Vilaseca *et al. BMC Psychology* (2025) 13:196
https://doi.org/10.1186/s40359-025-02494-6

BMC Psychology

STUDY PROTOCOL **Open Access**

The use of video feedback to promote developmentally supportive parent–child interactions with young children with ASD or at risk: study protocol for a randomized controlled trial (VIFEPOPA-RCT)

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Abstract

Background Autism Spectrum Disorder (ASD) is a neurodevelopmental condition characterized by difficulties in social communication and interaction, and repetitive and restrictive behaviors and interests from an early age. ASD often negatively affects caregiver-child interactions, caregiver emotional well-being and self-efficacy, and quality of family life. Positive caregiver–child interactions are crucial for good developmental outcomes, leading to the development of Parent-Mediated Interventions (PMIs). PMIs tend to follow an expert model where professionals provide direct instruction on treatment techniques and parental behaviors. However, research supports a shift towards a more collaborative and reflective approach, using coaching strategies that highlight caregiver strengths and encourage self-reflection. This study tests a video-feedback intervention (VFI) with parents of young children at risk of ASD.

Methods A randomized controlled trial (RCT) with 60 families, recruited from Early Intervention Centers in Spain, meeting inclusion criteria: adequate use of internet, child aged 24–36 months with a high risk of ASD (M-CHAT-R score ≥ 8), and participant primary caregiver (mother or father) with high anxiety, depression, or parental stress (score ≥ 1 SD above M), and low or medium–low developmentally supportive parental behaviors (PICCOLO score ≤ 40). Families will be randomly assigned to an intervention group (receiving usual services plus VFI) or a control group (usual services). The intervention includes twelve bi-weekly 90-min sessions over six months, with the caregiver. Outcome measures include parenting behaviors, emotional state, self-efficacy, family quality of life, and child development collected at pre-intervention, post- intervention and six-month follow-up.

Discussion The study will assess whether the intervention enhances developmentally supportive parental behaviors, emotional well-being, self-efficacy, and family quality of life, with a secondary positive impact on child development. If proven effective, it could be a cost-effective intervention with both short and long-term benefits.

Trial registration ClinicalTrials.gov Identifier NCT06604988. Registered on September 17, 2024. Retrospectively registered.

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Keywords Adult–child interaction, Autism Spectrum Disorder, Early Intervention, Positive Parenting, Developmentally Supportive Interactions, Developmentally Supportive Parental Behaviors, Family-Centered Intervention

Background

Autism spectrum disorder (ASD) is a chronic neurodevelopmental disorder characterized by impairments in social communication and interaction as well as the presence of repetitive and restrictive behaviors and interests [1] from a very early age. Those impairments clearly impact these children's development and their relationships with people around them. These effects of ASD lead to considerable parental stress and caregiving burden across the lifespan, which further disrupt parent's psychological well-being, parent's self-efficacy, and the family's quality of life [2–5]. The social communication difficulties presented by children with ASD, which involve less eye contact, fewer communicative signals, and ambiguous communication signals, negatively affect interactions with their parents and other family members and generally lead to behavioral problems during daily activities at home [6, 7].

Overall, these impairments in social communication and interaction by children with ASD are likely to negatively impact the caregiver's behaviors [8, 9]. Parents' interactions with children with ASD tend to show less flexibility, sensitivity and synchrony, as a result of the difficulties inherent to the disorder [10] and furthermore, caregivers tend to exercise an intrusive and directive parenting style that not only does not support child development [11, 12], but can negatively affect it [13, 14]. It is evident that interactions with a child with ASD represent a greater challenge for parents than interactions with a child with typical development [15]. Therefore, it is crucial for early intervention services to target developmentally supportive parenting for families with a child with ASD to improve parents' and family wellbeing, and children's developmental outcomes.

The key role of Positive Parenting in child development

Various studies have shown that positive parent–child interactions predict good developmental outcomes in families with children with disabilities [16–19]. Parents can provide emotional support and cognitive and linguistic stimulation during their interactions at home in their daily routines with long term benefits for child's language and communication, cognitive development and adaptative functioning [20]. Maternal and paternal responsiveness and cognitive and linguistic stimulation have been associated with better cognitive and language outcomes in very young children with intellectual disabilities and with ASD [19, 21]. Positive parenting interventions in families with children with ASD benefit both caregiver-child interaction and child development [22–25]. Promoting sensitive and responsive interactions between parents and children with ASD, in their homes, has improved adult–child interaction and children's linguistic, cognitive, and social communication skills [7, 22, 26]. Thus, interventions to support parenting should be a priority for the child population with or at risk for ASD [17, 27].

Parent-mediated interventions and their effectiveness for families with young children with ASD

Parent-mediated interventions (PMIs), often part of comprehensive intervention programs, teach mothers and fathers to implement specific treatment techniques with the child and seek to increase positive caregiver behaviors of parents that have been empirically linked to aspects of child development. PMIs usually entail intensive professional training to support parents to assist children with developmental delays or disabilities [28]. PMIs promote parent–child engagement and address behavior support, communication and social interaction by increasing parental skills through didactic instruction, role-play, coaching, in-home practice assignments or in person or virtual home visits [29]. Also, PMIs have improved parental stress [30] and parental self-efficacy [31] as well as family cohesion and family quality of life [26]. There are two distinct theoretical approaches in PMIs.

On the one hand, some PMI programs based on behavioral learning principles focus on key foundational behaviors that have been identified prior to the intervention. Skills across several domains are targeted, such as skills in the areas of communication, social interaction, cognition, or fine and gross motor actions. Some of the programs from this perspective involve parents in what has been called Naturalistic Developmental Behavioral Interventions (NDBIs). Some examples of these programs are, Pivotal Response Training (PRT) [32], Hanen's "More Than Words" program (HMTW) [33], Parent delivery–Early Start Denver Model (P-ESDM) [34]; Project ImPACT [35]; Joint Attention Symbolic Play Emotion Regulation (JASPER) [36]; Focused Playtime Intervention (FPI) [37]; or Reciprocal Imitation Training (RIT) [38]. All these programs combine relationship-focused developmental interventions with the principles of applied behavior analysis [39].

On the other hand, other PMIs are more focused on the quality of parent–child interaction, such as The Play and Language for Autistic Youngsters (PLAY) [40], the Transactional Intervention Program (TRIP) [41], the Relationship Focused Intervention (RFI) [23, 42, 43] and the DIR/Floortime approach [44]. These programs intend to positively influence the child's development by improving caregiver-child interactions. They have predefined intervention aims, and they use the same strategies to address each of the different domains (communicative, cognitive, motivation and social-emotional functioning). PMIs that focus on caregiver-child interaction usually are less expensive than those previously mentioned above [45]. For a review of these programs and others carried out with families with children with ASD, see [5, 45, 46].

PMIs are considered empirically validated interventions to improve child's development [5]. However, a variety of factors related to the children, parents, and study design can affect the results and their validity. Recent systematic reviews assess intervention effectiveness for families with a child with ASD [7, 26, 47, 48]. For example, a meta-analysis of the efficacy of 19 randomized-control trials of parent-mediated interventions for children with ASD age 1–6 years showed only small improvements based on measures of ASD symptom severity, socialization, and cognition, describing improvements in communication (including language) as trivial [26]. A review of studies of parent-mediated interventions delivered remotely for parents of children with ASD living outside urban areas, noted preliminary evidence but a lack of well controlled studies and design limitations such as not defining the population or not using standardized measures [47]. These findings suggest a need for further research examining the appropriateness and feasibility of parent-mediated interventions.

