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Original Article

AI-guided cough monitoring feedback versus standard care for improving treatment adherence in drug-sensitive pulmonary tuberculosis patients.

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ABSTRACT

Background: Suboptimal adherence to prolonged tuberculosis treatment compromises therapeutic response and increases the risk of unfavourable outcomes. Patient-facing acoustic feedback may provide objective reinforcement of early symptomatic improvement. **Objective:** To determine whether smartphone-delivered, AI-generated cough-frequency feedback improves medication adherence and week-six sputum culture conversion in adults with drug-sensitive pulmonary tuberculosis. **Methods:** This parallel-group randomized controlled trial enrolled 94 adults with newly diagnosed, bacteriologically confirmed drug-sensitive pulmonary tuberculosis from tertiary-care clinics in the Islamabad–Rawalpindi region. Participants were allocated to standard care plus AI-guided cough feedback or standard care alone. Medication adherence was measured using electronic pillboxes, while sputum culture status, cough severity, and acoustic cough frequency were assessed over six weeks. Complete-case analyses included 88 participants. **Results:** Mean adherence was higher in the intervention group than in the control group (94.2% ± 4.1% versus 86.5% ± 7.8%; mean difference 7.7 percentage points, 95% CI 5.0 to 10.4; p<0.001). Week-six culture conversion occurred in 90.9% and 70.5%, respectively (risk ratio 1.29, 95% CI 1.04 to 1.60; p=0.016). Week-six cough severity was also lower in the intervention group. **Conclusion:** AI-generated cough feedback was associated with improved short-term adherence and week-six culture conversion, but longer intention-to-treat trials are required. **Keywords:** Acoustic Monitoring; Artificial Intelligence; Cough; Medication Adherence; Mobile Health; Randomized Controlled Trial; Tuberculosis.

INTRODUCTION

Tuberculosis remains a major cause of infectious-disease morbidity and mortality worldwide despite the availability of effective multidrug treatment regimens (1). Standard treatment for drug-sensitive pulmonary tuberculosis requires sustained adherence to daily combination therapy for at least six months. Although these regimens are highly effective when taken as prescribed, their prolonged duration, medication-related adverse effects, socioeconomic barriers, treatment fatigue, and perceived early recovery may contribute to missed doses or premature discontinuation. Inadequate adherence increases the risks of persistent infection, treatment failure, relapse, continued transmission, and the emergence of drug-resistant tuberculosis, making effective and scalable adherence-support strategies an important component of tuberculosis control (2).

Directly observed therapy has historically been used to support adherence by requiring a healthcare worker or trained observer to verify medication administration. Although this approach provides direct oversight, repeated travel, scheduling demands, stigma, workforce requirements, and implementation costs may limit its acceptability and sustainability for both patients and healthcare systems (3). Digital adherence technologies have therefore been introduced as alternatives or adjuncts to conventional supervision. These approaches include short-message reminders, electronic medication monitors, smart pillboxes, and video-observed therapy. Evidence suggests that such technologies may improve treatment monitoring and facilitate earlier identification of missed doses; however, most primarily document medication-taking behaviour or provide reminders rather than presenting patients with objective evidence of their symptomatic response to therapy (4).

Cough is a prominent symptom of pulmonary tuberculosis and commonly decreases after the initiation of effective treatment. Its frequency may therefore serve as a candidate digital marker of symptomatic change, although cough patterns may also be influenced by airway inflammation, environmental exposure, comorbid respiratory conditions, medication use, and individual cough sensitivity (5). Conventional assessment relies largely on patient recall and intermittent clinical evaluation, which may not accurately represent changes occurring throughout the day or during sleep. Advances in acoustic signal processing and artificial intelligence have enabled consumer devices, including smartphones, to detect and quantify cough events with limited active input from the user. These technologies offer a non-invasive method for monitoring longitudinal changes in respiratory symptoms, although their clinical value depends on algorithmic accuracy, recording conditions, patient engagement, and appropriate interpretation of the generated data (6).

Presenting longitudinal cough-frequency trends directly to patients may provide an additional behavioural feedback mechanism. Visible evidence of declining cough frequency could strengthen patients' perception of treatment benefit and support continued medication-taking behaviour, whereas an unexpected increase or lack of improvement might prompt clinical reassessment. This proposed mechanism is consistent with self-monitoring and feedback-based approaches to health-behaviour modification, but it has not been established that patient-facing acoustic feedback improves tuberculosis treatment adherence or microbiological response (7). Existing mobile-health interventions in tuberculosis have largely focused on reminders, electronic monitoring, or remote observation, while evidence evaluating physiological feedback generated from passively recorded respiratory symptoms remains limited (8).

