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VALIDATION OF A MOBILE APPLICATION FOR EARLY DETECTION OF DEVELOPMENTAL DELAYS IN CHILDREN AGED 0 TO 5 YEARS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Early identification of developmental delays in young children optimizes neurodevelopmental outcomes, but coverage and frequency of clinic-based assessments remain inadequate in low-resource settings. Mobile health (mHealth) innovations offer scalable solutions, yet require rigorous validation.

Objective: To validate a mobile application for home-based developmental screening in children aged 0–5 years compared to the Denver Developmental Screening Tool II (DDST-II) and assess parental acceptability.

Methods: A prospective observational study enrolled 340 term, low-risk children (0–60 months) at Saveetha Medical College and Hospital in Chennai. Parents used the custom mobile application for milestone surveillance, while paediatricians, blinded to app results, administered the DDST-II. Sensitivity, specificity, and agreement (Cohen's kappa) were calculated. Parental satisfaction was assessed via Likert scale.

Results: App and DDST-II screening had substantial agreement (κ=0.814, $p<0.001$), with sensitivity and specificity of 89.7% and 89.1%, respectively. Most parents (96.5%) reported high satisfaction scores. Baseline awareness of developmental milestones was moderate to low in over 75% of participants.

Conclusions: The app is as reliable as the DDST-II for detecting developmental delays and highly accepted by users, suggesting robust potential for mHealth integration in routine child care and public health interventions.

INTRODUCTION

Early childhood is a period marked by rapid neurodevelopment, encompassing physical, cognitive, linguistic, and psychosocial domains (1,2). In India, where 1–3% of children under five are affected by global developmental delay (GDD), early identification is critical to optimize outcomes and enable timely intervention (3,4). However, significant barriers persist: many parents have poor awareness of normal milestones, access to developmental specialists is limited, and traditional clinical assessments like the Denver Developmental Screening Test II (DDST-II) require in-person visits and trained personnel (5,6). Consequently, children may be lost to follow-up with crucial delays missed during subsequent months.

Mobile health (mHealth) technology offers an opportunity to democratize developmental surveillance, leveraging smartphone penetration to empower caregivers with tools for milestone tracking and education (7,8). While apps have proliferated in other medical contexts, their validation in pediatric developmental screening remains limited, especially in low- and middle-income countries (9-11). Most existing studies are from high-resource settings and use indirect

parent-reported methodologies, with limited comparison to gold-standard clinical screening. Bridging this gap, this study investigates the diagnostic performance of a custom mobile application, aligned with Indian Academy of Pediatrics (IAP) guidelines, in detecting developmental delays among children aged 0–5 years, compared to conventional DDST-II evaluations.

This study further assesses caregivers' baseline knowledge, satisfaction, and user experience, thus addressing both clinical efficacy and real-world acceptability. The findings provide critical evidence on integrating digital health platforms into pediatric and public health protocols for under-fives in India.

METHODS

Study Design and Setting

Prospective observational study at the Department of Paediatrics, Saveetha Medical College & Hospital, Chennai, India, from January 2024 to January 2025.

Participants

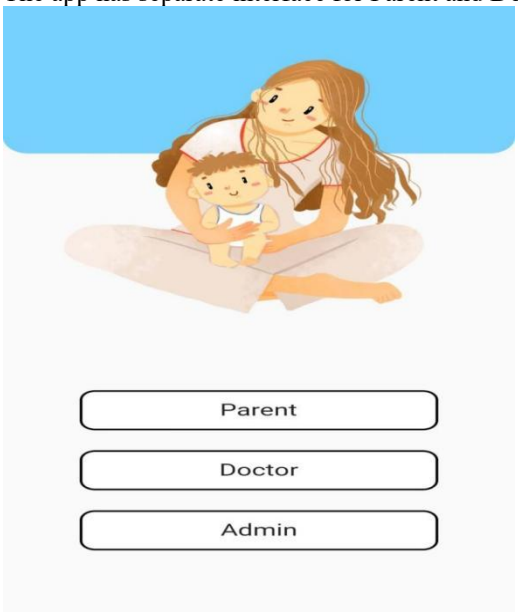
- **Inclusion criteria:** Term-born children aged 0–60 months without significant perinatal complications; caregivers capable of smartphone use.
- **Exclusion criteria:** Preterm births, congenital anomalies, chronic illnesses affecting development, or inability/unwillingness to use the app.