A Cochrane Review of 17 studies involving 919 children with ASD, found strong evidence of proximal impact on parent–child interactions involving shared attention, and parent synchrony [7]. However, only small effect sizes were found for intervention effects on children, such as changes in their comprehension and ASD characteristics; findings were inconclusive regarding language and communication, adaptive behavior, and parenting stress. Finally, a recent meta-analysis of group design studies of early interventions for young children with autism spectrum disorder focused on different types of interventions, with 15 outcome categories and 1,615 effect sizes across 6,240 participants [48]. When the analysis was limited to RCT designs and to more reliable outcomes, no intervention showed significant effects on any outcome. The majority of interventions examined were those focused on behavioral learning principles.

Going beyond the expert model in PMIs

Most of the PMIs are based on an expert model approach. From this model, professionals train parents, in groups or in one-to-one format, giving specific instruction for how to use a specific strategy. The professional is the expert who presumably knows which strategies work well for which parents and which ones don't, and when to use them at one time or another. However, usually the strategies or models are the same for all families, regardless of their strengths, preferences, peculiarities, or needs, or whether parents are trained individually or in a group. Additionally, as it has been pointed out, interventions aimed at promoting child development through parenting predominantly emphasize reducing inappropriate caregiver behaviors [49]. We could say that most interventions have a corrective approach, focused on modifying the caregivers' behaviors that mothers and fathers do not perform correctly or adequately (for example, not giving the child time to respond to suggestions or not responding often enough to infant vocalizations) or an instructional approach, aimed at teaching mothers and fathers to perform certain behaviors or develop certain skills (for example, detecting a child's subtle communicative signals and responding to them contingently).

The expert model of PMIs has some advantages, mainly providing referrals, information, and support to parents. Nevertheless, it has important inconveniences. Parents are expected to learn to carry out the trained behaviors in their daily lives, which may not be easy or automatic. Furthermore, it sends parents an implicit message that they are not competent enough to support their child's development [50].

Currently, there is a change of focus in parenting interventions, replacing corrective or explicitly instructional strategies, typical of the expert model, with strategies aimed at strengthening existing parental skills to a greater or lesser extent, which means focusing on the positive aspects of parenting exercised by mothers and fathers at home. Studies that compare different intervention strategies with families with children with disabilities conclude that family-centered programs based on the caregivers' strengths, sometimes called "parenting coaching models," can have important and powerful effects on parenting and child development [29, 51–56]. Although there are different coaching approaches, common features include observation, positive feedback, reflection, and collaborative planning and goal setting (preferably based on caregiver strengths [57–59]. There is strong evidence that coaching is effective in enhancing professionals' competence in early childhood education and early intervention settings [60, 61]. Promoting reflection and self-evaluation by parents can enable parents to interact with children more effectively and thereby increase their self-efficacy [62]. Moreover, the recommended practices for interventions with families of children with disabilities emphasize a family-centered approach [63] that involves reflecting jointly with parents about the interactions they have with their children in their natural contexts, fundamentally the home, and working collaboratively to actively engage families in using these interactions to support their children's development [64–66].

Therefore, although it seems clear and necessary to involve parents in interventions with children with ASD, the challenge currently lies in being able to identify which procedures are most effective in achieving changes in the way in which caregivers interact with their children and ensuring that these changes are maintained in the long term [46].

Video Feedback Intervention

Parent coaching interventions that adopt a family-centered and strengths-based approach are increasingly using video-feedback intervention (VFI). VFI, which has demonstrated effectiveness for families of children with ASD and other neurodevelopmental disabilities [67–70], includes a wide range of procedures aimed at promoting positive parenting, based on evidence-based principles of child development. VFI allows parents to observe themselves interacting with their children "from outside" [67]. Video-recordings or video-self-recordings of parent–child interactions, viewed together with the professional, offer an asynchronous resource by which mothers and fathers observe themselves interacting with their own child in their natural context. This process empowers the family and increases their active, positive participation in the intervention [71]. Generally, the professional carrying out the intervention selects the most relevant fragments of the video and views them together with the caregivers, guiding parents' self-reflection regarding their beliefs, feelings and knowledge about positive parenting and child development. VFI can be carried out in person or remotely [53, 54]. The use of remote VFI in "tele-intervention" represented a boon in its use, especially during the pandemic [55]. Remote VFI allows greater flexibility in intervention and clearly contributes to cost savings when compared to in-person intervention visits in family homes [71]. VFI can be based on proposing, together with caregivers, new behaviors or the improvement or increase of existing ones, from an approach based on strengths and collaboration and avoiding directive attitudes [72]. Previous research has shown that VFI predicts better child development and better parent–child interactions in diverse contexts and in populations with normal development and with neurodevelopmental disabilities or at risk [55, 67, 73–76].

Nevertheless, evidence supporting VFI with parents of very young children with or at-risk for ASD is limited. From our point of view and from the research literature, there is still a lack of the systematization needed to guide professionals to effectively implement VFI, despite evidence of its effectiveness on parenting and child development in this population [9, 77]. There is also a lack of studies assessing the impact that video-feedback intervention focused on the caregivers' behaviors has on parental well-being, self-efficacy and the family's quality of life.

Logic model of our intervention protocol: a strengths-based collaborative video feedback intervention

Our intervention protocol is in line with PMIs that focus on parent–child interactions from a collaborative or facilitative approach, in contrast to the expert model described above. The general principles that define our intervention, as can be seen in Fig. 1, are that it is: a) relationship-based; b) focused on parent's strengths; c) collaborative; and d) facilitative.

Firstly, the intervention is relationship-based in a double sense. On the one hand, it is based on establishing a secure and confident relationship between the intervenor and the caregiver [78, 79]. On the other hand, the intervention focuses on both the parent and child in their interactions with each other [78, 80, 81].

Secondly, the intervention is based on caregiver's strengths for supporting child development [58, 59, 82, 83]. To identify these strengths, a practical observational measure of developmentally supportive caregiver behaviors (DSCB) is needed by practitioners to identify and promote positive, responsive, encouraging, and stimulating behaviors when interacting with their child (caregiver strengths). Identifying these behaviors that support a child's early development is a key part of the intervention. One such measure is Parenting Interactions with Children: Checklist of Observations Linked to Outcome*s* (PICCOLO) [84]. Developed specifically for practitioners providing direct services to individual families with infants or young children, PICCOLO provides a tool for observing specific DSCBs that predict better child outcomes in cognitive, language, and social-emotional development for both typically developing children [85–87] and for those with early disabilities [18, 19, 51]. DSCBs that support children's early development fall into four domains of caregiver-child interaction: affection or warmth, sensitive responsiveness, encouragement

