

# Protocol for a randomized pilot study (FIRST STEPS): implementation of the Incredible Years-ASLD® program in Spanish children with Autism and preterm children with communication and/or socialization difficulties

**Fátima Valencia**

Hospital General Universitario Gregorio Marañón

**Elena Urbiola**

Hospital General Universitario Gregorio Marañón

**Marina Romero González** (✉ [marinarglez@gmail.com](mailto:marinarglez@gmail.com))

Hospital Regional Universitario de Málaga <https://orcid.org/0000-0003-4842-821X>

**Inmaculada Navas-Domenech**

Hospital Regional Universitario de Málaga

**Maria Elias**

Hospital Sant Joan de Deu

**Alexandra Garriz**

Hospital General Universitario Gregorio Marañón

**Almudena Ramirez**

Hospital Regional Universitario de Málaga

**Laia Villalta**

Hospital Sant Joan de Deu

---

## Study protocol

**Keywords:** parenting intervention, pilot, ASD, preterm children, child development

**Posted Date:** November 17th, 2020

**DOI:** <https://doi.org/10.21203/rs.3.rs-33653/v1>

**License:** © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

---

**Version of Record:** A version of this preprint was published at Trials on April 20th, 2021. See the published version at <https://doi.org/10.1186/s13063-021-05229-1>.

# Abstract

Having access to parenting interventions in the early years is key to improve developmental outcomes of children with neurodevelopmental problems. The Incredible Years® (IY) Parent Program is a group intervention that has demonstrated efficacy in terms of reducing stress in parents, as well as improving behavioral, emotional and social outcomes in children. The program has been recently adapted for families of children with autism or language delays (IY-ASLD®). This intervention has not yet been implemented in the Spanish Public Health System, where there is a scarcity of evidence-based interventions being offered to families with young children presenting neurodevelopmental problems. The main aims of this study are to determine the feasibility of implementing the IY-ASLD® program within Spanish Child Mental Health Services, as well as to examine parents' acceptability and satisfaction with the intervention. As a secondary objective, we aim to evaluate its preliminary effectiveness in terms of reducing parental stress and behavioral difficulties in their children. The FIRST STEPS study is a multicenter, pilot randomized controlled trial comparing the IY-ASLD® program with a treatment-as-usual (TAU) condition. Approximately 70 families of children with Autism Spectrum Disorder (ASD) and preterm children with communication and/or socialization difficulties (aged 2–5 years) will be recruited. Families will be assessed prior to randomization and after the intervention.

The FIRST STEPS pilot trial will demonstrate the feasibility and acceptability of reliably implementing the IY-ASLD® program within the Spanish Public Health System. The results of this study could represent a first step to inform policy makers in Spain when designing evidence-based healthcare pathways for families of children presenting ASD symptoms or neurodevelopmental difficulties at early stages.

## Introduction

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder involving social communication disturbances and a restricted pattern of interests, present before age 3(1).

Preterm children are at particular risk of presenting a broad range of developmental difficulties, such as language delay, communication and social disturbances, as well as ASD (2–4). Both children with ASD and preterm children are more likely to exhibit internalizing and externalizing difficulties early in life (5–8).

The persistence of conduct problems in these young children has implications for their developmental trajectory, including the emergence of comorbid mental disorders, social problems, as well as future maladaptation (9,10,11).

Early intervention is crucial to improve these children's outcomes. At early stages of development, troubling signs (e.g. communication difficulties) can be targeted and treated with no need to wait for a full-blown diagnosis. This approach allows treatment to reach toddlers with a wide range of neurodevelopmental difficulties, preventing interventions to be limited to particular diagnostic categories.

Parent-mediated interventions can have a large and sustained effect at a relatively low cost (12), improving a broad range of developmental domains (13). Also, caring for children with neurodevelopmental disorders can be very stressful for parents, which could in turn lead to lower effectiveness of interventions (14) and parental mental health problems (15). Thus, it is of utmost importance to support the parents of these children in their task of promoting their children's development (16,17). With this aim, evidence-based parenting interventions have been developed for children with ASD symptoms and for preterm children (13,18). However, these interventions are insufficiently available within the Spanish Public Health System.

### **Group interventions (The Incredible Years Autism Spectrum and Language Delays program: IY-ASLD®)**

Group interventions show promise as a valuable resource to help parents cope with children's behavioral, social and emotional difficulties. This therapeutic approach has demonstrated effectiveness in terms of improving dysfunctional parenting styles, reducing children's behavioral problems (19) and increasing parents' ability to facilitate their children's communication skills and vocabulary (20,21). Group interventions also provide social support for parents (22,23). This is especially important for parents who are more likely to experience depression and stress during the early years of their child's life. This is the case for parents of children with ASD (24,25) and those of preterm children (26), who have identified a need for parenting support to promote their children's development (27).

The Incredible Years® parenting programs (28) are a set of interventions recommended by the NICE guidelines (29), primarily focused on strengthening the parent-child interaction and improving parenting skills in order to prevent or reduce children's behavioral problems. The effectiveness of the Incredible Years program has been widely demonstrated in multiple randomized controlled trials, showing an improvement in terms of parental stress levels, depression and parental coping, as well as in children behavior difficulties (30,31). A range of developmentally appropriate interventions for different age groups is offered.

