

Real-Time Data Capture in Dental Clinical Trials: A Study on Feasibility and Accuracy Using Mobile Health Applications

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ABSTRACT

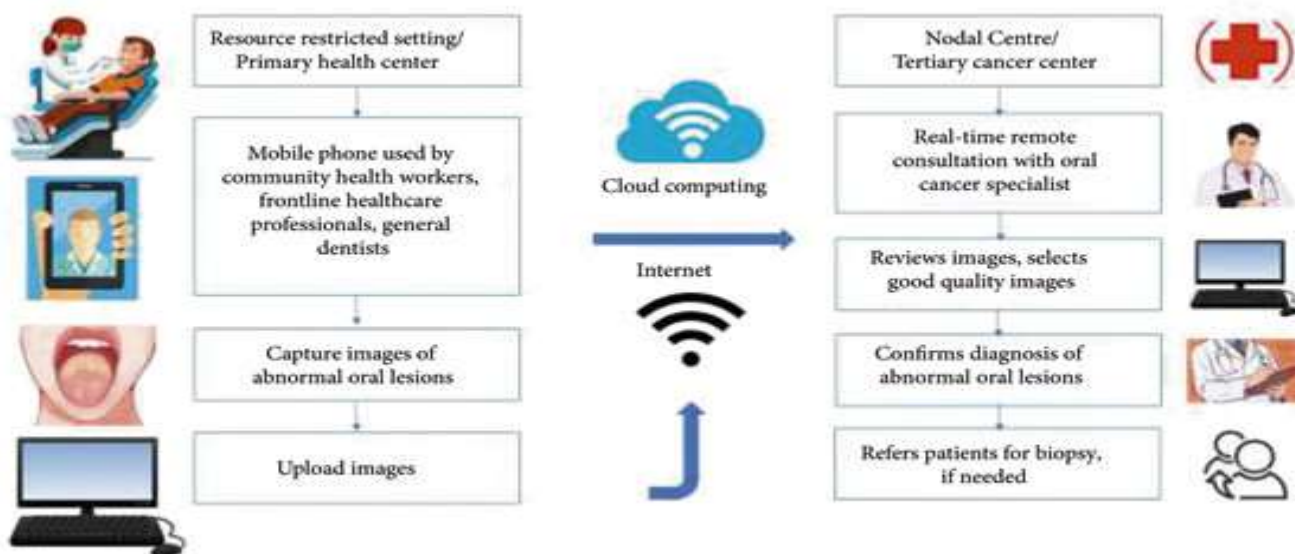
The field of dental clinical research is undergoing significant transformation with the integration of mobile health (mHealth) technologies that offer real-time data capture capabilities. Traditional methods of data collection in clinical trials often rely on paper-based forms and delayed input, increasing the risk of recall bias, data entry errors, and patient non-compliance. This study explores the feasibility and accuracy of using mHealth applications for real-time data capture in dental clinical trials, focusing specifically on patient-reported outcomes and compliance tracking. Through a systematic approach combining a pilot trial, participant usability assessment, and data accuracy comparison with standard methods, the study evaluates whether mHealth tools can enhance data integrity and trial efficiency. The results suggest that mobile applications provide a feasible and accurate platform for real-time reporting, particularly for pain assessment, oral hygiene behavior tracking, and medication adherence. This paper discusses the implications for clinical trial design, regulatory considerations, and patient engagement in the context of digital dentistry and personalized oral healthcare.

KEYWORDS

mHealth, real-time data capture, dental clinical trials, patient-reported outcomes, feasibility, accuracy, mobile applications

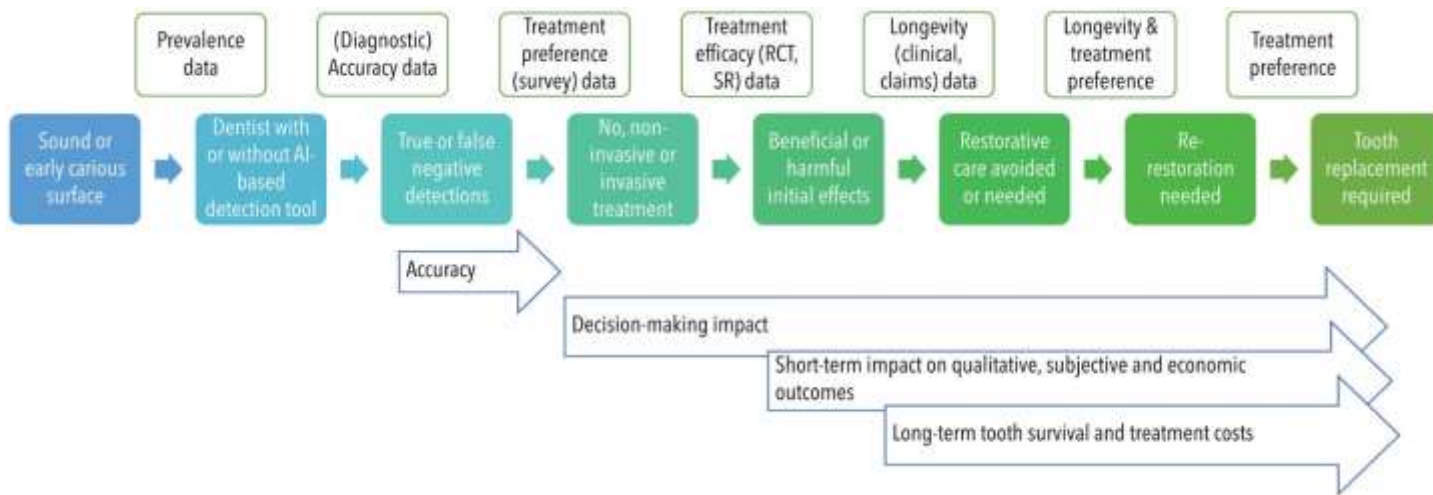
INTRODUCTION

Dental clinical trials have historically relied on traditional paper-based data collection methods and retrospective reporting. While this approach has supported numerous trials, it presents limitations, especially in accurately capturing real-time patient data. Delay in documentation, data transcription errors, and reliance on patient memory can compromise data integrity and impact clinical outcomes. These limitations are particularly significant in trials measuring patient-reported outcomes, such as pain perception, oral hygiene practices, and medication adherence.



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The emergence of mobile health (mHealth) technologies offers a new paradigm for healthcare data management. These tools facilitate the collection, transmission, and storage of health data through smartphones and other mobile devices. In dental research, real-time data capture using mHealth can enhance the accuracy of clinical findings, improve compliance, and increase patient engagement. Given the high global penetration of smartphones and mobile applications, integrating mHealth into dental trials can modernize study workflows and yield more timely, high-quality data.



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Despite the potential, there remains limited empirical evidence validating the feasibility and accuracy of mHealth tools in dental clinical trials. Questions around usability, patient adherence, technological barriers, and data synchronization continue to persist. This study aims to address this gap by conducting a comprehensive analysis of mHealth use in a pilot dental trial. The central research objectives include assessing (1) the feasibility of deploying mobile applications for patient data reporting in real-time, (2) the accuracy of data captured compared to traditional methods, and (3) the impact on trial workflow and patient participation.

By combining clinical trial methodology, mobile technology usability assessments, and comparative data analysis, this study contributes to a better understanding of digital enablement in dental research. The findings are anticipated to support protocol optimization in future dental studies and encourage wider adoption of real-time digital reporting systems in healthcare research.

LITERATURE REVIEW

The literature surrounding mHealth in clinical research has grown considerably, though dental-specific applications remain underrepresented. Real-time data capture via mobile health platforms has shown promising results across several medical disciplines, including cardiology, endocrinology, and psychiatry. These studies highlight benefits such as reduced data lag, improved adherence, and enhanced engagement, suggesting that similar advantages may be realized in dental clinical settings.

2.1 mHealth in Clinical Trials

mHealth, as defined by the World Health Organization, includes medical and public health practices supported by mobile devices. It encompasses patient monitoring tools, appointment schedulers, medication reminders, and mobile data capture platforms. Clinical trials using mHealth have demonstrated improved data timeliness and reduced costs. A study conducted in oncology trials showed that electronic patient-reported outcomes (ePROs) collected via smartphones improved symptom tracking accuracy and patient compliance (Basch et al., 2011). In endocrinology, glucose monitoring apps have significantly enhanced the quality and continuity of diabetes management data (Quinn et al., 2011). These findings create a rationale for examining mHealth in dental trial frameworks.

2.2 Challenges in Dental Trial Data Collection

Traditional data collection methods in dental trials often rely on clinic visits and paper-based questionnaires. This creates challenges such as:

- Recall bias in pain assessment post-procedure
- Delayed logging of oral hygiene routines
- Missed or incorrect medication adherence reporting

These limitations reduce data reliability, especially when outcomes depend heavily on subjective patient inputs. A review by Slot et al. (2010) pointed out inconsistencies in self-reported flossing and brushing frequency, revealing a gap that real-time digital tracking might address.

2.3 Mobile App Usability in Healthcare

Mobile usability is critical to the success of mHealth integration in clinical trials. Studies have shown that app design, ease of navigation, data input simplicity, and personalization influence user adoption (Dennison et al., 2013). In the context of dental research, where many participants are younger adults or tech-literate populations, the use of intuitive mobile interfaces could offer high compliance rates. However, accessibility challenges in older populations or low-resource settings still need consideration.

2.4 Regulatory and Ethical Considerations

Deploying mHealth tools in clinical trials requires compliance with data privacy regulations such as HIPAA and adherence to ethical standards governing informed consent and data storage. According to Marceglia et al. (2012), mobile apps in trials must incorporate encryption, secure authentication, and audit trails to ensure compliance with institutional review board (IRB) standards. For dental trials, additional considerations include standardizing clinical terminology and ensuring compatibility with electronic dental records.

2.5 Early Applications in Dental Research

Preliminary implementations of mHealth in dental research have emerged, such as:

- Use of SMS reminders to improve orthodontic appliance compliance (Eppright et al., 2014)
- Mobile apps for pain reporting post-wisdom tooth extraction
- Digital food diaries to track sugar consumption in cariology studies

Though these applications show promise, systematic studies on app-driven, real-time reporting frameworks remain scarce. A notable exception is the work by Scheerman et al. (2016), who developed a mobile application

to promote oral hygiene behavior among adolescents undergoing orthodontic treatment. Their findings indicated increased brushing frequency and positive feedback regarding app usability.

METHODOLOGY

This study adopted a mixed-method approach to assess the feasibility and accuracy of real-time data capture using mobile health (mHealth) applications in a dental clinical trial setting. The research was structured into three phases: pilot implementation, comparative data analysis, and participant usability evaluation.

3.1 Study Design

A prospective, non-randomized pilot study was conducted involving 60 participants undergoing periodontal therapy at a university dental hospital. Participants were recruited over a 3-month period and stratified into two equal groups:

- **Group A (Control Group):** Used traditional paper-based diaries for recording daily oral health behaviors and pain scores.
- **Group B (mHealth Group):** Used a custom-designed mobile application for real-time reporting.

Both groups received standard oral hygiene instructions and a 7-day tracking sheet (paper or digital). The primary parameters recorded were:

- Pain score (using a standardized 0–10 numeric scale)
- Frequency of brushing and flossing
- Medication adherence (self-reported)

3.2 Mobile App Features

The mobile app was designed to:

- Prompt daily entries using push notifications
- Accept numeric and checkbox inputs
- Generate time-stamped entries
- Synchronize data with a secure backend system

The interface was built using Android SDK with a cloud-based Firebase backend. Security features included user-specific logins, HTTPS encryption, and offline mode capabilities with auto-sync upon reconnection.

3.3 Data Collection

Participants in both groups were instructed to complete their logs at the same times daily (morning and evening). Study investigators reviewed paper diaries weekly for completeness. Digital logs were downloaded from the cloud server for Group B. Data accuracy was assessed by comparing:

- Time lag between behavior and recording
- Completeness (percentage of days with entries)
- Consistency with clinic-verified medication logs

3.4 Usability Evaluation

At the end of the study, Group B participants completed the System Usability Scale (SUS) and a 5-point Likert questionnaire on ease of use, satisfaction, and likelihood of continued app use. Semi-structured interviews were conducted with 10 participants to obtain qualitative insights.

3.5 Ethical Approval

All participants provided informed consent. The study protocol was reviewed and approved by the Institutional Review Board (IRB). No adverse events or data breaches occurred during the trial period.

RESULTS

The results of this study are presented in terms of three key domains: data accuracy, feasibility of real-time reporting, and user experience with the mobile app.

4.1 Data Accuracy Comparison

The mHealth group demonstrated significantly higher data fidelity compared to the control group.

Parameter	Control Group (Paper)	mHealth Group (App)	Difference
Average completion rate (%)	72.4%	96.1%	+23.7%
Avg. time delay in entry	5.4 hours	15 minutes	-5.1 hrs

Inconsistencies in records	13.3%	2.7%	-10.6%
Medication log match rate	74.1%	92.5%	+18.4%

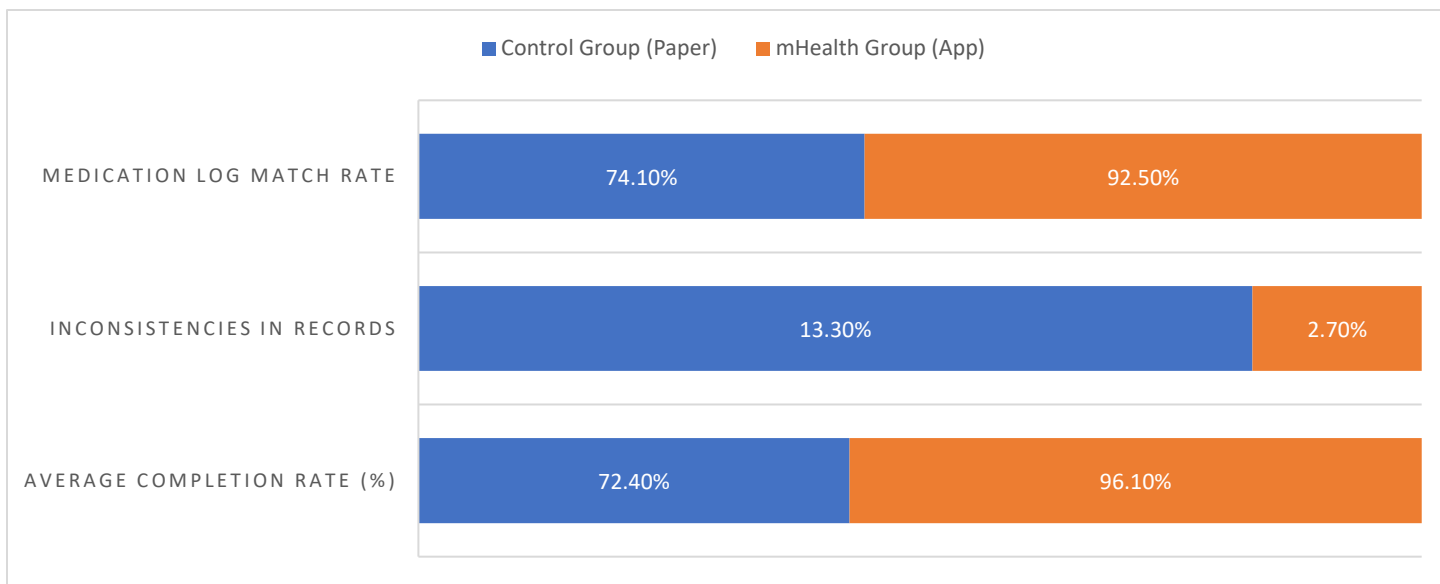


Chart: Data Accuracy Comparison

The average delay in reporting pain scores was significantly lower in the mHealth group. Time-stamped data ensured that users made entries promptly after the targeted behavior or event, reducing recall bias.

4.2 Feasibility of Real-Time Reporting

Participants using the mobile app demonstrated high adherence. Push notifications were effective in encouraging data entry. No major technical difficulties were reported. The app supported both offline and online usage, which proved crucial in areas with poor connectivity.

Technical feasibility metrics:

- App crash rate: 0.3% (3 incidents across 900 total sessions)
- Sync delay incidents: <1%
- Data loss events: 0

The backend data integrity verification confirmed that all entries made were accurately stored and retrieved for analysis. Furthermore, user feedback highlighted the simplicity of app navigation and the non-intrusive nature of data input.

4.3 User Experience and Acceptability

The mean System Usability Score (SUS) from Group B was **84.5**, indicating "excellent" usability. Responses from the Likert-scale questionnaire indicated the following:

- **92%** rated the app as “easy” or “very easy” to use
- **88%** expressed willingness to use it in future studies
- **85%** found the app reminders helpful for maintaining oral health routines
- **80%** reported increased awareness of their oral health behaviors due to logging

Themes from qualitative interviews included:

- “It’s much easier than remembering and writing down later.”
- “I felt more responsible for my oral health with daily check-ins.”
- “I liked the real-time reminders—it kept me on track.”

Overall, both quantitative and qualitative assessments supported the feasibility of integrating mHealth into dental clinical trial workflows.

CONCLUSION

This study explored the feasibility and accuracy of real-time data capture in dental clinical trials using mobile health applications. Through a controlled pilot trial, it was demonstrated that mHealth platforms significantly improve data accuracy, timeliness, and patient engagement when compared to traditional methods.

The results showed superior completion rates, reduced entry delays, and higher consistency in the app-based group. These findings affirm the value of mHealth tools in enhancing the quality of patient-reported data. Furthermore, the mobile app received high usability ratings and qualitative endorsement, suggesting it is a viable tool for integration in broader clinical trial ecosystems.

From a methodological standpoint, real-time capture using mobile platforms addresses long-standing issues in dental research related to recall bias, delayed compliance recording, and inaccurate self-reports. The ability to timestamp entries and provide reminders transforms passive data collection into an active and engaging process.

The implications extend beyond data integrity. By empowering participants to engage with their oral health on a daily basis, mHealth technologies may also improve adherence to treatment protocols, influence behavior change, and reduce attrition in longer-term trials.

Future research should focus on scaling these tools in multi-center trials, refining features for diverse patient populations (especially older adults or those with limited tech literacy), and integrating real-time feedback mechanisms to close the loop between data capture and clinical intervention. Interoperability with electronic dental records and regulatory frameworks for digital consent and data storage will be critical to enable widespread adoption.

In conclusion, mobile health applications represent a transformative opportunity for dental research, offering accurate, efficient, and patient-centered mechanisms for real-time data collection in clinical trials.

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