

Culturally Adapted Home-Based Intervention to Improve Child's Development in Arab Toddlers in Israel: Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background

Arab toddlers in Israel face socioeconomic and cultural barriers that increase their risk for delays in early language and cognitive development. Early childhood is a sensitive period in which timely, culturally appropriate intervention can support foundational skills. However, few interventions are tailored for this population. This study aims to evaluate a home-based, culturally adapted program designed to improve language, communication, and cognitive abilities in Arab toddlers aged 18 to 36 months.

Methods

This block-randomized controlled trial includes two parallel arms: an intervention group receiving eight weekly home-based sessions and an attention-control group receiving parallel health-promotion visits. Families will be recruited through well-baby clinics. Eligible participants are toddlers aged 18 to 36 months who show mild developmental vulnerabilities and whose caregivers consent to participate. A total of 240 children will be allocated (1:1) to either the intervention or control group. The intervention focuses on optimizing the home environment, promoting child engagement, and enhancing parental responsiveness across play, routines, and shared story time. Outcomes will be assessed at baseline and one month post-intervention. Primary outcomes include language and cognitive development measured using standardized developmental assessments. Secondary outcomes include parental concerns about child development. Mixed-effects linear regression models will evaluate intervention effects.

Discussion

This study addresses a major gap in early developmental support for Arab toddlers in Israel. By integrating culturally adapted content with evidence-based responsive caregiving strategies, the intervention aims to provide an accessible and contextually grounded model for improving early developmental outcomes. The findings may inform scalable, community-based approaches for disadvantaged minority populations.

Trial registration

ClinicalTrials.gov: **NCT07233525**. Registered **14 November 2025**.

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 marginalisation, and underutilization of daycares and health services. During this critical developmental period, early intervention is essential for enhancing children's linguistic and cognitive skills, which are foundational for later academic and social success (Heidlage et al., 2020; Izett et al., 2021; Markkula et al., 2024). However, despite the importance of targeted early childhood programs, there is a significant lack of evidence 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.

1. Early language and cognitive interventions

Early intervention targeting linguistic, communication, and cognitive skills is essential for reducing developmental challenges in young children with or at risk for language impairments (Brown et al., 2018; Buschmann et al., 2009; Colmar, 2011; Heidlage et al., 2020; Markkula et al., 2024). Language abilities in early childhood are critical predictors of performance across developmental domains and have lasting impacts (Justice et al., 2009; Skibbe et al., 2008; Rescorla, 2009). They provide a foundation for future literacy skills, such as reading, decoding, comprehension, and written expression (Dickinson et al., 2010). Delays in language development significantly increase the risk of challenges with literacy-related tasks, which may hinder academic achievement (Catts et al., 2002; Skibbe et al., 2008).

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 (Conti-Ramsden et al., 2013; Yew & O'Kearney, 2013) and may struggle with social competence and peer relationships compared to their typically developing peers (Forrest et al., 2024; van Barneveld et al., 2025). These difficulties often persist into adolescence and adulthood, placing individuals at a continued risk for social, emotional, and learning challenges throughout their lives (See Forrest et al., 2024, and van Barneveld et al., 2025). Early intervention plays a pivotal role in

mitigating these risks. It supports academic achievement and fosters stronger social and emotional development by targeting language, communication, and cognitive skills.

Similarly, cognitive skills such as problem-solving are crucial for children's overall development and ability to navigate challenges effectively (Dusek & Ayhan, 2014; Solby et al., 2021). Mastery of problem-solving not only enhances cognitive growth but also equips children to regulate their emotions, adapt to complex situations, and develop resilience (Hall et al., 2024). Conversely, the absence of these foundational skills can hinder their ability to achieve their aspirations and cope with life's demands effectively (Livingston et al., 2025). Early intervention in problem-solving skills can prepare children to face novel challenges, helping them succeed across various life domains. Therefore, fostering both language and problem-solving abilities through early intervention is vital for supporting children's holistic development and ensuring their long-term success.

2. 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 (Bruner, 1983; Vygotsky, 1978; Wood et al., 1976). 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 (1983) 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, emphasising reciprocal engagement and collaboration.