Artificial-intelligence applications have increasingly been investigated for respiratory-sound detection, disease classification, and digital biomarker development (9). Nevertheless, technical detection of cough does not by itself demonstrate that displaying cough trends to patients improves adherence or clinical outcomes. Randomized evidence is needed to distinguish the effect of patient-facing feedback from the effects of routine digital monitoring and standard tuberculosis care. Accordingly, this study evaluated whether six weeks of smartphone-delivered, AI-generated cough-frequency feedback, provided in addition to standard care, improved electronically measured medication adherence and week-six sputum culture conversion compared with standard care alone among adults with newly diagnosed, bacteriologically confirmed drug-sensitive pulmonary tuberculosis (10).

MATERIALS AND METHODS

This parallel-group randomized controlled trial was conducted in tertiary-care pulmonology clinics in the Islamabad–Rawalpindi metropolitan region of Pakistan between October 2025 and May 2026. The study included participant recruitment, baseline assessment, randomized allocation, and a six-week intervention and outcome-assessment period. The trial compared standard tuberculosis care with the same standard care supplemented by patient-facing, artificial-intelligence-guided acoustic cough monitoring. The study was designed to determine whether providing patients with visual feedback

regarding changes in their cough frequency improved medication adherence and early sputum culture conversion.

The required sample was calculated using effect estimates from previous smartphone-based digital-adherence studies, with 80% statistical power, a two-sided significance level of 5%, equal allocation between groups, and allowance for anticipated attrition. The resulting recruitment target was 94 participants, with 47 assigned to each study group. Adults aged 18–65 years were eligible if they had newly diagnosed, bacteriologically confirmed drug-sensitive pulmonary tuberculosis, owned a smartphone compatible with the study application, and demonstrated sufficient digital literacy to operate the application. Individuals were excluded if they had multidrug-resistant tuberculosis, chronic obstructive pulmonary disease, asthma, current tobacco-smoking status, or concurrent use of antitussive medication that could materially influence recorded cough frequency.

Potential participants attending the participating pulmonology clinics were assessed against the eligibility criteria. Those meeting the criteria underwent baseline clinical and demographic assessment before randomization. A computer-generated allocation sequence assigned participants in a 1:1 ratio to the intervention or control group. Allocation assignments were placed in sequentially numbered, sealed, opaque envelopes and disclosed after completion of baseline assessment. Participants could not be blinded because the intervention involved access to a visible smartphone feedback dashboard. Outcome assessors and laboratory personnel responsible for processing sputum specimens were kept unaware of treatment allocation.

Participants in both groups received standard care for drug-sensitive pulmonary tuberculosis, including the routinely prescribed short-course multidrug treatment regimen, directly observed therapy, and clinical review every two weeks. Medication-taking behaviour in both groups was monitored using electronic medication-event monitoring pillboxes. Each device recorded the date and time at which the pillbox was opened. Medication adherence was calculated as the percentage of scheduled treatment doses associated with a recorded pillbox opening during the six-week assessment period. Because device opening does not independently confirm medication ingestion, this measure was interpreted as electronically monitored medication-taking behaviour.

In addition to standard care, participants assigned to the intervention group received access to a smartphone-based acoustic cough-monitoring application. During sleeping hours, the application passively processed ambient acoustic signals using a convolutional neural-network model to identify and count cough events. Acoustic processing was performed locally on the smartphone, and daily cough-frequency estimates were converted into longitudinal visual trends. Participants viewed updated feedback on their smartphone dashboard each morning, allowing them to observe changes in recorded cough frequency over time as an indicator of symptomatic response. The digital feedback did not replace routine clinical evaluation, microbiological testing, or standard adherence support.

The co-primary outcomes were electronically monitored medication adherence during the six-week intervention and sputum culture conversion at week six. Medication adherence was expressed as the percentage of prescribed doses represented by recorded pillbox-opening events. Sputum culture status was assessed at baseline and at the end of the six-week intervention, and conversion was defined according to the laboratory result recorded at the week-six assessment. Secondary outcomes included subjective cough severity measured using a 100-mm visual analogue scale and change in objectively recorded cough frequency over the study assessment points. Six-week intervention retention was also recorded. This outcome was distinguished from completion of the full antituberculosis treatment course, which extended beyond the study's six-week observation period.