The IY-ASLD® program has been specifically developed to target the needs and concerns of parents of children aged 2-5 years in the Autistic Spectrum or with language delays (32). The program encourages positive parent-child relationships to promote children's emotion regulation, social competence, language skills, school readiness, and peer relationships. The intervention teaches parents how to play in a child-directed way but with a specific focus on encouraging children's communication and social engagement. It also focuses on how to use positive discipline to set limits and handle misbehavior. A pragmatic randomized controlled trial has been recently published, supporting the feasibility of delivering this intervention in the UK National Health Service (NHS), and showing good levels of acceptability, compliance and fidelity to the program (33,34).

The IY-ASLD® program has never been trialed in Spain, where the Public Health System has shown a lack of resources to perform evidence-based early interventions for neurodevelopmental problems (35). Thus, the validation and implementation of group interventions such as the IY-ASLD® program, is a

priority in terms of offering Spanish families better and earlier interventions that are brief, intensive, cost-effective and based on scientific evidence.

## **Aims and Hypotheses**

The main aim of the present study is to examine the feasibility of implementing the IY-ASLD® program in the Spanish Public Health System. Secondly, we aim to explore initial evidence of the effects of treating parents of preschool children with ASD and preterm children with communication and/or socialization difficulties.

In relation to the primary objective, research hypothesis are as follows:

- I. It is possible to recruit and randomize families to an intervention group and a TAU condition.
- II. Parents accept to participate in the program.
- III. Parents' compliance with the program is acceptable (attending at least 8 of the 14 sessions and a minimum of 6 out of 12 parents finishing the intervention).
- IV. Parents report acceptable levels of satisfaction with the program.
- V. The program can be reliably implemented in the Spanish Public Health System.

In relation to the secondary objective, research hypothesis are as follows:

- I. Parents who received the intervention present reduced levels of parental stress when compared to the control group.
- II. Parents who received the intervention show reduced levels of depressive symptoms and Expressed Emotions when compared to the control group.
- III. Parents who received the intervention present an increase in their positive parenting skills when compared to the control group.
- IV. Parents who received the intervention report a decrease in the levels of children's externalizing and internalizing symptoms when compared to the control group.

In order to achieve these goals, we designed a controlled randomized pilot study that will be conducted within the Spanish Public Health System, where participating families will be randomly allocated to the intervention group (receiving the IY-ASLD® program) or to the treatment as usual condition (TAU) on a 1:1 ratio.

## **Methods**

This is a multi-centric study that will be carried out in Child and Adolescent Mental Health Services from three Hospitals in Spain: Hospital Materno-Infantil in Málaga (HMIM), Hospital General Universitario Gregorio Marañón in Madrid (HGUGM) and Hospital Sant Joan de Déu in Barcelona (HSJD). Eligible

participants will be parents of children diagnosed with ASD and parents of preterm children with communication and/or socialization difficulties.

## Sample

The IY-ASLD® program will be implemented in Child and Adolescent Mental Health Services in each site. In two of them (HMIM and HGUGM) parents of children with ASD will be recruited (n=48) and in one site (HSJD) parents of preterm children with communication and/or socialization difficulties will be included (n=24). Participating families will be randomly allocated to the TAU condition or to the intervention group within each site.

For the sample size calculation, we used the outcome Parental Stress, measured through the questionnaire Parental Stress Index Short Form (PSI-SF) (36). This is a 36-item scale, with a range of 180 points. There is data showing that a decrease of 16.5 points in the total scale stress score can be seen after attending an IY program (37). Given that this study will be conducted with parents of children presenting neurodevelopmental difficulties, we anticipated that the decrease in the PSI-SF score would be lower. We estimated the necessary sample size considering a power of 80%,  $\alpha = 0.05$ , a difference between pre and post-test of 10 points, and a standard deviation of 20 (38). We estimated 34 participants needed per arm of the study. Thus, we aim to recruit approximately 70 participants. Also, a sample of approximately 70 participants has been recommended in similar feasibility studies (39).

## Eligibility criteria

Inclusion criteria:

1. a. HMIM and HUGM sites: parents/caregivers of children diagnosed with ASD (clinical diagnosis performed by psychiatrists or clinical psychologists in the service, based on DSM-V diagnostic criteria).
- b. HSJD site: parents/caregivers of preterm children (<37 weeks of gestational age) with communication and/or socialization difficulties (defined as Vineland-III scores below 1SD in any of the communication or socialization subdomains).
2. Children aged 2-5 years.
3. Parents/caregivers showing good understanding of Spanish language.
4. Parents/caregivers consenting to take part in the study and signing the informed consent.

Exclusion criteria:

1. Attending another structured parenting program (focused on improving parental strategies to help their children with their developmental or regulation difficulties) during the intervention phase of the study.
2. Looked-after children.

## **Recruitment**

Parents/caregivers will be recruited between January and February 2020 within the Child and Adolescent Mental Health Services of each hospital site, where patients have previously been assisted for their neurodevelopmental difficulties (Figure 1). A leaflet with inclusion and exclusion criteria will be handed out to clinicians working in the services. Clinicians will be asked to discuss the study with eligible families and will ask the families permission to be contacted by study researchers. If they agree to be contacted about the project, a research assistant will call the family to discuss the study further. If the family is interested in participating in the study and meets inclusion criteria, an appointment will be made with parents to sign the informed consent and to complete the pre-intervention assessment. During this visit, researchers will make sure that participants receive all the necessary information and have the opportunity to ask any questions. Participants will be able to discontinue the treatment sessions or drop out from the control group at any point at their request.

