STUDY PROTOCOL

A Stratified, Assessor-Blinded, Randomized Controlled Trial to Assess the Effectiveness of a Mobile Health (Mhealth) Intervention to Promote Development in Children Under 42 Months of Age: Study Protocol

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Abstract

Background Early childhood development profoundly impacts well-being. Mobile health (mHealth) technologies are increasingly integrated into healthcare due to their scalability, affordability, ability to deliver personalized interventions. This paper presents a randomized controlled trial evaluating the effectiveness of a culturally appropriate mobile-based intervention in promoting early childhood development and improving caregivers' knowledge, attitudes, and practices.

Methods This assessor- and analyst-blinded, stratified RCT evaluates a mHealth intervention for children under 42 months. The intervention is a culturally appropriate mobile-based educational program focusing on cognitive, motor, and language development delivered via a mobile application. We will recruit 110 at-risk caregiver-child pairs (identified by ASQ) from a developmental center in West Azerbaijan, Iran. Participants will be stratified by developmental concern type and randomly assigned (1:1) to intervention or control using a computer-generated, stratified block sequence. The intervention group will receive the mobile program plus standard care; the control group will receive standard care only. Developmental outcomes will be measured using the Bayley scales at baseline and four months. Secondary outcomes include caregivers' KAP measured by a structured questionnaire. Primary analysis will use ANCOVA. Outcome assessors and data analysts will be blinded.

Expected Results We predict children in the intervention group will show greater improvements in cognitive, motor, and language domains than controls. Caregivers in the intervention group will show higher KAP scores. Findings will provide evidence supporting adapted mHealth interventions in low-income settings.

Discussion This rigorous trial addresses an evidence gap in low- and middle-income settings with limited access to developmental supports. Despite blinding challenges in behavioral interventions, methodological safeguards minimize bias. Results will inform digital health strategies and may serve as a model for integrating mHealth into early childhood care systems in resource-limited settings.

Keywords Early childhood development, mHealth, Mobile health, Randomized controlled trials

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1 Introduction

Background

During the early stages of childhood development, the human brain develops rapidly,[1] and attention to children's development during this period can have lifelong effects on each person's personal and social life.[2,3] In fact, the early years of children's lives lay the foundations for the human capital infrastructure of societies.[4] Therefore, promoting optimal childhood development has been included as a key goal in the global development agenda for the third millennium [5,6] and has attracted considerable attention from national communities and international organizations such as the World Health Organization (WHO), the World Bank, and the United Nations International Children's Emergency Fund (UNICEF).[7] With the support of these organizations, the Nurturing Care Framework (NCF), including adequate nutrition, good health, security, learning opportunities, and responsive care, has been proposed.[8,9] Studies have shown that development-promoting activities within this framework can have positive effects on children's physical, social, and emotional development.[10]

A variety of methods have been used to promote early childhood development.[11] Some studies have used education for caregivers through training classes,[12] while others have used brochures and manuals to educate caregivers or integrated interventions.[13] Intervention tools, especially in recent years, have moved towards the use of information technology.[14,15] These tools include a wide range of tools approaches, including the use of multimedia tools[16] and online communication,[[17–19] the use of websites and portals,[20,21] the use of augmented reality games,[22,23] the word-counting systems,[24] and even motion recognition sensors.[25]

MHealth tools are effective in improving health services.[26,27] With their high accessibility and low cost, these tools can eliminate the problems of providing services in remote areas.[28] They can also provide mental health support to parents by automatically monitoring and promoting early childhood development (ECD)[29] and help to report accurate results,[30,31] especially in resource-limited environments such as low and middle-income countries (LMICs).[32,33] In addition, this tool has opened a new window to solve health problems by providing personalized services for each individual.[34] This tool can affect the literacy and knowledge of individuals and improve their insight and performance.[35] It has been shown that mHealth tools, especially if they are in the form of nurturing care, can have positive effects in various areas of child development.[36] The use of smartphones, especially apps, has been used to promote child development, especially in high-income countries, but most of them lack the necessary quality and need to be designed with a scientific method [37,38] and evaluated for clinical effectiveness.[39]

MHealth can strengthen the interaction between the patient and other health-related factors, including general practitioners, specialists, health managers, and other relevant fields.[40] In this case, it is important to adapt intervention tools to the local culture and attitudes of the community so that they can influence the knowledge of child caregivers.[41] Of course, government policies, the establishment of relevant laws, and the adoption of coordinated interpectoral policies are also important.[42]

To our knowledge, there are few studies examining smartphone interventions in the context of child development. Furthermore, the impact of smartphone interventions on children, as well as the impact of these interventions on parental knowledge, attitudes, and practices, has not been measured.

Objectives

This study protocol outlines the design and methodology of a randomized clinical trial (RCT) aimed at evaluating:

1. Whether a mobile phone-based intervention is more effective than conventional interventions in improving ECD outcomes.
2. The impact of the intervention on parents' knowledge, attitudes, and performance (KAP) regarding ECD.

We detail the trial design, randomization process, intervention components, outcome measures, and statistical analysis plan to ensure reproducibility and transparency.