Of the 94 randomized participants, 88 completed the six-week intervention and had outcome data available for the reported analyses. The principal analyses were therefore conducted as complete-case comparisons involving 44 participants in each study group. Baseline demographic and clinical

characteristics were summarized for the full randomized sample. Continuous variables were reported as means and standard deviations, whereas categorical variables were reported as frequencies and percentages. Distributional assumptions for continuous variables were assessed using the Shapiro–Wilk test.

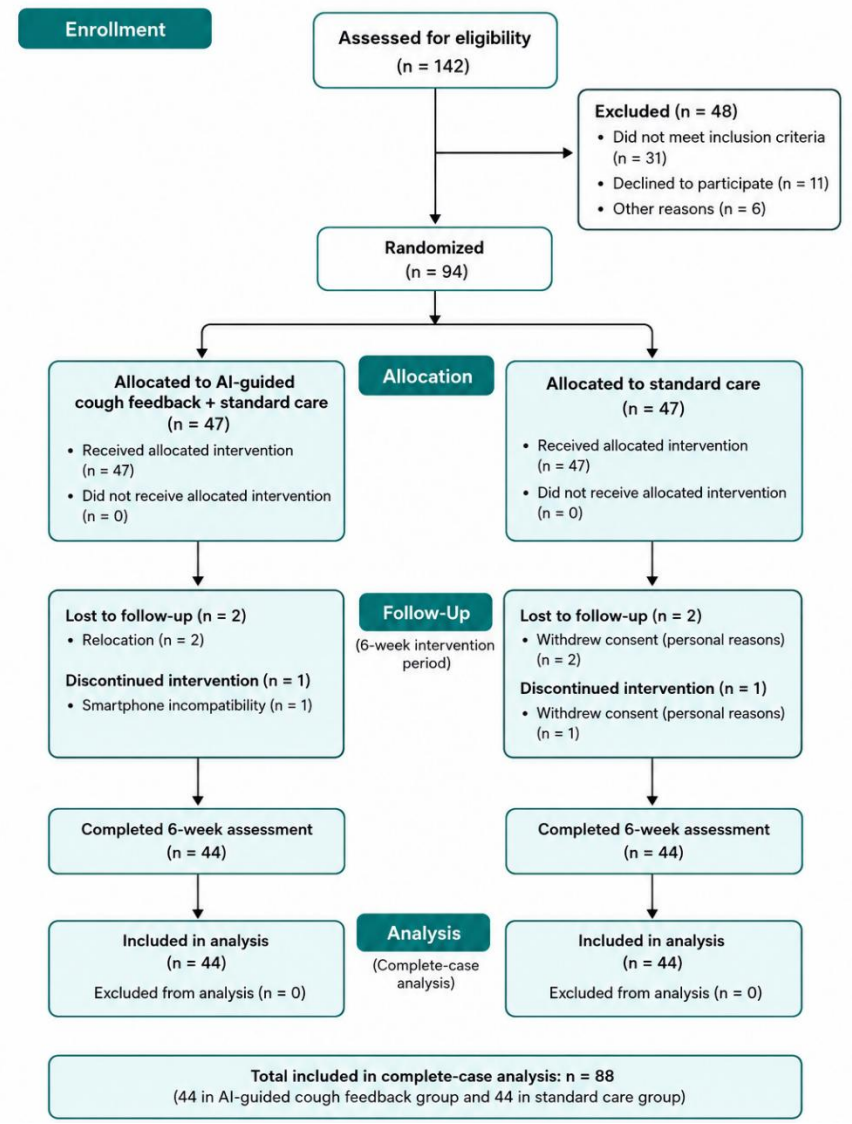

Figure 1 CONSORT Flowchart

Medication-adherence percentages were compared between groups using an independent-samples t-test, with the treatment effect reported as a mean difference and 95% confidence interval. Week-six sputum culture conversion was compared between groups using categorical-data analysis, with absolute group proportions and their difference reported. Changes in cough-severity scores from baseline to week six were examined within each group using paired-samples t-tests. Longitudinal cough-frequency measurements were evaluated using repeated-measures analysis of variance to estimate the effects of time, treatment group, and the time-by-group interaction. Pearson's correlation coefficient was used within the intervention group to examine the association between the magnitude of cough-frequency reduction and electronically monitored medication adherence. All tests were two-sided, and statistical significance was set at $p<0.05$.