## **Randomization**

After completing baseline measures, families taking part in the study will be randomly allocated to the intervention group or to the TAU condition within each center. Randomization will be conducted using the Program R 3.6.2 (R Foundation for Statistical Computing), generating a replicable process fixing a random seed. Allocation will be stratified by developmental level.

An independent researcher will carry out the randomization process, and researchers who are responsible for patient recruitment or for intervention delivery will not be involved. Due to the pragmatic and clinically focused nature of the study, further blinding procedures will not be possible.

## **Intervention**

The IY-ASLD® program is a 14-session group-based intervention for parents of children presenting neurodevelopmental difficulties. One of the main principles of the intervention is the collaborative approach, promoting parents' discussion around the topics of interest and facilitating a solution-based perspective. The intervention includes video modeling and emphasizes the importance of practice-based learning through role-play. The IY-ASLD® program takes into consideration the different developmental level of each children and pairs parents according to this variable in role-play and other one-to-one discussions. Weekly home tasks will be assigned to parents and families will be phoned each week to encourage home-based practice (32).

Fidelity to the treatment manual will be ensured in different ways. Group interventions will be conducted by experienced clinicians (Child and Adolescent Psychiatrists and Clinical Psychologists), officially trained in the IY-ASLD® model by an accredited trainer. Group leaders will complete weekly checklists regarding fidelity to the intervention and participants will also complete weekly parent evaluations. Group leaders will be supervised by certified supervisors and will pursue accreditation according to the IY-ASLD® program standards.

## Measures (Table 1).

### *Baseline and sample descriptors*

At baseline, the following sociodemographic and child clinical variables will be assessed: family structure, child's age, gender, medical conditions, type and date of psychiatric diagnosis, psychotropic medication, educational status, current and past mental health interventions for parents and for the child and neurodevelopmental problems in siblings. Socioeconomic status will be determined using the Hollingdale's Index of Social Position (40).

At baseline, the following questionnaires will be administered:

The Modified Checklist for Autism in Toddlers-Revised with Follow-up (M-CHAT-R/F). (41). This tool is a parent-reported 20-item questionnaire screening ASD symptoms in children aged 24-30 months. This instrument will be administered before the intervention to describe children's social communication difficulties. The Spanish translation has shown valid and reliable results.

Social Communication Questionnaire (SCQ). (42). It is a 40-item parent report measure, yes/no format, based on the Autism Diagnostic Interview-Revised (ADI-R) (43). The Lifetime version of this questionnaire will be administered before the intervention with the same aim as the M-CHAT-R, in children aged between 30 months and 5 years. It is a robust tool that has shown good validity, and it has been widely adopted by both the research and clinical community.

Vineland Adaptive Behavior Scale-III (VABS-III, parent/caregiver report form) (44). It assesses adaptive functioning in different areas: communication (receptive, expressive, written), socialization (interpersonal/play and leisure time/coping), daily living skills (personal, domestic, community) and motor skills (fine and gross). It also generates a final adaptive composite score. This instrument will be used before the intervention to collect the level of functioning in different developmental areas. It has been considered a very efficient tool to measure the adaptive behavior profile of preschool children with developmental problems and shown an excellent test-retest reliability ) (45).

Developmental Profile-3 (DP-3) (46). This is a 180-item parental questionnaire assessing developmental delays in different domains: motor, adaptative, socio-emotional, cognitive, and communication. It also computes an overall general development score. It will be used before the intervention to collect the child developmental level. It has shown good internal consistency.

### *Primary outcomes (feasibility)*

Parents' engagement with the program and participant retention will be monitored throughout, expecting they will attend at least 8/14 sessions with a minimum of 6 parents out of 12 (>50%) finishing the program.

Autism Program Parent Weekly Evaluation (47). This instrument is part of the IY-ASLD® program materials and will be used to collect information regarding compliance and satisfaction throughout the study.

Autism Program Parent Final Satisfaction Questionnaire (47). This questionnaire is included within the IY-ASLD® program. It will be used to measure the acceptability and satisfaction with the intervention after the last session. It covers five areas: (1) the overall program; (2) usefulness of teaching format; (3) usefulness of specific teaching strategies; (4) evaluation of the group facilitators and (5) the parent group.

Implementation fidelity will be ensured and monitored throughout the intervention process, following the strategies described above.

*Secondary outcomes (preliminary effectiveness for parental outcomes)*

ASD-P Parent Strategies Questionnaire (47). This is a 60-item questionnaire included within the IY-ASLD® program. It is divided into 5 subdomains regarding different strategies that will be learned throughout the program to promote social, emotional, language and academic development, and how often parents use these strategies. This tool will be administered before and after the program implementation.

Parent Stress Inventory-Short Form (PSI-SF) (36). This is a 36-item questionnaire that specifically focuses on assessing parental stress associated with the care of their offspring. It has three domains: Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child, which combine to form a Total Stress scale. This tool will be administered before and after the intervention. It has shown good internal consistency.