2 Methods

Study design

This study was designed as an experimental, two-arm, parallel-group RCT. This design was chosen because of its robustness in establishing causal relationships and its ability to minimize confounding factors.[43] The objective was to evaluate the effectiveness of a mHealth intervention on child development indicators. The intervention group used a smartphone application in addition to the usual care. The intervention group will be managed by a system. Recommendations will be selected by clinicians and sent to their mobile phones. The control group will receive the usual interventions. Figure 1 illustrates the study's flow, participant progression, intervention pathway, and evaluation timeline.

Study setting

This study will be implemented in West Azerbaijan Province, one of Iran's 31 provinces. The province covers an area of approximately 23,000 square kilometers and has a population of over 3 million. Enrollment of children will begin in mid-2026. With the support of

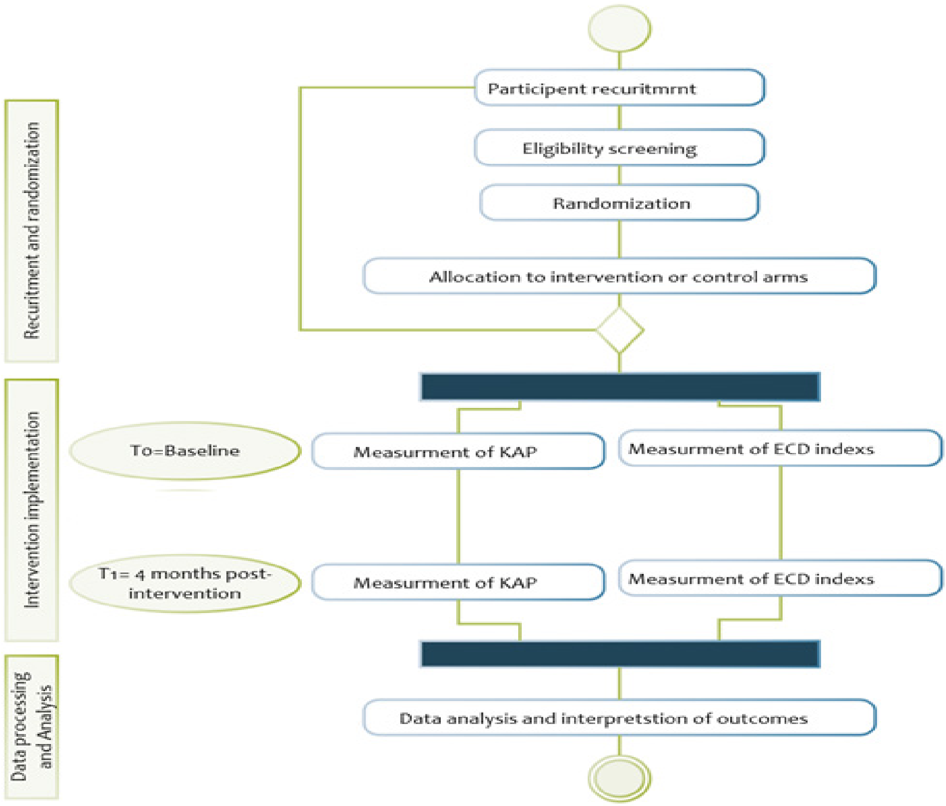

Figure 1 Study flowchart depicting participant progression, intervention pathway, and evaluation timeline.

Urmia University of Medical Sciences, the research team will be based at the provincial referral clinic for growth and development.

With the support of Urmia University of Medical Sciences, the research team was based at the provincial referral clinic for growth and development. A child development specialist delivers a standardized training program that includes exercises to enhance children's cognitive, motor, and socio-emotional development. Four trained trainers are stationed at the Comprehensive Development (Growth) Center. Each has completed at least one day of theoretical training and four days of practical training in measuring child development and growth indicators. Two of these trainers will conduct sessions at the center.

The program content is provided by the Iranian Ministry of Health and is fully adapted to the local culture and environment. The trained specialists administer the Bayley Scales of Infant and Toddler Development using a standardized procedure to identify developmental delays. A child development specialist supervises the entire process, and parents of children identified with developmental delays receive appropriate guidance and counseling.

Participants

In Iran, children are screened in primary health care centers in various developmental domains using the Ages and Stages Questionnaire (ASQ). Children who are susceptible to developmental delay are referred to the Child Development and Development Reference Clinic. In this study, all child-caregiver pairs who are referred to the Child Development and Development Reference Clinic of Urmia University of Medical Sciences will be included in the study until the number of samples is complete, and the following conditions are met.

The inclusion criteria for child-caregiver pairs are as follows:

- The child is less than 42 months old.
- The child's caregiver has a smartphone.
- The child's guardian has at least a high school diploma.

Child-caregiver pairs will be excluded from the study under the following conditions:

- The child has a developmental disorder, i.e., his/her composite developmental score is less than 70 on the Bayley Scales of Infant and Toddler Development. [44]
- The parents plan to travel abroad in the next 4 months or move to a distant location.
- The child received other effective complementary interventions (such as referral to another specialist or clinic) during the intervention.

