ISRCTN75231331 https://doi.org/10.1186/ISRCTN75231331

Pilot randomized clinical trial implementation of a parenting program in Spanish children with autism in special education schools

Submission date
24/09/2025

Recruitment status
Recruiting

Registration date
15/12/2025

Overall study status
Ongoing

Last Edited
22/12/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is characterized by impairments in communication, social interaction, and the presence of repetitive behaviors, frequently accompanied by comorbid conditions such as epilepsy, gastrointestinal disturbances, and emotional dysregulation. These challenges extend to the mental health of caregivers, particularly parents. Evidence-based early interventions, including structured parent training programs, have demonstrated efficacy in enhancing family well-being. The IY-ASLD® program, validated in international contexts, aims to mitigate behavioral issues in children with ASD. Despite its proven effectiveness, implementation in Spain remains limited. Special education settings are proposed as optimal environments for deployment.
The first phase of this study aims to evaluate the feasibility of implementing the IY-ASLD® program in a special needs school. In a second phase of the study, we aim to explore evidence of effectiveness and preliminary cost-effectiveness of the IY-ASLD® program in parents of children with ASD, aged 2-5, who are enrolled in a special education school in Madrid.

Who can participate?
Parents or legal guardians of patients between 2 and 5 years-old diagnosed with ASD

What does the study involve?
This project will consist on two phases:
In an initial phase, a pilot feasibility study will be conducted to evaluate the feasibility of implementing a parenting program for parents of children with ASD in special education schools. This study will be carried out following the guidelines for the design and evaluation of pilot and feasibility studies.
In a second phase, and if the results of the pilot study are satisfactory, a pragmatic, randomized, controlled clinical trial comprising a 14-week intervention with a 12-month follow-up period, will be conducted to evaluate the effectiveness of implementing this parenting program for parents of children with ASD in special education schools.
Participating families will be randomly allocated to the intervention group (the IY-ASLD® program) or to the control group receiving the standard care in special education on a 1:1 ratio.

Assessment points for both the feasibility and the clinical trial will comprise baseline, directly after the end of treatment (post-treatment), and follow-ups 6 and 12 months post-treatment.

What are the possible benefits and risks of participating?
There are no risks associated with participating in this study. Some fatigue may occur after completing the questionnaires. Participation will not result in direct personal benefit. However, altruistically, participants will contribute to a better understanding of the effects of a parenting program aimed at preventing socio-emotional difficulties in children with ASD

Where is the study run from?
Hospital General Universitario Gregorio Marañón in Madrid, Spain

When is the study starting and how long is it expected to run for?
The study is starting on March 2025 and is expected to run for 2 years, until December 2027

Who is funding the study?
This study is funded by the Alicia Koplowitz Foundation (Spain)

Who is the main contact?
Laura Sevilla Cermeño, lauramaria.sevilla@salud.madrid.org

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Laura María Sevilla Cermeño

ORCID ID
https://orcid.org/0000-0002-6471-0402

Contact details
Calle Ibiza 43
Madrid
Spain
28009
+34 669592256
lauramaria.sevilla@salud.madrid.org

Additional identifiers

Protocol serial number
IY-ASLD-SCHOOL

Study information

Scientific Title
Protocol for a pilot randomized clinical trial: implementation of the Incredible Years-ASLD® program in Spanish children with autism in special education schools

Acronym
IY-ASLD-SCHOOL

Study objectives
The first phase of this study aims to evaluate the feasibility of implementing The Incredible Years® Autism Spectrum and Language Delays program (IY-ASLD) in a special needs school. In a second phase of the study, we aim to explore evidence of effectiveness and preliminary cost-effectiveness of the IY-ASLD program in parents of children with ASD, aged 2-5, who are enrolled in a special education school in Madrid.
Specific objectives are:
1. To measure the intervention´s fidelity, acceptability and satisfaction
2. To explore the effect of the program on parental strategies of children with ASD, on parental depressive and stress symptoms, and on parental quality of life.
3. To examine the program´s impact on the core symptomatology of ASD and on the internalising and externalising symptomatology of children with ASD, whose parents receive the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2025, Research Ethics Committee on Medicinal Products of the Gregorio Marañón Hospital (C/ Dr. Esquerdo 46, Madrid, 28007, Spain; +34 (0)91 586 7007; ceim.hgugm@salud.madrid.org), ref: Y-ASLD-SCHOOL

Primary study design
Interventional

Study design
A (first phase) pilot feasibility study and a (second phase) pragmatic randomized controlled clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of of behavioral problems and other psychopathology (anxiety, hyperactivity, or social difficulties) in children diagnosed with Autism Spectrum Disorder.