Beck Depression Inventory (BDI) (48). This is a 21-item screening tool assessing the severity of depressive symptoms. It is a standardized and validated questionnaire, often used in mood disorder assessments. It will be collected before and after the intervention. It has good reliability.

Alabama Parenting Questionnaire-Preschool revision (APQ-Pr). (49). This is a 32-item parent-reported questionnaire measuring parenting practices that are consistently associated with disruptive child behaviors. This version has 3 dimensions: Positive Parenting, Inconsistent Parenting and Punitive Parenting. It will be collected before and after the intervention. This measure has shown good internal consistency and validity.

Autism-Specific Five Minute Speech Sample (AS-FMFSS). (50) This is a narrative 5-minute interview used to measure parental expressed emotions for children with ASD and related disorders. Parents are asked to speak about their child and the parent-child relationship (51) - *"I'd like you to speak for 5 minutes, telling me what kind of person (child name) is and how the two of you have got along together over the past 6 months."* Speech samples are audiotaped, transcribed, and coded following four global categories (a) Initial Statement, (b) Warmth, (c) Relationship, (d) Emotional Over-Involvement and critical comments (e) and positive comments (f). Expressed emotions will be measured before and after the intervention.

Benson et al. (51), assessed 30 randomly selected speech sample by three different raters. Inter-rater reliability and code-recode reliability on two separate occasions, for all six AS-FMSS components and for total EE score were both in the good to excellent range.

#### *Other outcomes (preliminary effectiveness for child outcomes)*

Child Behavior Checklist (CBCL 1.5-5) (52). This is a parent-reported 99-item inventory that addresses specific externalizing and internalizing behaviors. The sum of scores form a total problems score and it also includes scores for externalizing and internalizing difficulties subdomains. It will be collected before and after the intervention. It has shown good internal consistency, also in children diagnosed with ASD (53).

#### **Data collection**

Data will be collected at baseline (before performing randomization), and after finishing the IY-ASLD® intervention. Parents consenting to participate (mother, father or both) will be offered a hospital appointment before and after the intervention with a research assistant to complete the assessment, including self-report measures, children outcome measures, and a voice recording for the ASFMSS tool. Those parents who discontinue or deviate from the intervention protocols will receive a telephone call by the research assistant to arrange further hospital appointments or to check if they are willing to complete the questionnaires for the main outcomes on the phone.

The timeline for participants' enrollment, data collection and the conduction of the intervention are scheduled in Table 1.

#### **Data analysis**

Descriptive analysis will be used for primary outcomes (e.g. recruitment rates, number of sessions attended by participants, proportion attending at least 8 out of 14 sessions, and proportion finishing the program). Attrition and satisfaction rates with the program will be also described.

Differences in baseline and descriptive variables between intervention and TAU conditions will be explored. Differences between-site will also be analyzed. These variables will be controlled for in the main analyses.

For secondary outcomes, analysis will follow an intention-to-treat basis. Differences between treatment groups in parental levels of stress, expressed emotions and parenting practices will be analyzed using general linear models, controlling for important confounding variables, such as socio-demographic variables, severity of symptoms at baseline or treatment site. Further secondary analysis will use similar methods to compare groups for additional child outcomes (i.e. CBCL externalizing problems).

Missing data (i.e. missing item responses in questionnaires) will be treated following the instructions stipulated in the questionnaire's manual. Imputation methods will be considered for full-case missing

data. Analysis will be conducted using SPSS/STATA statistical packages.

## **Trial Status**

The protocol for the current pilot study was registered in ClinicalTrials.gov (ID number: NCT04358484. Unique Protocol ID: PIC-220-19) and it was released in April 2020. The study began on January 2020, and the anticipated finish date was September 2020. The recruitment process was carried out during the same period in the 3 sites, from 3<sup>rd</sup> of February to 2<sup>nd</sup> of March.

## **ETHICS**

The study has received ethical approval from the Ethics Committee at each site. The trial data set will be stored in institutional encrypted computers and will itself be encrypted with a password. Only staff involved in the study will be authorized to access the data. Participants will be informed about all protection data procedures and will be able to disengage from the study at any point, without affecting their usual clinical care. Written information regarding these aspects will be handed, and contact details from research assistants will be offered in order to clarify any doubts or worries participants might have.

Participants will be informed of potential benefits and risks of participating in the study. Due to the nature of the study, it is unlikely that taking part in the research will result in any damage. After families are provided with sufficient information about the project, they will be asked to sign the written informed consent.

The study will be conducted following the principles developed by the World Medical Association, outlined in the Declaration of Helsinki.