A parent's responsiveness—the ability to notice, interpret, and appropriately respond to their child's cues—is a critical determinant of 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 (Rogoff, 1990; Vygotsky, 1978). Maternal responsiveness, in particular, has been shown to enhance linguistic development by enriching the language environment (Brady et al., 2009; Tamis-LeMonda et al., 2000; 2002; 2014). 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 (Tamis-LeMonda et al., 2001). Moreover, joint attention, where parent and child focus on the same object or event, was required for language acquisition, as it aligns adult speech with the child's interests, making the input both relevant and comprehensible (Tomasello & Farrar, 1986; Moore & Dunham, 1995; Capelli et al., 2025). 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 Mermelshtine, 2017, and Ismail et al., 2024 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 (Miller et al., 2024; Tamis-LeMonda et al., 2001; Mermelshtine, 2017). These strategies included responsiveness to object exploration, play, language and communication and focus on various behaviours such as: (1) Non-verbal 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.

3. Social factors in parent-implemented intervention

Children from disadvantaged communities and low-income households are widely accepted as having lower well-being, as reflected in their internalizing behaviours, externalizing behaviours, and 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 (Bradley & Corwyn, 2002; Keating & Hertzman, 1999; Mendelson et al., 2008).

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 (Brooks-Gunn & Markman, 2005). Some argue that lower SES often limits access to essential resources, like nutrition, housing, and learning materials, needed for healthy development (Bradley & Corwyn, 2002). At the same time, economic hardship increases parental stress, which can negatively impact parenting behaviours and contribute to children's emotional and behavioural difficulties (Koutra et al., 2025). 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 (Conger et al., 1992; Elder et al., 1992; McLoyd & Shanahan, 1993).

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; Miller et al., 2024). Parent-implemented interventions were effective in improving receptive and expressive language in children at risk for language impairment (LI) due to low socioeconomic status (SES) (Heidlage et al., 2020; Suskind et al., 2024). For example, Miller et al. (2024) 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.

4. Early Childhood in Arab Society in Israel

The Arab population in Israel accounts for 21% of the country's 9.1 million inhabitants (Central Bureau of Statistics, 2020). This community is characterized by a relatively young demographic, with 43% of the population under the age of 18 and a median age of 22. Despite its youthful composition, Arab society faces numerous social and economic challenges that significantly impact early childhood development.

Most Arab localities in Israel are small to medium-sized and are located in the country's social and geographic periphery, contributing to economic and social disadvantages. Nearly all Arab localities (95%) are classified in the country's lowest socioeconomic clusters, with 11% ranked in the lowest cluster of all (cluster 1; Central Bureau of Statistics, 2020). High poverty rates are a persistent issue, with 63% of Arab children living below the poverty line. Participation in daycare for children under three is limited, with only 18% enrolled, and the child welfare system mandates that 40% of daycare attendance be met.

Arab infants are at heightened risk of mortality, primarily due to congenital malformations and inherited diseases (Kasirer et al., 2021). Among children aged 1–5 years, unintentional injuries are the leading cause of death, accounting for 23% of fatalities. Developmental delays and mental health issues are more prevalent among Arab children compared to national averages. However, these conditions are often underdiagnosed and undertreated, with many children reaching healthcare services at a later stage and in more severe conditions (Mahajna et al., 2016).

The systemic and structural challenges faced by the Arab community underscore the urgent need for targeted interventions to support early childhood development. Tailored approaches must address the unique cultural, social, and economic contexts of Arab society to ensure young children and their families have access to equitable resources and opportunities for growth and well-being.

5. The current study

This study aims to develop and evaluate a culturally competent, home-based intervention

designed to enhance language and cognitive skills in Arab children in Israel aged 18–36 months. The intervention is guided by an ecological perspective (Bronfenbrenner, 1979; 1995), considering the interplay between the child's characteristics, the caregiver's responsiveness, and the broader social, physical, and linguistic environment. By addressing these interconnected factors, the study provides a holistic approach to supporting early development in a population at heightened risk for developmental challenges. The intervention is intentionally designed to be simple and direct, ensuring accessibility and applicability for all parents, regardless of socioeconomic background. Delivered in the family's home environment, the program consists of eight sessions over eight weeks. A key intervention component involves guiding parents to optimise their physical home environment to support their child's play, language, and communication development.