RESULTS

A total of 142 individuals with suspected pulmonary tuberculosis were assessed for eligibility. Of these, 94 met the eligibility criteria and were randomized equally to the AI-guided cough-feedback intervention or standard-care control group, with 47 participants assigned to each group. During the six-

week intervention, three participants in each group discontinued participation. In the intervention group, two participants were lost to follow-up following relocation and one discontinued because of smartphone incompatibility. In the control group, three participants withdrew consent for personal reasons. The reported complete-case analysis therefore included 88 participants, with 44 participants in each group.

Baseline characteristics were summarized for all 94 randomized participants. The groups were similar in age, sex distribution, sputum culture status, and baseline cough frequency. The absolute standardized mean differences for the reported baseline variables ranged from 0.00 to 0.11, indicating no important observed imbalance in these characteristics.

Table 1. Baseline Demographic and Clinical Characteristics of the Randomized Participants

Characteristic	Intervention Group (n=47)	Control Group (n=47)	Standardized Mean Difference
Age, years	37.9 ± 10.8	38.9 ± 11.6	−0.09
Male sex	25 (53.2)	27 (57.4)	−0.09
Positive sputum culture	47 (100.0)	47 (100.0)	0.00
Baseline cough count, events/24 hours	281.2 ± 59.4	287.8 ± 64.9	−0.11

Data are presented as mean ± standard deviation or n (%). A negative standardized mean difference indicates a lower value in the intervention group. Baseline significance tests were not performed because treatment allocation was randomized.

In the complete-case analysis, mean electronically monitored medication adherence was 94.2% ± 4.1% in the intervention group and 86.5% ± 7.8% in the control group. The unadjusted between-group mean difference was 7.7 percentage points (95% CI 5.0 to 10.4; p<0.001), favouring the intervention. The corresponding standardized mean difference was large (Hedges' g=1.22).

Week-six sputum culture conversion occurred in 40 of 44 participants (90.9%) receiving AI-guided feedback and 31 of 44 participants (70.5%) receiving standard care. The absolute risk difference was 20.5 percentage points (95% CI 4.5 to 36.4), and the risk ratio was 1.29 (95% CI 1.04 to 1.60; p=0.016). Thus, among participants included in the complete-case analysis, the probability of week-six culture conversion was approximately 29% higher in the intervention group.

Table 2. Complete-Case Comparison of Co-Primary Outcomes at Week Six

Outcome	Intervention Group (n=44)	Control Group (n=44)	95% CI	p-value
Medication adherence, %	94.2 ± 4.1	86.5 ± 7.8	5.0 to 10.4	<0.001
Medication adherence, standardized effect	—	—	—	—
Sputum culture conversion	40 (90.9)	31 (70.5)	4.5 to 36.4	0.016
Sputum culture conversion	40 (90.9)	31 (70.5)	1.04 to 1.60	0.016

Continuous data are presented as mean ± standard deviation and categorical data as n (%). Effect estimates were derived directly from the reported complete-case summary data. The medication-adherence comparison was based on an independent-groups mean difference. The sputum-conversion estimates compare the proportions observed at week six.

Subjective cough severity decreased in both groups during the six-week intervention. In the intervention group, the mean visual analogue scale score declined from 74.2 ± 12.5 mm at baseline to 18.4 ± 8.1 mm at week six, corresponding to a reported within-group decrease of 55.8 mm (95% CI 51.3 to 60.3; p<0.001). In the control group, the mean score declined from 75.6 ± 11.9 mm to 32.1 ± 10.4 mm, with a reported decrease of 43.5 mm (95% CI 38.8 to 48.2; p<0.001).

The clinically relevant randomized comparison was the difference between groups at follow-up. At week six, the mean cough-severity score was 13.7 mm lower in the intervention group than in the control group (95% CI −17.7 to −9.7; p<0.001). The standardized between-group difference at week six was large (Hedges' g=−1.46). Because the participant-level covariance between baseline and follow-up scores was

unavailable, a confidence interval for the between-group difference in individual change scores could not be derived reliably from the reported aggregate values.

Table 3. Cough-Severity Outcomes During the Six-Week Intervention

Measure	Intervention Group (n=44)	Control Group (n=44)	Between-Group Effect	95% CI	p-value
Baseline VAS score, mm	74.2 ± 12.5	75.6 ± 11.9	—	—	—
Week-six VAS score, mm	18.4 ± 8.1	32.1 ± 10.4	Mean difference: −13.7 mm	−17.7 to −9.7	<0.001
Reported within-group decrease, mm	55.8	43.5	—	—	—
Within-group decrease, 95% CI	51.3 to 60.3	38.8 to 48.2	—	—	—
Standardized week-six difference	—	—	Hedges' g: −1.46	—	—

VAS, visual analogue scale. Lower scores indicate lower perceived cough severity. Negative between-group estimates favour the intervention. The within-group change estimates and confidence intervals are those reported in the source manuscript; the week-six between-group estimate was calculated directly from the reported means, standard deviations, and group sizes.

Repeated-measures analysis of the objectively recorded cough-frequency data showed a significant effect of time, indicating that cough frequency declined during follow-up across the study sample ($F[2,172]=312.45$; $p<0.001$). A significant group effect was also observed ($F[1,86]=18.24$; $p<0.001$). More importantly, the time-by-group interaction was significant ($F[2,172]=14.82$; $p<0.001$), indicating that the pattern of cough-frequency change differed between the intervention and control groups. The interaction corresponded to a partial eta-squared of approximately 0.15, representing a large longitudinal group difference. The means and variability at each cough-assessment occasion were not available in the reported manuscript and therefore could not be reproduced in the table.

Within the intervention group, greater reduction in objectively recorded cough frequency was positively associated with higher electronically monitored medication adherence ($r=0.68$; 95% CI 0.48 to 0.81; $p<0.001$). This represented a strong unadjusted association but did not establish that cough feedback mediated the effect of the intervention on adherence.

Six-week retention was examined separately from completion of the full antituberculosis treatment course. All 44 intervention participants included in the complete-case dataset remained under observation at the week-six assessment, compared with 41 of 44 control participants according to the secondary-outcome data. The absolute difference was 6.8 percentage points. Because of the small number of non-retention events and a zero cell in the intervention group, Fisher's exact test was more appropriate than the originally reported Pearson chi-square test; the resulting two-sided p-value was 0.241. This result did not provide evidence of a statistically significant difference in six-week retention.

Table 4. Longitudinal Cough-Frequency Analysis, Adherence Association, and Six-Week Retention

Outcome	Effect Estimate or Test Statistic	95% CI	p-value
Main effect of time on cough frequency	$F(2,172)=312.45$	—	<0.001
Main effect of treatment group	$F(1,86)=18.24$	—	<0.001
Time × group interaction	$F(2,172)=14.82$	—	<0.001
Time × group interaction effect size	Partial $\eta^2=0.15$	—	—
Cough-frequency reduction correlated with adherence	$r=0.68$	0.48 to 0.81	<0.001
Six-week retention: intervention	44/44 (100.0)	—	—
Six-week retention: control	41/44 (93.2)	—	—
Between-group retention comparison	Fisher's exact test	—	0.241

The repeated-measures model included three assessment occasions, as indicated by the reported numerator degrees of freedom, although the exact occasions and occasion-specific cough-frequency values were not provided. Partial η^2 was calculated from the reported interaction F statistic and degrees of freedom. The correlation was an unadjusted analysis restricted to the intervention group. Six-week retention should not be interpreted as completion of the standard full tuberculosis treatment course.

Overall, the complete-case findings showed higher electronically monitored medication adherence and a higher week-six sputum culture conversion proportion among participants receiving AI-guided cough feedback. The intervention group also had lower subjective cough-severity scores at week six and a more favourable longitudinal cough-frequency trajectory. However, these estimates were based on 88 of the 94 randomized participants. A definitive intention-to-treat analysis requires outcome data or valid imputed estimates for all randomized participants and should remain the primary analysis in the final trial report.

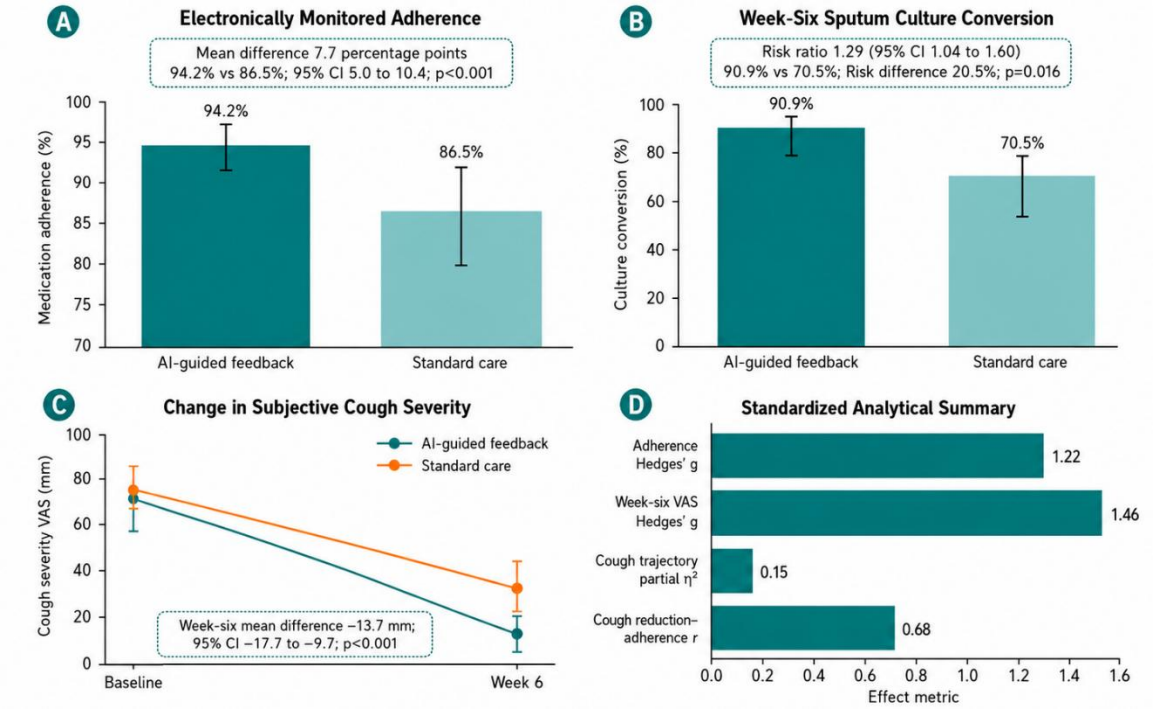

Figure 2 The figure shows that AI-guided cough feedback was associated with higher medication adherence, greater week-six sputum culture conversion, and a larger reduction in subjective cough severity than standard care, with substantial standardized effects and a strong positive association between cough reduction and adherence.

DISCUSSION

This randomized controlled trial found that participants receiving AI-generated cough-frequency feedback alongside standard tuberculosis care had higher electronically monitored medication adherence and a greater proportion of week-six sputum culture conversion than participants receiving standard care alone. The intervention group also reported lower cough-severity scores at week six and demonstrated a more favourable longitudinal cough-frequency pattern. These findings suggest that patient-facing physiological feedback may complement established digital adherence technologies during the early phase of treatment for drug-sensitive pulmonary tuberculosis. However, the reported estimates were derived from the 88 participants who completed the six-week assessment rather than all 94 randomized participants and should therefore be interpreted as complete-case findings.

The higher medication adherence observed in the intervention group is consistent with evidence indicating that digital technologies can support tuberculosis treatment monitoring and medication-taking behaviour (2,3). Conventional digital adherence tools, including electronic medication monitors, reminders, and video-observed therapy, primarily document treatment activity or facilitate remote supervision (4). The present intervention differed by providing participants with a visual representation of changes in an objectively monitored respiratory symptom. This feedback may have helped patients recognize short-term symptomatic improvement and maintain engagement with treatment. Nevertheless, the study did not directly measure motivation, self-efficacy, perceived treatment benefit, or app engagement, and the behavioural pathway through which the intervention may have influenced adherence remains uncertain.

Week-six sputum culture conversion occurred in 90.9% of participants in the intervention group and 70.5% of participants in the control group. Early culture conversion is commonly used as an indicator of initial microbiological response to antituberculosis therapy, although it does not independently establish cure, long-term treatment success, or freedom from relapse (11). Treatment response is influenced by baseline bacterial burden, disease severity, cavitation, pharmacological exposure, host characteristics, and adherence throughout the complete treatment course (12,13). The higher culture-conversion proportion observed in the intervention group may therefore be compatible with improved medication-taking behaviour, but the current analysis cannot confirm that adherence mediated the microbiological effect. A formal mediation analysis and adjustment for relevant baseline clinical variables would be required to evaluate this pathway.

The significant time-by-group interaction for objectively recorded cough frequency indicates that the pattern of cough reduction differed between the study groups during the six-week observation period. Cough monitoring may offer a useful non-invasive method for documenting symptomatic change, but cough frequency should not be treated as a direct measure of mycobacterial burden. Acoustic cough counts can be affected by airway inflammation, household noise, recording duration, device placement, comorbid respiratory conditions, and algorithmic misclassification (17–19). The observed association between cough-frequency reduction and medication adherence was strong, but it was unadjusted and restricted to the intervention group. It therefore supports an association between the two measures without establishing directionality or causation.

The reduction in subjective cough severity observed in both groups was expected during the early treatment phase. The lower week-six score in the intervention group may reflect a more favourable symptomatic course, greater adherence, increased awareness of improvement, or a combination of these factors. Because participants were aware of their group assignment and the intervention displayed daily symptom trends, expectancy and reporting effects cannot be excluded. Future studies should combine subjective cough measures with standardized objective recording procedures and prespecified clinical and microbiological outcomes.

Several features strengthen the study. Random allocation was used, allocation concealment was attempted through sequentially numbered opaque envelopes, and laboratory personnel and outcome assessors were reported to be unaware of group assignment. Medication-taking behaviour was measured electronically rather than solely through participant recall, reducing reliance on self-reported adherence. The study also evaluated behavioural, symptomatic, acoustic, and microbiological outcomes, providing a multidimensional assessment of the intervention during early tuberculosis treatment.

Important limitations must also be considered. First, the primary analyses excluded six randomized participants and were therefore complete-case rather than intention-to-treat analyses. Exclusion after randomization may introduce attrition bias, even though the number of withdrawals was equal between groups. Second, follow-up was limited to six weeks and did not evaluate completion of the full antituberculosis regimen, treatment failure, relapse, acquired drug resistance, long-term pulmonary outcomes, or mortality. Third, medication-event monitoring documented pillbox opening rather than confirmed ingestion. Fourth, smartphone ownership and digital literacy were eligibility requirements, limiting generalizability to patients without reliable access to compatible devices or sufficient technological familiarity.

The technical reporting of the intervention was also limited. The available information did not fully describe the cough-detection algorithm, validation dataset, operating-system compatibility, minimum recording duration, handling of background noise, false-positive and false-negative detection rates, software version, or app-use adherence. Ambient nocturnal audio monitoring also raises privacy and data-governance considerations, including the handling of raw audio, local storage, encryption, retention, access, and incidental recording of household members. These factors require explicit

evaluation before wider implementation, particularly in crowded households and resource-constrained settings.

The trial was conducted within one metropolitan region and may not represent rural communities or populations with different socioeconomic, linguistic, cultural, and housing conditions. Digital adherence interventions may also have differential effects according to education, health literacy, age, disease severity, and previous experience with mobile technologies (6–8). Multicentre studies should therefore examine treatment-effect consistency across clinically and socially diverse populations. Economic evaluation is also needed because any reduction in in-person monitoring requirements must be balanced against costs associated with software development, device compatibility, technical support, cybersecurity, and clinical oversight.

Future trials should use prospectively registered protocols, clearly defined co-primary outcomes, intention-to-treat analyses, and follow-up across the complete tuberculosis treatment course. They should report standardized microbiological procedures, app-validation performance, prespecified handling of missing data, adverse events, implementation outcomes, and patient acceptability. Comparisons between patient-facing physiological feedback, reminders alone, electronic monitoring without feedback, and conventional supervision could help determine which component produces the greatest benefit. Explainable and clinically interpretable AI systems will be particularly important where algorithmic outputs influence patient behaviour or clinical decision-making (20).

CONCLUSION

Among participants who completed the six-week assessment, the addition of smartphone-delivered, AI-generated cough-frequency feedback to standard tuberculosis care was associated with higher electronically monitored medication adherence, a greater proportion of week-six sputum culture conversion, lower subjective cough severity, and a more favourable cough-frequency trajectory than standard care alone. These findings support further evaluation of patient-facing acoustic feedback as an adjunct to early tuberculosis treatment support. However, the short follow-up, complete-case analysis, smartphone eligibility requirements, and limited technical reporting prevent conclusions regarding full-course treatment completion, long-term clinical effectiveness, scalability, or routine implementation.

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