## **Discussion**

The main aim of the study is to pilot the IY-ASLD® intervention in Public Mental Health Services in Spain. The current study has several strengths. Firstly, to the best of our knowledge this is the first time that this program will be conducted in Spain. This is relevant in terms of improving the availability of treatments for children with neurodevelopmental difficulties within the Spanish Public Health System. Also, given that this intervention has been designed and tested in other countries (US and UK), it is important to test if it can be implemented in Spain, where we have language, cultural and healthcare system differences. Moreover, the IY-ASLD® program will be tested in different areas within Spain, providing a broad view of its feasibility across the country. Secondly, the present study targets a broad range of patients with early neurodevelopmental problems, as not only those meeting diagnostic criteria for ASD are included, but parents of premature children with socialization and/or communication difficulties are also offered the intervention. Different strategies have been put into place in order to provide coherence and internal consistency to the study. Group leaders have attended the official training and will be following the procedures established in the program to assure the fidelity to the intervention. Finally, preliminary efficacy will be analyzed, which could inform the importance of conducting a larger randomized

controlled trial. Some limitations need to be taken into consideration. Participants will be recruited and treated in mental health services that are not based in the community and serve the whole region. This could affect recruitment or dropout rates because of the long travelling distances for participants to attend a weekly intervention. Also, the sample size might be limited in terms of power for some effect analyses. However, it is of note that we are introducing validated measures that go beyond parent-reported questionnaires to assess parent-child relationships (i.e. ASFMFSS), which is of paramount importance when evaluating parenting interventions and children in preschool years.

Overall, the results of this study will inform the acceptability and feasibility of implementing, and culturally adapting, the IY-ASLD® intervention for Spanish families. The results will be described in a final report to the funder, and they will be published in peer-reviewed journals.

This trial will represent a first step to plan future projects, which could guide policy makers to fund and further implement the intervention within the Spanish Public Health System.

## **Declarations**

### **Ethics approval and consent to participate**

As mentioned above, the study received ethical approval from the Ethics Committee at each of the three sites. After providing families with sufficient verbal and written information about the project (including all protection data procedures, the potential benefits and risks of participating in the study, and the option to disengage from the study at any point without affecting their usual clinical care), they will be asked to sign the written informed consent.

The study will be conducted following the principles developed by the World Medical Association, outlined in the Declaration of Helsinki.

### **Consent for publication**

Before signing in the consent form, all participant families will be provided with written information about the study. This includes the aims of the study, families' voluntary participation, the duration of the study, the timeline of families' participation, the potential risks and benefits of participating in the study, all data protection measures, and their consent for including anonymous study data on scientific publications.

### **Availability of data and materials**

As mentioned above, the trial data set will be stored in institutional encrypted computers and will itself be encrypted with a password. Only staff involved in the study will be authorized to access the data.

### **Competing interests**

The views expressed in this publication are those of the authors and they all report no potential conflict of interest.

## Funding

This paper reports on independent research financially supported by the Alicia Koplowitz Foundation.

## Authors' contributions

FV, MR-G, and LV conceived and designed the study. FV, MR-G, LV, EU, IN and ME conducted the study. AG and AR collected recruitment data. FV, MR-G, LV, and EU drafted the manuscript. All authors critically reviewed the manuscript and were responsible for its final approval. All authors had full access to the study data and can take responsibility for the integrity and the accuracy of the data. FV, MR-G, and LV are the guarantors for the study.

The sponsor/collaborator for the study is Fundació Sant Joan de Déu. Phone: 0034 93 600 97 51. Email: ceic@fsjd.org

## Acknowledgments

Not applicable.

## References

1. APA. Cautionary Statement for Forensic Use of DSM-5. In: Diagnostic and Statistical Manual of Mental Disorders, 5th Edition. American Psychiatric Publishing, Inc; 2013.
2. Stanley F, Blair E, Alberman E. Cerebral palsies: epidemiology and causal pathways. Wiley, editor. Vol. 151. Cambridge University Press,; 2000.
3. Harel-Gadassi A, Friedlander E, Yaari M, Bar-Oz B, Eventov-Friedman S, Mankuta D, et al. Risk for ASD in Preterm Infants: A Three-Year Follow-Up Study. *Autism Res Treat*. 2018;52(10):819–29. DOI: 10.1155/2018/8316212
4. Michelotti J, Charman T, Slonims V, Baird G. Follow-up of children with language delay and features of autism from preschool years to middle childhood. *Dev Med Child Neurol*. 2002;44(12):812–9. DOI: 10.1017/S0012162201002985
5. Hartley SL, Sikora DM, McCoy R. Prevalence and risk factors of maladaptive behaviour in young children with autistic disorder. *J Intellect Disabil Res*. 2008;52(10):819–29. DOI: 10.1111/j.1365-2788.2008.01065.x
6. Mazefsky CA, Herrington J, Siegel M, Scarpa A, Maddox BB, Scahill L, et al. The role of emotion regulation in autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. 2013;52(7):679–88. DOI: 10.1016/j.jaac.2013.05.006
7. Totsika V, Hastings RP, Emerson E, Berridge DM, Lancaster GA. Behavior problems at 5 years of age and maternal mental health in autism and intellectual disability. *J Abnorm Child Psychol*. 2011;39(8):1137. DOI: 10.1007/s10802-011-9534-2