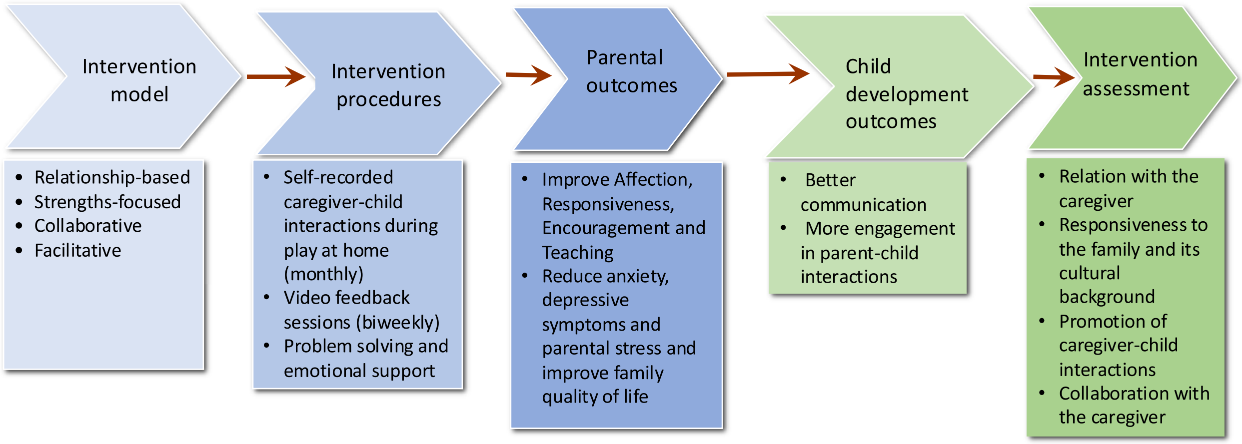


Fig. 1 Logic model of parental intervention

or scaffolding, and teaching or cognitive and linguistic stimulation.

Thirdly, the intervenor is not presented as an expert that instructs the caregiver to perform in a particular way, but a collaborative partner with professional knowledges about child development and neurodevelopmental disorders. This partner supports parents as they discover ways to improve their parental competencies [58, 88].

Finally, according to the characteristics that we have just pointed out, the intervention can be globally described as facilitative. A facilitative intervention, as proposed by [50], emphasizes child development and the caregiver behaviors that promote it; focuses on caregiver-child interaction; builds on the caregiver's strengths; and addressees broad foundations of development (security, exploration and communication). This approach is designed to facilitate, or make easier, a caregiver's developmentally supportive interactions with a child.

According to these guiding principles, an intervention procedure has been designed that includes self-recording caregiver-child interactions during play at home, video feedback sessions with the participating caregiver, and problem solving and emotional support to the caregiver. As Fig. 1 illustrates, the intervention procedure aims to have a positive direct impact on caregivers, not only by increasing caregiver interaction behaviors that support a child's development, but also by increasing caregiver well-being. According to a recent systematic review, family-centered and video-feedback interventions have shown to be effective in improving a caregiver's feeling of competence and self-efficacy as well as the family's quality of life [89].

The caregivers' behaviors targeted by the intervention are those that support child development, so an indirect impact of the intervention on child development is expected, especially in communication and social engagement. Recent literature has shown a positive impact of PMIs on social communication of young children with ASD [46, 90, 91]. Nevertheless, as systematic reviews and meta-analyses have shown, strong evidence of a high impact of PMIs on developmental outcomes of children with ASD has not been consistently proven [7, 26, 47, 48].

According to our logic model, the mechanisms by which the intervention would positively impact parental outcomes and child development are the relationship between the intervenor and the caregiver, the intervenor's sensitivity and responsiveness to the characteristics and conditions of the family, the emphasis on caregiver-child interactions, and the collaborative approach. An observational assessment of this approach with Home Visit Rating Scale – 3 (HOVRS-3) [56] will be conducted to assess the intervention sessions according to these parameters.

Aims and hypotheses

The primary aim of the proposed study is to assess the efficacy of an intervention to improve caregiver competencies through the observation of caregiver-child interaction, using video-feedback coaching strategies based on parental strengths, working collaboratively with parents to plan each subsequent session. Particularly, in this work, our aim is to describe the intervention protocol after a presentation of the general principles of our intervention model.

We will implement and assess the intervention in a group of parents with young children at risk of autism spectrum disorders (ASD). The intervention's impact on four outcomes will be assessed: (1) developmentally supportive parental behaviors, (2) emotional distress of parents (anxiety, depression, stress), (3) parental self-efficacy, and (4) the family's quality of life. Differential change in individual trajectories will be analyzed for the four outcomes, comparing families receiving the intervention to those assigned to a control group. We hypothesize that (1) developmentally supportive parental behaviors of parents, measured with PICCOLO, after the intervention will be significantly higher in the intervention group (IG) than in the control group (CG); (2) levels of anxiety, depression, and/or stress of parents after intervention will be significantly lower in the IG than in the CG; (3) parents' parental self-efficacy after intervention will be significantly higher in the IG than in the CG; and (4) family quality of life after intervention will be significantly higher in the IG than in the CG. Also, we hypothesize that individual trajectories in families within the IG will show changes in the outcome variables consistent with these expectations during the intervention period. We hypothesize that these positive changes will not be observed in the CG, who will continue receiving the usual early intervention services.

With respect to intervention assessment, we hypothesize that there will be significant and positive associations between key outcomes of the study and the scores obtained on the HOVRS-3 measure [56] of four evidence-based home visiting practices: relationship building with families, responsiveness to family strengths, facilitating caregiver-child interaction, collaboration with caregivers.

Finally, we expect to find a secondary benefit on children's development, assessed with the DP-3 (Developmental Profile-3) [92], particularly in the communication and social adaptation areas, in which children with ASD often show delays [93].

Methods

Participants

The sample will consist of 60 families, specifically 60 main caregivers (mother or father, at the family's decision) and her/his young child at risk of ASD, who personally volunteer to participate in the study. These participants will be recruited from Early Intervention Centers in Spain. Families will be randomly assigned to an intervention group, which will receive the VFI, or to a control group, which will continue to receive services as usual. All families will continue to be enrolled in the program offered by the Early Intervention Centers. Recruitment will conclude at the end of February 2025.

Inclusion criteria

- Adequate family internet access.
- Child aged between 24 and 36 months.
- Child with a M-CHAT-R score compatible with high risk of ASD according to the manual [94] (score $\geq$ 8).
- Main caregiver with a high score in at least one of the following variables: a) anxiety quantified using the Hospital Anxiety and Depression Scale (HADS) [95, 96] (score $\geq$ 7); b) depression quantified using the HADS (scores $\geq$ 7); c) stress measured using the stress dimension of the Parenting Stress Scale Short Form (PSI-F) [97, 98] (score $\geq$ 86; beyond one SD).
- Primary caregiver with a low level or medium–low level of developmentally supportive parental behaviors, quantified by the total score on the Spanish version of the Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO) [21, 84, 86, 99, 100] (score < =40). Forty points correspond to the 16% of the lowest scores in the Spanish validation sample for mothers, at 36 months of child's age. Cut scores corresponding to the 16% lowest scores vary according to parent gender and child's age [100].

Exclusion criteria

- The family is currently receiving or has received in the last twelve months an intervention to improve parental interactions like the one proposed in this protocol, using positive feedback guidance based on observation of parent–child interaction.
- Caregiver without a level of written and spoken Spanish that allows the intervention to be carried out.
- Caregiver without internet connection for videoconferences.
- Caregiver with diagnosed mental health problems, excluding anxiety or depression symptoms.
- Child with serious physical disability or multiple disabilities.

Instruments

Data from the families and the professionals

Sociodemographic questionnaire for parents An *ad-hoc* questionnaire will collect sociodemographic data referring to the child (birth date), gender, attendance at nursery, school or other educational or health services, prenatal health, postnatal health, the family (marital status, family structure), and the parents (gender, age, educational level, working status, civil status, monthly family income).

