STUDY PROTOCOL | Article in Press

Culturally adapted home-based intervention to improve child's development in Arab toddlers in Israel: study protocol for a randomized controlled trial

Niveen Omar[1,2] · Michael Davidovitch[3,4] · Hazar Zahalka[5] · Muhammad Mahajnah[6,7] · Ortal Slobodin[1]

Received: 7 December 2025 / Accepted: 27 September 2026
© The Author(s) 2026

Abstract

Background Arab toddlers in Israel may face structural, socioeconomic, and linguistic barriers to early developmental support, while few culturally adapted early interventions have been evaluated in this population. This trial aims to determine whether a culturally adapted, home-based parent-implemented intervention improves broad developmental performance and expressive vocabulary in Arab toddlers aged 18–36 months compared with an attention-control programme.

Methods This is a two-arm, parallel-group, superiority randomized controlled trial with 1:1 allocation. A total of 240 children will be recruited through approximately 50 Maternal and Child Health Clinics (Tipat Halav) serving Arab communities in northern, central, and southern Israel. Eligible children will be aged 18–36 months, have no significant sensory impairment or severe medical condition, have birth weight ≥ 1500 g, and demonstrate low-average developmental performance, approximately 1–2 standard deviations below the mean, on language or cognitive assessment. Participating caregivers must be willing to complete the eight-session programme and have a Patient Health Questionnaire-9 score < 10. Randomization will be stratified by age group (18–24 vs. 24–36 months) and region (North, Centre, South). Participants and intervention providers cannot be blinded because of the nature of the intervention; outcome assessors will be independent of intervention delivery and blinded to allocation. The intervention comprises eight weekly home-based sessions targeting the home learning environment, child engagement, and caregiver responsiveness during play, daily routines, and shared story time. The attention-control group will receive eight parallel home-based sessions addressing general child health topics without direct language or cognitive stimulation. Outcomes will be assessed at baseline and 1 month after the final session. The two primary outcomes are the Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale (CAT-CLAMS) Full-Scale Developmental Quotient (FSDQ) and expressive vocabulary measured using the 100-item Arabic Short Form MacArthur-Bates Communicative Development Inventory (CDI). Secondary outcomes include CAT and CLAMS Developmental Quotients, receptive vocabulary, and parent-reported developmental concerns. Primary outcomes will be analyzed in separate baseline-adjusted analysis of covariance (ANCOVA) models, with adjustment for age stratum and region; multiplicity across the two primary outcomes will be controlled using the Holm

This Article in Press is shared early to give you faster access to new research. It is citable and carries a permanent DOI. The final edited version will replace it automatically.

https://doi.org/10.1186/s13063-026-10034-9

Published online: 06 October 2026

procedure. No serious intervention-related harms are anticipated; adverse events or safeguarding concerns identified during study activities will be documented and managed according to study procedures.

Discussion This trial will evaluate a culturally and linguistically adapted home-based developmental intervention for Arab toddlers in Israel. The findings may inform the design and delivery of accessible parent-implemented early developmental programmes in similar community settings.

Trial registration ClinicalTrials.gov, NCT07233525. Registered 14 on November 2025. Trial record: https://clinicaltrials.gov/study/NCT07233525. First planned enrolment: 20 November 2025.

Keywords Child development · Culturally adapted intervention · Arab toddlers · Parent-implemented intervention, Language development, Cognitive development

Abbreviations

CAT-CLAMS	Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale
CDI	Communicative Development Inventory
PEDS	Parents' Evaluation of Developmental Status
PHQ-9	Patient Health Questionnaire-9
RCT	Randomized controlled trial
SES	Socioeconomic status
REDCap	Research Electronic Data Capture

Background

Like other disadvantaged groups, such as children from low socioeconomic status (SES) backgrounds or ethnic minority communities, Arab children aged 0–3 years in Israel are considered at high risk for health, cognitive, and educational disadvantages. This increased risk stems from multiple structural and socio-cultural factors, including poverty, geographic and social marginalization, and underutilization of daycares and health services. During early childhood, interventions that support linguistic and cognitive development may contribute to later academic and social outcomes [28, 33, 41]. However, despite the importance of targeted early childhood programmes, evidence remains limited regarding the efficacy of early interventions specifically for ethnic minority disadvantaged populations. This study aims to develop a comprehensive protocol for a home-based, culturally competent early childhood language and cognitive intervention. This intervention will combine culturally adapted and developmental principles and be evaluated for its potential to improve language and cognitive skills in children aged 18–36 months. Additionally, it will be designed from an ecological perspective, considering the characteristics of the child, caregiver, and the broader physical, social, and linguistic environment.

Early language and cognitive interventions

Early intervention targeting linguistic, communication, and cognitive skills may help reduce developmental challenges in young children with or at risk for language impairments [8, 10, 15, 28, 41]. Language abilities in early childhood are associated with later performance across developmental domains and have lasting impacts [35, 48, 50]. They provide a foundation for future literacy skills, such as reading, decoding, comprehension, and written expression [18]. Delays in language development significantly increase the risk of challenges with literacy-related tasks, which may hinder academic achievement [13, 50].

Beyond academic outcomes, early language delays are also linked to social and emotional difficulties. Children with language impairments often exhibit higher rates of challenging behaviours and emotional symptoms [17, 63] and may struggle with social competence and peer relationships compared to their typically developing peers [22, 59]. These difficulties often persist into adolescence and adulthood, placing individuals at a continued risk

for social, emotional, and learning challenges throughout their lives (See [22] and [59]). Early intervention may help mitigate some of these risks by supporting language, communication, and cognitive development.

Similarly, cognitive skills such as problem-solving contribute to children's overall development and their ability to respond to challenges [19, 52]. Mastery of problem-solving not only enhances cognitive growth but also equips children to regulate their emotions, adapt to complex situations, and develop resilience [27]. Conversely, the absence of these foundational skills can hinder their ability to achieve their aspirations and cope with life's demands effectively [40]. Interventions that support problem-solving may help children respond to novel challenges. Accordingly, fostering language and problem-solving abilities through early intervention may support children's broader development.

Parent-implemented interventions

Parents play a foundational role in fostering their children's language and cognitive development, a perspective deeply rooted in the theories of Lev Vygotsky and Jerome Bruner [9, 61, 62]. They emphasised that learning occurs within social interactions, where caregivers act as mediators or "scaffolds" to support the child's development until they can independently master new skills. Similarly, Bruner [9] described the importance of joint attention and guided discovery, where parents structure interactions to align with the child's cognitive level, gradually enabling the child to assume greater control over their learning. Parents create a rich context for cognitive and linguistic development through shared activities such as play, conversation, and problem-solving tasks, emphasizing reciprocal engagement and collaboration.

A parent's responsiveness—the ability to notice, interpret, and appropriately respond to their child's cues—is associated with language and cognitive outcomes. Responsive parenting involves following the child's focus of attention, providing contingent feedback, and supporting joint engagement. This approach aligns with Vygotsky's concept of scaffolding, where sensitive parental input helps structure interactions and fosters self-regulation in children [49, 61]. Maternal responsiveness, in particular, has been shown to enhance linguistic development by enriching the language environment [4, 54–56]. For instance, mothers who follow their infant's focus of attention and provide contingent input, such as labelling objects and expanding the child's utterances, facilitate the earlier achievement of key language milestones, including first words and combinatorial speech [54]. Moreover, joint attention, where parent and child focus on the same object or event, is required for language acquisition, as it aligns adult speech with the child's interests, making the input both relevant and comprehensible ([57]; Moore & Dunham, 1995; [11]). Also, parental responsiveness has been found to influence cognitive development. For instance, parental scaffolding was found to promote the development of children's problem-solving skills (see [44] and [32] for a comprehensive review).