Mobile Application

The app was developed incorporating IAP developmental milestones with monthly age-appropriate milestone questions . Separate interfaces for parents and clinicians were created.

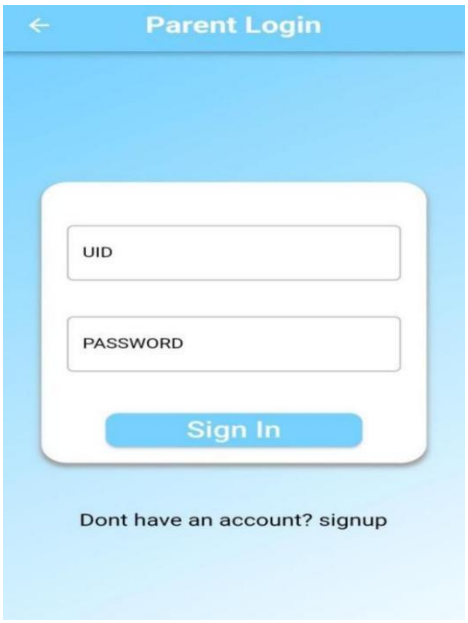
FEATURES OF APP

The app has separate interface for Parent and Doctor with login ID and Password



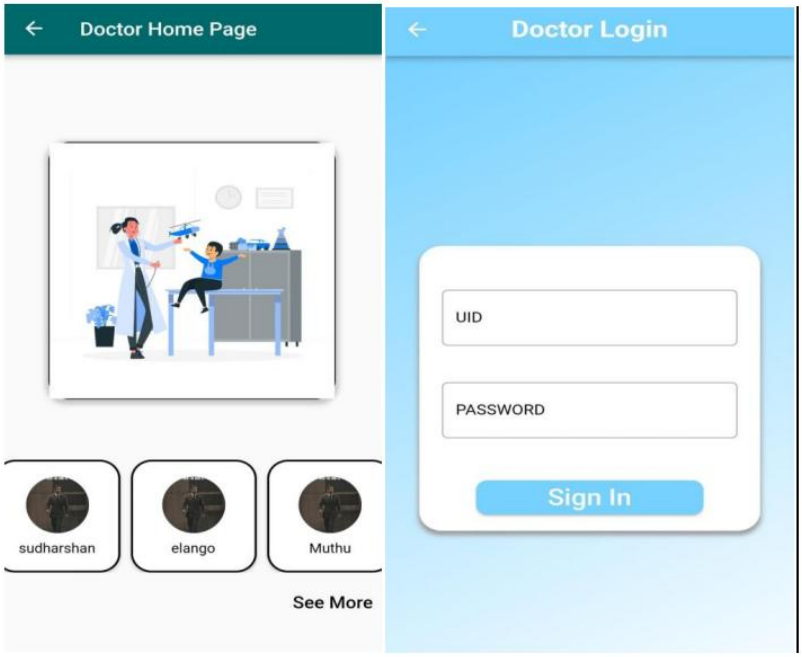
PARENT'S INTERFACE:

Opens with the login page

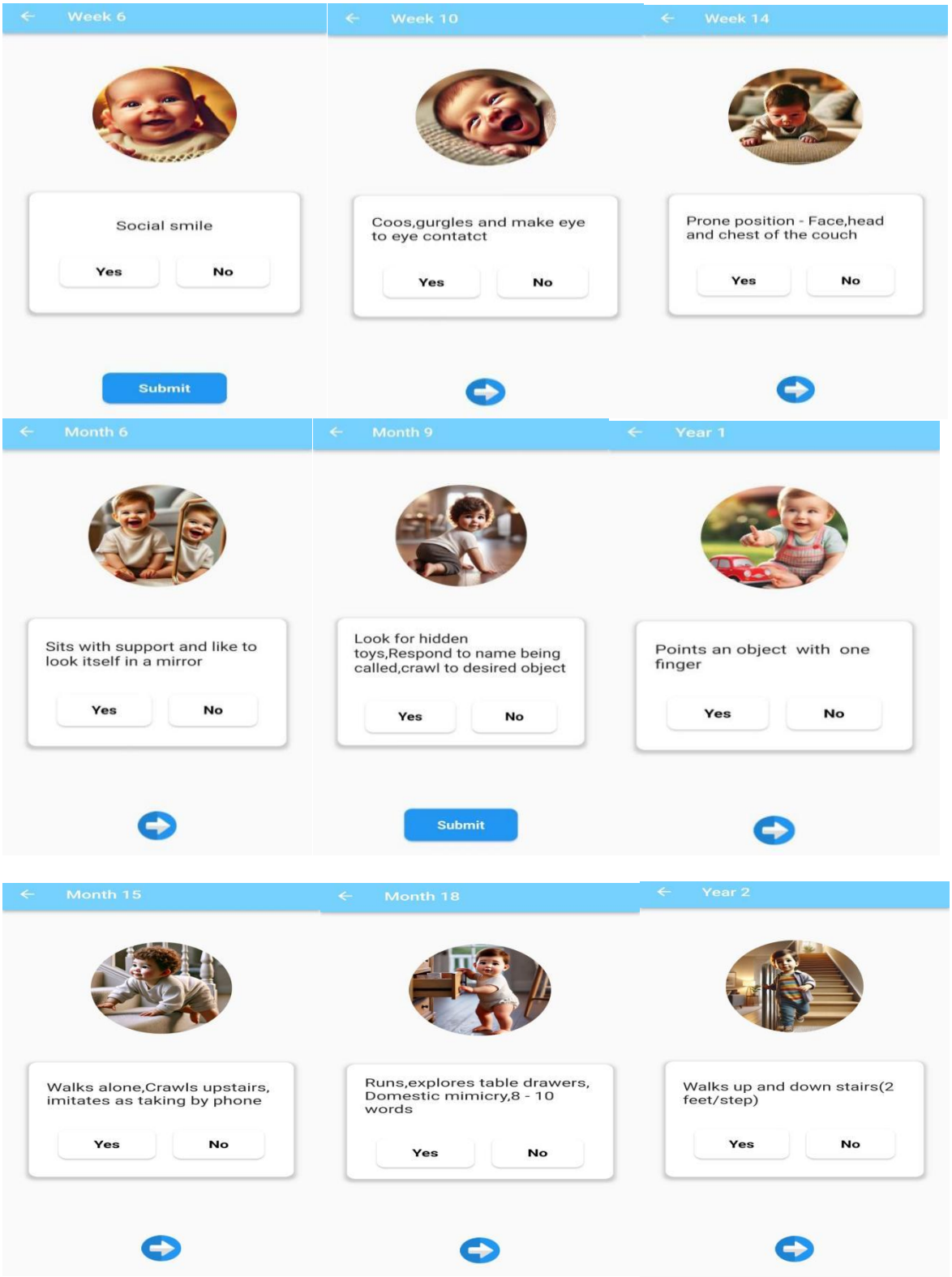


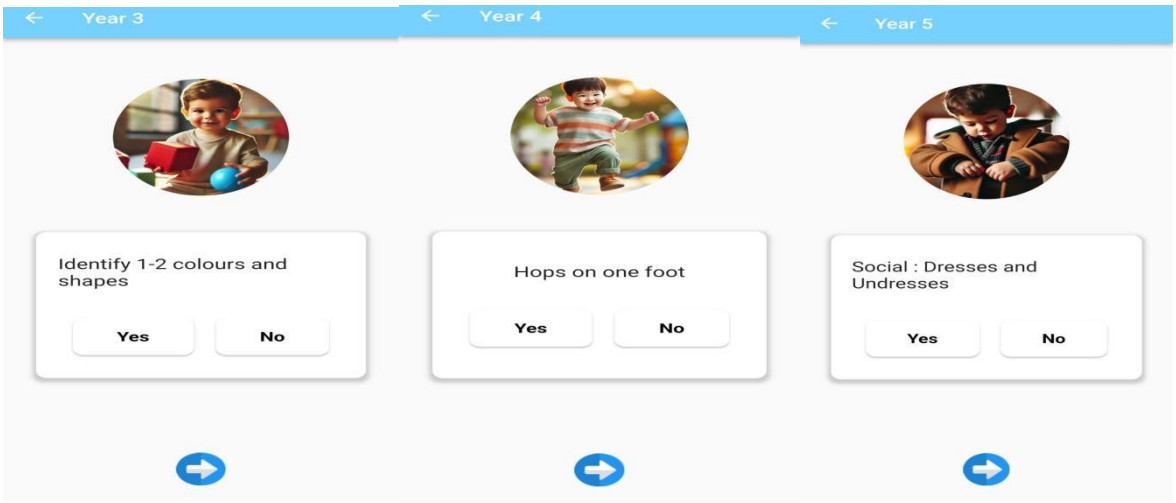
DOCTOR'S INTERFACE:

Doctor's homepage shows the list of patient who are under follow up with him



Milestone related questions will be available according to the age to be answered by the parents with picture depiction for easy understanding


Week 6
Social smile
Yes
No
Submit
Week 10
Coos,gurgles and make eye to eye contatct
Yes
No
Week 14
Prone position - Face,head and chest of the couch
Yes
No
Month 6
Sits with support and like to look itself in a mirror
Yes
No
Month 9
Look for hidden toys,Respond to name being called,crawl to desired object
Yes
No
Submit
Year 1
Points an object with one finger
Yes
No
Month 15
Walks alone,Crawls upstairs, imitates as taking by phone
Yes
No
Month 18
Runs,explores table drawers, Domestic mimicry,8 - 10 words
Yes
No
Year 2
Walks up and down stairs(2 feet/step)
Yes
No



KEY FEATURES OF APP:

Developmental Milestones Tracker: Based on IAP guidelines, the app tracks milestones in cognitive, social, emotional, language, and motor skills using age appropriate questions.

Parental Guidance: Information on activities to support developmental milestones such as interacting with the child, encouraging the child.

Feedback and Alert System: Allows parents to input concerns and alerts healthcare providers if necessary.

Procedures

- Baseline demographic data and parental knowledge assessed.
- Parents used the app monthly to record developmental milestones.
- Pediatricians, blinded to app data, performed standardized DDST-II screening.
- Parental satisfaction regarding app usability was assessed via a 5-point Likert scale.

Sample Size

Sample size of 340 was calculated based on developmental delay prevalence of 3% with 95% confidence and 5% margin of error.

Statistical Analysis

- Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the app compared to DDST-II.
- Agreement measured with Cohen's kappa.
- Analyses performed using SPSS v29; significance set at $p < 0.001$.

Ethical Considerations

- Approved by Institutional Ethics Committee (008/09/2024/IEC/SMCH).
- Written informed consent obtained from caregivers.

RESULTS

Table 1: Demographic Characteristics

Age Group (months)	Frequency	Percentage
0–12	127	37.5
13–36	151	44.4
37–60	62	18.1
Total	340	100.0

Mean child age: 20.6 ± 15.4 months; 183 males (53.8%), 157 females (46.2%).

Table 2: Parental Baseline Knowledge of Developmental Milestones

Score (out of 5)	Frequency	Percentage
2	192	56.5
3	69	20.3
4	79	23.2

No caregiver scored 5.

Table 3: Developmental Delay Detection: App vs. DDST-II

Developmental Status	DDST-II	App
No Delay	305	303
Delay	35	37
Total	340	340

Cross-tabulation:

	DDST-II Delay	DDST-II No Delay
App Delay	30	7
App No Delay	5	298

- Sensitivity: 89.7%
- Specificity: 89.1%
- PPV: 81.1%
- NPV: 96.7%
- Cohen's kappa: 0.814 ($p < 0.001$), indicating substantial agreement.

Table 4: Parental Satisfaction

Satisfaction Score	Frequency	Percentage
5 (Very satisfied)	177	52.1
4 (Satisfied)	151	44.4
≤3	12	3.5