Questionnaire for professionals For every child, his/her main reference professional at the child's Early Intervention Center will complete a questionnaire, elaborated *ad-hoc,* to gain information about the professional profile including academic qualifications (academic background, professional update courses), experience, and characteristics of the intervention approach usually conducted by that professional with young children at risk of ASD.

Instruments for primary measures

Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO) Caregiver behaviors in self-recorded videos of parent–child interactions will be observed and scored with the Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO) [84, 86], which has been validated in Spain with mothers [21] and fathers [99]. PICCOLO is a 29-item observational measure of caregiver interactions with children aged between four and 47 months. Each item corresponds to a positive parental behavior linked to children's developmental outcomes. Items are scored according to frequency and consistency as 0 (absent, not observed), 1 (rare, minor, or emerging) and 2 (clear, definitive, strong, or frequent). The items are grouped into four domains: (a) affection (7 items), which involves the physical and verbal expression of affection, positive emotions, positive evaluation and positive regard (e.g., "Shows emotional warmth", "Smiles at child"); (b) responsiveness (7 items), which includes reacting sensitively to a child's cues and expressions of needs or interests and reacting positively to the child's behavior (e.g., "Changes pace or activity to meet child's interests or needs", "Follows what child is trying to do"); (c) encouragement (7 items), which considers the parents' support of their child's efforts, exploration, independence, play, choices, creativity and initiative (e.g., "Encourages child to handle toys" or "Supports child in doing things on his/her own"); and (d) teaching (8 items), which includes cognitive stimulation, explanations, conversation, joint attention and shared play (e.g., "Explains reasons for something to child", "Labels objects or actions for child"). The instrument generates a score for each domain from 0 to 14 (0 to 16 for the teaching domain) and a total score between 0 and 58. The psychometric properties of PICCOLO have been found to be satisfactory for the original and the Spanish version. For mothers, Cronbach's α coefficients were 0.91 for the original measurement sample [84, 86] and 0.88 for the Spanish validation sample [21], 0.78/0.59 for the affection domain, 0.75/0.75 for the responsiveness domain, 0.77/0.79 for the encouragement domain, and 0.80/0.68 for the teaching domain. For fathers, corresponding Cronbach's α coefficients were 0.91/0.91 for the total father PICCOLO score in the original measurement sample [84, 86] and the Spanish sample [99] respectively, 0.70/0.80 for the affection domain, 0.81/0.85 for the responsiveness domain, 0.75/0.81 for the encouragement domain, and 0.66/0.79 for the teaching domain. PICCOLO has shown predictive validity for children's developmental outcomes for typically developing children [84–86] and children with identified disabilities [18, 19, 101].

With respect to PICCOLO, the last two signatories of the article are authors of the original version of PICCOLO published by Brookes and have rights to use it. The two co-first authors of the article are authors of the Spanish version of PICCOLO, published by Publications of the University of Valencia (PUV) and Publications of the University of Barcelona (Publicacions UB), through an agreement with Brookes. They also hold the rights to use the tool.

Hospital Anxiety and Depression Scale (HADS) The Spanish version [95] of the Hospital Anxiety and Depression Scale (HADS) [96] will be used to assess anxiety and depression symptoms in parents. The HADS is a self-reporting screening questionnaire composed of 14 items (seven items concerning depression symptoms and seven for anxiety symptoms) scored on a Likert scale from 0 to 3 points, with demonstrated adequate psychometric properties in Spanish samples [102].

Parenting Stress Scale Short Form (PSI-SF) The Spanish adaptation [98] of the Parenting Stress Scale in its abbreviated version (PSI-SF, Parenting Stress Index-Short Form [97] will be used to assess parental stress. The scale allows obtaining a total score or by factors. The exploratory factor analysis for the Spanish adaptation identified two factors: Childrearing Stress and Personal Distress, which accounted for 48.77% of the variance. The internal consistency of these factors was high (Childrearing Stress: 0.90 and Personal Distress: 0.87). For inclusion criteria we used the total score.

Perceived Parental Competence Scale (PSOC) To evaluate parental self-efficacy, the Spanish adaptation [103] of the PSOC-Parental Sense of Competence Scale by Johnston and Mash [104] will be administered. In the Spanish adaptation of the PSOC (PSOC-E), the two-factor structure (satisfaction and efficacy) was confirmed, and adequate reliability and validity indices were obtained. The internal consistency coefficient was 0.85 for the total scale, and 0.78 and 0.85 for the satisfaction and efficacy dimensions respectively [103].

Families in Early Intervention Quality of Life (FEIQoL) The Families in Early Intervention Quality of Life [105] in its Spanish version [106] will be used. The FEIQoL asks families to rate 39 FQoL features (i.e., items) on a 5-point rating scale from 1 = poor to 5 = excellent, and it usually takes 20 min to complete. The FEIQoL, in its original American version, is comprised of four factors: Family Relationships, Access to Information and Services, Overall Life Situation, and Child Functioning. According to factor analyses, three factors (Family Relationships, Access to Information and Services, and Child Functioning) have a better fit with Spanish families than the four original ones [106]. The scale shows a high internal consistency for the total score (α = 0.94) and its factors ranged from α = 0.74 to α = 0.89.

Home Visiting Rating Scales (HOVRS-3) To examine the quality of this highly individualized VFI process carried out with caregivers, four scales (relationship building with families, responsiveness to family strengths, facilitation of caregiver–child interaction, and collaboration with caregivers) of the Home Visit Rating Scale, version 3 (HOVRS-3) will be used [56]. Positive HOVRS-3 scores are predictive of greater parent involvement and improved child language scores [56]. HOVRS-3 is composed of a list of relevant practices with indicators at four levels of quality (excellent, good, adequate, needs support) within each of the scale domains. The scale demonstrated high values of validity and reliability (alphas between 0.69 to 0.91 depending on subscales), good agreement between observers (Kappa > 0.75) as well as adequate predictive validity [56].

Client Satisfaction Questionnaire (CSQ-8) and Working Alliance Inventory Adapted to Home Visiting – Short Revised (WAI-SR-HV) To evaluate family satisfaction with the intervention, we will use the Spanish version [107] of the Client Satisfaction Questionnaire (CSQ-8) [108]. It is a short questionnaire of 8 items with a Likert-type response range from 1 to 4. It includes two open questions regarding the most valued aspects of the intervention and those that should be improved. The original tool presented an adequate internal consistency, obtaining an alpha of 0.93. When used in the Spanish population, it is suitable, obtaining an Alpha between 0.83 and 0.90. To add greater validity and to be able to obtain data on caregivers' perceptions of the quality of their working relationship with the VFI intervenor, we will use the Spanish version [109] of the Working Alliance Inventory Adapted to Home Visiting – Short Revised (WAI -SR-HV) [110, 111].

Instruments for secondary measures

M-CHAT-R The Modified Checklist for Autism in Toddlers Revised (M-CHAT-R) questionnaire will be administered to assess the risk of ASD of the children [94]. M-CHAT-R is a detection tool that parents complete in relation to their child's usual behavior that allows, according to the scores obtained, to identify a low risk (scores 0–2), moderate risk (3–7), or high-risk (8–20) of presenting ASD. M-CHAT-R is a highly sensitive tool, designed to ensure that as many cases of ASD as possible are detected at early ages (16–30 months).

MCHAT-R downloads are available for free from this website https://www.mchatscreen.com/. By downloading files from this website, we agree to follow the stablished guidelines.