Usual care

The Iranian Ministry of Health provides primary care to all children from birth at first-level health centers. In these centers, children are screened for development using the ASQ. Children who are at risk for developmental delays are then referred to a comprehensive developmental clinic. In these clinics, the Bayley Scales of Infant and Toddler Development is used to determine a developmental disorder definitively. Children either have a developmental disorder and are referred to a specialist doctor, or have developmental delays or are at risk of such delays, and receive targeted education provided by doctors, and supplementary activities are delivered through brochures and booklets. Follow-up visits are conducted during subsequent appointments to monitor progress. Both the intervention and control groups in this study receive the usual interventions; however, in the intervention group, supplementary activities are provided in the form of a mobile application in addition to the usual materials. This application facilitates interaction between the child's caregiver and the treatment team (Figure 2).

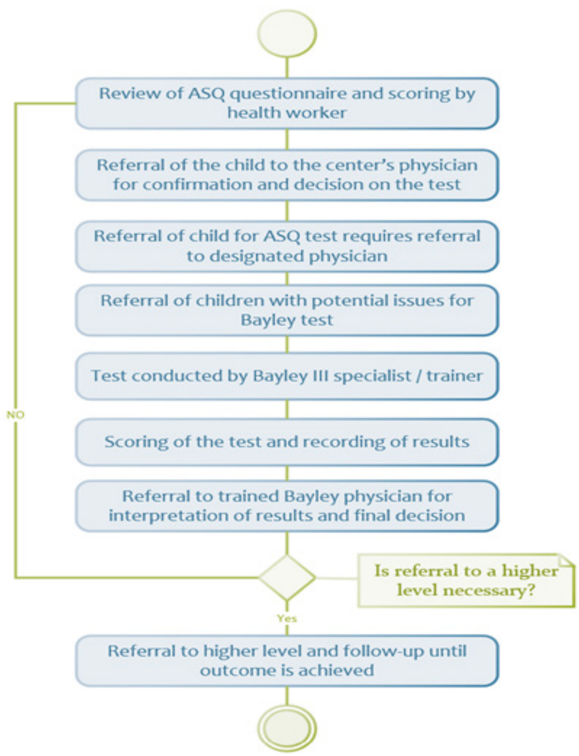

Figure 2 Implementation process of Bayley III [45]

Intervention

The intervention tool is an educational content management system and a mobile application that provides educational content in three main areas of child development. The design of this system will be done after collecting requirements from doctors and care providers using a requirements gathering questionnaire. The implementation of the system will be done using the programming languages ASP.NET and Android Studio. The software system manages the communication between the team of specialists and the child's caregivers, and child-specific recommendations are sent to the parents. Parents discuss the sent recommendations with the child. If necessary, the parents provide feedback and communicate with the health team. In the next in-person monitoring, recommendations related to improving development are updated, and the next monitoring cycle begins.

The content of this system has been created based on the Iranian Ministry of Health guidelines for child development. This content is defined as a standard. The doctor can also upload the content that he wants to provide to the child's caregivers. In addition to this content, the system also includes general information about child development and other standard educational materials in this field.

The system consists of two main parts. In the first part, a web application is available to the child development specialist who views the child's information. He can view/delete/edit the child's activities during the period and can also send standard activities to the child's caregivers based on the guidelines of the Iranian Ministry of Health and the Child Development Department. In the second part, there is a mobile application that receives the activities sent by the doctor and keeps a record of the activities performed. In addition, the caregiver can use general educational information and interact with the relevant doctor in the form of a chat.

Sample size

In this study, the sample size refers to the number of pairs of caregivers and children studied in the two intervention and control groups. To obtain the sample size, and α error of 0.05, a test power of 80%, and a ratio of participants in the two groups of 1:1 were considered. The population standard deviation for the composite score index for development was 15, and a mean difference of 6 points was estimated for the test to be significant. In this way, the sample size was estimated to be 98 samples (49 per group) based on two independent samples.[46] Accounting for a 12% attrition rate, a total of 110 parent-child pairs will be recruited. Sampling will continue among parents who visit the Child Development Clinic at Urmia University of Medical Sciences and have children meeting the inclusion criteria, until the target sample size is achieved.

Recruitment Sample size

Participants will be selected from parent-child pairs referred to the Growth and Development Clinic by primary health centers. Trained research associates will assess the children using the Bayley Scales of Infant and Toddler Development. Those meeting the inclusion criteria will have informed consent obtained for data collection and long-term follow-up. Upon enrollment, the KAP questionnaires will be administered, and participants will be randomly assigned to either the intervention or the control groups.

Randomization and allocation

In this study, 110 samples will be equally allocated into intervention and control groups in a 1:1 ratio. To ensure balanced group sizes, a stratified block randomization procedure will be employed, implemented through a component within the study software system. Given that participants are categorized into three distinct developmental domains (language, motor, and cognitive), a separate randomization sequence will be generated for each stratum. For this purpose permuted blocks of random assignments (using '0' for control and '1' for intervention) with varying block sizes (e.g., four and six) will be created for each domain using the true random number service RANDOM.ORG. [47] These sequences are then securely uploaded into the system's allocation module. Upon enrollment and confirmation of eligibility, the recruiting clinician will enter the participant's assigned developmental domain into the system. The system will then automatically and irrevocably assign the participant to the next available intervention or control group within the corresponding domain-specific randomization sequence. This process ensures concealment of allocation, as the clinician cannot foresee future assignment.