Interventions
The intervention consists of weekly 2-hour sessions over a 14-week period. The program includes home-based activities that parents/legal guardians are expected to complete and each family will receive a weekly phone call to encourage and support them in completing these tasks. Each parent group may include up to 14 parents.
The program focuses on promoting healthy parent-child relationships, providing parents with behavioral management tools, and encouraging adaptive behaviors in children, among other goals. It emphasizes the importance of practice-based learning through role-playing.
The program will be delivered by experienced mental health professionals specifically certified according to the IY-ASLD® program standards. This accreditation includes support from certified supervisors during the initial weeks of program implementation. Both the official training and

accreditation, as well as the initial supervision, are conducted online.
The Spanish-translated and validated version of the program will be used.

Control group: The control group will receive standard care in special education. This standard intervention consists of individualized attention to the specific needs of the students, promoting learning in areas such as communication and language, personal autonomy, social skills, and knowledge of the environment. This intervention involves the coordinated work of an interdisciplinary team, which, together with families, offers a comprehensive approach and prepares the students for the transition to compulsory basic education.
Families allocated to the intervention group will also receive standard care in special education.

Randomization will be conducted after completion of the baseline assessment and signing of the informed consent. Families will be randomly assigned to one of two arms: the intervention group or the control group. As this is a pragmatic clinical trial, randomization will be carried out under the usual conditions of the participating schools, and potential external variables that may influence outcomes will be considered in the statistical analysis. Data analyses will be performed using SPSS version 29.0 and R version 4.3.1. An independent researcher will perform the randomization process. Researchers involved in patient recruitment or intervention delivery will not participate in the allocation procedure.

Intervention Type
Behavioural

Primary outcome(s)
1. Sociodemographic variables (Family structure, age of the parents and the child, child's sex, ethnicity, medical comorbidities and psychiatric diagnoses, age at ASD diagnosis and location where it was made, financial aid received, current psychotropic pharmacological treatments, school grade, behavioral treatments previously or currently received, and psychiatric disorders in siblings (if any)) measured using a questionnaire ar baseline
2. The socioeconomic status of the family unit measured using the Hollingshead-Rendlich scale at baseline
3. Program fidelity and participant retention measured by registering participant attendance to sessions and percentage of participants who complete evaluations at baseline, post-intervention, 6 and 12 months of follow-up
4 Feasibility of implementing IY-ASLD® program in special education measured by a weekly parental evaluation and a final parental satisfaction questionnaire of the IY-ASLD® program at post-intervention, 6 and 12 months of follow-up

Key secondary outcome(s)
1. The preliminary effectiveness of IY-ASLD® program measured using the ASD-P Parenting Strategies Questionnaire, the Patient Health Questionnaire-9, the Parenting Stress Inventory-Short Form, the Social Communication Questionnaire, the Adaptive Behavior Assessment System, the Autism Impact Measure, the Child Behavior Checklist at baseline, post-intervention, 6 and 12 months of follow-up
2. The cost-effectiveness of the intervention measured by a brief cost diary including the costs of training to develop the IY-ASLD® parenting program and the costs associated with its implementation (materials, team members' work hours etc.) and by the EQ-5D-Y scale and the Client Sociodemographic and Service Receipt Inventory at post-intervention, 6 and 12 months of follow-up

Completion date

30/12/2027

Eligibility

Key inclusion criteria
1. Parents or legal guardians of patients diagnosed with ASD (clinical diagnosis by a psychiatrist or clinical psychologist from the Madrid Health Service, according to DSM-5 diagnostic criteria).
2. Children aged between 2 and 5 years of age (inclusive) at the time of the baseline assessment.
3. Patients must be enrolled in one of the special education schools included in the HGUGM mental health liaison program.
4. Parents must have a high level of knowledge and understanding of the Spanish language.
5. Informed consent for the study must be signed by the minors' parents or legal representatives.

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
5 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Receiving another intervention from a structured parenting program during the intervention phase of this study.
2. Refusal to sign the informed consent form
3. Guardianship or custody of the child by the authorities at the time of the intervention.

Date of first enrolment
12/03/2025

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Spain

Study participating centre
Hospital General Universitario Gregorio Marañón
Calle Ibiza 43
Madrid
Spain
28009

Sponsor information

Organisation
Hospital General Universitario Gregorio Marañón

ROR
https://ror.org/0111es613

Funder(s)

Funder type
Charity

Funder Name
Fundación Alicia Koplowitz

Alternative Name(s)
Alicia Koplowitz Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Spanish		26/09/2025	No	Yes