Developmental Profile-3 (DP-3) The Spanish interview version of the Developmental Profile-3 (DP-3) will be used in the parent interview to assess child development, as a secondary measure. It consists of a total of 193 items that are not applied in their entirety in the interview version but selected depending on the age of the child. It can be applied from birth to twelve years and eleven months of age [92]. DP-3 is the Spanish adaptation of the latest version of the original Developmental Profile–II [112]. Its constructs and theoretical structure are based on the multidimensional model of child development by Alpern and Boll [113], which considers five major areas of development: motor skills, language and communication, socio-emotional development, cognitive development, and adaptive behavior. It is a screening tool that allows a quick evaluation to detect possible delays in those five areas of child development, offering also a global development index of the child. Cronbach's alpha values calculated separately for the different age groups, range between 0.83 and 0.86 for the entire sample in the interview version. The general development index shows an average internal consistency of 0.96. The correlations between subscales were moderate, between 0.50 and 0.60, which was expected, given that each of them evaluates a different developmental area. Furthermore, each of the subscales shows a higher correlation with the general development index than with any of the other subscales, which supports the independent use of the different subscale scores.

Procedure

The Early Intervention Center's professionals who are blind to study group placement will complete a questionnaire sent to them. To verify the inclusion criteria, the M-CHAT-R [94] will be completed by the professional working with the child based on the information provided by the parents and their own knowledge about the child.

Caregivers of children enrolled in the Center will be provided with written information about the project, informed consent forms, questionnaires to complete, and instructions to self-record 10 min of play interaction at home with their child. Families meeting the inclusion criteria will be randomly assigned to the intervention or the control group. A member of the project staff will contact the family by phone to answer questions and expand the information, depending on whether the participant belongs to the video-feedback intervention group (VFI) or the control group (CG).

All the materials (informed consent, questionnaires, videos) will be shared through Teams private channels. The intervention sessions will be online, conducted by the Teams platform. Microsoft Teams is designed with robust security features to ensure the safe sharing of private data [114], and it is the platform recommended by the Ethical Committee of the University of Barcelona.

Four intervenors have been trained by the two first authors of this paper to assess PICCOLO from the videorecorded caregiver-child interactions. The training consisted of weekly meetings for a month, each lasting 2.5 h. Each observer received the coding material previously and in the first meeting they discussed and commented on each of the items of the instrument. Subsequently, they independently viewed and scored 20 videos, using the item descriptors. Interrater agreements for every subscale and total score were between 0.73 (good) and 0.88 (very good), according to Fleiss [115], exceeding interrater agreement in the original measurement sample, which ranged from 0.69–0.80 [84, 86]. The VFI protocol was designed by the two first authors of the protocol with the collaboration of two of the original authors of the PICCOLO, Lori Roggman and Mark Innocenti. All intervenors are psychologists with experience in developmental assessment, analysis of adult–child interaction, and work with families.

Study design

All the participants, both in the VFI group (described above) and the Control group (standard intervention), will answer questionnaires on emotional distress (anxiety, depression, parental stress), parental self-efficacy, and family quality of life at the time of verifying the inclusion criteria (T0), just after finishing the intervention (T1; 6 months from being recruited and assigned to one of the two study arms), and six months after finishing the intervention (T2; follow-up). As a secondary variable, child development will be assessed, for both groups, at the same three measurement occasions (pre, post, follow-up). M-CHAT-R will be used only at T0, to verify compliance of the inclusion criterion of presenting a high risk of ASD.

Our intervention will be conducted for the VFI group, in addition to the intervention that children usually receive in their Early Intervention Centers. Children and their families from the control group will also receive the intervention typically provided by the Centers. Thus, our VFI will be complementary and different from that carried out by the Early Intervention Centers. Although Spain has been transitioning for years towards an intervention model focused on the family, Early Intervention Centers predominantly use a child-centered approach. Studies show that the percentage of time early intervention professionals spend with families is below international recommendations. Family-centered practices emphasize working with families within their natural contexts and empowering them to support their child's development, but this approach faces resistances from both families and professionals. Transitioning to family-centered practices requires to shift toward a more collaborative relationship with families (for more details about Early Intervention in Spain see [116–119].

Before the first VFI session, a preliminary or orientation session will be held. In this session, the first contact with the caregiver will be established to identify their concerns, interests, and needs, to explain the intervention procedure to the family and introduce the caregiver to the PICCOLO observational tool to identify positive caregiver behaviors that benefit and promote child development. The main caregiver will be told that the focus of the intervention will be on positive caregiver behaviors observed in the videos, which the intervenor will discuss with the caregiver. The caregiver will be informed that their next meeting will be the first intervention session, before which the intervenor will have seen a video previously sent to him/her by the caregiver, and that in this session they will talk about positive aspects of the interaction with their child. In the final part of this orientation session, the child's development will be assessed with the DP-3 interview [92]. The caregiver will be informed that assessing the child's development will help the intervenor to know more about the child.

Bimonthly VFI sessions will be conducted for 6 months (a total of 12 sessions per family) via videoconference with the participant caregiver at home. Each session will last approximately 60 to 90 min. Before the first session, the family will be asked to record a 10-min video of play interaction with their child at home following the instruction "Play with your child as you usually do." Some play materials will be suggested: i) children's books, ii) toys for symbolic or fictional play and iii) manipulative toys (for example, puzzles or building games). Caregivers will use their own toys and they will be encouraged to use two or three different toys during the recording.

The caregiver will record one video every two sessions, that is, at end of the evenly numbered sessions (2, 4, 6, etc.), so that each video will be used in two intervention sessions. One video for every two sessions is required, instead of one per session, to reduce demand on the family, to maximize the usefulness of the 10 min videos as a resource for identifying existing strengths in parent–child interactions, and to allow time for the family to change before another video is recorded. Every video will be used for intervention within a time limit of one month, because a newer video may show more or newer positive caregiver behaviors. The video recorded to assess inclusion criteria will be the material for the first two sessions.

The intervention sessions will be carried out by specialized professionals, noted above, who have been trained in positive video feedback strategies by the main researchers of the project. Intervention fidelity will be assessed with the HOVRS-3 with minor adaptations to our context reviewed by the measure developers [56] and according to a checklist derived from the intervention structure, analyzing 20% of the VFI sessions carried out by the professionals in this research.

Participants in the control group will not receive the intervention, but they will self-record caregiver-child play interactions under the same conditions as the intervention group at the three time points in which the questionnaires will be answered and the child's development will be assessed. Participants in this group will receive monthly phone calls from a member of the team, to maintain contact and talk about changes in the child or the family context.

Figure 2 presents a scheme of the protocol design, and the measures included.

Intervention session structure

Figure 3 illustrates the general structure of intervention sessions.