Both groups will receive conventional interventions in accordance with the standards of the Iranian Ministry of Health. In addition, participants allocated to the intervention group will receive the supplementary intervention in the form of a mobile application and an educational system.

Blinding

In this study, blinding of outcome assessors and data analysts will be implemented. Due to the nature of the intervention, full blinding of participants was not feasible, as those in the intervention group received the mobile application link. In the study process, the inclusion of participants in the intervention or control group is conducted by sending the application download link to the mobile phone, so the assessors of the outcome indicators will not be aware of the type of participant group. In addition, the data analysis will be performed by an analyst who is blind to the type of participant group in the study. Since the care provider (physician) performing the intervention will necessarily be aware of the allocation of participant groups, he or she will not be involved in outcome measurement or data analysis, thus minimizing potential bias.

Data collection, data management, monitoring and auditing

Various tools are used for developmental screening of children. One of the most common tools is the ASQ questionnaire.[48,49] This questionnaire is globally valid and is used in Iran as a child development-screening tool in health centers. This questionnaire has a total of 30 questions for children aged 2 to 60 months and assesses 5 areas of communication (speech and language), problem solving, interpersonal-social skills, and gross and fine motor skills, with six questions in each area with options of (not yet), 0 points, 5 points (sometimes), or 10 points (yes). Children who score less than 2 standard deviations from the mean in one or more areas are identified and referred to comprehensive child development centers for further evaluation. The validity and reliability of the ASQ questionnaire for Iranian children have been proven.[50]

The Bayley Scales of Infant and Toddler Development, Third Edition (Bayley III) is a diagnostic tool for developmental delay in children. It is used to definitively diagnose cases referred as developmental delay in screening tests. The Bayley Scales is considered the gold standard for diagnosing developmental disorders. It covers children between 1 and 42 months of age and assesses the child's developmental level in five areas. If the child development specialist diagnoses a severe developmental disorder, referral to higher-level centers is made, and if developmental delay is diagnosed, activities are provided to increase the child's potential. The validity and reliability of the Bayley Scales for Iranian children have been proven.[51]

A researcher-made questionnaire will be used for the KAP study. Using scientific sources and documents, the main indicators in the KAP questionnaire are determined and the indicators are categorized. After the structural validity is confirmed by a pediatrician, the questionnaire is presented to 5 faculty members of Urmia University of Medical Sciences to examine the content validity. Corrections, comments, and suggestions of the professors are applied to the questionnaire, and thus the validity of the instrument is obtained. The reliability of this questionnaire is evaluated in the way that the questionnaire is presented to 10 parents selected from the sample population receiving services. After a 10-day interval, the same parents are questioned again. The results are evaluated and the questions that have defects are corrected. Then, the questionnaire is given to 10 other parents and after 10 days, these parents are questioned again. This process continues until new information is obtained. Then, the data is collected and their reliability is measured with the Cronbach's alpha test to confirm the reliability of the questionnaire.

Statistical Assessment and analysis

Developmental outcomes in children will be assessed using the Bayley Scales of Infant and Toddler Development. Key indicators will be measured in three domains: motor development including gross and fine motor skills, language development including expressive and perceptual skills, and cognitive development. Outcomes will be measured at two time points: baseline and four months post-intervention. The primary analysis will use Analysis of Covariance (ANCOVA) to compare post-intervention scores between the intervention and control groups, using baseline scores as a covariate. For KAP study, data will be collected using a questionnaire developed by the researcher. Paired t-tests will be used to compare KAP scores within each group from baseline to post-intervention. Additionally, independent samples t-tests will be used to compare the post-intervention KAP scores between the intervention and control groups. For all statistical tests, a two-sided significance threshold of $p < 0.05$ will be applied. Data analysis will be performed using IBM SPSS Statistics software by an independent statistician to ensure impartiality.

Ethics and dissemination

The trial is scheduled to commence in mid-2026, with participant recruitment expected to conclude by the end of the same year. Informed consent will be obtained from participants, who will be informed that their participation is entirely voluntary and that they may withdraw at any time without any impact on their standard care. The study findings will be disseminated through publication in peer-reviewed journals and presentation at scientific conferences. Furthermore, the results will be submitted to the Iranian Ministry of Health.

3 Expected Results

Recruitment for this randomized controlled trial is scheduled to begin in mid-2026, and enrollment will continue until 110 caregiver-child pairs are enrolled and randomly assigned equally (1:1) to the intervention or health control group. The study will be conducted in West Azerbaijan Province, Iran, with the research team based at the provincial Development and Growth Referral Clinic, supported by Urmia University of Medical Sciences.

The intervention will consist of a smartphone health-based educational program that delivers culturally appropriate content provided by the Iranian Ministry of Health. The program targets three key areas of child development: cognitive, motor, and socioemotional skills. Child development specialists will conduct delivery and four trained educators based at the Comprehensive Development Center, all of whom have received standardized theoretical and practical training in measuring child development indicators. Fidelity and adherence to the intervention will be assessed throughout the study.