8. Yaari M, Mankuta D, Harel-Gadassi A, Friedlander E, Bar-Oz B, Eventov-Friedman S, et al. Early developmental trajectories of preterm infants. *Res Dev Disabil*. 2018;81:12–23. DOI: 10.1016/j.ridd.2017.10.018
9. Simonoff E, Pickles A, Charman T, Chandler S, Loucas T, Baird G. Psychiatric disorders in children with autism spectrum disorders: Prevalence, comorbidity, and associated factors in a population-derived sample. *J Am Acad Child Adolesc Psychiatry*. 2008;47(8):921–9. DOI: 10.1097/CHI.0b013e318179964f
10. Mathewson KJ, Chow CHT, Dobson KG, Pope EI, Schmidt LA, Van Lieshout RJ. Mental health of extremely low birth weight survivors: A systematic review and meta-analysis. *Psychol Bull*. 2017;143(4):347–83. DOI: 10.1037/bul0000091
11. Smith JD, Dishion TJ, Shaw DS, Wilson MN, Winter CC, Patterson GR. Coercive family process and early-onset conduct problems from age 2 to school entry. *Dev Psychopathol*. 2014;26(4pt1):917–32. DOI: 10.1017/S0954579414000169
12. Sanders, Matthew R. MRD. Behavioral family intervention. Allyn & Bacon, editor. MA,US: Needham Heights; 1993.
13. Colditz P, Sanders MR, Boyd R, Pritchard M, Gray P, O’Callaghan MJ, et al. Prem Baby Triple P: A randomised controlled trial of enhanced parenting capacity to improve developmental outcomes in preterm infants. *BMC Pediatr*. 2015;15(1):15. DOI: 10.1186/s12887-015-0331-x
14. Osborne LA, McHugh L, Saunders J, Reed P. Parenting stress reduces the effectiveness of early teaching interventions for autistic spectrum disorders. *J Autism Dev Disord*. 2008;38(6):1092. DOI: 10.1007/s10803-007-0497-7
15. Benson PR, Karlof KL. Anger, Stress Proliferation, and Depressed Mood Among Parents of Children with ASD: A Longitudinal Replication. *J Autism Dev Disord*. 2009 Feb 16;39(2):350–62. DOI: 10.1007/s10803-008-0632-0
16. Webster-Stratton, C., Dababnah, S., & Olson E. The Incredible Years® Group Based Parenting Program for Young Children with Autism Spectrum Disorder. In *Handbook of Parent-Implemented Interventions for Very Young Children with Autism*. Cham: Springer; 2018. 261–282 p.
17. Treyvaud K, Anderson VA, Howard K, Bear M, Hunt RW, Doyle LW, et al. Parenting behavior is associated with the early neurobehavioral development of very preterm children. *Pediatrics*. 2009;123(2):555–61. DOI: 10.1542/peds.2008-0477
18. Hutchings J, Pearson-Blunt R, Pasteur M-A, Healy H, Williams ME. A pilot trial of the Incredible Years® Autism Spectrum and Language Delays Programme. *Good Autism Pract*. 2016;
19. Whittingham K, Sofronoff K, Sheffield J, Sanders MR. Stepping stones triple p: An rct of a parenting program with parents of a child diagnosed with an autism spectrum disorder. *J Abnorm Child Psychol*. 2009;37(4):469. DOI: 10.1007/s10802-008-9285-x
20. McConachie H, Randle V, Hammal D, Le Couteur A. A controlled trial of a training course for parents of children with suspected autism spectrum disorder. *J Pediatr*. 2005;147(3):335–40. DOI: 10.1016/j.jpeds.2005.03.056

21. Wetherby AM, Guthrie W, Woods J, Schatschneider C, Holland RD, Morgan L, et al. Parent-implemented social intervention for toddlers with autism: An RCT. *Pediatrics*. 2014;134(6):1084–93. DOI: 10.1542/peds.2014-0757
22. Dababnah S. Pilot Trial of The Incredible Years for Parents of Preschool Children with Autism Spectrum Disorder [Internet]. 2014. available from <https://cdr.lib.unc.edu/concern/dissertations/dv13zt45s>. Last accessed 22 may 2020
23. Dababnah S, Parish SL. Feasibility of an empirically based program for parents of preschoolers with autism spectrum disorder. *Autism*. 2016;20(1):85–95. DOI: 10.1177/1362361314568900
24. Hastings RP, Kovshoff H, Ward NJ, Degli Espinosa F, Brown T, Remington B. Systems analysis of stress and positive perceptions in mothers and fathers of pre-school children with autism. *J Autism Dev Disord*. 2005;35(5):635. DOI: 10.1007/s10803-005-0007-8
25. Herring S, Gray KM, Taffe J, Tonge B, Sweeney D, Einfeld S. Behaviour and emotional problems in toddlers with pervasive developmental disorders and developmental delay: Associations with parental mental health and family functioning. *J Intellect Disabil Res*. 2006;50(12):874–82. DOI: 10.1111/j.1365-2788.2006.00904.x
26. Feldman R, Eidelman AI. Maternal postpartum behavior and the emergence of infant-mother and infant-father synchrony in preterm and full-term infants: The role of neonatal vagal tone. *Dev Psychobiol*. 2007;49(3):290–302. DOI: 10.1002/dev.20220
27. Nicolaou M, Rosewell R, Marlow N, Glazebrook C. Mothers' experiences of interacting with their premature infants. *J Reprod Infant Psychol*. 2009;27(2):182–94. DOI: 10.1080/02646830801922796
28. Webster-Stratton C, Hancock L, Briesmeister JM, Schaefer CE. Training for parents of young children with conduct problems: Content, methods, and therapeutic processes. *Handbook of parent training: Parents as co-therapists for children's behavior problems* (2nd ed.). 1998.
29. National Institute for Clinical Excellence. National Institute for Clinical Excellence. Parent training/education programmes in the management of children with conduct disorders. A Health Technology appraisal. 2006.
30. Hutchings J, Gardner F, Bywater T, Daley D, Whitaker C, Jones K, et al. Parenting intervention in Sure Start services for children at risk of developing conduct disorder: Pragmatic randomised controlled trial. *Br Med J*. 2007;334(7595):678. DOI: 10.1136/bmj.39126.620799.55
31. Jamila Reid M, Webster-Stratton C, Beauchaine TP. Parent training in head start: A comparison of program response among african american, asian american, caucasian, and hispanic mothers. *Prev Sci*. 2001;2(4):209–27. DOI: 10.1023/A:1013618309070
32. Webster-Stratton, Carolyn; Dababnah, Sarah; Olson E. The Incredible Years® Group-Based Parenting Program for Young Children with Autism Spectrum Disorder. En *Handbook of Parent-Implemented Interventions for Very Young Children with Autism*. Springer, Cham.; 2018. 261–282 p.
33. Dababnah S, Parish SL. Incredible Years Program Tailored to Parents of Preschoolers With Autism: Pilot Results. *Res Soc Work Pract*. 2016;26(4):372–85. DOI: 10.1177/1049731514558004