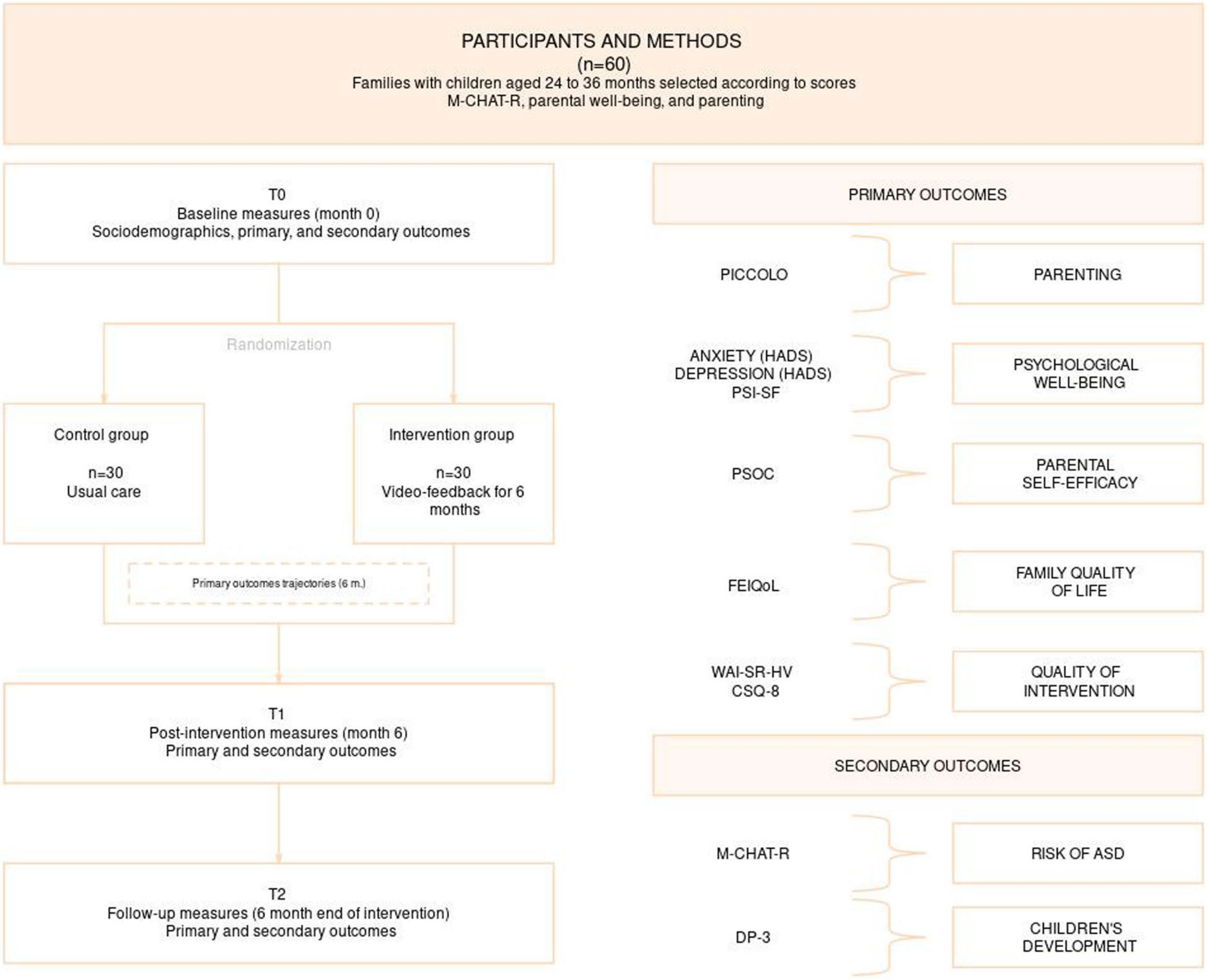
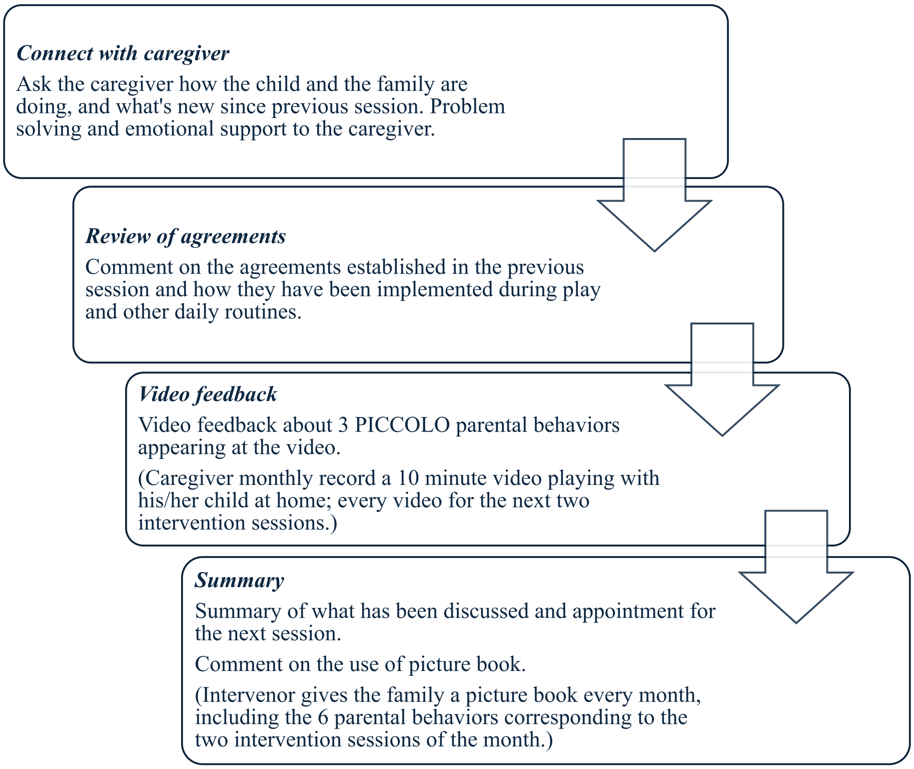


Fig. 2 Protocol design



Connect with caregiver

Ask the caregiver how the child and the family are doing, and what's new since previous session. Problem solving and emotional support to the caregiver.

Review of agreements

Comment on the agreements established in the previous session and how they have been implemented during play and other daily routines.

Video feedback

Video feedback about 3 PICCOLO parental behaviors appearing at the video.

(Caregiver monthly record a 10 minute video playing with his/her child at home; every video for the next two intervention sessions.)

Summary

Summary of what has been discussed and appointment for the next session.

Comment on the use of picture book.

(Intervenor gives the family a picture book every month, including the 6 parental behaviors corresponding to the two intervention sessions of the month.)

Fig. 3 Structure of the intervention sessions

The session begins by asking the caregiver about the news since the last session, about the child's progress and how the caregiver and the family are doing. The caregiver is also asked to comment on whether she has been able to implement the goals selected together in the previous session as well as discuss what is working for them and what is not. Each session will focus on three specific caregiver's behaviors, selected from the 29 items of PICCOLO. The PICCOLO behaviors will not be addressed in the sessions in a predetermined or consistent order across all participants, but rather they will be order individualized to each caregivers' strengths, beginning with the PICCOLO behaviors that they already do often or sometimes. The behaviors focused on in each session will be selected based on a combination of criteria, that the behavior: a) appears in the video recording for that session; and b) belongs to at least two different PICCOLO domains (affection, responsiveness, encouragement, teaching). In the first sessions, preference will also be given to those behaviors that best connect with the parent's main concerns about child's development and to behaviors that have appeared clearly, frequently and consistently in the video (PICCOLO score of 2), although in some cases PICCOLO items that have scored 1 may also be used. It is to be expected that, in the course of the family's participation, all the behaviors included in PICCOLO will appear in one or more of the recordings. Behaviors that do not appear can be introduced through the strategy of linking with other behaviors in which parents show strength. For example, if a caregiver scores high on naming objects, a link can be established between naming and asking the child to name objects; or if a parent is responsive to child vocalizations (Responsiveness) this parenting behavior can be noted to the parent to encourage them to also repeat or expand the child's vocalizations (Teaching).

In each session, the caregiver will be shown video clips that clearly show the identified positive caregiver's behaviors and how they relate to what the child is doing, to give the primary caregiver the opportunity to observe themselves performing positive behaviors. Informative and reflective feedback will be provided to the caregiver.

Video feedback begins with the intervenor asking the caregiver questions about the video clip that is being shared and analyzed. These questions are a valuable aspect of coaching interventions [59] identifying four types of reflective questions: awareness, analysis, alternatives, and action. Awareness questions promote the caregiver's recognition about what they already know or do. These are *who*, *what*, *when*, and *where* questions. For example: "What do you see yourself doing in this video segment? "When do you usually do…?", "At what times or activities do you usually…?", "Where do you usually do…?". Analysis questions encourage the caregiver to compare the current state with the desired one. They are *how* and *why* questions. For example, "Why would you say you have done…?", "Why do you think what you did will help your child's development?" or "How did you do it?". Questions about alternatives encourage the caregiver to think about options to achieve goals in the future, as, for example, "What other games do you think you can introduce to continue…?" or "At what times do you think you could practice…?". Finally, action questions help the caregiver and the intervenor to plan together. For example, "What games do you think you could do for the next video?" or "At what other times do you think you could do what we have discussed (repeat or expand the child's vocalizations)?".

These questions promote self-reflection by the caregivers and guide him/her to find ways to attend to the child's and the family's needs and concerns about the child's development between the intervention sessions. At the end of the first session, the intervenor will design, in collaboration with the caregiver, an individualized family support program, specifying what behaviors he/she can continue to carry out at home in daily routines to promote the child's development. This plan will be prepared in writing and sent to parents by email. In each session, the objectives of the previous plan and how they have been carried out at home will be reviewed with the main caregiver. Doubts and concerns of the caregiver will be addressed. These will vary for each child and family.

From the reflective questions posed by the intervenor and the answers and comments provided by the caregiver, informative feedback is co-constructed for every positive behavior. After the review and discussion of the video clips, the intervenor formulates summarized informative feedback, using guidelines developed by Innocenti and Roggman [52], using a series of prompts: describe what the parent did for this item, describe how the child responded, explain how it helps the child's development in ways that matter to the parent, and ask about other opportunities to interact similarly with the child.

In addition, every two sessions the caregiver will be provided with visual support for the video feedback sessions in a book with pictures or images taken from the audiovisual records (electronic book, e-book, or a PowerPoint or PDF document). Each page of the book will illustrate a caregiver behavior that supports child's development and corresponds with an item of PICCOLO. The image will be accompanied by a brief description of the caregiver's behavior and its relation to child development, in simple and direct language, as if the child or parent were speaking. Text accompanying the image can be included below the image (for example, "I love that my mom plays what I want to play" or "I like it when my mom encourages me to try something new"), balloons typical of comics (for example, the mother says "I am happy when my daughter say a word or two and I can repeat what she says", or the child can say, "Yum, this soup is good!"). The child's "words" in the book usually seem very encouraging to the caregiver. In addition, the text will include some reference on the benefits for the child's development, as, for example, "…and it helps me to learn words" or "…it makes me feel safe".

These picture books will be sent to parents along with the biweekly plan. Parents are encouraged to read the book with their child between video feedback visits, and to share it with other caregivers of the child and/or other family members. This "book-making" intervention has been found effective for families with children with disabilities and those at-risk for later school failure [120, 121] and has been used successfully in other studies to reinforce positive aspects of the interaction between a caregiver and his/her child [52, 122].

Figure 4 shows some examples of picture book pages.

Each session will close with a summary of what has been discussed, and an appointment will be set for the next session.

Sample size determination

A power analysis has been carried out considering possible differences in the primary response variables after completing the intervention. Taking as reference the effects found in this type of interventions based on the improvement of parental relationships [9, 123], various scenarios have been simulated, calculating the sample sizes necessary for separate contrasts. In this sense, those results obtained in intermediate situations (i.e. conservative) have been considered in relation to the effect sizes and the desired statistical power. Specifically, to detect moderate effect sizes (e.g. standardized differences between groups around 0.5 in the primary variables), with a statistical power of 90% and an alpha risk of 0.05, 25 families will be necessary in each group. Assuming a 20% loss throughout the longitudinal study, the total sample required will be 60 families.

Randomization

Families that meet study entry criteria will be randomly assigned to one of the two study arms by a software routine. This routine generates anonymous IDs and then randomly assigns them to either the intervention or the control group. Thus, random assignment will be made before any recruitment, thus reducing allocation bias. Additionally, groups' equivalence will be tested for all

Afection 4. Is physically close to the child.

I like that my dad is close to me when we play, so he sees what I do and can help me. That gives me confidence.

Responsivity 2. The caregiver changes pace or activity to meet child's interests or needs.

When I get bored of a game, mom notices and suggests I play something else. That makes me feel like she understands me and helps me communicate.

Encouragement 3. Supports child in making choices.

My dad lets me choose. I like that, I feel that I can make decisions and that I can convey what I want, communicate.

Teaching 6. Does activities in a sequence of steps.

My dad helps me learn that there are things that have to be done in order: first you have to put the car at the top of the ramp, let it fall and park it. We repeat it several times in the same way.

Fig. 4 Samples of images of the picture books

primary outcomes as well as relevant covariates (e.g., sociodemographic factors).

Blinding

Single blinding will be applied during the evaluation/recording phases of variables, as well as in the statistical analysis phase. In this regard, anonymous alphanumerical IDs will be employed by the coders and data analysts. Study group assignment will not be shared with the Early Intervention Centers.

Equipment

The program requires that the families have an internet connection and the ability to auto record caregiver-child interactions (tablet, mobile phone, computer, camera, etc.). Participants will receive an invitation to add a private Teams channel.

Data analysis

The statistical analyses proposed for this project will largely follow the principles and recommendations for controlled trials of randomized groups included in the CONSORT guide [124]. The primary and secondary variables proposed in the project will be summarized for each group depending on their measurement scale (frequencies, means, standard deviations, medians, IQRs, 95% confidence intervals). With the objective of quantifying the effectiveness of the intervention, parametric and/or non-parametric tests will be used, depending on the distributional characteristics of the primary response variables in the samples, after completing the intervention (post-intervention measure; T1). The comparison of the groups 6 months after the end of the intervention (follow-up measure; T2) will be carried out using a generalized estimating equations (GEE) model; thus, allowing control for the baseline -T0, and accounting for the interdependence between post measurement and follow-up. In this case, factors corresponding to time (weeks 0, 24, 48), group (intervention, control), and their interaction will be taken as fixed effects.

To evaluate trajectories of change in the variables related to parenting, parental self-efficacy, and psychological well-being, random-effects models will be used. In all cases a Gaussian response will be assumed but the distributional assumptions of the residuals in the different models will be checked and validated. In these models, the fixed factor of greatest interest is the interaction between time (there will be 3 measurement occasions that occurred in weeks 0 to 24) and the group (intervention, control). As random effects, the intercepts (estimated constants in the baseline) and the terms related to change patterns due to time will be included in the models if these improve model fit. Adding interactions between change patterns and group might also provide highly relevant information to demonstrate the effectiveness of the intervention.