The primary outcomes are children's developmental scores, assessed using the Bayley Scales of Infant and Toddler Development, covering the domains of motor (gross and fine), language (verbal and receptive), and cognitive. Assessments will be conducted at baseline and four months (end of intervention). Children identified as having developmental delays will receive appropriate counseling and referral under the supervision of a child development specialist. Children in the intervention group are expected to show greater improvement in developmental scores than in the control group. The primary analysis will compare post-intervention outcomes between groups using appropriate parametric tests, with baseline scores adjusted for as necessary. A two-sided p value < 0.05 will define statistical significance .analyses will follow the intention-to-treat principle, conducted by an independent statistician.

Secondary outcomes focus on caregivers' KAP regarding early childhood development. The researcher using a structured questionnaire will collect data, and scores are expected to be higher in the intervention group after the intervention.

Overall, this trial is expected to provide strong evidence on the effectiveness of an ambulatory health-based educational system in promoting early childhood development. By providing structured, evidence-based content and monitoring child development outcomes and caregiver engagement, this study aims to provide valuable insights for health professionals and policymakers seeking scalable interventions in low-income settings.

4 Discussion

This protocol describes a carefully designed, assessor- and analyst--blinded, stratified, RCT to assess the effectiveness of a mHealth intervention aimed at promoting ECD in children under 42 months of age. RCT study can clarify the impact of these systems by creating greater interaction between parents and the health team, along with detailed assessments of child development indicators.[52] Furthermore, conducting studies that increase interaction between parents and the health team has been identified as a research challenge, given the critical importance of the first five years in shaping children's cognitive, emotional, and physical development.[53]

The proposed trial addresses a significant gap in the literature by testing a technology-based intervention that uses mHealth platforms to provide timely, accessible, and tailored support to caregivers. Previous studies have demonstrated the potential of mHealth tools to improve health behaviors and service utilization.[54–56] However, few have rigorously evaluated their impact on developmental outcomes using a stratified RCT design.

[57] Using this robust methodology, our study aims to generate high-quality evidence on the effectiveness of mHealth in enhancing developmental milestones that can inform policy and planning decisions globally.

A key strength of this study is the stratified, assessor-blinded design, which minimizes bias and strengthens the validity of the findings. Furthermore, the use of standardized and validated developmental assessment tools ensures reliable measurement of outcomes.[58] The scalability and adaptability of the intervention to diverse contexts further enhance its potential impact on public health. Furthermore, by targeting children under 42 months of age, the intervention is aligned with global priorities such as the Sustainable Development Goals and the Foster Care Framework.

Despite these strengths, some challenges are anticipated. Ensuring consistent engagement with the mHealth platform among caregivers may be challenging, particularly in populations with limited digital literacy or intermittent access to the Internet. To mitigate this, this study includes user-friendly interfaces and ongoing technical support. Furthermore, while an assessor-blinded design reduces bias, full blinding in behavioral interventions can be challenging, and we will carefully monitor potential instances of blinding.

If effective, this mHealth intervention could serve as a model for integrating digital health strategies into early childhood programs, especially in LMICs. These findings will help increase the evidence base supporting technology-based health promotion and may stimulate further research to examine cost-effectiveness, long-term effects, and adaptation to other developmental domains or age groups.

5 Conclusion

This study protocol provides a comprehensive design for evaluating an innovative mHealth intervention targeting early childhood development. The results will provide valuable insights into the feasibility, acceptability, and effectiveness of digital health tools in supporting caregivers and improving child development outcomes. Ultimately, this research has the potential to provide scalable solutions that address critical gaps in care and early childhood development globally.

Declarations

Acknowledgments
None to declare.

Artificial Intelligence Disclosure
No artificial intelligence (AI) tools were used to generate scientific content, analyze data, or draw conclusions. All interpretations, analyses, and conclusions are those of the authors. AI tools were used solely to assist with language correction and clarity.

Authors' Contributions
Bahlol Rahimi and Ghanbar Tavassoli conceived the study and designed the methodology. Bahlol Rahimi and Ghanbar Tavassoli developed the randomization, blinding procedures, and statistical analysis plan. Ghanbar Tavassoli drafted the first version of the protocol manuscript. All authors critically revised the manuscript and approved the final version. Bahlol Rahimi is the guarantor of the study protocol.

Availability of Data and Materials
Not applicable.

Conflict of Interest
The authors declare that they have no competing interests.

Consent for Publication
Not applicable.

Ethical Considerations
The study protocol has received ethical approval under the Code of Ethics IR.UMSU.REC.1403.030 from Urmia University of Medical Sciences as part of a doctoral thesis. Additionally, this controlled clinical trial has been registered with the Iranian Clinical Trials Registry under number IRCT20240710062380N1.

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References

1. Thompson RA. Early Brain Development and Public Health. Dela J Public Health. 2024;10(4):6–11. doi:10.32481/djph.2024.10.03.
2. Black MM, Walker SP, Fernald LCH, Andersen CT, DiGirolamo AM, Lu C, et al. Early childhood development coming of age: science through the life course. Lancet. 2017;389(10064):77–90. doi:10.1016/S0140-6736(16)31389-7.
3. Trude ACB, Richter LM, Behrman JR, Stein AD, Menezes AMB, Black MM. Effects of responsive caregiving and learning opportunities during pre-school ages on the association of early adversities and adolescent human capital: an analysis of birth cohorts in two middle-income countries. Lancet Child Adolesc Health. 2021;5(1):37–46. doi:10.1016/S2352-4642(20)30309-6.
4. Richter LM, Daelmans B, Lombardi J, Heymann J, Boo FL, Behrman JR, et al. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. Lancet. 2017;389(10064):103–18. doi:10.1016/

S0140-6736(16)31698-1.

5. Daelmans B, Darmstadt GL, Lombardi J, Black MM, Britto PR, Lye S, et al. Early childhood development: the foundation of sustainable development. Lancet. 2017;389(10064):9–11. doi:10.1016/S0140-6736(16)31659-2.

6. Black MM, Behrman JR, Daelmans B, Prado EL, Richter L, Tomlinson M, et al. The principles of Nurturing Care promote human capital and mitigate adversities from preconception through adolescence. BMJ Glob Health. 2021;6(4):e004436. doi:10.1136/bmjgh-2020-004436.

7. World Health Organization, United Nations Children's Fund (UNICEF), World Bank Group. Nurturing Care for Early Childhood Development: A Framework for Helping Children Survive and Thrive to Transform Health and Human Potential [Internet]. Geneva: World Health Organization; 2018. 55. Available from: https://www.who.int/publications/i/item/9789241514064.

8. Daelmans B, Manji SA, Raina N. Nurturing care for early childhood development: global perspective and guidance. Indian Pediatr. 2021;58(Suppl 1):11–5.

9. Britto PR, Lye SJ, Proulx K, Yousafzai AK, Matthews SG, Vaivada T, et al. Nurturing care: promoting early childhood development. lancet. 2017;389(10064):91–102. doi: 10.1016/S0140-6736(16)31390-3.

10. Zhang L, Ssewanyana D, Martin MC, Lye S, Moran G, Abubakar A, et al. Supporting Child Development Through Parenting Interventions in Low- to Middle-Income Countries: An Updated Systematic Review. Front Public Health. 2021;9:671988. doi:10.3389/fpubh.2021.671988.

11. 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. doi:10.1371/journal.pmed.1003602.

12. Hamadani JD, Mehrin SF, Tofail F, Hasan MI, Huda SN, Baker-Henningham H, et al. Integrating an early childhood development programme into Bangladeshi primary health-care services: an open-label, cluster-randomised controlled trial. The Lancet Global Health. 2019;7(3):e366–75. doi:10.1016/S2214-109X(18)30535-7.

13. Weber MW, Jullien S, Redlich C, Hall J, Carai S. Improving primary health care for children and adolescents in Europe. Glob Pediatr. 2024;9:None. doi: 10.1016/j.gpeds.2024.100194.

14. Utidjian L, Abramson E. Pediatric Telehealth: Opportunities and Challenges. Pediatr Clin North Am. 2016;63(2):367–78. doi:10.1016/j.pcl.2015.11.006.

15. Jin MX, Kim SY, Miller LJ, Behari G, Correa R. Telemedicine: Current Impact on the Future. Cureus. 2020;12(8):e9891. doi:10.7759/cureus.9891.

16. Boonzaaijer M, van Wesel F, Nuysink J, Volman MJM, Jongmans MJ. A home-video method to assess infant gross motor development: parent perspectives on feasibility. BMC Pediatr. 2019;19(1):392. doi:10.1186/s12887-019-1779-x.

17. Ward V, Abdalla S, Raheel H, Weng Y, Godfrey A, Dutt P, et al. Implementing health communication tools at scale: mobile audio messaging and paper-based job aids for front-line workers providing community health education to mothers in Bihar, India. BMJ Glob Health. 2021;6(Suppl 5). doi:10.1136/bmjgh-2021-005538.

18. Unger JA, Ronen K, Perrier T, DeRenzi B, Slyker J, Drake AL, et al. Short message service communication improves exclusive breastfeeding and early postpartum contraception in a low- to middle-income country setting: a randomised trial. BJOG. 2018;125(12):1620–9. doi:10.1111/1471-0528.15337.

19. Trude ACB, Martins RC, Martins-Silva T, Blumenberg C, Carpena MX, Del-Ponte B, et al. A WhatsApp-Based Intervention to Improve Maternal Social Support and Maternal-Child Health in Southern Brazil: The Text-Message Intervention to Enhance Social Support (TIES) Feasibility Study. Inquiry. 2021;58:469580211048701. doi:10.1177/00469580211048701.

20. Wooldridge AR, Ramadhani WA, Hanson K, Vazquez-Melendez E, Kendhari H, Shaikh N, et al. Web-Based Mindfulness-Based Interventions for Well-being: Randomized Comparative Effectiveness Trial. Ergonomics. 2022;65(3):334–47. doi:10.1080/00140139.2021..

21. Yafie E, Ashari ZM, Samah NA, Setyaningsih D, Putri D, Wahyuningtyas I. Development of SMART-P to improve parental locus of control and children's social-emotional development. Int J Eval & Res Educ ISSN. 2024;2252(8822):8822.

22. Vidal-Balea A, Blanco-Novoa Ó, Fraga-Lamas P, Fernández-Caramés TM. Developing the Next Generation of Augmented Reality Games for Pediatric Healthcare: An Open-Source Collaborative Framework Based on ARCore for Implementing Teaching, Training and Monitoring Applications. Sensors (Basel). 2021;21(5). doi:10.3390/s21051865.

23. Schweizer F, Willinger L, Oberhoffer-Fritz R, Müller J, Jonas S, Reimer LM. KIJANI: Designing a Physical Activity Promoting Collaborative Augmented Reality Game. Stud Health Technol Inform. 2024;313:113–20. doi:10.3233/SHTI240021 .

24. Christakis DA, Lowry SJ, Goldberg G, Violette H, Garrison MM. Assessment of a Parent-Child Interaction Intervention for Language Development in Children. JAMA Netw Open. 2019;2(6):e195738. doi:10.1001/jamanetworkopen.2019.5738.

25. Quantified Assessment of Infant's Gross Motor Abilities Using a Multisensor Wearable. J Vis Exp. 2024. doi:10.3791/65949.

26. Staiano AE, Newton RL, Beyl RA, Kracht CL, Hendrick CA, Viverito M, et al. mHealth Intervention for Motor Skills: A Randomized Controlled Trial. Pediatrics. 2022;149(5):e2021053362. doi:10.1542/peds.2021-053362 .

27. Domin A, Spruijt-Metz D, Theisen D, Ouzzahra Y, Vögele C. Smartphone-Based Interventions for Physical Activity Promotion: Scoping Review of the Evidence Over the Last 10 Years. JMIR Mhealth Uhealth. 2021;9(7):e24308. doi:10.2196/24308.

28. Elbert NJ, van Os-Medendorp H, van Renselaar W, Ekeland AG, Hakkaart-van Roijen L, Raat H, et al. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. J Med Internet Res. 2014;16(4):e110. doi:10.2196/jmir.2790.

29. MacKinnon AL, Silang K, Penner K, Zalewski M, Tomfohr-Madsen L, Roos LE. Promoting Mental Health in Parents of Young Children Using eHealth Interventions: A Systematic Review and Meta-analysis. Clin Child Fam Psychol Rev. 2022;25(3):413–34. doi:10.1007/s10567-022-00385-5.

30. du Toit MN, van der Linde J, Swanepoel DW. mHealth developmental screening for preschool children in low-income communities. J Child Health Care. 2021;25(4):573–86. doi:10.1177/1367493520970012.

31. Areemit R, Saengnipanthkul S, Sutra S, Lumbiganon P, Pornprasitsakul P, Paopongsawan P, et al. Effectiveness of a Mobile App (KhunLook) Versus the Maternal and Child Health Handbook on Thai Parents' Health Literacy, Accuracy of Health Assessments, and Convenience of Use: Randomized Controlled Trial. J Med Internet Res. 2023;25:e43196. doi:10.2196/43196 .

32. Knop MR, Nagashima-Hayashi M, Lin R, Saing CH, Ung M, Oy S, et al. Impact of mHealth interventions on maternal, newborn,

and child health from conception to 24 months postpartum in low- and middle-income countries: a systematic review. BMC Med. 2024;22(1):196. doi:10.1186/s12916-024-03417-9 .

33. Singh K, Walters MR. Use of mHealth in promoting maternal and child health in “BIMARU” states of India “A health system strengthening strategy”: Systematic literature review. PLOS Digit Health. 2024;3(2):e0000403. doi:10.1371/journal.pdig.0000403.

34. Munson E, Hall KS. Opportunities for Increasing Access to Person-Centered Abortion Care Through Telehealth. Am J Public Health. 2024;114(2):152–4. doi:10.2105/AJPH.2023.307541.

35. Seyyedi N, Rahimi B, Eslamlou HRF, Afshar HL, Spreco A, Timpka T. Smartphone-Based Maternal Education for the Complementary Feeding of Undernourished Children Under 3 Years of Age in Food-Secure Communities: Randomised Controlled Trial in Urmia, Iran. Nutrients. 2020;12(2):587. doi:10.3390/nu12020587.

36. Tavassoli G, Samimi T, Farrokh-eslamlou H, Lotfnezhad Afshar H, Gozali E, Timpka T, et al. The Effect of mHealth Interventions on Early Childhood Development: A Systematic Review. Human Behavior and Emerging Technologies. 2025;2025(1):9566241. doi:10.1155/hbe2/9566241.

37. DeWitt A, Kientz J, Liljenquist K. Quality of Mobile Apps for Child Development Support: Search in App Stores and Content Analysis. JMIR Pediatr Parent. 2022;5(4):e38793. doi:10.2196/38793.

38. LaMonica HM, Crouse JJ, Song YJC, Alam M, Ekambareshwar M, Loblay V, et al. Developing a Parenting App to Support Young Children’s Socioemotional and Cognitive Development in Culturally Diverse Low- and Middle-Income Countries: Protocol for a Co-design Study. JMIR Res Protoc. 2022;11(10):e39225. doi:10.2196/39225.