34. 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; DOI: 10.1002/aur.2265
35. Lasa Zulueta, A., Jorquera Cuevas, C., Solana Azurmendi, B., & Del Arco Heras S. Evaluación de la calidad asistencial en el SNS de los trastornos mentales graves en la infancia. *Estudio en Salud Mental Infanto-Juvenil. Estudio en Salud Mental Infanto-Juvenil. Informes de Evaluación de Tecnologías Sanitarias. OSTEBA. Vitoria: Ministerio de Sanidad, Servicios Sociales e Igualdad. Servicio de Evaluación de Tecnologías Sanitarias del País Vasco.* 2014.
36. Zaidman-Zait A, Mirenda P, Zumbo BD, Wellington S, Dua V, Kalynchuk K. An item response theory analysis of the Parenting Stress Index-Short Form with parents of children with autism spectrum disorders. *J Child Psychol Psychiatry.* 2010;51(11):1269–77. DOI: 10.1111/j.1469-7610.2010.02266.x
37. Hutchings J, Bywater T, Daley D. Early prevention of conduct disorder: How and why did the North and Mid Wales Sure Start study work? *J Child Serv.* 2007;2(2):4–14. DOI: 10.1108/17466660200700012
38. Haskett ME, Ahern LS, Ward CS, Allaire JC. Factor structure and validity of the parenting stress index-short form. *J Clin Child Adolesc Psychol.* 2006;35(2):302–12. DOI: 10.1207/s15374424jccp3502\_14
39. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: A simulation study. *Trials.* 2014;15(1):264. DOI: 10.1186/1745-6215-15-264
40. Hollingshead A. Two factor index of social position. New Haven, Connecticut: Yale University; 1957.
41. Canal-Bedia R, García-Primo P, Martín-Cilleros MV, Santos-Borbujo J, Guisuraga-Fernández Z, Herráez-García L, et al. Modified checklist for autism in toddlers: Cross-cultural adaptation and validation in Spain. *J Autism Dev Disord.* 2011;41(10):1342–51. DOI: 10.1007/s10803-010-1163-z
42. Rutter Bailey, A., & Lord, C. M. *Manual of the Social Communication Questionnaire.* Los Angeles, CA. 2003.
43. Le Couteur A, Lord C RM. The autism diagnostic interview-revised (ADI-R). Vol. 29, *Western Psychological Services.* 2003. p. 30.
44. Paul R, Miles S, Cicchetti D, Sparrow S, Klin A, Volkmar F, et al. Adaptive behavior in autism and pervasive developmental disorder-not otherwise specified: Microanalysis of scores on the vineland adaptive behavior scales. *J Autism Dev Disord.* 2004;34(2):223–8. DOI: 10.1023/B:JADD.0000022612.18116.46
45. Balboni G, Pedrabissi L, Molteni M, Villa S. Discriminant Validity of the Vineland Scales: Score Profiles of Individuals With Mental Retardation and a Specific Disorder. *Am J Ment Retard.* 2001 Apr 1;106(2):162. DOI: 10.1352/0895-8017(2001)106<0162:DVOTVS>2.0.CO;2
46. Alpern GD. *Developmental profile 3 (DP-3).* Western Psychological Services. Los Angeles,CA; 2007.
47. The Incredible Years® :Measures and Forms for Researchers and Clinicians [Internet]. available from <http://www.incredibleyears.com/for-researchers/measures/>. Last accessed 22 May 2020.