Building on the principles of responsiveness, studies on parent-implemented interventions aim to enhance language and cognitive outcomes by equipping parents with strategies to create meaningful learning experiences in natural contexts [44, 45, 54]. These strategies included responsiveness to object exploration, play, language and communication and focus on various behaviours such as: (1) Nonverbal and verbal turn-taking: Encouraging reciprocal exchanges that mimic conversational dynamics; (2) Joint attention: Responding to and extending the child's focus on objects or events; and (3) Linguistic modelling: Expanding the child's language by introducing more complex expressions while maintaining their intended meaning. Such approaches are believed to be particularly effective because they integrate learning opportunities into contexts where children are naturally motivated to engage, accelerating skill development. Moreover, they can address parenting differences that influence child development, often related to cultural and social background differences.

Social factors in parent-implemented intervention

Evidence indicates that children from disadvantaged communities and low-income households may experience poorer developmental and psychosocial outcomes, including differences in behavioural, cognitive, and language

development. They consistently exhibit patterns of underachievement that emerge early, remain stable over time, and lead to poor academic performance, as well as negative long-term academic and psychosocial difficulties [3, 36, 43].

Nearly half of the gap between children who are ready to succeed in school and those who are not could be explained by differences in parenting, often linked to social background [7]. Some argue that lower SES often limits access to essential resources, like nutrition, housing, and learning materials, needed for healthy development [3]. At the same time, economic hardship increases parental stress, which can negatively impact parenting behaviours and contribute to children's emotional and behavioural difficulties [37]. The Family Stress Model integrates these perspectives, showing that financial strain undermines both tangible and intangible parenting resources, ultimately affecting children's cognitive and socioemotional outcomes [16, 20, 42].

However, studies have shown that when parents actively engage with their children in a responsive and nurturing manner, it can help protect the child from the developmental risks associated with low-income environments (Chase-Lansdale et al., 1995; Duncan et al., 1994; Hustedt et al., 2002; [45]). Global evidence supports modest effects of parenting interventions on early development. In a systematic review and meta-analysis of 102 randomized controlled trials conducted across multiple countries, parenting interventions were associated with improvements in cognitive development (standardized mean difference [SMD] = 0.32, 95% CI 0.23–0.40) and language development (SMD = 0.28, 95% CI 0.18–0.37) during the first three years of life [34]. A separate meta-analysis of parent-implemented language interventions found an effect on expressive vocabulary (Hedges' g = 0.42, 95% CI 0.19–0.65), whereas the pooled effect on receptive vocabulary was smaller and not statistically significant (g = 0.18, 95% CI −0.11–0.48) [28]. For example, Miller et al. [45] examined the efficacy of video-based interaction intervention in improving early language and literacy skills in low-income Latinx and Black children aged 4 years. They found that increases in parental cognitive stimulation as a result of the intervention were associated with improvements in children's early language and literacy skills.

This highlights the importance of parent-implemented early developmental interventions that enhance parent–child interactions and parental talk quality, particularly in disadvantaged communities such as the Arab community in Israel, which is the focus of this research.

Early childhood in Arab society in Israel

The Arab population in Israel accounts for approximately 21% of the national population [14]. Population-based evidence indicates disparities in the utilization of child health services between Arab and Jewish populations in Israel. In a study of more than 250,000 children in the Haifa and Western Galilee districts, Arab children had lower utilization of several child health services, including physician visits, laboratory testing, and imaging procedures, compared with Jewish children [23]. These findings document population-level differences in the utilization of child health services.

Developmental surveillance data also indicate disparities within specific Arab subgroups. In a national study of more than one million children from birth to six years, developmental milestone attainment was examined across language, social, fine-motor, and gross-motor domains. After adjustment for sociodemographic characteristics, Bedouin origin was associated with a higher likelihood of failure to attain developmental milestones [24]. These findings highlight the importance of identifying populations that may benefit from additional developmental surveillance and support.

The importance of culturally responsive early-intervention services has also been highlighted among Arabic-speaking families in Israel. A study of an early-intervention programme delivered through Mother-Child Health Centres to at-risk families in East Jerusalem emphasized the relevance of family-centred care, effective parent–provider interaction, and sociocultural adaptation of services [26]. Together, this evidence supports the evaluation of culturally and linguistically adapted interventions delivered within accessible community health centres and tailored to the social and cultural contexts of Arab families in Israel.

The current study

This study evaluates a culturally adapted, home-based intervention designed to support language and cognitive development in Arab children in Israel aged 18–36 months. The intervention is informed by an ecological perspective [5, 6], considering the interplay between child characteristics, caregiver responsiveness, and the broader physical, social, and linguistic environment. The programme consists of eight weekly sessions delivered in the family's home and focuses on optimization of the home learning environment, child engagement, and caregiver responsiveness across play, daily routines, and shared story time.

The primary objectives are:

1. To determine whether the intervention improves overall developmental performance, measured by the Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale Full-Scale Developmental Quotient (CAT-CLAMS FSDQ), compared with the attention-control programme.
2. To determine whether the intervention improves expressive vocabulary, measured as the total number of words produced on the Arabic Short Form MacArthur-Bates Communicative Development Inventory (CDI), compared with the attention-control programme.

The secondary objectives are:

1. To determine whether the intervention improves CAT Developmental Quotient (DQ) compared with the attention-control programme.
2. To determine whether the intervention improves CLAMS Developmental Quotient (DQ) compared with the attention-control programme.
3. To determine whether the intervention improves receptive vocabulary, measured as the total number of words understood on the Arabic Short Form CDI, compared with the attention-control programme.
4. To determine whether the intervention reduces the likelihood of one or more predictive developmental concerns, measured using the Parents' Evaluation of Developmental Status (PEDS), compared with the attention-control programme.

Outcomes will be measured at baseline and 1 month after completion of the 8-week intervention.

Methods

Study design

This study is a two-arm, parallel-group, superiority randomized controlled trial with a 1:1 allocation ratio. Participants will be assigned to either the intervention arm, which receives the culturally adapted home-based developmental intervention, or the attention-control arm, which receives a home-based health-promotion programme. Outcomes will be measured at baseline and one month after completion of the 8-week intervention. Because of the nature of the intervention, participants and intervention providers cannot be blinded to allocation; outcome assessors will remain blinded to treatment allocation.

Study setting and recruiting centres

Participants will be recruited through approximately 50 Maternal and Child Health Clinics (Tipat Halav) serving Arab communities in the North, Centre, and South of Israel. Tipat Halav clinics provide routine preventive and developmental health care for infants and young children and are routinely accessed by families within their local communities. The participating clinics cover different geographic regions and communities, thereby allowing

recruitment from a broad range of Arab families. During routine developmental visits, clinic nurses will identify children who may meet the study eligibility criteria and provide their caregivers with information about the trial.

Participating sites are Maternal and Child Health Clinics serving the target Arab communities. Intervention providers are study team members who have completed study-specific intervention training and are fluent in the relevant local Arabic dialect. No additional site- or provider-level eligibility criteria are prespecified.

Participants

Participants will include children aged 18–36 months and their primary caregivers. Participants will be recruited through the participating Maternal and Child Health Clinics (Tipat Halav) described above during routine visits at 18 or 24 months. Inclusion criteria are: (1) children aged 18–36 months with no significant sensory impairments or severe medical conditions; (2) children who score in the low-average range (approximately −1 to −2 SD below the mean) on language or cognitive measures in the CAT-CLAMS assessment; (3) birth weight ≥ 1500 g; (4) caregiver willingness to participate in the eight-session intervention; and (5) absence of moderate or severe caregiver depressive symptoms, defined as a Patient Health Questionnaire-9 (PHQ-9) score < 10.

The PHQ-9 is a validated nine-item self-report measure of depressive symptom severity over the preceding 2 weeks [38]. Each item is rated from 0 ("not at all") to 3 ("nearly every day"), yielding a total score ranging from 0 to 27. Caregivers with scores ≥ 10 will be excluded from participation.

Baseline and demographic variables

Child age will be derived from date of birth and recorded in months; child sex will be recorded as male or female; gestational age at birth will be recorded in completed weeks; and birth weight, assessed during eligibility screening, will be recorded in grams. Chronic health conditions and developmental concerns will be recorded as yes/no variables, with free-text details where applicable. Daytime care arrangement will be categorized as home, day-care centre, nursery, caregiver, kindergarten, or other.

Caregiver age will be recorded in years. Relationship to the child will be categorized as mother, father, or other caregiver. Highest educational attainment will be categorized as less than high school, high school, technical/college diploma, bachelor's degree, or master's degree or higher. Employment status will be categorized as full-time employed, part-time employed, not currently employed, student, or other. Family locality will be recorded as free text, and geographic region will be categorized as North, Centre, or South. Number of children in the family will be recorded as a count, and the study child's birth order will be categorized as first, second, or third or later. Languages spoken at home will be recorded as reported by the caregiver.

Ages at developmental milestones, including first word, babbling, crawling, unsupported sitting, independent standing, independent walking, gesture use, imitation of sounds or words, response to name, and use of simple utensils, will be recorded in months.

Participant Reporting Outcomes Equity, Diversity and Inclusion (PRO EDI)

Table 1 summarises the expected participant characteristics across the six core PRO EDI domains: age; sex; gender; race, ethnicity and ancestry; socioeconomic status; and geographic location. The table describes the anticipated trial population and the rationale for inclusion or reporting of each characteristic.

Sample size

The sample size was calculated a priori using G*Power 3.1 [21] for a baseline-adjusted ANCOVA framework. Previous meta-analyses of parenting and parent-implemented language interventions reported standardized effects of 0.32 for cognitive development and 0.28 for language development [34], and effects of $g = 0.42$ for expressive

Table 1 Participant Reporting Outcomes Equity, Diversity and Inclusion (PRO EDI) characteristics of the anticipated trial population

Characteristic	Expected participant characteristics and rationale
Age	Child participants will be aged 18–36 months at enrolment. This age range was selected because the intervention targets early language, communication, and cognitive development during toddlerhood, a period in which caregiver-mediated support may be developmentally important. Primary caregivers will be adults who are able and willing to participate in the eight-session home-based intervention or attention-control programme
Sex	The trial will aim to include both male and female children who meet the eligibility criteria. No child will be excluded on the basis of sex. Child sex will be recorded and reported descriptively to allow assessment of the distribution of sex across trial arms and to support interpretation of intervention reach and generalisability
Gender	Gender identity is not expected to be directly applicable to child participants because of their young age. Participation will be open to mothers, fathers, and other primary caregivers who meet the eligibility criteria, and caregivers will not be excluded on the basis of gender
Race, ethnicity and ancestry	The trial is designed for Arab toddlers and their caregivers in Israel. Participants are therefore expected to be from Arabic-speaking Arab communities. This characteristic is central to the study because the intervention is culturally and linguistically adapted for this population, including delivery by team members fluent in local dialects and use of dialect-sensitive assessment and intervention materials. Relevant information on family background and language(s) spoken at home will be collected to describe the sample and support interpretation of the findings
Socioeconomic status	The trial focuses on a population facing socioeconomic and structural disadvantage, and aims to include families from a range of socioeconomic circumstances within Arab communities in Israel. Socioeconomic status is relevant because it may influence access to early childhood services, caregiver resources, home learning opportunities, and engagement with a home-based intervention. The demographic questionnaire will collect indicators such as caregiver education, employment status, number of children in the household, and related family background variables. These data will be used to describe the sample and assess comparability across trial arms
Geographic location	Participants will be recruited through community healthcare centres/ Maternal and Child Health clinics in Arab communities in Israel. Geographic location is relevant because Arab localities in Israel are often located in social and geographic peripheries, and location may influence access to services, recruitment, intervention delivery, and generalisability. Randomization will be stratified by region, defined as North, Centre, and South, to support balanced representation across trial arms

vocabulary and $g = 0.27$ for global expressive language [28]. On this basis, a standardized between-group effect of $d = 0.35$ was selected as the planning assumption. Assuming a correlation of $r = 0.50$ between baseline and follow-up scores, this corresponds to an ANCOVA-adjusted effect of $d = 0.404$ and Cohen's $f = 0.202$. With 80% power, 1:1 allocation, and a conservative $\alpha = 0.025$, corresponding to the most stringent threshold under the Holm procedure for two primary outcomes, the required sample size was 236 participants. The planned recruitment target is therefore 240 participants, with 120 participants per group. No clustering adjustment was applied because randomization is at the individual-child level, only one child per family is enrolled, and participating clinics serve as recruitment sites rather than randomization clusters.

Randomization

After obtaining informed consent and completing baseline assessments, participants will be randomly assigned to either the intervention or control group in a 1:1 allocation ratio. Randomization will be stratified by age group (18–24 months vs. 24–36 months) and region (North, Centre, South) to ensure balanced representation across these key variables.

Randomization will be conducted using a secure, electronic randomization system, managed by an independent researcher who is not involved in participant recruitment, intervention delivery, or outcome assessment. Allocation will be concealed until the point of assignment, ensuring that enrolment staff remain blinded to upcoming group allocations during recruitment.

Given the nature of the intervention, blinding of participants is not feasible; however, outcome assessors will remain blinded to group allocation to minimize assessment bias.

Intervention

The intervention comprised eight sessions designed to enhance language, communication, and problem-solving skills in children aged 18–36 months. It integrated three foundational aspects: adjustments to the physical environment (Session 1), promoting the child's characteristics and involvement (Session 2), and enhancing the caregiver's responsiveness (Sessions 3–8). The intervention targeted three key contexts—play, daily routines, and story time—beginning with principles introduced in the play context and later generalized to daily routines and shared story time interactions.

1. Physical Environment (Session 1): Parents were guided to create safe, accessible spaces that encourage exploration, independent play, and learning. Strategies included arranging age-appropriate toys, ensuring accessibility, and minimizing distractions to enhance communication, support learning, and foster independence and problem-solving.
2. Child Characteristics and Involvement in Play (Session 2): Parents learned about the role of play types (e.g. sensory, symbolic, construction) in child development and how to foster engagement by following the child's interests and cues.
3. Parent Responsiveness During Object Exploration (Session 3): The training focused on observing the child's exploratory behaviours (e.g. looking, holding, and manipulating objects) and responding with verbal labels, expansions, and encouragement to deepen engagement.
4. Parent Responsiveness During Play (Session 4): Training focused on scaffolding interactions through strategies such as imitation, descriptive commentary, questions, affirmation, and prompts to enhance communication, sustained engagement, and creative problem-solving during play.
5. Nonverbal Communication (Session 5): Parents were trained to respond and establish shared focus (joint attention) to allow learning and enrich interactions.
6. Encouraging Productions (Session 6): This session focused on modelling, expanding, and validating the child's verbal attempts, tailoring input to the child's developmental level to support language use and learning.
7. Application in Daily Routines (Session 7): Parents were trained to integrate the learned principles into daily routines (e.g. meals, bath time, dressing), using these natural interactions to support communication, learning, and problem-solving in familiar contexts.
8. Application in Storytime (Session 8): Parents were trained to integrate responsiveness principles during shared book reading, including dialogic reading techniques such as asking questions, expanding verbalizations, and connecting story content to the child's world.

The intervention was grounded in responsive behaviours and contextual interactions, as observed and analyzed by Tamis-LeMonda [54, 55]. It provided explicit guidance to parents on when and how to respond across various contexts, including object exploration, play, and both verbal and nonverbal communication. Responsive strategies included imitation, affirmation, description, labelling, questioning, and a range of prompts (e.g. verbal, physical, and modelled) designed to support engagement, promote language development and problem-solving skills, and encourage independent thinking.

The intervention emphasized caregiver responsiveness as the central mechanism of support, starting with the playtime context and extending to generalization in daily routines and shared story time. Each session combined explanations, demonstrations, and hands-on practice, with individualized feedback to ensure effective implementation and promote developmental outcomes.

Control group

Families in the control group will receive a structured, general health-promotion intervention focusing on healthy lifestyle practices for young children. This intervention includes eight weekly sessions delivered in a similar

format and schedule as the experimental group. The sessions cover practical topics related to child health and development, such as:

- Transitioning from bottle-feeding to cup drinking
- Diaper changing routines and toilet training readiness
- Promoting healthy sleep habits and routines
- Nutritional guidance for toddlers includes safe food preparation and encouraging independent eating.
- Understanding childhood vaccinations and their role in child health

Each session combines parental guidance with practical strategies for implementing at home. The control group intervention is designed to offer supportive engagement without directly targeting language or cognitive stimulation, thereby serving as an attention-control condition that allows for comparison of outcomes without introducing the specific linguistic and cognitive elements of the experimental intervention.

Outcome measures

Primary outcomes

CAT-CLAMS Full-Scale Developmental Quotient (FSDQ) Overall developmental performance will be assessed using the Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale (CAT-CLAMS; [30]), a standardized developmental assessment for infants and young children. The CAT component assesses visual-motor problem-solving and adaptive cognitive abilities, whereas the CLAMS component assesses language development. For each component, the Developmental Quotient (DQ) is calculated as the developmental age-equivalent divided by chronological age and multiplied by 100. A DQ of 100 therefore represents developmental performance corresponding to chronological age. The Full-Scale Developmental Quotient (FSDQ) is calculated as the mean of the CAT DQ and CLAMS DQ, with higher scores indicating more advanced developmental performance relative to chronological age. The FSDQ will constitute the primary developmental outcome. Published validation evidence has demonstrated significant correlations between CAT-CLAMS scores and the Bayley Scales of Infant Development; Hoon et al. [30] reported sensitivity of 88% and specificity of 67% for identifying substantial cognitive delay.

Arabic Communicative Development Inventories (CDI)—words only The Arabic Short Form MacArthur-Bates Communicative Development Inventory (CDI)—Words Only [1] will be used to assess receptive and expressive vocabulary. The instrument consists of 100 words, for which caregivers report whether each word is understood and/or produced by the child. The Arabic short form was developed across 17 Arabic dialects, including Palestinian Arabic. Because participants are recruited from three regions of Israel with local dialectal variation, the word list was adapted to ensure cultural and linguistic relevance across the participating communities. The primary language outcome will be expressive vocabulary, defined as the total number of words produced (range 0–100), with higher scores indicating a larger expressive vocabulary. Receptive vocabulary, defined as the total number of words understood (range 0–100), will be analyzed as a secondary outcome. The 100-word short form demonstrated test–retest reliability in Egyptian Arabic. Concurrent validity of the full Arabic CDI Words Only was supported by correlations with the Arabic Language Test, with the authors indicating that this validity could reasonably extend to the short form [1].

Secondary outcomes

Parents' Evaluation of Developmental Status (PEDS) Secondary outcomes will include the CAT DQ, CLAMS DQ, CDI receptive vocabulary, and parental developmental concerns measured using the Parents' Evaluation of Developmental Status (PEDS). CAT and CLAMS DQs will be analyzed separately to characterize cognitive/adaptive and language development, respectively. CDI receptive vocabulary will be defined as the total number of words understood, ranging from 0 to 100, with higher scores indicating a larger receptive vocabulary. PEDS responses of "Yes" or "A little" will be coded as endorsed concerns and interpreted according to the standard age-specific scoring procedure. The PEDS secondary outcome will be the presence of one or more predictive developmental concerns. The PEDS has published evidence supporting its validity and screening accuracy [25].

Procedure

Participants will be recruited through maternal and child health clinics. Nurses at these centres will be trained to identify children aged 18 or 24 months who may be at risk for developmental delays during routine developmental check-ups. Nurses will provide a brief explanation of the study to eligible families and distribute informational flyers containing a QR code. Interested families can scan the code to submit their names and contact details. A follow-up phone interview will be conducted with each family to provide comprehensive information about the study. Upon obtaining informed consent, families will be randomly assigned to either the intervention or control group. A trained team member, fluent in the family's local dialect and based in the same region, will then contact the family to deliver the home-based intervention, following the procedures specified in the intervention protocol.

Assessments will be conducted at two time points: baseline, before the start of the intervention, and 1 month after completion of the intervention. At each time point, an independent assessor who is not involved in intervention delivery will evaluate the child's language and cognitive development using the CAT/CLAMS. Parents will also complete the Arabic version of the Communicative Development Inventory (CDI) to measure the child's expressive and receptive vocabulary and the Parents' Evaluation of Developmental Status (PEDS) to report concerns regarding their child's developmental progress.

At baseline, caregivers will additionally complete the Patient Health Questionnaire-9 (PHQ-9) [38] and a structured demographic questionnaire. The demographic questionnaire will collect child characteristics, including birth history, gestational age, chronic health conditions, developmental concerns, current care arrangements, and age at key developmental milestones such as first words, crawling, and walking. Caregiver and household characteristics will include caregiver age, relationship to the child, education level, employment status, number of children in the household, and language(s) spoken at home. These data will be used to describe the study sample and the distribution of baseline characteristics across trial groups (Fig. 1 and Table 2 present the full study procedure and assessment timeline).

Plans for communication of trial results

The trial results will be disseminated to relevant audiences, including healthcare professionals, policymakers, and the broader scientific community, through peer-reviewed publications, conference presentations, and reports in publicly accessible clinical trial databases. There are no publication restrictions on the findings. In addition, families who express interest in receiving the results of their child's assessments or the overall study findings will be provided with this information in a clear and culturally appropriate format. This may include a brief summary report or a phone call from a trained team member.

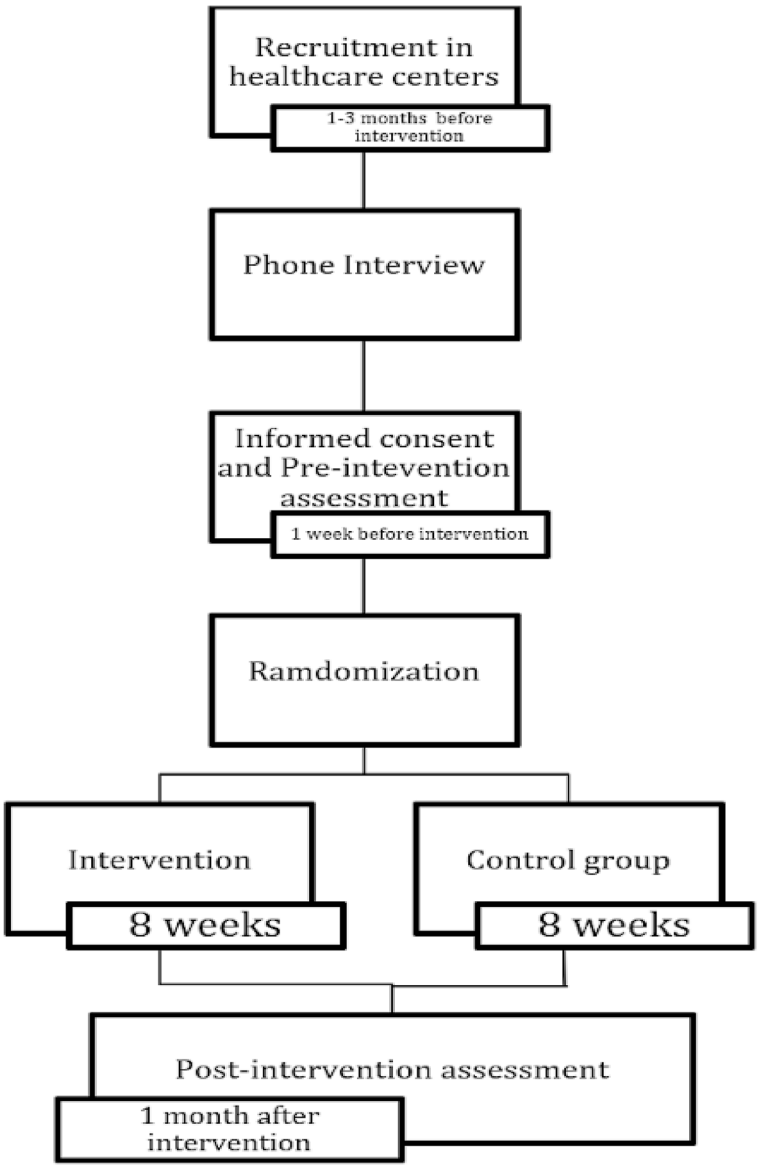

Fig. 1 Overview of the study procedure from recruitment to post-intervention assessment

Training of the intervention team

All members of the intervention team, including those responsible for delivering the intervention and conducting assessments, will undergo a comprehensive, multi-component training programme to ensure consistency, fidelity, and ethical conduct across all study activities. The training will cover the following key domains:

1. Intervention Protocol

   Team members will receive in-depth instruction on the content, goals, and delivery procedures of the intervention. Training will include demonstrations, role-playing, and practice sessions to promote adherence to the intervention protocol and culturally responsive engagement with families.
2. Assessment Procedures

   Research assistants responsible for outcome assessment are speech and language therapists with prior experience in developmental and language assessment. They will receive study-specific training in the standardized administration and scoring of the CAT/CLAMS, the Communicative Development Inventory (CDI),

https://doi.org/10.1186/s13063-026-10034-9

Table 2 Participant timeline (schedule of enrolment, interventions, and assessments)

	TIMEPOINT	Screening ($-t_1$) maternal and child health clinics visit	Baseline/randomization (T_0) Home visit	Intervention period weeks 1–8 (T_1–T_8)	Post-intervention follow-up (T_9) 1 month after last session
ENROLMENT					
Eligibility screen	**(maternal and child health clinics nurse review, preliminary developmental concern)**	**X**			
Informed consent			**X**		
Demographic questionnaire	**Child and family characteristics**		**X**		
PHQ-9 (caregiver)	**Depressive symptoms for eligibility**		**X**		
Randomization	**Stratified randomization (age group, region)**		**X**		
INTERVENTION /COMPARATOR					
Home-based developmental intervention (experimental arm)	**8 weekly home visits focusing on environment, child engagement, and parental responsiveness**			**X**	
Home-based health-promotion program (control arm)	**8 weekly home visits on general child health topics**			**X**	
ASSESSMENTS					
CAT-CLAMS	**Child language and cognitive development**		**X**		**X**
Arabic CDI (Words Only)	**Parent-reported receptive and expressive vocabulary**		**X**		**X**
PEDS	**Parents' Evaluation of Developmental Status**		**X**		**X**

Abbreviations: CAT-CLAMS Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale, *CDI* Communicative Development Inventory, *PEDS* Parents' Evaluation of Developmental Status, *PHQ-9* Patient Health Questionnaire-9

and the Parents' Evaluation of Developmental Status (PEDS), including supervised practice and review of scoring procedures. Outcome assessors will be independent of intervention delivery and blinded to treatment allocation to minimize assessment bias.

3. Confidentiality and Ethical Conduct

   Team members will be trained in ethical principles of research, including informed consent procedures, protection of participant confidentiality, and professional conduct during interactions with families. They will also be trained to recognize and respond appropriately to any concerns related to child protection or safeguarding.

4. Data Collection and Management

   The team will be instructed on the accurate and secure collection of both quantitative and qualitative data. This includes maintaining fidelity checklists, tracking session attendance, and entering data into secure

systems. Emphasis will be placed on data anonymization, secure storage, and adherence to data protection regulations.

5. Cultural and Linguistic Competency
   Given the home-based and family-centred nature of the study, training will include strategies for culturally sensitive communication and engagement. Team members will be fluent in local dialects and trained to work effectively with diverse families.
6. Personal Safety and Risk Management
   To ensure the safety of team members during home visits, training will include risk assessment procedures, personal safety guidelines, and protocols for communicating with the study co-ordinator in the event of emergencies or unexpected events.

Ongoing supervision, refresher sessions, and fidelity monitoring will be implemented throughout the study to support continuous learning and ensure the high-quality implementation and collection of data.

Data management

All study data will be managed in compliance with the author's institution and university ethical guidelines to ensure participant confidentiality, data accuracy, and secure storage. Data will be collected using standardized instruments and forms. Interventionists/assessors will be trained in all data management procedures, including secure data entry, quality control, and confidentiality protocols.

Each family will be assigned a unique study ID to anonymize their data. Identifiable information (e.g. names, contact details) will be stored separately in an encrypted and password-protected file, accessible only to the main researcher. Assessment and intervention data will be entered into a secure, web-based REDCap database hosted on the authors' university servers with daily automated backups.

REDCap will be used for electronic data entry, validation checks, and audit trails. Built-in data validation rules will minimize entry errors, and double data entry or periodic cross-checks will be performed to ensure data accuracy. Paper-based forms, where applicable, will be stored in locked cabinets and digitized promptly. Only the principal investigator and designated study statisticians will have access to the final de-identified dataset. Data will be shared externally only in anonymized form and only upon reasonable request, subject to ethical approvals and institutional policies.

Quantitative data (e.g. CAT/CLAMS scores, CDI, PEDS, PHQ-9) will be entered directly into REDCap, while any qualitative notes or fidelity checklists will be de-identified and stored in encrypted files linked to the study ID. Access to REDCap will be role-restricted to authorized team members based on their responsibilities.

Data will be retained for 7 years, consistent with the author's university policy and shared in de-identified form only, in accordance with ethical approvals and participant consent. Regular audits and data quality checks will be conducted to maintain the integrity of the dataset and support robust analysis and reporting.

The study-specific demographic questionnaire is provided in the Supplementary Materials. Standardized assessment instruments are cited in the Outcome Measures section and are not reproduced.

Harms

This trial involves a low-risk, behavioural intervention. No adverse physical events are expected. Minor emotional discomfort during home visits will be monitored at each session, and any safeguarding concerns will be reported following standard clinic procedures.

Trial Steering Committee

A Trial Steering Committee will oversee the conduct and progress of the trial. The committee will comprise the principal investigator and two independent members: a statistician/methodologist and a child-development specialist. The independent members will not be involved in participant recruitment, intervention delivery, outcome assessment, or day-to-day trial management. The committee will review recruitment progress, protocol adherence, participant safety, major protocol deviations, and overall study conduct at regular intervals.

A separate Data Monitoring Committee is not planned because this study evaluates a low-risk behavioural intervention and no interim efficacy or futility analyses are planned. Trial conduct and participant safety will instead be reviewed by the Trial Steering Committee. No formal statistical stopping boundaries are specified. Unexpected safety or ethical concerns arising during the trial will be reviewed by the Trial Steering Committee and managed in accordance with the approved study procedures.

Auditing

No independent auditing is planned. The Helsinki Committee at Hillel-Yaffe Medical Centre may review study conduct according to institutional policy.

Protocol amendments

Any protocol changes requiring ethics approval will be submitted to the Helsinki Committee and updated in ClinicalTrials.gov. Relevant changes will be communicated to the study team and, when necessary, to participating families.

Ancillary and post-trial care

No additional post-trial care is planned. Families may continue accessing routine health services, and developmental concerns identified during assessments will be referred through standard care pathways. No biological specimens will be collected, and no ancillary studies requiring additional consent are planned; therefore, no additional consent provisions are required.

Statistical analysis

Baseline characteristics will be summarized by randomized group. Approximately normally distributed continuous variables will be presented as means and standard deviations, skewed continuous variables as medians and interquartile ranges, and categorical variables as frequencies and percentages. No significance testing will be performed to compare baseline characteristics between randomized groups.

Primary analyses will follow the *intention-to-treat principle*, with all randomized participants analyzed according to their assigned treatment group. The two primary outcomes will be analyzed separately using baseline-adjusted linear regression models (ANCOVA).

For the *CAT-CLAMS Full-Scale Developmental Quotient (FSDQ)*, the dependent variable will be the post-intervention FSDQ, with treatment group as the main independent variable and baseline FSDQ included as a covariate. For *CDI expressive vocabulary*, the dependent variable will be the post-intervention number of words produced, with treatment group as the main independent variable and baseline expressive-vocabulary score included as a covariate. Both models will additionally adjust for the randomization stratification variables, namely age-group stratum and geographic region. Treatment effects will be reported as adjusted mean differences with 95% confidence intervals and corresponding two-sided p-values.

Because two primary outcomes are prespecified, the family-wise Type I error rate will be controlled at 0.05 using the *Holm step-down procedure*. Holm-adjusted *p*-values will be used for confirmatory inference for the two primary outcomes.

Secondary continuous outcomes, including the *CAT Developmental Quotient (DQ)*, *CLAMS DQ*, and *CDI receptive-vocabulary score*, will be analyzed using separate baseline-adjusted linear regression models, adjusting for the corresponding baseline outcome, treatment group, age-group stratum, and geographic region. The *PEDS secondary outcome*, defined as the presence of one or more predictive developmental concerns, will be analyzed using logistic regression, where data permit, adjusting for baseline PEDS status and the randomization stratification variables. Adjusted odds ratios with 95% confidence intervals will be reported. Secondary analyses will be considered supportive, and no formal multiplicity adjustment will be applied across secondary outcomes.

Model assumptions for linear regression, including linearity, normality and homoscedasticity of residuals, will be evaluated using graphical and residual diagnostics. The extent and reasons for missing data will be summarized by randomized group. If missing outcome data are substantial, multiple imputation under a missing-at-random assumption will be used, with sensitivity analyses conducted to assess the robustness of findings to the handling of missing data.

Statistical analyses will be performed using R statistical software [47]. Linear and logistic regression models and Holm multiplicity adjustment will be implemented using the base R stats package. If multiple imputation is required, it will be performed using the mice package [58]. The R version and package versions used will be reported in the final trial report.

A detailed *Statistical Analysis Plan (SAP)* will be finalized before database lock and before examination of treatment-group outcome differences. The SAP will prespecify analysis populations, model specifications, handling of missing data, multiplicity procedures, and sensitivity analyses. Any deviations from the prespecified analysis plan will be documented and justified. The SAP will follow published recommendations for prospective reporting of statistical analysis plans for randomized controlled trials [29].

The final trial report will be prepared in accordance with the *CONSORT 2025* reporting guideline for randomized trials.

Discussion

This study protocol outlines a culturally adapted, home-based intervention designed to enhance early language and cognitive development among Arab toddlers in Israel. Targeting a disadvantaged population facing both structural and cultural barriers, the intervention integrates theory-driven strategies with community-based delivery to improve accessibility, cultural relevance, and developmental outcomes.

Parenting interventions are known to yield benefits for low socioeconomic status (SES) families in promoting cognitive, language, and motor development [34]. However, underutilization of services in these communities is common due to limited awareness, stigma, transportation challenges, and lack of coverage [51]. The current study aims to overcome these barriers by providing a culturally relevant, home-based intervention that employs a proactive outreach model. Recruiting families through nurses in maternal and child health clinics—trusted healthcare providers—has proven effective for engaging low-SES minority families [2], while home delivery reduces logistical burdens and supports learning in familiar, natural environments.

Global calls for culturally appropriate intervention and assessment in speech and language research [60] are addressed through this study's use of dialect-sensitive tools, mother-tongue-speaking interventionists, and community-based recruitment. These elements also help mitigate known cultural biases in child development research [12].

Practically, delivering the programme in families' homes introduces challenges, including environmental distractions, safety concerns for staff, and scheduling variability. These are managed through flexible protocols, training, and supervision. Sustaining caregiver engagement over eight weeks may also be difficult, given families' time

constraints and daily stressors; however, personalized feedback and culturally resonant messaging are expected to support retention.

While the intervention focuses on caregiver responsiveness—a factor associated with child language and cognitive growth [39]—some limitations remain. Individual characteristics such as child age, birth order, and parental education may influence outcomes. Additionally, the intervention does not address parental mental health, though maternal depression is known to affect both child development and intervention success [46]. Families with moderate-to-severe depressive symptoms are excluded, which improves internal validity but limits generalizability.

Another limitation is the short follow-up period (1 month), which restricts the ability to draw conclusions about the long-term impact. Future studies should incorporate longer-term assessments to examine sustained gains. Despite these challenges, this study represents a meaningful step toward developing scalable, culturally grounded interventions for disadvantaged populations and advancing equity in early child development.

Trial status

This protocol is Version 1.0, dated October 2025. Recruitment and data collection commenced on 15 January 2026 and are currently ongoing. As of September 2026, 76 families have been recruited**.** Recruitment is expected to be completed by December 2027, with study completion anticipated by March 2028.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1186/s13063-026-10034-9.

Acknowledgements The authors thank the participating maternal and child health clinics staff for their support in recruitment and community engagement. The authors also acknowledge the contributions of the intervention team and assessors who will deliver the program and carry out study procedures.

Dissemination plans Study findings will be disseminated through peer-reviewed publications, conference presentations, and community reports. Families who indicate interest will receive a brief summary of their child's assessment results and of the overall study findings in a culturally appropriate format.

Authors' contributions Niveen Omar: Conceptualization; Methodology; Project administration; Writing – original draft. Michael Davidovitch: Conceptualization; Writing – review & editing. Hazar Zahalka: Methodology; Investigation; Writing – review & editing. Muhammad Mahajnah: Conceptualization; Writing – review & editing. Ortal Slobodin: Funding acquisition; Supervision; Methodology; Writing – review & editing. Niveen Omar and Michael Davidovitch contributed equally to this work. Muhammad Mahajnah and Ortal Slobodin contributed equally as senior authors.

Funding This study is funded by the Israeli Ministry of Health. The funder has no role in the study design; data collection, management, analysis, or interpretation; writing of the manuscript; or the decision to submit the manuscript for publication.

Data availability As this is a study protocol, no datasets have yet been generated. Following study completion, anonymized data will be made available from the corresponding author on reasonable request, in accordance with ethical approvals and institutional guidelines.

Declarations

Ethics approval and consent to participate Ethical approval for this study was granted by the Helsinki Committee, Hillel-Yaffe Medical Centre, Israel (Approval No. 0159-22-HYMC, approved 13 July 2023). Written informed consent is obtained from all participating caregivers prior to enrolment. Participation is voluntary, and caregivers may withdraw at any time without any consequences for their child's care.

Consent for publication Not applicable. This protocol does not include identifiable personal data from participants.

Competing interests The authors declare no competing interests.

Open Access This article is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License, which permits any non-commercial use, sharing, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if you modified the licensed material. You do not have permission under this licence to share adapted material derived from this article or parts of it. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by-nc-nd/4.0/.

References

1. Abdelwahab AGS, Forbes S, Cattani A, Goslin J, Floccia C. An adaptation of the MacArthur-Bates CDI in 17 Arabic dialects for children aged 8 to 30 months. Lang Learn Dev. 2021;17(4):425–46. https://doi.org/10.1080/15475441.2021.1916502.
2. Aliyas Z, Collins PA, Chrun-Tremblay S, Bayram T, Frohlich KL. "Hard-to-reach" or hardly reaching? Critical reflections on engaging diverse residents from low socio-economic status neighborhoods in public health research. Int J Public Health. 2023;67:1605296. https://doi.org/10.3389/ijph.2022.1605296.
3. Bradley RH, Corwyn RF. Socioeconomic status and child development. Annu Rev Psychol. 2002;53:371–99.
4. Brady N, Warren SF, Sterling A. Interventions aimed at improving child language by improving maternal responsivity. Int Rev Res Ment Retard. 2009;37:333–57. https://doi.org/10.1016/S0074-7750(09)37010-X.
5. Bronfenbrenner U. The ecology of human development: experiments by nature and design. Harvard University Press; 1979. https://doi.org/10.2307/2065974.
6. Bronfenbrenner U. Developmental ecology through space and time: a future perspective. In: Moen P, Elder GH Jr., Lüscher K, Eds. Examining lives in context. 1995. p. 619–647. https://doi.org/10.1037/10176-018.
7. Brooks-Gunn J, Markman LB. The contribution of parenting to ethnic and racial gaps in school readiness. Future Child. 2005;15(1):139–68.
8. Brown MI, Westerveld MF, Trembath D, Gillon GT. Promoting language and social communication development in babies through an early storybook reading intervention. Int J Speech Lang Pathol. 2018;20(3):337–49.
9. Bruner JS. Child's talk: learning to use language. New York, NY: W. W. Norton & Company; 1983.
10. Buschmann A, Jooss B, Rupp A, Feldhusen F, Pietz J, Philippi H. Parent-based language intervention for 2-year-old children with specific expressive language delay: a randomised controlled trial. Arch Dis Child. 2009;94(2):110–6.
11. Capelli E, Grumi S, Vercellino L, Provenzi L. Joint attention and exogenous attention allocation during mother-infant interaction at 12 months associate with 24-month vocabulary composition. Front Psychol. 2025;16:1516587.
12. Carter JA, Lees JA, Murira GM, Gona J, Neville BGR, Newton CRJC. Issues in the development of cross-cultural assessments of speech and language for children. Int J Lang Commun Disord. 2005;40(4):385–401.
13. Catts HW, Fey ME, Tomblin JB, Zhang X. A longitudinal investigation of reading outcomes in children with language impairments. J Speech Lang Hear Res. 2002;45(6):1142–57.
14. Central Bureau of Statistics. Population of Israel on the eve of 2021. Israel Central Bureau of Statistics. 2020. https://www.cbs.gov.il.
15. Colmar S. A book reading intervention with mothers of children with language difficulties. Australas J Early Child. 2011;36(2):104–12.
16. Conger RD, Conger KJ, Elder GH Jr., Lorenz FO, Simons RL, Whitbeck LB. A family process model of economic hardship and adjustment of early adolescent boys. Child Dev. 1992;63(3):526–41. https://doi.org/10.2307/1131344.
17. Conti-Ramsden G, Mok PLH, Pickles A, Durkin K. Adolescents with a history of specific language impairment (SLI): strengths and difficulties in social, emotional, and behavioral functioning. Res Dev Disabil. 2013;34(11):4161–9. https://doi.org/10.1016/j.ridd.2013.08.043.
18. Dickinson DK, Golinkoff RM, Hirsh-Pasek K. Speaking out for language: why language is central to reading development. Educ Res. 2010;39(4):305–10.
19. Dusek G, Ayhan AB. A study on problem-solving skills of children from broken-family and full-parents families attending regional primary boarding school. Proc Soc Behav Sci. 2014;152:137–142. https://doi.org/10.1016/j.sbspro.2014.09.170.
20. Elder GH Jr., Conger RD, Foster EM, Ardelt M. Families under economic pressure. J Fam Issues. 1992;13(1):5–37. https://doi.org/10.1177/019251392013001002.
21. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. Behav Res Methods. 2009;41:1149–60.

22. Forrest CL, Gibson JL, Redmond SM. Concurrent and longitudinal associations of developmental language disorder with peer victimization in adolescence: evidence from a co-twin study. J Child Psychol Psychiatry. 2024;65(3):438–47.
23. Ghanayem D, Kasem Ali Sliman R, Schwartz N, Cohen H, Shehadeh S, Hamad Saied M, et al. Healthcare utilization is increased in children living in urban areas, with ethnicity-related disparities: a big data analysis study. Eur J Pediatr. 2024;183(4):1585–94.
24. Girshovitz I, Amit G, Goldshtein I, Zimmerman DR, Baruch R, Akiva P, et al. Increased rates of unattained developmental milestones among Israeli children between 2016 and 2020: a national report. Isr J Health Policy Res. 2023;12:38. https://doi.org/10.1186/s13584-023-00586-5.
25. Glascoe FP. The value of "Parents' Evaluations of Developmental Status" in detecting and addressing children's developmental and behavioral problems. Diagnostique. 1998;23(4):185–203.
26. Golos A, Tartir R, Abo-Halka MF, Tekuzener E. Quality of early intervention program services in Mother-Child Health Care Centers for at-risk population: multiple perspectives. Phys Occup Ther Pediatr. 2025;45(4):541–57. https://doi.org/10.1080/01942638.2025.2473934.
27. Hall JR, Francis A, Little TD. How are we measuring resilience in children? A systematic review of measurement tools and developmental correlates. J Appl Dev Psychol. 2024;87:101617.
28. Heidlage JK, Cunningham JE, Kaiser AP, Trivette CM, Barton EE, Frey JR, et al. The effects of parent-implemented language interventions on child linguistic outcomes: a meta-analysis. Early Child Res Q. 2020;50:6–23.
29. Hemming K, Kearney A, Gamble C, Li T, Jüni P, Chan A-W, et al. Prospective reporting of statistical analysis plans for randomised controlled trials. Trials. 2020;21:898. https://doi.org/10.1186/s13063-020-04828-8.
30. Hoon AH Jr., Pulsifer MB, Gopalan R, Palmer FB, Capute AJ. Clinical Adaptive Test/Clinical Linguistic Auditory Milestone Scale in early cognitive assessment. J Pediatr. 1993;123(1):S1–8. https://doi.org/10.1016/S0022-3476(05)81587-2.
31. Hopewell S, Chan A-W, Collins GS, et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. BMJ. 2025;389:e081123. https://doi.org/10.1136/bmj-2024-081123.
32. Ismail N, Juhari R, Madon Z, Arshat Z, Daud MN, Azam ND. Parental scaffolding and problem-solving skills in early childhood: a systematic literature review. Libr Prog Int. 2024;44(3):6072–6081. https://doi.org/10.48165/bapas.2024.44.2.1.
33. Izett E, Rooney R, Prescott SL, De Palma M, McDevitt M. Prevention of mental health difficulties for children aged 0–3 years: a review. Front Psychol. 2021;11:500361. https://doi.org/10.3389/fpsyg.2020.500361.
34. Jeong J, Franchett EE, Ramos de Oliveira CV, Rehmani K, Yousafzai AK. Parenting interventions to promote early child development in the first three years of life: a global systematic review and meta-analysis. PLoS Med. 2021;18(5):e1003602. https://doi.org/10.1371/journal.pmed.1003602.
35. Justice LM, Bowles RP, Pence Turnbull KL, Skibbe LE. School readiness among children with varying histories of language difficulties. Dev Psychol. 2009;45(2):460–76.
36. Keating DP, Hertzman C. Early social environments and developmental gradients in health and cognition. In: Keating DP, Hertzman C, editors. Developmental health and the wealth of nations: social, biological, and educational dynamics. New York, NY: Guilford Press; 1999. p. 3–17.
37. Koutra K, Mouatsou C, Margetaki K, Mavroeides G, Kampouri M, Chatzi L. From early stress to adolescent struggles: how maternal parenting stress shapes the trajectories of internalizing, externalizing, and ADHD symptoms. Pediatr Rep. 2025;17(4):Article 76. https://doi.org/10.3390/pediatric17040076.
38. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16:606–13.
39. Leffel K, Suskind D. Parent-directed approaches to enrich the early language environments of children living in poverty. Semin Speech Lang. 2013;34(4):267–78. https://doi.org/10.1055/s-0033-1353443.
40. Livingston V. Resilience, adversity, and social supports in childhood and adolescence. Child Youth Serv Rev. 2025;5(3):108.
41. Markkula A, Pyhälä-Neuvonen R, Stolt S. Interventions and their efficacy in supporting language development among preterm children aged 0–3 years: a systematic review. Early Hum Dev. 2024;195:106057. https://doi.org/10.1016/j.earlhumdev.2024.106057.
42. McLoyd VC, Shanahan MJ. Poverty, parenting, and child development. Am Psychol. 1993;48(12):1273–8. https://doi.org/10.1037/0003-066X.48.12.1273.
43. Mendelson T, Kubzansky LD, Datta GD, Buka SL. Neighborhood income and individual socioeconomic position influence risk for depressive symptoms in adolescents: results from the Project on Human Development in Chicago Neighborhoods. Soc Sci Med. 2008;66(6):1090–102.
44. Mermelshtine R. Parent–child learning interactions: a review of the literature on scaffolding. Br J Educ Psychol. 2017;87(2):241–54. https://doi.org/10.1111/bjep.12147.
45. Miller EB, Canfield CF, Roby E, Wippick H, Shaw DS, Mendelsohn AL, et al. Enhancing early language and literacy skills for racial/ethnic minority children with low incomes through a randomized clinical trial: the mediating role of cognitively stimulating parent–child interactions. Child Dev. 2024;95(4):1172–85. https://doi.org/10.1111/cdev.14064.

46. Murray L, Cooper P, Arteche A, Stein A, Tomlinson M. Randomized controlled trial of a home-visiting intervention on infant cognitive development in peri-urban South Africa. Dev Med Child Neurol. 2016;58(3):270–6. https://doi.org/10.1111/dmcn.12876.
47. R Core Team. R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. 2025.
48. Rescorla LA. Age 17 language and reading outcomes in late-talking toddlers: support for a dimensional perspective on language delay. J Speech Lang Hear Res. 2009;52(1):16–30. https://doi.org/10.1044/1092-4388(2008/07-0171).
49. Rogoff B. Apprenticeship in thinking: cognitive development in social context. New York, NY: Oxford University Press; 1990.
50. Skibbe LE, Grimm KJ, Stanton-Chapman TL, Justice LM, Pence KL, Bowles RP. Reading trajectories of children with language difficulties from preschool through fifth grade. Read Writ. 2008;21(1–2):95–123.
51. Slobodin O, Masalha R. Challenges in ADHD care for ethnic minority children: a review of the current literature. Transcult Psychiatry. 2020;57(3):468–83. https://doi.org/10.1177/1363461520902885.
52. Solby H, Radovanovic M, Sommerville JA. A new look at infant problem-solving: using DeepLabCut to investigate exploratory problem-solving approaches. Front Psychol. 2021;12:705108. https://doi.org/10.3389/fpsyg.2021.705108.
53. Suskind DL, Leffel KR, Graf E, Hernandez MW, Gunderson EA, Sapolich SG, et al. A parent-directed language intervention for children of low socioeconomic status: a randomized controlled pilot study. J Child Lang. 2016;43(2):366–406. https://doi.org/10.1017/S0305000915000033.
54. Tamis-LeMonda CS, Bornstein MH, Baumwell L. Maternal responsiveness and children's achievement of language milestones. Child Dev. 2001;72(3):748–67.
55. Tamis-LeMonda CS, Bornstein MH. Maternal responsiveness and early language acquisition. In: Kail RV, editor. Advances in child development and behavior, vol. Vol. 29. Academic Press; 2002. p. 89–127. https://doi.org/10.1016/S0065-2407(02)80052-0.
56. Tamis-LeMonda CS, Kuchirko Y, Song L. Why is infant language learning facilitated by parental responsiveness? Curr Dir Psychol Sci. 2014;23(2):121–6.
57. Tomasello M, Farrar MJ. Joint attention and early language. Child Dev. 1986;57(6):1454–63. https://doi.org/10.2307/1130423.
58. van Buuren S, Groothuis-Oudshoorn K. Mice: multivariate imputation by chained equations in R. J Stat Softw. 2011;45(3):1–67. https://doi.org/10.18637/jss.v045.i03.
59. van Barreveld M, Scheper A, Vissers C, Duinmeijer I, Hakvoort B. Social–emotional functioning and quality of life in language disorders: a systematic review of development from childhood to adolescence. Int J Lang Commun Disord. 2025;60(3):e70039.
60. Verdon S, McLeod S, Wong S. Supporting culturally and linguistically diverse children with speech, language and communication needs: overarching principles, individual approaches. J Commun Disord. 2015;58:74–90. https://doi.org/10.1016/j.jcomdis.2015.10.002.
61. Vygotsky LS. Mind in society: the development of higher psychological processes. In: Cole M, John-Steiner V, Scribner S, Souberman E, editors. Cambridge, MA: Harvard University Press; 1978.
62. Wood D, Bruner JS, Ross G. The role of tutoring in problem solving. J Child Psychol Psychiatry. 1976;17(2):89–100. https://doi.org/10.1111/j.1469-7610.1976.tb00381.x.
63. Yew SGK, O'Kearney R. Emotional and behavioural outcomes later in childhood and adolescence for children with specific language impairments: meta-analyses of controlled prospective studies. J Child Psychol Psychiatry. 2013;54(5):516–24. https://doi.org/10.1111/jcpp.12009.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Authors and Affiliations

Niveen Omar[1,2] · Michael Davidovitch[3,4] · Hazar Zahalka[5] · Muhammad Mahajnah[6,7] · Ortal Slobodin[1]

✉ Niveen Omar
nivin.omar13@gmail.com

Michael Davidovitch
davidom13@gmail.com

Hazar Zahalka
hazar.z@meuhedet.co.il

Muhammad Mahajnah
MUHAMADMAH@hymc.gov.il

Ortal Slobodin
ortalslo@bgu.ac.il

[1] School of Education, Ben-Gurion University of the Negev, Be'er Sheva, Israel

[2] School of Psychology, Cardiff University, Cardiff, UK

[3] Kahn-Sagol-Maccabi Research and Innovation Institute, Maccabi Healthcare Services, Tel Aviv, Israel

[4] Dina Recanati School of Medicine, Reichman University, Herzliya, Israel

[5] Child Developmental and Pediatric Neurology Services, Meuhedet Healthcare Services, Hadera, Israel

[6] Child Neurology and Development Centre, Hillel-Yaffe Medical Centre, Hadera, Israel

[7] The Ruth and Bruce Rappaport Faculty of Medicine, Technion – Israel Institute of Technology, Haifa, Israel