39. Arabiat D, Al Jabery M, Robinson S, Whitehead L, Mörelius E. Interactive technology use and child development: A systematic review. Child Care Health Dev. 2023;49(4):679–715. doi:10.1111/cch.13082.

40. Hamberger M, Ikonomi N, Schwab JD, Werle SD, Fürstberger A, Kestler AM, et al. Interaction Empowerment in Mobile Health: Concepts, Challenges, and Perspectives. JMIR Mhealth Uhealth. 2022;10(4):e32696. doi:10.2196/32696.

41. Karimi M, Emarati A, Nafei Z, Shamsi F, Gashty Mazar N, Akbarian E. Unveiling developmental delays in early childhood: insights from a comparative study of the Bayley Scales (BSID-III) and the ASQ-3 in Iran. BMC Pediatrics. 2025;25(1):158. doi:10.1186/s12887-025-05491-1.

42. Bornstein MH, Rothenberg WA, Lansford JE, Bradley RH, Deater-Deckard K, Bizzego A, et al. Child Development in Low- and Middle-Income Countries. Pediatrics. 2021;148(5):e2021053180. doi:10.1542/peds.2021-053180.

43. Caruso D, Ferreira JC. Randomized controlled trials: advantages and pitfalls when studying causality. J Bras Pneumol. 50(1):e20240052. doi:10.36416/1806-3756/e20240052 PubMed PMID: 38536988; PubMed Central PMCID: PMC11095923.

44. Bayley N. Bayley scales of infant and toddler development-III. Psychological Corporation; 2006.

45. niafam.com. ناکدوک لماکت همانرب [Internet]. [cited 2025 Aug 19]. Available from: https://vch.iums.ac.ir/ناکدوک لماکت همانرب

46. Power and Sample Size Determination [Internet]. [cited 2023 Aug 25]. Available from: https://sphweb.bumc.bu.edu/otlt/mph-modules/bs/bs704_power/bs704_power_print.html

47. RANDOM.ORG. True Random Number Service [Internet]. 2026. Available from: https://www.random.org/

48. Squires J, Bricker DD, Twombly E, others. Ages & stages questionnaires. Vol. 465. Paul H. Brookes Baltimore; 2009.

49. Faruk T, King C, Muhit M, Islam MK, Jahan I, Baset K ul, et al. Screening tools for early identification of children with developmental delay in low- and middle-income countries: a systematic review. BMJ Open. 2020;10(11):e038182. doi:10.1136/bmjopen-2020-038182.

50. Shariatpanahi G, Vameghi R, Ghanbari N, Barekati SH, Lornejad HR, Abolghasemi N. Cultural adaptation, validation, and standardization of a developmental screening tool (ASQ-3) in Iranian children. Iran J Child Neurol. 2024;18(2):55–71. doi:10.22037/ijcn.v18i2.39595.

51. Azari N, Soleimani F, Vameghi R, Sajedi F, Shahshahani S, Karimi H, et al. A Psychometric Study of the Bayley Scales of Infant and Toddler Development in Persian Language Children. Iran J Child Neurol. 2017;11(1):1. doi:10.22037/ijcn.v11i1.12056.

52. Andargeery SY, El-Rafey DS. A randomized controlled trial of the effectiveness of the mHealth program in improving the lifestyle of nursing students. Sci Rep. 2025;15(1):9765. doi:10.1038/s41598-024-80982-2.

53. Bozicevic L, Lucas C, Magai DN, Ooi Y, Maliwichi L, Sharp H, Gladstone M. Evaluating caregiver-child interactions in low- and middle-income countries: a systematic review of tools and methods. J Reprod Infant Psychol. 2025;43(5):1301-1336. doi: 10.1080/02646838.2024.2321615.

54. Christakis DA, Lowry SJ, Goldberg G, Violette H, Garrison MM. Assessment of a Parent-Child Interaction Intervention for Language Development in Children. JAMA Netw Open. 2019;2(6):e195738. doi:10.1001/jamanetworkopen.2019.5738.

55. Le Roux EW, Eccles R, Abdoola S, Graham M, van der Linde J. The effect of a parental mHealth resource on language outcomes in 4-to 5-year-old children. South African Journal of Childhood Education. 2022;12(1):1026 doi:10.4102/sajce.v12i1.1026.

56. Shorey S, Chong Y, Shi L, Chua J, Thilagamangai, Mathews J, et al. Evaluating the Effects of the Supportive Parenting App on Infant Developmental Outcomes: Longitudinal Study. JMIR MHealth and UHealth. 2023;11(1). doi:10.2196/43885.

57. Jäggi L, Hartinger SM, Fink G, McCoy DC, Alvarado Llatance M, Hinckley K, et al. Parenting in the Digital Age: A Scoping Review of Digital Early Childhood Parenting Interventions in Low- and Middle-Income Countries (LMIC). Public Health Rev. 2025 Jan 21;45:1607651. doi:10.3389/phrs.2024.1607651.

58. Singh A, Squires J, Yeh CJ, Heo KH, Bian H. Validity and reliability of the developmental assessment screening scale. J Family Med Prim Care. 2016;5(1):124–8. doi:10.4103/2249-4863.184636.