48. Beck AT, Steer RA, Brown GK. Manual for the beck depression inventory The Psychological Corporation. San Antonio, TX. 1996;78(2):490–8.
49. de la Osa N, Granero R, Penelo E, Domènech JM, Ezpeleta L. Psychometric Properties of the Alabama Parenting Questionnaire-Preschool Revision (APQ-Pr) in 3 Year-Old Spanish Preschoolers. *J Child Fam Stud*. 2014;23(5):776–84. DOI: 10.1007/s10826-013-9730-5
50. Daley, D., & Benson PR. Manual for coding expressed emotion in parents of children with autism spectrum disorders: The autism-specific five minute speech sample. Boston, MA: Center for Social Development and Education U of MB, editor. 2008.
51. Benson PR, Daley D, Karlof KL, Robison D. Assessing expressed emotion in mothers of children with autism. *Autism*. 2011 Jan 29;15(1):65–82. DOI: 10.1177/1362361309352777
52. Pandolfi V, Magyar CI, Dill CA. Confirmatory factor analysis of the Child Behavior Checklist 1.5-5 in a sample of children with autism spectrum disorders. *J Autism Dev Disord*. 2009;39(7):986–95. DOI: 10.1007/s10803-009-0716-5
53. Pandolfi V, Magyar CI, Dill CA. An initial psychometric evaluation of the CBCL 6-18 in a sample of youth with autism spectrum disorders. *Res Autism Spectr Disord*. 2012;6(1):96–108. DOI: 10.1016/j.rasd.2011.03.009

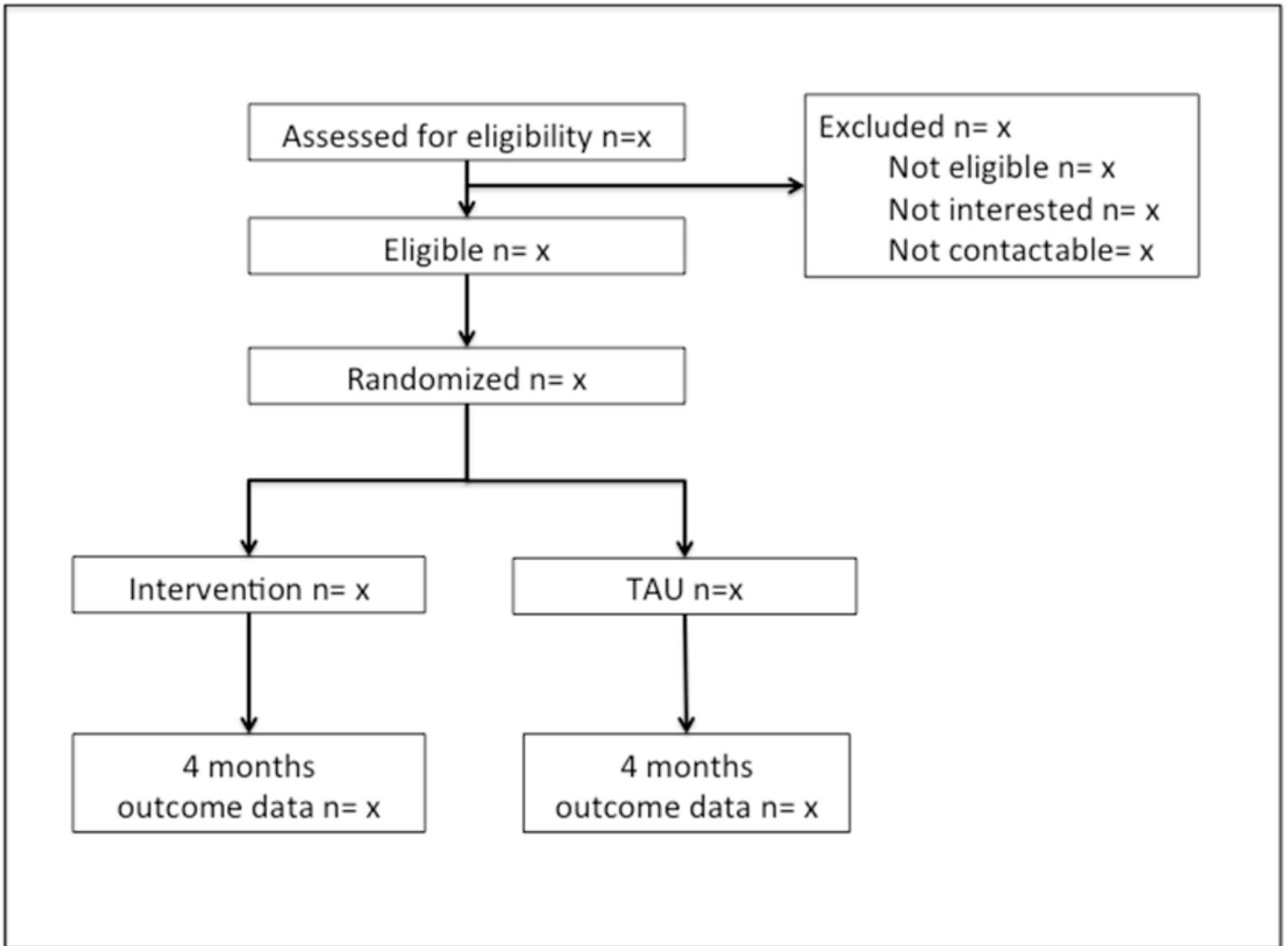
## Appendix

1. Consent form for participants
2. Information sheet for participants

## Tables

Due to technical limitations, table 1 is only available as a download in the Supplemental Files section.

## Figures



**Figure 1**

Participant flow diagram

## Supplementary Files

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

- [Table1.docx](#)
- [AnnexI.CI.docx](#)
- [AnnexII.HI.docx](#)
- [SPIRITChecklistFIRSTSTEPS.doc](#)