Additionally, the sessions focus on enhancing parental responsiveness, emphasising behaviours such as joint attention, contingent feedback, and sensitivity to the child's interests and developmental level. The intervention also considers the child's characteristics, including interests and preferences, to foster engagement and promote meaningful interactions. The child's language and cognitive abilities will be assessed before and after the intervention using the CAT-CLAMS test and Arabic Communicative Development Inventories (Arabic-CDI) to evaluate the program's efficacy. By integrating culturally tailored strategies with evidence-based practices, this study aims to contribute to the limited body of research on early childhood interventions in the Arab community in Israel and provide a scalable model for enhancing developmental outcomes in disadvantaged low SES populations.

Methods

Study Design

This study employs a pre-post, block-randomised controlled trial (RCT) design to evaluate the effectiveness of a culturally adapted, home-based intervention targeting the language and cognitive development of Arab toddlers in Israel. Guided by an ecological perspective, the study considers factors such as the child’s characteristics, the caregiver’s responsiveness, and the family’s physical and social environment. Participants will be block-randomised to either the intervention arm (home-based early childhood intervention) or the control arm (home-based health education).

Participants

Participants will include children aged 18–36 months and their primary caregivers. Families will be recruited from community healthcare centres (well-baby clinics) at the age of 12, 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) a birth weight ≥ 1500 grams; (4) caregivers who are willing to participate in the eight session intervention; and (5) caregivers who do not present with moderate or severe depressive symptoms, as determined by a baseline screening using the Patient Health Questionnaire-9 (PHQ-9).

The PHQ-9 is a validated and widely used self-report instrument that assesses the severity of depressive symptoms over the preceding two weeks, based on DSM-5 criteria (Kroenke et al., 2001). It consists of 9 items rated on a 4-point Likert scale (0 = "not at all" to 3 = "nearly every day"), with total scores ranging from 0 to 27. In line with clinical guidelines, parents who scored ≥10 were excluded from participation, as moderate-to-severe depressive symptoms could interfere with intervention engagement and confound outcomes.

Caregivers also completed a structured demographic questionnaire to collect background information about the child and family. The questionnaire included items about the child’s birth history (e.g., gestational age, chronic health conditions, and developmental concerns), current care arrangements, and key developmental milestones (e.g., age of first words, crawling, and walking). It also gathered caregiver information such as age, relationship to the child, education level, employment status, number of children in the household, and language(s) spoken at home. These data were used to describe the sample and ensure comparability across participants.

All enrolled families provided written informed consent, and the study protocol was approved by the authors’ institutions.

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.

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/well-baby 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. Randomisation will be stratified by region, defined as North, Centre, and South, to support balanced representation across trial arms.

Sample Size

Based on a systematic review and meta-analysis (Jeong et al., 2011) of parenting interventions to promote early child development in the first three years of life (111 articles representing 102 unique RCTs), we expected an intervention effect size of 0.3. A priori power calculations using G*POWER software revealed that for an alpha of 0.05 a minimum of 240 participants were required.

Randomisation

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. Randomisation 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.

Randomisation will be conducted using a secure, electronic randomisation 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 generalised 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 minimising 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 verbalisations, and connecting story content to the child's world.

The intervention was grounded in responsive behaviours and contextual interactions, as observed and analysed by Tamis-LeMonda (2001, 2002). 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:

The primary outcomes of this study are the child's language and cognitive development, assessed using the Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale (CAT-CLAMS; Hoon et al., 1993). This standardised paediatric assessment tool is specifically designed to evaluate developmental delays in infants and young children up to 36 months. It provides a structured and comprehensive evaluation of communication, adaptive behaviour, and cognitive abilities.

The CAT-CLAMS comprises two components that assess distinct aspects of early development:

1. Cognitive Adaptive Test (CAT):

- Evaluate cognitive abilities and adaptive behaviours, focusing on problem-solving skills.
- Includes age-appropriate tasks such as object permanence and attention to visual and auditory stimuli.
- Administered directly to the child using visual-motor problem-solving tasks requiring interaction.

2. Clinical Linguistic and Auditory Milestone Scale (CLAMS):

- Assesses language development and auditory processing milestones, including babbling, word recognition, and early word production.
- Facilitates the early identification of language or auditory delays.

Language and problem-solving abilities are evaluated separately through the CLAMS and CAT components, respectively, providing distinct measures of developmental progress.

