, and quality of life.
3. Contributes to better future health services for autistic youth.
Risks or inconveniences:
1. Time spent on questionnaires and appointments may cause minor strain or school absence.
2. Some children might find new routines or discussions emotionally challenging.

Where is the study run from?
The study is coordinated by Child and Adolescent Mental Health Services (CAMHS) at
1. Innlandet Hospital Trust (Norway)
2. Lovisenberg Diaconal Hospital (Norway)

When is the study starting and how long is it expected to run for?
January 2025 to December 2028

Who is funding the study?
The project is funded by the South-Eastern Norway Regional Health Authority (Helse Sør-Øst) and supported by the participating hospitals.

Who is the main contact?
Dr Stian Orm, stian.orm@sykehuset-innlandet.no

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
U1111-1329-5830

Study information

Scientific Title
Empowering autistic youth with personalized intervention: a randomized controlled trial

Acronym
Empower Autistics

Study objectives
Empower Autistics aims to improve the well-being of autistic youth and their families by determining the effectiveness of a personalized, modular cognitive-behavioral intervention for autistic youth delivered in Child and Adolescent Mental Health Services (CAMHS). We will meet this aim by running a randomized controlled trial (RCT) comparing the modular cognitive-behavioral intervention “SEBASTIEN” to treatment as usual (TAU). SEBASTIEN is adapted to each youth's challenges. Hence, Empower Autistics addresses the demand for personalized and tailored health services to an increasing autistic population. In total 148 children and adolescents (6 to 18 years) with autism will be recruited from CAMHS at Innlandet Hospital Trust and Lovisenberg Diakonal Hospital. Participants will be randomly allocated to SEBASTIEN (intervention group) or TAU. The intervention group receives 16x60-minutes of individually tailored sessions. For both SEBASTIEN and TAU, Empower Autistics will (1) identify what challenges autistic youth, their parents, and their teachers experience and need help with, (2) determine whether SEBASTIEN can mitigate the challenges experienced by autistic youth and their families, (3) identify predictors and mechanisms of improvement, and (4) enhance patient safety through monitoring adverse events and implement a program for therapist skills-training. The knowledge gained from Empower Autistics can be directly applied in CAMHS upon the project's completion.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/08/2025, REK Sør-Øst D (Postboks 1130, Oslo, 0318, Norway; +47 (0)22845572; rek-sorost@medisin.uio.no), ref: 869536

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions

The experimental group will receive Schema-, Emotion-, and Behavior-Focused Therapy (SEBASTIEN) for youth with autism. Youth randomized to SEBASTIEN will receive 16 x 60 minutes individually tailored sessions according to parent and youth ratings on the Youth Top Problems (YTP) scale for autism-related clinical needs.

The control group will receive treatment as usual (TAU) at their Child and Adolescent Mental Health Services (CAMHS). Youth randomized to TAU will receive care and support at their local CAMHS (hospital service) and in their municipality. Clinicians at the CAMHS will be informed about the results from the personalized assessment (e.g., Youth Top Problems scale).

Participants will be individually randomized after baseline assessment. To ensure roughly equal sample size throughout the study, we will use block randomization with varying blocks, from 4 to 16 participants in each block. The randomization list will be generated by a researcher independent of the project, and the randomizations will be performed by hospital staff independent from the project/study team.

Intervention Type
Behavioural

Primary outcome(s)
Top three problems of the parent- and self-reported autism-adapted Youth Top Problem scale (Wood et al., 2022) collected at baseline, post-treatment, and 3-, 12-, and 24-months follow-up. The YTP will also be collected weekly from baseline to post-treatment (20 weeks) to inform treatment and for secondary analysis

Key secondary outcome(s))
1. Internalizing and externalizing problems measured using the Brief Problem Checklist (BPC; Chorpita et al., 2010) at baseline, post-treatment, and 3-, 12-, and 24-months follow-up
2. Quality of life measured using the KIDSCREEN-10 (Ravens-Sieberer et al., 2010) at baseline, post-treatment, and 3-, 12-, and 24-months follow-up
3. Autism symptoms rated by parents measured using the Social Responsiveness Scale (SRS-2; Constantino & Gruber, 2005) at baseline, post-treatment, and 3-, 12-, and 24-months follow-up

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Clinically confirmed autism diagnosis
2. 6 to 18 years of age
3. Autism symptoms above the clinical cutoff (measured with the Social Responsiveness Scale [SRS-2])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Child

Lower age limit
6 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Intellectual disability (i.e., IQ <70)
2. Severe hearing impairment (without correction)

Date of first enrolment
03/11/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Norway

Study participating centre
Innlandet Hospital Trust
Postboks 104
Brumunddal
Norway
2381

Study participating centre
Lovisenberg Diaconal Hospital
Postboks 4970 Nydalen
Oslo
Norway
0440

Sponsor information

Organisation

Innlandet Hospital Trust

ROR
https://ror.org/02kn5wf75

Funder(s)

Funder type
Government

Funder Name
Helse Sør-Øst RHF

Alternative Name(s)
South-Eastern Norway Regional Health Authority, Southern and Eastern Norway Regional Health Authority, helsesorost, Helse Sør-Øst RHF, helse-sor-ost-rhf, HSØ RHF - South-Eastern Norway Regional Health Authority, sorost

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
Contingent upon the ethical approval and the consent forms signed by participants, IPD from this study cannot be made freely available to other researchers. However, the data can be made available through access to the secure server upon request to the PI Dr Stian Orm (stian.orm@sykehuset-innlandet.no), contingent on approval from the ethical committee (REK).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes