ORIGINAL RESEARCH ARTICLE

Enhancing Latent Tuberculosis Infection Treatment Adherence with Mobile Health Intervention: A Quasi-Experimental Study

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ABSTRACT

Introduction: While detecting active TB is central to public health efforts, modelling indicates that reducing latent TB through preventive therapy is crucial. Current regimens mitigate risk but are lengthy and have side effects, necessitating support for uninterrupted treatment. This paper presents the development and evaluation of a digital health platform designed to enhance adherence among LTBI patients.

Methods: A Quasi-experimental study was conducted among LTBI patients in Delhi. A total of 163 participants were allocated to intervention (n=82) and control (n=81) groups. Participants were followed up for 6 months post recruitment. Effectiveness of mobile application was evaluated through quantitative tools.

Results: Intervention group participants showed slightly higher treatment completion rates (65.91%), in comparison to participants in control group (63%). The analysis demonstrated no correlation of gender, age, education and employment with treatment completion rates in intervention group. While text and video-based interventions have shown success, there remains a need for more user-centric digital health interventions in this area, given the limited number of studies to date.

Conclusion: The mobile health applications can be useful for LTBI care. However, there is a need of involving users during development so that continued interest of users can be ensured.

Keywords: Latent TB Infection, Digital Health Technology, M-Health Application, Treatment Adherence, Tuberculosis

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INTRODUCTION

The End TB Strategy of the World Health Organization (WHO) aims to reduce tuberculosis (TB) deaths by 95% and incidence by 90% worldwide by the year 2035.[1] While detecting active TB cases has been the mainstay of public health response to TB, model indicates that lowering reservoir of latent TB infections (LTBI) through preventative therapy is crucial to achieving these challenging goals.[2] A state of enduring immune response to Mycobacterium tuberculosis antigen stimulation without clinically evident active tuberculosis is known as LTBI.[3]

LTBI can be efficiently managed to avoid active TB, resulting in significant benefits for individuals, communities, and nations alike. Currently, existing treatment methods can lower the chance of getting active TB by 60% to 90%, however, therapy is not feasible and has the risk of significant and fatal side effects.[3] Therefore, it is essential to support patients in completing their treatment without any hindrance. One of the solutions for this can be the use of digital technologies. In 2015 and 2017, WHO organized technical meetings to explore the integration of digital technologies into the End TB Strategy which resulted in the development of a conceptual framework for grouping digital health innovations.[4,5]

Digital health innovations such as short messaging service (SMS), video observed treatment (VOT), and event monitoring devices have been integrated into practice, tested, and evaluated in field trials focused specifically on TB prevention and care.[5,6] However, effective implementation of digital health intervention requires due consideration in terms of the larger context of the health system and patient population in which they will operate.[7] Innovations, based on user feedback can be one of the effective solutions to ensure the optimum use of digital intervention. Increasing patient or user involvement in the design of technological tools is essential to creating digital health solutions that are relevant, usable, and effective.[8] The user-centric design describes a wide range of techniques that allow end users, including patients, to influence the design of technology.[8]

The present study has been conducted to assesses the effectiveness of the mobile application to address the needs of LTBI patients and healthcare providers in improving treatment adherence and management. By evaluating the "My Treatment Friend" application, this research aims to provide valuable insights into the potential benefits and challenges associated with integrating digital health solutions into LTBI care. These findings could inform future improvements and the strategic use of mobile technologies in latent tuberculosis management. The present study was conducted as a part of PhD research and the study protocol was published elsewhere.[9]

METHODOLOGY

Ethical consideration: The present study is approved by the Institutional Review Board- University Research Ethics Committee of DIT University, Uttarakhand, India with a protocol number: DITU/UREC/2022/04/8. Informed consent was sought from all participants involved in the study process.

Study design: We conducted a quasi-experimental study which was conducted in a chest clinic of New Delhi from April 2023 to June 2024 to implement and evaluate a "My Treatment Friend' mobile application for the patients with LTBI. The LTBI patients were matched based on gender and were allocated to intervention and control groups (1:1 ratio). Figure-1 provides the study framework as per CONSORT guidelines.[10]

Sample size estimation: Assuming an alpha level of 0.05 and a statistical power of 80%, it was projected that the intervention group would attain an 80% adherence rate, in contrast to 60% in the control group. This calculation determined the need for a total sample size of 162 participants, with 81 in each group.

Study procedure: As a first step, a mobile application "My Treatment Friend" was developed based on users- Pulmonologists, and LTBI patient's feedback. The development of the application includes multiple pretesting phase such as questionnaire pretesting among LTBI patients and testing of the prototype application among LTBI patients. Information was put into designing to improve it further to come out with the final application and then made it available on google play store.

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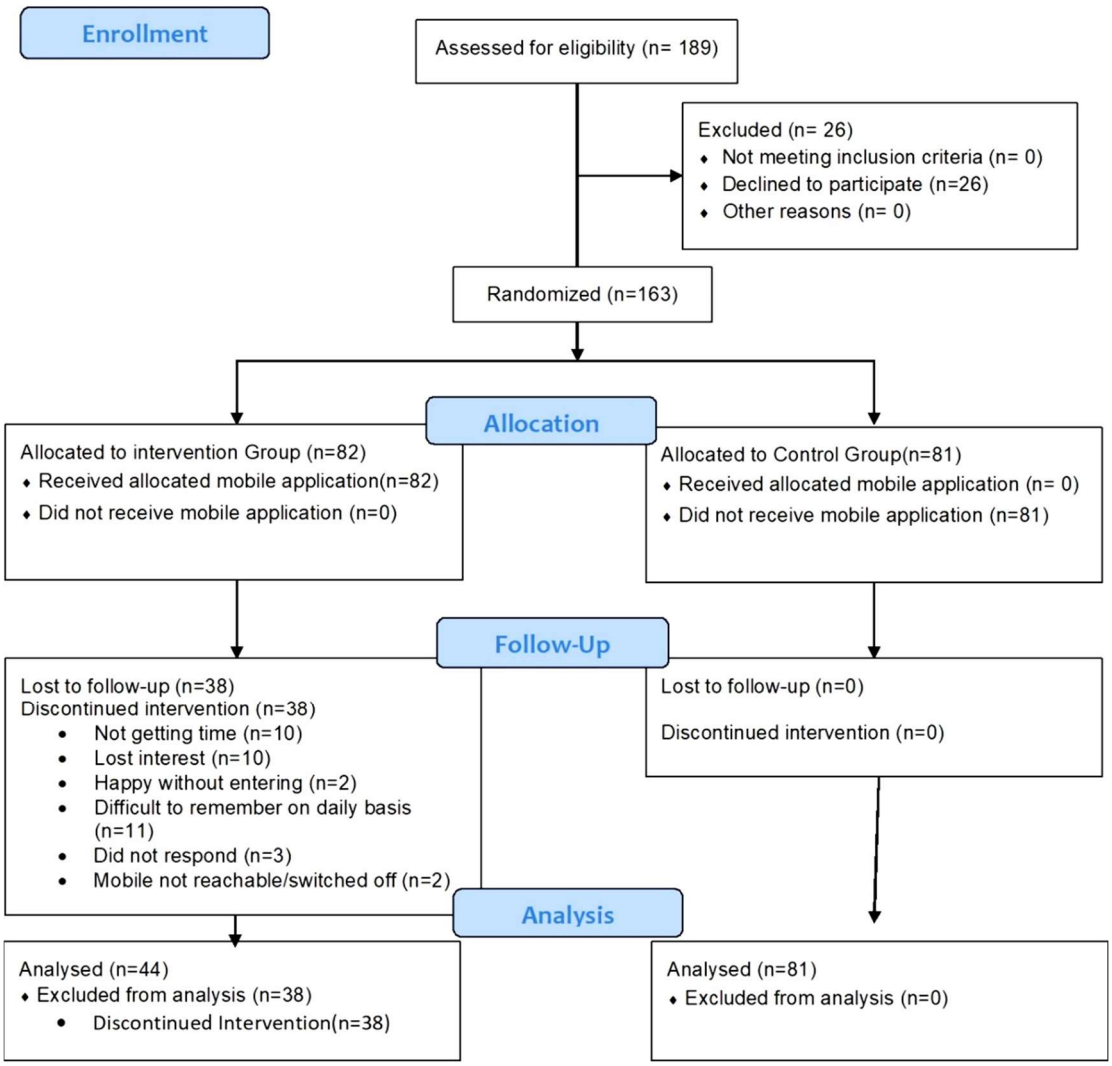

Fig 1: CONSORT flow diagram

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After completion of the development of mobile application, access of smartphone application was given to 82 patients from intervention group. During September to December 2023, a total of 189 LTBI patients were approached and out of them 163 household contacts of pulmonary TB patients of all ages, scheduled for a six-month daily isoniazid treatment, were recruited in the study using convenience sampling.

Patients were recruited using socio demographic information such as name, age, gender, place of living, education, employment status, language, preferred message time, mobile number, and the name of their chest clinic in the mobile application. The digital consent has been made mandatory once patient login first time in the application. Once consent has been sought, an OTP will be sent to the patients preferred email address. Entering this OTP will grant access to the application. In terms of data security, this platform follows international protocol on data confidentiality, and patient information is all password protected. The baseline quantitative assessment was conducted at the time of recruitment and patients were asked to use the mobile application for the period of 6 months.

Eligibility criteria

Inclusion criteria: Patients scheduled for six monthly isoniazid (INH), Patients with access to

android mobile phone, have started LTBI treatment, willing to participate and in case of minor patients, parents or guardians are agree to give consent were included.

Exclusion criteria: Patients who did not have android mobile phones, suffering from active tuberculosis and unwilling to participate were excluded.

Description of Intervention- ***"My Treatment Friend"*** **Application**

Both patient login and admin login are separate and each patient registers with his/her email with OTP and full control is given to the patient to follow treatment adherence in LTBI. Application's interface screenshots are given in annexure-1. The components of mobile application are as follows:

A. **Health update**: In this section, patients need to fill in the update about their medicine as per the questions given in application and then click on submit. All information provided by the patient will be visible on the admin dashboard.
B. **Notifications**: In this section, patients can see all notifications and messages sent by the treating provider and clinic.

Study tools: Participants received detailed information about the study at the time of recruitment and a comprehensive debriefing on mobile application has been done. Baseline data was collected via a Google Form questionnaire, with patients providing informed consent through an embedded acceptance. Endline data was collected from the intervention group using a Likert scale questionnaire to assess participant perceptions and satisfaction.

Data Analysis: Data were managed through MS Excel and analyzed using SPSS-20 software to ensure accuracy and reliability. The Pearson chi-square test was utilized to identify and compare distribution differences between the intervention and control groups, with a significance level established at 5% (p value < 0.05). The analysis primarily concentrated on several key areas: demographic profiles of the participants and the correlation between the use of the mobile application, treatment outcomes and correlation of demographic profile characteristics with treatment completion. This statistical approach was designed to provide a comprehensive assessment of the mobile application's impact on treatment adherence among LTBI patients, thereby contributing valuable insights into its effectiveness and potential areas for improvement.

RESULTS

Baseline characteristics: The comparison between the intervention and control groups reveals several key differences. Gender distribution shows a slightly higher proportion of males in the intervention group (58.5%) compared to the control group (43.2%), with a p-value of 0.05, suggesting a marginally significant difference. Age distribution did not show significant differences, though the control group had more participants in the youngest and oldest age brackets. Language proficiency shows a notable difference, with the control group being exclusively Hindi-speaking, while 11% of the intervention group also spoke English (p=0.009). Educational levels were somewhat similar across groups, with a higher percentage of participants in the control group having education beyond the 12th grade, though this difference was not statistically significant (p=0.113). Employment status varied significantly (p<0.001), with more intervention group members engaged in labour work and private jobs, while the control group had more students and homemakers.

Table-1: Demographic characteristics of study participants

Variables	Intervention (n=82)(%)	Control (n=81) (%)	P-Value
Gender			
Male	48 (58.5)	35 (43.2)	0.05
Female	34 (41.5)	46 (56.8)	
Age (in yrs.)			
1-5	2 (2.4)	15 (18.5)	0.365
16-30	34 (41.5)	24 (29.6)	
31-50	41 (50.0)	30 (37.0)	
>50	5 (6.1)	12 (14.8)	
Language			
Hindi	73 (89.0)	81 (100)	0.009
Hindi & English	9 (11)	0 (0)	
Education			
Upto Class 5th	15 (18.3)	9 (11.1)	0.113
Upto Class 10th	27 (32.9)	18 (22.2)	
Upto Class 12th	17 (20.7)	26 (32.1)	
Graduation	20 (24.4)	28 (34.6)	
Post graduation	3 (3.7)	0 (0)	
Employment			
Business	18 (22)	23 (28.4)	<0.001
Government Job	2 (2.4)	0 (0)	
House maker	19 (23.2)	26 (32.1)	
Labour work	17 (20.7)	0 (0)	
Private Job	11 (13.4)	2 (2.5)	
Student	14 (17.1)	28 (34.6)	
Unemployed	1 (1.2)	2 (2.5)	
Diabetes Status			
Yes	1 (1.2)	2 (2.5)	0.62
No	81 (98.8)	79 (97.5)	
Tobacco Consumption Status			
Yes	4 (4.9)	1 (1.2)	0.367
No	78 (95.1)	80 (98.8)	

Table 2: Treatment completion rates and side effect reporting

Variables	Intervention (n=44) (%)	Control (n=81)(%)	P-value
Treatment completed			
Yes	29 (65.91)	51 (63)	0.743
No	15 (34.09)	30 (37)	
Side effect reported			
Yes	15 (34.09)	0	
No	29 (65.9)	0	
Reasons for discontinuation (n=38)			
Not getting time	10 (26.3)	0	
Lost interest	10 (26.3)	0	
Happy without entering	2 (5.26)	0	
Difficult to remember on daily basis	11 (28.9)	0	
Did not respond	3 (7.9)	0	
Mobile not reachable/switched off	2 (5.26)	0	

Table-3: Association of treatment completion in mobile application users with demographic characteristics

Variables	Treatment Completed (n=44)		P-value
	Yes (%)	No (%)	
Gender			
Male	19 (65.5)	7 (46.7)	0.228
Female	10 (34.5)	8 (53.3)	
Age			
1-15	1(3.4)	0 (0)	0.825
16-30	9 (31)	6 (40)	
31-50	16 (55.2)	8 (53.3)	
>50	3(10.3)	1 (6.7)	
Education			
1-5	4 (13.8)	2 (13.3)	0.393
6-10	13 (44.8)	4 (26.7)	
11-12	4 (13.8)	6 (40)	
Graduation	7 (24.1)	3 (20)	
Post graduation	1 (3.4)	0 (0)	
Employment			
Business	11 (37.9)	2 (13.3)	0.534
Government job	1 (3.4)	0 (0)	
House maker	6 (20.7)	5 (33.3)	
Labour work	3 (10.3)	4 (26.7)	
Private Job	4 (13.8)	2 (13.3)	
Student	3 (10.3)	2 (13.3)	
Unemployed	1 (3.4)	0 (00	

There were no significant differences in diabetes status (p=0.62) or tobacco consumption (p=0.367) between the groups. The table-1 provides the detailed overview about demographic characteristics.

Impact of mobile application on treatment adherence: A total of 82 participants were given access to mobile application out of which 44 participants used the application throughout the treatment completion period and remaining 38 discontinued the use of application in between due to multiple reasons. A total of 26.3% of participants in the intervention group discontinued due to lack of time. Same percentage of participants discontinued because they lost interest in using mobile application. Approx. 5.26% of participants in the intervention group stopped because they felt satisfied without using the application. Nearly 28.9% of participants in the intervention group discontinued due to difficulty remembering daily use. The reasons were not listed for remaining participants due to lack of response.

Table 2 summarizes the analysis of the treatment completion rates. The treatment completion rates are relatively similar between the intervention and control groups, with the intervention group showing a slightly higher rate of 65.91% compared to 63.00% in the control group. The p-value of 0.743 suggests that this difference in treatment completion rates is not statistically significant. Data further revealed that 34.09% reported side effects, while 65.9% participants did not report any side effects.

Association of treatment completion in intervention group: Table-3 discovers the correlation between treatment completion of intervention group participants who used mobile application and various demographic factors including gender, age group, education level, and employment status, with corresponding p-values to report statistical significance. The data reveals that gender does not significantly correlate with treatment completion, as both males (62.1%) and females (37.9%) show similar rates, with a p-value of 0.228 indicating no statistical significance. Age group analysis shows the highest completion rate (55.2%) among the age group of 31-50 years, but no statistically significant difference has been reported with p value 0.825. The treatment completion rates for education level show that up to class 10th education have the highest rate (44.8%), yet no statistically significant difference has been found with p value00.393. Participants in business (37.9%) and homemakers (20.7%) show higher completion rates, but these differences are not statistically significant with p value 0.534. Overall, the analysis demonstrates that none of the demographic factors analyzed significantly correlate with treatment completion rates, as all p-values are well above the conventional threshold for statistical significance (>0.05).

Feedback of users on mobile application: In this study, more than three fourth (77.2%) participants reported that they were comfortable using the "My Treatment Friend" app, while only 15.9% felt uncomfortable, and 6.8% were

neutral. Regarding receiving messages and alerts through the app, approximately 79.5% of users found this feature convenient, with only 4.5% finding it bothersome, and 15.9% being indifferent. Similarly, over 77% of users had no issues with receiving tuberculosis education and information through the app. A small proportion (4.5%) expressed dissatisfaction, while 18.2% were neutral. All users confirmed that they received daily messages as scheduled. Regarding medication reminders, 86.3% of users found them useful, whereas 13.6% did not. Likewise, 86.3% of users believed the application was beneficial for reporting side effects, with 13.6% holding a contrary view. A similar trend was observed in the application's support for treatment completion, with 86.3% of users finding it beneficial and 13.6% finding it less so. The table-4 provides the analysis of participants responses on application's effectiveness.

Table-4: Participants feedback on application "My Treatment Friend"

Variables	Intervention Group (n=44) (%)
Comfortable in using the mobile application	
Strongly disagree	0 (0)
Disagree	7 (15.9)
Neutral	3 (6.8)
Agree	24 (54.5)
Strongly agree	10 (22.7)
Comfortable to receive messages in mobile application	
Disagree	2 (4.5)
Neutral	7 (15.9)
Agree	25 (56.8)
Strongly agree	10 (22.7)
Comfortable receiving general TB education or information through mobile applications	
Disagree	2 (4.5)
Neutral	8 (18.2)
Agree	24 (54.5)
Strongly agree	10 (22.7)
Worried while using text messages from mobile application	
Strongly disagree	10 (22.7)
Disagree	26 (59.1)
Neutral	5 (11.4)
Agree	3 (6.8)
Received the daily message on mobile application	
Strongly agree	44 (100)
Received messages from 7 am to 12 noon on daily basis	
Strongly agree	44 (100)
Text message reminder helped you in taking medicine	
Disagree	6 (13.6)
Agree	28 (63.6)
Strongly agree	10 (22.7)
Application helped in reporting side effects to your treating doctor	
Disagree	6 (13.6)
Agree	28 (63.6)
Strongly agree	10 (22.7)
Application helped you in communicating effectively with clinic	
Disagree	6 (13.6)
Agree	28 (63.6)
Strongly agree	10 (22.7)
Regular reminders helped you in completion of treatment	
Disagree	6 (13.6)
Agree	28 (63.6)
Strongly agree	10 (22.7)

DISCUSSION

This study was conducted among 163 LTBI patients to find out the impact of mobile health application "My Treatment Friend" on treatment adherence and outcomes. It was observed that the participants who used the mobile application throughout their treatment period showed higher treatment completion rates (65.9%) whereas in control group, the completion rate was 63%. It depicts that slight improvement was observed in treatment completion rates of intervention group. A study conducted by CL Lam et al. revealed a notable improvement in treatment completion rates within the intervention group as compared to

the usual care group, with the intervention group achieving a completion rate of 88%, while the usual care group had a significantly lower rate of 64.9%.[11] Additionally, research by Szu-Hsuan Chen et al., which employed video-based technology for managing latent tuberculosis, further supported the findings of present study.[12]

Conversely, a study by Johnston et al. utilized a text message-based intervention for LTBI care and found nearly identical treatment completion rates between the intervention group (79.4%) and the control group (81.9%).[13] Furthermore, there was no observable difference in treatment adherence rates between the two groups. The study also assessed secondary outcomes related to Health-Related Quality of Life (HRQoL) and found no correlation with the intervention. Similarly, Belknap et al. conducted a study on a self-administration with reminders technology, reported a comparable overall treatment completion rate across both intervention and control groups.[14] These findings suggest that while text message-based and reminder-based interventions are promising tools for patient engagement, and they may not significantly impact treatment completion or adherence rates in the context of LTBI care.

The current study also demonstrated that very few patients (34.09%) reported side effects due to the medicines. The factors behind this may be evaluated further to understand the scope in this area. This study reported a high dropout rate of 46% and the major reasons were the lack of time and losing interest, it necessitates involving more features into the application which can enhance interests of users. The application may be supported by games, reward coupons or vouchers for continuous engagement with participants.

Data shows that a considerable number of downloaded applications are either utilized just once or removed within a month, underscoring the necessity to consider not just accessibility but also the real utilization of these resources.[15] Having the application users involved is likely to ensure that application is easy to use and fit for purpose so that they will promote it. The Ottawa Charter for Health Promotion and the WHO Global Strategy for Health for All by 2030 also emphasize community engagement in designing, implementing, and evaluating public health programs.[16] Studies indicate that the active involvement of users is essential for the effectiveness of web-based interventions aimed at behavior change and mobile health applications, resulting in improved health results.[17,18] Moreover, utilizing user experience research in the patient-focused development of a digital health product yields valuable insights that can enhance the product's adoption and effectiveness potential.[19]

The studies suggest that participants perceived their opinions as respected and heard, and they felt appreciated for their input in a technology development setting by researchers.[20,21] However, creating a successful mobile app tailored to user preferences based on their feedback is highly challenging. Despite abundant user feedback, many new applications struggle with low download rates.[22] Additionally, some users are reluctant to provide feedback. The utilization of digital platforms for TB care has been explored. However, digital health interventions that aim to improve patient health and quality of life often overlook patient involvement.[23] For LTBI care also, a few digital interventions have been explored and most of them have not mentioned about user's perspective understanding before designing it.

In addition, understanding how to use digital technologies effectively is crucial for patient-centered treatment support and resource allocation.[24] These technologies can be adapted from other fields that have tailored solutions to patients' and providers' perspectives to enhance feasibility in the TB context.[25] Moreover, these technologies can improve TB care by reducing costs and inconvenience, especially as mobile devices become increasingly used for communication.[23] Therefore, digital health technologies based on user or user-centered design could be beneficial in improving LTBI care by enhancing treatment adherence, screening retention, and potentially reducing costs.

Limitations

While our study offers valuable insights, its reach to limited site suggests caution in generalizing the findings. This limitation highlights the importance of conducting additional research across diverse settings to identify the most effective strategies for improving treatment adherence among LTBI patients.

Conclusion

Although the intervention group showed a slightly higher treatment completion rate, the

lack of statistical significance (p=0.743) indicates that the intervention did not significantly impact treatment adherence. Further research is necessary to identify factors that could improve the effectiveness of such interventions. In addition, there is a need to integrate more user-centered features into the mobile application to maintain and enhance user engagement over time. The positive feedback from most participants highlights the potential of digital health interventions to improve treatment adherence and outcomes in LTBI patients, emphasizing the importance of incorporating these technologies into standard healthcare practices.

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