Arabic Communicative Development Inventories (CDI) – Words Only:

We used the Arabic Short Form MacArthur-Bates Communicative Development Inventories (CDI) – Words Only, developed by the Plymouth Babylab, to assess receptive and expressive vocabulary (Abdelwahab et al., 2021). Communicative Development Inventories (CDI) are widely used vocabulary checklists with a long history in studying early language development. This version is designed for children aged 8 to 36 months and consists of 100 words. For each word, both comprehension and production are assessed through a parental report. The tool is available in 17 dialects of Arabic, including Palestinian Arabic, which our participants speak. Since our participants were drawn from three regions in Israel, each characterised by its local dialect, the word list was adapted to ensure cultural and linguistic relevance across these regional variations. While normative data are currently available for

the Egyptian dialect, they can be reasonably extrapolated to the remaining versions, including the adapted form used in this study.

Secondary Outcomes

Parents' Evaluation of Developmental Status (PEDS)

To capture parental perspectives on their child's development, we administered the Parents' Evaluation of Developmental Status-Revised (PEDS-R) at both pre- and post-intervention time points. The PEDS-R is an evidence-based screening tool that systematically elicits and addresses parents' concerns across multiple developmental domains, including language, motor skills, self-help, early academic abilities, behaviour, and social-emotional functioning.

Procedure

Participants will be recruited through community healthcare centres (well-baby clinics). Nurses at these centres will be trained to identify children aged 12, 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: before the start of the intervention (baseline) and one month after the intervention has been completed. At each time point, an independent assessor (not involved in delivering the intervention) will evaluate the child's language and cognitive development using the CAT/CLAMS tool. During both assessment sessions, parents will also complete the following measures: 1) The Arabic version of the Communicative Development Inventory (CDI) to assess the child's expressive and receptive vocabulary, and 2) The Parents' Evaluation of Developmental Status (PEDS) to gather parental insights on their child's developmental progress. Additionally, before the intervention begins, parents will complete a demographic questionnaire and the Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001). This procedure ensures standardized assessments while maintaining cultural and linguistic alignment with participating families (See figure 1 and Table 1 for the full procedure).

Table 2: Participant Timeline (Schedule of enrolment, interventions, and assessments)

	TIMEPOINT	Screening (-t₁) Well-baby clinic visit	Baseline / randomisation (T₀) Home visit	Intervention period Weeks 1–8 (T₁–T₈)	Post- intervention follow-up (T₉) 4 weeks after last session
ENROLMENT					
Eligibility screen	(well-baby clinic nurse review, preliminary developmental concern)	X			
Informed consent			X		
Demographic questionnaire	Child and family characteristics		X		
PHQ-9 (caregiver)	Depressive symptoms for eligibility		X		
Randomisation	Block randomisation (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-	8 weekly home visits on			X	

promotion program (control arm)	general child health topics		
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

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.

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 program 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

Training will include the administration of standardized tools used in the study, including the CAT/CLAMS, the Communicative Development Inventory (CDI), and the Parents' Evaluation of Developmental Status (PEDS). Emphasis will be placed on administering assessments objectively and reliably, as well as on strategies to minimize bias when the same team member is involved in both intervention and assessment.

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-centered 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 coordinator 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.

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.

Auditing

No independent auditing is planned. The Helsinki Committee at Hillel-Yaffe Medical Center 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.

Statistical Analysis

Mixed-effects linear regression models will be employed to investigate the impact of the intervention on children's cognitive and language development. In all models, the child or family will be included as a random effect to account for repeated measures and within-family clustering. The primary model will include fixed effects for Group (Intervention vs. Control) and Time (Pre- vs. Post-Intervention) to assess their impact on the composite CAT/CLAMS score, which evaluates both cognitive and language abilities. Two additional models will use the same fixed effects to evaluate the intervention's effect on expressive and receptive language skills separately, based on performance in both the CAT/CLAMS and the Arabic version of the Communicative Development Inventory (CDI). Parents' Evaluation of Developmental Status (PEDS) will be included as a fixed covariate in all models to assess whether parental perceptions mediate or moderate the intervention effects.

Model assumptions (e.g., normality of residuals, homoscedasticity) will be evaluated using residual diagnostics and visual inspection (e.g., Q-Q plots). Missing data will be handled using multiple imputation or maximum likelihood estimation, depending on the pattern and extent of missingness. All results will be reported with 95% confidence intervals and standardized effect sizes, in addition to p-values. Statistical analyses will be conducted using RStudio Desktop (version 2025.05.1-513).

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 particularly strong benefits for low socioeconomic status (SES) families in promoting cognitive, language, and motor development (Jeong et al., 2021). However, underutilization of services in these communities is common due to limited awareness, stigma, transportation challenges, and lack of coverage (Slobodin & Masalha, 2020). 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 well-baby clinic nurses—trusted healthcare providers—has proven effective for engaging low-SES minority families (Aliyas et al., 2023), 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 (Verdon et al., 2015) 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 (Carter et al., 2005).

Practically, delivering the program 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 key driver of child language and cognitive growth (Leffel & Suskind, 2013)—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 (Murray et al., 2016). Families with moderate-to-severe depressive symptoms are excluded, which improves internal validity but limits generalizability.

Another limitation is the short follow-up period (one month), which restricts the ability to draw conclusions about the long-term impact. Future studies should incorporate longer-term assessments to examine sustained gains (Suskind et al., 2024). 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.

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.

Declarations

Trial status

This protocol is **Version 1.0**, dated **October 2025**.
Recruitment is anticipated to begin on **20 November 2025** and is expected to be completed by **1 December 2026**.
Study completion is anticipated by **31 December 2026**.

At the time of manuscript submission, no participants have been enrolled.

Ethics approval and consent to participate

Ethical approval for this study was granted by the Helsinki Committee, Hillel-Yaffe Medical Center, Israel (Approval No. 0159-22-HYMC, approved 13 July 2023). Written informed consent will be 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.

Availability of data and materials

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.

Competing interests

The authors declare no competing interests.

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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.

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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.

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Figures

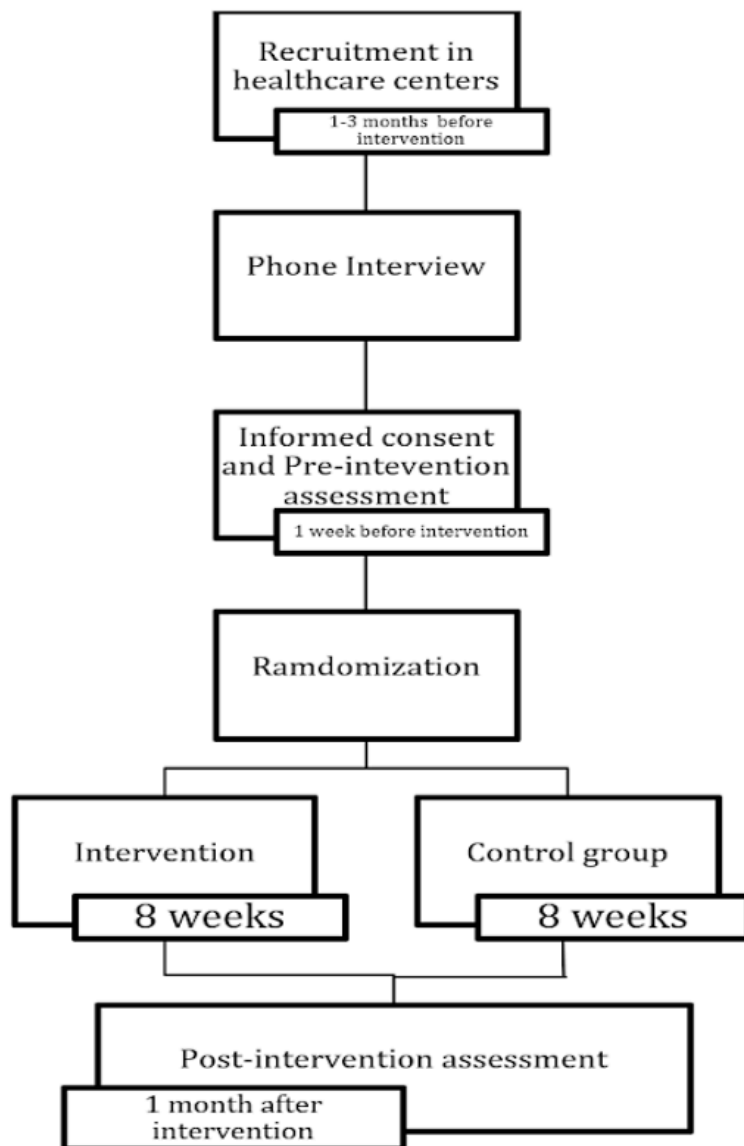


Figure 1

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

Supplementary Files

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