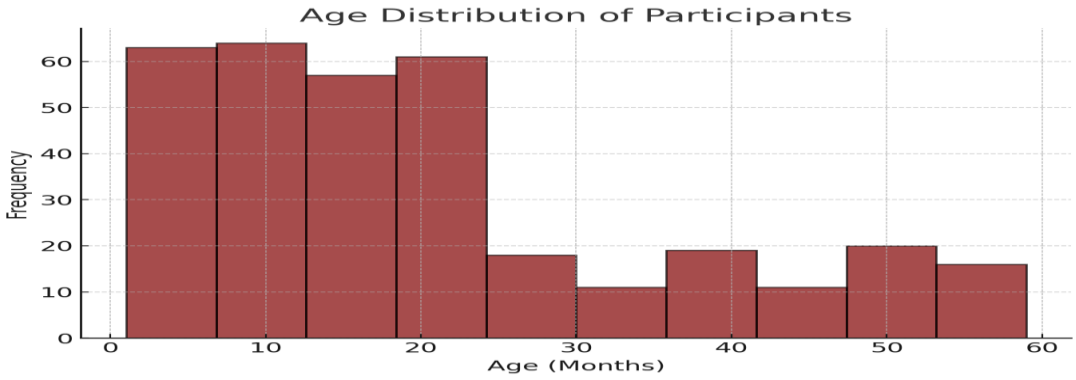


Figure 1: Age Distribution Histogram

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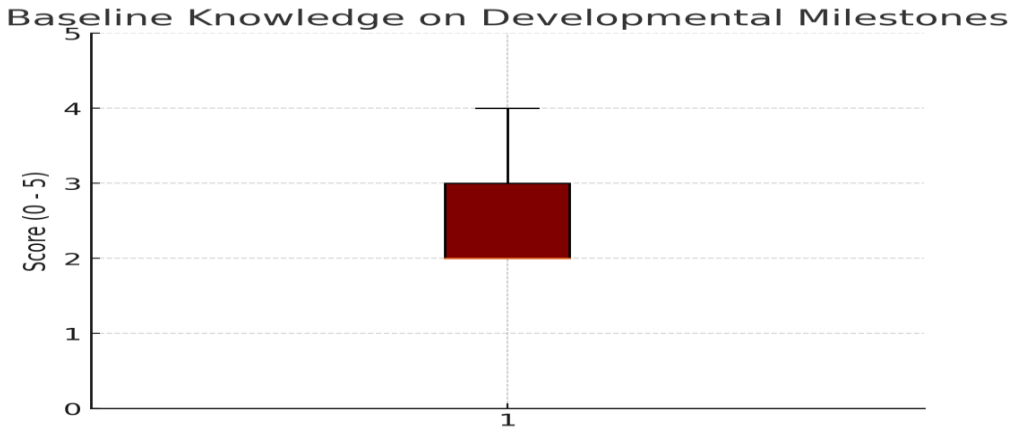

Figure 2: Baseline Parental Knowledge

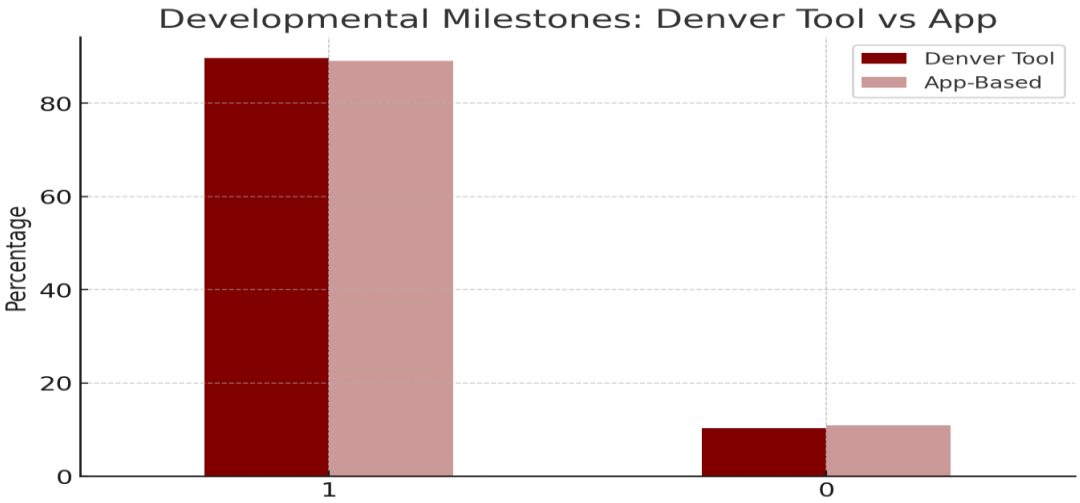

Figure 3: Comparison of Developmental Delay Detection by App vs. DDST-II Bar Graph