Data care

Families will send audiovisual records through private channels of the Teams platform. As we indicated previously, Teams has been identified as a secure way to transmit personally identifying information [114]. All information collected in this project will be treated confidentially, maintaining anonymity at all times. Participants will be entered into the databases with an alphanumeric identifier without reference to personal information that could reveal their identity. The databases, therefore, will be anonymized and will be hosted on servers at the University of Barcelona, guaranteeing security. The people in charge of computer data management and the evaluators will be different people, so the anonymity of the participants will once again be guaranteed.

Ethics

The study was approved by the University of Barcelona's Bioethics Commission (CBUB) according to the International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), and the WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects. Institutional Review Board (IRB00003099). Participants signed an informed consent document.

Feasibility of the study and planned contingency plan

In every study it is necessary to anticipate those critical aspects or difficulties that we may encounter during its execution, as well as schedule an appropriate contingency plan for this. In our case, there may be difficulty obtaining the sample. To do this, we have different collaborating centers that are interested in the research, and we also have other contacts from Early Care Centers. Likewise, as it is a longitudinal study, we could have participating families who drop out of the study. This has been considered in the sample estimate, increasing the required sample by 20%. Additionally, a critical point lies in the training of interveners, specifically in the difficulty in achieving quality standards. To this end, and as a contingency plan, the Ips of the project will be able to accompany/advise the interveners in the first phases in case they do not reach these standards at the beginning of the phase of contact with families. Finally, in the analytical phase, there may be difficulty fitting some of the models (see Data Analysis section), especially in the case of trajectories modeling. If necessary, Bayesian models will be used which, despite being affected by the sample size in terms of precision and statistical power, allow estimating the effects without the main convergence problems of the maximum likelihood estimators.

Discussion

This protocol describes an RCT to test whether a strengths-based VFI (12–18 h over 6 months) exerts a positive effect in caregivers' behaviors measured by PICCOLO [21, 84, 86, 99, 100] and in other measures such as caregiver emotional distress, parental self-efficacy and family quality of life in mothers and fathers with children with ASD or at risk between 24 and 36 months old. The VFI protocol is based on recommended practices [63] and in collaborative work with families to build positive relationships with them [51, 125].

This protocol has five key strengths: (1) This study will remedy the lack of scientific evidence on strengths-based parent mediated interventions for autism spectrum disorder (2) [7, 90, 126]. This will be the first study to test the 29 items of PICCOLO, a practical observational measure of developmentally supportive caregiving behaviors, as a resource for early intervention professionals to provide effective positive feedback to caregivers about how they can increase their support of their children's development. (3) This will be one of few studies to analyze the long-term results of a parent-mediated intervention in mothers and fathers of children with or at risk for ASD. The present study was designed as a longitudinal approach to evaluate the impact of an intervention based on VFI, as well as the stability of its impact over time. In this sense, the effectiveness of the intervention can be adequately assessed by using a randomized group design. By having 3 measurement occasions for the main outcomes, it will be possible to estimate the patterns of individual change and to study whether there are differences in these depending on the group to which the family was assigned. (4) To have a control group increases the rigor of the study to evaluate the effectiveness of the intervention (5) Including fathers in this intervention is an added merit, since the majority of VFI has been done with mothers.

This protocol also has some limitations. First, the sample size is one of the main limitations of this study. We have established a sample size that allows us to detect moderate to high differences, according to the effect sizes found in previous studies and considering a loss of cases throughout the longitudinal study. However, this sample size for the two-arm study might be insufficient for modeling purposes. Additionally, having only three measurement points throughout the study will not allow the inclusion of nonlinear patterns of change in the models of individual trajectories.

Another limitation is that the control group, receiving services as usual, are often working with professionals who continue to develop their skills, using various professional development resources, and may therefore be learning about more equitable and engaging approaches for working with families, which may increase their effectiveness. Information from the professionals working with these families may be valuable for identifying and statistically controlling for improvements in their services that could potentially limit group differences. Additionally, an underlying issue is the intensity of intervention, considering that we are increasing the amount of intervention time that children and their families receive, adding an average of two hours per month to those that they are receiving at their Centers. We may not be able to differentiate between the effects of our intervention protocol and the effects of increasing the intervention amount of time. Nevertheless, we should consider that the quantity of time may not be the most relevant factor, but rather the quality of intervention [127].

Also, we are using a screening test to recruit children with ASD or at risk. The M-Chat-R is a screening test that has some limitations, such as false positives. For this reason, we will consider a high score (M-CHAT-R scores equal or higher than 8 points) to be sure that children present a high risk of autism. It would be appropriate to confirm this diagnosis using the standardize Autism Diagnostic Observation Schedule (ADOS) [128].

In conclusion, if this VFI intervention program proves to be effective, it could be generalized to other caregivers with children with neurodevelopmental disorders or developmental delays and could be applied to other families receiving early intervention services. Additionally, the video-conference approach used in this study could be a very cost-effective intervention for families with children with developmental delays who live far away or have few resources.

Finally, this VFI intervention program could help train early intervention professionals to use effective coaching strategies with families using a family centered approach, working more with families instead of working directly with the child [51, 119]. Also, it could help families with children with developmental delays to interact more with their children at home and thereby more effectively promote their development. Scientific evidence suggests that coaching caregivers of young children with ASD or at risk at home, leads to children's improved language and communication behaviors, social and cognitive functioning, adaptative behavior and daily living skills [129, 130]. Caregivers are accustomed to observing what a professional does with their child, rather than interacting with their child during early intervention sessions [130], therefore, we need a change in point of view, both for professionals and for families. This VFI protocol could add to the evidence supporting responsive, collaborative, strengths-based parent-mediated interventions for autism spectrum disorder, that is likely to be more appealing to parents than being trained to be behaviorists [5, 126].

Abbreviations

ASD	Autism Spectrum Disorder
PMI	Parent-Mediated Intervention
NDBI	Naturalistic Developmental Behavioral Intervention
DSCB	Developmentally Supportive Caregiver Behaviors
RCT	Randomized Controlled Trial
VFI	Video-feedback intervention
IG	Intervention Group
CG	Control Group

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40359-025-02494-6.

Supplementary Material 1.
Supplementary Material 2.

Acknowledgements

We would like to extend our gratitude to all the children and parents currently participating in this study, as well as the early intervention professionals who have facilitated our contact with these families. We appreciate the financial aid from the Spanish Ministry of Science and Innovation, and from the University of Barcelona for publishing in open Access.

Authors' contributions

The study protocol was designed by all the authors, basing on earlier works of LAR and MSI. RV and MR will lead the study and the preparation of publications, as principal investigators. They will be also responsible for the ethics application and reporting, participant selection, recruitment and data collection. All authors will work in the interpretation of data. DL will take on a lead role in the data management and analysis. LAR and MSI will provide supervision throughout the study. All authors drafted, reviewed and approved the final version of this manuscript.

Authors' information

Not applicable.

Funding

This project is supported by the Spanish Ministry of Science and Innovation (PID2020-113401RB-I00). The funding body undergone independent peer-review and approved the design of the study but did not participate in writing the manuscript.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study has been approved by the University of Barcelona's Institutional Ethics Committee, Institutional Review Board (IRB 00003099, http://www.ub.edu/recerca/comissiobioetica.htm). The research will be conducted in accordance with the Helsinki Declaration. Signed consent will be obtained from all participants' parents by paper. Findings will be disseminated through local seminars, international conferences and peer reviewed journals. Manuscript is adhered to SPIRIT guidelines for protocols. It was registered in ClinicalTrials.gov, Identifier NCT06604988. Registered on September 17, 2024. Retrospectively registered.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 5 February 2025 Accepted: 17 February 2025

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