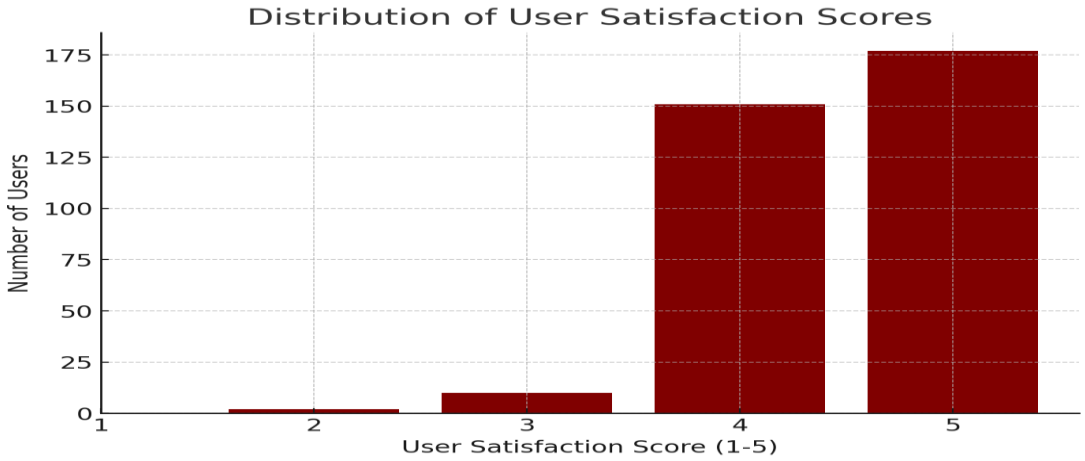

Figure 4: Parental Satisfaction with App — Likert Score Histogram

DISCUSSION

This study highlights the effectiveness of a mobile application in tracking developmental milestones in children aged 0 to 5 years. The integration of digital tools in pediatric healthcare can bridge gaps in early screening, improving diagnostic

accuracy, parental engagement, and timely intervention. The app showed strong agreement with traditional tools, as indicated by Cohen's Kappa values, demonstrating its reliability as a parental and clinical screening tool. Furthermore, it enhances the accessibility of developmental monitoring in resource-limited settings, addressing barriers faced by parents and healthcare providers in ensuring early childhood care.

Developmental delays affect a significant proportion of children worldwide, with a higher burden in low- and middle-income countries (LMICs) due to factors such as nutritional deficiencies, inadequate healthcare access, and limited parental awareness . Studies indicate that early screening and intervention significantly improve long-term cognitive, motor, and social outcomes. Screening tools such as the Bayley Scales of Infant Development, the Ages and Stages Questionnaire, and the Denver Developmental Screening Test have been widely employed for developmental assessments. However, conventional methods require clinic visits, making scalability challenging in remote areas.

Our results align with findings from Gupta et al., who found that digital developmental tracking improved early detection rates by 30% compared to paper-based assessments. Additionally, maternal knowledge and engagement have shown a strong correlation with early identification of developmental issues. By incorporating educational modules and clear interfaces, the app both empowered mothers and improved the accuracy of reported developmental surveillance.

The home-based app allows for continuous surveillance beyond clinic visits, addressing critical follow-up gaps especially in the 3.5–9 month interval when milestone acquisition is rapid. Minor discrepancies between app and clinical assessments likely reflect inherent limitations in subjective parental reporting.

The app-based approach demonstrated high sensitivity and specificity for detecting developmental delays, with few false negatives/positives. Parental knowledge was predominantly moderate or low before intervention, but high app engagement and satisfaction suggest digital tools can overcome knowledge and healthcare access gaps (46,19). mHealth interventions offer unique advantages: scalability, home-based usability, and real-time parental empowerment, while simultaneously educating and engaging caregivers (67,68,70).

Limitations noted include variability in parental compliance, digital literacy barriers, and technical limitations such as device/software reliability. The study was limited to term, low-risk children; thus, generalizability to high-risk groups requires further research.

Nonetheless, the robust concordance ($\kappa = 0.814$) validates the clinical use of such digital tools and reveals their potential integration in early child health protocols. Importantly, the study aligns with national and WHO recommendations for leveraging digital health to improve early childhood outcomes .

CONCLUSION

The validated mobile application demonstrates high diagnostic accuracy, user satisfaction, and operational feasibility for home-based developmental surveillance in Indian children under five. By leveraging digital health solutions, these tools enhance accessibility, efficiency, and precision in pediatric care. The ability to integrate real-time tracking with automated reminders ensures that caregivers can actively participate in their child's health monitoring, bridging gaps often encountered in traditional healthcare systems.

Broader integration of such solutions, especially in public health surveillance, may facilitate earlier identification of at-risk children and timely interventions. The integration of artificial intelligence, telemedicine, and public health initiatives will further elevate the potential of digital healthcare solutions, ensuring better health outcomes for children worldwide. As technology continues to evolve, sustained efforts should focus on optimizing these applications to provide equitable, effective, and scalable healthcare solutions for future generations.

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